## The Objective

Prevent healthcare-associated surgical-site infections (SSIs).

## The Problem

Traditional infection control programs are directionally correct, but insufficient to enable organizations to "chase zero" and reduce the harm of preventable healthcare-associated infections (HAIs). [Denham, 2009a; Denham, 2009b] Certifying, purchasing, and quality organizations agree that such departments need to be restructured and integrated into performance improvement programs. [Denham, 2009c] It is estimated that nearly 2 million patients experience a healthcare-associated infection each year; of these infections, 22 percent are SSIs. [Klevens, 2007] SSIs are infections that occur within 30 days after an operation and can involve the skin, subcutaneous tissue of incision, fascia, muscular layer, or the organ or surrounding space.

SSIs have the second highest frequency of any adverse event occurring in hospitalized patients and are the third most common health-care-associated infection (HAI). Approximately 500,000 SSIs occur each year in 2 to 5 percent of patients undergoing inpatient surgeries. [Anderson, 2008] Estimated rates for operative wound classifications are as follows: clean contaminated cases 3.3 percent, contaminated cases 6 percent, and dirty cases 7.1 percent. The national rate of SSI averages between 2 and 3 percent for clean cases, and an estimated 40 to 60 percent of these infections are preventable. [Kirkland, 1999; de Lissovoy, 2009]

The severity of SSI harm to patients is significant, resulting in increased mortality, readmission rate, length of hospital stay, and cost for patients who incur them. [Levinson, 2008] Each SSI is associated with an average of 9.7 additional postoperative hospital days. [Cruse, 1980; Cruse, 1981; de Lissovoy, 2009] According to the American Heart Association, approximately 700,000 open-heart procedures are performed each year in the United States; more than 67 percent of those are coronary artery bypass grafts (CABG). Mediastinitis can occur after an open-heart surgical procedure with rates of between 0.5 and 5.0 percent, with a mortality rate as high as 40 percent. In 2006, 2.7 percent of Medicare patients acquired postoperative pneumonia or a thromboembolic event. [AHRQ, 2009b] Patients with SSI have a 2 to 11 times higher risk of death

compared to operative patients without SSI. [Kirkland, 1999; Engemann, 2003] Approximately 8,205 patients die from an SSI each year. [Klevens, 2007] Seventy-seven percent of deaths in patients with an SSI are directly attributable to the infection. [Mangram, 1999]

The preventability of SSIs has been studied, and guidelines and recommendations for their prevention have been published by multiple professional organizations; the key recommended practices are consistent among them. [Anderson, 2008; WHO, 2008; WHO, 2009] These include: 1) proper selection and administration of antimicrobial prophylaxis, as well as timely discontinuation postoperatively; [Mangram, 1999; Bratzler, 2004; Bratzler, 2006; Kirby, 2009; Pan, 2009; Quinn, 2009] 2) avoidance of hair removal at the operative site, unless the presence of hair will interfere with the operation; [Mangram, 1999] and 3) maintaining blood glucose level at less than 200 mg/dL in patients undergoing cardiac surgeries. [Bratzler, 2006] The use of specific skin preparation solutions has been shown to reduce SSI by 40 percent. [Darouiche, 2008; Darouiche, 2010] Surveillance for SSI should be performed, and ongoing findings and feedback should be communicated to surgical personnel and organizational leadership. [Anderson, 2008]

Costs of SSIs vary depending on the type of operative procedure and the type of infecting pathogen; published estimates range from $3,000 to $29,000. [Coello, 1993; Vegas, 1993; Kirkland, 1999; Hollenbeak, 2000] However, the recent Pennsylvania Health Care Cost Containment Council found that the median cost of an SSI was $153,132, compared to a hospital stay with no infection of $33,260, resulting in an increased cost per patient of $119,872. [PHC4, 2008] Using the consumer price index for inpatient hospital services, the aggregate attributable hospital costs due to SSI range from $11,874 to $34,670 in 2007 dollars. [Scott, 2009] Using the 2005 Healthcare Cost and Utilization Project National Inpatient Sample (HCUP NIS) database, 6,891 cases of SSI were identified. On average, SSI extended the length of stay by 9.7 days, with an increase in cost of $20,842 per admission. Nationally, these SSI cases contributed to an additional 406,730 hospital days and hospital costs exceeding $900 million. Readmissions of 91,613 patients for treatment of SSI accounted for 521,933 days at a cost of nearly $700 million. [de Lissovoy, 2009] Sub-classifying analysis of SSIs into superficial incisional, deep

incisional, and organ/space categories will provide better precision in cost forecasting and a reality check to performance improvement cost-benefit assessments. [Anderson, 2008]

