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Prevention of Surgical Site Infection Using An Evidence Based Bundled Approach

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Faculty Disclosure

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Speaker's Bureau – Johnson & Johnson Health Care Systems Inc

Objectives

- Describe three key practices that should be assesed during direct surgical case observations to prevent surgical site infections (SSIs)
- List the elements of the seven-step bundle for SSI Prevention
- Develop a multidisciplinary team to implement the 7 S Bundle

Recent SSI Guidelines

GLOBAL GUIDELINES FOR THE PREVENTION OF SURGICAL SITE INFECTION

World Health Organization

http://www.who.int/gpsc/ssi-prevention-guidelines/en/

SPECIAL ARTICLES

American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update

Kristen A Ban, MD, Joseph P Minei, MD, FACS, Christine Laronga, MD, FACS, Brian G Harbrecht, MD, FACS, Eric H Jensen, MD, FACS, Donald E Fry, MD, FACS, Kamal MF Itani, MD, FACS, E Patchen Dellinger, MD, FACS, Clifford Y Ko, MD, MS, MSHS, FACS, Therese M Duane, MD, MBA, FACS

Guidelines for the prevention, detection, and management of surgical site infections (SSI) have been published previously.[1-3] This document is intended to update earlier guidelines based on the current literature and to provide a concise summary of relevant topics.

Surgical site infections are both common and morbid. Surgical site infections are now the most common and costly of all hospital-acquired infections, accounting for 20% of all hospital-acquired infections. Surgical site infections are associated with increased length of stay and a 2- to 11-fold increase in the risk of mortality. Although most patients recover from an SSI without long-term adverse sequelae, 77% of mortality in patients with an SSI can be attributed to the infection itself.[1,4]

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The incidence of SSI is 2% to 5% in patients undergoing inpatient surgery.[1] Estimated annual incidence varies widely, ranging from 160,000 to 300,000 in the US.[1,4] These estimates are likely understated, given the surveillance challenges after discharge.

The financial burden of SSI is considerable; it ranks as the most costly of the hospital-acquired infections.[5] The annual cost of SSI in the US is estimated at $3.5 to $10 billion.[1] Increased costs from SSIs are driven by increased length of stay, emergency department visits, and readmissions. On average, SSI extends hospital length of stay by 9.7 days, and increases the cost of hospitalization by more than $20,000 per admission. More than 90,000 readmissions annually are attributed to SSIs, costing an additional $700 million per year. Because up to 60% of SSIs were estimated to be preventable with the use of evidence-based measures,[1] SSI has become a pay-for-performance metric and a target of quality-improvement efforts.

The most widely used definition of SSI has been provided by CDC.[3] This definition is used for research, quality improvement, public reporting, and pay-for-performance comparisons. According to this definition, SSIs are classified by depth and tissue spaces involved. A superficial incisional SSI involves only the skin or subcutaneous tissue, a deep incisional SSI involves the fascia or muscular layers, and an organ space SSI involves any part of the body opened or manipulated during a procedure, excluding the previously mentioned layers.

Numerous risk factors have been identified for the development of an SSI after surgery. These risk factors can be broadly separated into intrinsic (patient) factors that are modifiable or nonmodifiable, as well as extrinsic (eg procedure, facility, preoperative, and operative) factors (Table 1). Potentially modifiable patient risk factors include glycemic control and diabetic status, dyspnea, alcohol and smoking status, preoperative albumin <3.5 mg/dL, total bilirubin >1.0 mg/dL, obesity, and immunosuppression. Nonmodifiable patient factors include increasing age, recent radiotherapy, and history

JACS 2016; 224:59–74

Clinical Review & Education

JAMA Surgery | Special Communication

Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017

Sandra I. Berríos-Torres, MD; Craig A. Umscheid, MD, MSCE; Dale W. Bratzler, DO, MPH; Brian Leas, MA, MS; Erin C. Stone, MA; Rachel R. Kelz, MD, MSCE; Caroline E. Reinke, MD, MSHP; Sherry Morgan, RN, MLS, PhD; Joseph S. Solomkin, MD; John E. Mazuski, MD, PhD; E. Patchen Dellinger, MD; Kamal M. F. Itani, MD; Elie F. Berbari, MD; John Segreti, MD; Javad Parvizi, MD; Joan Blanchard, MSS, BSN, RN, CNOR, CIC; George Allen, PhD, CIC, CNOR; Jan A. J. W. Kluytmans, MD; Rodney Donlan, PhD; William P. Schecter, MD; for the Healthcare Infection Control Practices Advisory Committee

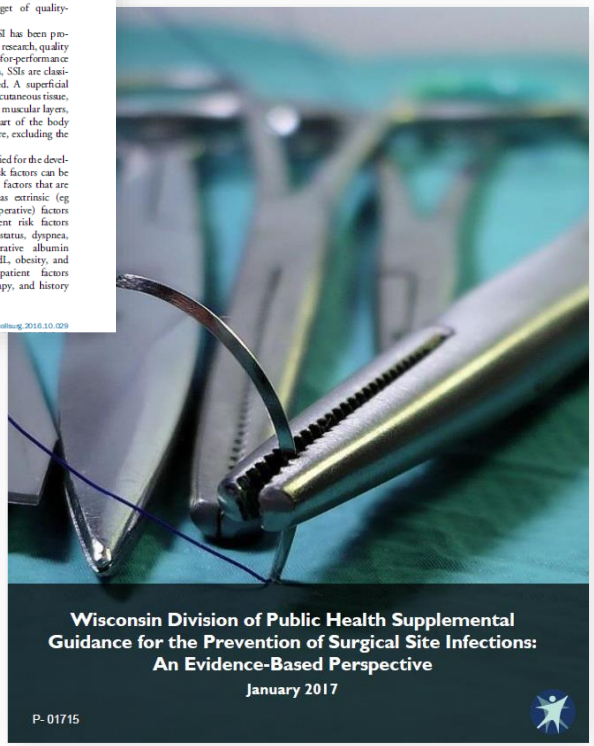
IMPORTANCE The human and financial costs of treating surgical site infections (SSIs) are increasing. The number of surgical procedures performed in the United States continues to rise, and surgical patients are initially seen with increasingly complex comorbidities. It is estimated that approximately half of SSIs are deemed preventable using evidence-based strategies.

OBJECTIVE To provide new and updated evidence-based recommendations for the prevention of SSI.

Invited Commentary

Supplemental content

JAMA Surg online May 2, 2017



wi-ssi-prevention-guidelines.pdf

Comparative Analysis of WHO, Proposed CDC, ACS and Wisconsin SSI Prevention Guidelines

INTERVENTION	WHO Guidelines	CDC Guidelines	ACS Guidelines	WISCONSIN SSI Prevention
Normothermia	Maintain normothermia	Maintain normothermia	Maintain normothermia	Maintain normothermia – FAW reduces incidence of SSI
Wound Irrigation	No recommendation	Intraoperative irrigation recommended – povidone iodine	No recommendation	Intraoperative irrigation recommended – CHG
Antimicrobial Prophylaxis	Short durational	Short durational	Short durational	Short durational – Follow ASHP weight-based dosing
Glycemic Control	Recommended	Recommended	Highly beneficial	Highly beneficial HA1c $\leq$6.7
Perioperative Oxygenation	Recommended	Administer increased FIO_2 during surgery after extubation, immediate postop period	Recommended	Recommended – Strongest evidence in colorectal surgery
Preadmission Showers	Advised patients to bathe or shower with soap	Advise patients to bathe or shower with soap or antiseptic agent – at least night before surgery	Advise patients to bathe/shower with CHG	Two standardized shower/cleansing with 4% or 2% CHG night before/morning (surgery)
Antimicrobial Sutures	Use antimicrobial sutures independent of type of surgery	Consider use of triclosan-coated sutures for prevention of SSI	Recommended for clean and clean-contaminated abdominal procedures	The use of triclosan sutures represents 1a clinical evidence

Distribution and Rank Order of Pathogens Frequently Reported to the National Healthcare Safety Network (NHSN) – Surgical Site Infections

Pathogens Involved with SSIs	Rank
Staph aureus (includes MRSA)	**1**
E.Coli	**2**
Coagulase neg staph	3
Enterococcus faecalis	4
Pseudomonas aerug	5
Klebsiella spp	6
Bacteroides	7
Enterobacter	8
Enterococcus spp	9
Proteus spp	10
Enterococcus faecium	11
Candida albicans	12

Weiner L, et al. NHSN 2011-2014 Infect Control Hosp Epidemiol 2016;37:1288–1301

Pathogens Survive on Surfaces

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

1. Beard-Pegler et al. 1988.. *J Med Microbiol*. **26**:251-5.
2. BIOQUELL trials, unpublished data.
3. Bonilla et al. 1996. *Infect Cont Hosp Epidemiol*. **17**:770-2
4. Boyce. 2007. *J Hosp Infect.* **65**:50-4.
5. Duckworth and Jordens. 1990. *J Med Microbiol*. **32**:195-200.
6. French et al. 2004. *ICAAC*.
7. Kramer et al. 2006. *BMC Infect Dis*. **6**:130.
8. Otter and French. 2009. *J Clin Microbiol*. **47**:205-7.
9. Smith et al. 1996. *J Med*. **27**: 293-302.
10. Wagenvoort et al. 2000. *J Hosp Infect*. **45**:231-4.
11. Wagenvoort and Joosten. 2002. *J Hosp Infect*. **52**:226-7.

Prior Room Occupancy Increases Risk of HAI

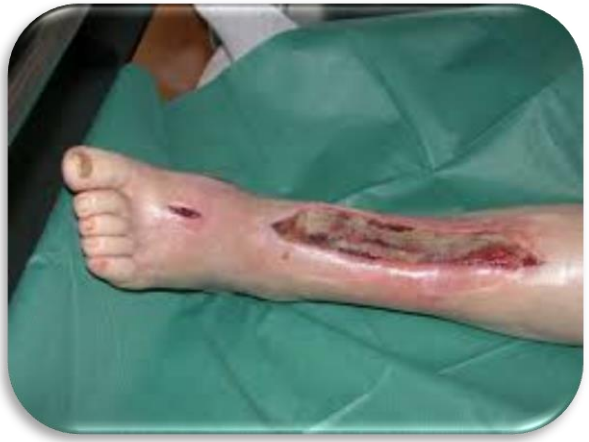
Study	Healthcare associated pathogen	Likelihood of patient acquiring HAI based on prior room occupancy (comparing a previously 'positive' room with a previously 'negative' room)
Martinez 2003[1]	VRE – cultured within room	2.6x
Huang 2006[2]	VRE – prior room occupant	1.6x
	MRSA – prior room occupant	1.3x
Drees 2008[3]	VRE – cultured within room	1.9x
	VRE – prior room occupant	2.2x
	VRE – prior room occupant in previous two weeks	2.0x
Shaughnessy 2008[4]	*C. difficile* – prior room occupant	2.4x
Nseir 2010[5]	*A. baumannii* – prior room occupant	3.8x
	P. aeruginosa – prior room occupant	2.1x

1. Martinez *et al. Arch Intern Med* 2003; 163: 1905-12.
2. Huang *et al. Arch Intern Med* 2006; 166: 1945-51.
3. Drees *et al. Clin Infect Dis* 2008; 46: 678-85.
4. Shaughnessy. ICAAC/IDSA 2008. Abstract K-4194.
5. Nseir et al. Clin Microbiol Infect 2010

Mortality Risk is High Among Patients with SSIs

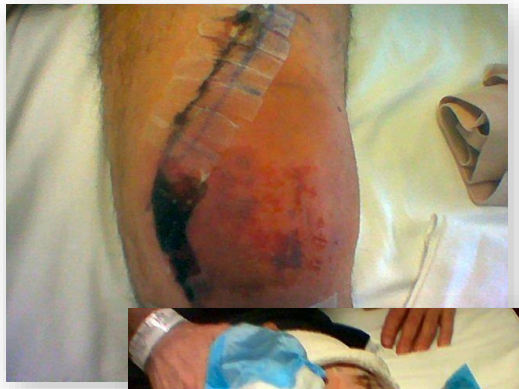
- A patient with an SSI is:
  - **5x** more likely to be readmitted after discharge[1]
  - **2x** more likely to spend time in intensive care[1]
  - **2x** more likely to die after surgery[1]

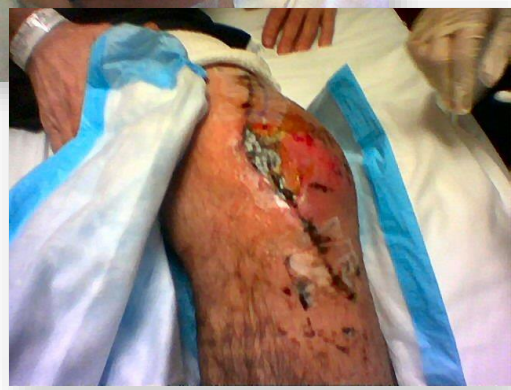
- Mortality risk is higher when SSI is due to MRSA
  - A patient with MRSA is **12x** more likely to die after surgery[2]



1. *WHO Guidelines for Safe Surgery* 2009.
2. Engemann JJ et al. *Clin Infect Dis.* 2003;36:592-598.

Special Risk Population: Orthopedic Implants





- Hip or Knee aspiration
- If positive – irrigation and debridement
- Removal of hardware may be necessary
- Insertion of antibiotic spacers
- Revisions at future date
- Long term IV antibiotics in community or rehab
- Future worry about the joint

In other words…
DEVASTATING FOR THE PATIENT AND SURGEON

A 7 S Bundle Approach to Preventing Surgical Site Infections

7 “S” Bundle to Prevent SSI

www.7sbundle.com

SAFETY – Safe operating room

SCREEN – Screening for risk factors and presence of MRSA & MSSA

SHOWERS – Shower – 2% CHG washcloths or 4% chlorhexidine soap – night before and morning of surgery

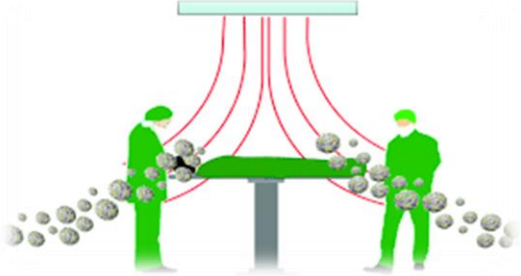
SKIN PREP – Skin preparation with alcohol-based antiseptics, such as CHG/alcohol or Iodophor/alcohol

SOLUTION – Surgical Irrigation prior to closure to remove exogenous contaminants – use of 0.05% chlorhexidine irrigant vs antibiotic irrigations

SUTURES – Suture closure with Triclosan coated antimicrobial sutures

SKIN CLOSURE – Skin adhesive to seal incision and/or antimicrobial dressing to prevent exogenous contamination in post-op period

#1 Safe Operating Room



#1 – Is it a Safe Operating Room?

- ✓ Traffic control, number staff in room
- ✓ Air handling systems: filtration, cleaning of grills, temps, humidity
- ✓ Evaluate forced air warmer hose placement
- ✓ Heater cooler (cardiac surgery) maintenance for air current transmission
- ✓ SCIP: hair clipping, warmers, oxygenation, surgical prophylaxis, Foley catheter removal < 48 hrs.
- ✓ Room turnover and terminal cleaning procedures
- ✓ Surgical technique and handling of tissues
- ✓ Instrument cleaning/sterilization process, biological indicators, ultrasonic washer
- ✓ Storage of supplies, supply bins, carts, tables, OR equipment

1. AORN Gap Analysis for Environmental Disinfection 2017

AORN Guidelines Related to Infection Prevention

www.aorn.org – Evidence Based Guidelines

Aseptic Practice

- Patient Skin Antisepsis
- Environmental Cleaning
- Hand Hygiene in the Perioperative Setting
- Surgical Attire
- Sterile Technique

Patient and Worker Safety

- Sharps Safety
- Transmissible Infections and isolation in the OR
- Environment of Care

Sterilization and Disinfection

- Flexible Endoscopes
- High Level Disinfection
- Instrument Cleaning
- Packaging Systems
- Sterilization

Surgical Care Improvement Program (SCIP)

1. Surgical prophylaxis: selection, time, discontinuation of abx - stop when incision is closed

2. Hair clippers
   - AORN Guideline: Patient Skin Antisepsis
     ii Recommendation II.b.1, page 56 – The patient's hair should be removed in a location **outside** the operating or procedure room

3. Warming patient (pre-op, post-op) for cell function and wound healing

4. Increased oxygen – for wound healing

5. Remove Foley catheter within 48 hours

https://manual.jointcommission.org/releases/archive/TJC2010B/SurgicalCareImprovementProject.html

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?

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

Abstract

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

Nationalizing Risk Reduction—The SCIP Mandate

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

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

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

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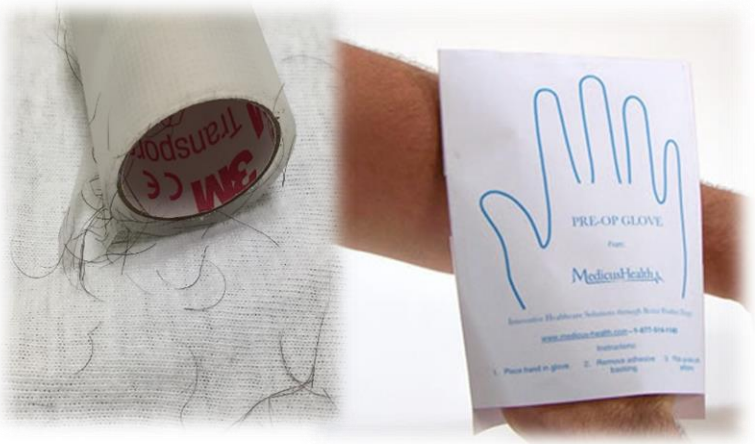
[3]Universal Health Services, King of Prussia, Pennsylvania.
[4]Department of Pharmacy, Froedtert Hospital, Milwaukee, Wisconsin.
Presented in part at a scientific symposium of the Thirtieth Annual Meeting of the Surgical Infection Society, Las Vegas, Nevada, April 17–20, 2010.

Challenges with Hair Clipping in OR

- Clipping should always be done **outside** of the OR whenever possible
- Removal of stray hairs from clipping should be done using current methods (tape and/or suction), while clipping on top of a disposable under pad
- Remove and dispose of single-use clipper head immediately after use and clean the clipper unit according to manufacturer instructions before storing
- In cases of excessive amounts of hair, use *vacuum-assisted suction device* and associated single-use disposable tubing



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

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journal homepage: www.ajicjournal.org

Major Article

Perioperative hair removal in the 21st century: Utilizing an innovative vacuum-assisted technology to safely expedite hair removal before surgery

Charles E. Edmiston Jr PhD [a,*], Russell K. Griggs MS [b], Judith Tanner PhD [c], Maureen Spencer MEd, RN [d], Gary R. Seabrook MD [a], David Leaper DSc [e]

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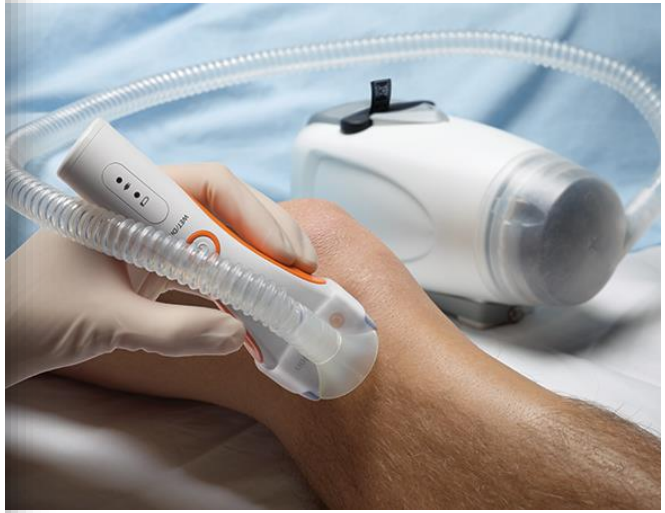
Background: Perioperative hair removal using clippers requires lengthy cleanup to remove loose hairs contaminating the operative field. We compared the amount of hair debris and associated microbiologic contamination produced during clipping of surgical sites using standard surgical clippers (SSC) or clippers fitted with a vacuum-assisted hair collection device (SCVAD).

Methods: Trained nurses conducted bilateral hair clipping of the chest and groin of 18 male subjects using SSC or SCVAD. Before and during clipping, measurements of particulate matter and bacterial contamination were evaluated on settling plates placed next to each subject's chest and groin. Skin condition after clipping and total clipping/cleanup times were compared between SSC and SCVAD.

Results: The microbial burden recovered from residual hair during cleanup in the SSC group was 3.9 $\log_{10}$ CFU and 4.6 $\log_{10}$ CFU from respective, chest, and groin areas. Use of the SCVAD resulted in a significant ($P < .001$) reduction in both residual hair and microbial contamination within the operative field compared with SSC.

Conclusions: Use of SCVAD resulted in significant ($P < .001$) reduction in total time required to clip and clean up residual hair contaminating the operative field compared with standard practice (ie, SSC), eliminating the need to physically remove dispersed hairs, which can harbor a significant microbial burden, from within the operative field.

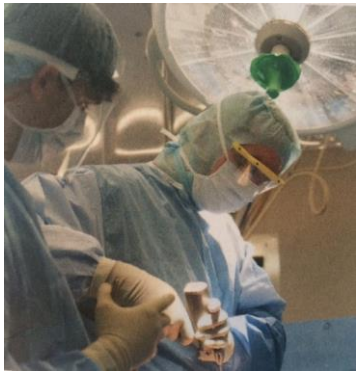


Surgical Attire – Head Covering

- Normal individuals shed more than 10 million particles from their skin every day
- Approximately 10% of skin squames carry viable microorganisms
- Estimated that individuals shed approximately 1 million microorganisms from their bodies each day

Personnel entering the semi-restricted and restricted areas should cover the head, hair, ears, and facial hair

- A clean surgical head cover or hood that confines all hair and completely covers the ears, scalp skin, sideburns, and nape of the neck should be worn
- Personnel wearing scrub attire should not remove the surgical head covering when leaving the perioperative area
- Personnel should remove surgical head coverings whenever they change into street clothes and go outside of the building
- Reusable head coverings should be laundered in a healthcare accredited laundry facility after each daily use and when contaminated



- Boyce, Evidence in Support of Covering the Hair of OR Personnel AORN Journal ● Jan 2014
- AORN Guidelines: Surgical Attire Guideline

Environmental Cleaning

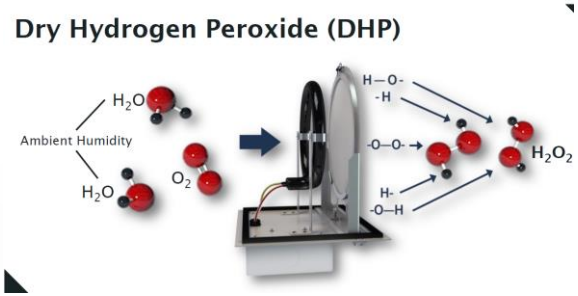
- Evaluate between room cleaning procedures
- Terminal cleaning procedures on evening/night shift
- Are there sufficient staff to terminally clean all OR rooms?
- Microfiber cloths versus sani cloths
- Microfiber mops versus string mops
- Evaluate contact time for disinfectants

AORN Guideline – Environmental Cleaning

EBR - Technology for OR Air & Environmental Disinfection

Movable UV-C robots for OR terminal cleaning[1]

Movable air treatment system with HEPA filter and UV-C[2]



Dry Hydrogen Peroxide Air and Surface Disinfection[3]

Permanent ceiling light fixture 402nm disinfection [4]

24/7 UV=C air disinfecting ceiling fixture[5]

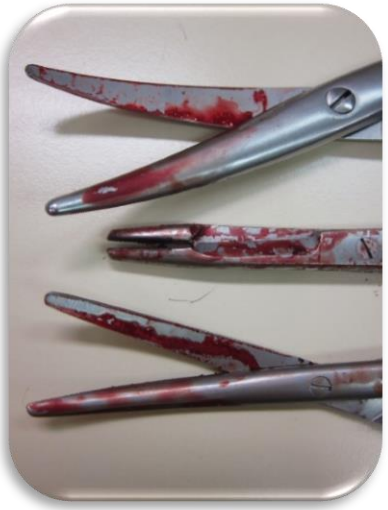
Temperature controlled air flow (TcAF)[6]

Evidence-Based Research (EBR)

1. Spencer M, et al: A model for choosing an automated ultraviolet-C disinfection system and building a case for the C-suite: Two case reports. AJIC 2016
2. Parvizi J et al. Is it Time to Reassess Microbial Contamination of Operating Room Air as a Risk Factor in Total Joint Arthroplasty. AJIC Nov 2017
3. Sanguinet J, Edmiston C. Evaluation of dry hydrogen peroxide in reducing microbial bioburden in a healthcare facility. AJIC 2021
4. Murrell L, Kinzel Hamilton E, Johnson H, Spencer M. Influence of a visible-light continuous environmental disinfection system on microbial contamination and surgical site infections in an orthopedic operating room. AJIC 2018
5. Guimera D, Trzil J. et al. Effectiveness of a shielded ultraviolet C air disinfection system in an inpatient pharmacy of a tertiary care children's hospital. AJIC 2017
6. Alsved M, Civilis A, et al. Temperature-controlled airflow ventilation in operating rooms compared with laminar airflow and turbulent mixed airflow. JHI 2018

Cleaning/Sterilization of Instruments

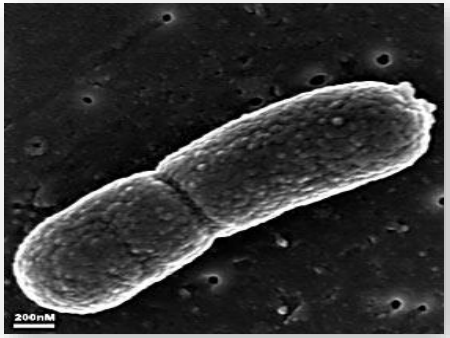
- Inspection/cleaning of Instruments
  - Lumens, grooves, sorting, hand cleaning, disassembly
- Ultrasonic washers in SPD
  - machine quality monitor (Sonacheck)
  - routine cleaning and maintenance
- Pre-soaking and rinsing of tissue and blood from the instruments in enzymatic or instrument cleaner
- Reduce immediate use steam sterilization (IUSS) – purchase additional instruments and trays
- Use new separate instruments for closing colorectal cases based on expert consensus

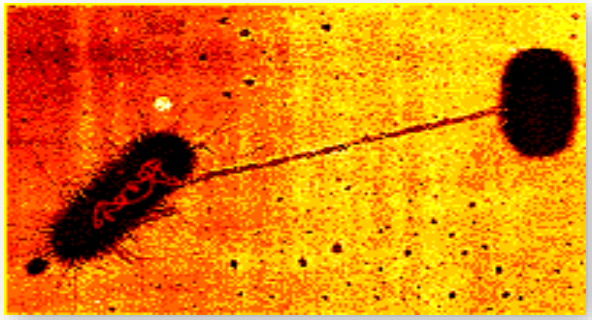


AORN Guideline – Cleaning and Care of Surgical Instruments

AORN Hand Hygiene Guideline

- Organisms multiply every 20 minutes
- Communication to pass R Factors to antibiotic resistance
- III.a. Personnel should perform hand hygiene
  - Before and after patient contact
  - Before performing a clean or sterile task
  - After risk for blood or body fluid exposure
  - After contact with patient surroundings
  - When hands are visibly soiled
  - Before and after eating
  - After using the restroom





Communication between organisms to pass resistance factors

Changing gloves prior to closure for colorectal cases based on expert consensus

Anesthesia Patient Safety Foundation

Section Editor: **Sorin J. Brull**

Hand Contamination of Anesthesia Providers Is an Important Risk Factor for Intraoperative Bacterial Transmission

Randy W. Loftus, MD,* Matthew K. Muffly, MD,* Jeremiah R. Brown, PhD, MS,*
Michael L. Beach MD, PhD,* Matthew D. Koff, MD,* Howard L. Corwin, MD,*
Stephen D. Surgenor, MD,* Kathryn B. Kirkland, MD,* and Mark P. Yeager, MD*

Anesth Analg 2011:112:98-105

Table 2. Baseline Provider Hand Contamination[a]

Organism	Providers N/total (%)
MRSA	12/164 (7%)
MSSA	18/164 (11%)
VRE	4/164 (2%)
Enterococcus (non-VRE)	1/164 (0.6%)
Staph other	164/164 (100%)
Micrococcus	110/64 (67%)
Corynobacterium	14/164 (9%)
Streptococcus	128/164 (78%)
Gram negative[b]	81/164 (49%)

MRSA = methicillin-resistant Staphylococcus aureus; MSSA = methicillin-sensitive Staphylococcus aureus; VRE = vancomycin-resistant Enterococcus.

