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

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Charles E. Edmiston, Jr., PhD, CIC, FIDSA, FSHEA, FAPIC
Emeritus Professor of Surgery
Medical College of Wisconsin
Milwaukee

Gwen Borlaug, MPH, CIC, FAPIC
Director, Healthcare-Associated Infections Prevention Program
Wisconsin Division of Public Health
Madison

Jeffrey P. Davis, MD, FIDSA
Chief Medical Officer and State Epidemiologist for Communicable Diseases
Wisconsin Division of Public Health
Madison

Jon C. Gould, MD, FACS (National Surgical Quality Improvement Program Champion)
Alonzo P. Walker Professor in General Surgery
Chief, Division of General Surgery
Medical College of Wisconsin
Milwaukee

Michael Roskos, MD, FACS (National Surgical Quality Improvement Program Champion)
General Surgery
Franciscan Healthcare in La Crosse - Mayo Clinic Health System
La Crosse

Gary R. Seabrook, MD, FACS (Perioperative Surgical Champion)
Professor and Chief, Division of Vascular Surgery
Medical College of Wisconsin
Senior Medical Director, Surgical Services
Froedtert Hospital
Milwaukee

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Introduction

Surgical site infections (SSIs) are the most frequently reported healthcare-associated infection (HAI) in Wisconsin, with more than 900 SSIs reported annually to the Wisconsin Division of Public Health (DPH) during 2013-2015. Approximately 1.5 percent of surgical procedures performed in Wisconsin are complicated by an SSI, and the Centers for Disease Control and Prevention (CDC) reports that mortality associated with SSIs is as high as 3 percent nationally. Furthermore, the fiscal burden of these adverse events can approach $10 billion annually in the United States.[1-5]

During May 2017, the CDC published the Healthcare Infection Control Practices Advisory Committee (HICPAC) Guidelines for the Prevention of SSIs (HICPAC SSI Prevention Guidelines), which is the first update since publication of the 1999 SSI prevention guidelines.[6] Because the evidence on which the HICPAC SSI Prevention Guidelines are based is limited to randomized controlled trials published prior to 2015, DPH determined that supplemental guidance incorporating current evidence-based data from well-designed laboratory studies, prospective cohort clinical studies, case-control studies, randomized controlled trials, systematic reviews, and meta-analyses was necessary to provide surgical teams with the most recent and relevant SSI prevention strategies available.

The 2017 Wisconsin Division of Public Health Supplemental Guidance for the Prevention of Surgical Site Infections: An Evidence-Based Perspective (WDPH SSI Prevention Guidance) was written by a statewide panel of content experts and was reviewed by three distinguished national and international surgical care experts. This guidance is intended to enhance, not replace, the HICPAC SSI Prevention Guidelines. DPH recommends that surgical teams follow the HICPAC SSI Prevention Guidelines, but the WDPH SSI Prevention Guidance supersedes the HICPAC SSI Prevention Guidelines in areas where the WDPH SSI Prevention Guidance provides stronger, more current evidence for certain SSI prevention interventions.

The HICPAC SSI Prevention Guidelines contain two sections. The Core Section describes recommendations that should be applied to all surgical procedures, and addresses six specific content areas: antimicrobial prophylaxis (AMP), non-parenteral antimicrobial prophylaxis, glycemic

control, normothermia, oxygenation, and antiseptic prophylaxis (Please note: For the purpose of clarity we have combined the non-parenteral antimicrobial prophylaxis and antiseptic prophylaxis section into a single table on page 12).

The Prosthetic Joint Arthroplasty Section contains additional recommendations for these frequently performed procedures that can result in SSIs causing significant human and economic burden. This section addresses blood transfusion, systemic immunosuppressive therapy, intra-articular corticosteroid injection, anticoagulation, orthopedic space suits, postoperative antimicrobial prophylaxis duration with drain use and biofilms.[6] Each topic in the two sections of the HICPAC SSI Prevention Guidelines was graded according to the strength of evidence described in the table below.