Beginning October 1, 2008, the Centers for Medicare & Medicaid Services (CMS) has selected SSIs, including mediastinitis after CABG; certain orthopedic procedures (spine, neck, shoulder, elbow); and bariatric surgery for obesity (laparoscopic gastric bypass, gastroenterostomy, laparoscopic gastric restrictive surgery); as hospital-acquired conditions that will no longer receive a higher reimbursement when not present on admission. [CMS/HAC, 2008]

There is intense research of HAIs, and it will take time to understand the absolute magnitude of preventability and the value of risk assessment methods; however, there is full consensus that actions need to be taken now to reduce SSIs with what is currently known. [Denham, 2005; Denham, 2009d]

## Safe Practice Statement

Take actions to prevent surgical-site infections by implementing evidence-based intervention practices. [Mangram, 1999; WHO, 2008; IHI, 2009b; JCR, 2010]

## Additional Specifications

- Document the education of healthcare professionals, including nurses and physicians, involved in surgical procedures about healthcare-acquired infections, surgical-site infections (SSIs), and the importance of prevention. Education occurs upon hire and annually thereafter, and when involvement in surgical procedures is added to an individual's job responsibilities. [Bratzler, 2004; Bratzler, 2006; TMIT, 2008; Chatzizacharias, 2009; Rosenthal, 2009]
- Prior to all surgical procedures, educate the patient and his or her family as appropriate about SSI prevention. [Torpy, 2005; Schweon, 2006]
- Implement policies and practices that are aimed at reducing the risk of SSI that meet regulatory requirements, and that are aligned with evidence-based standards (e.g., CDC and/or professional organization guidelines). [Mangram, 1999; Dellinger, 2005; Bratzler, 2006; Anderson, 2008; WHO, 2009]

- Conduct periodic risk assessments for SSI, select SSI measures using best practices or evidence-based guidelines, monitor compliance with best practices or evidence-based guidelines, and evaluate the effectiveness of prevention efforts. [Bratzler, 2006]
- Ensure that measurement strategies follow evidence-based guidelines, and that SSI rates are measured for the first 30 days following procedures that do not involve the insertion of implantable devices, and for the first year following procedures that involve the insertion of implantable devices. [Horan, 1992; Biscione, 2009]
- Provide SSI rate data and prevention outcome measures to key stakeholders, including senior leadership, licensed independent practitioners, nursing staff, and other clinicians. [Mangram, 1999]
- Administer antimicrobial agents for prophylaxis with a particular procedure or disease according to evidence-based standards and guidelines for best practices. [ASHP, 1999; Mangram, 1999; Antimicrobial, 2001; IHI, 2009a]
  - Administer intravenous antimicrobial prophylaxis within one hour before incision to maximize tissue concentration (two hours are allowed for the administration of vancomycin and fluoroquinolones). [Bratzler, 2004; Bratzler, 2006]
  - Discontinue the prophylactic antimicrobial agent within 24 hours after surgery (within 48 hours is allowable for cardiothoracic procedures). [Bratzler, 2004; Bratzler, 2006]
- When hair removal is necessary, use clippers or depilatories. Note: Shaving is an inappropriate hair removal method. [Mangram, 1999]
- Maintain normothermia (temperature >36.0°C) immediately following colorectal surgery. [Kurz, 1996]
- Control blood glucose during the immediate postoperative period for cardiac surgery patients. [Bratzler, 2006; Dronge, 2006; Kao, 2009]
- **Preoperatively, use chlorhexidine gluconate 2% and isopropyl alcohol solution as skin antiseptic preparation, and allow appropriate drying time per product guidelines.** [Darouiche, 2008; Darouiche, 2010]

## Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services (CMS) care settings, to include ambulatory surgical center and inpatient service/hospital.