[a] Samples taken upon entry to the patient environment but before patient contact and after an opportunity to perform hand hygiene.

[b] E. coli, Klebsiella, Serratia, Pseudomonas, and Acinetobacter.

?antibiotic resistant strains

Anesth Analg 2011:112:98-105

Table 3. Evidence for Intraoperative Transmission of Bacterial Pathogens from Anesthesia Provider Hands to the Anesthesia Environment and Patient IV Catheters

	Case 1			Case 2			
	Before case 1	End case 1		Before case 2		End case 2	
	Provider hands (site B)	Stopcock	Machine APL/D	Machine APL/D	Provider hands (site E)	Stopcock	Machine APL/D
Direction of transmission →							
Organism							
Micro	Attending		X				
S. epi	Attending	X					
S. hae	Attending	X					
S. epi	Attending	X					
S. epi	Attending				Attending[a]		
S. epi	Attending		X			X	X
Micro	Attending		X			X	
S. epi	Attending		X	X			X
Strep	Resident	X					X
Pseudo	Attending						
Pseudo	Resident		X				X
Micro	Resident	X		X		X	X
MRSA	Resident		X	X	Attending[a]		X
MSSA	Resident		X				X
S. auric	CRNA		X	X			
Micro	CRNA			X	Attending[a]		X
S. epi	CRNA			X			
Micro					CRNA[a]	X	X

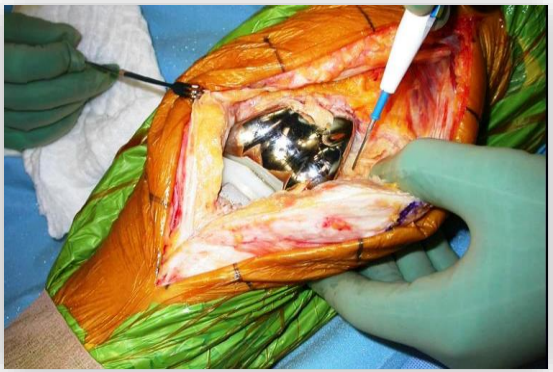
Sites were cultured as described, and pathogens were found at the times and locations noted.

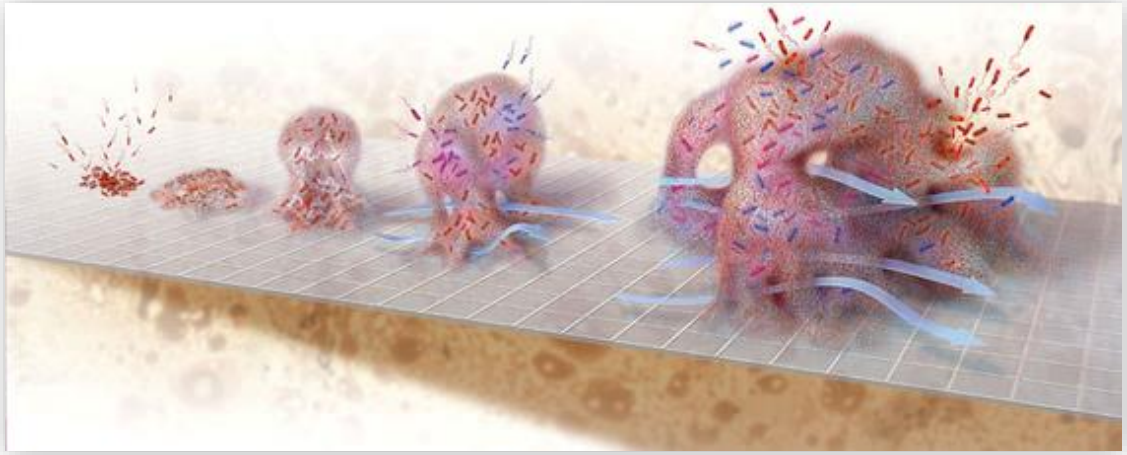
APL = anesthesia machine adjustable pressure limiting valve; D = anesthesia machine inhaled agent concentration dial; X = transmission event confirmed by biotype analysis; S. epi = Staphylococcal epidemidis; S. hae=Staphylococcal haemolyticus; Strep = streptococcus; Pseud = pseudomonas; MRSA = methicillin-resistant Staphylococcal aureus; MSSA = methicillin-sensitive Staphylococcal aureus; S. auric = Staphylococcal auricularis; CRNA = certified registered nurse anesthetist.

[a] Provider was negative at the start of case 1; hands contaminated by bacterial organisms brought in by other providers.

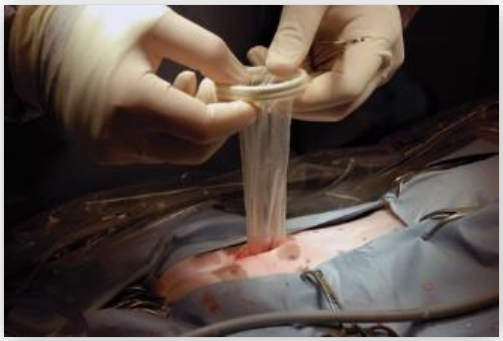
Anesth Analg 2011:112:98-105

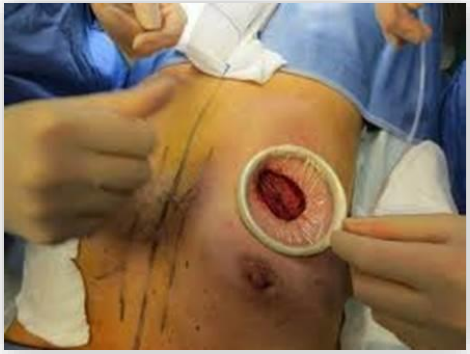
Risk: Cross Contamination and Biofilm Formation on Implanted Material: Orthopedic Implants, Devices, Stopcocks, Catheters, Grafts, Mesh, etc.





Abdominal Wound Protector/Retractor for Colon Surgery Shown to Reduce SSI





Orthopedic joint replacement wound protector

Horiuchi et al: A Wound Protector Shields Incision Sites from Bacterial Invasion SURGICAL INFECTIONS Volume 11, Number 6, 2010

Reid et al: Barrier Wound Protection Decreases Surgical Site Infection in Open Elective Colorectal Surgery: A Randomized Clinical Trial DISEASES OF THE COLON & RECTUM VOLUME 53: 10 (2010)

#2 SCREEN for Risk Factors and MRSA and MSSA Colonization

Why the Focus on *Staphylococcus Aureus*?

- Prevalence of *S. aureus* nasal and skin carriage
  - MSSA: 20 - 40% of healthy individuals
  - MRSA: 1 - 4% of the population
- Morbidity and mortality*
  - 80,460 invasive MRSA infections
  - 11,285 related deaths
- Healthcare costs**
  - $ 60,000 per MRSA-infected patient > >$100,000 joint infection
  - $ 9.7 Billion annually

* U.S. 2011 – CDC **2013 CDC Antibiotic Threat Report

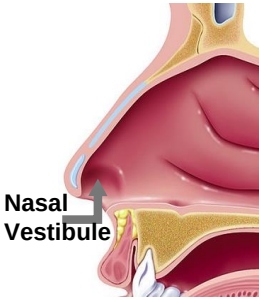
Linkage of the Nose to *S. aureus* Infections

- Published *S. aureus* auto-infection rates, based on nasal swab and subsequent infection isolates, range **between 76% and 86%**[6]
- Meta-analysis of joint surgery patients indicated a **significant 6-fold greater risk of SSIs in nasal carriers** of *S. aureus*[7]
- Retrospective study of patients actively screened on admission showed that those positive for nasal MRSA had 20 times greater odds of developing MRSA infections than those who were not[8]

6. Coates T, et al. J Antimicrob Chemother (2009) 64:9-15.
7. Levy P-Y, et al. Orthop Traumatol Surg Res (2013) 99:645-51.
8. Marzek NS and Bessesen MT. AJIC (2016) 44:405-408.

Why is Nasal Colonization Important?

Contribution to Transmission



- Average person touches their nose and face **dozens of times** each hour[1]
- In one representative study, **50%** of the 133 participants' hands had the **same isolates** of *S. aureus* on their hands as in their nasal vestibules[2]
- In a VA study, infection and nasal MRSA strains were concordant in **86% of patients.**[3]
- In studies of nurses with patient-care contact, nasal carriage of MSSA falls within the **20% – 40%** range of the general population[4]
- In a study of surgical patients, the only significant risk factor for *S. aureus* SSI was the presence of **high level carriage** in the nose[5]

1. Nicas M, Best D. J Occ Env Hyg (2008) 5:347-352
2. Kalmeijer MD, et at. ICHE (2000) 21:319-323
3. Tammelin A, et al. ICHE (2003) 24:686-689
4. Steed LL, et al. AJIC (2014) 42:841-846.
5. Stenehjem E, et al. ICHE (2015) 36:587-589.

Table 4. Infection risk factor

Risk factor	Odds ratio (confidence interval)	p value
Current tobacco use	3.00 (1.78 5.06)	< 0.001
Current or history of bone cancer	12.85 (4.64 35.59)	< 0.001
Diabetes mellitus	2.44 (1.55 3.82)	< 0.001
Hepatitis B	7.34 (0.96 56.1)	0.027
Hepatitis C	5.59 (2.21 14.19)	< 0.001
MRSA colonization or prior infection	7.34 (2.85 18.91)	< 0.001
MSSA colonization or prior infection	8.64 (3.75 19.89)	< 0.001
Staphylococcal colonization or prior infection	6.52 (3.41 12.51)	< 0.001
Underweight (BMI < 18.5 kg/m^2)	1.90 (0.26 13.7)	0.56
Overweight (BMI 25.0 29.9 kg/m^2)	0.60 (0.24 1.50)	0.24
Obese (BMI 30.0 39.9 kg/m^2)	0.84 (0.51 1.41)	0.52
Morbid obesity (BMI 40.0 49.9 kg/m^2)	1.28 (0.61 2.65)	0.51
Super obesity (BMI 50 + kg/m^2)	15.69 (5.97 41.21)	< 0.001
Obesity hypoventilation syndrome	10.2 (1.17 88.5)	0.01

MRSA = methicillin resistant *Staphylococcus aureus*; MSSA = methicillin susceptible *S aureus*; BMI = body mass index.

Everheart JS et al. Medical comorbidities are independent preoperative risk factors for surgical infections after total joint arthroplasty. Clin orthoped relat res. March22, 2013 online pub

THE JOURNAL OF BONE & JOINT SURGERY

JB&JS

This is an enhanced PDF from The Journal of Bone and Joint Surgery

The PDF of the article you requested follows this cover page.

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

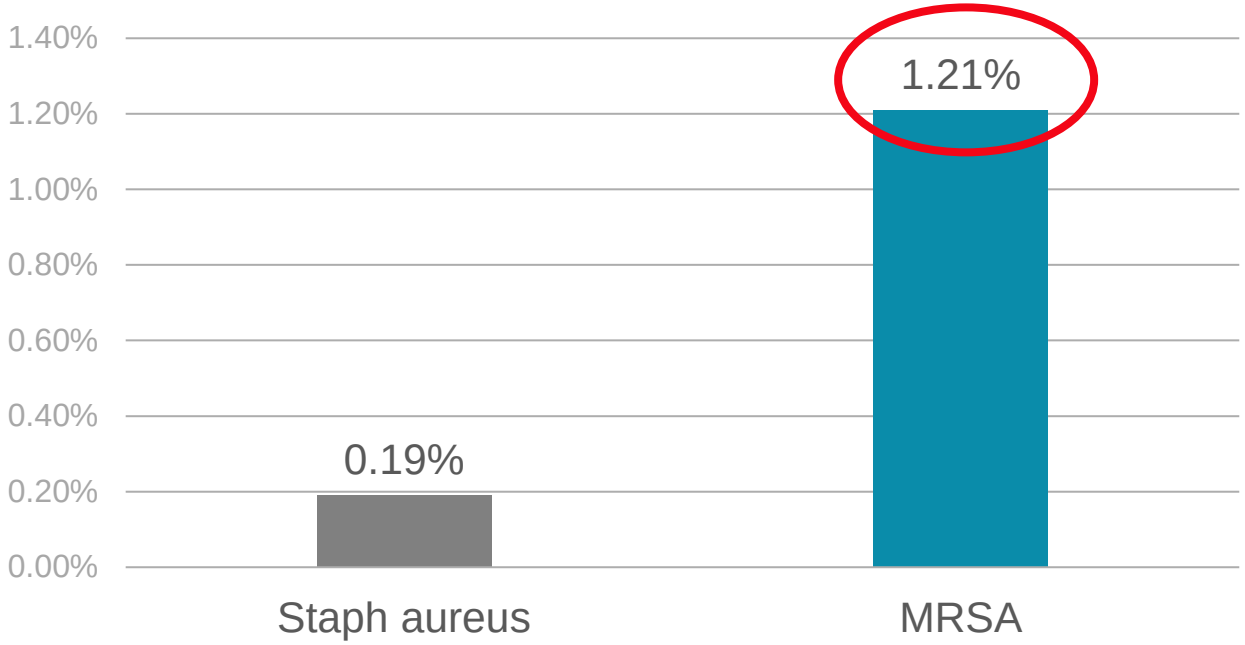
David H. Kim, Maureen Spencer, Susan M. Davidson, Ling Li, Jeremy D. Shaw, Diane Gulczynski, David J. Hunter, Juli F. Martha, Gerald B. Miley, Stephen J. Parazin, Pamela Dejoie and John C. Richmond

J Bone Joint Surg Am. 2010;92:1820-1826. published Jul 7, 2010; doi:10.2106/JBJS.I.01050

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

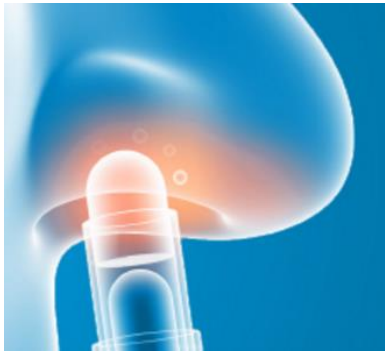
	Control Period 10/2005-6/2006	Study Period 6/2006-9/2007	p value
N	5293	7019	
MRSA Infection	10 (0.18%)	4 (0.06%)	0.0315
MSSA Infection	14 (0.26%)	9 (0.13%)	0.0937
Total SSIs	24 (0.46%)	13 (0.18%)	**0.0093**

SSI– Increased Risk with MRSA Colonization



- MRSA colonized patients still had an increased risk of SSI despite decolonization
- Seven (7) *Staph aureus* infections in 2712 positives 0.19%
- Seven (7) MRSA infections in the 576 positives 1.21%
- Statistically significant difference **p=<.05**

Nasal Alcohol Antiseptic – HCWs



American Journal of Infection Control 42 (2014) 841-6

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major article

Reduction of nasal *Staphylococcus aureus* carriage in health care professionals by treatment with a nonantibiotic, alcohol-based nasal antiseptic

Lisa L. Steed PhD [a], Justin Costello BA [b], Shivangi Lohia MD [b], Taylor Jones BS [b], Ernst W. Spannhake PhD [c], Shaun Nguyen MD, MA, CPI [b,*]

[a] Department of Pathology and Laboratory Medicine, Medical University of South Carolina, Charleston, SC
[b] Department of Otolaryngology, Head and Neck Surgery, Medical University of South Carolina, Charleston, SC
[c] Department of Environmental Health Sciences, Johns Hopkins School of Public Health, Baltimore, MD

Key Words:
Ethanol
Nasal colonization
Bacterial burden
Infection control

Background: Antibiotics used to reduce nasal colonization by *Staphylococcus aureus* in patients before admission are inappropriate for carriage reduction on a regular basis within a hospital community. Effective nonantibiotic alternatives for daily use in the nares will allow reduction of this bacterial source to be addressed.

Methods: Our study tested the effectiveness of a nonantibiotic, alcohol-based antiseptic in reducing nasal bacterial carriage in health care professionals (HCPs) at an urban hospital center. HCPs testing positive for vestibular *S aureus* colonization were treated 3 times during the day with topical antiseptic or control preparations. Nasal *S aureus* and total bacterial colonization levels were determined before and at the end of a 10-hour workday.

Results: Seventy-eight of 387 HCPs screened (20.2%) tested positive for *S aureus* infection. Of 39 subjects who tested positive for *S aureus* infection who completed the study, 20 received antiseptic and 19 received placebo treatment. Antiseptic treatment reduced *S aureus* colony forming units from baseline by 99% (median) and 82% (mean) ($P < .001$). Total bacterial colony forming units were reduced by 91% (median) and 71% (mean) ($P < .001$).

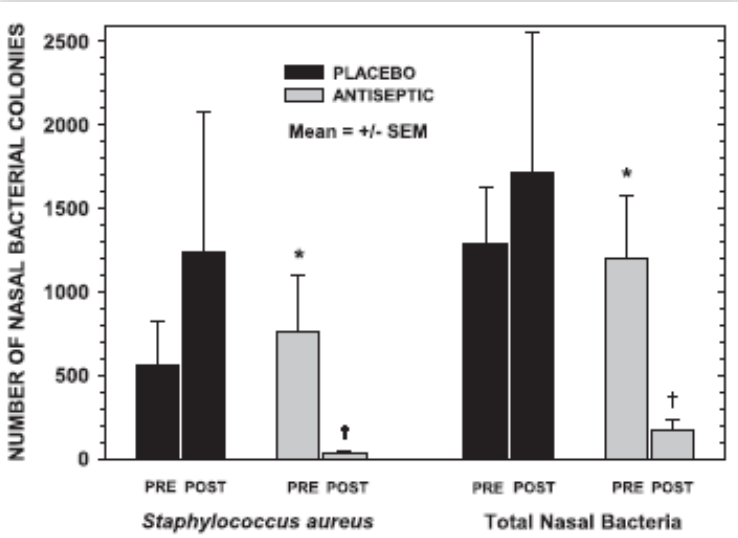


Fig 2. Nasal vestibular bacterial colonization in baseline (PRE) and posttreatment (POST) samples. Numbers of colony forming units in identical samples plated onto CHROMagar SA (Becton, Dickenson & Co, Franklin Lakes, NJ) and tryptic soy agar blood agar plates for assessment of *Staphylococcus aureus* and total bacterial colonization before and after treatment, as described in detail in the Methods section. *No significant difference from the baseline value in the corresponding placebo-treated group. †Significantly different ($P < .001$) from the PRE value.

Marshall Medical Center, CA

$64k
SAVINGS
maintaining
low MRSA rates

Introduced daily nasal decolonization with Nozin to MRSA patients (history, colonized or active). Reduced use of contact precautions. Maintained low MRSA infection rates throughout the study.

Deatherage N. Am. J. Infect. Control. 2016. 44(S6), S101-S102 — 12 MO.

Northwest Healthcare, AZ

64%
REDUCTION
in spine fusion SSI

Replaced nasal povidone iodine with Nozin, paired with existing preoperative CHG bathing, for all spine fusion and laminectomy patients. Reduced spine fusion SSI by 64% and laminectomy SSI by 100%. Estimated cost avoidance of $164,000 associated with infections prevented.

Candray K. Open Forum Infect Dis. 2020. 7(S1), S479 — 3 MO.

Riverside University Health Medical Center, CA

63%
REDUCTION
all-cause SSI

Universal preoperative decolonization protocol replaced povidone iodine-based nasal antiseptic with Nozin, paired with preoperative existing CHG bathing. Results include a 63% reduction of all-cause SSI and $589,420 cost-savings from infections prevented.

Gnass S. Open Forum Infect Dis. 2020. 7(S1), S479 — 6 MO.

Bayfront Health Seven Rivers, FL

59%
REDUCTION
all-cause SSI

Introduced universal nasal decolonization for all preoperative patients added to existing CHG bathing protocol. Reduced all-cause SSI by 59% from average monthly baseline rate of 0.61 to 0.25. Represents an estimated cost avoidance of $457k. 86% of hospital staff reported increased satisfaction.

Cernich C. Am J Infect Control. 2020. 48(S8), S50 — 6 MO.

Baylor Scott & White Orthopedic and Spine Hospital – Arlington, TX

81%
REDUCTION
in *S aureus* SSI

Introduced a comprehensive nasal decolonization program with Nozin for spine surgery patients, combined with existing CHG bathing protocol. Achieved reduction in S aureus SSI in spine surgery from 1.76 to 0.33 per 100 surgeries.

Mullen A et al. Am J Infect Control. 2017. 45(5), S54-S56 — 15 MO.

WV University School of Medicine, WV

79%
REDUCTION
in SSI

Introduced pre- and post-op nasal decolonization with Nozin for total joint arthroplasty patients.

Bostian P et al. Poster presented at American Association of Orthopedic Surgeons (AAOS) Annual Conference. 2018. — 7 MO.

Wellstar Cobb Hospital, GA

100%
REDUCTION
in total hip and
total knee SSI

Added nasal decolonization with Nozin to existing preoperative CHG bath for total hip and knee replacement surgeries. Nasal decolonization continued post-op for length of stay. Reduced total hip SSI rate from 0.91 to 0.00 and total knee SSI from 0.36 to 0.00 per 100 procedures. $400K avoided annually, associated with joint SSI prevention.

Franklin S. Am. J. Infect. Control. 2020. 48(12), 1501-1503 — 12 MO.

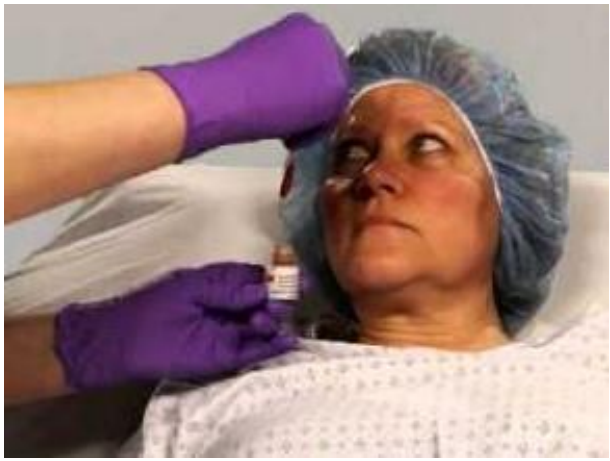
Medical University of SC Hospital, SC

99%
REDUCTION
in *S aureus*
nasal carriage

Nasal application of Nozin was effective in reducing S aureus and total bacterial carriage, suggesting the usefulness of this approach as a safe, effective, and convenient alternative to antibiotic treatment.

