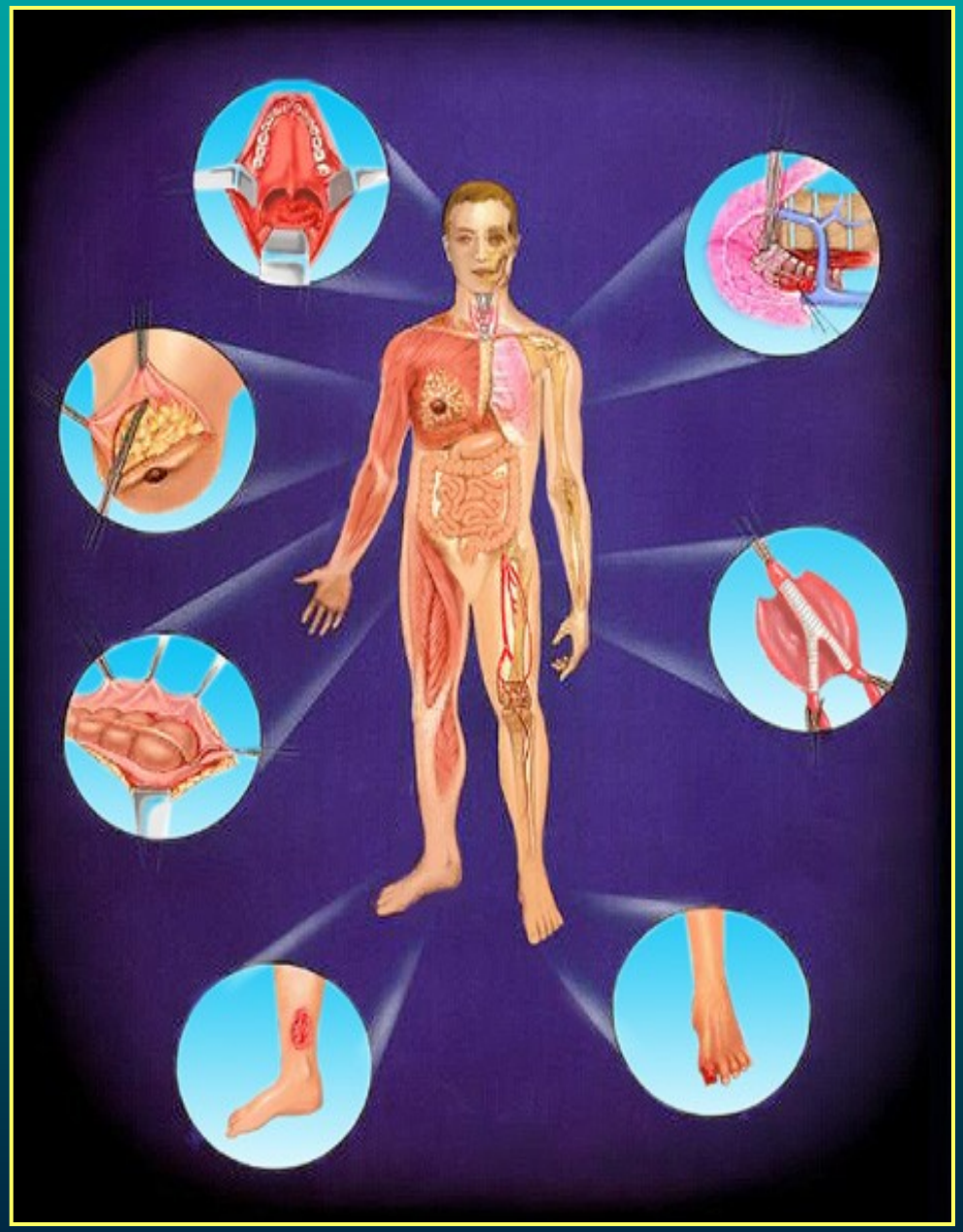

Validating Evidence-Based Practices – How to Teach an Old Dog New Tricks

Charles E. Edmiston Jr., PhD., CIC