Table. CDC SSI Guidelines Evidence-Based Criteria Grade[7, 8]

Category IA	A strong recommendation supported by high- to moderate-quality evidence suggesting net clinical benefits or harms.
Category IB	A strong recommendation supported by low-quality evidence suggesting net clinical benefits or harms, or an accepted practice, supported by low- to very low-quality evidence.
Category IC	A strong recommendation required by state or federal regulation.
Category II	A weak recommendation supported by any quality evidence suggesting a tradeoff between clinical benefits and harms.
No recommendation/unresolved issue	An unresolved issue for which there is either low- to very low-quality evidence with uncertain tradeoffs between benefits and harms or no published evidence on outcomes deemed critical to weighing the risks and benefits of a given intervention.

The HICPAC SSI Prevention Guidelines and strength of evidence for each recommendation are included in this document, and are followed by the WDPH SSI Prevention Guidance with the corresponding evidence-based references validating the recommendations. The WDPH SSI Prevention Guidance also addresses the evidence supporting staphylococcal surveillance and decolonization, and implementation of a surgical care bundle. Neither of these topics is included in the CDC-HICPAC SSI Prevention Guidelines.

Introduction Citations

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Core Considerations

Interventions for all surgical procedures

Antimicrobial Prophylaxis

HICPAC SSI Prevention Guidelines	WDPH SSI Prevention Guidance
1. Administer preoperative antimicrobial agents only when indicated, based on published clinical practice guidelines (**Category 1B**).	1. No difference in guidance recommendation.
2. Administer the appropriate parenteral prophylactic antimicrobial agent prior to skin incision in all cesarean sections (**Category 1A**).	2. No difference in guidance recommendation.
3. No recommendation can be made regarding the safety and effectiveness of weight-based dosing of parenteral prophylactic agents to prevent surgical site infection (**No recommendation/unresolved issue**)	3. Follow the 2013 American Society of Health-System Pharmacists (ASHP) guidelines for antimicrobial prophylaxis in surgery.[9] Administer prophylactic antibiotic agents based on the patient's Body Mass Index (BMI) or the patient's weight in kilograms. For example, patients with a BMI <30 (or <120 kg) should receive 2 grams of a beta-lactam agent; patients with a BMI ≥ 30 (or ≥120 kg) should receive 3 grams.
4. No recommendation can be made regarding the safety and effectiveness of intraoperative re-dosing of parenteral prophylactic antimicrobial agents for the prevention of SSI (**No recommendation/unresolved issue**).	4. Base re-dosing of antibiotic agents on the drug half-life and duration of surgery.[9]
5. 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**).	5. No difference in guidance recommendation.

HICPAC SSI Prevention Guidelines	WDPH SSI Prevention Guidance
6. This issue not addressed.	6. Include preoperative oral antibiotics in combination with mechanical bowel preparations (OA-MBP) as a safe and effective adjunctive strategy for reducing the risk of infection following colorectal surgery. Current peer-reviewed evidence indicates that OA-MBP should be part of a comprehensive colorectal surgical care bundle. [10-14]

Antimicrobial Prophylaxis Citations

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Glycemic Control

HICPAC SSI Prevention Guidelines	WDPH SSI Prevention Guidance
1. Implement perioperative glycemic control and blood glucose target levels of <200 mg/dl in diabetic and non-diabetic surgical patients (**Category 1A**).	1. Maintain a mean perioperative blood glucose level <200 mg/dl in diabetic and non-diabetic surgical patients. [15,16]
2. No recommendation can be made regarding the safety and effectiveness of lower or narrower blood glucose target levels and SSI (**No recommendation/unresolved issue**).	2. Avoid increased risk of hypoglycemic events and increased mortality associated with tight glycemic control (81 to 108 mg/dl). [17,18]
3. No recommendation can be made regarding hemoglobin A1C target levels and risk of SSI in diabetic and non-diabetic patients (**No recommendation/unresolved issue**).	3. Maintain hemoglobin A1C level <6.7. This has been shown to minimize postoperative infectious complications in surgical patients.[19,20]

