

The SSI Prevention Guidelines:

HICPAC's Method and Strengths

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Current SSI Burden

Burden-US

- 160,000 - 300,000 SSIs per year
- 2%-5% of patients undergoing inpatient surgery
- Most common and most costly HAI

Mortality

- 2-11 fold higher risk of death compared to non-infected operative patient
- 77% of deaths among SSI patients are directly attributable to SSI

Length of Hospital Stay

- ~7-11 additional postoperative hospital days

Cost

- Up to \$3.5 to 10 billion annually

Research

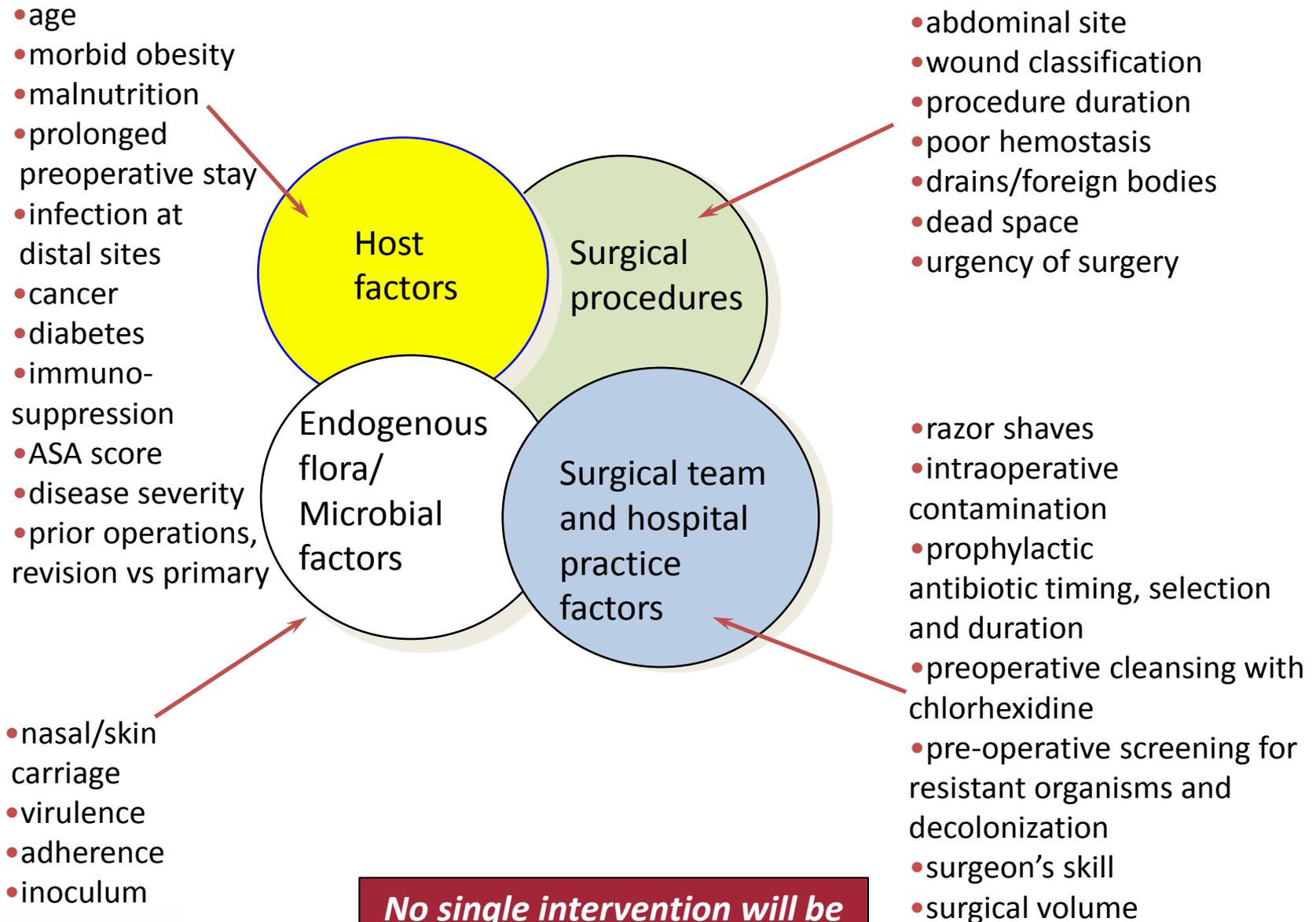
Original Investigation

Costs Associated With Surgical Site Infections in Veterans Affairs Hospitals

Marin L. Schweizer, PhD; Joseph J. Cullen, MD; Eli N. Perencevich, MD, MS; Mary S. Vaughan Sarrazin, PhD