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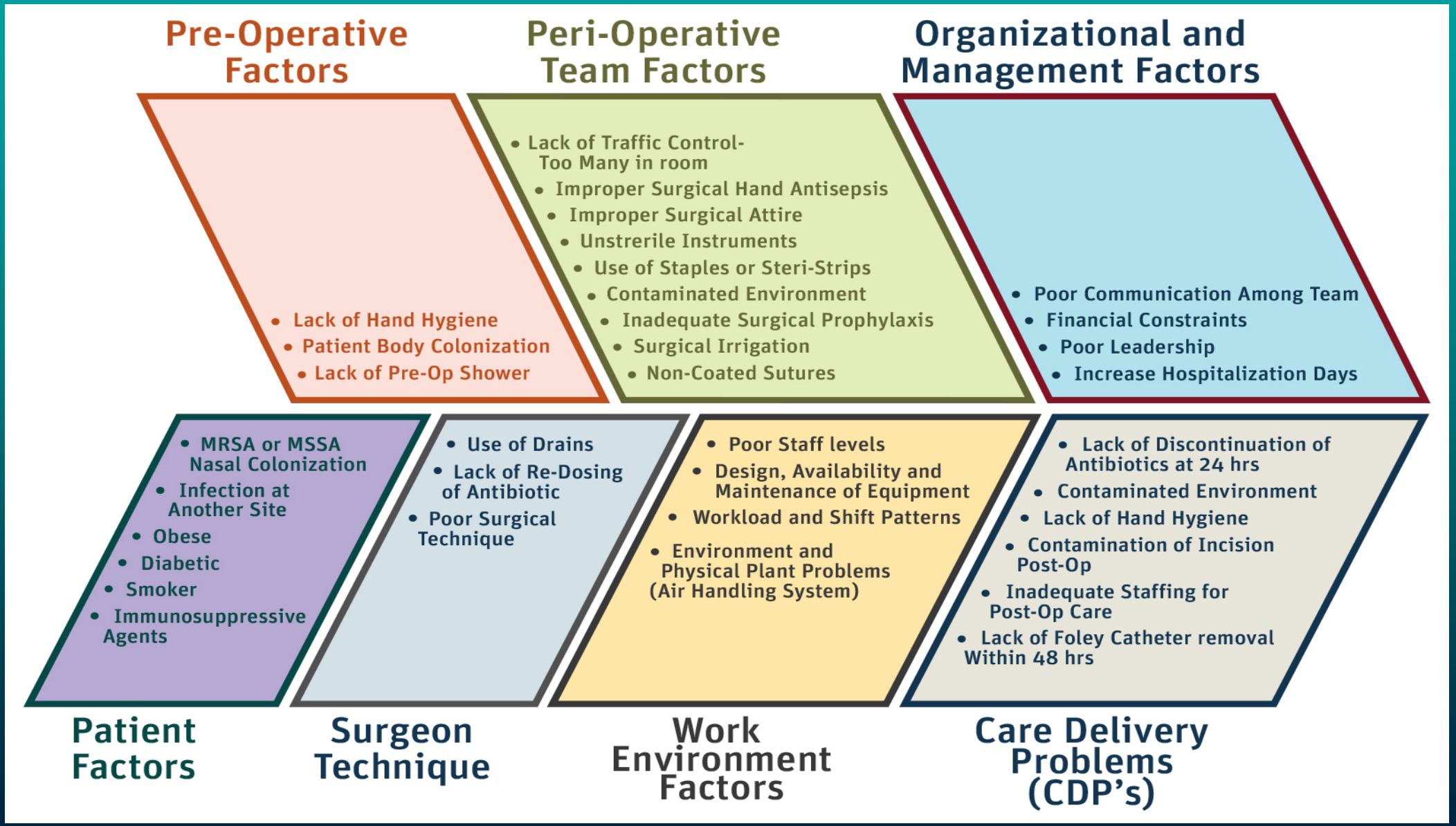
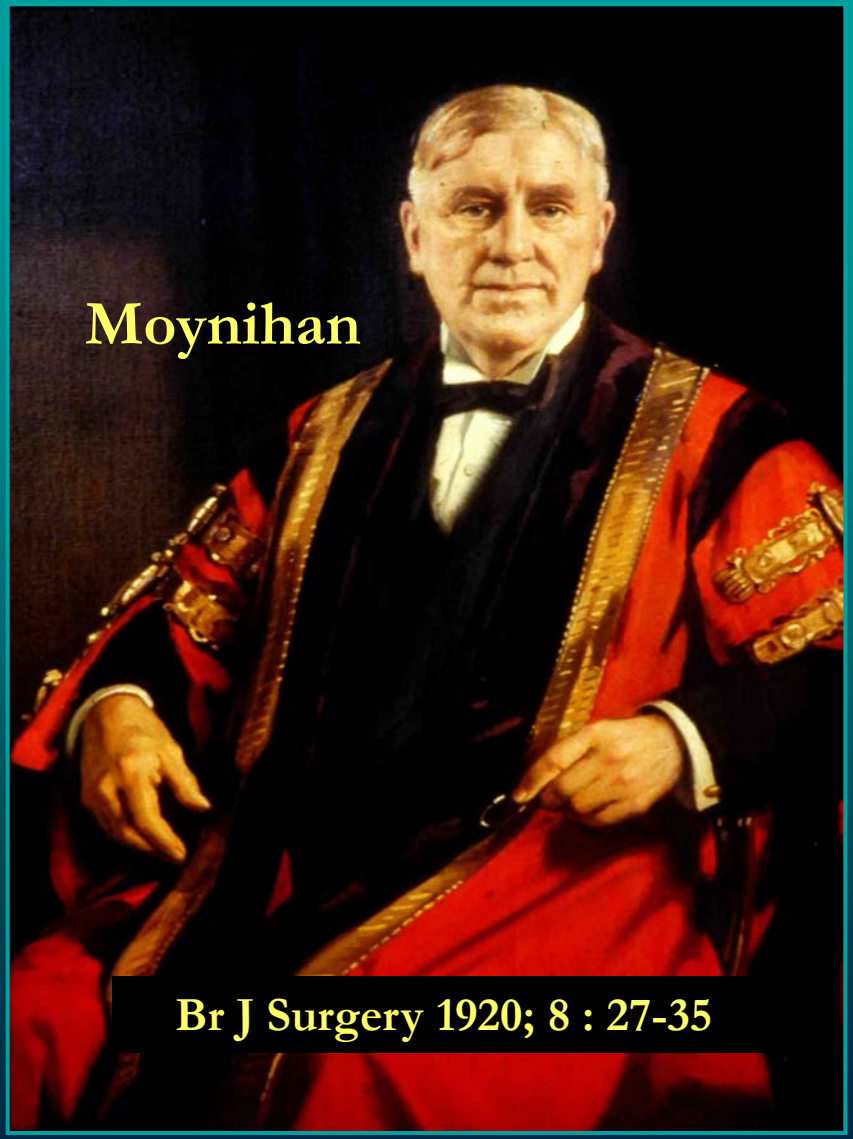
MEDICAL COLLEGE OF WISCONSIN