Steed L et al. Am. J. Infect. Control. 2014. 42(8), 841-846

Nasal Iodine Antiseptic



INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY JULY 2014, VOL. 35, NO. 7

ORIGINAL ARTICLE

Preventing Surgical Site Infections: A Randomized, Open-Label Trial of Nasal Mupirocin Ointment and Nasal Povidone-Iodine Solution

Michael Phillips, MD;[1,2] Andrew Rosenberg, MD;[1,2] Bo Shopsin, MD, PhD;[1,2] Germaine Cuff, RN, PhD;[2] Faith Skeete, RN;[1] Alycia Foti, BA;[1] Kandy Kraemer, RN;[1] Kenneth Inglima, MS;[1] Robert Press, MD, PhD;[1,2] Joseph Bosco, MD[1,2]

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY JULY 2014, VOL. 35, NO. 7

TABLE 2. Number of Subjects with Deep Surgical Site Infection (SSI) and SSI Rates

		Overall			*Staphylococcus aureus* infection		
Analysis	No. of subjects	No. of cases	Rate, cases per 100 subjects	*P*[a]	No. of cases	Rate, cases per 100 subjects	*P*[a]
Intent to treat							
Mupirocin	855	14	1.6	.1	5	0.6	.2
Povidone-iodine	842	6	0.7		1	0.1	
Per protocol							
Mupirocin	763	13	1.7	.06	5	0.7	.03
Povidone-iodine	776	5	0.6		0	0	

[a] By χ^2 test.

Compared to mupirocin, 3M™ Skin and Nasal Antiseptic provides more value, defined as quality of outcomes divided by cost.

Phillips M, Rosenberg A, Shopsin B, et al. Preventing surgical site infections: A randomized, open-label trial of nasal mupirocin ointment and nasal povidone-iodine solution. *Infect Control Hosp Epidemiol* 2014;35(7):826–832.

Objective

The purpose of this study is to compare the efficacy of 3M™ Skin and Nasal Antiseptic to Bactroban® nasal ointment. Decolonization with mupirocin presented barriers including poor patient compliance and concerns about antibiotic resistance that led to a search for an alternative.

Design

Investigator initiated, prospective, randomized, controlled, open-label trial comparing deep surgical site infection (SSI) within 90 days after surgery.

Surgeries

Arthroplasty or spine fusion.

Methods

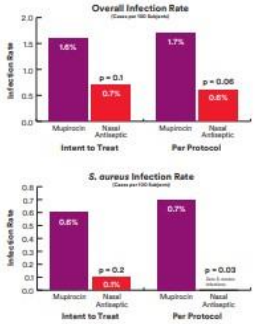
All patients were provided 2% CHG cloths for use the evening prior to and the morning of surgery.

Randomized to either:

- 3M™ Skin and Nasal Antiseptic (PI group), 1 dose given in the pre-operative hold area within 2 hours of incision.
- Bactroban® nasal ointment (antibiotic group), twice daily for the 5 days prior to surgery.

Results

1,697 patients were included in the intent-to-treat analysis and 1,539 in the per-protocol. Efficacy results in the intent to treat and per protocol groups are provided in the graphs below. Patients in the 3M™ Skin and Nasal Antiseptic group reported significantly fewer treatment-related adverse events (1.8% vs 8.9%, $p < 0.05$) than the mupirocin group.



Using 3M™ Skin and Nasal Antiseptic as part of the patient preparation protocol does not rely on patient compliance and eliminates the risk of mupirocin resistance which resulted in an average cost savings of $93.95 per patient.

Torres EG, Lindmair-Snell JM, Langan JW, Burnikel BG. Is preoperative nasal povidone-iodine as efficient and cost-effective as standard methicillin-resistant *Staphylococcus aureus* screening protocol in total joint arthroplasty? *J Arthroplasty.* 2016; 31: 215–218.

Objective

The purpose of this study was to compare the efficacy and cost of 3M™ Skin and Nasal Antiseptic to MRSA screening and treatment with mupirocin.

Design

Investigator initiated, retrospective, before-and-after intervention study comparing surgical site infection rates within 90 days of surgery and cost-effectiveness of each protocol.

Surgeries

Primary or revision total knee arthroplasty (TKA) or total hip arthroplasty (THA).

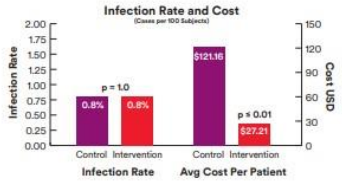
Methods

Control:
All patients undergoing primary or revision TKA or THA surgery from November 2011 – April 2013 were screened for MRSA. Those who were culture positive were treated preoperatively with mupirocin twice daily for 5 days.

Intervention:
May 2013 – October 2014 — All patients received 3M™ Skin and Nasal Antiseptic preoperatively.

All patients from both groups were also instructed to bathe with chlorhexidine gluconate (CHG) for 5 days before surgery and the operative leg was cleansed with a CHG wipe in preop on the day of surgery.

Results



1,853 patients were included; 849 in the control group, 1,004 in the intervention group.

There was no difference in the SSI rate between groups (0.8% in both groups); ($p = 1.0$).

There was a significant difference in the mean cost per case between the MRSA screening group ($121.16) and the 3M™ Skin and Nasal Antiseptic group ($27.21); ($p < 0.01$).

Supplementing decolonization protocol with 3M™ Skin and Nasal Antiseptic significantly lowered SSI rates in urgent lower extremity fracture repairs.

Urias DS, Varghese M, Simunich T, Morrissey S, Dumire R. Preoperative decolonization to reduce infections in urgent lower extremity repairs. *European Journal of Trauma and Emergency Surgery.* 2018:1–7. doi:10.1007/s00068-017-0896-1.

Objective

The purpose of this study was to measure the effectiveness in reducing SSIs in patients undergoing repair of urgent lower extremity fractures.

Design

Investigator initiated, retrospective review comparing SSI rates after surgery.

Prior to January 2013, patients were followed for 1 year. Post January 2013, patients were followed for 30 days (superficial SSI) and 90 days (deep incisional or organ/space).

Surgeries

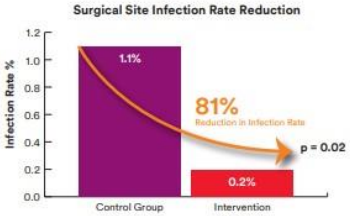
Trauma patients undergoing urgent lower extremity fracture (hip/femur, knee, tibia/fibula, and ankle) repair with hardware.

Methods

Pre-intervention group:
October 1, 2012 – September 30, 2014
Patients either bathed with 2% chlorhexidine gluconate (CHG) cloths or showered with 4% CHG solution. One bath/shower the night before surgery, if possible, and always the morning of surgery.

Intervention group:
October 1, 2014 – September 30, 2016
Patients followed pre-intervention CHG bath/shower protocol. And also received povidone-iodine skin and nasal antiseptic (PI-SNA) preoperatively within 1 hour of incision.

Results



1,746 unique patients underwent 1,892 surgeries; 862 patients in the pre-intervention group and 884 patients in the intervention group.

The change in SSI rate from 1.1% (10/930, pre-intervention) to 0.2% (2/962, intervention) was statistically significant (p value = 0.020).

Both cancer and decolonization were shown to be statistically significant independent risk factors for developing a post-operative SSI defined by the CDC criteria.

Universal decontamination protocol which includes a 5% povidone iodine solution intranasally may be considered an additional prevention strategy for SSIs in patients undergoing orthopedic surgery with implants.

Bebko SP, Green DM, Awad SS. Effect of a preoperative decontamination protocol on surgical site infections in patients undergoing elective orthopedic surgery with hardware implantation. *JAMA Surg.* Published online March 04, 2015. doi:10.1001/jamasurg.2014.3480.

Objective

The purpose of this study was to examine the effect a preoperative decontamination protocol had on SSI rates.

Design

Investigator initiated, prospective, before-and-after intervention, cohort study comparing surgical site infection rates within 30 days of surgery.

Surgeries

Elective orthopedic surgery with hardware implantation.

Methods

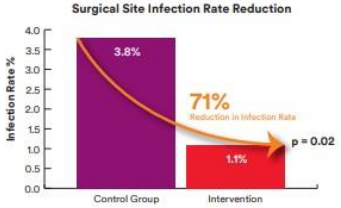
Control and intervention groups received standard perioperative prevention measures.

Intervention

Control:
October 1, 2012 – April 30, 2013
Standard perioperative preventative measures.

Preoperative decontamination protocol:
May 1, 2013 – December 31, 2013
2% chlorhexidine gluconate cloths and 0.12% chlorhexidine oral rinse the night before and morning of surgery AND 3M™ Skin and Nasal Antiseptic the morning of surgery.

Results



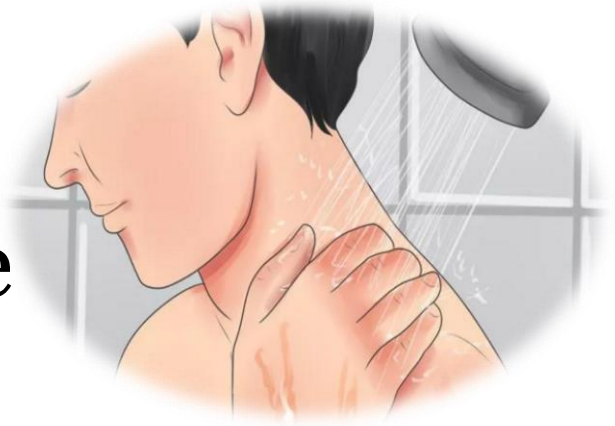
A total of 709 patients were included, 344 patients in control group, 365 patients in intervention group.

Multivariate logistic regression identified the decontamination protocol as a significant independent protective factor against SSI (OR 0.24 [95% CI, 0.08–0.77]; $p = 0.02$).

100% compliance to decontamination protocol in intervention group.

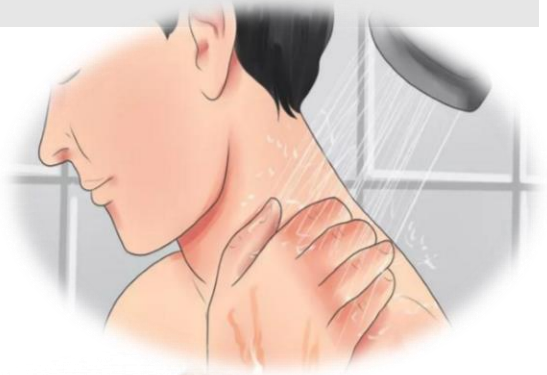
	Alcohol-based nasal antiseptic*	Povidone iodine nasal antiseptic	Mupirocin antibiotic
Topical solution	Clear/orange liquid	Brown thick liquid	Cream/ointment
Kills germs on contact	✓	✓	
Available to consumers without a prescription	✓	✓	
Kills broad spectrum of germs	✓	✓	
Formulated for daily use	✓		
Does not stain the skin	✓		✓
Convenient to apply	✓		

#3 Showers with Soap or Chlorhexidine Gluconate



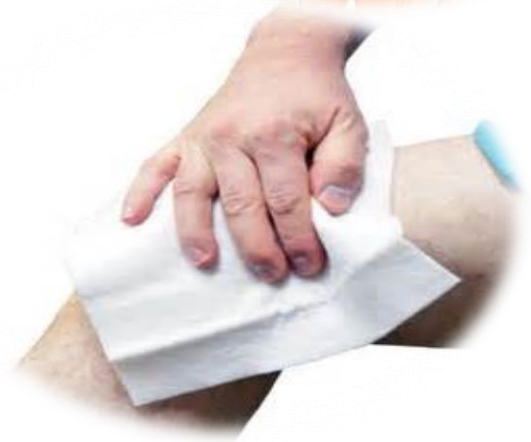
Risk Factors: Bacteria on Patient's Skin

2017 AORN Guideline for Preoperative Patient Skin Antisepsis:
Recommendation I, page 53 – *Patients should bathe or shower before surgery with either soap or an antiseptic.*



If using CHG cleansing:

- 4% Liquid chlorhexidine shower
  (two 4 oz. bottles
  night before and morning of surgery)
- 2% CHG impregnated washcloths
  (package of 6 cloths)



Research

Original Investigation

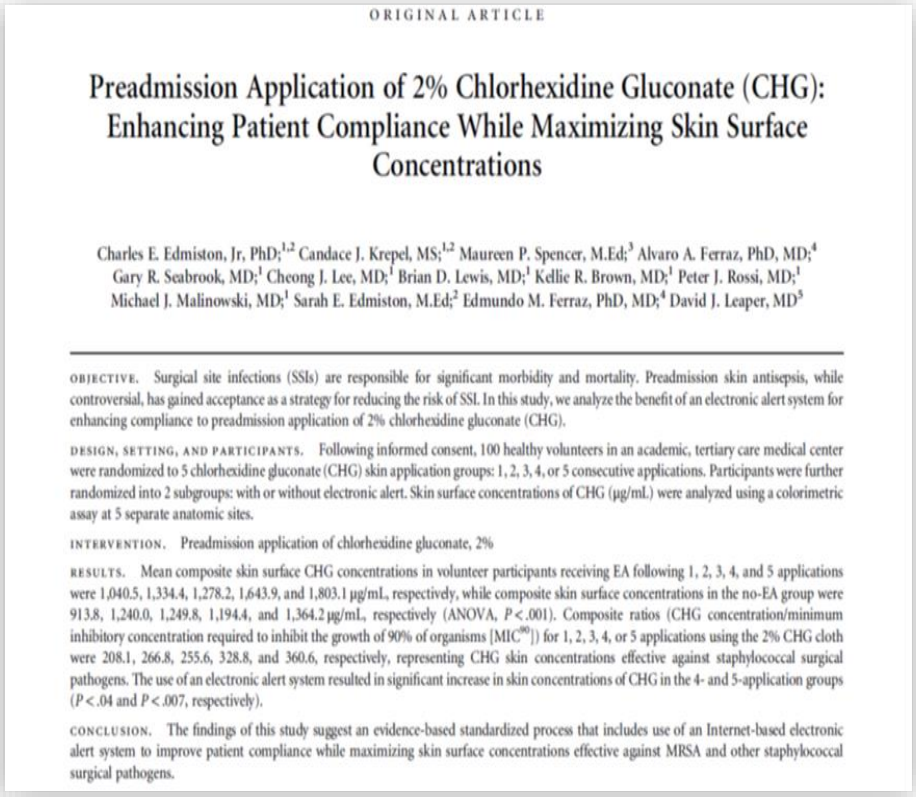
Evidence for a Standardized Preadmission Showering Regimen to Achieve Maximal Antiseptic Skin Surface Concentrations of Chlorhexidine Gluconate, 4%, in Surgical Patients

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 Surg 2015;150:1027-33



ORIGINAL ARTICLE

Preadmission Application of 2% Chlorhexidine Gluconate (CHG): Enhancing Patient Compliance While Maximizing Skin Surface Concentrations

Charles E. Edmiston, Jr, PhD;[1,2] Candace J. Krepel, MS;[1,2] Maureen P. Spencer, M.Ed;[3] Alvaro A. Ferraz, PhD, MD;[4] Gary R. Seabrook, MD;[1] Cheong J. Lee, MD;[1] Brian D. Lewis, MD;[1] Kellie R. Brown, MD;[1] Peter J. Rossi, MD;[1] Michael J. Malinowski, MD;[1] Sarah E. Edmiston, M.Ed;[2] Edmundo M. Ferraz, PhD, MD;[4] David J. Leaper, MD[5]

OBJECTIVE. Surgical site infections (SSIs) are responsible for significant morbidity and mortality. Preadmission skin antisepsis, while controversial, has gained acceptance as a strategy for reducing the risk of SSI. In this study, we analyze the benefit of an electronic alert system for enhancing compliance to preadmission application of 2% chlorhexidine gluconate (CHG).

DESIGN, SETTING, AND PARTICIPANTS. Following informed consent, 100 healthy volunteers in an academic, tertiary care medical center were randomized to 5 chlorhexidine gluconate (CHG) skin application groups: 1, 2, 3, 4, or 5 consecutive applications. Participants were further randomized into 2 subgroups: with or without electronic alert. Skin surface concentrations of CHG (μg/mL) were analyzed using a colorimetric assay at 5 separate anatomic sites.

INTERVENTION. Preadmission application of chlorhexidine gluconate, 2%

RESULTS. Mean composite skin surface CHG concentrations in volunteer participants receiving EA following 1, 2, 3, 4, and 5 applications were 1,040.5, 1,334.4, 1,278.2, 1,643.9, and 1,803.1 μg/mL, respectively, while composite skin surface concentrations in the no-EA group were 913.8, 1,240.0, 1,249.8, 1,194.4, and 1,364.2 μg/mL, respectively (ANOVA, $P < .001$). Composite ratios (CHG concentration/minimum inhibitory concentration required to inhibit the growth of 90% of organisms [MIC^{90}]) for 1, 2, 3, 4, or 5 applications using the 2% CHG cloth were 208.1, 266.8, 255.6, 328.8, and 360.6, respectively, representing CHG skin concentrations effective against staphylococcal surgical pathogens. The use of an electronic alert system resulted in significant increase in skin concentrations of CHG in the 4- and 5-application groups ($P < .04$ and $P < .007$, respectively).

CONCLUSION. The findings of this study suggest an evidence-based standardized process that includes use of an Internet-based electronic alert system to improve patient compliance while maximizing skin surface concentrations effective against MRSA and other staphylococcal surgical pathogens.

Edmiston et al. Infect Control Hosp Epidemiol 2016; 2016;37:254-259

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

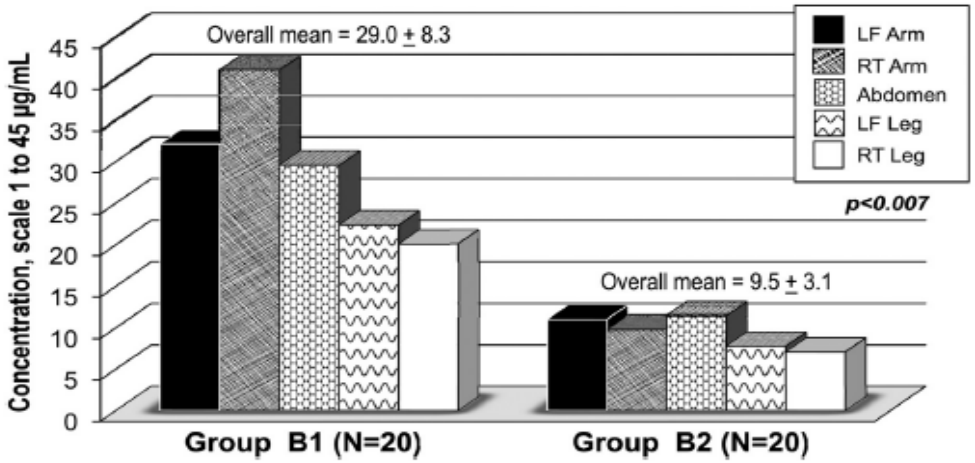


Figure 2. Mean skin-surface concentration (µg/mL) of 4% chlorhexidine gluconate after 3 preadmission showers. Group B1 subjects were alerted by short message service text, email, or voicemail. Group B2 subjects were not alerted before showering. The 90% minimum inhibitory concentration = 5 µg/mL for skin staphylococcal flora (including MRSA). LF, left; RT, right.

4% Liquid chlorhexidine shower (two 4oz bottles – night before and morning of surgery) – leave on skin for 1 minute in shower before rinsing

J Am Coll Surg 2014;■:1–9. © 2014

To Maximize Skin Surface Concentrations of CHG – 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
- 1-minute pause before rinsing (4% CHG)
- 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. Infect Control Hosp Epidemiol 2016; 2016;37:254-259

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

#4 **Skin Prep** – Alcohol-based Surgical Skin Prep

Skin Antiseptic Agents

Antiseptic agent	Rapidity of action	Persistent activity
Alcohol	Excellent	None
CHG	Moderate	Excellent
PI	Moderate	Minimal
CHG w/ alcohol	Excellent	Excellent
PI w/ alcohol	Excellent	Moderate
* New: Citric acid, sodium citrate, excipients w/alcohol	Excellent	Excellent

New Surgical Skin Prep - 2022

- In clinical trials, the new skin prep showed less skin irritation, and overall greater microbial reduction compared to a common alcohol/CHG prep

- Contains 70% isopropyl alcohol with functional excipients (citric acid and sodium citrate) and alkyl parahydroxybenzoates (with methylene blue as a colorant)

- Crnich CJ, Pop-Vicas AE, Hedberg TG, Perl TM. Efficacy and safety of a novel antimicrobial preoperative skin preparation. Infect Control Hosp Epidemiol 2019;40:1157–1163.

- Edmiston C, Lavin P, Spencer M, et al. Antiseptic efficacy of an innovative perioperative surgical skin preparation: A confirmatory FDA phase 3 analysis. Infect Control Hosp Epidemiol 2020; 41, 653–659

POSTER #152

"ANTISEPTIC EFFICACY OF AN INNOVATIVE PERIOPERATIVE SURGICAL SKIN PREPARATION: A CONFIRMATORY FDA PHASE 3 ANALYSIS", AN ICHE/SHEA PUBLICATION

Authored by: Charles E. Edmiston, Jr, PhD, Philip Lavin, PhD, Maureen Spencer, MEd, RN, Gwen Bortaug, MPH, Gary R. Seabrook, MD, and David Leaper, MD
Presented by: Maureen Spencer, M.Ed, RN, CIC, FAPIC[1], Todd Whitson, BSBA, BAM, MBAGM[2]
[1]Infection Preventionist Consultant, [2]Consultant – Acting Chief Commercial Officer, Zurax Pharma, Inc.

ABSTRACT

Background: An innovative approach to perioperative antiseptic skin preparation is warranted because of potential adverse skin irritation, rare risk of serious allergic reaction, and perceived diminished clinical efficacy of current perioperative antiseptic agents. The results of a confirmatory US Food and Drug Administration (FDA) phase 3 efficacy analysis of a recently approved innovative preoperative surgical skin antiseptic agent are discussed.

Methods: The microbial skin flora on abdominal and groin sites in healthy volunteers were microbiologically sampled following randomization to either ZuraGard™ (70% w/v isopropyl alcohol), a 2% chlorhexidine/70% isopropyl alcohol preparation (ChloraPrep®), or a control vehicle (ZuraGard vehicle). Mean $\log^{10}$ reduction of colony-forming units (CFU)/cm^2 was assessed at 30 seconds, 10 minutes, and 6 hours.

Results: For combined groin sites (1,721 paired observations) at all time points, the mean $\log^{10}$ CFU/cm^2 reductions were significantly greater in the ZuraGard group than in the ChloraPrep group ($P < .02$). Mean log10 CFU/cm^2 reductions across combined abdominal and groin sites at all time points (3,277 paired observations) were significantly greater in the ZuraGard group than in the ChloraPrep group ($P < .02$).

Conclusions: A confirmatory FDA phase 3 efficacy analysis of skin antisepsis in human volunteers documented that ZuraGard was efficacious in significantly reducing the microbial burden on abdominal and groin test sites, exceeding that of ChloraPrep. No significant adverse reactions were observed following the application of ZuraGard.

INTRODUCTION

Two major classes of perioperative antiseptic skin preparations are used in the United States:

- chlorhexidine gluconate (CHG)-based
- iodine (iodophor)-containing antiseptic agents

Current guidelines recommend the use of a perioperative antiseptic skin preparation that contains alcohol, which has an immediate impact on reducing the microbial burden. When combined with an additional agent, such as CHG or an iodophor, residual antiseptic activity results for the duration of the surgical procedure.

Products containing 70% isopropyl alcohol with 2% chlorhexidine gluconate (CHG) are widely used as a perioperative topical skin preparation in the United States.

- CHG is active against most common gram-positive and gram-negative surgical wound pathogens. However, its widespread use has been viewed as a potential risk for the emergence of resistance pathogens, which may impact its future utility.
- In addition, skin irritation and rare allergic reactions have been reported with antiseptic products containing CHG. Therefore, continued development of new, safe, and clinically effective antiseptic formulations are warranted.

A new 70% isopropyl alcohol-based antiseptic was evaluated in this study.

- It is formulated with the functional excipients citrate (citric acid and sodium citrate) and alkyl Parahydroxybenzoates that support the activity of alcohol, helping to maintain the persistent antimicrobial activity of the antiseptic agent.
- The colorant used was a methylene blue dye, but the formulation is also available in a colorless formulation.

MATERIALS AND METHODS

Study sites:
The antiseptic efficacy study involving an innovative preoperative antiseptic agent ZuraGard (Zurax Pharma, Middleton, WI) was conducted at 2 separate test laboratories:

- MicroBiotest, designated as Z73 (Sterling, VA)
- BioScience Laboratories, designated as Z74 (Bozeman, MT).
- Identical study protocols were reviewed and approved by 2 separate independent institutional review boards (MicroBioTest Laboratories and BioScience Gallatin.

The study was performed according to:

- The 2018 FDA Finalule, Safety and Effectiveness of Healthcare Antiseptics.
- The study protocol was approved by the FDA and registered on ClinicalTrials.gov. The ClinicalTrials.gov identifier for the MicroBio Test study is NCT02831998.
- The identifier for the BioScience Laboratory study is NCT02831816.

Two phase 3 randomized studies were combined for this confirmatory analysis. In each study, participants were randomized to 3 groups:

1. ZuraGard vehicle (without alcohol) versus ZuraGard
2. ZuraGard vehicle versus ChloraPrep
3. ZuraGard versus ChloraPrep. The present analysis presents results for the paired ZuraGard versus ChloraPrep comparison, which is based solely on the third group. Data for 2 locations (groin and abdomen) were collected for all study participants at 3 separate times: 30 seconds, 10 minutes, and 6 hours.

RESULTS

- Log-reduction patterns for ZuraGard and ChloraPrep and the ZuraGard negative control vehicle were similar across both studies.
- Table 3A–C lists the mean log10 CFU/cm2 reductions for the paired comparisons of the ZuraGard vehicle versus ZuraGard and ZuraGard vehicle versus ChloraPrep.
- Both active treatment groups ZuraGard and ChloraPrep outperformed the negative control ZuraGard vehicle, as expected.

