

Reducing The Risk of Surgical Site Infections: Comorbid Risk, Economic Analysis and Mitigation Through Evidence-Based Strategies

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Disclaimer – Caveat

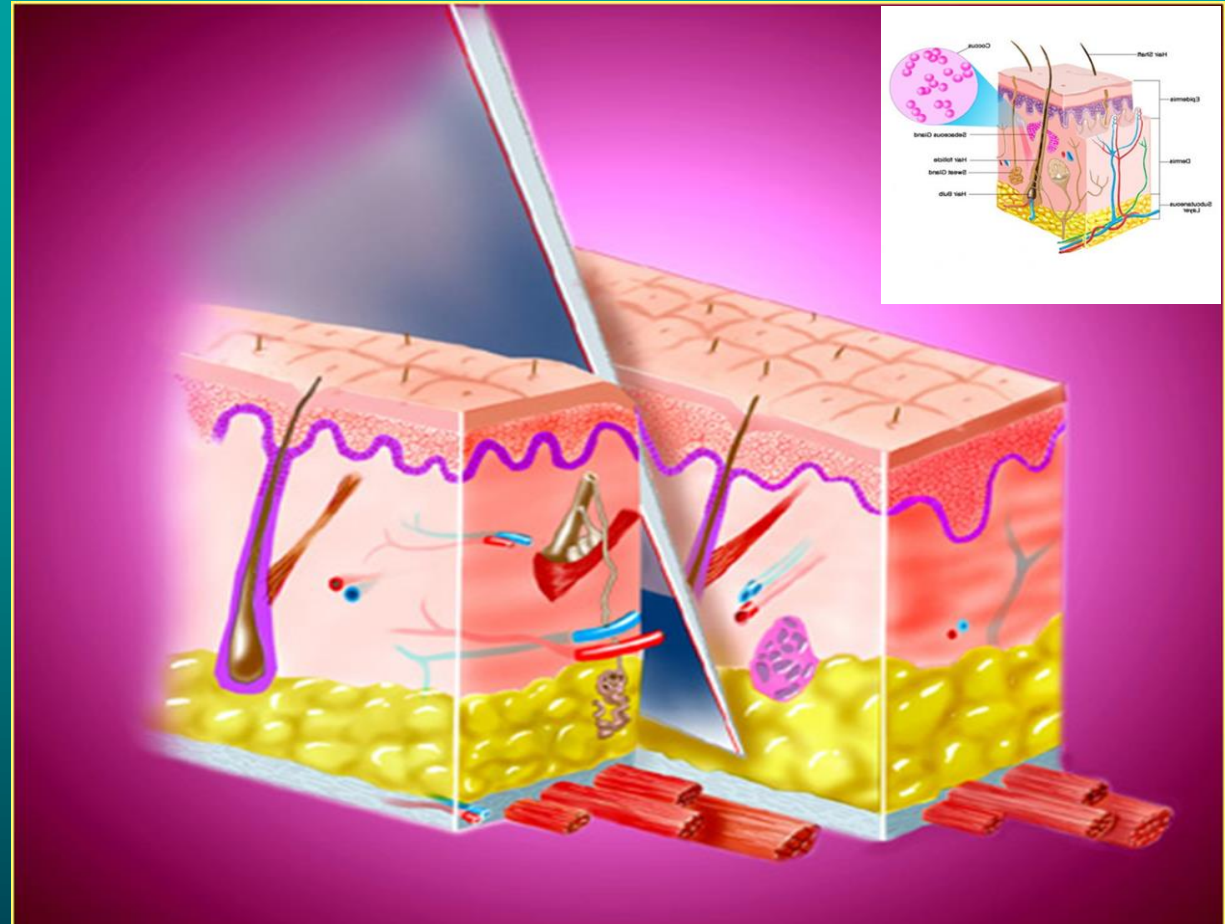
“I DON’T HAVE ALL OF THE ANSWERS”

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

“Every operation is an experiment in bacteriology”

“It’s all about the surgical wound”

Lord Moynihan



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

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

Wiley AM, et al. Clin Orthop Relat Res 1979;139:150-155

Question #1

What is the Real Risk and Financial Implications of a Surgical Site Infection Across the Surgical Spectrum?

Risk Stratification for Surgical Site Infections in Colon Cancer

Ramzi Amri, MD, PhD; Anne M. Dinaux, BSc; Hiroko Kunitake, MD; Liliana G. Bordeianou, MD; David L. Berger, MD

← Invited Commentary
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IMPORTANCE Surgical site infections (SSIs) feature prominently in surgical quality improvement and pay-for-performance measures. Multiple approaches are used to prevent or reduce SSIs, prompted by the heavy toll they take on patients and health care budgets. Surgery for colon cancer is not an exception.

OBJECTIVE To identify a risk stratification score based on baseline and operative characteristics.

DESIGN, SETTING, AND PARTICIPANTS This retrospective cohort study included all patients treated surgically for colon cancer at Massachusetts General Hospital from 2004 through 2014 (n = 1481).

MAIN OUTCOMES AND MEASURES The incidence of SSI stratified over baseline and perioperative factors was compared and compounded in a risk score.

RESULTS Among the 1481 participants, 90 (6.1%) had SSI. Median (IQR) age was 66.9 (55.9-78.1) years. Surgical site infection rates were significantly higher among people who smoked (7.4% vs 4.8%; $P = .04$), people who abused alcohol (10.6% vs 5.7%; $P = .04$), people with type 2 diabetics (8.8% vs 5.5%; $P = .046$), and obese patients (11.7% vs 4.0%; $P < .001$). Surgical site infection rates were also higher among patients with an operation duration longer than 140 minutes (7.5% vs 5.0%; $P = .05$) and in nonlaparoscopic approaches (clinically significant only, 6.7% vs 4.1%; $P = .07$). These risk factors were also associated with an increase in SSI rates as a compounded score ($P < .001$). Patients with 1 or fewer risk factors (n = 427) had an SSI rate of 2.3%, equivalent to a relative risk of 0.4 (95% CI, 0.16-0.57; $P < .001$); patients with 2 risk factors (n = 445) had a 5.2% SSI rate (relative risk, 0.78; 95% CI, 0.49-1.22; $P = .27$); patients with 3 factors (n = 384) had a 7.8% SSI rate (relative risk, 1.38; 95% CI, 0.91-2.11; $P = .13$); and patients with 4 or more risk factors (n = 198) had a 13.6% SSI rate (relative risk, 2.71; 95% CI, 1.77-4.12; $P < .001$).

CONCLUSIONS AND RELEVANCE This SSI risk assessment factor provides a simple tool using readily available characteristics to stratify patients by SSI risk and identify patients at risk during their postoperative admission. Thereby, it can be used to potentially focus frequent monitoring and more aggressive preventive efforts on high-risk patients.

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Risk Stratification

- Patient who smoked (7.4% vs 4.8%; $p = 0.04$)
- Patients who abused alcohol (10.6% vs 5.7%; $p = 0.04$)
- Patients with type 2 diabetics (8.8% vs 5.5%; $p = 0.046$)
- Obese patients (11.7% vs 4.0%; $p < 0.001$)
- Surgical site infection rates higher when operative duration longer than 140 minutes (7.5% vs 5.0%; $p = 0.05$)

These risk factors were also associated with an increase in SSI rates as a compounded score ($P < 0.001$).

- Patients with 1 or fewer risk factors (n = 427) - SSI rate of 2.3%
- Patients with 2 risk factors (n = 445) – SSI rate 5.2%
- Patients with 3 factors (n = 384) had a 7.8% SSI rate
- Patients with 4 or more risk factors (n = 198) > 13.5%

Estimated mean attributable cost of SSI treatment cited in the CDC guidelines ranges from \$10,443 to \$25,546 – However, is that data accurate?

Berríos-Torres SI, Umscheid CA, Bratzler DW, et al. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017 [published correction appears in JAMA Surg. 2017;152(8):784-791. doi:10.1001/jamasurg.2017.0904

Assessment of the Risk and Economic Burden of Surgical Site Infection Following Colorectal Surgery Using a US Longitudinal Database: Is There a Role for Innovative Antimicrobial Wound Closure Technology to Reduce the Risk of Infection?

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Brian Po-Han Chen, Sc.M.⁵ • Charles E. Edmiston, Jr, Ph.D.⁶

AQ1

BACKGROUND: Colorectal surgical procedures place substantial burden on health care systems because of the high complication risk, in particular, surgical site infections. Risk of postoperative colorectal surgical site infection is one of the highest of any surgical specialty.

OBJECTIVE: The purpose of this study was to determine the incidence, cost of infections after colorectal surgery, and potential economic benefit of using antimicrobial wound closure to improve patient outcomes.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text, and links to the digital files are provided in the HTML and PDF versions of this article on the journal's Web site (www.dcrjournal.com).

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Financial Disclosures: Drs Edmiston and Leaper, and M. Spencer are members of the Johnson and Johnson Speakers Bureau. M. Spencer is on the speaker's bureau for Ethicon. Drs Holy and Chitnis, and B.P.-H. Chen are employees of Johnson and Johnson, Inc. A. Hogan and Dr Wright are employees of CRG-Eversana Canada Inc, which was contracted by Ethicon, Inc, which provided funding to assist in the analysis and review of the manuscript.

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DISEASES OF THE COLON & RECTUM VOLUME XX: X (2020)

DESIGN: Retrospective observational cohort analysis and probabilistic cost analysis were performed.

SETTINGS: The analysis utilized a database for colorectal patients in the United States between 2014 and 2018.

PATIENTS: A total of 107,665 patients underwent colorectal surgery.

MAIN OUTCOME MEASURES: Rate of infection was identified between 3 and 180 days postoperatively, infection risk factors, infection costs over 24 months postoperatively by payer type (commercial payers and Medicare), and potential costs avoided per patient by using an evidence-based innovative wound closure technology.

RESULTS: Surgical site infections were diagnosed postoperatively in 23.9% of patients (4.0% superficial incisional and 19.9% deep incisional/organ space). Risk factors significantly increased risk of deep incisional/organ-space infection and included selective patient comorbidities, age, payer type, and admission type. After 12 months, adjusted increased costs associated with infections ranged from \$36,429 to \$144,809 for commercial payers and \$17,551 to \$102,280 for Medicare, depending on surgical site infection type. Adjusted incremental costs continued to increase over a 24-month study period for both payers. Use of antimicrobial wound closure for colorectal surgery is projected to significantly reduce median payer costs by \$809 to \$1170 per patient compared with traditional wound closure.

- Infection Rate (107,665 Colorectal Patients): 23.9%
- 50% of infections diagnosed at 3-25 days while 75% of infections diagnosed by/after 2 months
- CDC-NHSN & ACS-NSQIP closes the books on colorectal surveillance at 30-days

Colorectal

- SSIs in patients undergoing colorectal surgery between 2014 and 2018

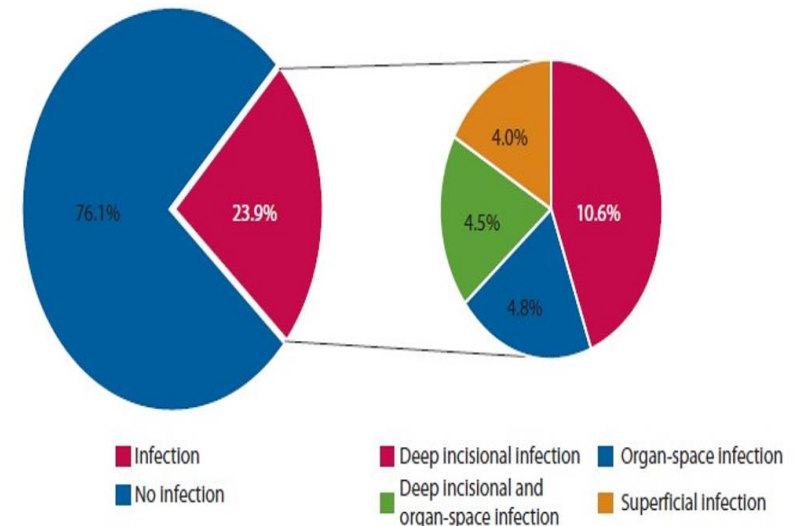


FIGURE 4. Surgical site infection rate at 6 months after the index colorectal surgery by infection type.

We Are Missing 30-35% of Colorectal Infections Due To Our Current Surveillance Strategies

Cost of Superficial and Deep/Organ Space Colorectal SSIs

TABLE 3. Summary of SSI costs from the database analysis by infection type, payer, and time point

Payers	Mean SSI cost (95% CI)			
	Deep incisional and organ-space	Deep incisional	Organ-space	Superficial
Commercial payers				
6 months	\$122,117 (\$117,490–\$127,007)	\$43,490 (\$42,120–\$44,888)	\$71,324 (\$67,859–\$74,904)	\$28,866 (\$26,690–\$31,115)
12 months	\$144,809 (\$137,819–\$152,062)	\$52,628 (\$50,633–\$54,670)	\$85,079 (\$79,641–\$90,747)	\$36,429 (\$33,085–\$39,910)
24 months	\$164,471 (\$152,816–\$176,759)	\$64,563 (\$61,143–\$68,097)	\$96,910 (\$87,550–\$106,844)	\$44,281 (\$38,538–\$50,350)
Medicare				
6 months	\$84,067 (\$77,457–\$91,069)	\$25,387 (\$22,884–\$28,010)	\$47,955 (\$44,325–\$51,764)	\$16,026 (\$12,884–\$19,375)
12 months	\$102,280 (\$92,575–\$112,670)	\$32,456 (\$28,832–\$36,280)	\$54,547 (\$49,293–\$60,111)	\$17,551 (\$13,040–\$22,408)
24 months	\$121,274 (\$104,102–\$140,169)	\$45,771 (\$38,679–\$53,407)	\$66,784 (\$56,992–\$77,402)	\$20,758 (\$12,538–\$29,834)

SSI = surgical site infection.