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

Risk is a Myriad of Events - SSI Fishbone Diagram

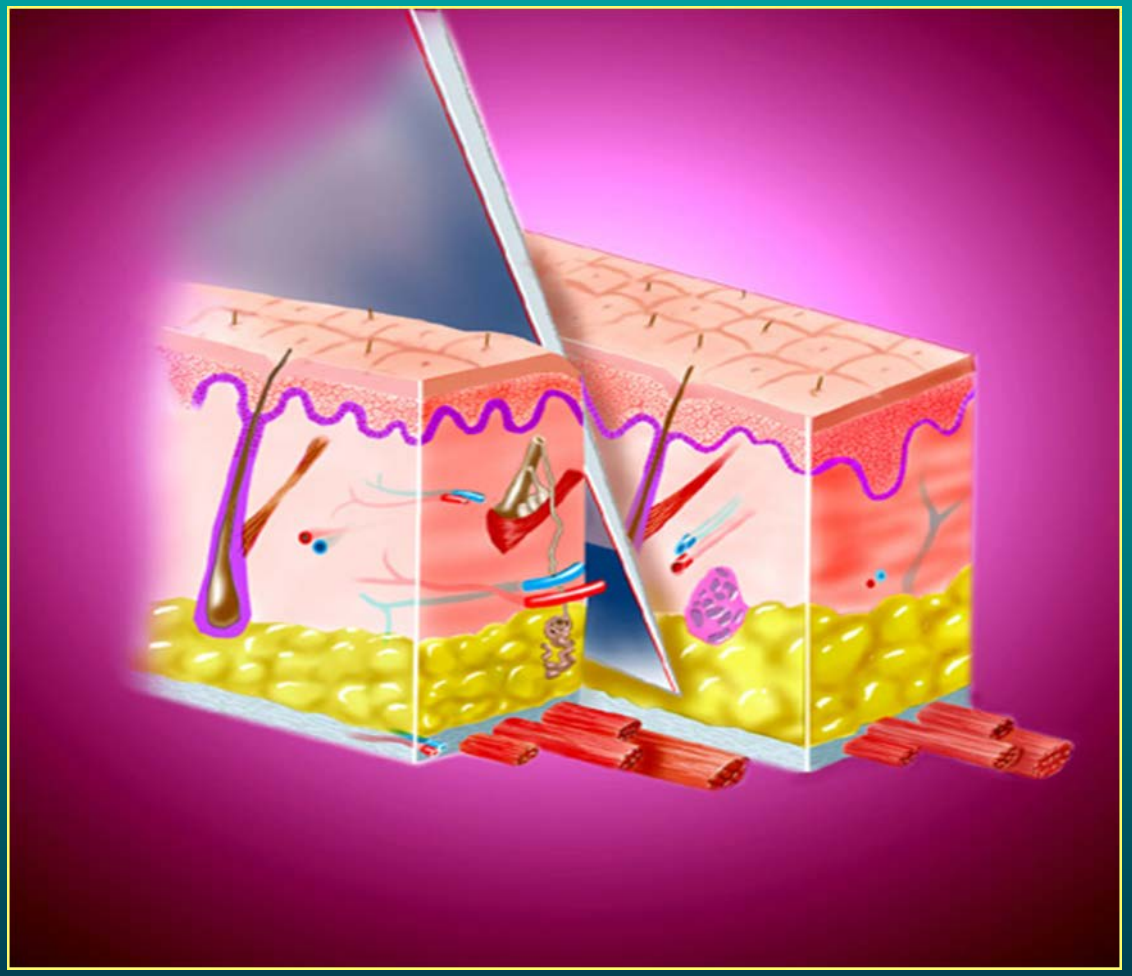


“Every operation is an experiment in bacteriology”



Br J Surgery 1920; 8 : 27-35

“It’s all about the surgical wound”



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

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

Evidence-Based Hierarchy

GUIDELINE FOR PREVENTION OF SURGICAL SITE INFECTION, 1999

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

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

Hospital Infection Control Practices Advisory Committee Membership List, January 1999