Table 3A. Mean Log_{10} CFU/cm^2 Reduction From Baseline With 95% Confidence Intervals at 30 Seconds Post Application

	Abdomen			Groin		
Study*	Vehicle Mean (95% CI)	ZuraGard Mean (95% CI)	ChloraPrep Mean (95% CI)	Vehicle Mean (95% CI)	ZuraGard Mean (95% CI)	ChloraPrep Mean (95% CI)
ZX-73	1.07 (0.93-1.21)	3.04 (2.73-3.35)	2.76 (2.48-3.03)	1.59 (1.42-1.75)	3.97 (3.63-4.32)	3.88 (3.44-4.33)
ZX-74	.071 (0.56-0.86)	2.90 (2.54-3.25)	2.56 (2.20-2.92)	1.22 (1.07-1.39)	3.97 (3.49-4.45)	3.87 (3.42-4.33)

Table 3B. Mean Log_{10} CFU/cm^2 Reduction From Baseline With 95% Confidence Intervals at 10 Minutes Post Application

	Abdomen			Groin		
Study*	Vehicle Mean (95% CI)	ZuraGard Mean (95% CI)	ChloraPrep Mean (95% CI)	Vehicle Mean (95% CI)	ZuraGard Mean (95% CI)	ChloraPrep Mean (95% CI)
ZX-73	1.46 (1.31-1.61)	3.41 (3.19-3.64)	3.27 (3.12-3.42)	2.21 (2.02-2.40)	4.84 (3.49-5.11)	4.62 (4.30-4.94)
ZX-74	1.00 (0.78-1.21)	2.74 (2.37-3.11)	2.84 (2.53-3.16)	1.6 (1.44-1.76)	4.19 (3.76-4.62)	4.24 (3.80-4.68)

Table 3C. Mean Log_{10} CFU/cm^2 Reduction From Baseline With 95% Confidence Intervals at 6 Hours Post Application

	Abdomen			Groin		
Study*	Vehicle Mean (95% CI)	ZuraGard Mean (95% CI)	ChloraPrep Mean (95% CI)	Vehicle Mean (95% CI)	ZuraGard Mean (95% CI)	ChloraPrep Mean (95% CI)
ZX-73	1.88 (1.00-1.37)	2.61 (2.22-3.01)	2.47 (2.09-2.85)	2.02 (1.79-2.24)	2.72 (2.35-3.09)	3.09 (2.75-3.44)
ZX-74	1.27 (1.10-1.64)	2.94 (2.61-3.28)	2.80 (2.43-3.16)	2.10 (1.91-2.28)	4.17 (3.69-4.64)	3.94 (3.62-4.27)

Note. CFU, colony-forming units; CI, confidence interval
*Studies ZX-72 and ZX-74; only vehicle pairs.

CONCLUSIONS

- The results of these large FDA phase 3 efficacy studies and confirmatory analysis demonstrate the effective antiseptic activity of ZuraGard compared to ChloraPrep, with no documented adverse effects.
- ZuraGard demonstrated an immediate and persistent antimicrobial efficacy, performing favorably compared to the current standard of care perioperative skin antiseptic agent, ChloraPrep.
- ZuraGard effectively reduces the endogenous microbial populations associated with surgical wound contamination with the additional advantage of avoiding the risk of IgE-mediated anaphylaxis or potential microbial resistance.
- This study provides a new antiseptic skin prep that will meet the evidence based research for the AORN Skin Prep Guideline

Rapid Deploy

Rapid Fill

References:

1. Cmich CJ, Pop-Vicas AE, Hedberg TG, Perl TM. Efficacy and safety of a novel antimicrobial preoperative skin preparation. Infect Control Hosp Epidemiol 2019;40:1157–1162.
2. Edmiston CE, Jr, et al. (2020). Antiseptic efficacy of an innovative perioperative surgical skin preparation: A confirmatory FDA phase 3 analysis. Infection Control & Hospital Epidemiology, 41: 652–659. https://doi.org/10.1017/ice.2020.27.
3. Edmiston CE, Spencer M. Patient care interventions to help reduce the risk of surgical site infections. AORN 2014;100:590–602.
4. FDA drug safety podcast: FDA warns about rare but serious allergic reactions with the skin antiseptic chlorhexidine gluconate. Food and Drug Administration website. https://www.fda.gov/Drugs/DrugSafety/DrugSafetyPodcasts/ucm540654.htm. Published 2017. Accessed August 12, 2020.
5. Hakkarainen TW, Oellinger EP, Evans HL, et al. Comparative effectiveness of skin antiseptic agents in reducing surgical site infection: AS report from the Washington State surgical care and outcomes assessment program. J Am Coll Surg 2014;218:236–244.
6. Kampf G. Acquired resistance to chlorhexidine: is it time to establish an antiseptic stewardship' initiative? J Hosp Infect 2016; 94:213–227.
7. Maiwald M, Chan ESY. The forgotten role of alcohol: a systematic review and meta-analysis of the clinical efficacy and perceived role of chlorhexidine in skin antisepsis. PLoS One 2012;7:e44277.
8. Sidhwa F, Kani KME. Skin preparation before surgery: options and evidence. Surg Infect 2015;16:14–23.

Presented at AORN 2021 - OR Manager 2021

CONTINUING EDUCATION

An Incision Closure Bundle for Colorectal Surgery

2.0 CE www.aornjournal.org/content/cme

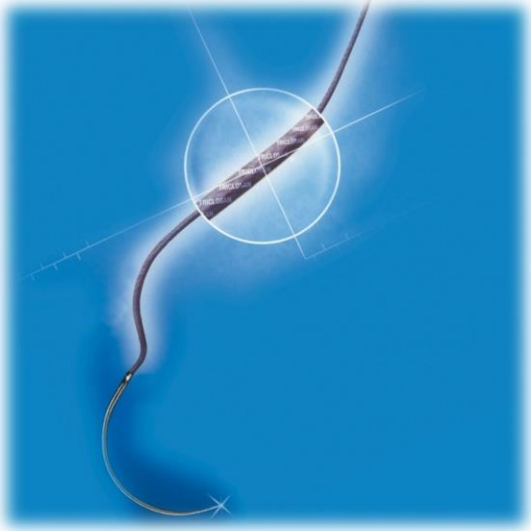
Charles E. Edmiston, Jr, PhD, CIC; David J. Leaper, MD, ChM, FRCS, FACS, FLS; Sue Barnes, BSN, RN, CIC, FAPIC; William Jarvis, MD; Marsha Barnden, MSN, RNC, CIC; Maureen Spencer, MEd, BSN, RN, CIC; Denise Graham; Helen Boehm Johnson, MD

Edmiston Jr et al AORN Journal May 2018, Vol. 107, No. 5

Wound Closure Bundle Components

Table 1. Recommended Incision Closure Bundle Elements

Bundle Element	Evidence
Outer surgical glove change before incision closure	• Expert opinion • ACS SSI prevention guideline[1] • Peer-reviewed papers[2-5]
Use of a dedicated sterile incision closure instrument tray	• Expert opinion • ACS SSI prevention guideline[1] • Peer-reviewed papers[2-5]
Irrigation with 0.05% CHG following the manufacturer's IFU before closure	• Peer-reviewed papers[6-16]
Use of antibacterial triclosan-coated sutures	• Peer-reviewed papers[17-28]
Removal of the surgical drape after applying the dressing	• Expert opinion • AST guideline[29]
Application of topical skin adhesive (with or without mesh) over subcuticular or absorbable skin suture or antimicrobial dressing	• Expert opinion • Peer-reviewed papers[30,31]
Comprehensive postoperative instructions for the patient	• Expert opinion • Peer-reviewed papers[2,32-37]



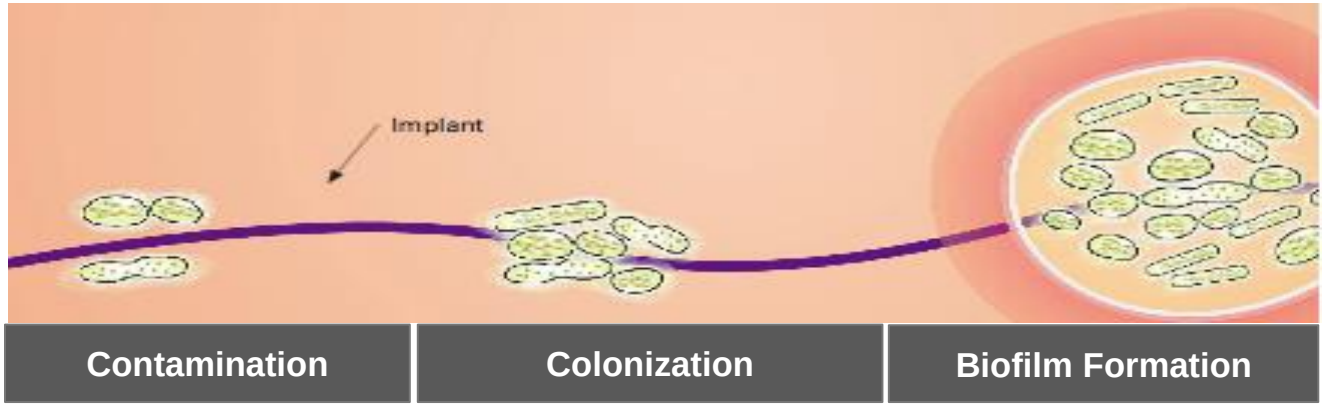
5 Sutures – Triclosan-coated Antimicrobial

Triclosan is used as a mild antiseptic in toothpaste, deodorant, antibacterial soap, mouthwash

Bacterial Colonization of Suture

Like all foreign bodies, sutures can be colonized by bacteria:

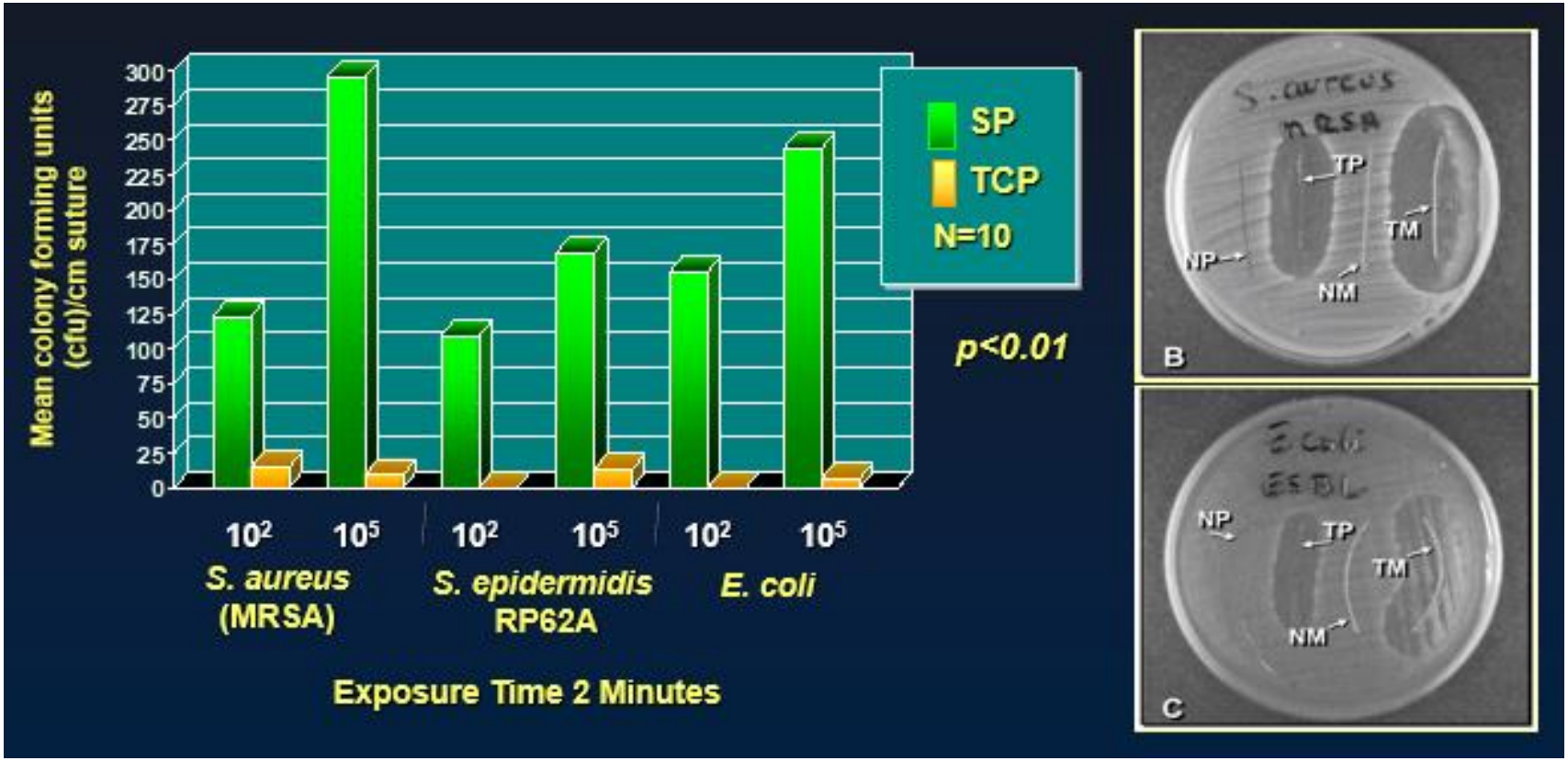
- Implants provide nidus for attachment of bacteria
- Bacterial colonization can lead to biofilm formation
- Biofilm formation increases the difficulty of treating an infection[1]



On an implant, such as a suture, it takes only 100 staphylococci per gram of tissue for an SSI to develop[2]

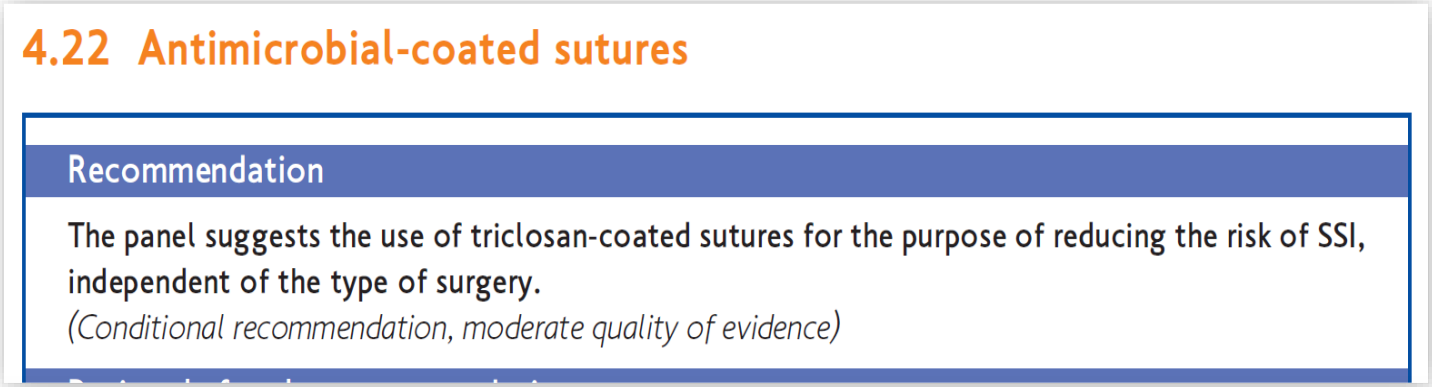
1. Edmiston C, et al. Microbiology of Explanted Suture Segments from Infected and Noninfected Surgical Patients. Journal of Clinical Microbiology. February 2013 Volume 51 Number 2 p. 417–421
2. Mangram AJ et al. Infect Control Hosp Epidemiol.1999;27:97-134..

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



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

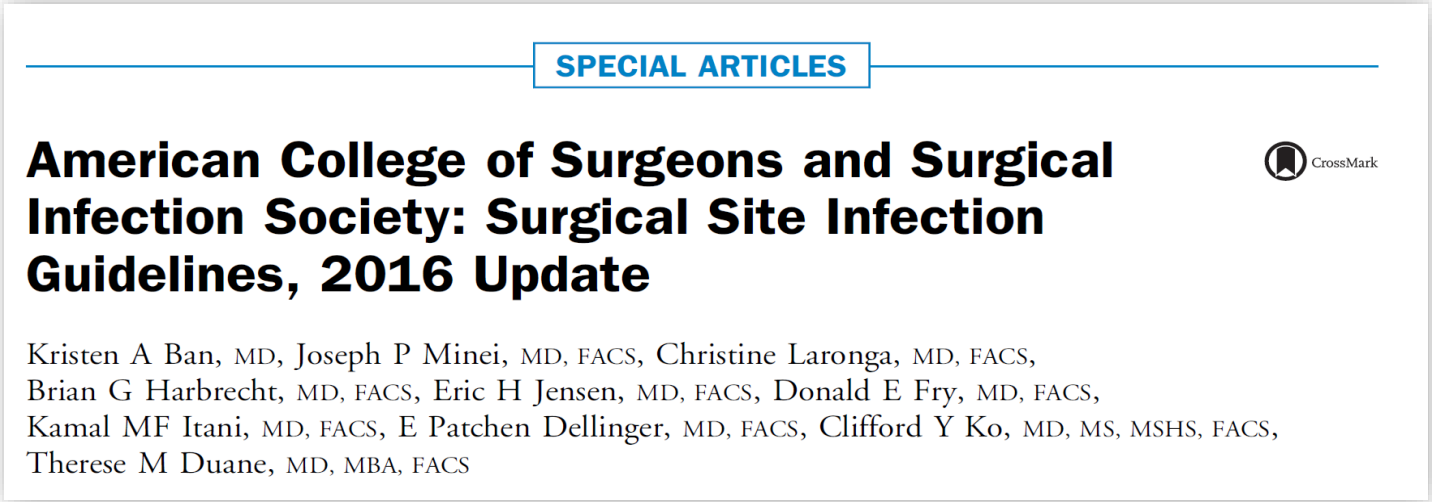
WHO, American College of Surgeons, CDC Recommend Antimicrobial Coated Sutures



4.22 Antimicrobial-coated sutures

Recommendation

The panel suggests the use of triclosan-coated sutures for the purpose of reducing the risk of SSI, independent of the type of surgery.
(Conditional recommendation, moderate quality of evidence)



SPECIAL ARTICLES

American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update

CrossMark

Kristen A Ban, MD, Joseph P Minei, MD, FACS, Christine Laronga, MD, FACS, Brian G Harbrecht, MD, FACS, Eric H Jensen, MD, FACS, Donald E Fry, MD, FACS, Kamal MF Itani, MD, FACS, E Patchen Dellinger, MD, FACS, Clifford Y Ko, MD, MS, MSHS, FACS, Therese M Duane, MD, MBA, FACS

"Numerous studies have demonstrated decreased risk of SSI with use of triclosan antibiotic suture compared with standard suture, including multiple randomized, controlled trials".

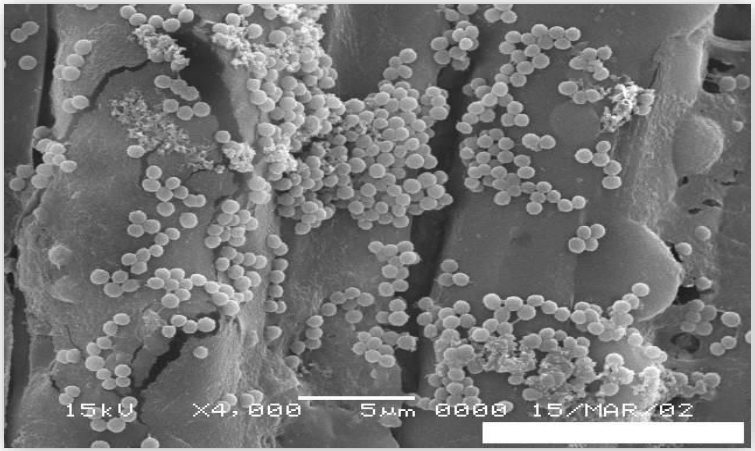
WHY? OR Air Current Contamination – End of the Case

In teaching hospitals:

- Surgeon leaves room
- Resident, Physician Assistant or Nurse Practitioner work on incision
- Circulating Nurse counts sponges
- Scrub Technician preparing instruments for Central Sterile Processing
- Anesthesia move in and out of room
- Instrument representative
- Students and Visitors

Potential for Contamination of Sutures

Suture with Staphylococcus colonies



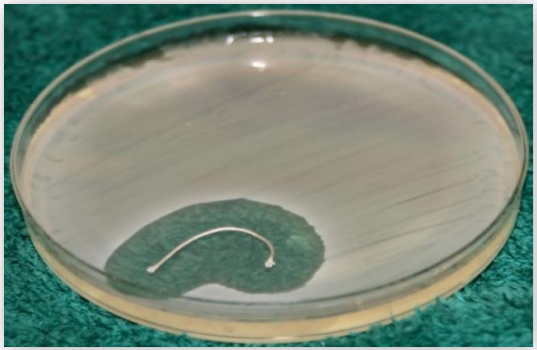
Air settling plates in the operating room at the last hour of a total joint case from the anesthesia cart, bovie cart, computer

Spencer et al: Reducing the Risk of Orthopedic Infections: The Role of Innovative Suture Technology. NAON 2010 Annual Congress - May 15-19, 2010

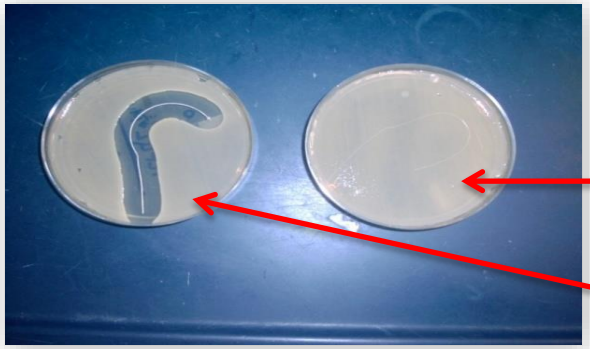
Antibacterial Suture Challenge

Studied the “zone of inhibition” around the suture

- A pure culture—0.5 McFarland Broth—of *S. aureus* was prepared on a culture plate
- An antibacterial suture was aseptically cut, planted on the culture plate, and incubated for 24 hrs. – held at 5 and 10 days



5-day zone of inhibition



10-day zone of inhibition

Spencer et al: Reducing the Risk of Orthopedic Infections: The Role of Innovative Suture Technology NAON 2010 Annual Congress - May 15-19, 2010

Evidenced Based Research – >20 Meta-Analyses

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

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

New England Baptist Hospital

Reducing the Risk of Orthopedic Infections: The Role of Innovative Suture Technology

NAON 2010 Annual C

Maureen Spencer, RN, M.Ed., CIC, Geoffrey Van Flandern, M.D., Wolfgang Fitz, M.D., Susan Davidson, M.D., Diane Gulczynski, RN, MS, CNOR, Li Ling, MSC, John Richmond, M.D.
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Abstract

Background:
The National Healthcare safety Network (NHSN) has reported an overall infection rate of 1.3% and 0.9%, respectively for total hip and knee replacement. These infections are associated with significant patient morbidity. An interdisciplinary study was carried out to determine the benefit of adoption of an innovative suture technology to reduce the risk of infection in patients undergoing total joint replacement.

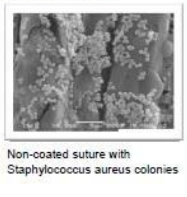
Method:
From September 2005 to August 2006, active surveillance was carried out in 3678 patients undergoing total joint replacement procedures. Cases of SSI were defined by NHSN criteria and patients were stratified by risk (ASA score, operative site and operative site). All patients during this study period were closed using a triclosan-coated polyglactin 910 suture material. Because of implantation of a biomedical device, active surveillance extended a full 12 months post-device implantation. The surgical infection rate observed during this period was compared to a historic interval, September 2004 to August 2005 and involved 3413 patients. All surgical variables with the exception of the suture technology during both study periods were identical. No other risk reduction strategies were implemented during the evaluation period.

Results:
During the suture evaluation period, 12 patients of 3678 total joint procedures (0.33%) developed SSI's compared to the 15 of 3413 in the historical control group (0.44%). No significant difference was observed in the SSI rate for the time intervals studied. However, subgroup analysis did document 6 fewer Staphylococcus aureus infections in the triclosan-suture group (N = 4) compared to the historical control (N = 10).

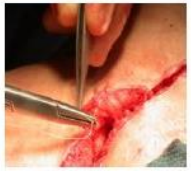
Conclusions:
Use of triclosan-coated sutures resulted in a slight reduction in overall surgical site infection rates and a 62% reduction in total joint infections involving Staphylococcus aureus. Further studies are warranted to evaluate the efficacy of impregnated suture technology to reduce the risk of surgical site infections.

Risk of Biofilm

- Biofilm is created when microorganisms like bacteria attach themselves to living or nonliving surfaces in internal or external environments
- For instance, postoperative bacteria may contaminate the tissue in a surgical wound as well as the suture material itself
- Furthermore, the bacteria develop extracellular polymers that promote greater adhesion and resistance to antimicrobial treatment



Non-coated suture with Staphylococcus aureus colonies



Purpose of Antibacterial Suture
To prevent colonization of the suture material by bacteria in surgical wounds, triclosan coated polyglactin 910 suture with antibacterial activity was developed. Several studies have showed a considerable decrease in bacteria adherence in vitro.

Properties Of Polyglactin 910 Coated Suture With Triclosan

- 2,4,4´-tri-chloro-2´-hydroxydiphenyl ether High-purity material that meets USP specifications for triclosan, with minimal residue content
- Biocompatible, nontoxic
- Contained in many consumer products (eg mouthwash, toothpaste, antibacteria soap)
- Affective against methicillin-sensitive and methicillin-resistant S aureus and S epidermidis (most common for device infections)
- Active against Escherichia coli and Klebsiella pneumoniae
- Compatible with suture processing and maintains excellent suture properties

In-vitro testing of triclosan suture on seeded agar plates with 0.5 MacFarland broth prepared clinical isolates of Staphylococcus aureus.
Agar plate on the left demonstrates a wide zone of inhibition around the triclosan-coated polyglactin braided suture 5 days after inoculation and incubation. The plate on the right shows a similar zone of inhibition around the suture at day 10 but does show breakthrough of bacteria at the cut ends of the suture. This breakthrough was not associated with emerging resistance but rather was associated with termination of antimicrobial activity. To the right of it is an agar plate with a non-coated suture as a control and shows bacterial growth surrounding the entire suture.