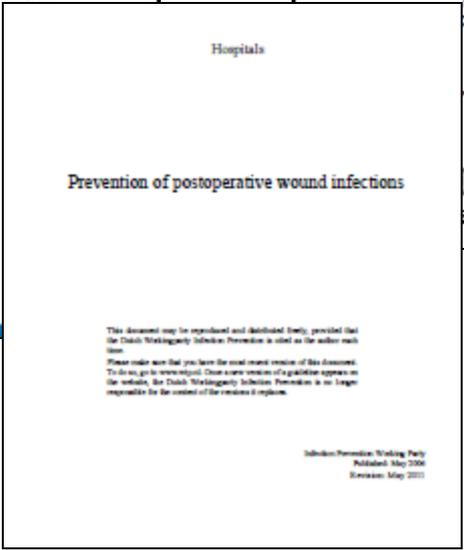
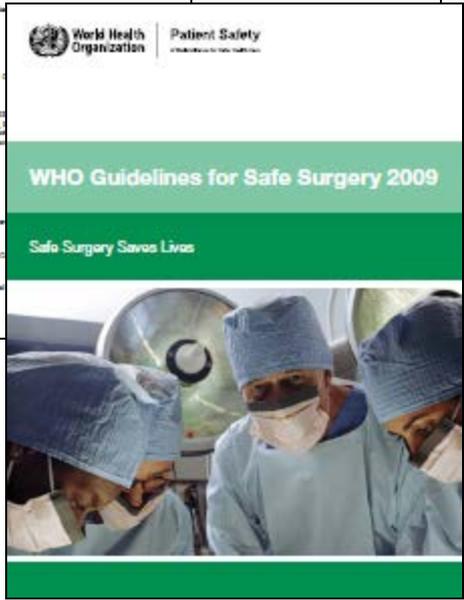
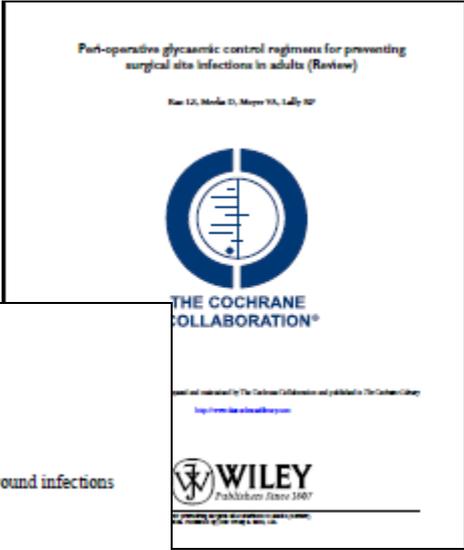
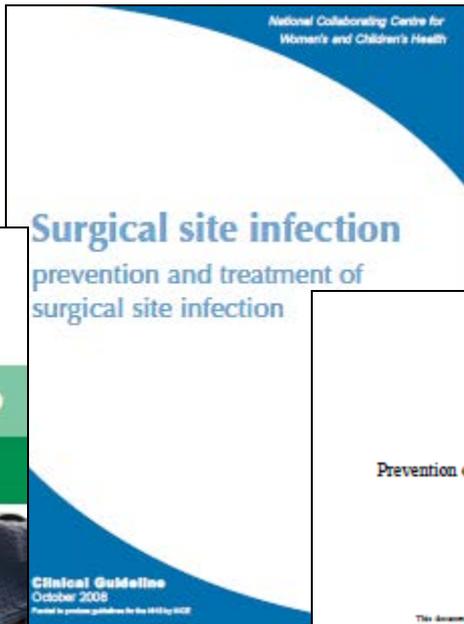
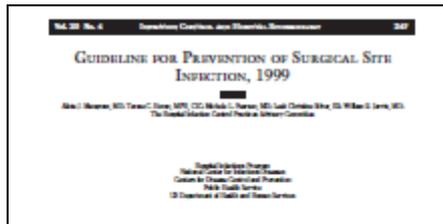
“The mean unadjusted costs were \$31,580 and \$52,620 for patients without and with an SSI, respectively. In the risk-adjusted analyses, the relative costs were 1.43 times greater for patients with an SSI than for patients without an SSI (95%CI, 1.34-1.52; difference, \$11,876). Deep SSIs were associated with 1.93 times greater costs (95% CI, 1.71-2.18; difference, \$25,721),.....”

Factors Affecting Rates of Surgical Site Infections



No single intervention will be sufficient to reduce SSI rates!

Prior HICPAC Guideline Published in 1999



Guideline for Prevention of Surgical Site Infection, 1999. http://www.cdc.gov/hicpac/pdf/guidelines/SSI_1999.pdf
 WHO Guidelines for Safe Surgery 2009. http://whqlibdoc.who.int/publications/2009/9789241598552_eng.pdf
 National Institute for Health and Clinical Excellence Surgical Site Infection: Prevention and Treatment of Surgical Site Infections
<http://www.nice.org.uk/nicemedia/pdf/CG74NICEGuideline.pdf>
 Netherlands Infection Prevention Working Party: Prevention of postoperative wound infections
http://www.wip.nl/UK/free_content/Richtlijnen/Prevention%20of%20postoperative%20wound%20infections%20.pdf
 Cochrane reviews (multiple) : <http://www.cochrane.org/>