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Major Article

Impact of patient comorbidities on surgical site infection within 90 days of primary and revision joint (hip and knee) replacement



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Key Words:
Total knee replacement
Total hip replacement
Surgical site infection
Comorbidity
Post-operative complications

Background: The frequency of primary and revision total knee and hip replacements (pTKRs, rTKRs, pTHRs, and rTHRs, respectively) is increasing in the United States due to demographic changes. This study evaluated the impact of preoperative patient and clinical factors on the risk of surgical site infection (SSI) within the 90-day period after primary and revision total joint replacements (TJR).

Methods: A retrospective observational cohort study was designed using the IBM MarketScan and Medicare databases, 2009-2015. Thirty-four comorbidities were assessed for all patients, and multivariable logistic regression models were used to evaluate factors associated with higher odds of SSI after adjusting for other patient and clinical preoperative conditions.

Results: The study included a total of 335,134 TKRs and 163,547 THRs. SSI rates were 15.6% and 8.6% after rTKR and rTHR, respectively, compared with 2.1% and 2.1% for pTKR and pTHR, respectively. Comorbidities with the greatest adjusted effect on SSI across all TJRs were acquired immunodeficiency syndrome (odds ratio [OR], 1.58; 95% confidence interval [CI], 1.06-2.34; $P = .0232$), paralysis (OR, 1.56; 95% CI, 1.26-1.94; $P < .0001$), coagulopathy (OR, 1.48; 95% CI, 1.36-1.62; $P < .0001$), metastatic cancer (1.48; 95% CI, 1.24-1.76; $P < .0001$), and congestive heart failure (OR, 1.39; 95% CI, 1.30-1.49; $P < .0001$).

Conclusions: SSI occurred most commonly among patients after revision TJR and were related to many patient comorbidities, including diabetes, congestive heart failure, and coagulopathy, which were significantly associated with a higher risk of SSI after TJR.

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

- 335,134 – TKR
- 14,488 – rTKR (revision)
- 163,547 – THR
- 11,791 – rTHR (revision)

- TKR – 2.2% Infection rate
- rTKR – 15.6% “ “
- THR – 2.1% “ “
- rTHR – 8.6% “ “

We found 34 comorbid risk factors
“..prevention is always better than the cost of resolving the problem.”

	Superficial SSI	Deep SSI
Primary TKA (pTKA)		
6 Months	\$14,298 (95%CI: \$7,583 - \$21,013)	\$41,381 (95%CI: \$22,901 - \$59,862)
12 Months	\$20,870 (95%CI: \$7,821 - \$33,920)	\$54,664 (95%CI: \$22,025 - \$87,303)
Revision TKA (rTKA)		
6 Months	\$27,138 (95%CI: \$7,294 - \$46,981)	\$58,158 (95%CI: \$41,745 - \$74,572)
12 Months	\$29,176 (95%CI: \$4,739 - \$53,612)	\$59,491 (95%CI: \$36,700 - \$82,281)

Edmiston CE, Spencer M, Gunja NJ, Holy CE, Ruppenkamp JW, Leaper DJ. Longitudinal rates, risk factors, and costs of superficial and deep incisional surgical site infection (SSI) after primary and revision total knee arthroplasty: a US retrospective claims database analysis. Online ahead of print: *Infection Control and Hospital Epidemiology*, 02 Feb 2023, :1-9 DOI: 10.1017/ice.2023.10

Primary Total Hip	6 months	12 months
Superficial	\$21,434 (95%CI; \$8,615 - \$34,252)	\$34,958 (95%CI: \$11,163-58,753)
Deep incisional (includes organ space infection)	\$54,521 (95%CI: \$7,093 – \$101,949)	\$76,472 (95%CI: \$4,927 - \$148,017)
Revision Total Hip	6 months	12 months
Superficial	\$38,519 (95%CI; \$13,845 - \$63,192)	42,879 (95%CI: \$15,575 - \$70,184)
Deep incisional (includes organ space infection)	\$53,884 (95%CI: \$29,636 – \$78,131)	\$55,605 (95%CI: \$21,516 - \$89,695)

Edmiston CE Jr, et al. Longitudinal Rates, Patient Risk Factors, and Economic Impact of Superficial and Deep Incisional Surgical Site Infection After Primary and Revision Total Hip Arthroplasty: A U.S. Retrospective Commercial Claims Database Analysis [published online ahead of print, 2023 Mar 20]. *Surg Infect* 2023;10.1089/sur.2022.376. doi:10.1089/sur.2022.376.



Assessment of risk and economic burden of surgical site infection (SSI) posthysterectomy using a U.S. longitudinal database

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ABSTRACT

Background: Surgical site infection posthysterectomy has significant impact on patient morbidity, mortality, and health care costs. This study evaluates incidence, risk factors, and total payer costs of surgical site infection after hysterectomy in commercial, Medicare, and Medicaid populations using a nationwide claims database.

Methods: IBM MarketScan databases identified women having hysterectomy between 2014 and 2018. Deep-incisional/organ space (DI/OS) and superficial infections were identified over 6 months postoperatively with risk factors and direct infection-associated payments by insurance type over a 24-month postoperative period.

Results: Analysis identified 141,869 women; 7.8% Medicaid, 5.8% Medicare, and 3.9% commercially insured women developed deep-incisional/organ space surgical site infection, whereas 3.9% Medicaid, 3.2% Medicare, and 2.1% commercially insured women developed superficial infection within 6 months of index procedure. Deep-incisional/organ space risk factors were open approach (hazard ratio, 1.6; 95% confidence interval, 1.5–1.8) and payer type (Medicaid versus commercial [hazard ratio, 1.4; 95% confidence interval, 1.3–1.5]); superficial risk factors were payer type (Medicaid versus commercial [hazard ratio, 1.4; 95% confidence interval, 1.3–1.6]) and solid tumor without metastasis (hazard ratio, 1.4; 95% confidence interval, 1.3–1.6). Highest payments occurred with Medicare (\$44,436, 95% confidence interval: \$33,967–\$56,422) followed by commercial (\$27,140, 95% confidence interval: \$25,990–\$28,317) and Medicaid patients (\$17,265, 95% confidence interval: \$15,247–\$19,426) for deep-incisional/organ space infection at 24-month posthysterectomy.

Conclusions: Real-world cost of managing superficial, deep-incisional/organ space infection after hysterectomy was significantly higher than previously reported. Surgical approach, payer type, and comorbid risk factors contributed to increased risk of infection and economic burden. Medicaid patients experienced the highest risk of infection, followed by Medicare patients. The study suggests adoption of a robust evidence-based surgical care bundle to mitigate risk of surgical site infection and economic burden is warranted.

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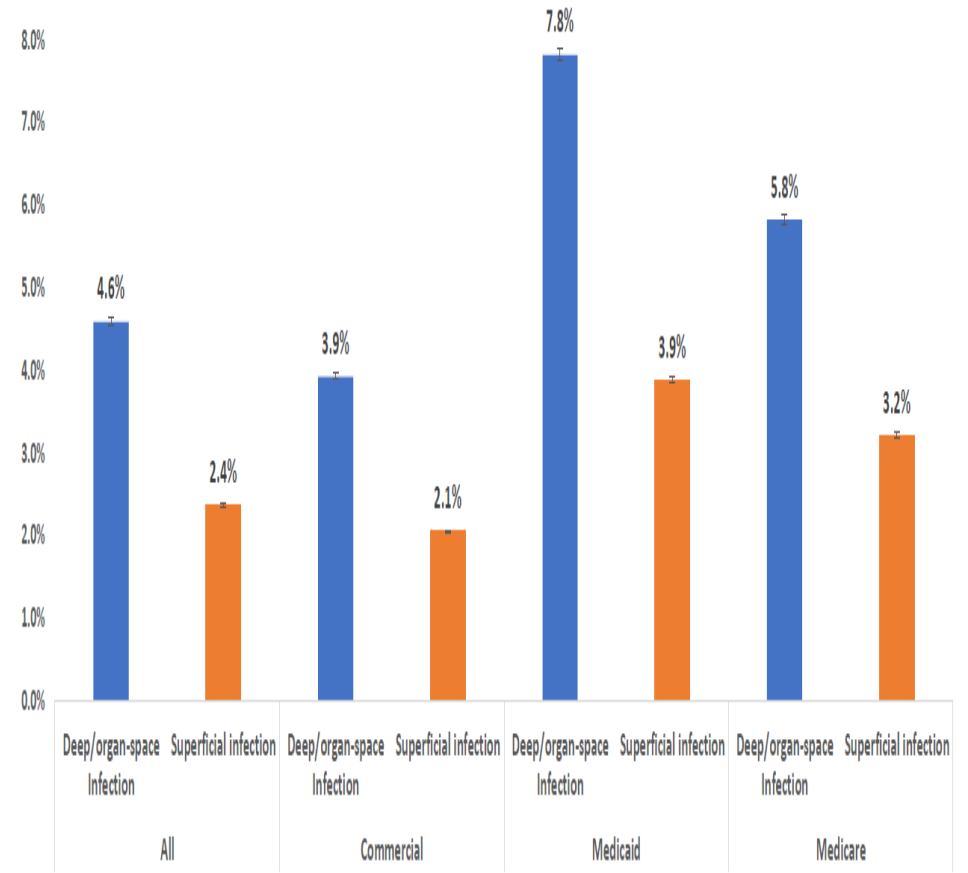
Introduction

After caesarean section, hysterectomy is the second most commonly performed surgical procedure in women of reproductive age in the United States.^{1,2} In 2006, the National Hospital Discharge Summary data reported that 569,000 women underwent hysterectomy; this figure rose to 600,000 by 2015.^{3–5} Surgical site

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
N = 149,869



SSI Rates	Superficial incisional	Deep/Organ space infection
Medicaid	3.9%	7.8%
Medicare	3.2%	5.8%
Commercial	2.1%	3.9%
Insurer	Cost	95% Confidence Interval
Medicare	\$44,436	\$33,967 - \$56,422
Commercial	\$27,140	\$25,990 - \$28,317
Medicaid	\$17,265	\$15,247 - \$19,426

Original Article

Risk and economic burden of surgical site infection following spinal fusion in adults

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Abstract

Background: Spinal fusion surgery (SFS) is one of the most common operations in the United States, >450,000 SFSs are performed annually, incurring annual costs >\$10 billion.

Objectives: We used a nationwide longitudinal database to accurately assess incidence and payments associated with management of post-operative infection following SFS.

Methods: We conducted a retrospective, observational cohort analysis of 210,019 patients undergoing SFS from 2014 to 2018 using IBM MarketScan commercial and Medicaid–Medicare databases. We assessed rates of superficial/deep incisional SSIs, from 3 to 180 days after surgery using Cox proportional hazard regression models. To evaluate adjusted payments for patients with/without SSIs, adjusted for inflation to 2019 Consumer Price Index, we used generalized linear regression models with log-link and γ distribution.

Results: Overall, 6.6% of patients experienced an SSI, 1.7% superficial SSIs and 4.9% deep-incisional SSIs, with a median of 44 days to presentation for superficial SSIs and 28 days for deep-incisional SSIs. Selective risk factors included surgical approach, admission type, payer, and higher comorbidity score. Postoperative incremental commercial payments for patients with superficial SSI were \$20,800 at 6 months, \$26,937 at 12 months, and \$32,821 at 24 months; incremental payments for patients with deep-incisional SSI were \$59,766 at 6 months, \$74,875 at 12 months, and \$93,741 at 24 months. Corresponding incremental Medicare payments for patients with superficial incisional at 6, 12, 24-months were \$11,044, \$17,967, and \$24,096; while payments for patients with deep-infection were: \$48,662, \$53,757, and \$73,803 at 6, 12, 24-months.

Conclusions: We identified a 4.9% rate of deep infection following SFS, with substantial payer burden. The findings suggest that the implementation of robust evidence-based surgical-care bundles to mitigate postoperative SFS infection is warranted.

(Received 14 October 2021; accepted 11 January 2022)

Risk and Economic Burden

- A previous meta-analysis of 27 studies (22,745 patients) the pooled incidence of SSI after spinal procedures was 3.1%, of which 1.4% were superficial SSIs and 1.7% were deep-incisional SSIs. The financial has been previously reported to be as much as \$25,962 per episode.
- A total of 210,019 patients undergoing SFSs between 2014 and 2018 were included in the analysis.
- In total, 13,813 patients (6.6%) experienced an SSI, of which 10,296 (4.9%) were deep-incisional SSIs and 3,517 (1.7%) were superficial incisional SSIs.
- Median postoperative time to infection was 44 day.