Examination Of The Potential For Air Current Contamination

To examine this potential risk, air settling plates were placed for the last hours of a total hip replacement and showed air current contamination from room activity. Often anesthesia, instrument reps, circulators and orderlies may move in and out of the room at the end of a case, resulting in air current transmission of common skin microorganisms. The blood agar plates show Staphylococcus colonies on the anesthesia cart, computer desk and bovie cart. This was the major reason for implementing coated sutures to the bundle of prevention measures, so tissues would be protected at a critical time when room contamination might occur from staff activity and movement.

Anesthesia Cart | Computer Desk | Bovie Cart

Results

During the suture evaluation period, 12 patients of 3678 total joint procedures (0.33%) developed SSI's compared to the 15 of 3413 in the historical control group (0.44%). No significant difference was observed in the SSI rate for the time intervals studied. However, subgroup analysis did document 6 fewer Staphylococcus aureus infections in the triclosan-suture group (N = 4) compared to the historical controls (N = 10).

Triclosan suture	Infections	Cases	Rate(%)		
			Lower	p	Upper
Pre-trial	15	3413	0.26	0.44	0.74
Trial	12	3678	0.20	0.33	0.63

Table 2: Orthopedic Infection During Historical Control Period (September 2004 – August 2005)

Surgical Procedure	NERH Infections	Cases	NERH Rate	NNIS Rate*	P Value
Hip Prosthesis: 0	1	653	0.2	0.86	0.041*
Hip Prosthesis: 1	2	822	0.2	1.65	0.001*
Hip Prosthesis: 2+3	1	191	0.5	2.52	0.064
Knee Prosthesis: 0	3	642	0.2	0.86	NS
Knee Prosthesis: 1	6	902	0.7	1.28	0.068
Knee Prosthesis: 2+3	2	203	1.0	2.26	NS
Total	**15**	**3413**	**0.44**		**p = <0.05***

NNIS data: January 1992-October 2004

Table 3: Orthopedic Infections During Suture Evaluation Period (September 2005–August 2006)

Surgical Procedure	NERH Infections	Cases	NERH Rate	NNIS Rate	P Value
Hip Prosthesis: 0	0	856	0.0	0.86	0.006*
Hip Prosthesis: 1	2	762	0.3	1.65	0.011*
Hip Prosthesis: 2+3	3	198	1.5	2.52	NS
Knee Prosthesis: 0	1	840	0.1	0.86	0.015*
Knee Prosthesis: 1	3	844	0.4	1.28	0.013*
Knee Prosthesis: 2+3	3	178	1.7	2.26	NS
Total	**12**	**3678**	**0.33**		***p = <0.05***

NNIS data: January 1992-October 2004

Table 4: Staphylococcus Surgical Site Infections in Historical Control Group (September 2004-August 2005)

Type of Joint	# SSI	# Procedures	Rate	#Staph aureus	SSI Rate
Hip	4	1666	0.25	3 (75%)	0.18
Knee	11	1747	0.63	7 (64%)	0.40
Total	**15**	**3413**	**0.44**	**10 (67%)**	**0.29***

Table 5: Staphylococcus Surgical Site Infections in Triclosan-Coated Suture Group (September 2005 - August 2006)

Type of Joint	#SSI	# Procedures	Rate	#Staph aureus	SSI Rate
Hip	5	1818	0.27	2 (40%)	0.11
Knee	7	1862	0.37	2 (28%)	0.11
Total	**12**	**3678**	**0.33**	**4 (33%)**	**0.11***

62% reduction in Staphylococcus aureus in treated group

Discussion

The Centers for Disease Control and Prevention (CDC) defines SSIs as those occurring within 30 days of an operation, and within 1 year if a non-human derived implant is placed surgically. Clearly exquisite surgical technique, antimicrobial prophylaxis, skin antisepsis and a competent infection control program are mainstays for preventing surgical site infections. In addition, other adjunctive strategies such as iodophor-impregnated incise drapes, appropriate hair removal techniques, ventilated surgical suits, laminar air flow, limited access to the operating room during procedure to reduce the risk of SSIs in orthope technologies aimed at reducing post control, increased tissue oxygenatio antibacterial irrigations, antibiotic ce dressings and antimicrobial impregn selected interventions are designed posture or to diminish wound bed co for wound healing.

It has been suggested that the impla nidus for bacterial colonization and the inoculum burden required develo contribute to subsequent infection. E a higher affinity for microbial adhere monofilament devices. The factors specific microbial species and the st material. Placement of a suture with antimicrobial substance within the w the risk of wound contamination and

In our study, use of triclosan-coated small reduction in the hip and total jo However, a marked reduction was n infections in both total knee and hip month evaluation period. The use of fascia and superficial skin layers wo end of the surgical case when possi occur within the wound bed. Antibac salient component of an overall risk timely and appropriate antimicrobial and other potential evidence-based clinical outcome in the surgical patie

Conclusions

Use of triclosan-coated sutures resu surgical site infection rates and a 62 involving Staphylococcus aureus. F evaluate the efficacy of impregnated of surgical site infections.

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Is Triclosan Harmful to Patients?

Triclosan Efficacy and Safety

- Primary mechanism of action – blocking lipid synthesis by inhibiting the enzyme enoyl-acyl carrier protein reductase. Broad-spectrum activity includes both Gram-positive and Gram-negative bacteria.[1]
- 30 years of experience with triclosan without any reports of acquired bacterial resistance.[2]
- Triclosan is thought to have **very low allergenic potential** and triclosan has very little potential to cause skin irritation, and acute skin irritation.[3,4]
- The irritant potential of triclosan is also considered to be very low.[5.6]
- Lab studies have shown that triclosan can react with the free chlorine in water to produce lesser amounts of potentially harmful compounds. There is no data to documents that this occurs outside of the laboratory.[7]
- The benefit of triclosan in the health care setting is well established**, benefits related to household use have not been clearly proven.**
- Maximal single-day exposure to triclosan is calculated to be 0.03 (Vicryl), 0.09 (PDS) and 0.08 mg/kg (Moncryl) body weight.[8,9] **The safety margin (range 160 to 2500) considered highly safe for triclosan.**

1. Nature 1998;394:531-532,
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#6 Solution – to Pollution is Dilution

Antibiotic Irrigation – Limited Evidence

- High-pressure pulsatile lavage and low-pressure pulsatile lavage result in **higher rates of deep bacterial seeding** in bone than does brush and bulb-syringe lavage[1]
- Higher irrigant pressures result in greater **osseous damage** and perhaps impairment of osseous healing[1]
- Kalteis et al. revealed that compared with brush and bulb-syringe lavage high and low-pressure pulsatile lavage resulted in **significantly ($p < 0.001$) higher rates of deep bacterial seeding in bone**[2]
- **No evidence that Bacitracin/Polymyxin irrigations reduce rate of SSI**[2]

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American Journal of Infection Control ■■ (2017) ■■-■■

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Practice Forum

Considering a new domain for antimicrobial stewardship: Topical antibiotics in the open surgical wound

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- Current existing published evidence is not sufficient to guide delivery method and volume. Expert opinion could instead be used to guide best practice.

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Intra-Operative Surgical Irrigation of the Surgical Incision: What Does the Future Hold—Saline, Antibiotic Agents, or Antiseptic Agents?

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

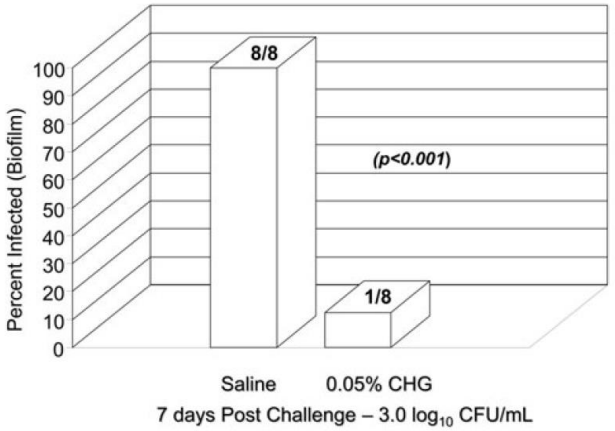

FIG. 5. Impact of Intraoperative saline and 0.05% chlorhexidine gluconate (CHG) irrigation on resolution of methicillin-resistant *Staphylococcus aureus* (MRSA) contaminated polypropylene mesh in Sprague-Dawley animal model at 7 day post-infection ($p < 0.001$). Total lavage volume, 200 mL, microbial counts expressed as $\log_{10}$ cfu/cm^2 surgical mesh, initial MRSA inoculum challenge, 3.0 $\log_{10}$ cfu/mL. CFU = colony-forming units.

SURGICAL INFECTIONS
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DOI: 10.1089/sur.2016.107

Topical Antimicrobials and the Open Surgical Wound

Donald E. Fry

Abstract

Background: Topical antiseptic and antibiotic agents have been used for the prevention of surgical site infections since Joseph Lister's original research on this subject. Although these agents are used extensively in clinical practice, evidence to support the use of topical antimicrobial agents remains limited.
Patients and Methods: The world literature on the use of antiseptic and antibiotic agents was evaluated to determine the current status of evidence to support the use of topical antimicrobial agents in the prevention of surgical site infections.
Results: Although several techniques of using topical antibiotic solutions, powders, antibiotic gauzes, and beads have some evidence for validation, there are equal numbers of reports that have failed to show benefit. There is little evidence to support the use of antiseptic solutions in the prevention of infections at the surgical site.
Conclusions: Additional clinical trials are necessary to provide evidence to support any of the methods for using topical antimicrobial agents to present surgical site infections. Dilute antiseptic agents should be considered in future trials when antimicrobial activity can be identified without local toxicity.

Yet another feature of chlorhexidine is the binding of the antiseptic agent to soft tissue. Chlorhexidine binds to epidermal, mucous, and subcutaneous tissues after topical application. The bound chlorhexidine has antiseptic effects that continue after the tissue binding, and it is unaffected by the local presence of blood [31]. As a dilute irrigation solution of open wounds and soft tissue infections, it can be anticipated that antiseptic effects will continue after application.

SCIENTIFIC ARTICLES

Polymyxin and Bacitracin in the Irrigation Solution Provide No Benefit for Bacterial Killing in Vitro

Goswami, Karan MD[1]; Cho, Jeongeun BA[1]; Foltz, Carol PhD[1]; Manrique, Jorge MD[1]; Tan, Timothy L. MD[1]; Fillingham, Yale MD[1]; Higuera, Carlos MD[1]; Della Valle, Craig MD[1]; Parvizi, Javad MD, FRCS[1]

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The Journal of Bone and Joint Surgery: September 18, 2019 - Volume 101 - Issue 18 - p 1689-1697
doi: 10.2106/JBJS.18.01362

Conclusions:

Irrigation with polymyxin-bacitracin was ineffective at bacterial eradication, and statistically inferior to povidone-iodine. Chlorhexidine lavage conferred the greatest in vitro cytotoxicity.

Clinical Relevance:

These data suggest that the addition of polymyxin-bacitracin to saline solution irrigation has little value. Given the cost and antimicrobial resistance implications, our findings, combined with prior clinical literature, provide adequate reason to avoid widespread use of antibiotics in irrigation solutions. Povidone-iodine may be a more effective and safer option.

Antibiotic irrigation solutions for prevention of surgical site infections: A call to action

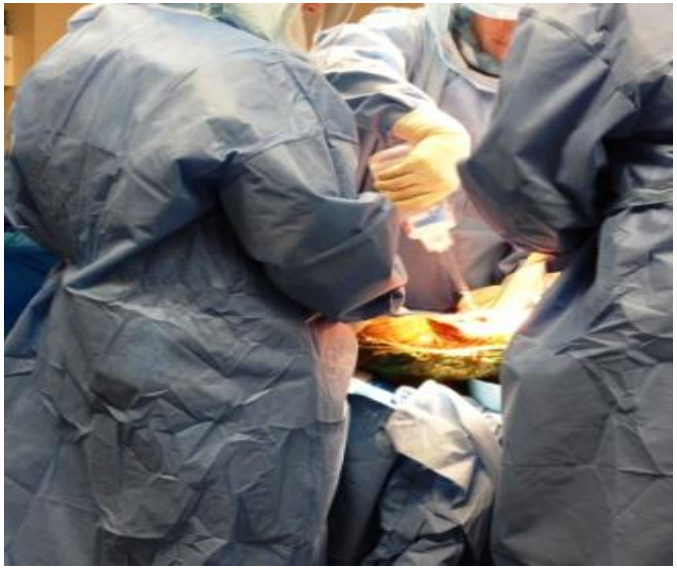
Karen Abboud, PharmD ✉, John Blee, PharmD, MS, BCPS, Punit J Shah, PharmD, BCPS, BCIDP

American Journal of Health-System Pharmacy, Volume 77, Issue 24, 15 December 2020, Pages 2040–2041, https://doi.org/10.1093/ajhp/zxaa316
Published: 20 October 2020

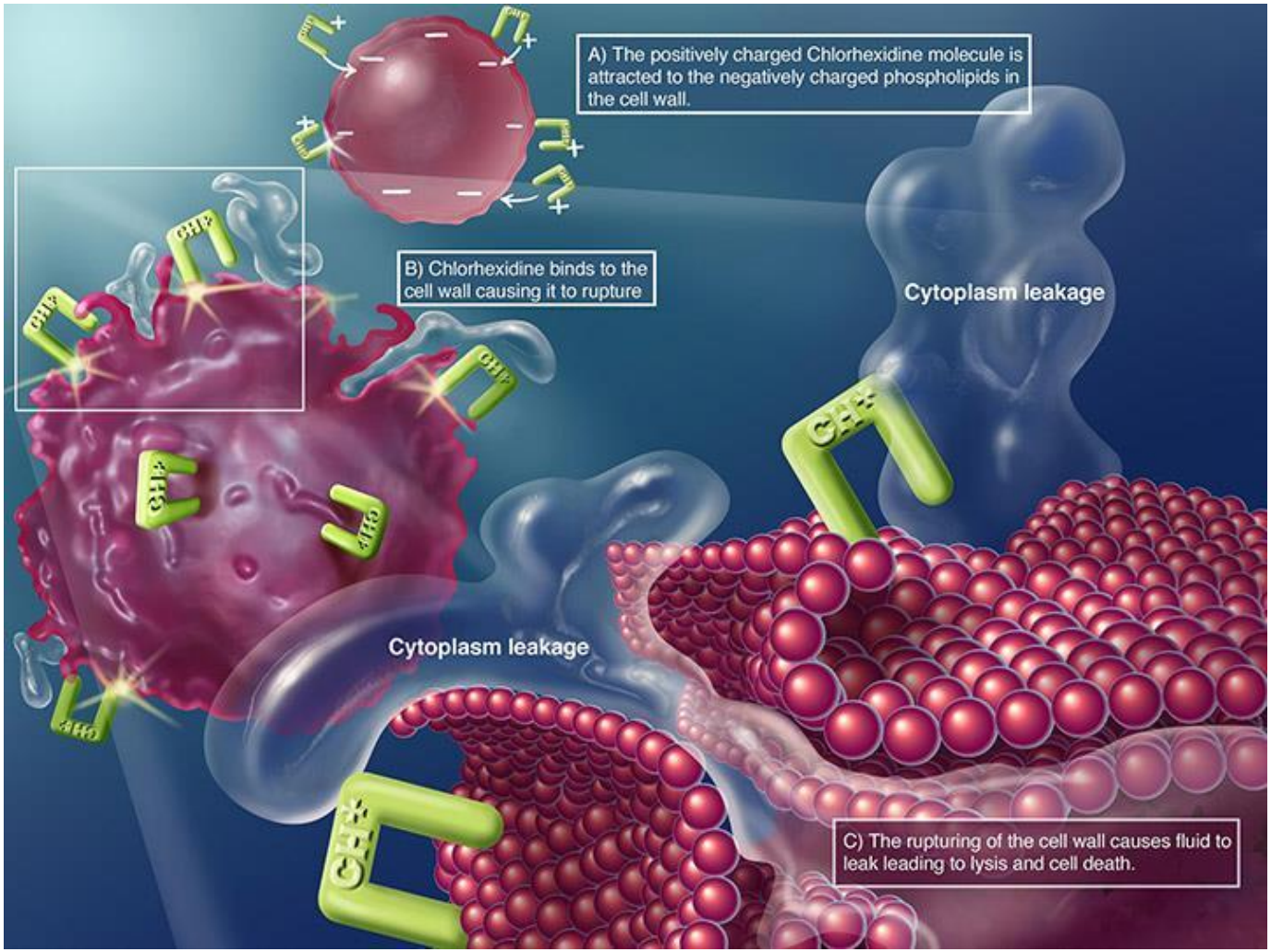
On January 31, 2020, the Food and Drug Administration (FDA) requested the voluntary withdrawal of bacitracin for injection from the market after the Antimicrobial Drugs Advisory Committee deemed that the risks of its labeled use, such as nephrotoxicity and anaphylactic reactions, outweigh any potential benefits. While bacitracin for injection has only received FDA approval to treat pneumonia and empyema in infants caused by staphylococci shown to be susceptible to the drug, it has mostly been used off-label for the intraoperative irrigation of surgical wounds to prevent surgical site infections (SSIs).[1] To date, the only FDA-approved products for wound irrigation include sterile normal...

Chlorhexidine 0.05% Irrigation Solution

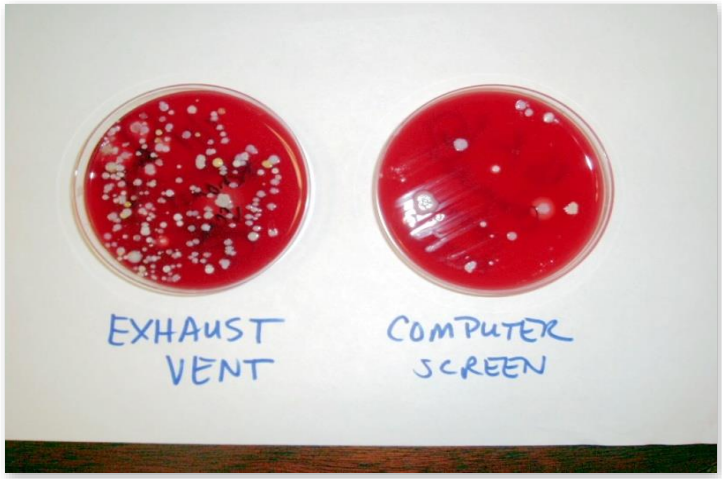
- Chlorhexidine Gluconate 0.05% is an excellent biocide that binds to tissues
- It has demonstrated antimicrobial efficacy and persistence in laboratory testing
- Mechanical action effectively loosens and removes wound debris
- Safe for mucous membranes – cleared by FDA

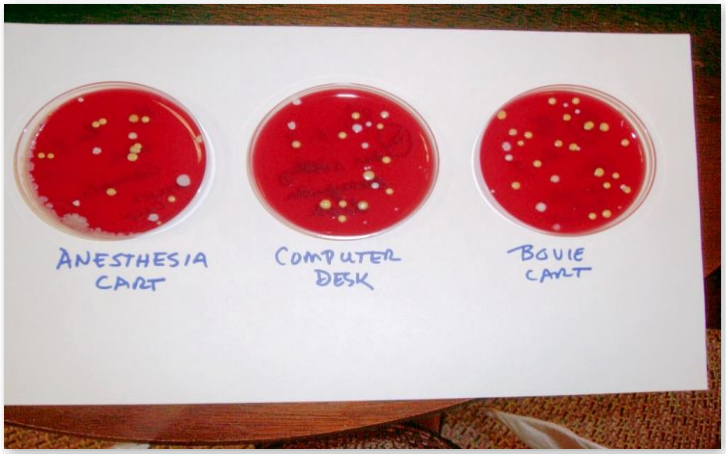


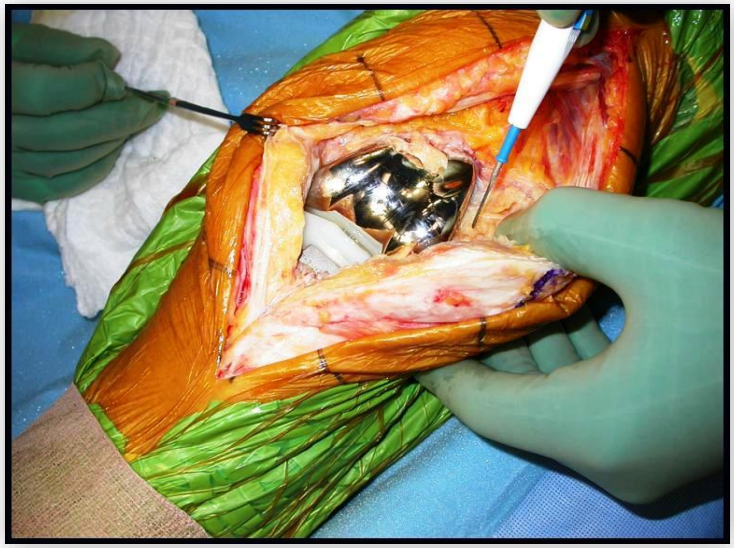
CHG is a Biocide that Binds to Bacterial Cell Wall



Flush Contaminants Before Closure







CHG Irrigant leaves a persistent antimicrobial action in the tissue

Fry D. Topical Antimicrobials and the Open Surgical Wound Surg Infec Vol 17, No 5 2016

- Antimicrobial Stewardship

  Antiseptic irrigation (vs Antibiotic)

  Antiseptic agents used in the facility

  Disinfectants used in the facility

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JBJI Journal of Bone and Joint Infection Open Access

Pursuit of the ideal antiseptic irrigation solution in the management of periprosthetic joint infections

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Table 2. Preparation of most common irrigation solutions.

Solution	Additive	Irrigation preparation
Povidone iodine	Antiseptic	17.5 mL 10 % PI + 500 cc NS or Surgiphor (0.5 %) (Surgiphor Wound Irrigation System FDA, 2021)
Chlorhexidine gluconate	Antiseptic	Irrisept (0.05 %) (Premkumar et al., 2020)
Acetic acid	Antiseptic	Available in 3 % concentration without dilution
Sodium hypochlorite	Antiseptic	Dakin's solution (0.5 %) Can be further diluted with 500 cc NS for 0.25 % concentration
Hypochlorous acid	Antiseptic	Vashe Wound Therapy Solution (Vashe, 2021)
0.1 % polyhexamethylene biguanide 0.1 % betaine	Antiseptic–surfactant combination	Prontosan Wound Irrigation Solution (B. Braun, 2021)
Ethanol Acetic acid Sodium acetate Benzalkonium chloride Sterile water	Antiseptic–surfactant combination	Bactisure Wound Lavage solution (Bactisure™, 2021)

PI: povidone iodine; NS: normal saline 0.9 %; L: liter; PA: Pennsylvania; GA: Georgia.

Reduction in Colon Surgical Site Infections using CHG Irrigant Solution

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5.88 **1.09**

Month - Year	August 2015	September 2015	October 2015	November 2015	December 2015	January 2016	February 2016	March 2016	April 2016	May 2016	June 2016	July 2016	August 2016	September 2016	October 2016	November 2016
Rate/100 Procedures	5.88	6.21	3.24	2.13	2.65	3.47	4.37	3.33	1.28	1.49	2.43	1.05	2.24	2.01	3.18	1.09

Clinical Issue:

- Colon surgical site infections (SSIs) have one of the highest rates of healthcare acquired infections that can lead to increased morbidity and mortality and use of hospitals resources
- Numerous clinical interventions with varying levels of supporting evidence have been implemented:
  - Appropriate antibiotic prophylaxis,
  - Normo-thermia,
  - Appropriate hair removal,
  - Glycemic control
  - Wound protectors
  - Mechanical bowel preparation.
- For this project a surgical irrigating solution, using a 0.05% chlorhexidine gluconate antiseptic was introduced in a 26-facility acute care system starting in June 2015.

Pre-Implementation: May 2015

- Manufacturer of the CHG irrigation solution visit the hospitals with the highest standardized infection ratio (SIR) for Colon SSI to educate perioperative nursing staff and physicians.

Implementation:

- Each Operating Room site purchased product
- Clinical Specialist contacted the OR Director and were assigned the week to visit for in-service education.
- The procedure involved irrigating the tissues after the fascia was closed with the 450ml of CHG, leaving it in the tissues for 1 minute, followed by a rinse with the 450ml of saline.

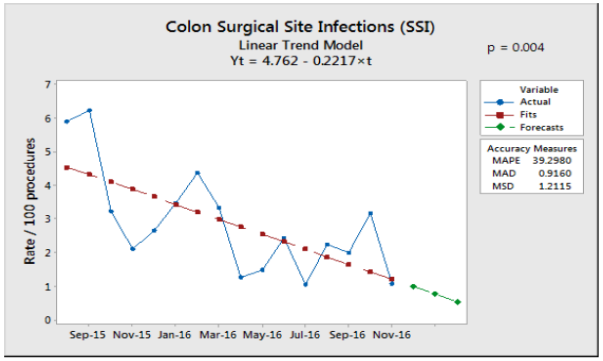
The Product Change: Irrisept CHG Irrigant

- A wound debridement and cleansing system that contains 0.05% Chlorhexidine Gluconate (CHG) in sterile water for irrigation
- Mechanism of action:
  - Mechanical action removes bacteria and debris without harming underlying tissues.
  - Bottle design allows users to control the delivery pressure of the solution through manual bottle compression. Grasping the bottle firmly, the user can control the direction and pressure needed to help remove bacteria, particulate and debris.
- Irrisept has successfully completed testing for acute systemic toxicity, cytotoxicity, neurotoxicity, skin irritation and immune allergic response.