Clinical Practice Guidelines for Antimicrobial Prophylaxis in Surgery

ASHP REPORT

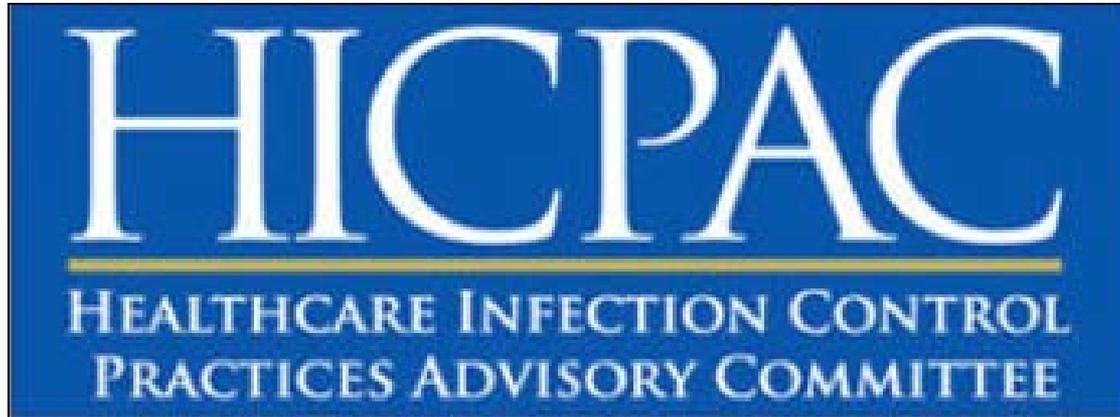
Clinical practice guidelines for antimicrobial prophylaxis in surgery

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

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



Surgical Infection Society



- Update of the 1999 HICPAC guideline on Prevention of Surgical Site Infections
 - Core section
 - Arthroplasty section
 - Effort started in 2011



Healthcare Infection Control Practices Advisory Committee (HICPAC)

HICPAC

About HICPAC

Member Roster

Charter

Event Calendar

Methodology Guideline

Publications

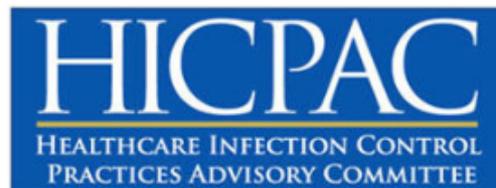
Proceedings & Presentations

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The Healthcare Infection Control Practices Advisory Committee (HICPAC) is a federal advisory committee assembled to provide advice and guidance to the Centers for Disease Control and Prevention (CDC) and the Secretary of the Department of Health and Human Services (HHS) regarding the practice of infection control and strategies for surveillance, prevention, and control of healthcare-associated infections, antimicrobial resistance and related events in United States healthcare settings. The primary activity of the Committee is to provide advice on periodic updating of existing CDC guidelines and development of new CDC guidelines. Additionally, this advice may take the form of resolutions or informal communications. [More...](#)



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Save the Date

HICPAC Teleconference:

Monday, May 11, 2015

Time: 2:00-3:00 pm Eastern Time

Bridgeline: 888-790-1864

Passcode: 5920580

[Agenda](#) [PDF - 280 KB]

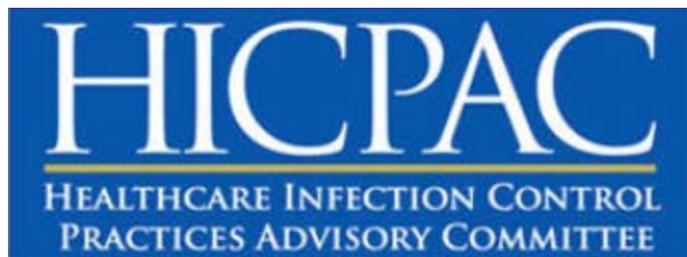
[Meeting materials](#) [PDF - 517 KB]

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BLOG

Join the conversation

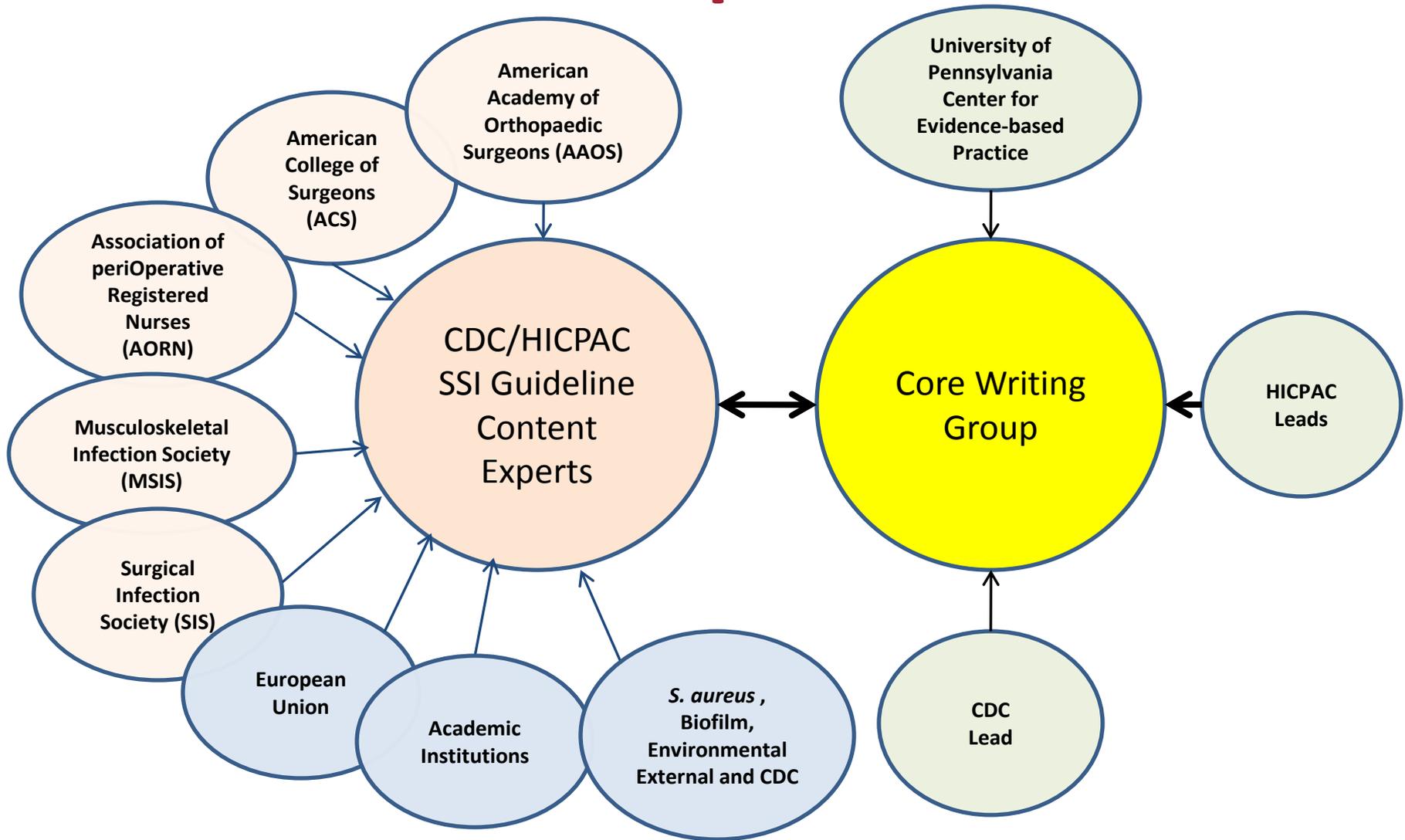
1 ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.



