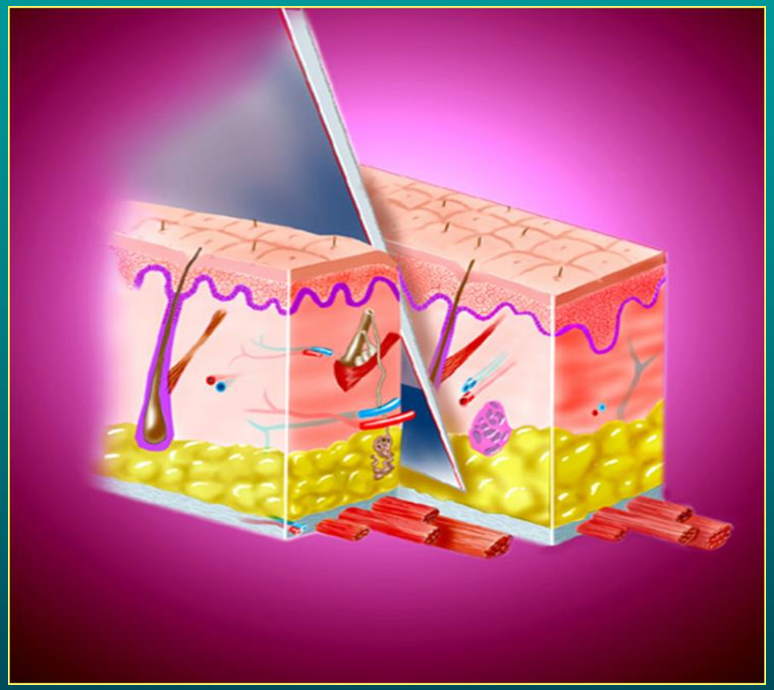
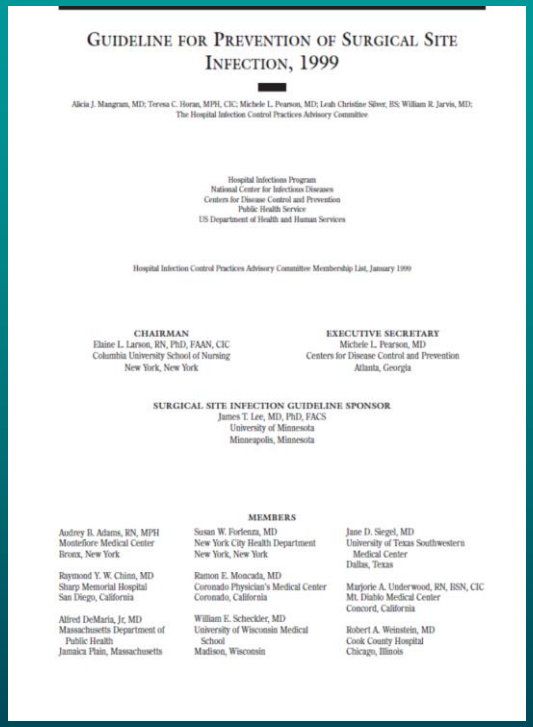
Discussion of the Wisconsin SSI Prevention Guidelines as a Supplement to the 2016 CDC-HICPAC SSI Prevention Guidelines



Charles E Edmiston, Jr., PhD, CIC, FIDSA, FSHEA, FAPIC - Emeritus Professor of Surgery, Medical College of Wisconsin, Milwaukee, WI & SSI Risk Reduction Consultant, Wisconsin Division of Public Health, Madison, WI

Score Card for 1999 CDC/HICPAC SSI Prevention Guidelines



GUIDELINE FOR PREVENTION OF SURGICAL SITE INFECTION, 1999

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

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

Hospital Infection Control Practices Advisory Committee Membership List, January 1999

CHAIRMAN
Elaine L. Larson, RN, PhD, FAAN, CIC
Columbia University School of Nursing
New York, New York

EXECUTIVE SECRETARY
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Centers for Disease Control and Prevention
Atlanta, Georgia

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Concord, California

Robert A. Weinstein, MD
Cook County Hospital
Chicago, Illinois

A Total of 71 Recommendations were made in 1999 Guidelines

Classification	No. Interventions (%)
Category 1A	8 (11.3%)
Category 1B	43 (60.6%)
Category II	11 (15.4%)
No recommendation (unresolved)	9 (12.7%)

Infection Control Hosp Epidemiol 1999;20:247-278

Evidence-Based Medicine is a Moving Target

Score Card for Proposed 2016 CDC/HICPAC SSI Prevention Guidelines

A Total of 40 Key Recommendations were Considered (28 Core + 12 Prosthetic Joint Arthroplasty)

Classification	Core (%)	Athroplasty (%)
Category 1A	6 (21.4%)	2 (16.7%)
Category 1B	3 (10.7%)	1 (8.3%)
Category 1C	0 (0%)	0 (0%)
Category II	5 (17.9%)	0 (0%)
No recommendation (unresolved)	14 (50%)	9 (75%)

https://www.regulations.gov/document?D=CDC-2014-0003-0002
https://www.cdc.gov/hicpac/pdf/mm/HICPAC-July2015-MeetingSummary.pdf

Proposed 2016 Proposed CDC-HICPAC SSI Prevention Guidelines

Intervention	Classification
Skin antisepsis, hair removal	Category 1A
Glycemic control	Category 1A
Preadmission shower (night before)	Category 1B
Systemic steroid use	Unresolved
Normothermia	Category 1A
Staphylococcal surveillance/decolonization	Not addressed
Enhanced oxygenation	Category 1A
Antimicrobial prophylaxis	Category 1B
Weight-based dosing	No recommendation
Oral antibiotics/mechanical bowel prep	Not addressed
Surgical attire and drapes	Not addressed
Redosing	Not addressed

https://www.regulations.gov/document?D=CDC-2014-0003-0002

"Sole dependence on RTCs, leads to the exclusion or failure to review and/or evaluate other type of epidemiologic studies that address important infection control issues or questions."

William Jarvis , MD – Posted to Public Comments on HICPAC Draft SSI Prevention Guidelines Docket ID: CDC-2014-0003

Interventions Designated as Category II, No Recommendation (Unresolved or Not Adequately Addressed) or Missing in Action (MIA)

Wisconsin Division of Public Health
Supplemental Guidance for the Prevention of Surgical Site Infections:
An Evidence-Based Perspective
November, 2016

Pub Number

Wisconsin Surgical Site Infection Prevention Expert Panel

Charles E. Edmiston, Jr., PhD, CIC, FIDSA, FSHEA, FAPIC
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Medical College of Wisconsin
Senior Medical Director, Surgical Services
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We gratefully acknowledge the contributions of the following individuals in the review of this guidance: David Leaper, D.Sc, MD, FRSC, FACS; Sue Barnes, RN, CIC; Maureen Spencer, RN, BSN, M.Ed, CIC

The Evidence is Compelling

- Weight-based dosing – NR*
- Redosing for long surgical procedures – NR
- Standardization of CHG shower/cleansing – NR*
- Antimicrobial sutures – Category II*
- Oral antibiotics/mechanical bowel prep - MIA
- Staphylococcal surveillance and decolonization (Arthroplasty) – MIA*
- Surgical care bundle – MIA*

NR = no recommendation
MIA = missing in action

www.regulations.gov/document?D=CDC-2014-0003-0002
www.cdc.gov/hicpac/pdf/mm/HICPAC-July2015-MeetingSummary.pdf