Mean SSI Cost (95% CI)		Deep Incisional	Superficial Incisional
Commercial payers	6 mo	\$59,766 (\$57,550–\$62,030)	\$20,800 (\$18,394–\$23,287)
	12 mo	\$74,875 (\$72,209–\$77,597)	\$26,937 (\$24,260–\$29,700)
	24 mo	\$93,741 (\$90,045–\$97,529)	\$32,821 (\$29,435–\$36,325)
Medicare	6 mo	\$48,662 (\$45,251–\$52,209)	\$11,044 (\$6,690–\$15,716)
	12 mo	\$53,757 (\$49,955–\$57,711)	\$17,967 (\$12,991–\$23,277)
	24 mo	\$73,803 (\$68,387–\$79,457)	\$24,096 (\$17,508–\$31,150)

A More Than a Typical Scenario

High Risk Patient – Comorbid Risk:

Immunosuppressive meds - RA

Diabetes

Advanced age

Prior surgery to same joint

Psoriasis

Malnourished

morbidity obesity

sAlb < 35

low sTransferrin

Remote sites of infection

Smokers

ASA = 4



Question #2

What Evidence Exist to Validate the Benefits of a Surgical Care Bundle?

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

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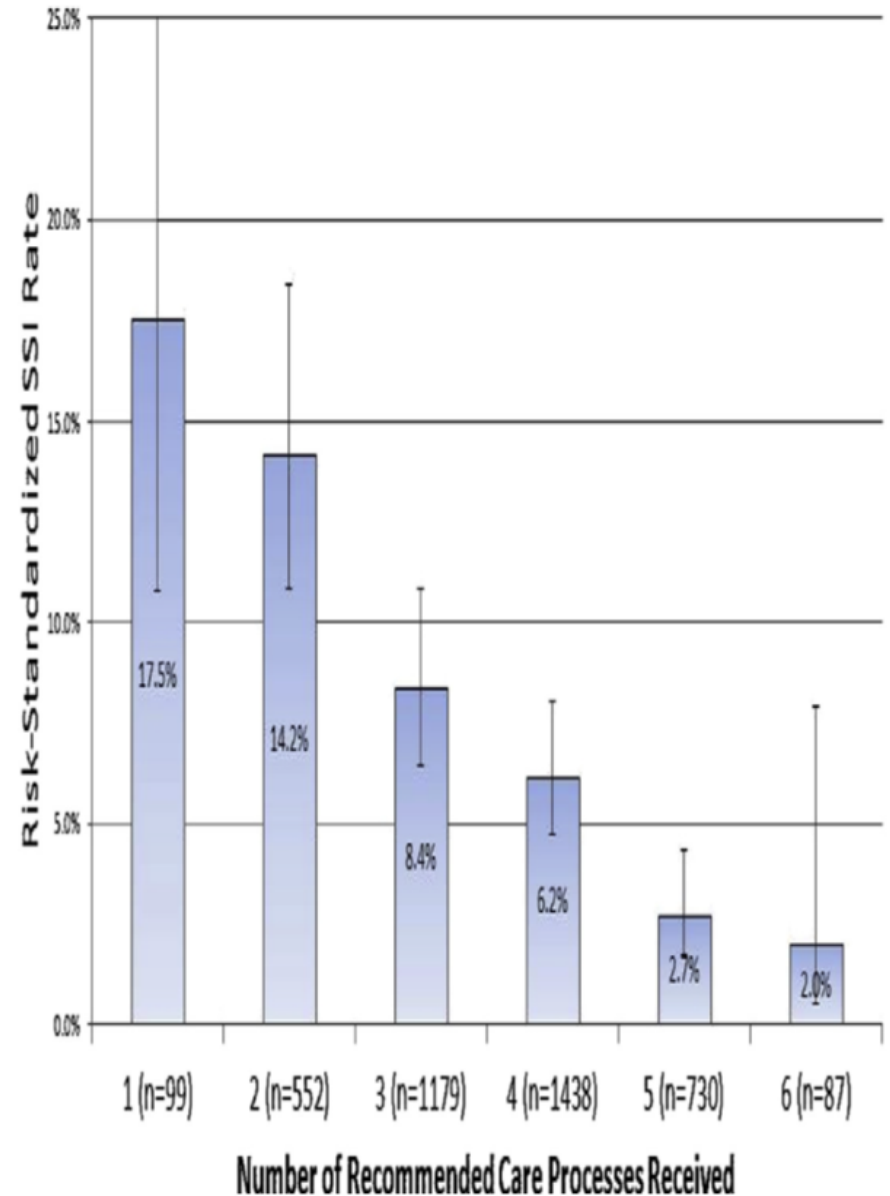
Background. Surgical site infection (SSI) remains a costly and morbid complication after colectomy. The primary objective of this study was to investigate whether a group of perioperative care measures previously shown to be associated with reduced SSI would have an additive effect in SSI reduction. If so, this would support the use of an “SSI prevention bundle” as a quality improvement intervention.

Methods. Data from 24 hospitals participating in the Michigan Surgical Quality Collaborative were included in the study. The main outcome measure was SSI. Hierarchical logistic regression was used to account for clustering of patients within hospitals.

Results. In total, 4,085 operations fulfilled inclusion criteria for the study (Current Procedural Terminology codes 44140, 44160, 44204, and 44205). A “bundle score” was assigned to each operation, based on the number of perioperative care measures followed (appropriate Surgical Care Improvement Project-2 antibiotics, postoperative normothermia, oral antibiotics with bowel preparation, perioperative glycemic control, minimally invasive surgery, and short operative duration). There was a strong stepwise inverse association between bundle score and incidence of SSI. Patients who received all 6 bundle elements had risk-adjusted SSI rates of 2.0% (95% confidence interval [CI], 7.9–0.5%), whereas patients who received only 1 bundle measure had SSI rates of 17.5% (95% CI, 27.1–10.8%).

Conclusion. This multi-institutional study shows that patients who received all 6 perioperative care measures attained a very low, risk-adjusted SSI rate of 2.0%. These results suggest the promise of an SSI reduction intervention for quality improvement; however, prospective research are required to confirm this finding. (*Surgery* 2014;155:602-6.)

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An Effective Bundled Approach Reduces Surgical Site Infections in a High-Outlier Colorectal Unit

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BACKGROUND: Surgical site infections are the most common hospital-acquired infection after colorectal surgery, increasing morbidity, mortality, and hospital costs.

OBJECTIVE: The purpose of this study was to investigate the impact of preventive measures on colorectal surgical site infection rates in a high-volume institution that performs inherent high-risk procedures.

DESIGN: This was a prospective cohort study.

SETTINGS: The study was conducted at a high-volume, specialized colorectal surgery department.

PATIENTS: The Prospective Surgical Site Infection Prevention Bundle Project included 14 preoperative, intraoperative, and postoperative measures to reduce surgical site infection occurrence after colorectal surgery. Surgical site infections within 30 days of the index operation were examined for patients during the 1-year period after the surgical site infection prevention bundle was implemented. The data collection and outcomes for this period were compared with the year immediately before the implementation of bundle elements. All of the patients who underwent elective colorectal surgery by a total of 17 surgeons were included. The following

procedures were excluded from the analysis to obtain a homogeneous patient population: ileostomy closure and anorectal and enterocutaneous fistula repair.

MAIN OUTCOME MEASURES: Surgical site infection occurring within 30 days of the index operation was measured. Surgical site infection–related outcomes after implementation of the bundle (bundle February 2014 to February 2015) were compared with same period a year before the implementation of bundle elements (prebundle February 2013 to February 2014).

RESULTS: Between 2013 and 2015, 2250 abdominal colorectal surgical procedures were performed, including 986 (43.8%) during the prebundle period and 1264 (56.2%) after the bundle project. Patient characteristics and comorbidities were similar in both periods. Compliance with preventive measures ranged between 75% and 99% during the bundle period. The overall surgical site infection rate decreased from 11.8% prebundle to 6.6% at the bundle period ($P < 0.001$). Although a decrease for all types of surgical site infections was observed after the bundle implementation, a significant reduction was achieved in the organ-space subgroup (5.5%–1.7%; $P < 0.001$).

LIMITATION: We were unable to predict the specific contributions the constituent bundle interventions made to the surgical site infection reduction.

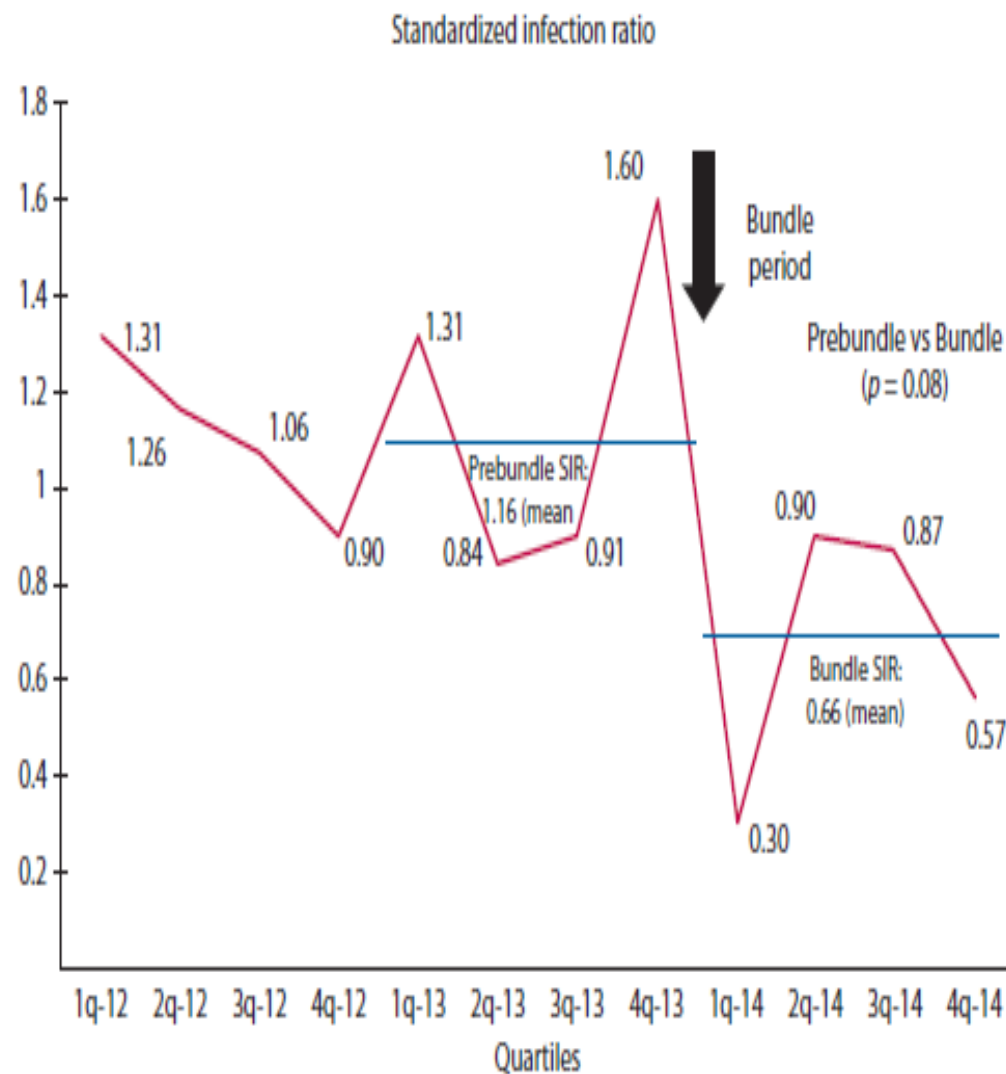
CONCLUSIONS: The prospective Surgical Site Infection Prevention Bundle Project resulted in a substantial decline in surgical site infection rates in our department. Collaborative and enduring efforts among multiple providers are critical to achieve a sustained reduction. See Video Abstract at <http://links.lww.com/>

Funding/Support: None reported.

Financial Disclosure: None reported.

Presented at the meeting of the Surgical Infection Society, Palm Beach, FL, May 18 to 21, 2016.

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Do surgical care bundles reduce the risk of surgical site infections in patients undergoing colorectal surgery? A systematic review and cohort meta-analysis of 8,515 patients

Judith Tanner, PhD,^a Wendy Padley, MSc,^b Ojan Assadian, MD,^c David Leaper, MD,^c Martin Kiernan, MPH,^d and Charles Edmiston, PhD,^e Nottingham, Leicester, Huddersfield, and London, UK, and Milwaukee, WI

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

Methods. We performed a systematic review and meta-analysis of randomized controlled trials, quasi-experimental studies, and cohort studies of care bundles to reduce SSI. The search strategy included database and clinical trials register searches from 2012 until June 2014, searching reference lists of retrieved studies and contacting study authors to obtain missing data. The Downs and Black checklist was used to assess the quality of all studies. Raw data were used to calculate pooled relative risk (RR) estimates using Cochrane Review Manager. The I^2 statistic and funnel plots were performed to identify publication bias. Sensitivity analysis was carried out to examine the influence of individual data sets on pooled RRs.

Results. Sixteen studies were included in the analysis, with 13 providing sufficient data for a meta-analysis. Most study bundles included core interventions such as antibiotic administration, appropriate hair removal, glycemic control, and normothermia. The SSI rate in the bundle group was 7.0% (328/4,649) compared with 15.1% (585/3,866) in a standard care group. The pooled effect of 13 studies with a total sample of 8,515 patients shows that surgical care bundles have a clinically important impact on reducing the risk of SSI compared to standard care with a CI of 0.55 (0.39–0.77; $P = .0005$).