Glycemic Control Citations

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Normothermia

HICPAC SSI Prevention Guidelines	WDPH SSI Prevention Guidance
1. Maintain perioperative normothermia (**Category 1A**).	1. No difference in guidance recommendation.
2. 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 (**No recommendation/unresolved issue**).	2. Consider use of forced-air warming (FAW) to reduce incidence of SSIs. Based on 67 trials (45 of which were randomized controlled trials) with 5,438 participants, a Cochrane Collaboration found that FAW reduced incidence of SSIs and complications among patients undergoing abdominal surgery.[21] It was also beneficial in preventing major cardiovascular complications in patients with substantial cardiovascular disease.[21] It has been suggested that use of FAW in laminar air flow operating rooms during orthopedic procedures may pose a risk for intraoperative wound contamination, however, there are no definitive clinical studies suggesting that FAW increases the risk of postoperative surgical site infections.[22,23] Normothermia should be maintained in the preoperative, intraoperative and in the postoperative environment.[24]

Normothermia Citations

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Oxygenation

HICPAC SSI Prevention Guidelines	WDPH SSI Prevention Guidance
1. For patients with normal pulmonary function undergoing general anesthesia with endotracheal intubation, administer an increased fraction of inspired oxygen (FiO_2) during surgery and after extubation in the immediate postoperative period. To optimize tissue oxygen delivery, maintain perioperative normothermia and adequate volume replacement (**Category IA**).	1. No difference in guidance recommendation.
2. Randomized controlled trials suggest uncertain trade-offs between benefit and harm regarding the administration of FiO_2 via endotracheal intubation during only the intraoperative period in patients with normal pulmonary function undergoing general anesthesia for the prevention of SSI. (**No recommendation/ unresolved issue**).	2. Consider use of high oxygen supplementation as an SSI risk reduction strategy during colorectal procedures. The use of high oxygen supplementation as an SSI risk reduction strategy is controversial. However, oxygen supplementation (80% FiO_2) during the perioperative period has been documented to reduce the risk of SSI in patients undergoing colorectal surgeries.[25,26] In heterogeneous patient populations comprised of abdominal, gynecological, breast-related or bariatric patient populations, supplemental oxygen administration demonstrated no SSI reduction benefit. [27-29]
3. Randomized controlled trials suggest uncertain trade-offs between benefit and harm regarding the administration of increased FiO_2 via facemask during the perioperative period in patients with normal pulmonary function undergoing general anesthesia without endotracheal intubation or neuraxial anesthesia (i.e., spinal, epidural or local nerve blocks) for the prevention of SSI (**No recommendation/unresolved issue**).	
4. Randomized controlled trials suggest uncertain trade-offs between benefit and harm regarding the administration of increased FiO2 via facemask or nasal cannula during only the postoperative period in patients with normal pulmonary function for the prevention of SSI (No recommendation/unresolved issue).	
5. No recommendation can be made regarding the optimal target level, duration, and delivery method of FiO_2 for the prevention of SSI (**No recommendation/ unresolved issue**).	

Oxygenation Citations

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Antiseptic and Non-Parenteral Antimicrobial Prophylaxis