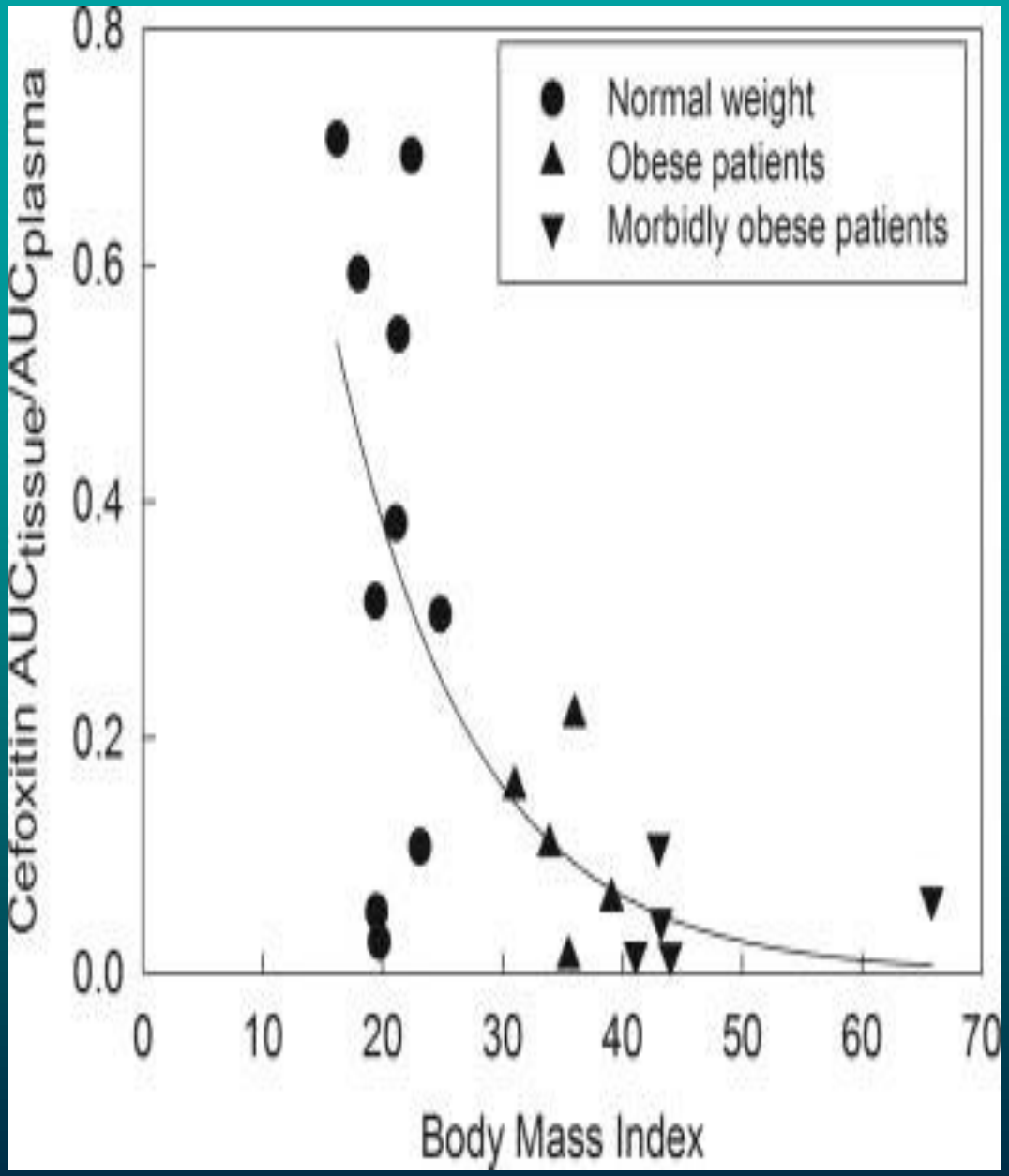
Antimicrobial Prophylaxis – Weight-Based Dosing Does BMI Increase Risk?

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

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

Organisms	n	Serum	Tissues
Staphylococcus aureus	70	68.6%	< 28%
S.epidermidis	110	34.5%	< 11%
E. coli	85	75.3%	< 57%
Klebsiella pneumoniae	55	80%	< 66%

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



Toma et al., Anesthesia Analgesia 2011;113:730-737

- **"Measured and dose-normalized subcutaneous cefoxitin concentrations and AUCs in the obese patients were significantly lower than in the normal-weight subjects.**
- **There was an inverse relationship between cefoxitin tissue penetration (AUC tissue/ AUC plasma ratio) and body mass index.**
- ❖ **Tissue penetration was substantially lower in the obese patients compared to normal weight controls (*p = 0.05*)."**
- **"This occurred despite 2-fold-higher cefoxitin dosage (1 to 2 gms).**
- ❖ **Diminished tissue antibiotic concentrations in morbid obesity may influence the incidence of SSIs."**

ASHP REPORT

Clinical practice guidelines for antimicrobial prophylaxis in surgery

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

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

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

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

Guidelines development and use

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

Preoperative Staphylococcal Surveillance

SURGICAL INFECTIONS
Volume 17, Number 2, 2016

DOI: 10.1089/sur.2015.257

Is Staphylococcal Screening and Suppression an Effective Interventional Strategy for Reduction of Surgical Site Infection?

Charles E. Edmiston, Jr,[1] Nathan A. Ledeboer,[2] Blake W. Buchan,[2] Maureen Spencer,[3] Gary R. Seabrook,[1] and David Leaper[3,4]

Abstract

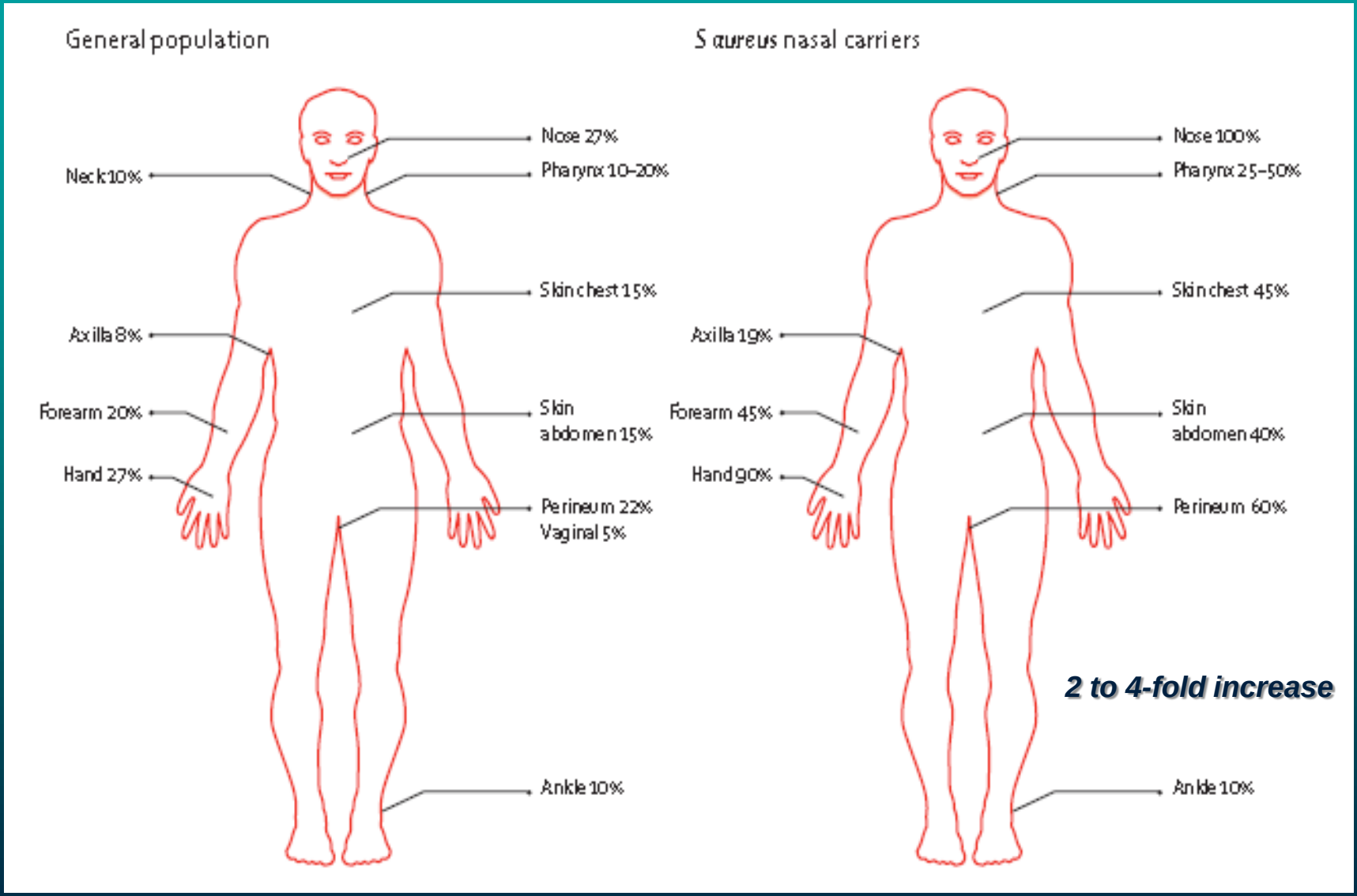
Background: *Staphylococcus aureus* has been recognized as a major microbial pathogen for over 100 y, having the capacity to produce a variety of suppurative and toxigenic disease processes. Many of these infections are life-threatening, with particularly enhanced virulence in hospitalized patients with selective risk factors. Strains of methicillin-resistant *Staphylococcus aureus* (MRSA) have rapidly spread throughout the healthcare environment such that approximately 20% of *S. aureus* isolates recovered from surgical site infections are methicillin-resistant, (although this is now reducing following national screening and suppression programs and high impact interventions).