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EXECUTIVE SECRETARY
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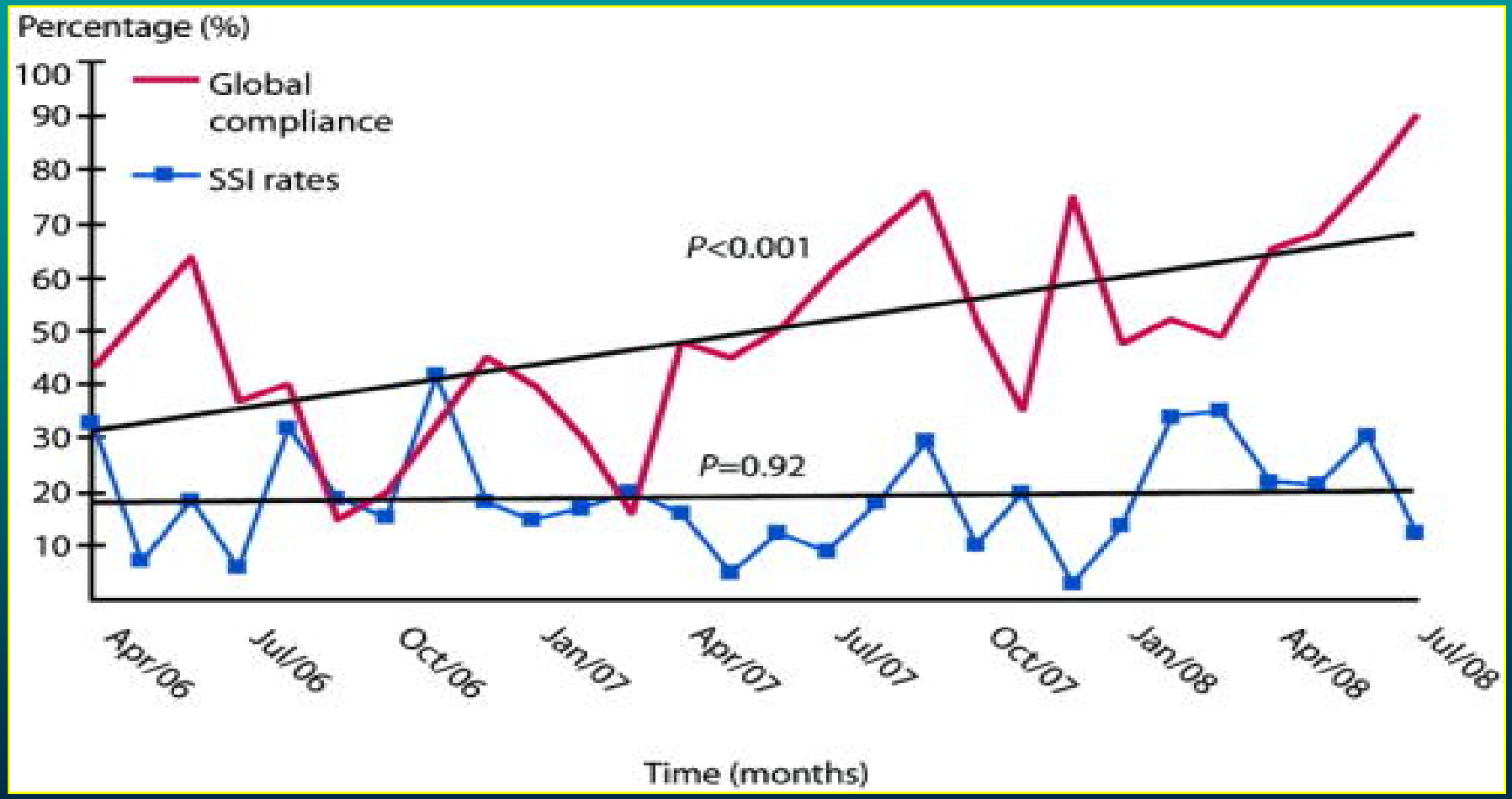
Chicago, Illinois

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

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

Is this the Holy Grail?

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



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

Journal of
Vascular Surgery
Official Publication of the Society for Vascular Surgery®
Volume 60 Number 6 December 2014

Evaluation of the Zenith Fenestrated Graft
Readmissions After Complex Aneurysm Repair
Hospital Factors in Mortality After AAA Repair
Rarity of Splenic Aneurysm Rupture in Pregnancy
Validation of SVS WIfI Classification
Smoking Cessation and Mortality in PAD
Role of Safety Net Hospitals in Vascular Surgery
Impact of SCIP on Surgical Site Infections

Mosby
www.jvascsurg.org
ISSN 0741-5214
2015 SAVS Abstracts

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

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

Objective: The Surgical Care Improvement Project (SCIP) is a national initiative to reduce surgical complications, including postoperative surgical site infection (SSI), through protocol-driven antibiotic usage. This study aimed to determine the effect SCIP guidelines have had on in-hospital SSIs after open vascular procedures.