Conclusion. The systematic review and meta-analysis documents that use of an evidence-based, surgical care bundle in patients undergoing colorectal surgery significantly reduced the risk of SSI. (*Surgery* 2015;158:66-77.)

From the School of Health Sciences,^a University of Nottingham, Nottingham; Faculty of Health and Life Sciences,^b De Montfort University, Leicester; Institute of Skin Integrity and Infection Prevention,^c University of Huddersfield, Huddersfield; Richard Wells Research Centre,^d University of West London, London, UK; and Department of Surgery,^e Medical College of Wisconsin, Milwaukee, WI

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

J Gastrointest Surg (2017) 21:1915–1930
DOI 10.1007/s11605-017-3465-3



REVIEW ARTICLE

Bundles Prevent Surgical Site Infections After Colorectal Surgery: Meta-analysis and Systematic Review

Aleksander Zywt^{1,2} · Christine S.M. Lau^{1,2} · H. Stephen Fletcher¹ · Subroto Paul¹

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Abstract

Introduction Colorectal surgeries (CRS) have one of the highest rates of surgical site infections (SSIs) with rates 15 to >30%. Prevention “bundles” or sets of evidence-based interventions are structured ways to improve patient outcomes. The aim of this study is to evaluate CRS SSI prevention bundles, bundle components, and implementation and compliance strategies.

Methods A meta-analysis of studies with pre- and post-implementation data was conducted to assess the impact of bundles on SSI rates (superficial, deep, and organ/space). Subgroup analysis of bundle components identified optimal bundle designs.

Results Thirty-five studies (51,413 patients) were identified and 23 (17,557 patients) were included in the meta-analysis. A SSI risk reduction of 40% ($p < 0.001$) was noted with 44% for superficial SSI ($p < 0.001$) and 34% for organ/space ($p = 0.048$). Bundles with sterile closure trays (58.6 vs 33.1%), MBP with oral antibiotics (55.4 vs 31.8%), and pre-closure glove changes (56.9 vs 28.5%) had significantly greater SSI risk reduction.

Conclusion Bundles can effectively reduce the risk of SSIs after CRS, by fostering a cohesive environment, standardization, and reduction in operative variance. If implemented successfully and complied with, bundles can become vital to improving patients’ surgical quality of care.

Keywords Surgical site infection · SSI · Bundle · Colorectal which ranges from 15.1 to over 30%.^{2–7} In 2014, the Joint

J Gastrointest Surg (2017) 21:1915–1930

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

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

METHODS: Baseline surgical site infection rates were determined retrospectively for cases of open uterine cancer, ovarian cancer without bowel resection, and ovarian cancer with bowel resection between January 1, 2010, and December 31, 2012, at an academic center. A perioperative bundle was prospectively implemented during the intervention period (August 1, 2013, to September 30, 2014). Prior established elements were: patient education, 4% chlorhexidine gluconate shower before surgery, antibiotic administration, 2% chlorhexidine gluconate and 70% isopropyl alcohol coverage of incisional area, and cefazolin redosing 3–4 hours after incision. New elements initiated were: sterile closing tray

and staff glove change for fascia and skin closure, dressing removal at 24–48 hours, dismissal with 4% chlorhexidine gluconate, and follow-up nursing phone call. Surgical site infection rates were examined using control charts, compared between periods using χ^2 or Fisher exact test, and validated against the American College of Surgeons National Surgical Quality Improvement Program decile ranking.

RESULTS: The overall 30-day surgical site infection rate was 38 of 635 (6.0%) among all cases in the preintervention period, with 11 superficial (1.7%), two deep (0.3%), and 25 organ or space infections (3.9%). In the intervention period, the overall rate was 2 of 190 (1.1%), with two organ or space infections (1.1%). Overall, the relative risk reduction in surgical site infection was 82.4% ($P=0.1$). The surgical site infection relative risk reduction was 77.6% among ovarian cancer with bowel resection, 79.3% among ovarian cancer without bowel resection, and 100% among uterine cancer. The American College of Surgeons National Surgical Quality Improvement Program decile ranking improved from the 10th decile to first decile; risk-adjusted odds ratio for surgical site infection decreased from 1.6 (95% confidence interval 1.0–2.6) to 0.6 (0.3–1.1).

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

(Obstet Gynecol 2016;127:1135–44)

DOI: 10.1097/AOG.0000000000001449

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

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Prevention of Orthopedic Prosthetic Infections Using Evidence-Based Surgical Site Infection Care Bundles: A Narrative Review

Charles E. Edmiston, Jr.¹ and David John Leaper²

Abstract

Background: The number of primary/revision total joint replacements (TJR) are expected to increase substantially with an aging population and increasing prevalence of comorbid conditions. The 30-day re-admission rate, in all orthopedic specialties, is 5.4% (range, 4.8%–6.0%). A recent publication has documented that the surgical site infection (SSI) infection rate associated with revision total knee (rTKR, 15.6%) and revision total hip (rTHR, 8.6%) arthroplasties are four to seven times the rate of the primary procedures (2.1%–2.2%). These orthopedic infections prolong hospital stays, double re-admissions, and increase healthcare costs by a factor of 300%.

Methods: A search of PubMed/MEDLINE, EMBASE and the Cochrane Library publications, which reported the infection risk after TKR and THR, was undertaken (January 1, 1995 to December 31, 2021). The search also included documentation of evidence-based practices that lead to improved post-operative outcomes.

Results: The evidence-based approach to reducing the risk of SSI was grouped into pre-operative, peri-operative, and post-operative periods. Surgical care bundles have existed within other surgical disciplines for more than 20 years, although their use is relatively new in peri-operative orthopedic surgical care. Pre-admission chlorhexidine gluconate (CHG) showers/cleansing, staphylococcal decolonization, maintenance of normothermia, wound irrigation, antimicrobial suture wound closure, and post-operative wound care has been shown to improve clinical outcome in randomized controlled studies and meta-analyses.

Conclusions: Evidence-based infection prevention care bundles have improved clinical outcomes in all surgical disciplines. The significant post-operative morbidity, mortality, and healthcare cost, associated with SSIs after TJR can be reduced by introduction of evidence-based pre-operative, intra-operative, and post-operative interventions.

Keywords: arthroplasty; comorbid risk; evidence-based interventions; evidence-based SSI prevention bundle; peri-prosthetic infection

MORE THAN 600,000 knee and nearly 300,000 hip replacement procedures are undertaken annually in the United States [1–4]. The number of primary and revision total joint replacement (TJR) are expected to increase by 2030 with an aging population and an increasing prevalence of arthritis and comorbid conditions [5,6]. The number of TJRs may

reach 572,000 primary hip replacements, 3.48 million primary knee replacements, 90,000 revision hip replacements, and 250,000 revision knee procedures [3]. The reported incidence of SSI ranges from 0.5% to 8% after both primary and revision TJR [4,6,7]. Factors shown to be associated with an increased risk include patient demographics, comorbid

Question #3

What are the Mechanistic Benefits of the Elemental Components of an Effective Surgical Care Bundle?

Selecting An Evidence-Based (EB) Surgical Care Bundle



Evidence-Based Interventions	Class	Mechanistic Benefits
Normothermia	1A	Less bleeding / preserve immune function in wound bed / enhanced wound healing
Perioperative antimicrobial prophylaxis – “Weight-based”	1A	Tissue antiseptics / intraoperative conc > MIC ⁹⁰ wound pathogens
Glycemic control	1A	Preserve granulocytic immune function / enhance wound healing
Antimicrobial (triclosan) coated sutures (fascia / subcuticular closure)	1A	Mitigate nidus of wound contamination / local tissue antiseptics / minimize the risk of biofilm formation
Preadmission CHG shower / cleansing	High-1A	Skin antiseptics / reduce skin bioburden
Perioperative skin-prep – 2% CHG / 70% alcohol	1A	Skin antiseptics / reduce skin bioburden
Separate wound closure tray	Moderate	Mitigate instrument contamination
Glove change prior to fascia / subcuticular closure	Moderate	Disrupt cross-contamination across tissue planes

Evidence-Based Interventions	Class	Mechanistic Benefits
Supplemental oxygen – Colorectal	Moderate to High	Enhanced tissue oxygenation and immune function / host-metabolic benefits
Oral antibiotics / Mechanical bowel prep – Colorectal	1A	Reduce microbiome bioburden (protease-producing bacteria) within the bowel lumen and on brush border surfaces
Wound edge protector – Colorectal, Vascular, OB/GYN	Moderate	Intraoperative wound antisepsis / minimizing wound contamination
Staphylococcal decolonization – Orthopedic and CT	1A	Mitigate <i>S. aureus</i> and MRSA wound contamination/ pathogenicity
Smoking cessation – Orthopedic, Neuro, CT - likely all surgical procedures	High to 1A	Preserve angiogenesis /reduce risk of dehiscence / enhance wound healing
Intraoperative irrigation of the surgical wound with 0.05% chlorhexidine gluconate	Moderate	Mitigate wound contamination prior to closure

The Patient's Journey Through a Risk-Filled Environment



So What Is This Big Deal About Normothermia?



ELSEVIER

Best Practice & Research Clinical Anaesthesiology
Vol. 22, No. 4, pp. 645–657, 2008
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available online at <http://www.sciencedirect.com>



2

Perioperative complications of hypothermia

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Perioperative hypothermia is a common and serious complication of anesthesia and surgery and is associated with many adverse perioperative outcomes. It prolongs the duration of action of inhaled and intravenous anesthetics as well as the duration of action of neuromuscular drugs. Mild core hypothermia increases thermal discomfort, and is associated with delayed post anaesthetic recovery. Mild hypothermia significantly increases perioperative blood loss and augments allogeneic transfusion requirement. Only 1.9 °C core hypothermia triples the incidence of surgical wound infection following colon resection and increases the duration of hospitalization by 20%. Hypothermia adversely affects antibody- and cell-mediated immune defences, as well as the oxygen availability in the peripheral wound tissues. Furthermore mild hypothermia triples the incidence of postoperative adverse myocardial events. Thus, even mild hypothermia contributes significantly to patient care costs and needs to be avoided.

Key words: anaesthesia; hypothermia; complication; perioperative; temperature; thermoregulation.

Why Is Hypothermia So Bad?

Impairs wound healing

Increases blood loss – impairs coagulation and platelet function

Increases the demand for tissue oxygen consumption

Inhibits granulocytic cell function in tangent with T-cell function –

Immune dysfunction

Increases risk of postop mortality in severely comorbid patients

Exacerbated by induction of anesthesia



Original Contribution

Unexpectedly high incidence of hypothermia before induction of anesthesia in elective surgical patients ☆☆☆★

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Keywords:

Core temperature;
Hypothermia;
Hypothermia before
induction of anesthesia;
Incidence of hypothermia;
Predictor of hypothermia

Abstract

Study objective: Perioperative hypothermia is a frequently observed phenomenon of general anesthesia and is associated with adverse patient outcome. Recently, a significant influence of core temperature before induction of anesthesia has been reported. However, there are still little existing data on core temperature before induction of anesthesia and no data regarding potential risk factors for developing preoperative hypothermia. The purpose of this investigation was to estimate the incidence of hypothermia before anesthesia and to determine if certain factors predict its incidence.

Design/setting/patients: Data from 7 prospective studies investigating core temperature previously initiated at our department were analyzed. Patients undergoing a variety of elective surgical procedures were included.

Interventions/measurements: Core temperature was measured before induction of anesthesia with an oral (314 patients), infrared tympanic (143 patients), or tympanic contact thermometer (36 patients). Available potential predictors included American Society of Anesthesiologists status, sex, age, weight, height, body mass index, adipose ratio, and lean body weight. Association with preoperative hypothermia was assessed separately for each predictor using logistic regression. Independent predictors were identified using multivariable logistic regression.

Main results: A total of 493 patients were included in the study. Hypothermia was found in 105 patients (21.3%; 95% confidence interval, 17.8%–25.2%). The median core temperature was 36.3°C (25th–75th percentiles, 36.0°C–36.7°C). Two independent factors for preoperative hypothermia were identified: male sex and age (>52 years).



The Optimal Time and Method for Surgical Prewarming: A Comprehensive Review of the Literature

Lauren Connelly, BSN, RN, Emily Cramer, BSN, RN, Quinn DeMott, BSN, RN, Jennifer Piperno, BSN, RN, Bethany Coyne, PhD, APRN, PNP-BC, Clara Winfield, BSN, CAPA, RN, Michael Swanberg, BSN, MA, PhD(c), RN

Purpose: Inadvertent hypothermia is a common problem in the operating room. This can contribute to many unfavorable outcomes – rising costs, increased complications, and higher morbidity rates.

Design: This review determined the optimal method and time to prewarm a surgical patient to prevent perioperative hypothermia.

Methods: CINAHL and PubMed were searched. Fourteen articles were ultimately included in this review.

Findings: Based on the literature reviewed, it was suggested that forced-air warming was most effective in preventing perioperative hypothermia. Eighty-one percent of the experimental studies reviewed found that there was a significantly higher temperature throughout surgery and in the postanesthesia care unit for patients who received forced-air prewarming.

Conclusions: Thirty minutes was found to be the average suggested amount of time for prewarming among the literature; however, a minimum of 10 minutes of prewarming was suggested to significantly reduce rates of hypothermia in perioperative patients and decrease the adverse effects of hypothermia.