Methods: Widespread nasal screening to identify MRSA colonization in surgical patients prior to admission are controversial, but selective, evidence-based studies have documented a reduction of surgical site infection (SSI) after screening and suppression.

Results: Culture methods used to identify MRSA colonization involve selective, differential, or chromogenic media. These methods are the least expensive, but turnaround time is 24–48 h. Although real-time polymerase chain reaction (RT-PCR) technology provides rapid turnaround (1–2 h) with exceptional testing accuracy, the costs can range from three to 10 times more than conventional culture methodology. Topical mupirocin, with or without pre-operative chlorhexidine showers or skin wipes, is the current ''gold-standard'' for nasal decolonization, but inappropriate use of mupirocin is associated with increasing staphylococcal resistance.

Conclusions: Selection of an effective active universal or targeted surveillance strategy should be based upon the relative risk of MSSA or MRSA surgical site infection in patients undergoing orthopedic or cardiothoracic device related surgical procedures.

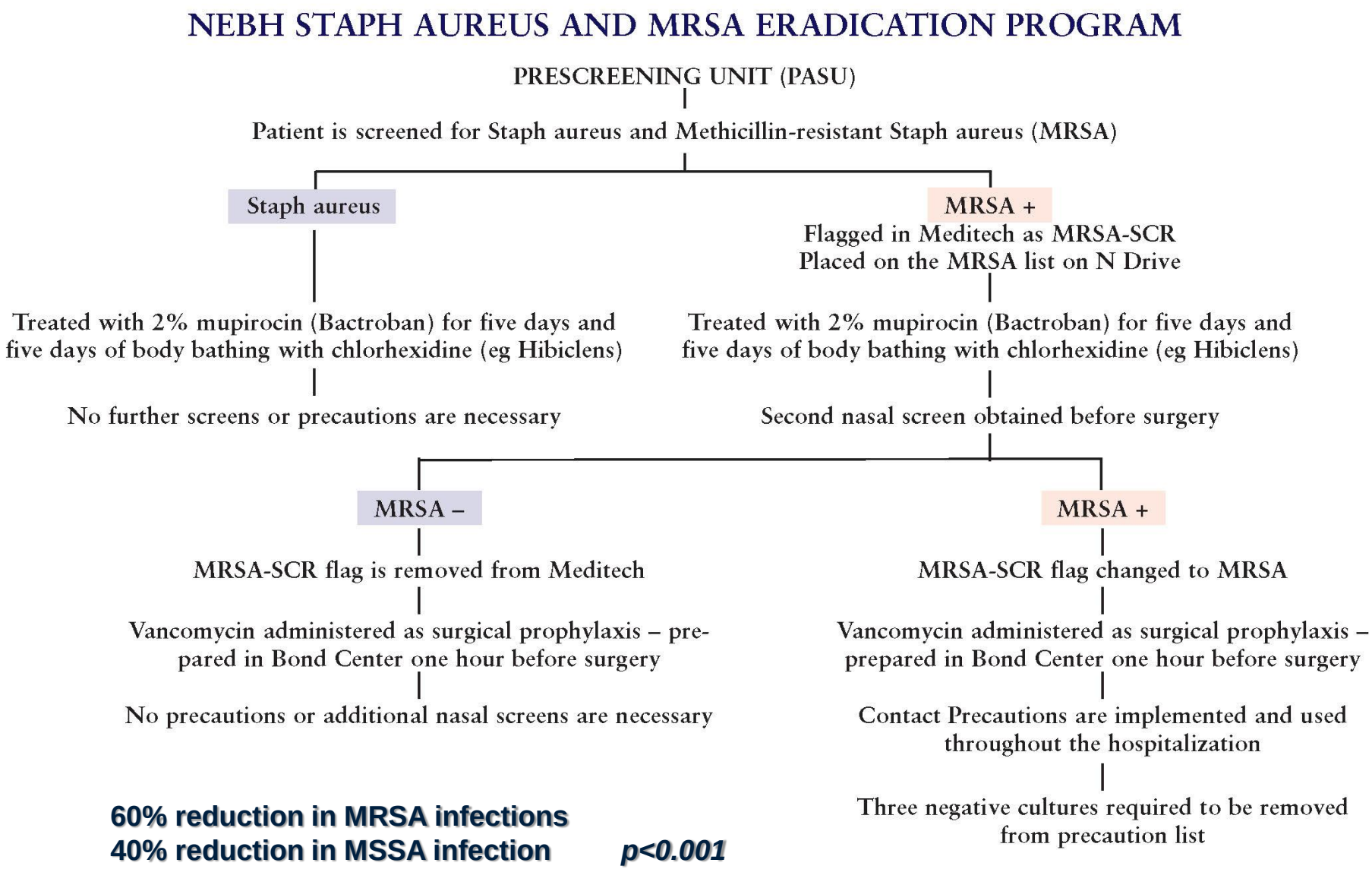
S. aureus Colonization: Impact of Nasal Carriage



Hill RLR et al. J Antimicrob Chemother 1988;22:377
Sanford MD et al. Clin Infect Dis 1994;19:1123

Lancet Infect Dis 2005;5:751

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



60% reduction in MRSA infections
40% reduction in MSSA infection ***p<0.001***

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

Staphylococcal Decolonization Strategies

Standardized Protocol – culture directed

- Mupirocin (BID) – 5 to 7 days (gold standard)
- CHG (2% or 4%) cleansing/shower
- Compliance rate unknown

Nasal Decolonization with 5%-10% Povidone Iodine – no culture

- Day of surgery – swab inner nares with 5-10% povidone buffered gel
- CHG (2% or 4%) cleansing/shower