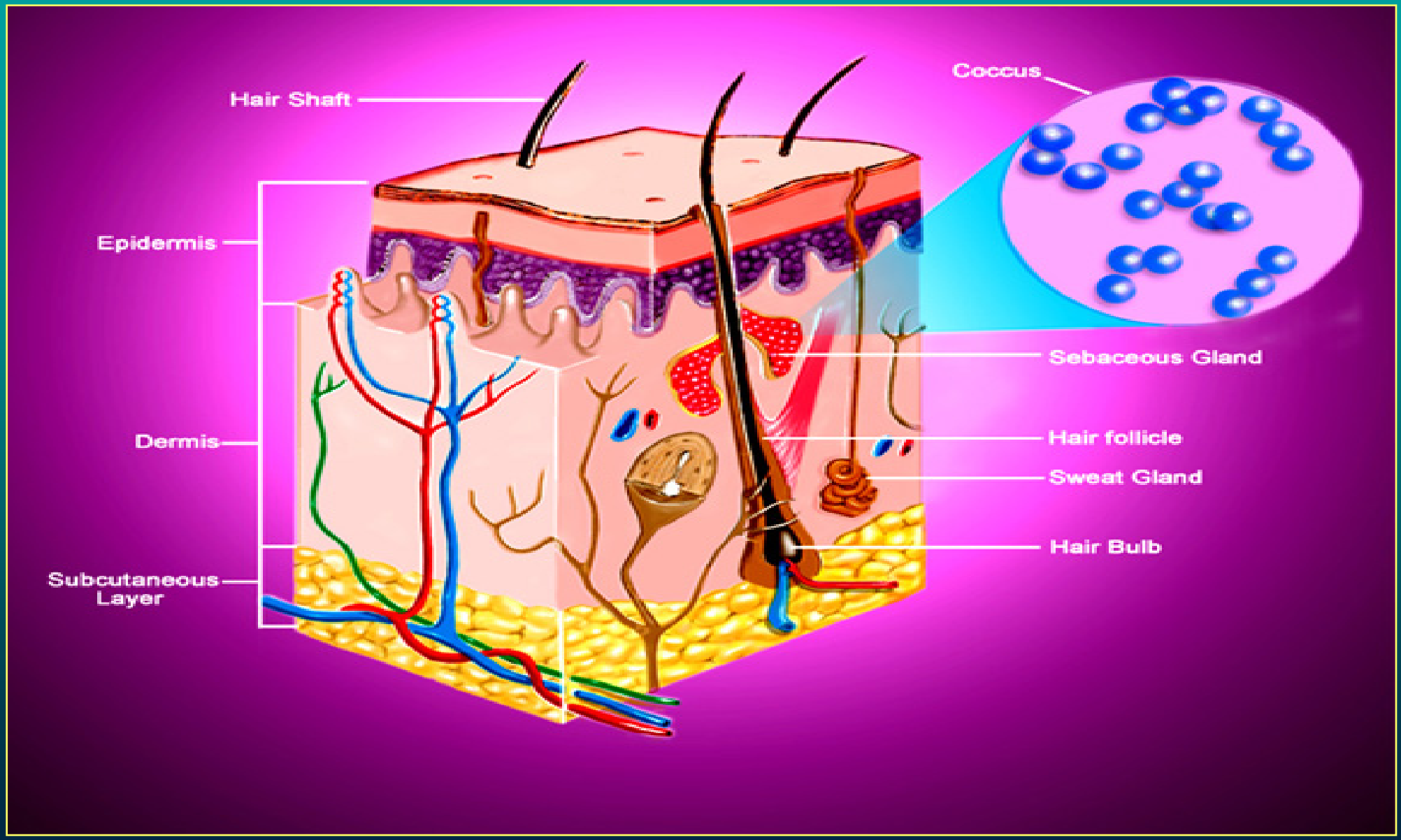
Methods: The Nationwide Inpatient Sample (NIS) was retrospectively analyzed using International Classification of Diseases, Ninth Revision, diagnosis codes to capture SSIs in hospital patients who underwent elective carotid endarterectomy, elective open repair of an abdominal aortic aneurysm (AAA), and peripheral bypass. The pre-SCIP era was defined as 2000 to 2005 and post-SCIP was defined as 2007 to 2010. The year 2006 was excluded because this was the transition year in which the SCIP guidelines were implemented. Analysis of variance and χ^2 testing were used for statistical analysis.

Results: The rate of SSI in the pre-SCIP era was 2.2% compared with 2.3% for carotid endarterectomy ($P = .06$). For peripheral bypass, both in the pre- and post-SCIP era, infection rates were 0.1% ($P = .22$). For open, elective AAA, the rate of infection in the post-SCIP era increased significantly to 1.4% from 1.0% in the pre-SCIP era ($P < .001$). Demographics and in-hospital mortality did not differ significantly between the groups.

Conclusions: Implementation of SCIP guidelines has made no significant effect on the incidence of in-hospital SSIs in open vascular operations; rather, an increase in SSI rates in open AAA repairs was observed. Patient-centered, bundled approaches to care, rather than current SCIP practices, may further decrease SSI rates in vascular patients undergoing open procedures. (J Vasc Surg 2014;60:1635-9.)

Adjunctive Components – The Preadmission Shower from an Evidence-Based Perspective

❖ Preadmission Showering/Cleansing



Microbial Ecology of Skin Surface

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

Surgical Microbiology Research Laboratory 2008 – Medical College of Wisconsin

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

Webster J, Osborne S

THE COCHRANE COLLABORATION®

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

http://www.thecochranelibrary.com

Draft Guideline for the Prevention of Surgical Site Infection

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

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

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

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

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

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

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

Measuring Patient Compliance

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

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

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

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

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

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

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

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

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

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

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

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

- Looking at the Preadmission Shower from a Pharmacokinetic Perspective

Dose
Duration
Timing

Research

Original Investigation

Evidence for a Standardized Preadmission Showering Regimen to Achieve Maximal Antiseptic Skin Surface Concentrations of Chlorhexidine Gluconate, 4%, in Surgical Patients