Implications for Perioperative Nursing:

- Replaces the use of antimicrobial irrigations, such as cefazolin, vancomycin, bacitracin and polymixin.
- Facilitates compliance with hospital antimicrobial stewardship
- Pre-packaged design is more efficient for preparation and dispensing to field
- Pharmacy no longer mixing irrigations
- Since CHG is a biocide and can efficiently attach to tissues it creates a residual antibacterial effect that can last for many days in the tissues.

P = 0.004



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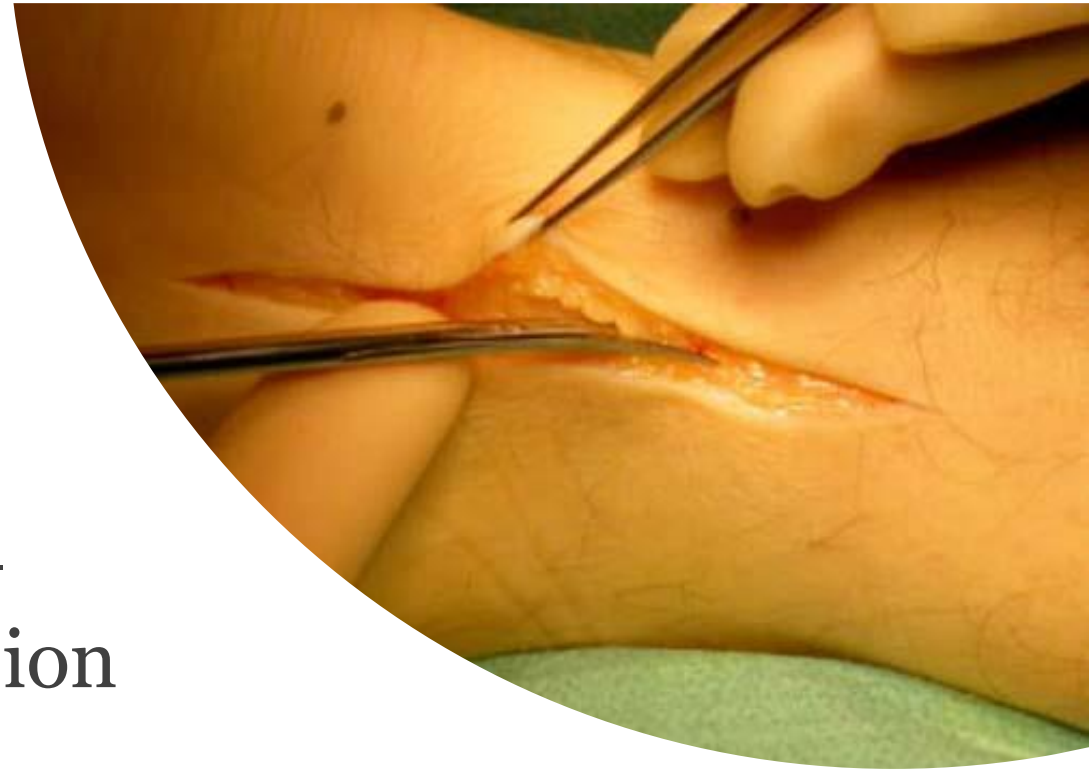
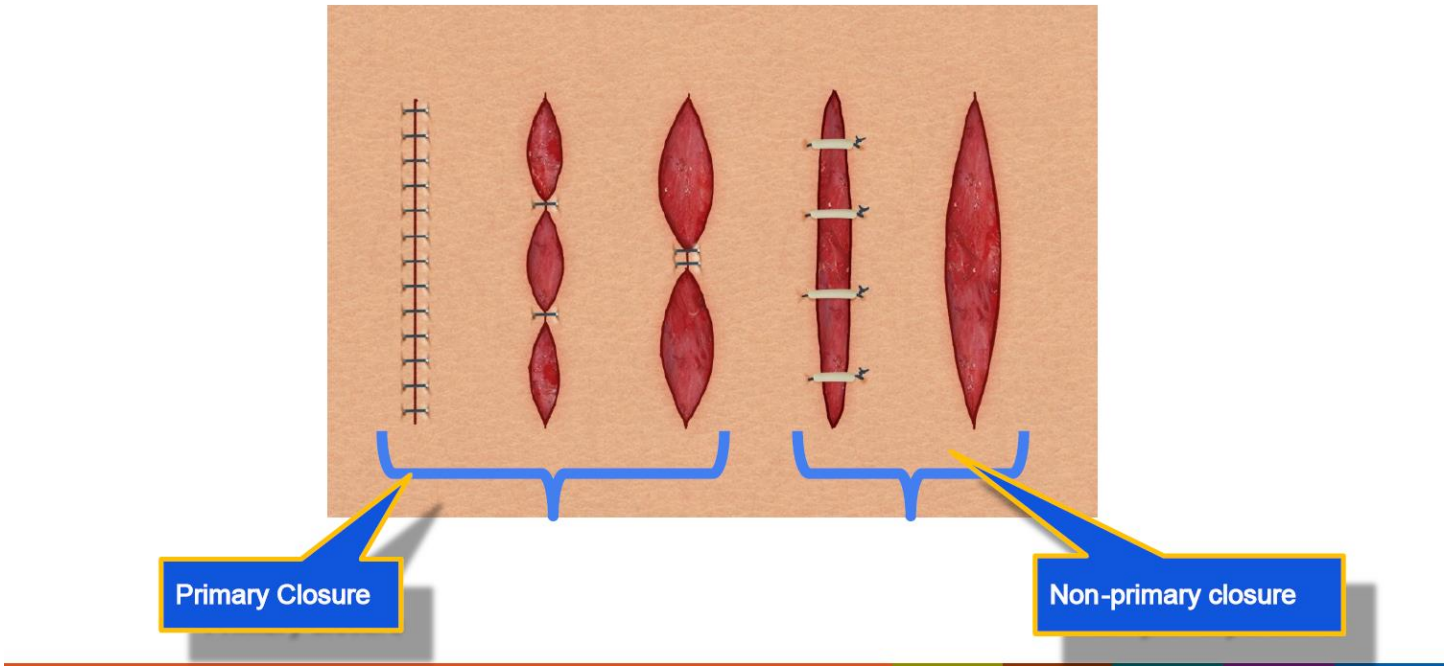


#7 **Skin** Adhesive – Care of Post-op Incision

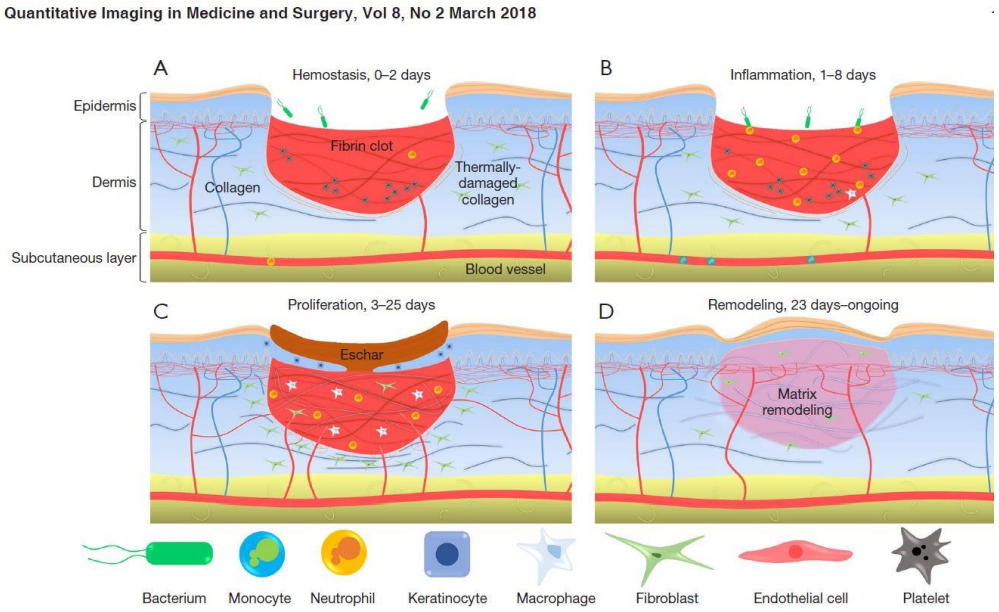
CDC: NHSN Surveillance

Denominator for Procedure Detail: Closure Technique



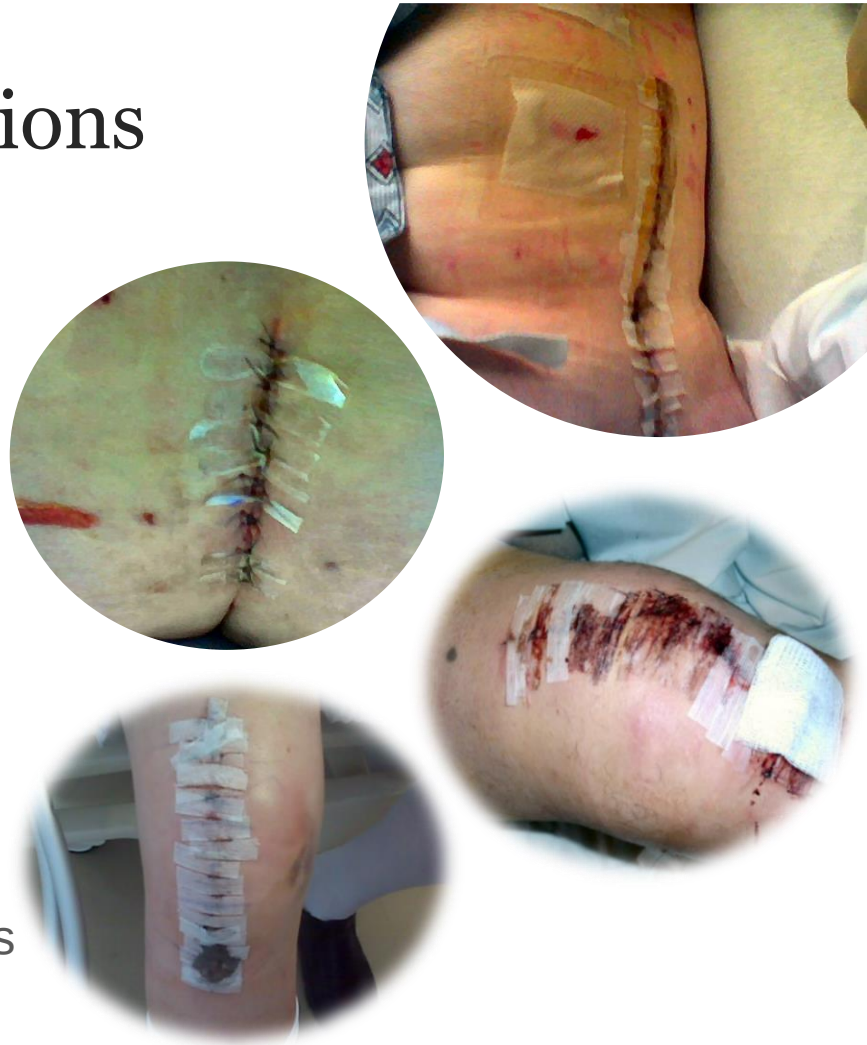
Stages of Wound Healing

- Challenges in healthcare:
  - Patients are discharged home or to rehab earlier after major surgery
  - Same-day surgeries have increased for orthopedic joint replacements
  - Nutritional deficiencies for proper wound healing
  - Increase in obesity and diabetes



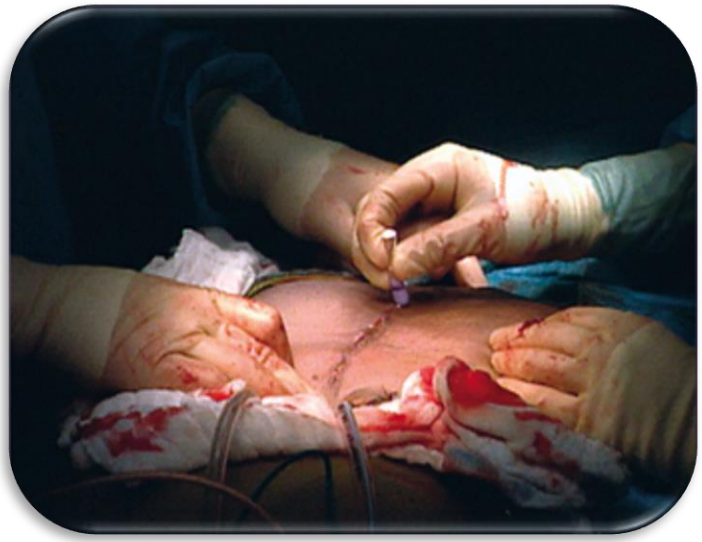
Challenges in Post-op Incisions

- Incision collects fluid – serum, blood – growth medium for organisms – small dehiscence
- Spine fusions – incisions close to the buttocks or neck
- Body fluid contamination from bedpans/commodes
- Heavy perspiration common with obese patients
- Friction and sliding – skin tears and blisters



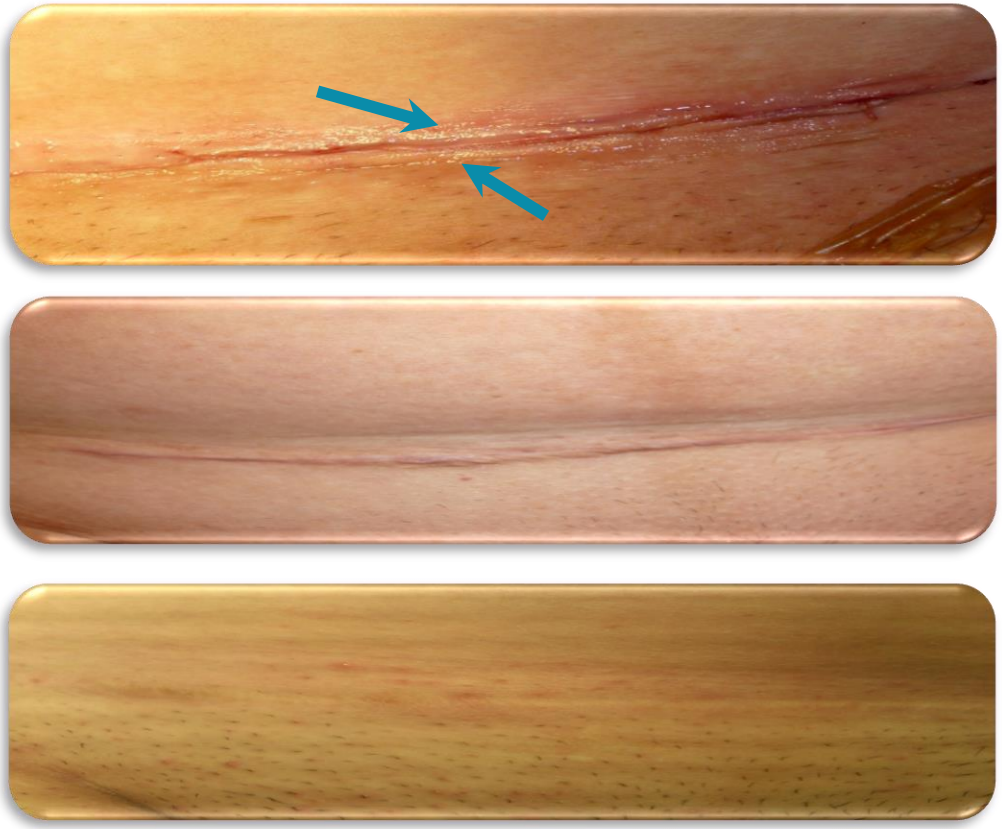
Consider Topical Skin Adhesive

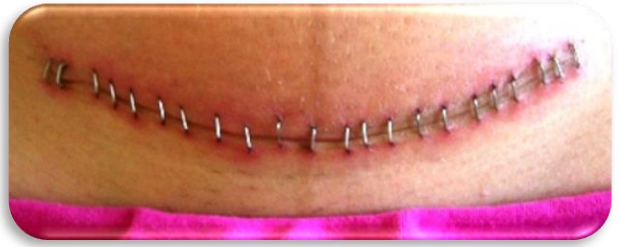
- Wounds are most vulnerable to infection in the first 48-72 hours[1] – during the time when most are **discharged**
- Until the epithelial barrier is complete (usually within 48 hours) wounds are solely dependent on the wound closure device to maintain integrity[1]
- Extent of microbial protection depends on barrier integrity[1]
- Effective barriers must maintain their integrity for the first 48 hours
- Incisional adhesive provides a strong microbial barrier that prevents bacteria from entering the incision site[2]



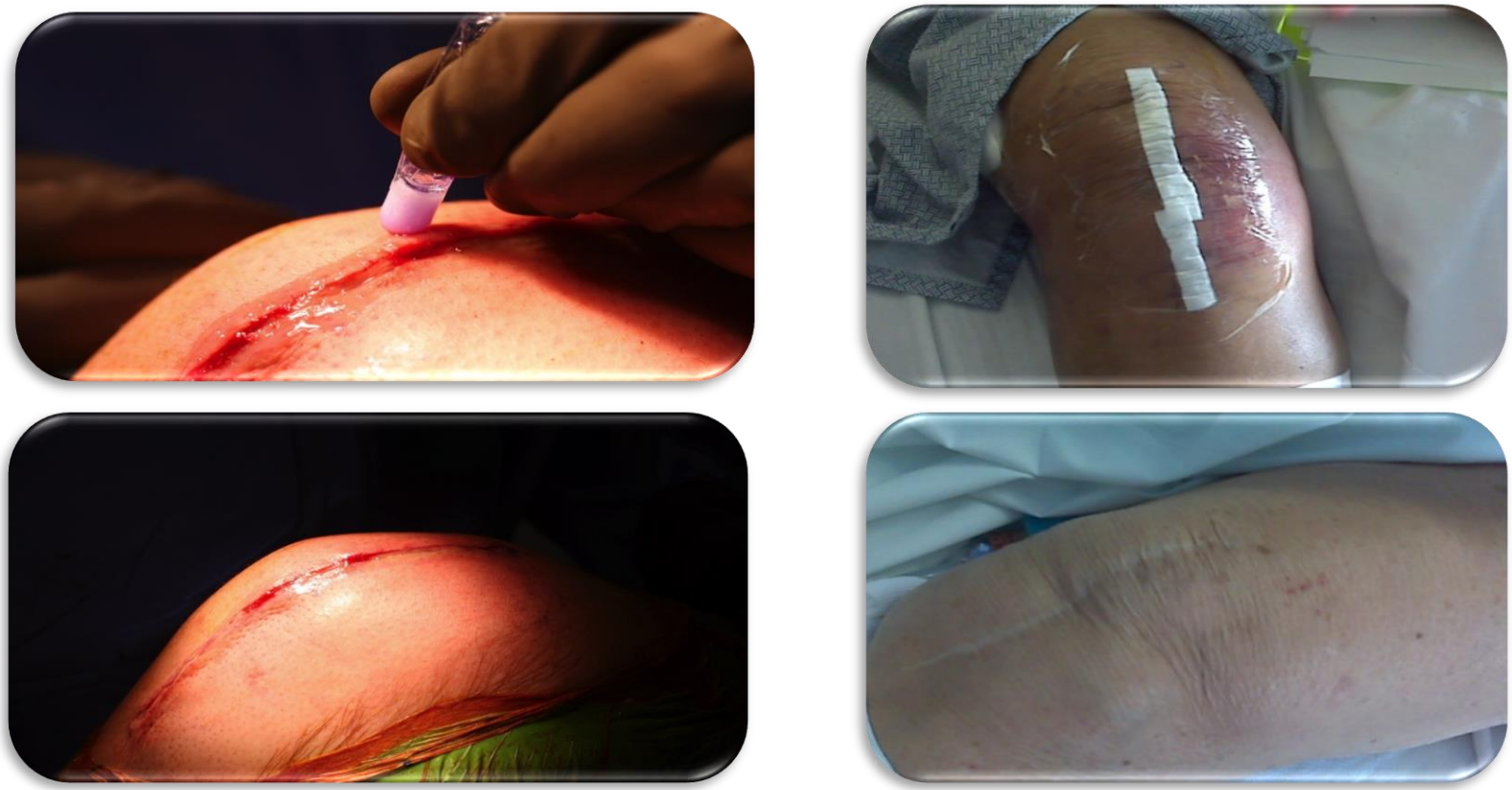
1. Fine and Musto. Wound healing. In: Mulholland et al. Greenfield's Surgery: Scientific Principles and Practice. 4th ed. 2005.
2. Bhende et al. Surg Infect (Larchmt). 2002;3:251-257.

C Section 6 Weeks Post-op and Beyond



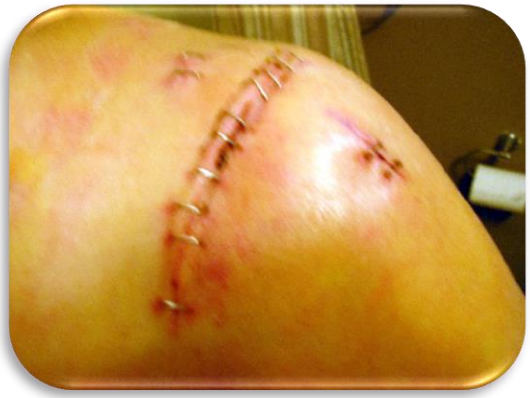


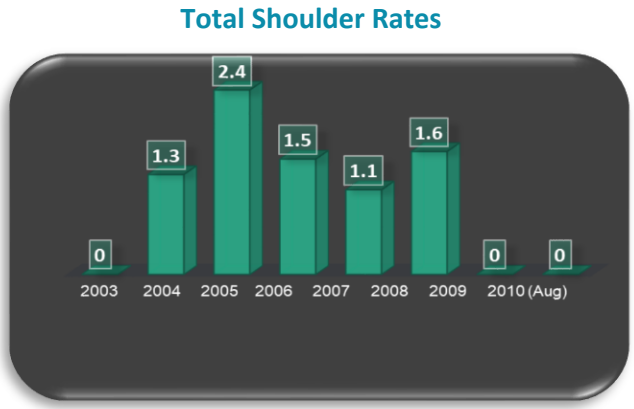
Incisional Adhesive on Total Knee Replacement

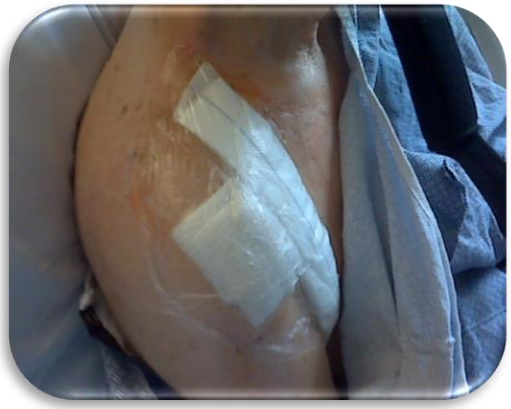


Independent research – New England Baptist Hospital, Boston, MA 2010

Incisional Adhesive and Total Shoulder Replacements



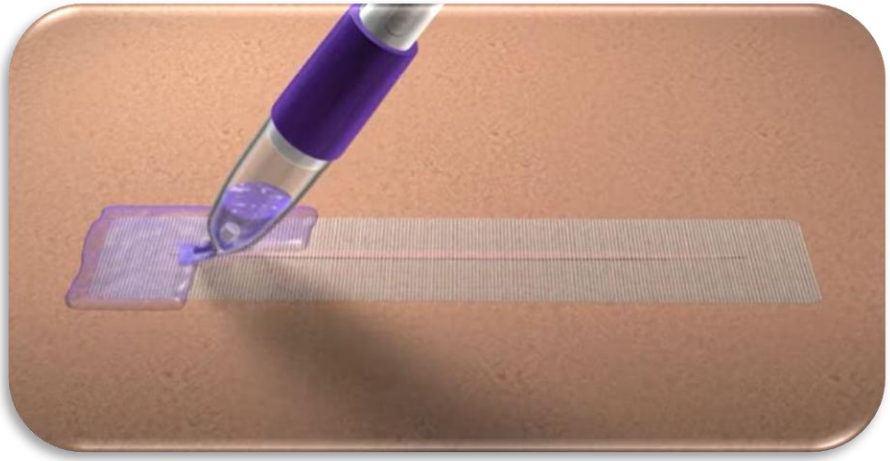


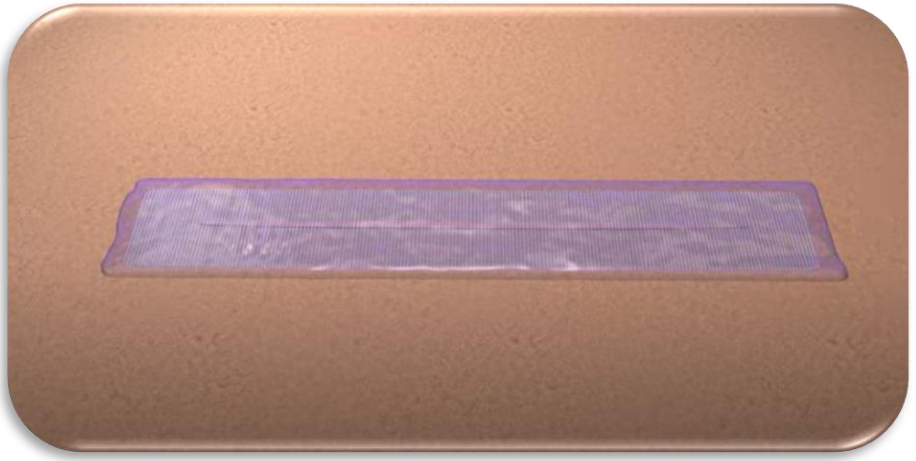


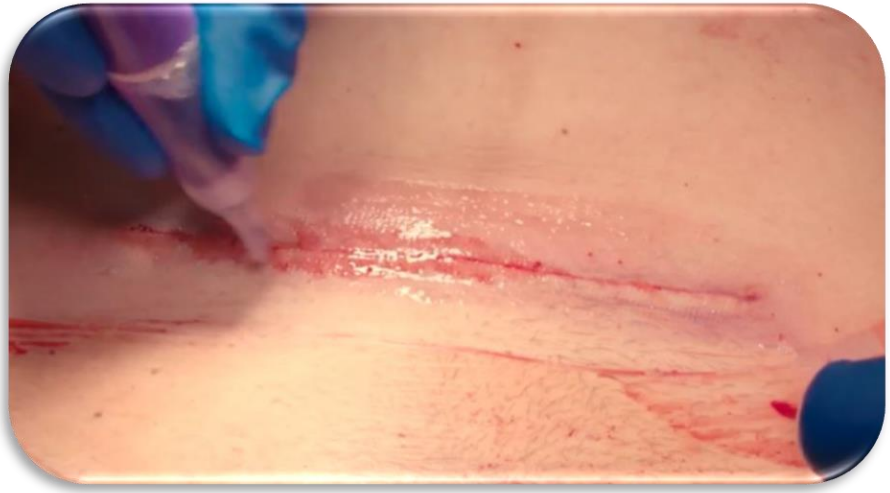
- *Cutibacterium acnes (C. acnes)* related total shoulder infections (TSR)
- Eliminated the use of **staples** for TSR
- Instituted the use of incisional adhesive
- Covered dressing until 2 week postop