## Example Implementation Approaches

- Perform expanded SSI surveillance to determine the source and extent of high SSI rates despite implementation of basic SSI prevention strategies. Consider expanding surveillance to include additional procedures, and possibly all National Healthcare Safety Network (NHSN) procedures. [Mangram, 1999]
- Implementation of the WHO 19-item surgical safety checklist has been estimated to save the lives of 1 in 144 surgical patients. [Haynes, 2009]
- Hospitals that have been successful in reducing SSIs have incorporated some, if not all, of the following elements as part of their prevention strategies and approaches: [Graf, 2009]
  - Appropriate and timely use of prophylactic antibiotics. [AHRQ, 2009a; AHRQ, 2009b; Pan, 2009; Ryckman, 2009]
  - Identify and treat all infections remote to the surgical site before elective surgery, and postpone elective surgeries until the infection has resolved.
  - Utilize mechanical and intraluminal antibiotic bowel preparation for patients undergoing elective colorectal surgery, as appropriate per patient clinical case. The literature is evolving and patients should be treated according to the latest evidence based practices. [Wille-Jørgensen, 2005; Guenaga, 2009; Howard, 2009; Slim, 2009]
  - Administer a prophylactic antimicrobial agent to patients, based on published guidelines and recommendations targeting the most common pathogens for the planned procedure.
  - Give appropriate weight-based guideline antibiotic dosing.
  - Ensure optimal antibiotic concentration by redosing based on antimicrobial agent half-life and length of procedure.
  - Utilize an intravenous route to administer prophylactic antimicrobial agents and antibiotics so that a bactericidal concentration is established in serum and tissues

when the incision is made (except for cesarean delivery, when antibiotics should be administered after cord clamp).

1. Give an intraoperative dose of antibiotic as indicated based on pharmacokinetics of the antibiotic and length of the surgical procedure.
2. If a cuff or tourniquet is used, fully infuse the antibiotic prior to inflation.
3. Use preprinted or computerized standing orders that specify antibiotic, timing, dose, and discontinuation.
4. Change operating room drug stocks to include only standard doses and standard drugs that reflect national guidelines.
5. Assign antibiotic dosing responsibilities to the anesthesia or holding area nurse to improve timeliness.
6. Use visible reminders, checklists, and stickers.
7. Involve pharmacy, infection control, and infectious disease staff to ensure appropriate selection, timing, and duration.

- Appropriate hair removal:
  - Remove hair from the incision site only if the hair interferes with the operation.
  - Educate patients not to shave themselves preoperatively. [Pan, 2009]
- Appropriate skin preparation:
  - Chlorhexidine gluconate 2% skin solutions have been shown to be more effective than iodine in reducing SSI. [Darouiche, 2008; Eiselt, 2009; Darouiche, 2010]
- Maintenance of postoperative glucose control:
  - Implement a glucose control protocol.
  - Regularly check preoperative blood glucose levels on all patients.
  - Assign responsibility and accountability for blood glucose monitoring and control.
- Establish postoperative normothermia, and maintain perioperative euthermia, based on the constellation of benefits beyond SSI for colorectal surgery patients.
  - Use warmed forced-air blankets preoperatively, during surgery, and in the post-anesthesia care unit (PACU).

- Increase the ambient temperature in the operating room.
- Use warming blankets under patients on the operating table.
- Use hats and booties on patients perioperatively.

## Strategies of Progressive Organizations

- Some organizations advocate maintaining perioperative glucose at specific target levels for patients with Type 1 Diabetes and for those who have Type 2 Diabetes with insulin deficiency.
- Establish implementation of perioperative supplemental oxygen therapy. [Casey, 2009; Qadan, 2009]

## Opportunities for Patient and Family Involvement [Denham, 2008; SHEA, N.D.]

- Consider including patients or families of patients who have experienced an SSI to serve on appropriate patient safety or performance improvement committees.
- Teach patients and families the proper care of the surgical site, as well as precautions for preventing infection.
- Teach patients and families to recognize the signs and symptoms of infection.
- Encourage patients to report changes in their surgical site or any new discomfort.
- Encourage patients and family members to make sure that doctors and nurses check the site every day for signs of infection.
- Invite patients to ask staff if they have washed their hands prior to treatment.
- Encourage patients and family members to ask questions before a surgical procedure is performed.

## Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts, and may not necessarily all address external reporting needs.

- **Outcome Measures** include trending the rate of SSIs per procedure over time and reporting SSIs as part of a multicenter registry, for example, NHSN. [NHSN, N.D.]

Also consider trending operational and financial outcomes associated with reduction in SSI patient complications. Use NHSN definitions where appropriate. [NHSN, N.D.]