Keywords: prewarming, perioperative hypothermia, forced air warming.
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Conflict of interest: None to report.

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<http://dx.doi.org/10.1016/j.jocan.2015.11.010>

INADVERTENT PERIOPERATIVE HYPOTHERMIA is a risk during all surgical procedures and is associated with surgical complications such as increased blood loss, impaired wound healing, and even cardiac arrest. Up to 70% of surgical patients develop perioperative hypothermia.¹ Perioperative hypothermia is defined by the American Society of PeriAnesthesia Nurses as a core temperature below 36°C.² Maintaining perioperative normothermia, defined as a core temperature of 36 to 38°C, is a high priority for the multidisciplinary surgical team because of the adverse effects of hypothermia. If intraoperative normothermia can be maintained, studies have found that this may reduce the length of a patient's hospital stay by 40%³ and may also reduce the rate of perioperative infections by up to 64%.^{2,3} These reductions in length of stay and postoperative

Standardization of the Preadmission Shower/Cleansing Strategy



- Scalp 6.0 Log₁₀ cfu/cm²
- Axilla 5.5 Log₁₀ cfu/cm²
- Abdomen 4.3 Log₁₀ cfu/cm²
- Forearm 4.0 Log₁₀ cfu/cm²
- Breast 6.0-9.0 Log₁₀ cfu/cm²
- Hands 4.0-6.6 Log₁₀ cfu/cm²
- Perineum 7.0-11.0 Log₁₀ cfu/cm²

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

4% Aqueous CHG

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

**CHG conc of approximately
1000 µg/ml**

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.


STANDARDIZATION OF THE 4% Chlorhexidine Gluconate (CHG) PREAMMISSION SHOWER

Include the following components in preadmission CHG shower regimens, as part of a comprehensive surgical site infection prevention program.

1. **Use** electronic alert systems (text messaging, emails, voice mails) to remind patients to complete the shower regimen.
2. **Emphasize** the importance of the shower regimen, and give patients both oral and written instructions.
3. **Provide** the CHG product free of charge to patients.
4. **Define** a precise amount of CHG (one 4 oz. bottle) to be used for each shower.
5. **Instruct** patients to take a 60-second pause (time-out) after application of the CHG before rinsing.
6. **Direct** patients to wear loose-fitting garments following each CHG shower, and to avoid using lotions, creams, emollients, or perfume.

Source: Edmiston CE, Cheong J, Krepel C, et al. Evidence for a standardized preadmission showering regimen to achieve maximal antiseptic skin surface concentrations of chlorhexidine gluconate, 4%, in surgical patients. *JAMA Surg*. 2015;150:1027-33.

 Wisconsin Division of Public Health
HAI Prevention Program ran
<https://www.dhs.wisconsin.gov/hai/index.htm>

 Wisconsin
Department of Health Services

P-00749 (12/2015)

www.dhs.wisconsin.gov/publications/p0/p00749.pdf

Remember the devil is always in the details

Edmiston et al. *JAMA Surg* 2015;150:
1027

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



Katherine E Hekman, MD, PhD, Eriberto Michel, MD, Eddie Blay Jr, MD, Irene B Helenowski, PhD, Andrew W Hoel, MD, FACS

BACKGROUND: Surgical site infection (SSI) poses a significant burden to patients and healthcare resources. Vascular Quality Initiative (VQI) data identify a higher rate of SSIs for lower extremity bypass than other vascular procedures. Bundled interventions have successfully reduced SSIs in other surgical procedures.

STUDY DESIGN: We evaluated our institution-specific VQI data for modifiable risk factors associated with index hospitalization SSI from January 2012 through October 2015. We implemented an evidence-based lower extremity bypass operation SSI reduction bundle (ie perioperative chlorhexidine showers and transverse groin incisions) and prospectively enrolled all patients who had lower extremity bypass procedures, with a target adherence rate of 50% per bundle component. Bundle adherence and SSI events were measured from March 2016 through August 2017. We carried out a pre-post evaluation of bundle effectiveness in reducing index hospitalization SSI.

RESULTS: In the pre-intervention period, 43 of 234 (18%) patients had SSI events. The only risk factors associated with SSI (ie female sex, diabetes, overweight BMI) were not readily modifiable. In an 18-month period after introduction of our intervention, adherence rates to preoperative chlorhexidine showers, a transverse incision, and a postoperative chlorhexidine shower were 71% (52 of 73), 48% (24 of 50), and 88% (64 of 73), respectively. Compliance with all applicable bundle components was 36% (26 of 73). The SSI rate post-intervention decreased from 18% to 4% (3 of 73). Intention-to-treat multivariable analysis showed a 97% SSI risk reduction with the bundle ($p = 0.002$). As-treated analysis identified 85% ($p = 0.02$) and 62% ($p = 0.047$) SSI risk reductions from the preoperative and postoperative chlorhexidine showers, respectively.

CONCLUSIONS: In this evaluation study of the effectiveness of a quality improvement intervention, SSIs were markedly decreased after implementation of our evidence-based bundle for lower extremity vascular bypass procedures. (J Am Coll Surg 2019;228:44–53. © 2018 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

Surgical site infection (SSI) poses a significant burden to both patients and healthcare resources. Among vascular surgery procedures, the lower extremity bypass has the

highest rate of SSI, at approximately 10%.¹ These SSI events lead to prolonged hospital stays and greater resource use.² More importantly, in the setting of

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

Bhaveen H. Kapadia MD, Julio J. Jauregui MD, Daniel P. Murray BA, Michael A. Mont MD

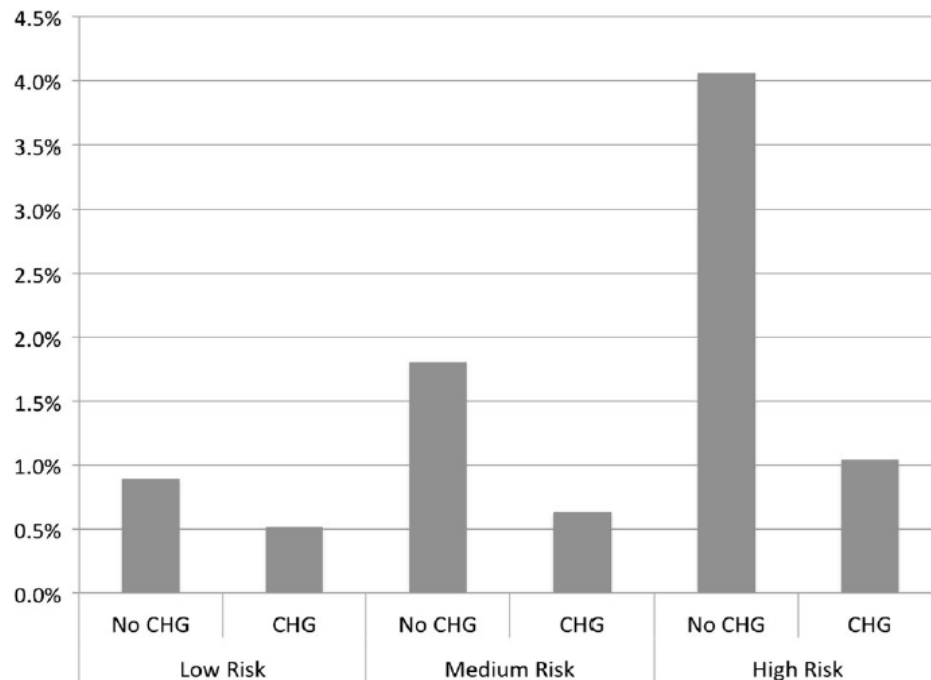


Fig. 1 Bar graph representing the incidence of infection stratified by risk classification. CHG = chlorhexidine gluconate.

Clinical practice guidelines for antimicrobial prophylaxis in surgery

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

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

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

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

Guidelines development and use

Members of ASHP, IDSA, SIS, and SHEA were appointed to serve on an expert panel established to ensure the validity, reliability, and utility

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

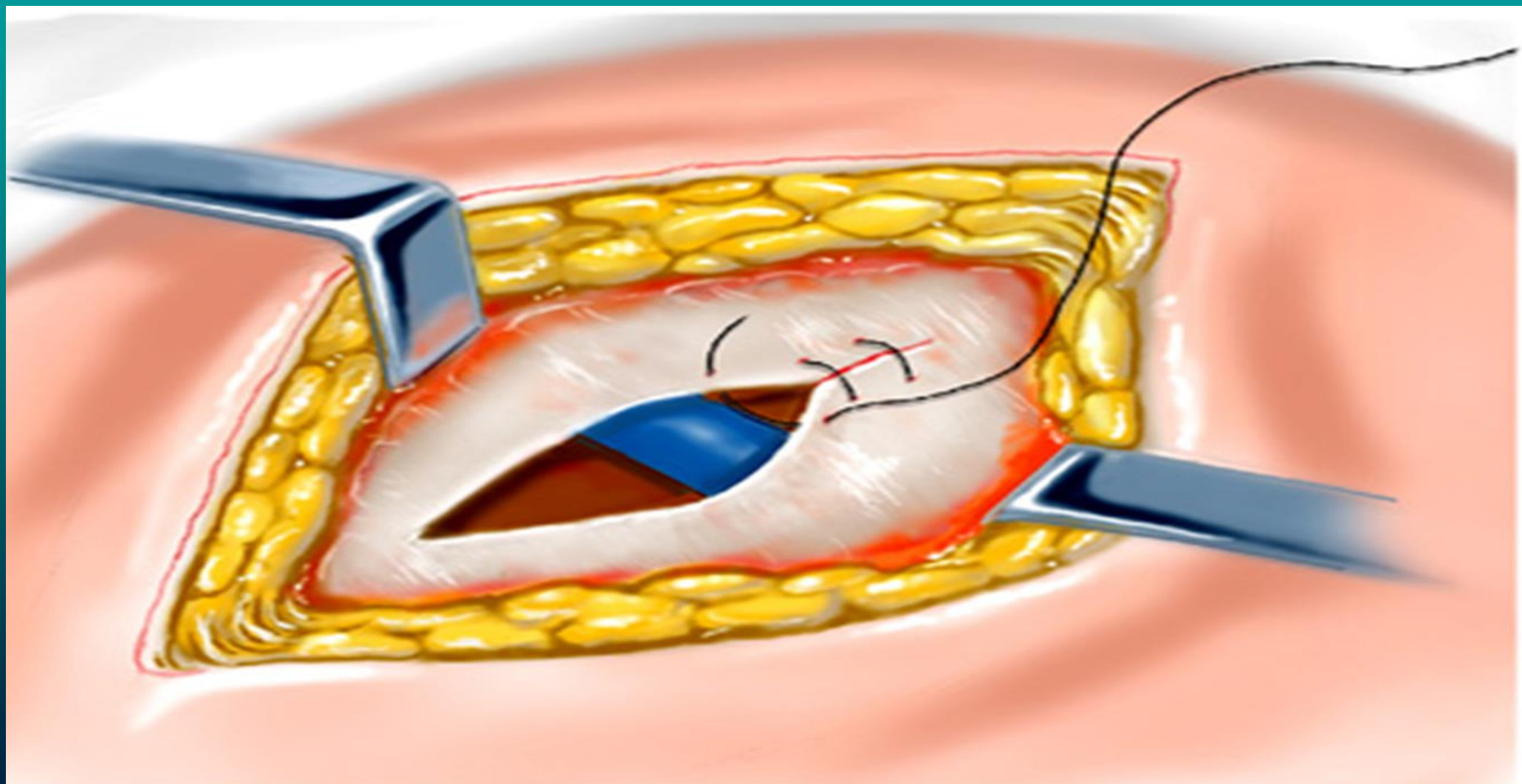
Are We Practicing Weight-Based Antimicrobial Prophylaxis?

“In obese patients, especially those who are morbidly obese, serum and tissue concentrations of some drugs may differ from those in normal-weight patients because of pharmacokinetic alterations that depend on the lipophilicity of the drug and other factors.”

“Considering the low cost and favorable safety profile of cefazolin, increasing the dose to 2 g for patients weighing more than <120 kg and to 3 g for those weighing \geq 120 kg can easily be justified.”