Evidence for the Preadmission Shower Microbial Ecology of Skin Surface

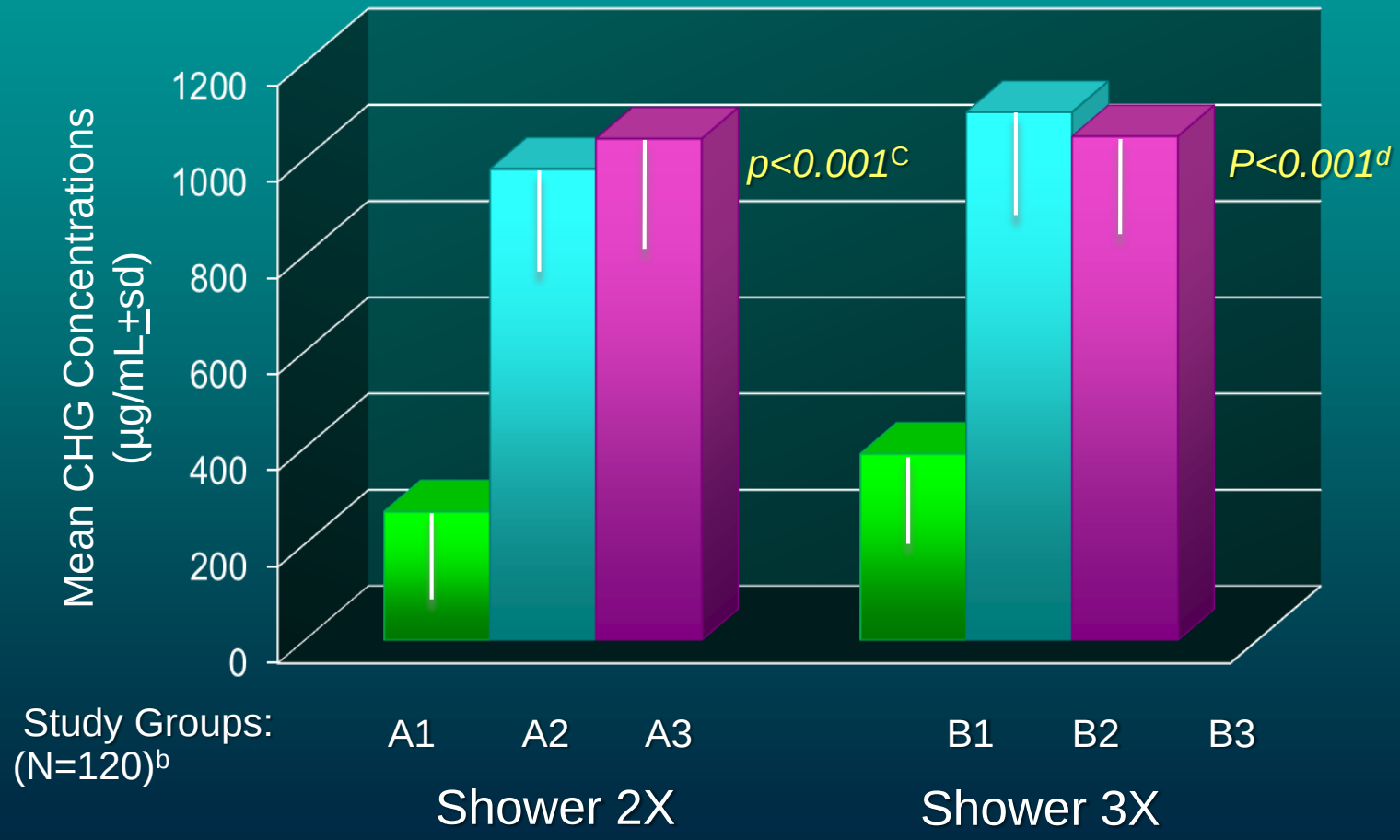
- Scalp 6.0 Log_{10} cfu/cm^2
- Axilla 5.5 Log_{10} cfu/cm^2
- Abdomen 4.3 Log_{10} cfu/cm^2
- Forearm 4.0 Log_{10} cfu/cm^2
- Hands 4.0-6.6 Log_{10} cfu/cm^2
- Perineum 7.0-11.0 Log_{10} cfu/cm^2

Surgical Microbiology Research Laboratory 2008 – Medical College of Wisconsin

Looking at the Preadmission Shower from a Pharmacokinetic Perspective

Dose
Duration
Timing

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



Edmiston et al. JAMA Surg 2015;150:1027-1033

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

4% Aqueous CHG

- An SMS, text or voicemail reminder to shower
- A standardized regimen – instructions – Oral and written
- 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

2% CHG Cloth

- An SMS, text or voicemail reminder
- Oral and written patient instructions – Cleanse gently
- TOTAL OF 3 PACKAGES PER APPLICATION INTERVAL – 3 NIGHT BEFORE AND 3 THE MORNING OF SURGERY
- Use both sides of the cloth – maximize release of CHG
- CLEANSE GENTLY

Remember the devil is always in the details

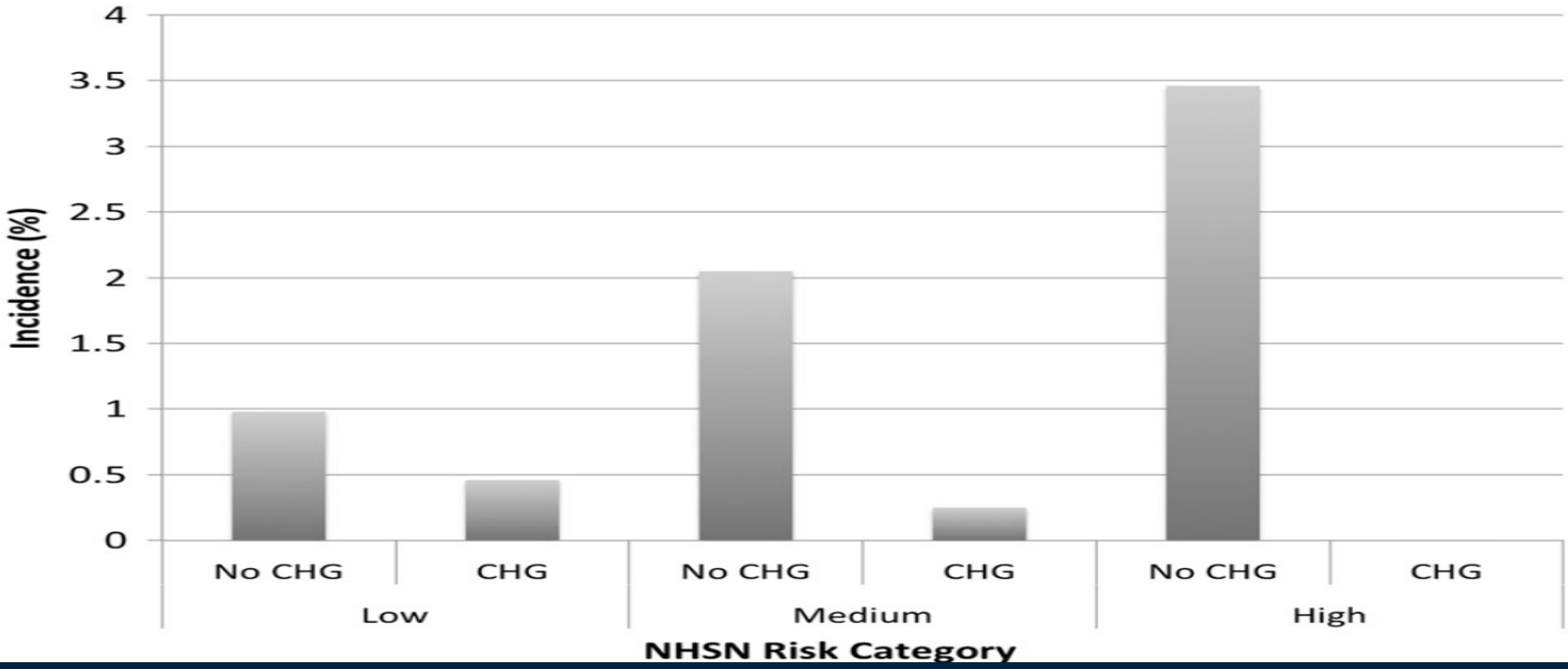
Edmiston et al. JAMA Surg 2015;150:1027-1033
Edmiston et al. Infect Control Hosp Epidemiol 2016; 2016;37:254-259

Clin Orthop Relat Res
DOI 10.1007/s11999-016-4767-6

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

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

Bhaveen H. Kapadia MD, Peter L. Zhou BA, Julio J. Jauregui MD,
Michael A. Mont MD



- Is CHG Safe for OB/GYN?