- National Quality Forum (NQF)-endorsed® outcome measures:
  1. #0130: Deep Sternal Wound Infection Rate [Hospital]: Percent of patients undergoing isolated CABG who developed deep sternal wound infection within 30 days post-operatively.
  2. #0299: Surgical-site infection rate [Hospital]: Percentage of surgical site infections occurring within thirty days after the operative procedure if no implant is left in place or with one year if an implant is in place in patients who had an NHSN operative procedure performed during a specified time period and the infection appears to be related to the operative procedure.
  3. #0450: Postoperative DVT or PE: Percent of adult surgical discharges with a secondary diagnosis code of deep vein thrombosis or pulmonary embolism.

- **Process Measures** include periodic assessment of compliance with all components of the prevention bundle, with actions to mitigate performance gaps.
  - NQF-endorsed® process measures:
    1. #0125: Timing of Antibiotic Prophylaxis for Cardiac Surgery Patients [Hospital]: Percent of patients undergoing cardiac surgery who received prophylactic antibiotics within one hour prior to of surgical incision (two hours if receiving vancomycin).
    2. #0126: Selection of Antibiotic Prophylaxis for Cardiac Surgery Patients [Hospital]: Percent of patients undergoing cardiac surgery who received prophylactic antibiotics recommended for the operation.
    3. #0128: Duration of Prophylaxis for Cardiac Surgery Patients [Hospital]: Percent of patients undergoing cardiac surgery whose prophylactic antibiotics were discontinued within 24 hours after surgery end time.
    4. #0264: Prophylactic Intravenous (IV) Antibiotic Timing [Hospital, Ambulatory Surgical Centers]: Percentage of ASC patients who received IV antibiotics ordered for surgical site infection prophylaxis on time.

5. #0269: Timing of Prophylactic Antibiotics - Administering Physician [Hospital, Ambulatory Surgical Centers]: Percentage of surgical patients aged > 18 years with indications for prophylactic parenteral antibiotics for whom administration of the antibiotic has been initiated within one hour (if vancomycin, two hours) prior to the surgical incision or start of procedure when no incision is required.
6. #0270: Timing of Antibiotic Prophylaxis: Ordering Physician [Hospital, Ambulatory Surgical Centers]: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics, who have an order for prophylactic antibiotic to be given within one hour (if fluoroquinolone or vancomycin, two hours), prior to the surgical incision (or start of procedure when no incision is required).
7. #0271: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures) [Hospital, Ambulatory Surgical Centers]: Percentage of non- cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic antibiotics AND who received a prophylactic antibiotic, who have an order for discontinuation of prophylactic antibiotics within 24 hours of surgical end time.
8. #0472: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision or at the Time of Delivery – Cesarean section [Hospital]: Percentage of patients undergoing cesarean section who receive prophylactic antibiotics within one hour prior to surgical incision or at the time of delivery.
9. #0527: Prophylactic antibiotic received within 1 hour prior to surgical incision SCIP-Inf-2.
10. #0528: Prophylactic antibiotic selection for surgical patients.
11. #0529: Prophylactic antibiotics discontinued within 24 hours after surgery end time.
12. #0301: Surgery patients with appropriate hair removal [Hospital]: Percentage of surgery patients with surgical hair site removal with clippers or depilatory or no surgical site hair removal.

13. #0515: Ambulatory surgery patients with appropriate method of hair removal [Ambulatory Care (office/clinic)]: Percentage of ASC admissions with appropriate surgical site hair removal.
14. #0300: Cardiac surgery patients with controlled 6 A.M. postoperative serum glucose: Percentage of cardiac surgery patients with controlled 6 A.M. serum glucose (</=200 mg/dl) on postoperative day (POD) 1 and POD 2.
15. #0452: Surgery patients with perioperative temperature management: Surgery patients for whom either active warming was used intraoperatively for the purpose of maintaining normothermia, or who had at least one body temperature equal to or greater than 96.8° F/36° C recorded within the 30 minutes immediately prior to or the 15 minutes immediately after anesthesia end time.
16. #0218: Surgery patients who received appropriate VTE prophylaxis within 24 hours prior to surgery to 24 hours after surgery end time: Percentage of surgery patients who received appropriate Venous Thromboembolism (VTE) Prophylaxis within 24 hours prior to surgery to 24 hours after surgery end time.
17. #0239: Venous Thromboembolism (VTE) Prophylaxis [Hospital]: Percentage of patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.
18. #0371: Venous Thromboembolism (VTE) Prophylaxis [Hospital]: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission.
19. #0372: Intensive Care Unit (ICU) VTE Prophylaxis [Hospital]: This measure assesses the number of patients who received VTE prophylaxis or have

documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer).