HICPAC SSI Prevention Guidelines	WDPH SSI Prevention Guidance
1. Perform intraoperative skin preparation with an alcohol-based antiseptic agent, unless contraindicated (**Category IA**).	1. Use 2% chlorhexidine gluconate (CHG) with 70% alcohol as the preferred intraoperative skin preparation agent. CHG is also a safe and effective antiseptic agent for obstetrical and gynecologic procedures.[30-32]
2. 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 IB**).	2. Ensure that all patients undergoing elective surgical procedures involving skin incisions undergo a standardized preadmission shower/cleansing with 4% aqueous or 2% (cloth coated) CHG.
3. Randomized controlled trials suggest uncertain trade-offs between benefit and harm regarding the optimal timing of the preoperative shower or bath, the total number of soap or antiseptic agent applications, or the use of chlorhexidine gluconate washcloths for the prevention of SSI (**No recommendation/ unresolved issue**).	3. Standardize the preadmission shower or cleansing process according to the protocols below. Recent randomized controlled trials have documented that high skin surface concentrations of CHG can be obtained by standardization of the preadmission shower or cleansing process using 4% aqueous chlorhexidine gluconate (CHG) or 2% CHG coated on a disposable polyester cloth.[33, 34] <u>4% Aqueous CHG Shower Protocol[33]</u> • Remind patients to perform the CHG shower regimen with a text message, email, or voicemail. • Provide patients with both oral and written instructions regarding the standardized CHG shower regimen. • Instruct patients to take two showers, one the evening before surgery, and one the morning of surgery. • Instruct patients to pause for one minute after applying the CHG and before rinsing. • Ensure patients use a total volume of 4 oz. of CHG for each shower. <u>2% CHG Polyester Cloth Cleansing[34]</u> • Remind patients to perform the CHG shower regimen with a text message, email, or voicemail. • Provide patients with both oral and written instructions regarding the standardized CHG cloth cleansing, emphasizing gentle application of the cloths to the skin.

HICPAC SSI Prevention Guidelines	WDPH SSI Prevention Guidance
	• Instruct patients to use a total of 12 cloths per cleansing—6 cloths the night before surgery, and another 6 cloths the morning of surgery. Ensure patients understand they should use both sides of the cloth to maximize release of the CHG onto the skin.
4. Consider intraoperative irrigation of deep or subcutaneous tissues with aqueous iodophor solution for the prevention of SSI. Intra-peritoneal lavage with aqueous iodophor solution in contaminated or dirty abdominal procedures is not necessary (**Category II**).	4. Consider use of intraoperative irrigation with aqueous 0.05% CHG. Current laboratory and animal studies suggest that aqueous 0.05% CHG is an effective intraoperative wound irrigation solution for reducing the risk of SSI. [35-38]
5. No recommendation can be made regarding the safety and effectiveness of soaking prosthetic devices in antiseptic solutions prior to implantation for the prevention of SSI (**No recommendation/unresolved issue**).	5. No difference in guidance recommendation.
6. Use of plastic adhesive drapes with or without antimicrobial properties is not necessary for the prevention of SSI (**Category II**).	6. No difference in guidance recommendation.
7. Application of microbial sealant immediately after intraoperative skin preparation is not necessary for the prevention of SSI (**Category II**).	7. No difference in guidance recommendation.
8. Evidence from randomized controlled trials was insufficient to evaluate the trade-offs between benefit and harm of repeat application of antiseptic agents to the patient's skin immediately before closing the surgical incision to prevent SSIs (**No recommendation/unresolved issue**).	8. No difference in guidance recommendation.
9. Consider use of triclosan-coated sutures to prevent SSIs **(Category II).**	9. Use triclosan-coated antimicrobial sutures to close surgical wounds. All surgical wounds are contaminated at the time of closure. The risk of infection is related to several comorbid factors, including presence of a foreign body (e.g., necrotic tissue, hematin and sutures) in the wound at closure. [39,40] Triclosan-coated sutures have been clinically shown to be safe for wound closure in adult and pediatric populations. [41-44] Triclosan-coated sutures are effective against both Gram-positive and Gram-negative surgical wound pathogens. [45,46] Several recent clinical trials, systematic reviews, and

HICPAC SSI Prevention Guidelines	WDPH SSI Prevention Guidance
	meta-analysis have determined that the use of triclosan antimicrobial sutures for closure of surgical wounds represents Category 1 clinical evidence in prevention of SSI. [47-52] Recommendations for the use of triclosan-coated sutures for wound closure are also included in the 2016 World Health Organization Global guidelines on the prevention of surgical site infection and the American College of Surgeons and Surgical Infection Society: Surgical Site Infection, 2016 Update. [53,54] Two recent meta-analyses and one clinical study have suggested that use of staples for wound closure is associated with an increased risk of wound complication, including infection in selective surgical disciplines (orthopedic and obstetrical). [55-57] Although further studies are warranted to validate this risk, clinicians should be aware of the current clinical findings when considering wound closure.
10. Do not apply antimicrobial agents (ointments, solutions or powders) to the surgical wound for the prevention of surgical site infection (**Category 1B**).	10. No difference in guidance recommendation.
11. Application of autologous platelet rich plasma is not necessary for the prevention of surgical site infection (**Category II**).	11. No difference in guidance recommendation.
12. Randomized controlled trials suggest uncertain trade-offs between benefit and harms regarding antimicrobial dressings applied to surgical incision after primary closure in the operating room for the prevention of surgical site infection (**No recommendation/unresolved issue**).	12. No difference in guidance recommendation.