American Journal of Infection Control ■■ (2016) ■■-■■

Contents lists available at ScienceDirect

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journal homepage: www.ajicjournal.org

Major Article

Safety and tolerability of chlorhexidine gluconate (2%) as a vaginal operative preparation in patients undergoing gynecologic surgery

Ahmed Al-Niaimi MD [a], Laurel W. Rice MD [a], Uppal Shitanshu MD [b], Bonnie Garvens MD [a], Megan Fitzgerald NP [a], Sara Zerbel MS [a], Nasia Safdar MD, PhD [a,c,*]

[a] School and Public Health, University of Wisconsin Medical, Madison, WI
[b] Universtity of Michigan, Ann Arbor, MI
[c] William S. Middleton Memorial Veterans Hospital, Madison, WI

Key Words:
Gynecologic surgery
chlorhexidine 2%
vaginal irritation
patient safety

Background: The use of chlorhexidine gluconate (CHG) as an intraoperative vaginal preparation has been shown to be more effective than vaginal povidone-iodine (PI) in decreasing vaginal bacterial colony counts. However, PI remains the standard vaginal preparation because of concerns of CHG's potential for vaginal irritation. The primary outcome of this study is a comparison of the rate of patient-reported vaginal irritation between 2% CHG and PI.

Methods: Consecutive patients were enrolled in a pre-post study. Group 1 consisted of consecutive patients who received PI as a vaginal preparation. Group 2 consisted of consecutive patients who received 2% CHG as a vaginal preparation. Patients used a standardized instrument to report irritation to trained nurse practitioners 1 day after surgery.

Results: A total of 117 patients received vaginal operative preparation during the course of the study, with 64 patients in group 1 and 53 patients in group 2. Of the patients in group 1, 60 (93.7%) reported no vaginal irritation, 3 (4.69%) reported mild irritation, and 1 (1.56%) reported moderate irritation. In group 2 (2% CHG vaginal preparation), all of the patients (100%) reported no vaginal irritation ($P = .38$).

Conclusions: The use of 2% CHG as a vaginal operative preparation is not associated with increased vaginal irritation compared with PI in gynecologic surgery. It can safely be used, taking advantage of its efficacy in reducing vaginal bacterial colony counts.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Randomized Trial Comparing Skin Antiseptic Agents at Cesarean Delivery

Methodius G. Tuuli, M.D., M.P.H., Jingxia Liu, Ph.D., Molly J. Stout, M.D., M.S.C.I., Shannon Martin, R.N., Alison G. Cahill, M.D., M.S.C.I., Anthony O. Odibo, M.D., M.S.C.E., Graham A. Colditz, M.D., Dr.P.H., and George A. Macones, M.D., M.S.C.E.

ABSTRACT

BACKGROUND

Preoperative skin antisepsis has the potential to decrease the risk of surgical-site infection. However, evidence is limited to guide the choice of antiseptic agent at cesarean delivery, which is the most common major surgical procedure among women in the United States.

METHODS

In this single-center, randomized, controlled trial, we evaluated whether the use of chlorhexidine–alcohol for preoperative skin antisepsis was superior to the use of iodine–alcohol for the prevention of surgical-site infection after cesarean delivery. We randomly assigned patients undergoing cesarean delivery to skin preparation with either chlorhexidine–alcohol or iodine–alcohol. The primary outcome was superficial or deep surgical-site infection within 30 days after cesarean delivery, on the basis of definitions from the Centers for Disease Control and Prevention.

RESULTS

From September 2011 through June 2015, a total of 1147 patients were enrolled; 572 patients were assigned to chlorhexidine–alcohol and 575 to iodine–alcohol. In an intention-to-treat analysis, surgical-site infection was diagnosed in 23 patients (4.0%) in the chlorhexidine–alcohol group and in 42 (7.3%) in the iodine–alcohol group (relative risk, 0.55; 95% confidence interval, 0.34 to 0.90; P=0.02). The rate of superficial surgical-site infection was 3.0% in the chlorhexidine–alcohol group and 4.9% in the iodine–alcohol group (P=0.10); the rate of deep infection was 1.0% and 2.4%, respectively (P=0.07). The frequency of adverse skin reactions was similar in the two groups.

CONCLUSIONS

The use of chlorhexidine–alcohol for preoperative skin antisepsis resulted in a significantly lower risk of surgical-site infection after cesarean delivery than did the use of iodine–alcohol. (Funded by the National Institutes of Health and Washington University School of Medicine in St. Louis; ClinicalTrials.gov number, NCT01472549.)

From the Department of Obstetrics and Gynecology (M.G.T., M.J.S., S.M., A.G.C., G.A.M.) and the Division of Public Health Sciences (J.L., G.A.C.), Washington University School of Medicine in St. Louis, St. Louis; and the Department of Obstetrics and Gynecology, University of South Florida, Tampa (A.O.O.). Address reprint requests to Dr. Tuuli at the Department of Obstetrics and Gynecology, Washington University School of Medicine in St. Louis, 4566 Scott Ave., Campus Box 8064, St. Louis, MO 63110, or at tuulim@wudosis.wustl.edu.