*Bratzler et al., Clinical Practice Guidelines for Antimicrobial Prophylaxis in Surgery.
Am Soc for Hosp Pharm 2013;70:195*

Can a Sutures Really be a Nidus for Infection?
The Role of Triclosan(Coated/Impregnated) Sutures as an Evidence-
Based Strategy for Reducing the Risk of Surgical Site Infections



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

S. D. ELEK AND P. E. CONEN

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(University of London), London, S.W.1*

Received for publication 9 August, 1957

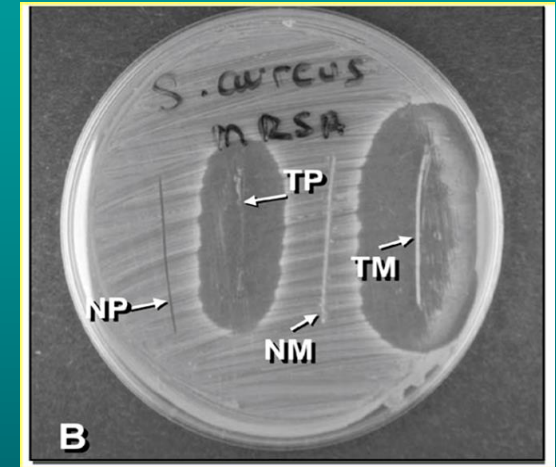
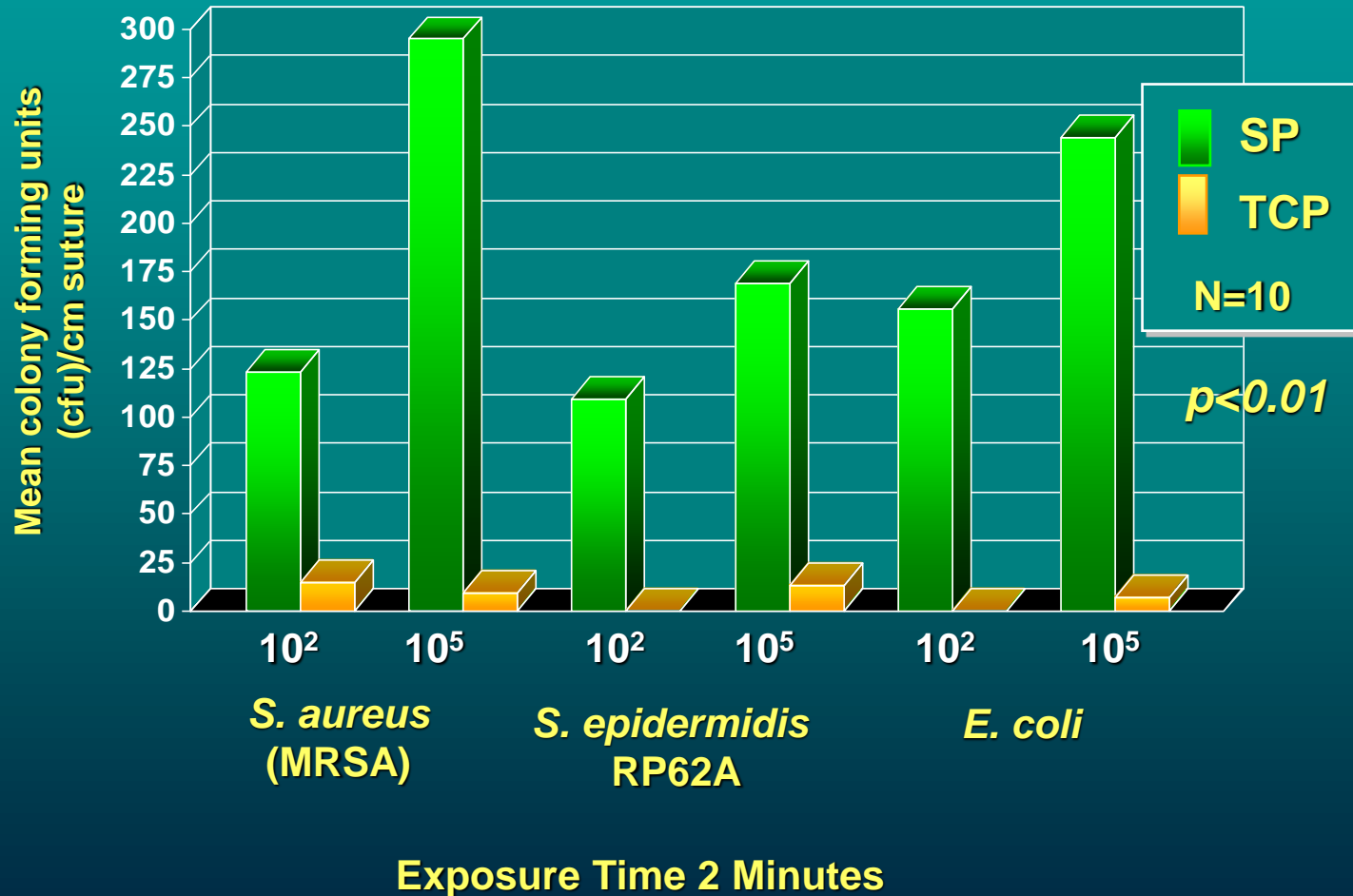
LITTLE direct evidence is available about the virulence of strains of *Staph. pyogenes* to man. Garré (1885) infected himself with a strain obtained from a fatal case of osteomyelitis by rubbing a whole slope culture into the skin of the left forearm. Small pustules appeared around the hair follicles within a few hours, which enlarged and eventually coalesced into a large carbuncle, which took three weeks to heal with much scar formation. Similar experiments were carried out subsequently by Bümm (1885) and by Bockhart (1887). In this early work the dosage was not stated with accuracy as the aim was to prove that staphylococci were the true cause of carbuncles and wound infections, rather than an attempt to compare the virulence of different strains. It is noteworthy that both Garré and Bockhart failed to produce lesions in some of their experiments, and similar failures by other early workers were referred to by Neisser (1928). No quantitative information is available at present on the susceptibility of different individuals and the relative virulence to man of different strains.

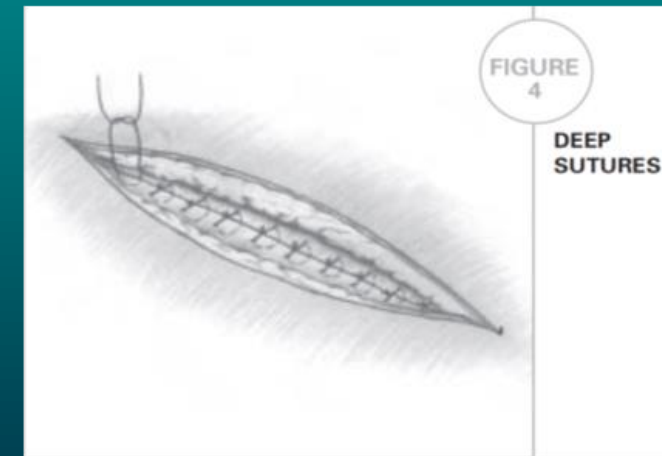
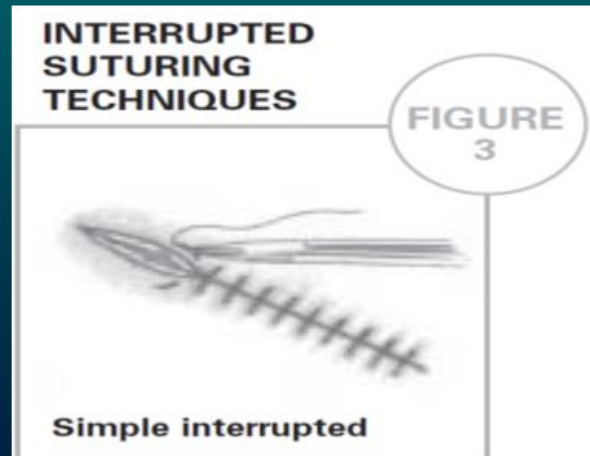
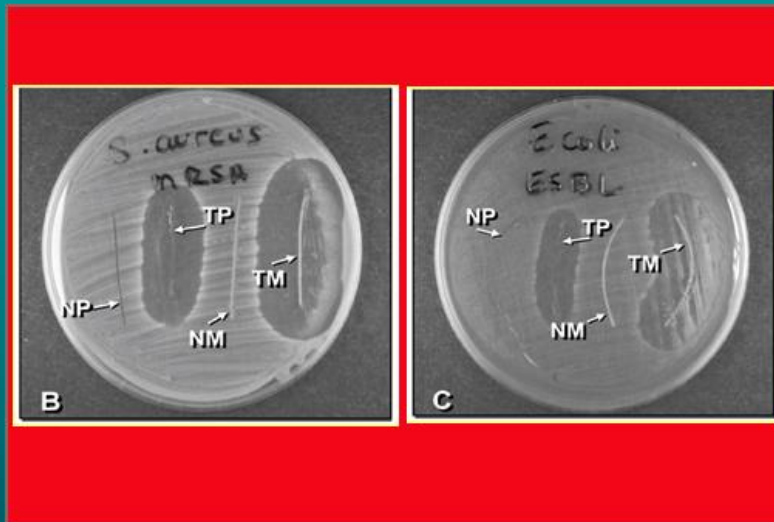
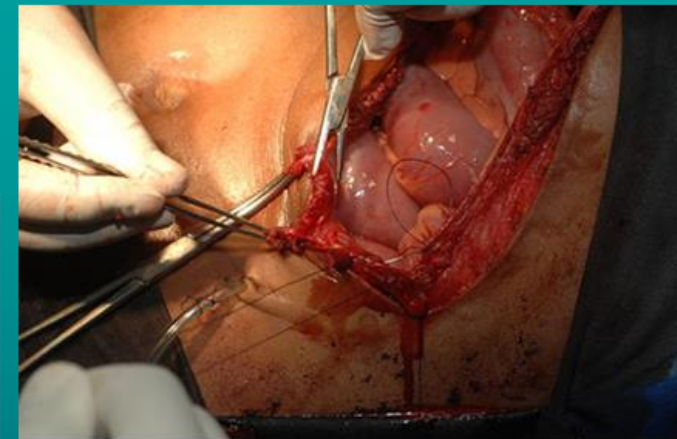
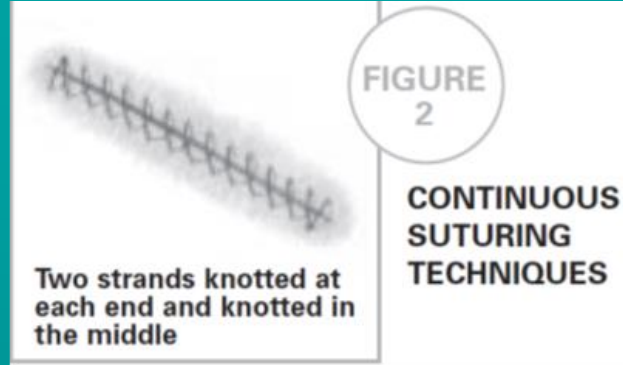
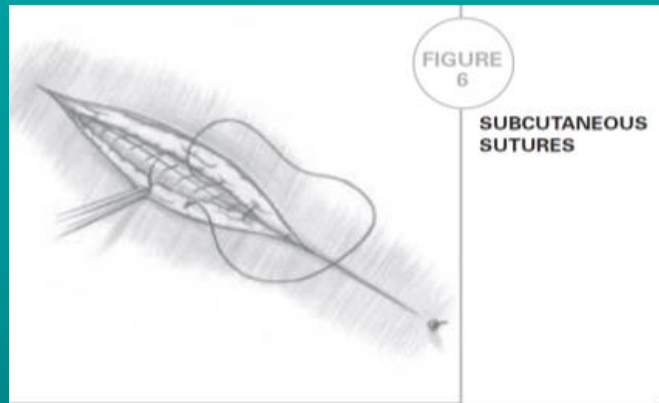
The virulence of a microbe always relates to a given animal species. The mere fact that lesions may be set up in one experimental animal gives little if any indication of virulence for another species. In staphylococcal infection, the traditional approach of using a convenient laboratory animal may be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

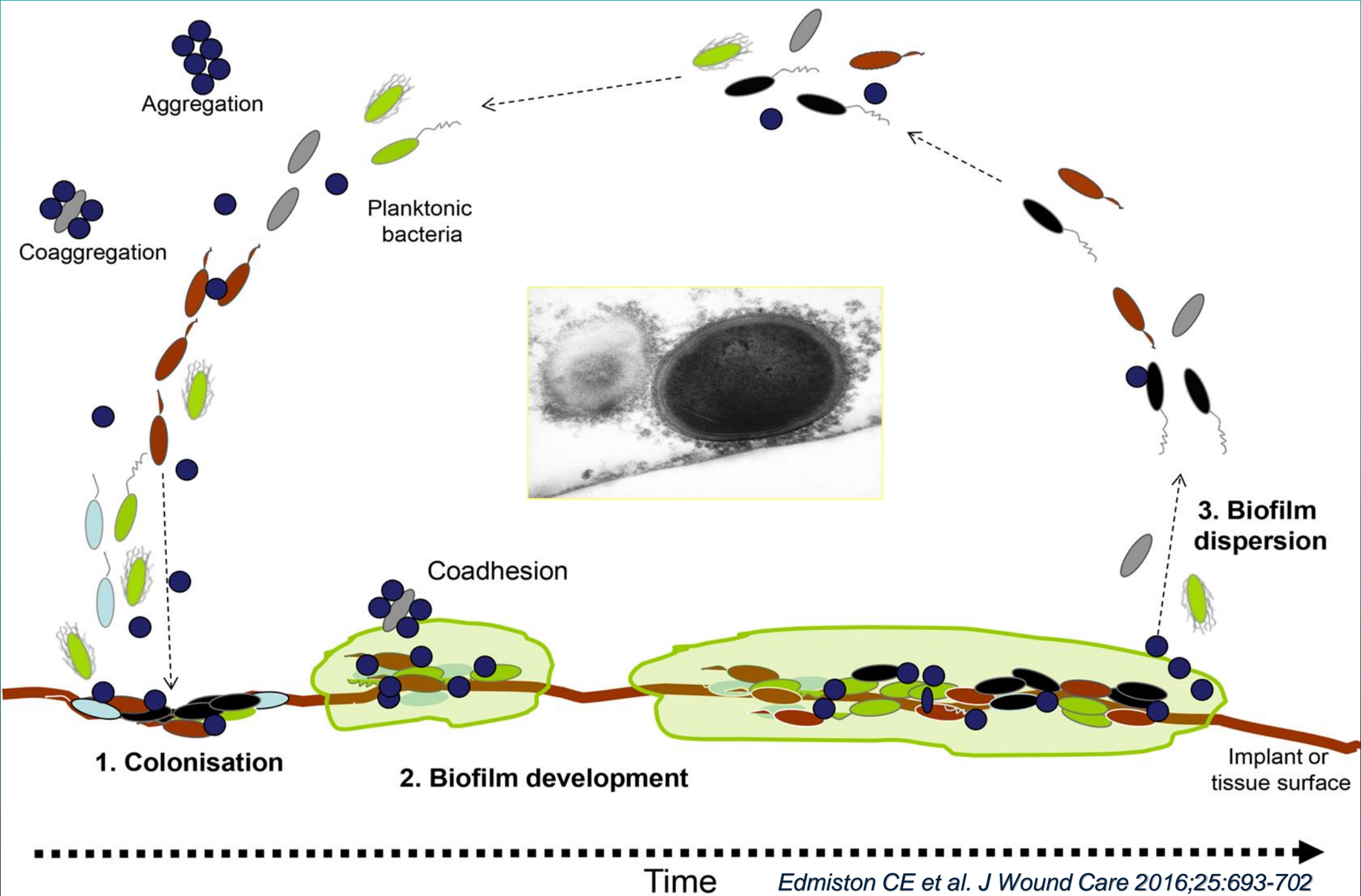
As yet we have virtually no information about the minimal infective dose of any pathogen to man: only circumstantial evidence and analogies are available. The advent of penicillin and other antibiotics however, has rendered direct inoculation in volunteers relatively safe. The extensive literature on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