Antiseptic and Non-Parenteral Antimicrobial Prophylaxis Citations

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Interventions for Prosthetic Joint Arthroplasty

HICPAC SSI Prevention Guidelines	WDPH SSI Prevention Guidance
1. Available evidence suggests uncertain trade-offs between benefit and harm of blood transfusions regarding the risk of SSI after prosthetic joint arthroplasty (**No recommendation/unresolved issue**).	1. No difference in guidance recommendation.
2. Do not withhold transfusion of necessary blood products from surgical patients as a means to prevent SSI (**Category IB**).	2. Balance the risk of complications from post-operative anemia with the potential increased risk of SSI following administration of blood products. Although some studies suggest that perioperative blood transfusion is associated with increased risk of SSI after selective pediatric and adult surgical procedures, this risk should be balanced with the undesirable complication of postoperative anemia. [58-65]
3. Available evidence suggests uncertain trade-offs between benefit and harm of systemic corticosteroid or other immunosuppressive therapy regarding the risk of SSI in prosthetic joint arthroplasty (**No recommendation/ unresolved issue**).	3. No difference in guidance recommendation.
4. Available evidence suggests uncertain trade-offs between benefit and harm of the use and timing of preoperative intra-articular corticosteroid injection regarding the incidence of SSI in prosthetic joint arthroplasty (**No recommendation/ unresolved issue**).	4. No difference in guidance recommendation. The concern that intra-articular steroid injection for postoperative pain management is a risk factor for SSI is at present controversial. However, the risk may be influenced by the presence of co-morbid risk factors; further studies are warranted. [66-68]
5. Available evidence suggests uncertain trade-offs between benefit and harm of venous thromboembolism prophylaxis regarding the incidence of SSI in prosthetic joint arthroplasty (**No recommendation/unresolved issue**).	5. No difference in guidance recommendation.
6. Available evidence suggests uncertain trade-offs between benefit and harm of orthopedic space suits or the health care personnel who should wear them for the prevention of SSI after prosthetic joint arthroplasty (**No recommendation/unresolved issue**).	6. No difference in guidance recommendation.

HICPAC SSI Prevention Guidelines	WDPH SSI Prevention Guidance
7. In prosthetic joint arthroplasty, 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**).	7. No difference in guidance recommendation.
8. Available evidence suggests uncertain trade-offs between benefit and harm regarding cement modifications and the prevention of biofilm formation or SSI in prosthetic joint arthroplasty (**No recommendation/ unresolved issue**).	8. No difference in guidance recommendation.
9. Literature reviews did not identify studies evaluating prosthesis modifications for the prevention of biofilm formation or SSI in prosthetic joint arthroplasty (**No recommendation/unresolved issue**).	9. No difference in guidance recommendation.
10. Literature reviews did not identify studies evaluating vaccines for the prevention of biofilm formation or SSI in prosthetic joint arthroplasty (**No recommendation/unresolved issue**).	10. No difference in guidance recommendation.
11. Literature reviews did not identify studies evaluating biofilm control agents such as biofilm dispersants, quorum-sensing inhibitors, or novel antimicrobial agents for the prevention of biofilm formation or SSI in prosthetic joint arthroplasty (**No recommendation/unresolved issue**).	11. No difference in guidance recommendation.