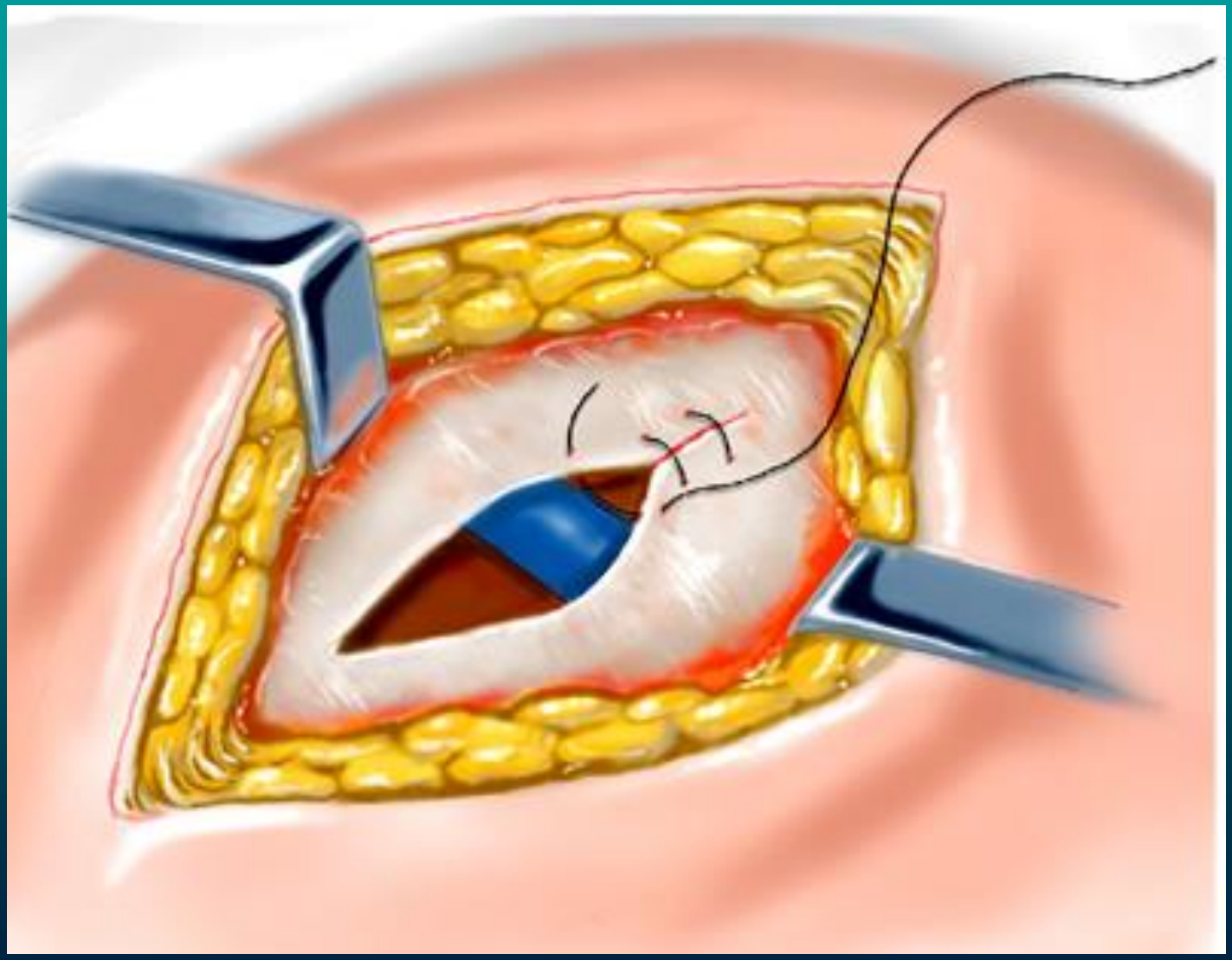
This article was published on February 4, 2016, at NEJM.org.

DOI: 10.1056/NEJMoa1511048

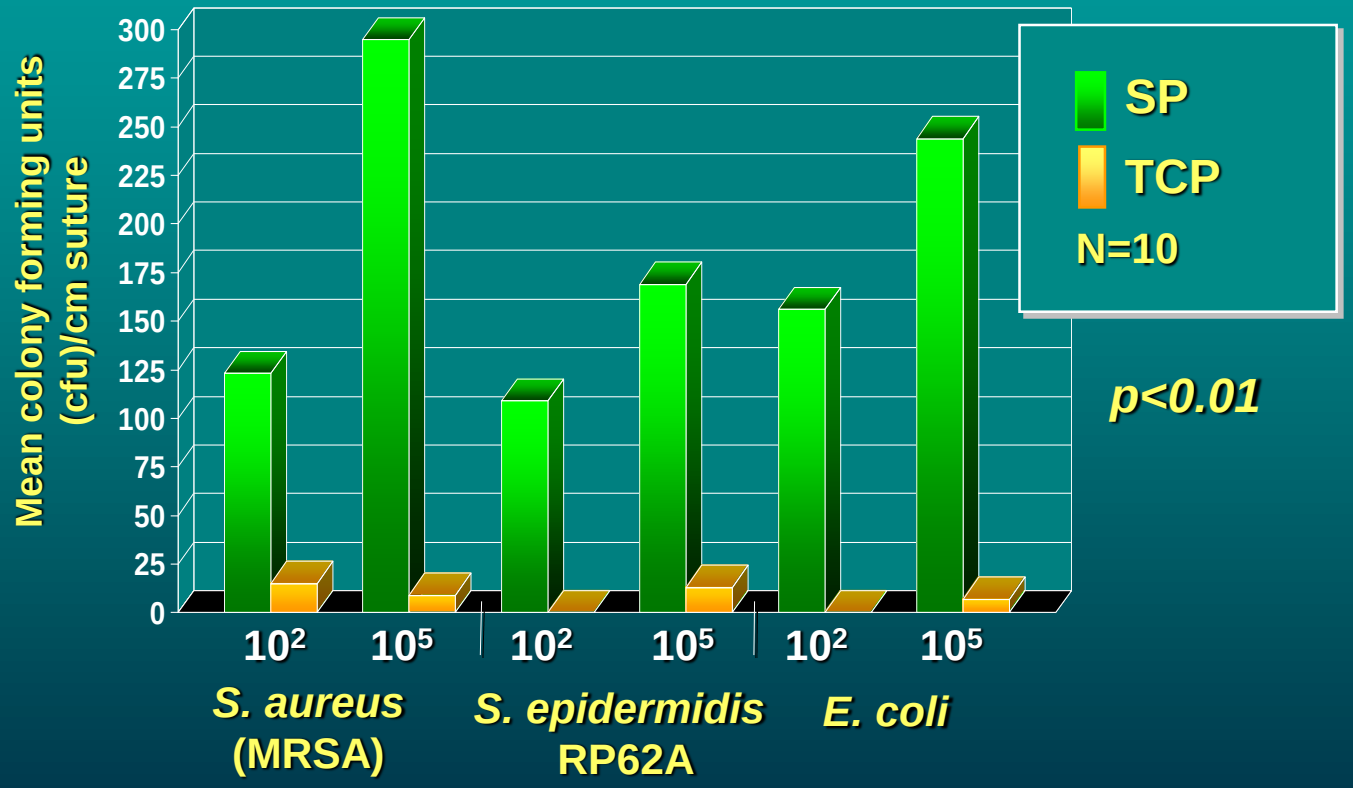
A recent committee opinion of the American College of Obstetricians and Gynecologist Committee on Gynecologic Practices states that, “Chlorhexidine gluconate (CHG) solutions with low concentrations of alcohol are safe and effective for use as vaginal operative preparations and may be used as an alternative to iodine-based preparations.”

American College of Obstetricians and Gynecologist, Women's Health Care Practice Committee Opinion No. 571: Solutions for surgical preparation of the vagina. Obstet Gynecology 2013;122:718-720.

Are There Evidence-Based Studies to Validate the Use of an Antimicrobial (Triclosan) Wound Closure Technology?



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



Exposure Time 2 Minutes

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

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

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

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

Charles E. Edmiston, Jr, PhD,[a] **Frederic C. Daoud, MD,**[b] *and* **David Leaper, MD, FACS,**[c] *Milwaukee, WI, Paris, France, and London, UK*

Background. *It has been estimated that 750,000 to 1 million surgical-site infections (SSIs) occur in the United States each year, causing substantial morbidity and mortality. Triclosan-coated sutures were developed as an adjunctive strategy for SSI risk reduction, but a recently published systematic literature review and meta-analysis suggested that no clinical benefit is associated with this technology. However, that study was hampered by poor selection of available randomized controlled trials (RCTs) and low patient numbers. The current systematic review involves 13 randomized, international RCTs, totaling 3,568 surgical patients.*

Methods. *A systematic literature search was performed on PubMed, Embase/Medline, Cochrane database group (Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Health Economic Evaluations Database/Database of Health Technology Assessments), and www.clinicaltrials.gov to identify RCTs of triclosan-coated sutures compared with conventional sutures and assessing the clinical effectiveness of antimicrobial sutures to decrease the risk for SSIs. A fixed- and random-effects model was developed, and pooled estimates reported as risk ratio (RR) with a corresponding 95% confidence interval (CI). Publication bias was assessed by analyzing a funnel plot of individual studies and testing the Egger regression intercept.*