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

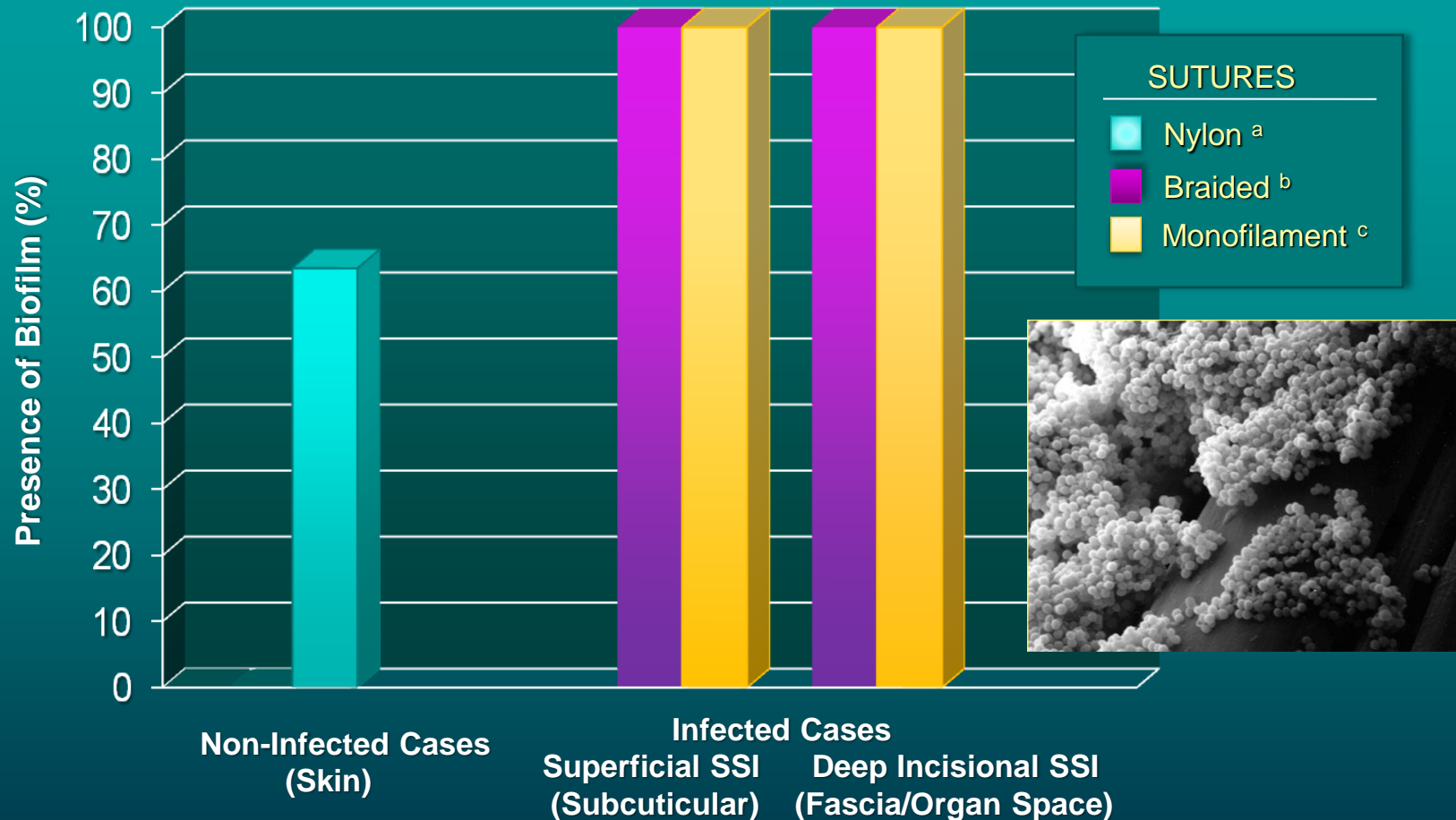
Mean Microbial Recovery from Standard Polyglactin Sutures Compared to Triclosan (Antimicrobial)-Coated Polyglactin Closure Devices







Presence of Biofilm on Selected Sutures from Non-infected and Infected Cases



^anon-infected nylon suture segments were randomly selected for microscopy, culture positive

^binfected braided suture segments were randomly selected for microscopy

^cinfected monofilament suture segments were randomly selected for microscopy



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.)

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.

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

- **2013** - Sajid et al. *Gastroenterol Report* 2013;42-50: 7 RCT (1631 patients) – Odds of SSI 56% less in triclosan suture group compared to controls ($p<0.04$)
- **2013** - Wang et al. *BJS* 2013;100-465: 17 RCT (3720 patients) – **30% decrease in risk of SSI** ($p<0.001$)
- **2013** - Edmiston et al. *Surgery* 2013;154:89-100: 13 RCT (3568 patients) – **27% to 33% decrease in risk of SSI** ($p<0.005$)
- **2014** - Daoud et al. *Surg Infect* 2014;15:165-181: 15 RCT (4800 patients) – **20% to 50% decreased risk of SSI** ($p<0.001$)
- **2015** - Apisarnthanarak et al. *Infect Cont Hosp Epidemiol* 2015;36:1-11: 29 studies (6,930 patients) – **26% reduction in SSI** ($p<0.01$)
- **2016** - Guo et al. *Surg Research* 2016; [doi:10.1016/j.jss.2015.10.015](https://doi.org/10.1016/j.jss.2015.10.015) – 13 RCT (5256 patients) (risk ratio [RR] 0.76, 95% confidence interval [CI] 0.65-0.88, $p < 0.001$)
- **2017** – Wu et al. *Eur J Clin Microbiol Infect Dis* 2017;36:19-32: 13 RCT (5,346 patients) (risk ratio [RR] 0.72, 95% confidence interval [CI] 0.59-0.88, $p<0.001$)
- **2017** – De Jonge et al. *BJS* 2017;104:e118-e133: 21 RCT (6,462 patients) (risk ratio [RR] **28% reduction**, 95% confidence ratio [CI] 0.60-0.88, $p<0.001$)
- **2019** – Ahmed I et al. *BMJ* 2019;9:029727; [doi.10.1136/bml-open-2019-029727](https://doi.org/10.1136/bml-open-2019-029727): 25 RCT (11,957 patients) – Test of overall effect: $Z = 5.2$ ($p<0.0001$)

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

Safety (>1 Billion strands)

- No MAUDE (FDA) reports (21 years) documenting significant evidence linking triclosan to adverse impact in surgical wounds; No evidence of pediatric toxicity, *Renko M. et al. Lancet Infectious Disease 2017;17:50–57 (N~1600)/50% reduction*); No evidence of chronic toxicity, carcinogenicity, reproductive toxicity, immunotoxicity, cytotoxicity or intracutaneous. reactivity *Roidricks et al. Crit. Rev. Toxicol. 2010;40:422. doi: 10.3109/10408441003667514.*

Microbicidal Activity (Spectrum)

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

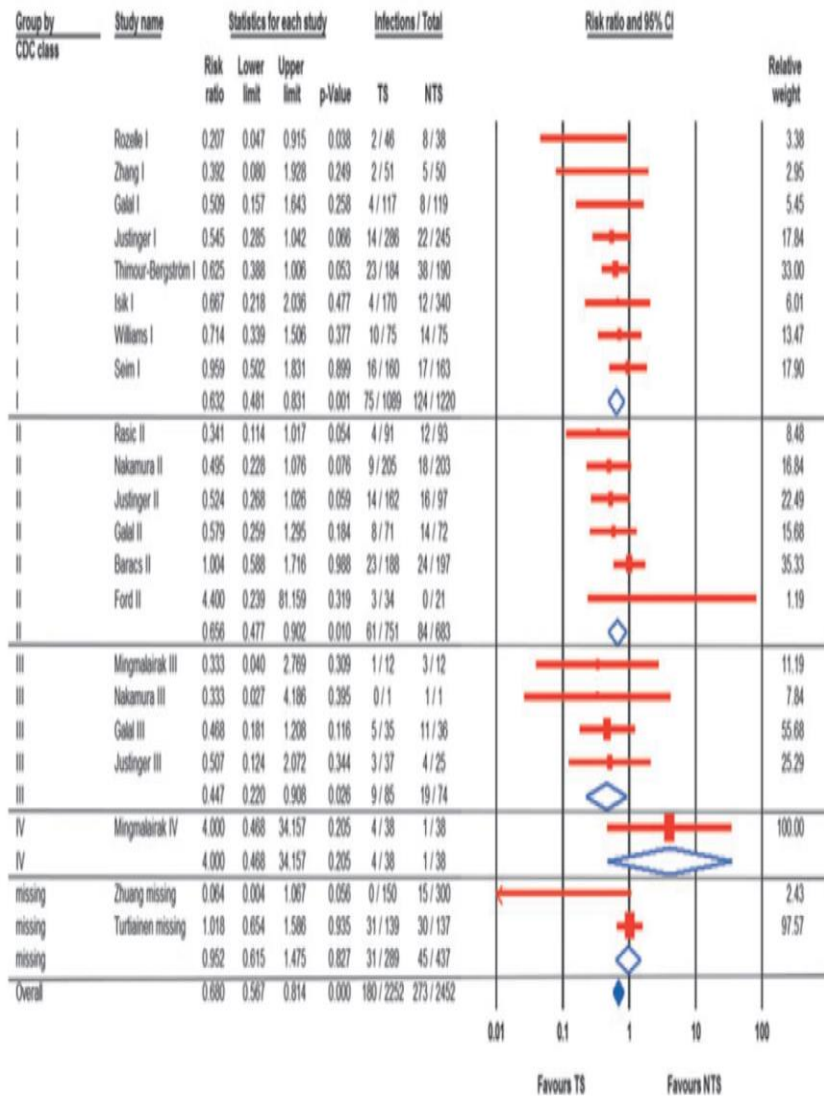
Evidence-based Clinical Effectiveness (Meta-Analysis)

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

Cost-Effectiveness

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

Random-effects pooled RR of SSIs - 15 RCTs - RR by CDC class



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

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

What about Class IV – Dirty surgical wounds?

RR: Risk Ratio. SSI: Surgical Site Infections. TS: Triclosan Sutures, NTS: Non-Triclosan Sutures, RCT: Randomized Controlled Trial



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

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Class IV wound



SUMMARY

Background: Surgical site infections (SSIs) are one of the most frequently reported types of hospital-acquired infection and are associated with substantial clinical and economic burden.

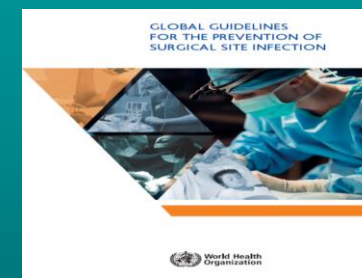
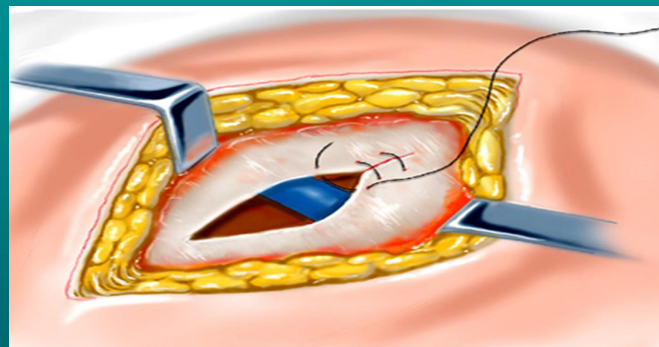
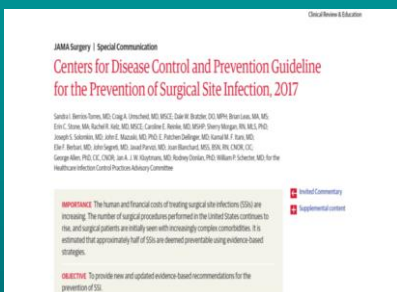
Aim: To assess the incidence of SSIs and analyze contributing risk factors in a real-world Spanish hospital setting before and after the implementation of triclosan-coated sutures (TCS).