HICPAC is a federal advisory committee made up of 14 external infection control experts who provide advice and guidance to the Centers for Disease Control and Prevention (CDC) and the Secretary of the Department of Health and Human Services (HHS) regarding the practice of healthcare infection control, strategies for surveillance and prevention and control of healthcare associated infections in United States healthcare facilities. One of the primary functions of the committee is to issue recommendations for preventing and controlling healthcare associated infections in the form of guidelines, resolutions and informal communications.

Members are recommended by the CDC and appointed by the Secretary of Health and Human Services from experts in the fields of infectious diseases, healthcare-associated infections, nursing, surgery, epidemiology, public health, health outcomes and related areas of expertise.

Participants



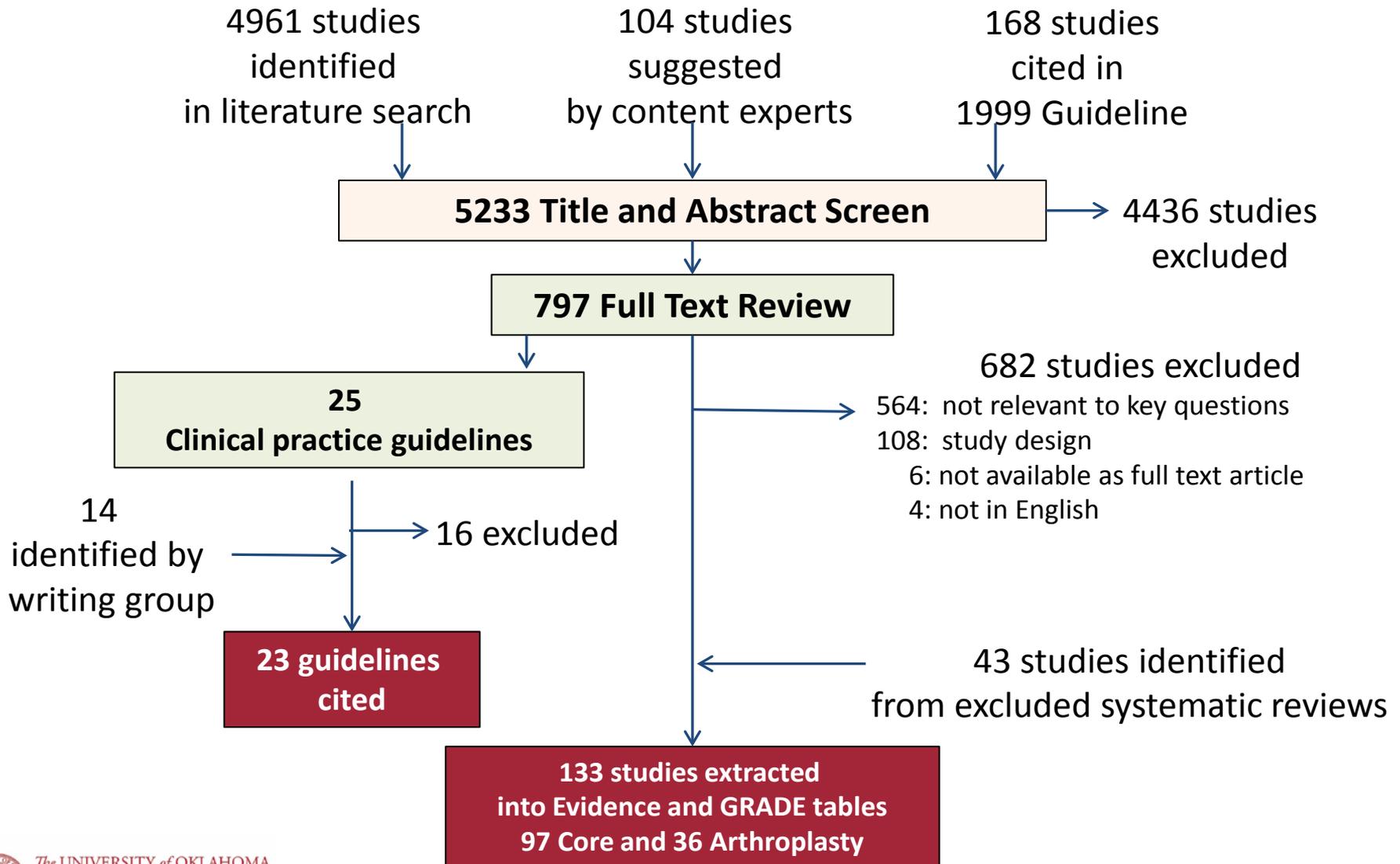
Methods for HICPAC Guidelines

- Identify potential topics within a guideline
- Develop key questions (more than 600 proposed for the SSI guideline)
- Do detailed literature reviews including
 - Title and abstract searches
 - Full text review by at least two authors
- Summarize findings, perform meta-analyses as needed, and Grade the evidence

Literature Search

- Searches are commonly performed in MEDLINE, EMBASE, CINAHL and Cochrane, and the resulting references are imported into reference management software, where duplicates can be resolved
 - Cochrane reviews ultimately included in guidelines are checked for updates prior to completion of the first guideline draft.

Study Selection Process – Round 1



Study Selection – Round 2

- Updated literature review
 - 500+ abstracts identified
 - 99 articles underwent full-text review by two authors (SBT, DWB)
 - 62 additional articles extracted into grade tables

Most of the new articles address use of triclosan-coated sutures, oxygenation, preoperative bathing, antibiotic duration, and antibiotic timing for C-section.

Full Data Abstraction

- Details including study author, year, design, quality, objective, population, setting, sample size, power, follow-up, and definitions and results of clinically relevant outcomes.
 - Also looked for reported adverse events
- In addition, we looked at industry sponsorship of trials to help ascertain publication bias

Grading the Evidence

Two components:

- Quality of body of evidence
 - extent to which confidence in estimate of effect adequate to support decision
- Strength of the recommendation
 - strong or weak

Grading the Evidence

Quality of the Body of Evidence

- **High**
 - We are very confident that the true effect lies close to that of the estimate of the effect.
- **Moderate**
 - We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
- **Low**
 - Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
- **Very low**
 - We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Grading the Evidence

| Type of evidence | Initial grade | Criteria to decrease grade | Criteria to increase grade | Overall quality grade |
|--|---------------|---|--|-----------------------|
| RCT | High | <u>Study quality limitations</u> Serious (-1) or very serious (-2) study quality limitations | <u>Strength of Association</u> Strong (+1) or very strong evidence of association (+2) | High |
| | | | | Moderate |