Results. *The meta-analysis (13 RCTs, 3,568 patients) found that use of triclosan antimicrobial-coated sutures was associated with a decrease in SSIs in selected patient populations (fixed effect: RR = 0.734; 95% CI: 0.590–0.913; P = .005; random-effect: RR = 0.693; 95% CI: 0.533–0.920; P = .011). No publication bias was detected (Egger intercept test: P = .145).*

Conclusion. *Decreasing the risk for SSIs requires a multifaceted "care bundle" approach, and this meta-analysis of current, pooled, peer-reviewed, randomized controlled trials suggests a clinical effectiveness of antimicrobial-coated sutures (triclosan) in the prevention of SSIs, representing Center for Evidence-Based Medicine level 1a evidence. (Surgery 2013;154:89-100.)*

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

Meta-analysis

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

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

[1]Department of Hepatobiliary Surgery, Affiliated Drum Tower Hospital, School of Medicine, Nanjing University, and [2]Jiangsu Province's Key Medical Centre for Liver Surgery, Nanjing, Jiangsu Province, China

Correspondence to: Professor Y. T. Ding, 321 Zhong Shan Road, Nanjing, Jiangsu Province, China 210008 (e-mail: dingyitao@yahoo.com.cn)

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

Methods: A systematic search of PubMed, Embase, MEDLINE, Web of Science®, the Cochrane Central Register of Controlled Trials and internet-based trial registries for RCTs comparing the effect of TCS and conventional uncoated sutures on SSIs was conducted until June 2012. The primary outcome investigated was the incidence of SSI. Pooled relative risks with 95 per cent confidence interval (c.i.) were estimated with RevMan 5.1.6.

Results: Seventeen RCTs involving 3720 participants were included. No heterogeneity of statistical significance across studies was observed. TCS showed a significant advantage in reducing the rate of SSI by 30 per cent (relative risk 0·70, 95 per cent c.i. 0·57 to 0·85; $P < 0·001$). Subgroup analyses revealed consistent results in favour of TCS in adult patients, abdominal procedures, and clean or clean-contaminated surgical wounds.

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

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

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

- *Wang et al, British J Surgery 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;36:169-179: 29 studies (11,900 patients) – 26% reduction in SSI (p<0.01)*
- *Guo et al, J Surg Research 2016;201:105-117.– 13RCT (5256 patients) (risk ratio [RR] 0.76, 95% confidence interval [CI] 0.65-0.88, P < 0.001)*

How Does One Evaluate An Antimicrobial Risk-Reduction Technology?

1. Safety
   - 700-750 million strands implanted since 2003 - No MAUDE (FDA) reports (in 13 years) documenting direct evidence linking triclosan to adverse impact in surgical wounds
2. Microbicidal Activity (Spectrum)
   - Documented Gram-positive and Gram-negative antimicrobial activity and no published studies have demonstrated that use of triclosan coated sutures are associated with the emergence of resistant surgical pathogens
3. Evidence-based Clinical Effectiveness (Meta-Analysis)
   - Currently 6 meta-analysis in the peer-literature document clinical efficacy of triclosan (antimicrobial) suture technology
4. Cost-Effectiveness
   - *Singh et al. Infect Control Hosp Epidemiol 2014;35:1013, Leaper and Edmiston. Brit J Surgery 2017 (in-press) -* documents that use of triclosan-coated sutures provides significant fiscal benefit to hospital, third party-payer and patient

Triclosan-containing sutures versus ordinary sutures for reducing surgical site infections in children: a double-blind, randomised controlled trial

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Summary

Background Surgical site infections (SSIs) are a pervasive problem in surgery. Sutures coated or impregnated with triclosan might reduce the occurrence of SSIs, but evidence of their efficacy is limited, especially in children.

Methods We designed a randomised, double-blind, controlled trial in patients who underwent elective or daytime emergency surgery at Oulu University Hospital (Oulu, Finland). We included children younger than 18 years staying in the paediatric surgery and orthopaedics ward for any elective or emergency surgery during the daytime and with anticipated use of absorbing sutures. Children were randomly allocated (1:1) to receive either triclosan-containing sutures or ordinary absorbing sutures. The primary outcome was the occurrence of superficial or deep surgical site infections according to the Centers for Disease Control and Prevention criteria within 30 days after surgery. The primary analysis was with modified intention to treat. This trial is registered at ClinicalTrials.gov, number NCT01220700.

Findings Between September, 2010, and December, 2014, 1633 children were recruited. In the modified intention-to-treat group, SSIs occurred in 20 (3%) of 778 patients allocated to receive triclosan-containing sutures and in 42 (5%) of 779 patients allocated to receive control sutures (risk ratio 0·48, 95% CI 0·28–0·80). To prevent one SSI, triclosan-containing sutures had to be used in 36 children (95% CI 21–111). One patient died from suspected mitochondrial disease; no other expected or unexpected adverse events were reported in either of the groups.

Interpretation Use of triclosan-containing sutures effectively reduced the occurrence of all SSIs compared with normal sutures. The results accord with the results of meta-analyses of previous studies in adults. Use of triclosan-containing sutures is a simple way to reduce SSIs in children.

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2016 SSI Prevention Guidelines

WHO (October 2016) – “Triclosan sutures may be used for the purpose of reducing the risk of SSI, independent of type of surgery.”

CDC-HICPAC Proposed Guidelines (12/2016) – Based upon multiple RCTs and evidence-based meta-analyses from independent investigators - Triclosan antimicrobial sutures are recommended as a strategy for the prevention of surgical site infections

What Constitutes the Ideal Surgical Care Bundle?

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

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Abstract

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

Nationalizing Risk Reduction—The SCIP Mandate

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

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

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

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Presented in part at a scientific symposium of the Thirtieth Annual Meeting of the Surgical Infection Society, Las Vegas, Nevada, April 17–20, 2010.

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

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Background. *Surgical site infection (SSI) remains a costly and morbid complication after colectomy. The primary objective of this study was to investigate whether a group of perioperative care measures previously shown to be associated with reduced SSI would have an additive effect in SSI reduction. If so, this would support the use of an "SSI prevention bundle" as a quality improvement intervention.*
Methods. *Data from 24 hospitals participating in the Michigan Surgical Quality Collaborative were included in the study. The main outcome measure was SSI. Hierarchical logistic regression was used to account for clustering of patients within hospitals.*
Results. *In total, 4,085 operations fulfilled inclusion criteria for the study (Current Procedural Terminology codes 44140, 44160, 44204, and 44205). A "bundle score" was assigned to each operation, based on the number of perioperative care measures followed (appropriate Surgical Care Improvement Project-2 antibiotics, postoperative normothermia, oral antibiotics with bowel preparation, perioperative glycemic control, minimally invasive surgery, and short operative duration). There was a strong stepwise inverse association between bundle score and incidence of SSI. Patients who received all 6 bundle elements had risk-adjusted SSI rates of 2.0% (95% confidence interval [CI], 7.9–0.5%), whereas patients who received only 1 bundle measure had SSI rates of 17.5% (95% CI, 27.1–10.8%).*
Conclusion. *This multi-institutional study shows that patients who received all 6 perioperative care measures attained a very low, risk-adjusted SSI rate of 2.0%. These results suggest the promise of an SSI reduction intervention for quality improvement; however, prospective research are required to confirm this finding. (Surgery 2014;155:602-6.)*

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Waits et al, Surgery 2014;155:602

Original Research

Using Bundled Interventions to Reduce Surgical Site Infection After Major Gynecologic Cancer Surgery

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OBJECTIVE: To investigate whether implementing a bundle, defined as a set of evidence-based practices performed collectively, can reduce 30-day surgical site infections.