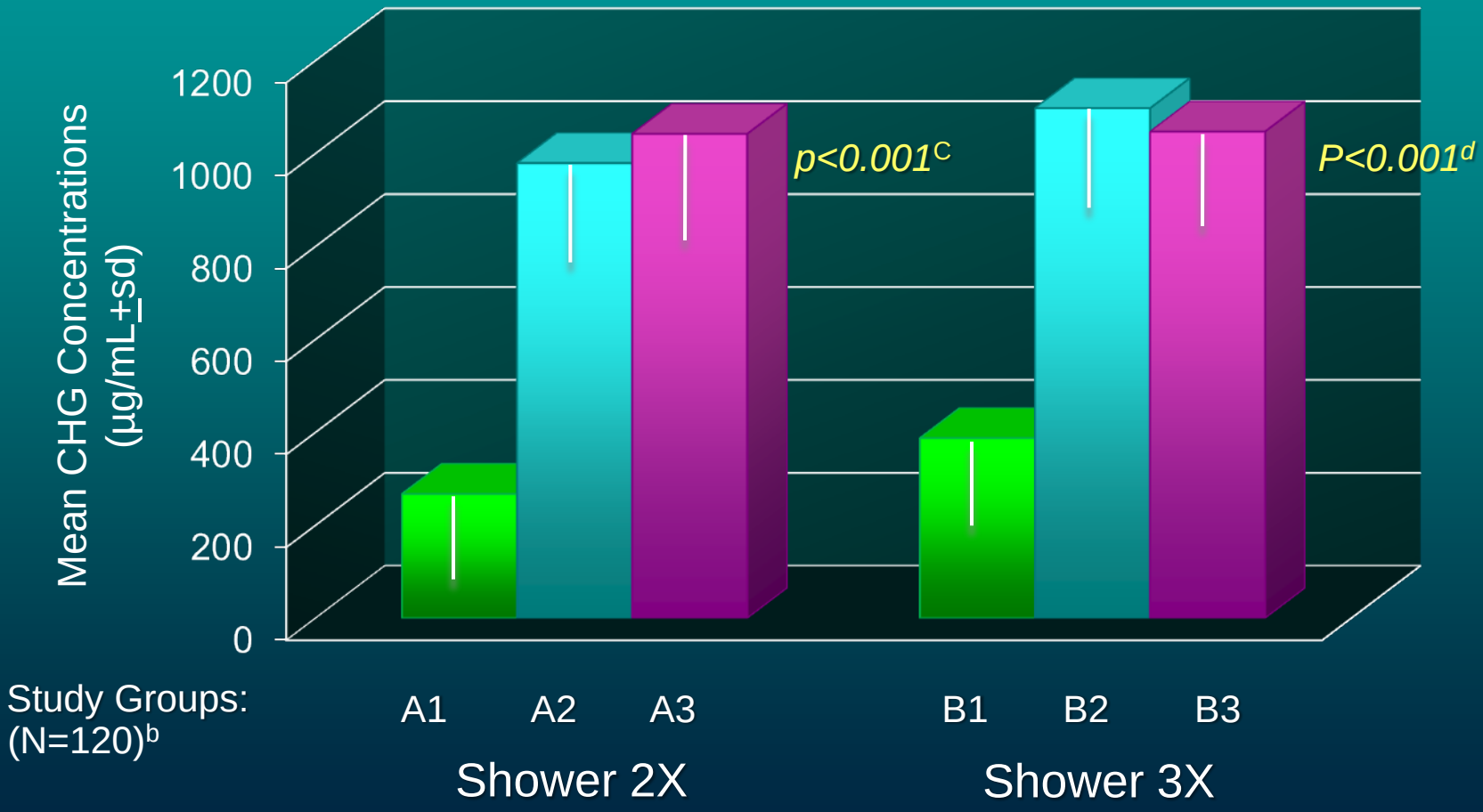
Charles E. Edmiston Jr, PhD; Cheong J. Lee, MD; Candace J. Krepel, MS; Maureen Spencer, MEd; David Leaper, MD; Kellie R. Brown, MD; Brian D. Lewis, MD; Peter J. Rossi, MD; Michael J. Malinowski, MD; Gary R. Seabrook, MD

Invited Commentary

IMPORTANCE To reduce the amount of skin surface bacteria for patients undergoing elective surgery, selective health care facilities have instituted a preadmission antiseptic skin cleansing protocol using chlorhexidine gluconate. A Cochrane Collaborative review suggests that existing data do not justify preoperative skin cleansing as a strategy to reduce surgical site infection.