| Observational study | Low | <u>Inconsistency</u> Important inconsistency (-1) | <u>Dose-Response</u> Evidence of a dose-response gradient (+1) | Low |
| Any other evidence (e.g. expert opinion) | Very low | <u>Indirectness</u> Some (-1) or major (-2) uncertainty about directness <u>Imprecision</u> Imprecise or sparse data (-1) <u>Publication bias</u> High risk of bias (-1) | <u>Confounding</u> Inclusion of unmeasured confounders increases the magnitude of effect (+1) | Very Low |

| Comparison | Outcome | Quantity and Type of Evidence | Findings | Starting GRADE | Decrease GRADE | | | | | Increase GRADE | | | GRADE of Evidence for Outcome | Overall GRADE of Evidence Base |
|--|------------------------|-------------------------------|--|----------------|----------------|-------------|------------|-----------|------------------|-----------------|---------------|-------------|-------------------------------|--------------------------------|
| | | | | | Study Quality | Consistency | Directness | Precision | Publication Bias | Large Magnitude | Dose-response | Confounders | | |
| Q 1. What are the most effective strategies for administering intravenous antimicrobial prophylaxis (AMP) to reduce the risk of surgical site infections? | | | | | | | | | | | | | | |
| Q1.A. How does the timing of preoperative AMP impact the risk of surgical site infection and what is the optimal timing? | | | | | | | | | | | | | | |
| Cesarean section AMP Timing: Preoperative vs. at cord clamping | SSI-Endometritis* | 1 SR (2170) | <ul style="list-style-type: none"> N=749 Mothers from 3 RCTs (3097, 3124, 9704) all undergoing Cesarean section, overall RR: 0.47 (95%CI 0.26-0.85); P=0.012 indicating a 53% overall reduction in risk with preoperative administration | High | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | High | High |
| | SSI Incisional | 1 SR (2170) | <ul style="list-style-type: none"> N=149 mothers from 3 RCTS (3097, 3124, 9704) ann undergoing cesarean section, overall RR: 0.60 (95%CI 0.30-1.21); P=0.151 (2170)indicating trend toward reduction in risk with preoperative administration, though it is not statistically significant | High | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | High | |
| | Neonatal Sepsis | 1 SR (2170) | <ul style="list-style-type: none"> N=771 Neonates from 3 RCTs (3097, 3124, 9704) all delivered by Cesarean section, preoperative administration did not significantly affect proven neonatal sepsis- Overall RR: 0.93 (95%CI 0.45-1.96); P=0.86 (2170) (3097) In 1 RCT 13 cases of sepsis among 357 neonates did not show different causative organisms between groups or increased antimicrobial resistance | High | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | High | |
| | Neonatal Sepsis Workup | 1 SR (2170) | <ul style="list-style-type: none"> N=771 Neonates delivered by cesarean section from 3 RCTs, preoperative administration did not significantly affect suspected sepsis that required workup: Overall RR: 1 (95%CI 0.71-1.42); P=0.99 | High | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | High | |
| | NICU Admission | 1 SR (2170) | <ul style="list-style-type: none"> N=681 Neonates from 2 RCTs (3097, 3124) all delivered by Cesarean section, preoperative administration did not significantly affect NICU admission- Overall RR: 1.07 (95%CI 0.51-2.24); P=0.86 (2170) | High | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | High | |