20. #0376: Incidence of Potentially Preventable VTE [Hospital]: This measure assesses the number of patients diagnosed with confirmed VTE during hospitalization (not present on arrival) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date.

- **Structure Measures** include verification that monitoring documentation incorporates the identification, stratification, and trending of specific risk factors of patients who have developed a SSI to determine the success of mitigation strategies.
- **Patient-Centered Measures** include evidence of education about the patient's role in perioperative infection risk reduction.

## Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural settings where invasive procedures are performed.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings where invasive procedures are performed.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty settings where invasive procedures are performed.

## New Horizons and Areas for Research

Further research is required to discern the optimal timing and use of antibiotics for specific patient profiles; the effectiveness of preoperative bathing with chlorhexidine-containing products; [Miller, 1996; Perl, 2002; Wilcox, 2003; Kallen, 2005; Nicholson, 2005] the effectiveness of routine screening for MRSA [Gould, 2009; Yano, 2009] and routine attempts to decolonize surgical patients with an antistaphylococcal agent in the preoperative setting; best strategies and evidence for maintaining oxygenation with supplemental oxygen during and following colorectal procedures; [Al-Niaimi, 2009;

Casey, 2009; Qadan, 2009] and the validity of preoperative intranasal and pharyngeal chlorhexidine treatment for patients undergoing cardiothoracic procedures. [Segers, 2006] Some organizations have learned from other industries, such as the food industry, and explored increasing the vigilance of environmental cleaning of high-contact surfaces in patient rooms, such as television remote control devices, and operating room equipment and devices, such as pulse oximeters that are shared or used across multiple patients. Other environmental design issues may have real importance to reducing preventable infections in the future. National harmonization efforts are being undertaken to optimize safety during the pre-operative, intra-operative, and post-operative periods, broadening the scope of a systematic approach to safe care of the surgical patient. [NPP, 2009]

## Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Safe Practice 19: Hand Hygiene, is the cornerstone of an organization's infection control program. Implementing Safe Practice 24: Multidrug-Resistant Organism Prevention, will also reduce infections by using standard evidence-based practice prevention.

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| **KEYWORDS for PubMed search** | **"surgical-site infection"; "surgical site infection"; 2009** |


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## Summary of Evidence:

**CDC Guidelines.** The 1999 CDC Guideline for Prevention of Surgical Site Infection speaks to chlorhexidine and povidone-iodine preparations for both preoperative antiseptic showering and for patient skin preparation in the operating room, referencing a number of citations. The relevant text follows:

**Preoperative antiseptic showering.** A preoperative antiseptic shower or bath decreases skin microbial colony counts. In a study of >700 patients who received two preoperative antiseptic showers, chlorhexidine reduced bacterial colony counts ninefold ($2.8x10^2$ to 0.3), while povidone-iodine or triclocarbanmedicated soap reduced colony counts by 1.3- and 1.9-fold, respectively. Other studies corroborate these findings. Chlorhexidine gluconate-containing products require several applications to attain maximum antimicrobial benefit, so repeated antiseptic showers are usually indicated. Even though preoperative showers reduce the skin's microbial colony counts, they have not definitively been shown to reduce SSI rates.

**Patient skin preparation in the operating room.** Several antiseptic agents are available for preoperative preparation of skin at the incision site. The iodophors (e.g., povidone-iodine), alcohol-containing products, and chlorhexidine gluconate are the most commonly used agents. No studies have adequately assessed the comparative effects of these preoperative skin antiseptics on SSI risk in well-controlled, operation-specific studies. …

Both chlorhexidine gluconate and iodophors have broad spectra of antimicrobial activity. In somecomparisons of the two antiseptics when used as preoperative hand scrubs, chlorhexidine gluconate achieved greaterreductions in skin microflora than did povidone-iodine and also had greater residual activity after a single application. Further, chlorhexidine gluconate is not inactivated by blood or serum proteins, but exert a bacteriostatic effect as long as they are present on the skin.