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General Comments Regarding Biofilms and SSIs

The global impact of SSIs on healthcare systems is considerable and it has been estimated that as many as 80 percent of SSIs may be related to the formation of a microbial biofilm.[69] Biofilm-mediated infections exhibit resistance to host defenses and often contribute to an excessive or inappropriate local inflammatory response. This leads to complement activation and formation of immune complexes, which in turn lead to tissue injury. [70-73] Unfortunately, the incidence of biofilm-associated SSIs is likely to increase because of the expanding use of implanted medical devices. Although investigators are currently focusing on biofilm-resistant polymers and other surface coatings that discourage microbial attachment, these efforts are in the initial stages and are unlikely to significantly alter SSI risk during the immediate future. Prevention of intraoperative contamination offers the greatest benefit for patients receiving an implantable medical device. Therefore, meticulous surgical technique, use of perioperative care bundles and awareness of the various possible avenues of intraoperative contamination that can occur at the time of implantation are rational strategies for improving surgical patient outcomes.

Finally, every institution should have specific policies and procedures in place for the management, sterilization, storage, and handling of biomedical devices prior to surgical implantation.

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Although staphylococcal surveillance and use of surgical care bundles are not included in the HICPAC SSI Prevention Guidelines, members of the WDPH SSI Prevention Expert Panel recommend these strategies in addition to the interventions described above, as part of a comprehensive surgical care improvement program.

Staphylococcal Surveillance

Results of several published studies suggest that suppression of the methicillin-sensitive *Staphylococcus aureus* (MSSA) and methicillin-resistant *S. aureus* (MRSA) carrier state is effective in reducing the occurrence of SSIs caused by these surgical wound pathogens.[74-79] Nasal mupirocin (twice daily for 5 to 7 days) with a minimum of two 4% aqueous CHG showers has been widely used for the suppression of nasal carriage of MSSA and MRSA. Although mupirocin has been viewed as the ‘‘gold standard’’ for suppressing staphylococci in the nares, the suppression of organisms in the nares on the morning of surgery using a swab coated with 5% or 10% povidone iodine (0.5% available iodine) has been shown to be an effective alternative.[80-82] Considering the current evidence-based literature, the following are justified:

a. Selection of an efficacious (risk-reducing, cost effective) active screening strategy should be based on the relative risk of MSSA or MRSA healthcare-associated infections among “at risk” surgical patients.
b. In the absence of targeted or universal screening, routine topical mupirocin or systemic antimicrobial agents is not currently recommended for the suppression of MSSA or MRSA carriage among surgical patients.
c. In the case of targeted screening, preoperative suppression may be considered for MSSA and MRSA colonized patients undergoing “at risk” surgical procedures, such as cardiovascular and vascular procedures with implantation of prosthetic grafts and orthopedic total joint procedures. The benefit of targeted screening and preoperative suppression in other device-related surgical procedures (i.e., implantation of neurosurgical hardware, hernia repair with mesh, etc.) is unknown and currently not supported by data.

d. Although the optimal suppression regimen is unclear, the following is recommended: a standardized regimen of topical nasal mupirocin (twice a day for 5-7 days) or an alternative approach involving the use of a nasal swab containing 5% or 10% povidone iodine applied to the nares 1 to 2 hours prior to surgery, along with a 2% or 4% chlorhexidine gluconate body cleansing/shower (once a day for 2 days) prior to surgical admission.