Edmiston et al. JAMA-Surgery August 26, 2015

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



Edmiston et al. JAMA-Surgery August 26, 2015

Invited Commentary

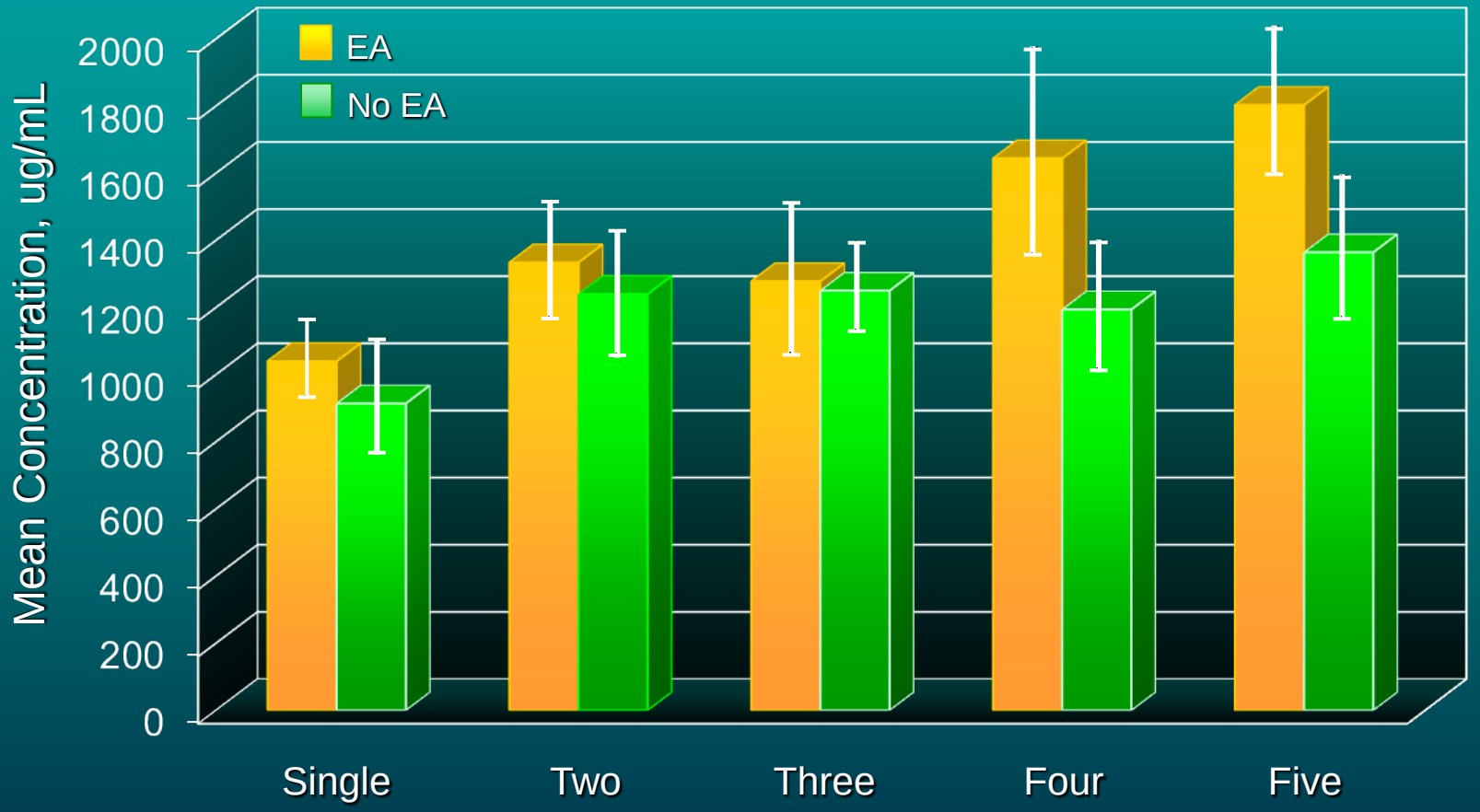
Chlorhexidine Gluconate, 4%, Showers and Surgical Site Infection Reduction

Zeinab M. Alawadi, MD, MS; Lillian S. Kao, MD, MS

Is chlorhexidine gluconate showering with a standardized regimen the answer to SSI prevention? Not in and of itself. Should a promising, safe, low-cost intervention be part of the answer? Yes. If we limit interventions to those with definitive, high-quality evidence, then our efforts to reduce SSIs will certainly be a wash.

Edmiston et al. JAMA-Surgery August 26, 2015

Composite Mean Skin Surface Concentrations of Chlorhexidine Gluconate 2%, Following Multiple Applications (5 Separate Anatomic Sites)



(n=20 per application interval, 6-2% cloths per cleansing session)

Edmiston et al, In Press Infect Control Hosp Epidemiol (Winter 2016)

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

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OJAN ASSADIAN, *MD, DTM&H;* **MAUREEN SPENCER,** *MEd, BSN, CIC;*
RUSSELL N. OLMSTED, *MPH, BS, CIC;* **SUE BARNES,** *BSN, RN, CIC;*
DAVID LEAPER, *MD, ChM, FRCS, FACS, FLS*

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

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

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

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

Some Final Thoughts

Surgical Innovation

The Surgeon Cost Report Card
A Novel Cost-Performance Feedback Tool

Keith Gunaratne, BSc; Michelle C. Cleghorn, MSc; Timothy D. Jackson, MD, MPH, FRCSC

What Is the Innovation?