Grade Table for every key question

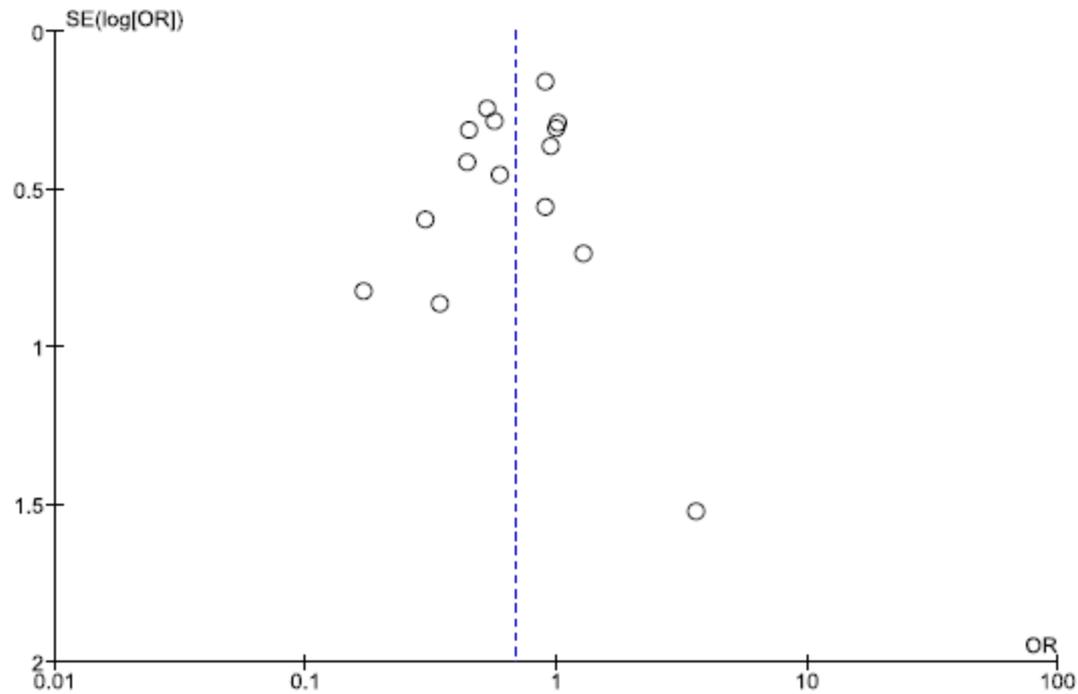
| Comparison | Outcome | Quantity and Type of Evidence | Findings | Starting GRADE | Decrease GRADE | | | | | Increase GRADE | | | GRADE of Evidence for Outcome | Overall GRADE of Evidence Base |
|---|------------------------------------|-------------------------------|--|----------------|----------------|-------------|------------|-----------|------------------|-----------------|---------------|-------------|-------------------------------|--------------------------------|
| | | | | | Study Quality | Consistency | Directness | Precision | Publication Bias | Large Magnitude | Dose-response | Confounders | | |
| Systemic Immunosuppressive Therapy: Biologic Agents (Non-Tumor Necrosis Factors [TNF] and Anti-TNFs) and Disease Modifying Antirheumatic Drugs-(DMARD) | | | | | | | | | | | | | | |
| Q18. How is the risk of SSI impacted by use of systemic corticosteroids or other immunosuppressive agents in arthroplasty patients? | | | | | | | | | | | | | | |
| Biologic-agents (non-TNF and anti-TNF) vs. DMARDs | SSI* | 2 OBS, (11035, 11004) | <ul style="list-style-type: none"> In meta-analysis of 2 OBS studies (N=528) , biologic agents were associated with a higher risk for SSI: OR: 5.90; 95% CI: 2.68 – 12.99; p<0.0001 (11035, 11004) In each of these studies, multivariate logistic regression analysis identified biologic agents as a significant risk factor SSI. | Low | 0 | 0 | 0 | 0 | 0 | 0 | +1 | 0 | Moderate | Very low |
| | PJI* | 2 OBS (11035, 11004) | <ul style="list-style-type: none"> In a meta-analysis of 2 OBS (N=528), biologic agents were not associated with a higher risk for PJI (OR: 3.59; 95% CI: 0.52 – 24.88; p=0.20) (11035) 3(0.7%) total organ/space SSIs among 420 RA patients undergoing THA or TKA: 1/48(2.08%) vs. 2/372(0.54%); p=0.27 (11004) 1/54(1.85%) vs. 0/54 (0%); p=0.50 | Low | 0 | 0 | 0 | -1 | 0 | 0 | 0 | 0 | Very low | |
| | Superficial SSI* | 2 OBS (11035, 11004) | <ul style="list-style-type: none"> In a meta-analysis of 2OBS (N=528), biologic agents associated with increased risk for superficial SSI (OR: 5.80; 95% CI: 2.55 – 13.18; p<0.0001) (11035) 24(5.7%) total superficial SSIs among 420 RA patients undergoing THA or TKA: 9/48 (18.75%) vs. 15/372(4.03%); p=0.0002 (11004) 7/54(12.96%) vs. 1/54(1.85%); p=0.06 | Low | 0 | 0 | 0 | 0 | 0 | +1 | 0 | 0 | Moderate | |
| | Adverse events of surgical wounds* | 1 OBS (13944) | <ul style="list-style-type: none"> 1 small study (N= 113): 2/39 (5.1%) vs. 5/74 (6.8%);OR 0.7459 (95%CI, 0.1380-4.0336);p=1.0000 (results include 4 ankle fusions) No difference on subanalysis (30 THAs and 65 TKAs- THA: none in either group; TKA: 4/51 (7.8%) vs. 1/14 (7.1%); OR 0.90 (95%CI, 0.09-8.80). 92.3% of all patients on biologic agents (infliximab and etanercept) were also on methotrexate (DMARD). | Low | 0 | 0 | 0 | -1 | 0 | 0 | 0 | 0 | Very low | |