METHODS: Baseline surgical site infection rates were determined retrospectively for cases of open uterine cancer, ovarian cancer without bowel resection, and ovarian cancer with bowel resection between January 1, 2010, and December 31, 2012, at an academic center. A perioperative bundle was prospectively implemented during the intervention period (August 1, 2013, to September 30, 2014). Prior established elements were: patient education, 4% chlorhexidine gluconate shower before surgery, antibiotic administration, 2% chlorhexidine gluconate and 70% isopropyl alcohol coverage of incisional area, and cefazolin redosing 3–4 hours after incision. New elements initiated were: sterile closing tray and staff glove change for fascia and skin closure, dressing removal at 24–48 hours, dismissal with 4% chlorhexidine gluconate, and follow-up nursing phone call. Surgical site infection rates were examined using control charts, compared between periods using χ^2 or Fisher exact test, and validated against the American College of Surgeons National Surgical Quality Improvement Program decile ranking.

RESULTS: The overall 30-day surgical site infection rate was 38 of 635 (6.0%) among all cases in the preintervention period, with 11 superficial (1.7%), two deep (0.3%), and 25 organ or space infections (3.9%). In the intervention period, the overall rate was 2 of 190 (1.1%), with two organ or space infections (1.1%). Overall, the relative risk reduction in surgical site infection was 82.4% (P=.01). The surgical site infection relative risk reduction was 77.6% among ovarian cancer with bowel resection, 79.3% among ovarian cancer without bowel resection, and 100% among uterine cancer. The American College of Surgeons National Surgical Quality Improvement Program decile ranking improved from the 10th decile to first decile; risk-adjusted odds ratio for surgical site infection decreased from 1.6 (95% confidence interval 1.0–2.6) to 0.6 (0.3–1.1).

CONCLUSION: Implementation of an evidence-based surgical site infection reduction bundle was associated with substantial reductions in surgical site infection in high-risk cancer procedures.

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Presented at the American College of Surgeons National Surgical Quality Improvement Program Annual Meeting, July 25–28, 2015, Chicago, Illinois.

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Johnson et al. Obstet Gynecol 2016;127:1135-1144

Implementation of bundled interventions greatly decreases deep sternal wound infection following cardiovascular surgery

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Objective: Surgical site infection (SSI), particularly deep sternal wound infection (DSWI), is a serious complication after cardiovascular surgery because of its high mortality rate. We evaluated the effectiveness of an SSI bundle to reduce DSWI and identify the risk factors for DSWI.

Methods: During the period January 2004 to February 2012, 1374 consecutive patients undergoing cardiovascular surgery via sternotomy were included. The cohort was separated into periods from January 2004 through February 2007 (period I, 682 patients) and March 2007 through February 2012 (period II, 692 patients). During period II, all preventive measures for DSWI were completed as an SSI bundle. We compared the DSWI rate between the 2 periods. Univariate and multivariate analyses were performed for the entire period to identify the risk factors for DSWI.

Results: DSWI occurred in 13 patients (1.9%) during period I and in 1 patient (0.14%) during period II. The DSWI rate during period II was significantly decreased by 93%, compared with period I ($P = .001$). Independent risk factors for DSWI included obesity (odds ratio [OR], 3.4; 95% confidence interval [CI], 1.00-11.75; $P = .049$), the use of 4 sternal wires (OR, 8.2; 95% CI, 1.39-48.14; $P = .020$), long operative time (OR, 4.4; 95% CI, 1.20-16.23; $P = .026$), and postoperative renal failure (OR, 9.0; 95% CI, 2.44-33.30; $P = .001$).

Conclusions: Complete implementation of simple multidisciplinary prevention measures as a bundle can greatly decrease the incidence of DSWI. (J Thorac Cardiovasc Surg 2014;148:2381-8)

See related commentary on pages 2388-9.

method. We also identified the most significant risk factors of DSWI.

Implementation of an Infection Prevention Bundle to Reduce Surgical Site Infections and Cost Following Spine Surgery

An estimated 158 000 surgical site infections (SSIs) occur in the Unites States annually, at a cost of $3.45 billion to $10.07 billion.[1,2] Investigations have demonstrated the efficacy of infection prevention bundles in reducing SSIs across multiple surgical specialties.[3,4] Neurosurgical SSIs incur the highest costs, and spine surgeries account for more than 1.01 million procedures annually, presenting an opportunity for reducing health care-related harm and expenditures.[5] We hypothesized that implementation of an infection prevention bundle would be associated with a reduction in SSIs and disease-specific costs.

Methods | The Cleveland Clinic Institutional Review Board approved this pragmatic, quasi-experimental cohort study, and it was conducted between March 2012 and December 2013. Informed consent was not required because this was a quality improvement initiative with minimal risk. A waiver of informed consent was obtained from the institutional review board. In January 2013, an infection prevention bundle was introduced at a single tertiary-care center. Patients undergoing discectomy, decompression, augmentation, or fusion of the spine were included. The analysis of the data was conducted in January 2015.

The bundle included 9 evidence-based components: (1) screening for *Staphylococcus aureus* nasal colonization and decolonization with mupirocin, (2) self-preparation bath with chlorhexidine gluconate, (3) self-preparation with chlorhexidine gluconate wipes,[6] (4) storage optimization of operating room supplies, (5) preoperative antibiotic adminis-

Table 1. Patient and Operative Characteristics (continued)

Statistic	No. (%) Preintervention	No. (%) Intervention Period	*P* Value
Smoking status			
Current	147 (15)	132 (17)	.14
Former	398 (41)	290 (36)	
Never	426 (44)	377 (47)	
Admission type			
Urgent/emergent	190 (20)	168 (21)	.55
Elective	781 (80)	631 (79)	
Length of stay, median (IQR), d	3 (1-5)	3 (1-5)	.72
Discharge status			
Home	556 (57)	475 (59)	.17
Home health	152 (16)	135 (17)	
SNF	189 (19)	133 (17)	
Acute rehabilitation	65 (7)	42 (5)	
Other[a]	9 (1)	14 (2)	
Diagnostic indication			
Degenerative	746 (77)	619 (77)	.77
Other[b]	151 (16)	116 (15)	
Malignancy	52 (5)	45 (6)	
Deformity	22 (2)	19 (2)	
Procedural category			
Fusion	457 (47)	355 (44)	.04
Revision	244 (25)	210 (26)	
Discectomy	151 (16)	137 (17)	
Vertebral augmentation	49 (5)	28 (4)	
Tumor resection	35 (4)	49 (6)	

50% reduction
P=0.01

Featherall et al. JAMA Surg 2016;151:988

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

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Surgery 2015;158:66-77

Based Upon Quality of Evidence - The Top 10 Evidence-Based (1A) Risk Reduction Interventions Eligible for Inclusion in a Surgical Care Bundle

Normothermia – All

Glycemic Control – All

Appropriate Antimicrobial Prophylaxis (Weight-Based Dosing) – All

Antimicrobial (Triclosan) Sutures (Fascial and Sub-cuticular closure) - All

Supplemental 0_2 - All

Appropriate Hair Removal - All

2% ot 4% CHG Preadmission Shower - All

70% alc/2% CHG Perioperative Skin Prep - All

Mechanical Bowel Prep/Oral Antibiotics – Colo-rectal

Staphylococcal Surveillance and Decolonization– Orthopedic/ CT

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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 infection: poor compliance with guidelines and care bundles. Int Wound J 2014; doi: 10.1111/iwj.12243

Abstract

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

Wisconsin Division of Public Health SSI Website

https://www.dhs.wisconsin.gov/hai/ssi-prevention.htm

"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