Methods: A prospective, observational study was conducted at Hospital Clínico Universitario de Santiago de Compostela, Spain. Enrolled patients underwent surgery in the following specialties: general surgery, urology, neurosurgery, gynaecology, and traumatology. The primary outcome of the study was SSI incidence, assessed at a 30-day follow-up. Secondary outcomes were length of hospital stay, and readmission, reintervention, and mortality rates, also at 30 days.

Findings: 5,081 patients were included in the study, of which 2,591 were treated using non-coated sutures (NCS) and 2,490 using TCS. After adjusting for potential confounders, TCS significantly reduced SSI rate by 36%, compared with NCS (odds ratio [OR]: 0.64; 95% confidence interval [CI]: 0.48–0.85; $P < 0.003$). When stratified by wound classification, a statistically significant reduction in SSI incidence, in favour of TCS use, was observed for Class IV (dirty) wounds (35.6% versus 22.7% for NCS and TCS, respectively; OR: 0.53; 95% CI: 0.31–0.90).

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

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

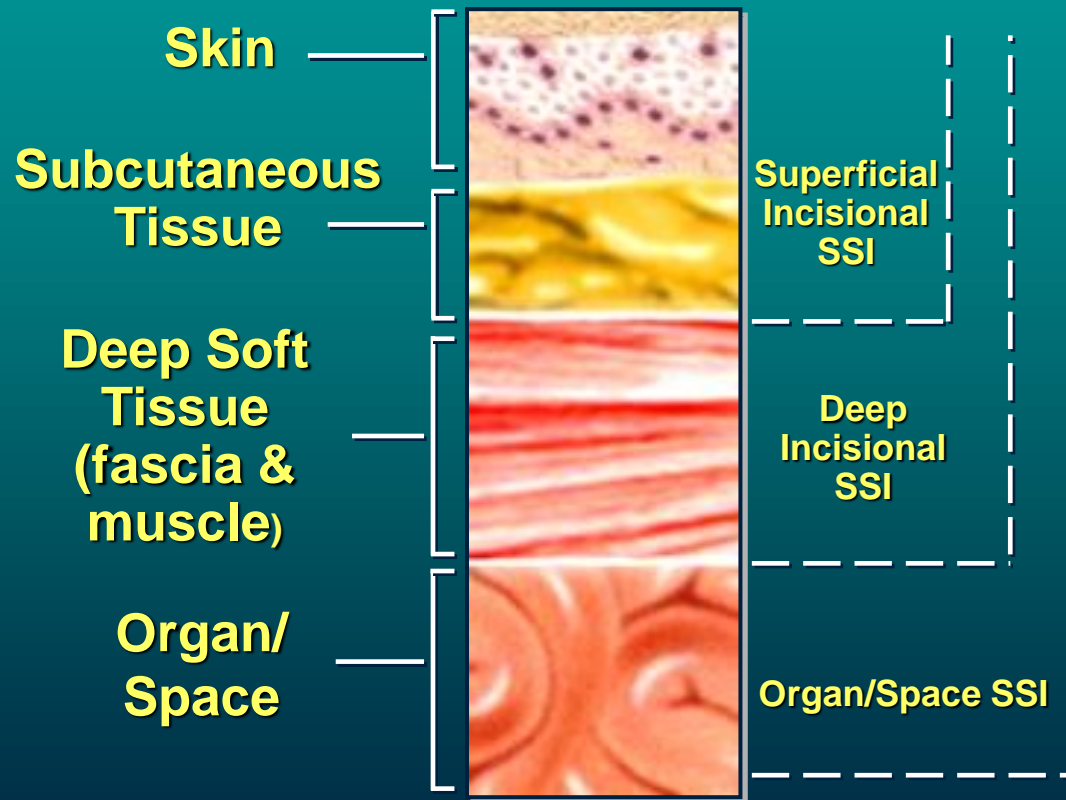


A 22 Year Evidence-Based Journey - >15 National, International and Societal SSI Prevention Guidelines Recommend the Use of Triclosan Coated/Impregnated Sutures

Question #4

What are the Major Barriers in the Implementation of an Effective Surgical Care Bundle and Are We Compliant to Our Evidence-Based Practices?

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



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

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

The Absolute Weakest Link

ORIGINAL ARTICLE

Surgical site infection: poor compliance with guidelines and care bundles

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Key words

Care bundles; Compliance; Guidelines;
Surgical site infection

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Leaper DJ, Tanner J, Kiernan M, Assadian O, Edmiston CE Jr. Surgical site infection: poor compliance with guidelines and care bundles. *Int Wound J* 2014; doi: 10.1111/iwj.12243

Abstract

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

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Effectiveness versus Uptake: The Challenges of Implementing Evidence-Based Strategies to Reduce Surgical Site Infection in Patients with Colon Surgeries

Lena Camperlengo,¹ Maureen Spencer,² Peter Graves,³ Walter Danker,⁴ and Charles Edmiston, Jr⁵

Abstract

Background: National and international recommendations for the prevention of surgical site infection (SSI) were published six years ago, but little is known about implementation in colon surgeries.

Methods: We conducted an observational study to evaluate the implementation of seven SSI-prevention elements in colon surgeries. Study coordinators recorded the implementation using an electronic case report. Surgeons completed a survey that identified key drivers of implementation. Three peer-to-peer calls and a study coordinator survey provided insights on the obstacles and drivers to implementation.

Results: The elements ranged in compliance from 100% to below 1%. Absence of documentation in the electronic medical record (EMR), conflicting local policies, and a lack of standardization of processes and products were significant obstacles in implementation.

Discussion: Standardizing peri-operative procedures may be accomplished by implementing guidelines. Using implementation science to reduce variability and stocking leads to product standardization with items that support evidence-based practices. Administration, material management, and surgical leadership all have a duty to the patient to reduce obstacles to implement evidence-based practices.

Conclusions: Our study reveals variability in the integration of published guidelines into clinical practice. Every surgical patient deserves the best possible care by using evidence-based guidelines and practices centered on reducing SSIs.

Keywords: colorectal; guidelines; implementation; standardization; SSI; sutures

SURGICAL SITE INFECTION (SSI) after colorectal surgery is a common complication associated with poor outcomes, longer length of stays, and increased re-admissions.¹ Reports indicate that up to 55% of infections in patients who had colorectal surgery could have been prevented.^{2,3} In 2016, the World Health Organization (WHO)⁴ and the American College of Surgeons (ACS)⁵ published evidence-based guide-

lines to reduce and prevent SSIs. The following year, the U.S. Centers for Disease Control and Prevention (CDC) published their SSI-prevention guidelines.⁶

The use of published guidelines,⁵⁻⁹ standardized SSI definitions, and surveillance reporting¹⁰⁻¹³ demonstrate benefit in colorectal SSI reduction. However, implementing them poses challenges, as does sustaining new behaviors.¹⁴ Key

Colorectal Service Compliance Rates 7 Bundled Components

Skin Antisepsis	96.6-100%
Prophylaxis	96.6-100%
Antimicrobial sutures	52.2-100%
Glycemic control	18.7-82%
Normothermia	12.5-61.7%
Mechanical Bowel Prep + Oral Abx	6.5-38.2%
Increased Oxygen	6.1-22%

Medical News & Perspectives

It Takes an Average of 17 Years for Evidence to Change Practice— the Burgeoning Field of Implementation Science Seeks to Speed Things Up

Rita Rubin, MA



Colorectal cancer screening with an at-home stool test is more convenient than with a colonoscopy, but an abnormal result on the former still requires a follow-up with the latter.

However, studies have shown that in safety-net health care systems, only around half of patients with an abnormal at-home stool test result get a follow-up colonoscopy within a year. University of Washington gastroenterologist Rachel Issaka, MD, MAS, noted in an interview with *JAMA*.

Issaka, not surprisingly, would like to raise that proportion. To accomplish her goal, she needed to find out why people were skipping their follow-up colonoscopy and what might help change their behavior and, possibly, *save their life*.

So she turned to the relatively new field of implementation science.

Put simply, “implementation science is really trying to close that gap between what we know and what we do,” Issaka explained. Or, as the National Cancer Institute’s David Chambers, DPhil, described his field, “implementation science is about bringing the best possible care to everyone.”

Chasm might be a better word to describe the gap between research and practice. A frequently cited estimate puts that gap at 17 years on average, and even then, only 1 in 5 evidence-based interventions make it to routine clinical practice.

“To some degree, the interventions do vary greatly in terms of their complexity,” Chambers acknowledged in an interview. “Some interventions may be easier to administer.”

In historically marginalized populations, the evidence-to-practice gap is often even more yawning, said general internist Nathalie Moise, MD, MS, director of implementation science research at Columbia University’s Center for Behavioral Cardiovascular Health.

“The hope of implementation science is that we can synthesize what works for whom and for where and for what disease and close that 17-year gap,” Moise told *JAMA*.

Implementing and “Deimplementing”

Clinical psychologist Rinad Beidas, PhD, was puzzled when she saw children with anxiety who weren’t receiving the standard treatment of cognitive behavioral therapy. “Why aren’t clinicians in the community using evidence-based practices?”

But her “light bulb moment” came after the death of someone close to her by suicide with a firearm and the birth of her son. Beidas recalled in an interview. She was surprised that her child’s pediatrician never asked whether she had a firearm in her home and, if so, how it was stored, even though the American Academy of Pediatrics recommended that pediatricians do so.

Her personal experience led Beidas to become the principal investigator for the ASPIRE trial, which stands for Adolescent and Child Suicide Prevention in Routine Clinical Encounters.

The aim of the trial is to determine the most effective way to implement a National Institute of Mental Health-funded, evidence-based firearm storage program in pediatric primary care. Pediatricians are supposed to deliver the program, which is endorsed by the American Academy of Pediatrics, during well-child visits. Families receive counseling about preventing children from handling firearms without a parent’s permission and are offered a free cable lock for safe storage.

ASPIRE is just one example of how implementation science has been developing steadily in recent years, said Beidas, chair of the Department of Medical Social

“Knowing what to do,
does not ensure,
doing what we know,”

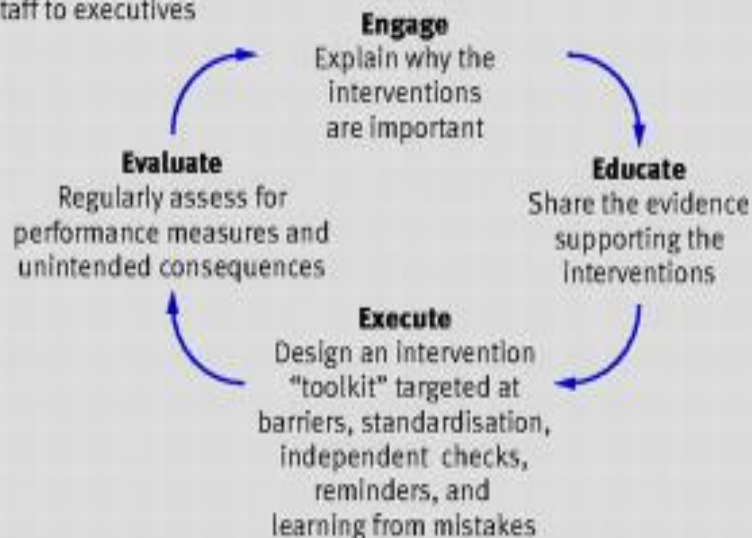
“Implementation
Science” – Closing
the Gaps

1. Summarise the evidence
Identify interventions associated with improved outcomes
Select interventions with the largest benefit and lowest barriers to use
Convert interventions to behaviours

2. Identify local barriers to implementation
Observe staff performing the interventions
"Walk the process" to identify defects in each step of implementation
Enlist all stakeholders to share concerns and identify potential gains and losses associated with implementation

3. Measure performance
Select measures (process or outcome)
Develop and pilot test measures
Measure baseline performance

4. Ensure all patients receive the interventions
Implement the "four Es" targeting key stakeholders from front line staff to executives



Overall concepts

Envision the problem within the larger healthcare system
Engage collaborative multidisciplinary teams centrally (stages 1-3) and locally (stage 4)

Everyone Needs To Be In The Loop!

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

- The efficacy of an evidence-based strategy to reduce the risk of SSI requires institutional compliance (quality) in which all healthcare professionals are engaged in the process and clear documentation of effort - The institution must have sufficient “skin in the game”
- All co-morbid pre, intra and postoperative risk must be considered when developing an effective mitigation strategy
- The cost of mitigation is always minuscule compared to the human and fiscal cost of a surgical site infection – In the case of wound closure: > 31 RCT/M-A documented triclosan (coated/impregnated) sutures as an effective 1A evidence-based risk-reduction strategy

Remember, our current surveillance strategies may miss 30-35% of postoperative infections – We can do better!

“SSI Prevention Is Not A Solo Recital But
Rather A Symphony And Our Evidence-
Based Interventions Are All Part Of That
Orchestra”

“So, When We Go Into The OR, Lets
Make Some Beautiful Music”