Grade Table for every key question

Risk of Bias

- Concealment
- Blinding
 - patients, caregivers, data collectors, adjudicators of outcome, analysts
- completeness of follow-up
- analyze as randomized all patients with outcome of interest
- Sponsorship

Funnel Plots



Consistency

Judgment of consistency

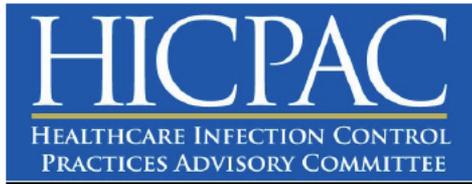
- – variation in size of effect
- – overlap in confidence intervals
- – statistical significance of heterogeneity
- – I^2 statistic (describes the percentage of variation across studies that is due to heterogeneity rather than chance)

Our Review of Meta-analyses

- Detailed review of each study in the meta-analysis
 - Specific attention to other factors known to influence rates of SSI (for example, systemic antimicrobial prophylaxis)
 - Evaluation of treatment and control groups – were they equal and were they treated the same way other than the intervention

Strength of Recommendations

- Degree of confidence that desirable effects of adhering to recommendation outweigh undesirable effects.
- Strong recommendation
 - benefits clearly outweigh risks/hassle/cost
 - risk/hassle/cost clearly outweighs benefit



Updating the Guideline Methodology of the Healthcare Infection Control Practices Advisory Committee (HICPAC)

Craig A. Umscheid, MD, MSCE ¹; Rajender K. Agarwal, MD, MPH ¹; and Patrick J. Brennan, MD ¹; for the Healthcare Infection Control Practices Advisory Committee (HICPAC) ²

¹ Center for Evidence-based Practice
University of Pennsylvania Health System
Philadelphia, PA



- **Category IA.** Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.
- **Category IB.** Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale; or an accepted practice (e.g., aseptic technique) supported by limited evidence.
- **Category IC.** Required by state or federal regulations, rules, or standards.
- **Category II.** Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale.
- **Unresolved issue.** Represents an unresolved issue for which evidence is insufficient or no consensus regarding efficacy exists.

Key Topics - Final

CORE

- ❑ Antimicrobial Prophylaxis
 - Topical antimicrobials/antiseptics
- ❑ Glycemic Control
- ❑ Normothermia
- ❑ Tissue Oxygenation
- ❑ Skin Preparation

ARTHROPLASTY

- ❑ Transfusion
- ❑ Immunosuppressive Therapy
- ❑ Anticoagulation
- ❑ Orthopedic exhaust (space) suits
- ❑ Antimicrobial prophylaxis duration with drains
- ❑ Biofilm

Disclaimer

- This guideline is not final
 - The discussion does not reflect the official position of the Centers for Disease Control and Prevention
 - The draft guideline will undergo CDC clearance
 - Expect the draft guideline to be published soon for additional public comment

Core Section

(Based on RCTs only)



Parenteral Antimicrobial Prophylaxis

- 1A. Administer preoperative antimicrobial agent(s) only when indicated, based on published clinical practice guidelines and timed such that a bactericidal concentration of the agent(s) is established in the serum and tissues when the incision is made (**Category IB**)
- 1B. Administer the appropriate parenteral prophylactic antimicrobial agent(s) prior to skin incision in all cesarean sections. (**Category IA**)
 - No further refinement of timing can be made for preoperative antimicrobial agent or administration relative to tourniquet inflation, based on clinical outcomes. (**No recommendation/unresolved issue**)

Antimicrobial Prophylaxis (cont)

- No recommendation can be made
 - Weight-adjusted dosing
 - Intraoperative redosing

(No recommendation/unresolved issue)

We did not identify randomized controlled trials (RCTs). Other organizations have made recommendations based on observational and pharmacologic studies.