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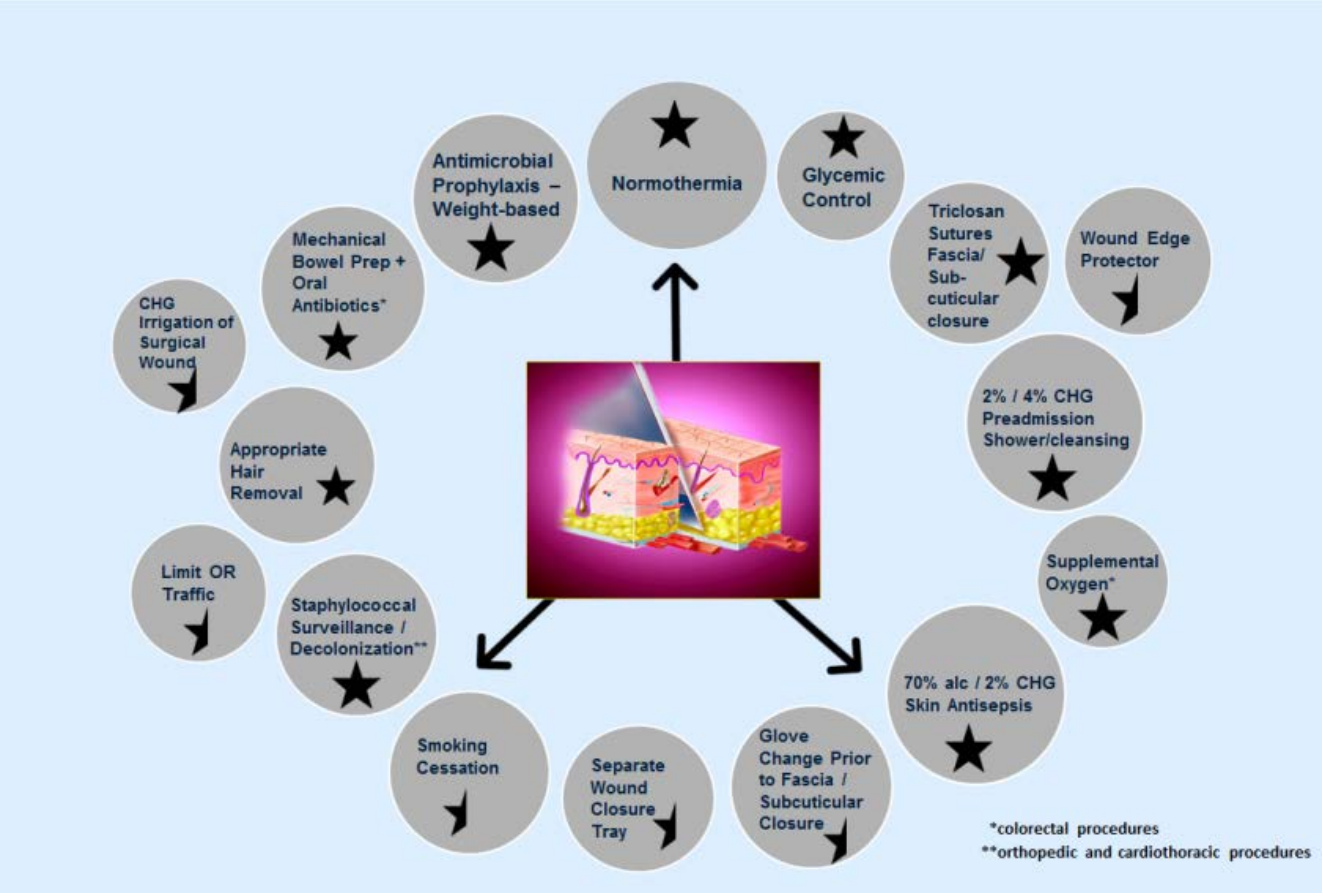
Surgical Care Bundles (SCB)

Recent peer-reviewed literature has documented the benefit of combining selective evidence-based interventional practices to form a comprehensive surgical care bundle for reducing the risk of postoperative infections. Surgical care bundles have been developed for colorectal, cardiothoracic, OB/GYN, vascular, and orthopedic procedures.[83-91] SCBs should be developed in collaboration with the surgical team (surgeons and OR nursing), infection preventionists and pharmacy personnel. Implementation of a SCB requires close monitoring to ensure 100 percent compliance, because poor compliance diminishes the preventive benefits of the SCB. [92]

Elements of the SCB with the strongest evidence are indicated with a full star in the figure below, and should be of first consideration when prioritizing surgical care process improvement activities.

Figure. Selective elements of the surgical care bundle from the evidence-based literature[83-91]



★ SSI risk reduction strategy fully vetted in peer-reviewed literature and documented as a crucial component of the SCB

★ SSI risk reduction strategy supported by less robust data, but should be considered in further development of an SCB

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