| Source (citation) | Study Objective | Population and Methods | Findings | Notes |
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| Swenson BR, Hedrick TL, Metzger R, et al. Effects of Preoperative Skin Preparation on Postoperative Wound Infection Rates: A Prospective Study of 3 Skin Preparation Protocols. Infect Control Hosp Epidemiol 2009; 30:964-971. | To compare effects of different skin preparation solutions on surgical site infection rates. | Single-center, unblinded, non-randomized protocol implementation comparison in context of overall risk reduction program.<br><br>From 1/1/2006 – 6/30/2007 compared SSI rates in adults (18 and up) undergoing general surgery (GI, colorectal, breast, oncologic, hepatobiliary, transplant, or endocrine) in a single large academic medical center who received one of 3 skin preparations.<br><br>Cases included elective & emergent; inpatients, outpatients, & those admitted following procedure. Pts who did not receive assigned prep were also followed. | Lowest infection rate in period 3 (3.9% compared with 6.4% (1) & 7.1% (2). P=.002.<br><br>Use of iodophor-based preparation associated with lower, but not statistically significant different, incidence of SSI | Compliance with use of 2% chlorhexidine - 70%isopropyl alcohol as well as iodine povacrylex in isopropyl alcohol preps was in 70% range. |

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| | | Over 18 months and 3,209 operations, compared 3 skin preparations sequentially, each for 6 month period:<br>1. Betadine scrub-pain w/isopropyl alcohol between; 2. ChloraPrep; 3. DuraPrep) – each was identified as the preferred modality. Tracked for SSIs for 30 days. Prep methods varied; no information whether due to mfg. recommendations.<br><br>Prep method outcomes analysis dichotomized two groups to a single iodophor-based group and compared to chlorhexidine-based group after finding no significant difference in the two separate iodophor-based prepped groups | | |
| Darouiche RO, Wall MJ, Itani KMF, et al. Chlorhexidine-alcohol versus povidone-iodine for surgical-site antisepsis. N Engl J Med 2010 Jan 7;362(1):18-26. | To compare effectiveness of chlorhexidine-alcohol (ChloraPrep) to povidone-iodine (Scrub Care Skin Prep Tray) as preoperative skin cleansing agent | Prospective, randomized (by hospital), six-center IRB approved clinical trial conducted between April 2004 and May 2008.<br><br>Rates of SSI were conducted in 849 adults (age 18 and older) undergoing clean-contaminated surgery (colorectal, small intestinal, gastroesophageal, biliary, thoracic, gynecologic, urologic) in six university-affiliated hospitals who had skin prep using either chlorhexidine-alcohol (409) or povidone-iodine (440) was completed. All received prophylactic antibiotics within 1 hour before initial incision.<br><br>Exclusions: Patients with history of allergy to chlorhexidine, alcohol, iodophor; evidence of infection at or adjacent to op site; perceived inability to follow patient's course for 30 days post surgery.<br><br>Patients & site investigators who diagnosed SSI were unaware of group to which assigned | Relative risk of infection was significantly lower in the chlorhexidine-alcohol "intention to treat" population<br>Any SSI (0.59, p=0.004))<br>Superficial (0.48, p=0.008)<br>Deep (0.33, p=0.05)<br><br>Lower for each of the 7 types of surgeries studied | |

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| Bibbo C, Patel DV, Gehrmann RM, et al. Chlorhexidine provides superior skin decontamination in foot and ankle surgery: a prospective randomized study. Clinical Orthopaedics and Related Research 2005 Sept 438:204-208. | To compare effectiveness of two skin preparation methods in skin decontamination in foot and ankle surgery. | Prospective, randomized study in one facility.<br><br>Study group included 127 patients ranging in age from 16 – 85 with intact, uninfected skin having clean elective foot and ankle surgery.<br><br>Patients were randomly assigned to skin preparation with povidone-iodine (n=67) or with chlorhexidine scrub and isopropyl paint (n=60). | 79% of patients in povidone-iodine group developed positive cultures vs 38% of those in chlorhexidine group. | |
| Miller J, Agarwal R, Umscheid CA, et al. Chlorhexidine versus povidone-iodine in skin antisepsis: a systematic review and cost analysis to inform initiatives to reduce hospital acquired infections. Poster session, University of Pennsylvania 2008. | To inform medical center purchasing decisions, efficacy and cost of chlorhexidine versus povidone-iodine in skin antisepsis was compared | Systenatic review of 9 rospective, randomized controlled clinical trial involving adults receiving topical antisepsis prior to surgery, blood cultures, and vascular or epidural catheter insertion.<br><br>Compared chlorhexidine gluconate with and without alcohol with povidone iodine with and without alcohol<br><br>2 studies related to skin preparation prior to surgery (Berry, 1982 & Bibbo, 2005) were reviewed. | Reported efficacy of chlorhexidine vs. betadine in lowering infection or contamination rate of RR (random) 0.26 for the Berry study and 0.48 RR (random) for the Bibbo study with an overall of 0.38. | Included to represent additional evidence not found in review of scholarly articles. |