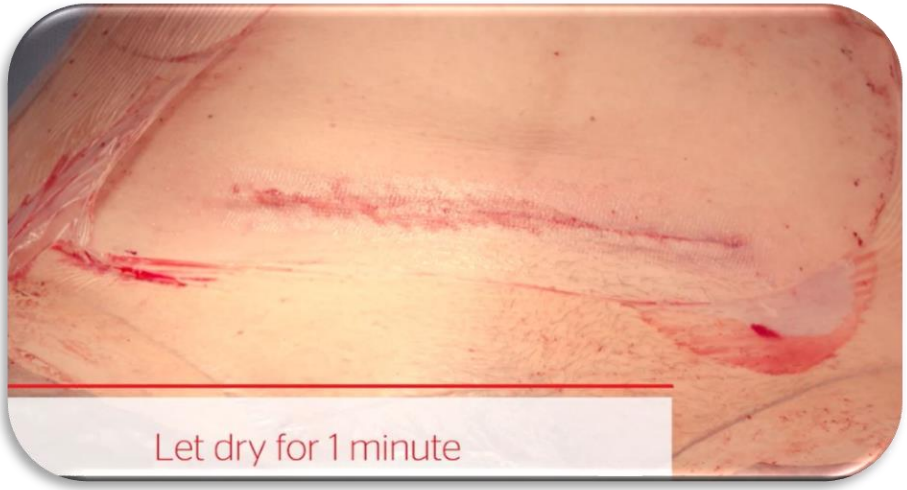
Skin Closure System

- Unique combination of 2 components
- A 2-octyl cyanoacrylate topical skin adhesive for proven strength and microbial protection
- A flexible, self-adhesive polyester mesh for superior approximation and healing
  - Sets in approximately 60 seconds when applied to mesh
- Contains initiator that accelerates polymerization of liquid adhesive
- Each dispenser contains 60 cm of tape

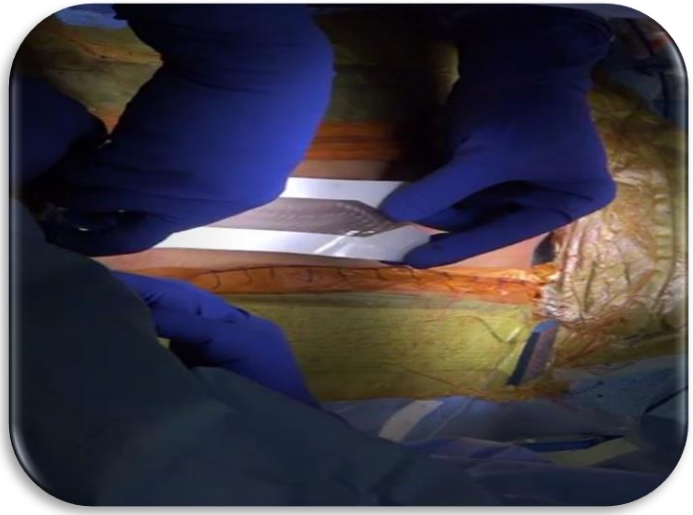


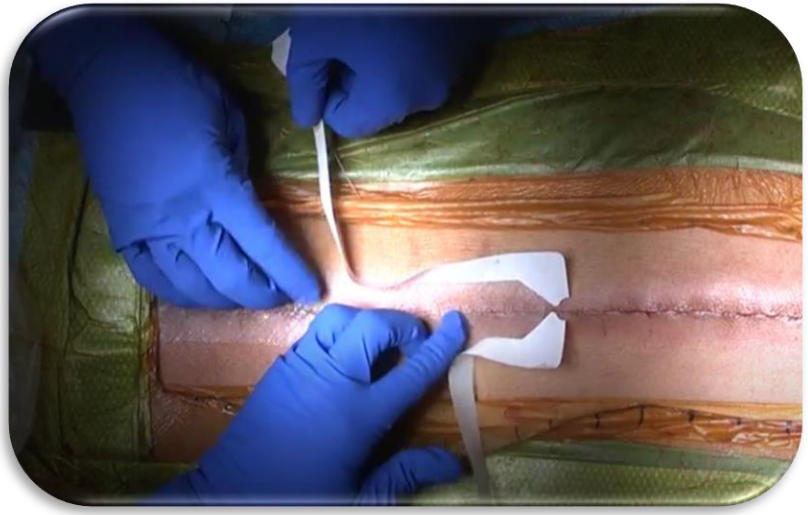


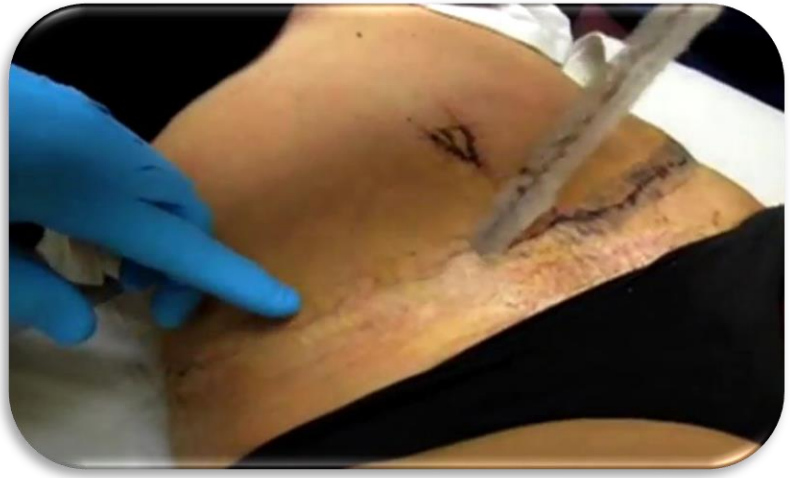



Let dry for 1 minute

Polyester Mesh Dressing for Long incisions – abdominoplasty, orthopedics, cardiac, C section







Contents lists available at ScienceDirect

Arthroplasty Today

journal homepage: http://www.arthroplastytoday.org/

Original Research

Polyester Mesh Dressings Reduce Delayed Wound Healing and Reoperations Compared with Silver-Impregnated Occlusive Dressings after Knee Arthroplasty

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Total knee arthroplasty
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ABSTRACT

Background: New dressings aimed at reducing surgical wound complications after knee arthroplast continue to evolve. We compared wound complications and reoperations between 2 dressings: 2-octy cyanoacrylate adhesive and polyester mesh (Dermabond® Prineo®, "mesh") and silver-impregnate occlusive dressings and n-butyl-2-cyancacrylate adhesive (AQUACEL® Ag SURGICAL cover dressin with SwiftSet™, "standard").

Methods: This retrospective cohort study reviewed 353 consecutive partial and total knee arthroplastie performed by a single surgeon; 6 were excluded for not using either dressing type. Thus, 347 cases wer separated into 2 cohorts: mesh (n = 176) and standard dressing (n = 171). Demographics and risk factor were similar, except for age. Surgical and closure techniques were consistent in all patients. Delaye wound healing was assessed by the surgeon at the 2-week office visit for drainage, suture abscess, c wound edge separation. Secondary outcome measures include infection, office-based closure, and return to the operating room for reclosure.

Results: There were 2 instances of delayed wound healing in the mesh group and 16 in the standard dressing group (1.14% vs 9.36%, $P \leq .0001$). There were significantly fewer reoperations in the mesh group than in the standard group (0 vs 2.33%, $P = .04$). There were no infections or office-based closures.

Conclusion: Mesh dressings were associated with fewer episodes of delayed wound healing and reoperations than the standard dressing. A possible mechanism may be that this brand of mesh distributes wound tension more evenly. In addition, because it remains in place longer during the immediate postoperative period, it may work via prolonged wound edge support.

Table 2
Results.

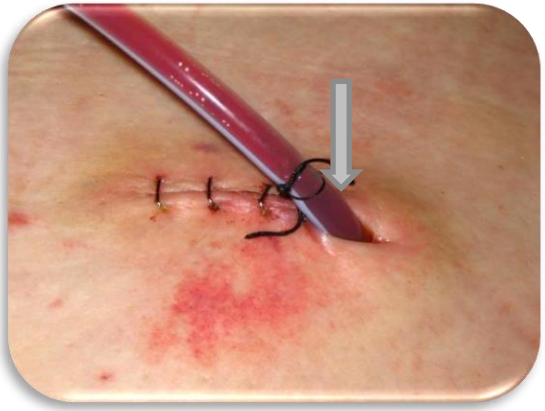
Variable	Standard dressing (n = 171)	Mesh (n = 176)	*P*-value
Delayed wound healing	16 (9.4%)	2 (1.1%)	<.0001[a]
Return to the OR	4 (2.3%)[b]	0 (0%)	.04[a]

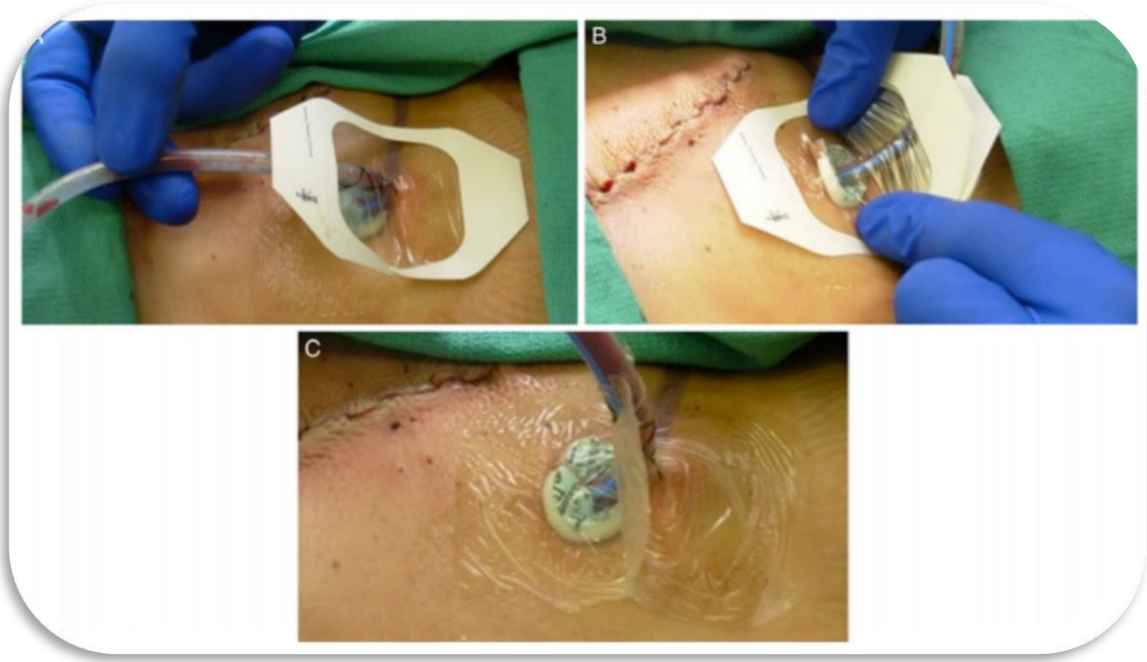
[a] Indicates statistical significance.
[b] One patient returned to the OR twice for wound closure.

Contraindications

- Do not use on any wounds with evidence of infection, gangrene, or on wounds of decubitus etiology.
- Do not use on mucosal surfaces or across mucocutaneous junctions (e.g., oral cavity, lips), or on skin that may be regularly exposed to body fluids or with dense natural hair (e.g., scalp).
- Do not use on patients with a known hypersensitivity to cyanoacrylate, formaldehyde, benzalkonium chloride, or pressure-sensitive adhesive.

CHG Disk Around Drain and Chest Tube Insertion Site To Prevent Ascending Migration of Bacteria



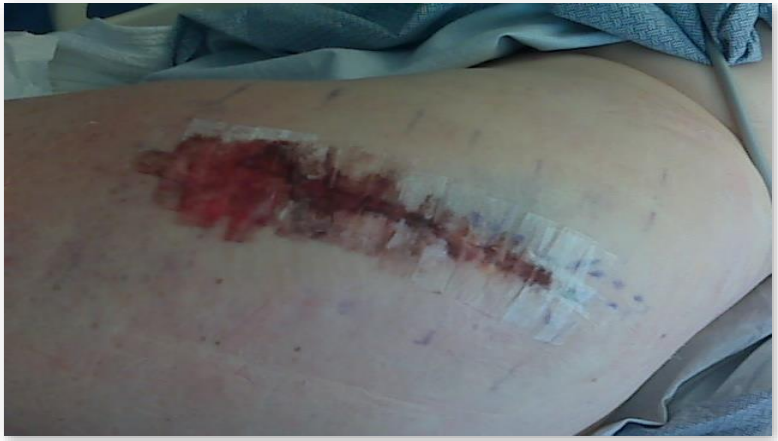


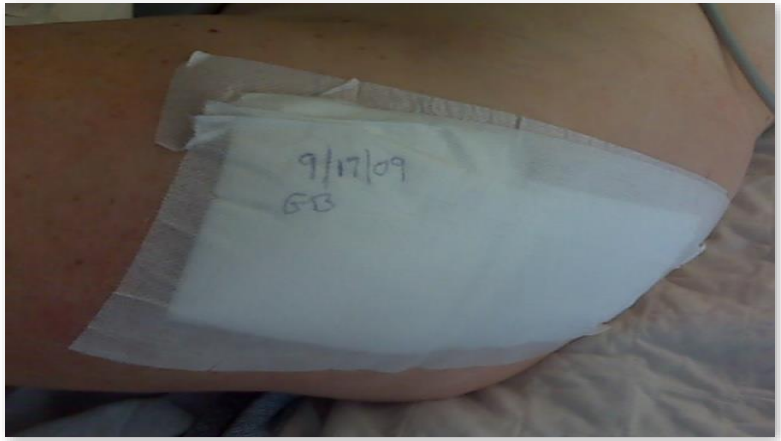
CDC 2017: There are also strong recommendations against the use of antimicrobial ointments or creams on umbilical catheter insertion sites and other insertion sites, because of their potential to promote fungal infections and antimicrobial resistance

Other Options to Consider When Adhesives are Contraindicated

(some patients may be allergic to adhesives)

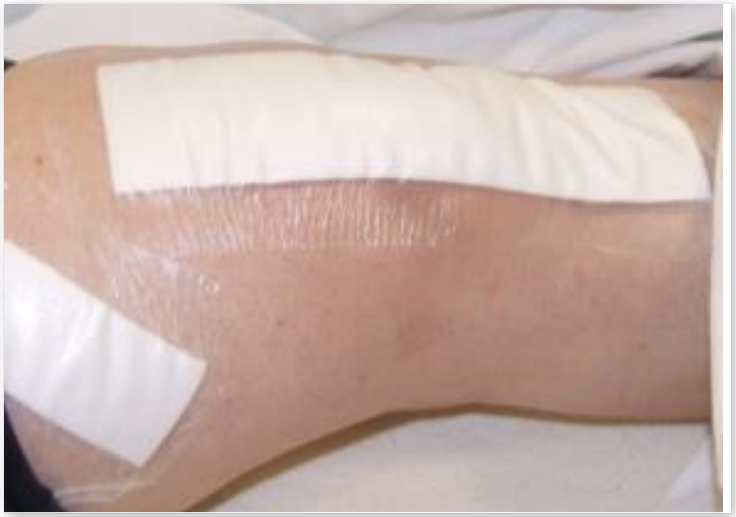
Antimicrobial (PHMB) Dressings with Hypoallergenic Fabric Tape





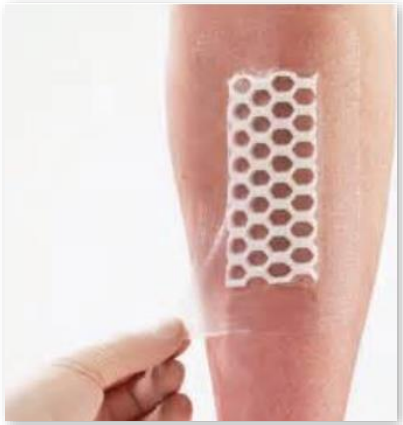
Spencer et al: The Use of Antimicrobial Gauze Dressing (AMD) After Orthopedic Surgery To Reduce Surgical Site Infections NAON 2010 Annual Congress - May 15-19, 2010

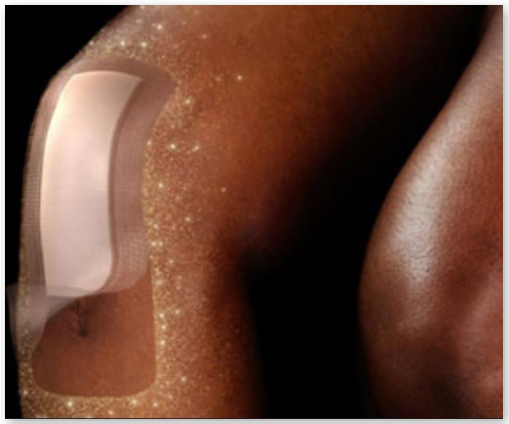
Silver Dressings

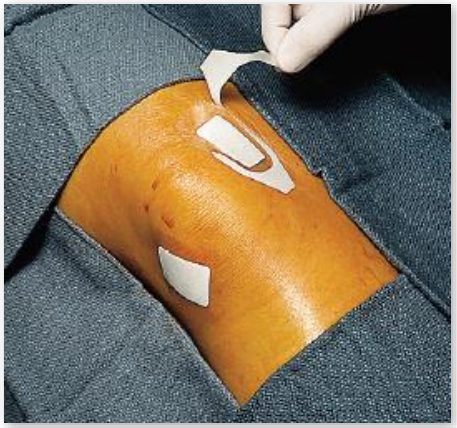


Silver dressing and transparent dressing left on until discharge or up to 7 days postop – seals the incision from exogenous contaminants

Other Dressings – Conduct Product Evaluations







In Conclusion…

Surgical Stewardship Multidisciplinary Team

The Joint Commission's
Implementation Guide
for
NPSG.07.05.01
on
Surgical Site Infections:
The SSI Change Project

Establish a Multidisciplinary Team

The team representatives

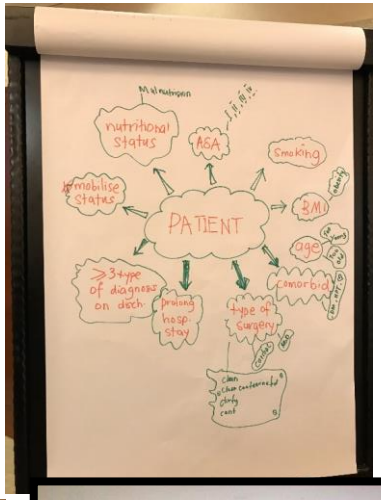
OR nursing, CSS, Surgeons & Anesthesia, Managers from infection control, healthcare quality, facilities and environmental services

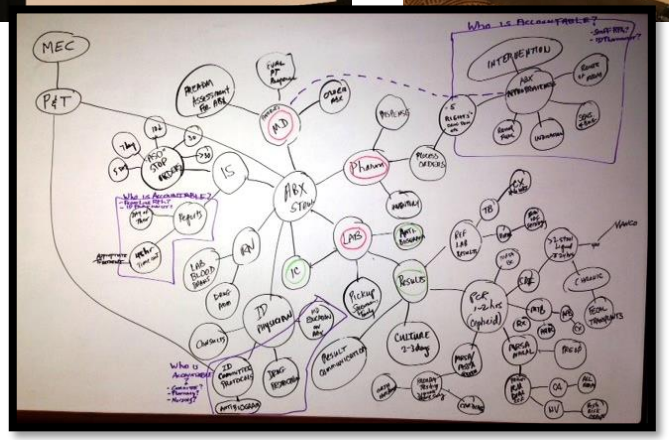
Evaluate

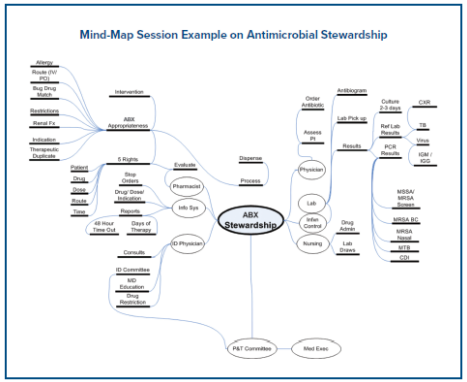
- Procedures and Practices
- Facility design and Environment of Care Issues
- Patient Risk Factors
- Infection Rates
- Innovative Infection Prevention Products and Practices

Spencer M, et al. A Multidisciplnary Team Working Toward Zero Infection Rate. Poster presented AORN 2006; March 19-23, 2006; Washington DC

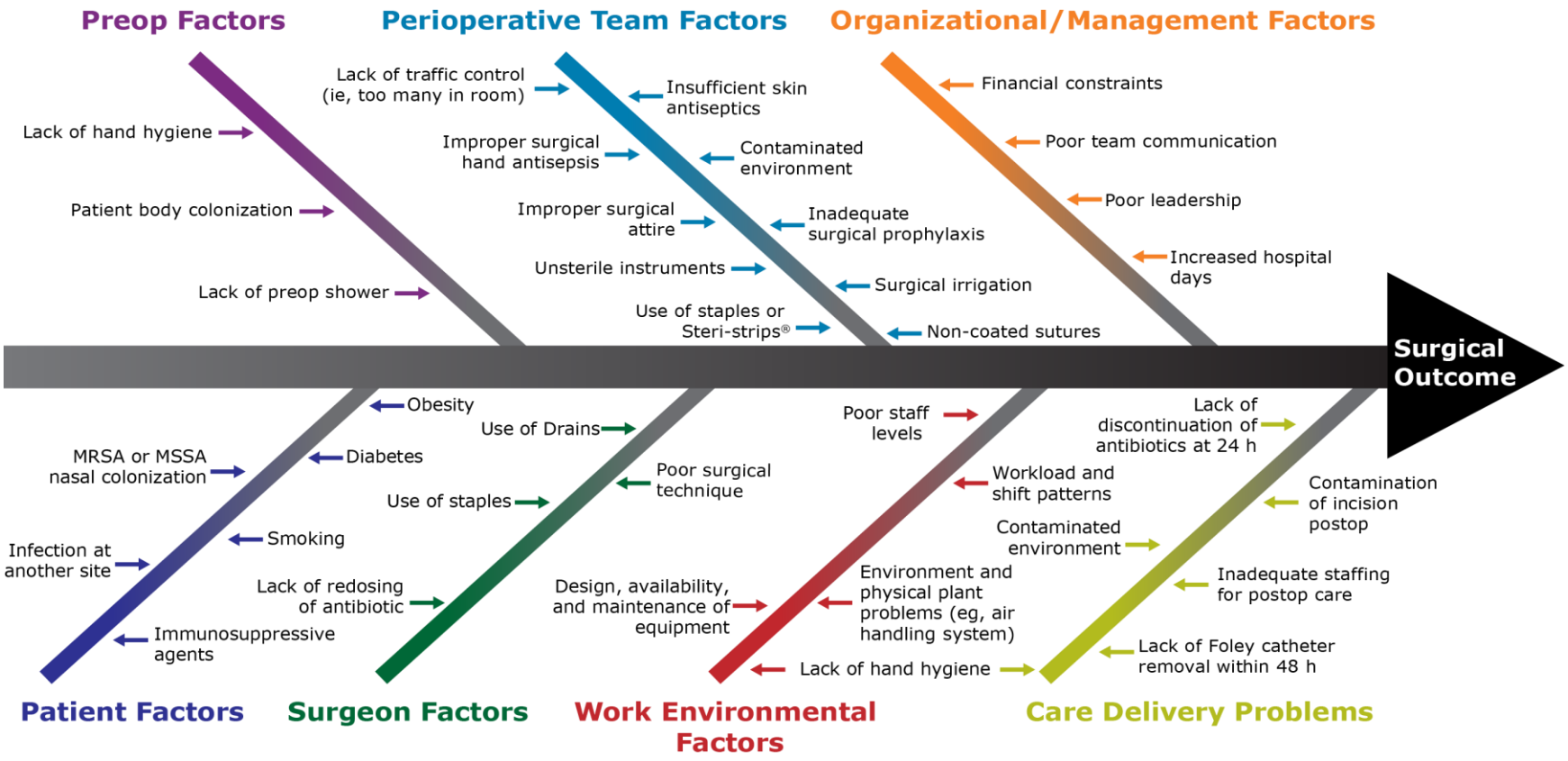
Engage Clinicians and Staff – Implementation Sessions







Many Risk Factors Influence SSI – Fishbone Diagram



One thing could lead to the failure

Collaborate with Vendors:

UHS Ethicon Infection Management Program for SSI Reduction

NPSG.07.05.01

Implement evidence-based practices for preventing surgical site infections.