We developed a novel cost-performance feedback tool to provide surgeons with a continuous assessment of operating room expenditures. This "Surgeon Cost Report Card" is an email message meant to increase surgeons' awareness of costs and encourage changes in behavior (**Figure**). A smartphone-compatible design maximizes usability. Cost data are aggregated and subdivided by item categories. Individual and collective averages are presented, promoting comparison with derived group standards by time period and procedure type. Intuitive color-coding is used to direct attention. It also reinforces the goal of cost reduction, taking advantage of the competitive culture intrinsic to surgical practice. Positive feedback is given by naming the best performer in the group, further encouraging healthy peer-to-peer competition. Privacy is protected by customizing the report card for individual surgeons. The report interval can be freely adjusted based on case volume to balance timely feedback with adequate sample size. Automation of the data processing required to generate the report card enables rapid deployment with minimal administrative requirements.

What Are the Key Advantages Over Existing Approaches?

Surgeons are integral to cost containment, but they must first understand costs and utilization before they can make appropriate practice modifications toward improved cost efficiency. This notion has led to educational initiatives that show promise.[1] However, such interventions are time-consuming and may not occur frequently enough to deliver timely information for real-time change, continuous reinforcement of cost reduction, and performance tracking against evolving benchmarks. Certainly, a surgeon's availability for regular participation in this forum is limited. Our report card addresses these challenges by leveraging reliance on and accessibility of email communication among physicians. Its smartphone compatibility and simplicity also mean that it can be read in seconds, increasing uptake and application of the information. Division meetings, which remain a key part of this strategy, can instead focus on identifying best-performer activities that could be adopted by colleagues to minimize total expenditure. Furthermore, the report card

mean (SD) cost of the operation decreased to $2859 ($391) (−5.9%) from September to December 2014 for 88 procedures. Seven months after implementation, the mean (SD) cost decreased to $2827 ($402) (−6.9%) from January to April 2015 for 107 procedures. The most efficient surgeon achieved a mean (SD) cost of $2492 ($410). With 293 gastric bypass procedures performed at our hospital in 2014, setting this target would mean potential yearly savings of up to $160 000 (18%) for Roux-en-Y gastric bypass procedures alone—the equivalent of 64 additional cases.

It is clear that goals for optimization cannot be at the expense of high-quality care. By comparing surgeons with their peers rather than promoting arbitrary minimization of costs, the report card will yield reasonable savings and reduce the variance in costs without compromising patient safety. Our institution also concurrently measures surgical outcomes through the American College of Surgeons National Surgical Quality Improvement Project. The next iteration of the report will incorporate outcomes data (including length of stay), operative times, and patient variables, providing a comprehensive valuation of the surgeon's performance as a function of quality, efficiency, and cost according to case-mix variability and complexity. Because our report card focuses on consumption of surgical resources, it does not capture the total cost per episode of care or its effect on service delivery during hospitalization. Increasing surgeons' awareness of health resource utilization across the entire inpatient visit and after discharge from hospital will also be important but will require reforming the information technology and standardizing the processes of case-cost reporting to support automation.

Figure. Sample of the Surgeon Cost Report Card

Gunaratne et al, JAMA Surgery Online Nov 4, 2015

Surgeons' Leadership Styles and Team Behavior in the Operating Room

Yue-Yung Hu, MD, MPH, Sarah Henrickson Parker, PhD, Stuart R Lipsitz, ScD, Alexander F Arriaga, MD, MPH, ScD, Sarah E Peyre, EdD, Katherine A Corso, MPH, Emilie M Roth, PhD, Steven J Yule, PhD, Caprice C Greenberg, MD, MPH, FACS

BACKGROUND: The importance of leadership is recognized in surgery, but the specific impact of leadership style on team behavior is not well understood. In other industries, leadership is a well-characterized construct. One dominant theory proposes that transactional (task-focused) leaders achieve minimum standards and transformational (team-oriented) leaders inspire performance beyond expectations.

STUDY DESIGN: We videorecorded 5 surgeons performing complex operations. Each surgeon was scored on the Multifactor Leadership Questionnaire, a validated method for scoring transformational and transactional leadership style, by an organizational psychologist and a surgeon researcher. Independent coders assessed surgeons' leadership behaviors according to the Surgical Leadership Inventory and team behaviors (information sharing, cooperative, and voice behaviors). All coders were blinded. Leadership style (Multifactor Leadership Questionnaire) was correlated with surgeon behavior (Surgical Leadership Inventory) and team behavior using Poisson regression, controlling for time and the total number of behaviors, respectively.

RESULTS: All surgeons scored similarly on transactional leadership (range 2.38 to 2.69), but varied more widely on transformational leadership (range 1.98 to 3.60). Each 1-point increase in transformational score corresponded to 3 times more information-sharing behaviors ($p < 0.0001$) and 5.4 times more voice behaviors ($p = 0.0005$) among the team. With each 1-point increase in transformational score, leaders displayed 10 times more supportive behaviors ($p < 0.0001$) and displayed poor behaviors 12.5 times less frequently ($p < 0.0001$). Excerpts of representative dialogue are included for illustration.

CONCLUSIONS: We provide a framework for evaluating surgeons' leadership and its impact on team performance in the operating room. As in other fields, our data suggest that transformational leadership is associated with improved team behavior. Surgeon leadership development, therefore, has the potential to improve the efficiency and safety of operative care. (J Am Coll Surg 2015; ■:1–11. © 2015 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

Hu et al, JACS on line Nov 2015

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 into disrepute)

1897	7.0%
1899	3.2%
1912	2.4%
1913	1.6%