Antibiotic Duration

- In clean and clean-contaminated procedures, do not administer additional prophylactic antimicrobial agent doses after the surgical incision is closed in the operating room, even in the presence of a drain. **(Category IA)**

Glucose control

- Implement perioperative glycemic control and use blood glucose target levels < 200 mg/dL in diabetic and non-diabetic surgical patients **(Category 1A)**
 - No recommendation can be made regarding the safety and effectiveness of lower or narrower blood glucose target levels and SSI. **(No Recommendation/unresolved issue)**
 - No recommendation can be made regarding hemoglobin A1C target levels and the risk of surgical site infection in diabetic and non-diabetic patients. **(No recommendation/unresolved issue)**

Normothermia

- Maintain perioperative normothermia **(Category 1A)**
 - No recommendation can be made regarding the safety or effectiveness of strategies to achieve and maintain normothermia, the lower limit of normothermia, or the optimal timing and duration of normothermia.

Other organizations have made recommendations based on existing evidence.

Oxygenation

- 6A. For patients with normal pulmonary function undergoing general anesthesia with endotracheal intubation, administer increased fraction of inspired oxygen (FiO₂) both intraoperatively and post-extubation in the immediate postoperative period. To optimize tissue oxygen delivery, maintain perioperative normothermia and adequate volume replacement. **(Category IA)**
 - 6B. RCT evidence suggests uncertain tradeoffs between benefits and harms regarding perioperative increased fraction of inspired oxygen (FiO₂) in patients with normal pulmonary function undergoing either general anesthesia without endotracheal intubation or neuraxial anesthesia (i.e., spinal, epidural, or local nerve blocks) for the prevention of surgical site infection. **(No recommendation/unresolved issue)**
 - 6C. RCT evidence suggests uncertain tradeoffs between benefits and harms regarding the administration of increased fraction of inspired oxygen (FiO₂) via facemask or nasal cannula during only the intraoperative period or the postoperative period for the prevention of surgical site infection in patients with normal pulmonary function. **(No recommendation/unresolved issue)**

Antiseptic Prophylaxis

- Advise patients to shower or bathe (full body) with either soap (antimicrobial or non-antimicrobial) or an antiseptic agent on at least the night before the operative day.
(Category 1B)
 - No recommendation can be made regarding the optimal timing of the preoperative shower or bath or the total number of soap or antiseptic agent applications for the prevention of surgical site infection. **(No recommendation/ unresolved issue)**

Antiseptic Prophylaxis

- Perform intraoperative skin preparation with an alcohol-based antiseptic agent, unless contraindicated. **(Category 1A)**
- Application of an antimicrobial sealant following intraoperative skin preparation is not necessary for the prevention of a surgical site infection. **(Category II)**
- Consider intraoperative irrigation of deep or subcutaneous tissues with aqueous iodophor solution (but not for contaminated or dirty abdominal procedures). **(Category II)**

No Recommendation/Unresolved Issues

- Weight-based antimicrobial dosing
- Intraoperative antimicrobial redosing
- Intraoperative antimicrobial irrigation
- Antimicrobial soaking of prosthetic devices
- Antimicrobial dressings applied to surgical incisions
- Optimal target for blood glucose control
- Value of the HbA1c for predicting SSI
- Best strategy for maintaining normothermia
- Oxygenation in non-endotracheal intubation surgery
- Best mechanism to deliver postoperative oxygen and the optimal FiO₂
- Optimal timing of preoperative bathing
- All of the orthopedic key questions except antimicrobial prophylaxis duration. No RCTs identified and only observational studies reviewed.

Still being evaluated..... ..triclosan-coated sutures

- **July 2013 draft:**
 - Do not use antimicrobial coated sutures for prevention of surgical site infection. (**Category IA**)
- **Mid-2014 Draft:**
 - RCT evidence suggests uncertain tradeoffs between the benefits and harms regarding the use of triclosan-coated sutures for superficial skin closure or for the use of sutures coated or impregnated with antimicrobials other than triclosan for any type of closure to prevent surgical site infection (**No Recommendation/Unresolved issue**)
- **After December 2014 HICPAC meeting:**
 - 2.C.1. Use triclosan-coated sutures for deep/fascial closure in colorectal surgery (**Category IA**)
 - 2.C.2. Consider triclosan-coated sutures for deep/fascial closure in surgical procedures other than colorectal surgery (**Category II**)
- **HICPAC meeting on 05/11/15:**
 - 2.C.1. Use triclosan coated sutures for deep and fascial closure if a triclosan-coated option is available for the suture appropriate to the surgery type and level of closure, and if triclosan is not contraindicated. (**Category IA**)

Strengths of the HICPAC Guideline Process

- Detailed methodology for extracting and grading evidence
- Open public process – draft recommendations published in the Federal Register
 - Meetings open to the public and time set aside for public comment
- Free of commercial influence

Challenges to the HICPAC Guideline Process

- Decision to limit SSI guideline (core section) to RCTs limited available literature to review
- Grading of the evidence can have some subjective elements
- Strength of recommendation
 - **Category IB.** Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale; or an accepted practice (e.g., aseptic technique) supported by limited evidence.
 - **Category II.** Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale.
 - **No recommendation/Unresolved issue** versus a specific recommendation against use (particularly if minimal harm)

Summary

- Look for a draft of the revised guideline to be open to public comment soon
 - Provide input
- Clearly a need for additional well-designed studies of many interventions deployed to reduce SSI

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