Elements of Performance for NPSG.07.05.01

1. Educate staff and licensed independent practitioners involved in surgical procedures about surgical site infections and the importance of prevention. Education occurs upon hire, annually thereafter, and when involvement in surgical procedures is added to an individual's job responsibilities.
2. Educate patients, and their families as needed, who are undergoing a surgical procedure about surgical site infection prevention.
3. Implement policies and practices aimed at reducing the risk of surgical site infections. These policies and practices meet regulatory requirements and are aligned with evidence-based guidelines (for example, the Centers for Disease Control and Prevention (CDC) and/or professional organization guidelines).
4. As part of the effort to reduce surgical site infections:
   - Conduct periodic risk assessments for surgical site infections in a time frame determined by the hospital.
   - Select surgical site infection measures using best practices or evidence-based guidelines.
   - Monitor compliance with best practices or evidence-based guidelines.
   - Evaluate the effectiveness of prevention efforts.

   Note: *Surveillance may be targeted to certain procedures based on the hospital's risk assessment.*
5. Measure surgical site infection rates for the first 30 or 90 days following surgical procedures based on National Healthcare Safety Network (NHSN) procedural codes. The hospital's measurement strategies follow evidence-based guidelines.

   Note 1: *Surveillance may be targeted to certain procedures based on the hospital's risk assessment.*

   Note 2: *The NHSN is the Centers for Disease Control and Prevention's health care–associated infection tracking system. NHSN provides facilities, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate health care–associated infections. For more information on NHSN procedural codes, see http://www.cdc.gov/nhsn/CPTcodes/ssi-cpt.html.*
6. Provide process and outcome (for example, surgical site infection rate) measure results to key stakeholders.
7. Administer antimicrobial agents for prophylaxis for a particular procedure or disease according to methods cited in scientific literature or endorsed by professional organizations.
8. When hair removal is necessary, use a method that is cited in scientific literature or endorsed by professional organizations.

“Infection Prevention Management Program” – Clinical Specialists observing/training during surgery

Program objective	Help hospitals **implement evidence-based practices to address risks for BSIs & SSIs** through the appropriate utilization of Ethicon devices
Potential outcomes	• **Address risks** for costly infections • **Reduce variation** in clinical practices and purchasing patterns • **Enhance engagement** of patients & staff throughout an episode of care
Innovative approach	 **Risk assessment**  **Clinician training**  **Patient education**

The Joint Commission’s National Patient Safety Goals 07.04.01 and 07.05.01 assess a facility’s evidence-based policies and practices aimed at reducing the risk of BSIs and SSIs

AORN Surgical Conference 2016: Standardizing a Wound Closure Bundle - 37.5% SSI Reduction

216: A Wound Prevalence Observational Study for the Prevention of Surgical Site Infections

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AORN Surgical Conference & Expo 2016
Session Type: Clinical Improvement/ Innovation
Session Name: 6024: Clinical Improvement/ Innovation Poster Session

ABSTRACT

Background: In June, 2014 an acute care hospital system conducted a Wound Closure Point Prevalence program to prevent post-op surgical site infection (SSI) The program monitored compliance with the Joint Commission NPSG 07.05.01. The prevalence program evaluated the adoption of antibacterial sutures (AS) and topical skin adhesives (TSA) as part of a corporate 7S bundle that was implemented in 2012 to reduce SSI. 10 hospitals participated out of the 25 hospitals in the system.

Method: The team consisted of trained nurse clinical specialists with operating room experience. Individual surgeons were in-serviced on the proper use of AS and TSA products. Observations also included some in L&D and ambulatory surgery. Other factors in wound closure observed were the use of staples, non-absorbable sutures, steri-strips, surgical drains and post-op dressing material. In addition, a lecture on the prevention of surgical site infections was presented to the surgical staff and administration to enlist commitment to teamwork in the reduction of SSIs.

Results: A total of 330 wound closure observations across 162 surgical procedures were observed. Surgical staple usage was highest among OB/GYN and Orth. Topical skin adhesive (TSA) usage had a wide variation in application techniques, applying more layers than required. Topical skin adhesive was often covered with unnecessary dressings. Evaluation of hip, knee, colon and hysterectomy rates in 2015 showed a 37.5% reduction in the participating hospitals through April 2015.

Conclusion: A direct observation program provided in-service on proper suture and closure technique. Reduction in excess TSA and dressings was observed as a result of individual training with surgeons, physician assistants and residents. Results also revealed a high inappropriate use of surgical drains and a need for drain site protocols. Hospitals established SSI teams to continue to work in implementing the corporate 7S Bundle program to reduce SSIs. (www.7sbundle.com).

PROGRAM OBJECTIVE

Evaluate adoption of wound closure technologies that are a part of UHS's 7S Bundle

- Identify risk factors for surgical site infection that can be addressed during wound closure

INNOVATIVE APPROACH

Risk assessments to identify gaps in policies
Staff training to reduce variation in practices
Patient education to engage patients in care

BROAD IMPACT

For patients...
Protect against known risks for infection

FOR UHS...

Standardize practices across facilities
Ensure appropriate utilization of devices
Demonstrate "Elements of Performance" for Joint Commission's NPSGs

METHODS:

Ten (10) facilities were selected for the wound prevalence study based on their standardized infection ratio for surgical site infections. Any facility with a SIR >1 were requested to participate in the observational study in the operating room to evaluate closure technique, the use of staples, drains, incisional adhesive and antimicrobial sutures. Experienced OR Clinical Specialists conducted onsite observations and collected information. They also provided in-service education to surgeons and other surgical staff. The observations occurred over 2-3 days in the 10 facilities.

Section 1a – Wound closure device utilization by incision site

Incision site	# of incisions observed	Absorbable	Absorbable (non-antibacterial)	Non-absorbable Sutures	Topical Skin Adhesive	Skin Staples	Dry wound dressing applied?
0-4 cm	222	78%	18%	4%	63%	10%	27%
5-9 cm	44	75%	14%	11%	55%	16%	66%
10-14 cm	22	68%	15%	17%	23%	26%	72%
15+ cm	41	76%	15%	11%	49%	22%	80%
TOTALS	330	74%	16%	10%	57%	15%	42%

Section 1b – Wound closure device utilization by incision location

Incision location	# of incisions observed	Absorbable	Absorbable (non-antibacterial)	Non-absorbable Sutures	Topical Skin Adhesive	Skin Staples	Dry wound dressing applied?
Abdomen	217	69%	22%	9%	63%	10%	22%
arm	2	100%				100%	100%
back (lower)	10	83%		17%	30%	40%	70%
back (upper)	1	55%		50%			100%
chest/breast	28	64%	21%	14%	64%	4%	71%
face	2	50%		50%			67%
foot	1			100%			100%
groin/pelvis	14	95%	2%	2%	43%	7%	57%
head	2			100%		50%	50%
hip	2	69%	21%		33%	33%	100%
knee	10	67%	12%	19%	40%	50%	100%
leg (lower)	6	100%			100%		33%
leg (upper)	2	100%			100%		50%
Neck	3	89%		11%	67%		67%
shoulder	2	100%					0%
umbilicus	18	81%	19%		56%		17%
TOTALS	330	74%	16%	10%	57%	15%	42%

Section 1c – Wound closure device utilization by surgical specialty

Surgical Specialty	# of incisions observed	Absorbable	Absorbable (non-antibacterial)	Non-absorbable Sutures	Topical Skin Adhesive	Skin Staples	Dry wound dressing applied?
Cardiac	10	93%	2%	5%	90%	10%	40%
General	166	75%	15%	10%	59%	10%	33%
Neuro	7	83%		17%	14%	14%	57%
OB/GYN	79	78%	20%	2%	54%	25%	46%
Oncology	3	67%		33%	33%		100%
Ortho	27	71%	14%	15%	30%	22%	81%
Plastic	13	49%	29%	22%	54%		92%
Urology	18	92%	5%	3%	89%		11%
Vascular	7	100%			86%	14%	29%
TOTALS	330	74%	16%	10%	57%	15%	42%

Wound closure device utilization by facility

# of incisions observed	Absorbable (anti bacterial) Sutures	Absorbable (non-antibacterial)	Non-absorbable Sutures	Topical Skin Adhesive	Skin Staples	Dry wound dressing applied?
45	86%	5%	9%	56%	11%	27%
29	93%	8%	2%	66%	2%	41%
19	73%		27%	21%	27%	74%
29	91%	5%	5%	79%	17%	38%
48	65%	33%	2%	67%	15%	40%
42	52%	31%	16%	60%	5%	40%
13	84%	5%	11%	54%	8%	15%
31	49%	42%	10%	58%	13%	32%
39	86%	7%	8%	77%	5%	44%
35	96%		4%	17%	43%	71%
330	74%	16%	10%	57%	15%	42%

NOTES:
- Generally, high availability of antibacterial sutures in hospital ORs
- Surgical staple usage highest among OB/GYN and Ortho
- Many surgeons and staff were not aware that they were using antibacterial sutures, nor were they familiar with the clinical evidence supporting the use of this technology (1st Note: lack of awareness is observed prior to education events)
- Some non-absorbable sutures (e.g. nylon, silk) were used for wound closure and drain securement

Topical skin adhesive application by facility

# of incisions observed	Hemostasis achieved?	Skin dry?	Wound in horizontal position?	Wound edges	Correct # of adhesive layers applied?	Dry wound dressing applied?
25	100%	100%	96%	100%	52%	16%
32	100%	100%	100%	100%	62%	31%
4	100%	100%	100%	100%	100%	50%
23	100%	100%	100%	100%	70%	26%
22	100%	52%	91%	100%	100%	28%
25	100%	100%	100%	100%	88%	28%
7	100%	100%	100%	100%	100%	0%
18	100%	100%	89%	100%	56%	0%
30	100%	100%	100%	100%	50%	33%
6	100%	100%	100%	100%	100%	33%
199	100%	92%	98%	100%	72%	24%

NOTES:
- Topical skin adhesive usage seen in a variety of incision sizes and locations
- Wide variation in application techniques
- Clinicians often applied more layers of topical skin adhesive than required by IFU
- Opportunity to use topical skin adhesive to add strength and protection to medium and large incisions, especially where sutures are currently being used
- Topical skin adhesive covered with many types of wound dressings

Section 3a – Surgical drain observations by incision site

Incision site	# of drains observed	ELIMINATCH® Dish used	Placed pricked side up	360 skin contact
0-4 cm	9	0%	0%	0%
5-9 cm	8	0%	0%	0%
10-14 cm	3	0%	0%	0%
15+ cm	21	29%	29%	5%
TOTALS	43	14%	14%	2%

Section 3b – Surgical drain observations by surgical specialty

Surgical Specialty	# of drains observed	ELIMINATCH® Dish used	Placed pricked side up	360 skin contact
Cardiac	7	0%	0%	0%
General	15	13%	13%	0%
Neuro	3	0%	0%	0%
Oncology	1	0%	0%	0%
Ortho	8	0%	0%	0%
Plastic	9	44%	44%	11%
TOTALS	43	14%	14%	2%

Section 3b – Surgical drain observations by incision location

Incision location	# of drains observed	ELIMINATCH® Dish used	Placed pricked side up	360 skin contact
Abdomen	13	15%	15%	8%
back (lower)	4	0%	0%	0%
back (upper)	1	0%	0%	0%
chest/ breast	12	21%	21%	0%
face	1	0%	0%	0%
groin/pelvis	1	0%	0%	0%
head	1	0%	0%	0%
knee	4	0%	0%	0%
leg (lower)	4	0%	0%	0%
Neck	1	0%	0%	0%
TOTALS	43	14%	14%	2%

NOTES:
- Surgical drain placement observed across several surgical procedures
- Surgical drain sites were rarely protected with an antimicrobial CHG device
- Opportunity to protect all surgical drain sites from entry/unintentional contamination
- OR staff noted that central lines placed in OR typically are protected on nursing floor

SSI	Count	Expected	UHS SIR	National SIR
Abd Hysterectomy	12	20	0.67	0.83
Colon	41	63	0.65	0.98
CABG	6	16	0.39	0.55

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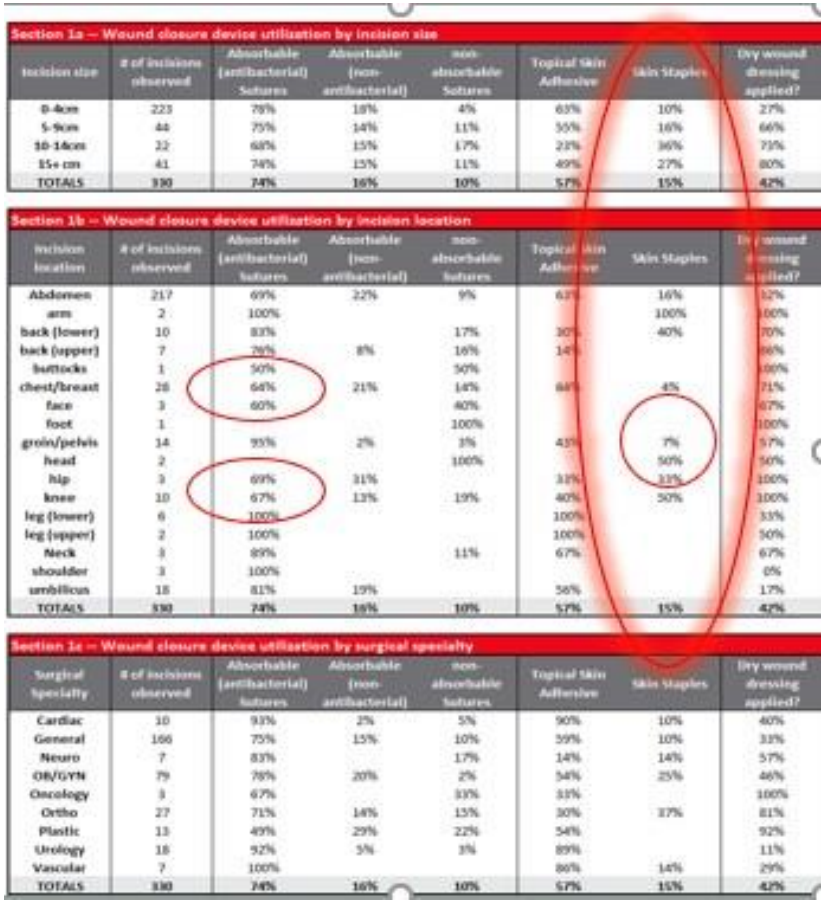
Program can help hospitals identify infection risks & variation in clinical practices



Section 1a -- Wound closure device utilization by incision size

Incision size	# of incisions observed	Absorbable (antibacterial) Sutures	Absorbable (non-antibacterial)	non-absorbable Sutures	Topical Skin Adhesive	Skin Staples	Dry wound dressing applied?
0-4cm	223	78%	18%	4%	63%	10%	27%
5-9cm	44	75%	14%	11%	55%	16%	66%
10-14cm	22	68%	15%	17%	23%	36%	73%
15+ cm	41	74%	15%	11%	49%	27%	80%
TOTALS	330	74%	16%	10%	57%	15%	42%

Section 1b -- Wound closure device utilization by incision location

Incision location	# of incisions observed	Absorbable (antibacterial) Sutures	Absorbable (non-antibacterial)	non-absorbable Sutures	Topical Skin Adhesive	Skin Staples	Dry wound dressing applied?
Abdomen	217	69%	22%	9%	63%	16%	32%
arm	2	100%				100%	100%
back (lower)	10	83%		17%	30%	40%	70%
back (upper)	7	78%	8%	16%	14%		86%
buttocks	1	50%		50%			100%
chest/breast	28	64%	21%	14%	64%	4%	71%
face	3	60%		40%			67%
foot	1			100%			100%
groin/pelvis	14	95%	2%	3%	43%	7%	57%
head	2			100%		50%	50%
hip	3	69%	31%		33%	33%	100%
knee	10	67%	13%	19%	40%	50%	100%
leg (lower)	6	100%			100%		33%
leg (upper)	2	100%			100%		50%
Neck	3	89%		11%	67%		67%
shoulder	3	100%					0%
umbilicus	18	81%	19%		56%		17%
TOTALS	330	74%	16%	10%	57%	15%	42%

Section 1c -- Wound closure device utilization by surgical specialty

Surgical Specialty	# of incisions observed	Absorbable (antibacterial) Sutures	Absorbable (non-antibacterial)	non-absorbable Sutures	Topical Skin Adhesive	Skin Staples	Dry wound dressing applied?
Cardiac	10	93%	2%	5%	90%	10%	40%
General	166	75%	15%	10%	59%	10%	33%
Neuro	7	83%		17%	14%	14%	57%
OB/GYN	79	78%	20%	2%	54%	25%	46%
Oncology	3	67%		33%	33%		100%
Ortho	27	71%	14%	15%	30%	37%	81%
Plastic	13	49%	29%	22%	54%		92%
Urology	18	92%	5%	3%	89%		11%
Vascular	7	100%			86%	14%	29%
TOTALS	330	74%	16%	10%	57%	15%	42%

Section 3c -- Surigcal drain observations by surgical specialty

Surgical Specialty	# of drains observed	BIOPATCH® Disc used	Placed printed side up	360 skin contact
Cardiac	7	0%	0%	0%
General	15	13%	13%	0%
Neuro	3	0%	0%	0%
Oncology	1	0%	0%	0%
Ortho	8	0%	0%	0%
Plastic	9	44%	44%	11%
TOTALS	**43**	**14%**	**14%**	**2%**

Case Study: 25-hospital Health Care System

IDN goals

- Standardize practices across facilities
- Implement evidence-based infection control practices
- Identify potential risks for infection

Assessed wound closure practices in

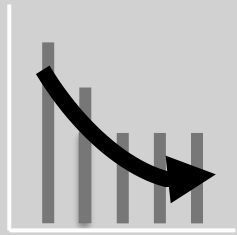
12

different hospitals

Hospital system reported a drop in SSI rates for

37.5%

of categories tracked*



Reduced IDN inventory by

106

SKUs

Patient Safety Work Product

Example #2:
Prospective evaluation of CHG surgical irrigant in colorectal surgery

Reduction in Colon Surgical Site Infections using CHG Irrigant Solution

Maureen Spencer, RN, BSN, M.Ed., CIC | Jacqueline Christie, RN, BSN, MPH, CIC
Patricia Tyrrell, RN, BSN, CNOR | Gail Pietrzyk, DNP, RN, CNOR

UHS of Delaware, Inc. a subsidiary of Universal Health Services Inc., King of Prussia, PA

5.88

1.09

Month - Year	August 2015	September 2015	October 2015	November 2015	December 2015	January 2016	February 2016	March 2016	April 2016	May 2016	June 2016	July 2016	August 2016	September 2016	October 2016	November 2016
Rate/100 Procedures	5.88	6.21	3.24	2.13	2.65	3.47	4.37	3.33	1.28	1.49	2.43	1.05	2.24	2.01	3.18	1.09

Clinical Issue:

- Colon surgical site infections (SSIs) have one of the highest rates of healthcare acquired infections that can lead to increased morbidity and mortality and use of hospitals resources
- Numerous clinical interventions with varying levels of supporting evidence have been implemented:
  - Appropriate antibiotic prophylaxis,
  - Normo-thermia,
  - Appropriate hair removal,
  - Glycemic control
  - Wound protectors
  - Mechanical bowel preparation.
- For this project a surgical irrigating solution, using a 0.05% chlorhexidine gluconate antiseptic was introduced in a 26-facility acute care system starting in June 2015.

Pre-Implementation: May 2015

- Manufacturer of the CHG irrigation solution visit the hospitals with the highest standardized infection ratio (SIR) for Colon SSI to educate perioperative nursing staff and physicians.

Implementation:

- Each Operating Room site purchased product
- Clinical Specialist contacted the OR Director and were assigned the week to visit for in-service education.
- The procedure involved irrigating the tissues after the fascia was closed with the 450ml of CHG, leaving it in the tissues for 1 minute, followed by a rinse with the 450ml of saline.

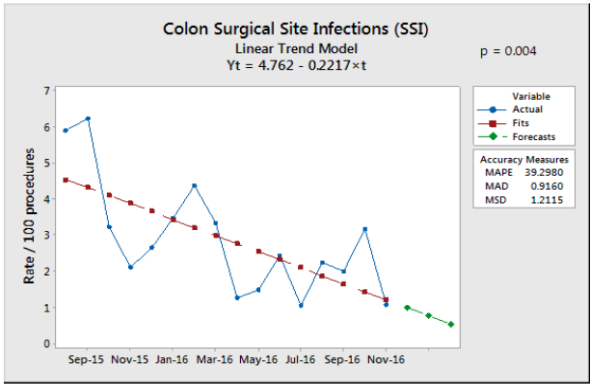
The Product Change: Irrisept CHG Irrigant

- A wound debridement and cleansing system that contains 0.05% Chlorhexidine Gluconate (CHG) in sterile water for irrigation
- Mechanism of action:
  - Mechanical action removes bacteria and debris without harming underlying tissues.
  - Bottle design allows users to control the delivery pressure of the solution through manual bottle compression. Grasping the bottle firmly, the user can control the direction and pressure needed to help remove bacteria, particulate and debris.
- Irrisept has successfully completed testing for acute systemic toxicity, cytotoxicity, neurotoxicity, skin irritation and immune allergic response.

Implications for Perioperative Nursing:

- Replaces the use of antimicrobial irrigations, such as cefazolin, vancomycin, bacitracin and polymixin.
- Facilitates compliance with hospital antimicrobial stewardship
- Pre-packaged design is more efficient for preparation and dispensing to field
- Pharmacy no longer mixing irrigations
- Since CHG is a biocide and can efficiently attach to tissues it creates a residual antibacterial effect that can last for many days in the tissues.

P = 0.004



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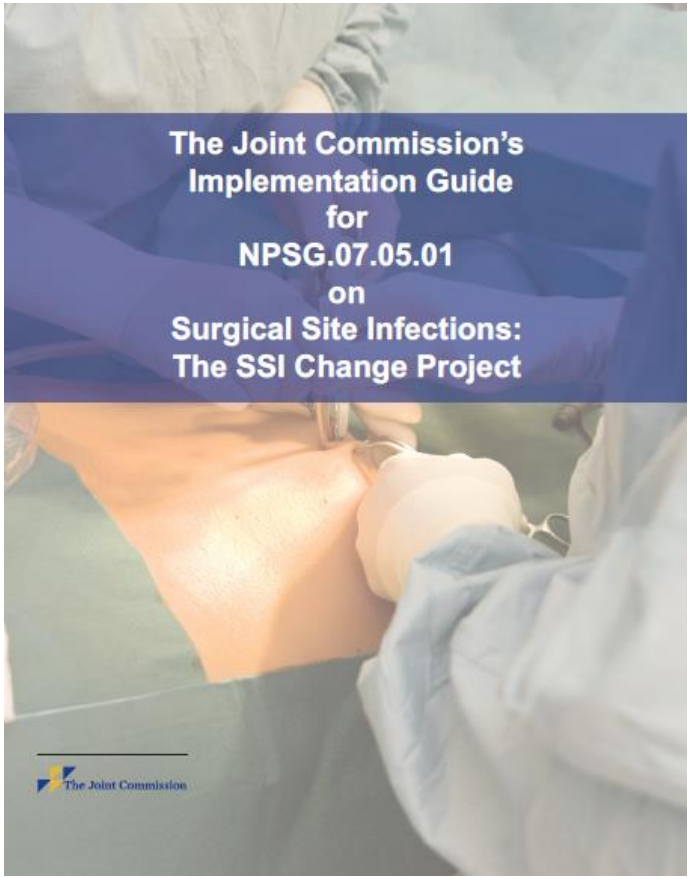
In Conclusion: Surgical Stewardship Team

- Senior leadership and Surgeons – must be involved and lead the effort
- Implement TJC NPSG 07.05.01 Implementation Guide
- Defined goal of zero tolerance for HAIs
- Communication – effective and consistent
- Ongoing and creative education
- Financial support to the Infection Prevention and Surgical Stewardship Program



Does the 7 S Bundle Work?

2016 Standardized Infection Ratio (SIR) Jan-Dec

Reporting Metric	Infection Count	Number Expected	Cost Avoidance	UHS SIR	National SIR	% SIR Difference	SIR p-value	Lower CI	Upper CI
CLABSI - ICU/Med Surg	204	265	$2,794,654	0.77	0.50	54.20	0.00	0.67	0.88
CAUTI ICU/Med Surg	178	321	$128,128	0.55	0.55	0.73	0.00	0.48	0.64
C. difficile HO LabID Events	883	843	-$451,400	1.05	0.92	13.80	0.18	0.98	1.12
MRSA bacteremia HO LabID Events	66	61	-$173,285	1.09	0.87	25.17	0.48	0.85	1.38
SSI - Abdominal Hysterectomy	10	24	$290,990	0.42	0.83	-49.28	0.00	0.21	0.75
SSI - Colon Surgery	51	75	$498,840	0.68	0.98	-30.71	0.00	0.51	0.89
SSI - Hip Surgery	22	32	$207,850	0.69	0.78	-11.92	0.07	0.44	1.02
SSI - Knee Surgery	18	29	$228,635	0.62	0.59	4.24	0.03	0.38	0.95
SSI - C-sections	15	35	$415,700	0.43	0.27	57.78	0.00	0.25	0.69
SSI - Spinal Surgery	20	26	$124,710	0.78	0.67	16.42	0.26	0.49	1.18
SSI - CABG	4	17	$270,205	0.24	0.55	-56.00	0.00	0.08	0.59
TOTALS	**1267**	**1463**	**$4,335,027**						

SIR p-value

Statistically Significant	**(p < 0.05)**	★
Not Statistically Significant	**(p = 0.05)**	★
Not Statistically Significant	**(p > 0.05)**	☆

UHS SIR

	# of Infections is below expected
	# of Infections is equal to expected
	# of Infections is above expected

C. diff SIRs calculated quarterly

SIR not calculated when Expected ≤ 0

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Thank You

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