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Care Bundles in Surgical Site Infection Prevention: A Narrative Review

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Abstract

Purpose of Review Surgical site infections are healthcare-associated infections that cause significant morbidity and mortality. Best practices in prevention of these infections are combined in care bundles for consistent implementation.

Recent Findings Care bundles have been used in nearly all surgical specialties. While the composition and size of bundles vary, the effect of a bundle depends on the number of evidence-based interventions included and the consistency of implementation. Bundles work because of the cooperation and collaboration among members of a team. Bundles for prevention of surgical site infections should address the multiple risk factors for infection before, during, and after the surgery.

Summary Bundles increase standardization of processes and decrease operative variance that both lead to reductions in surgical site infections.

Keywords Surgical site infection · Bundle · Infection prevention · Healthcare associated infection · Cross infection · Enhanced recovery after surgery

Introduction

Surgical site infection (SSI) is an infection related to a surgical procedure that occurs at or near the incision site. It is the most common healthcare-associated infection (HAI) after surgery. Despite advances in infection control practices, SSIs remain a significant cause of morbidity and mortality, resulting in increased length of hospitalization and cost.

A care bundle is a combination of successful interventions that, when implemented completely and consistently, can yield superior results to the implementation of individual measures. Since the development of the "bundle" concept for improvement of critical care processes and patient outcomes, it has been used in different areas of medicine and surgery, including surgical site infection prevention. Different interventions to prevent SSIs are often bundled because multiple patient-related and procedure-related factors affect the SSI risk. This paper reviews the use of bundles in SSI prevention.

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Epidemiology of SSIs

The global incidence of SSI ranges from 2.5 to 7% [1, 2]. In low- and middle-income countries, SSI affects up to a third of patients with a pooled incidence of 11.8 per 100 surgical procedures [3, 4•]. In high-income countries, though the rates of SSI are lower, varying between 1.2 and 5.2% [3], they remain to be the most frequent type of HAI.

The incidence of SSIs varies widely between procedures, surgeons, hospitals, and patients [5]. It is estimated that SSIs occur in 1–3% of patients undergoing inpatient surgery [6, 7•]. In 2021, 21 186 SSIs were reported to the United States Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) out of 2 759 027 operative procedures, which was about a 3% increase in the SSI standardized infection ratio (SIR) related to all NHSN operative procedure categories combined compared to the previous year [6]. SSIs are associated with 2–11 times increased risk of mortality [8, 9] with 77% of SSI-associated deaths directly attributable to the SSI [10].

The cost of SSIs is significant, with an estimated annual cost of $3.3–10 billion [11–13]. They can extend hospital length of stay by 9.7 days and increase hospitalization cost by more than $20 000 per admission [12, 14•].

Microbiology of SSIs

Microorganisms that cause SSIs can be endogenous or exogenous. Endogenous flora of the patient is the source of majority of infections. Incision of the skin or mucous membranes exposes tissues, becoming at risk for contamination with endogenous flora. This contamination is likely to lead to SSI if the surgical site is contaminated with > 10^5 microorganisms per gram of tissue [15] and with inoculum as low as 100 colony-forming units when foreign material is present at the site [16]. About 70–95% of all SSIs arise from the microbiome of the patient's skin or nares [17]. Studies on alternative skin preparation regimens [18, 19] and separate nasal decolonization [20, 21], as well as mapping of the skin microbiome and disproportionate SSIs following incisions at specific sites [17, 22–32] all support this. The most commonly isolated microorganisms are *Staphylococcus aureus*, coagulase-negative staphylococci, streptococci, *Enterococcus* spp., and *Escherichia coli* [5, 33, 34].

Exogenous sources of SSI are those not originating from the patient's flora. These include members of the surgical team, the operating room environment, instruments, and materials brought to the sterile field during the procedure. Exogenous flora are predominantly aerobes, especially Gram-positive organisms such as staphylococci and streptococci [10].

Microorganisms that cause SSIs vary by surgical location. Overall, *S. aureus* is the most common cause of SSIs. Infections caused by resistant pathogens lead to worse clinical outcomes compared to those caused by susceptible microorganisms [8, 35].

Risk Factors for SSI

Many factors, patient-related or procedure-related, have been associated with increased likelihood of SSI (Table 1). Some factors are nonmodifiable, like age, history of radiation, and history of prior skin and soft tissue infection. Modifiable risk factors, such as glucose control, tobacco use, and malnutrition, can be optimized to decrease the risk of developing an SSI.

Table 1 Risk Factors for SSI (Adapted from Ban [14•] and Calderwood [45•])

Patient-related factors	Procedure-related factors
Nonmodifiable	Procedure
Increased age	Emergency
Recent radiation	Increasing complexity
History of prior skin and soft tissue infection	Higher wound classification
Modifiable	Surgical skill/technique
Diabetes	Facility
Obesity	Inadequate ventilation
Current tobacco use	Increased operating room traffic
Hypoalbuminemia	Contaminated environmental surfaces
Immunosuppression	Nonsterile surgical equipment
Anticoagulation	Preoperative
Preoperative infections	Inadequate skin preparation
S. aureus nasal colonization	Inadequate/inappropriate antimicrobial prophylaxis (antibiotic choice, timing, dosing)
	Hair removal method
	Intraoperative/Postoperative
	Longer operative time
	Blood transfusion
	Breach in asepsis
	Presence of foreign material
	Decreased tissue oxygenation
	Perioperative hypothermia
	Postoperative hyperglycemia
	Poor wound care
	Wound contamination from patient
	Wound contamination from operating room personnel

Tobacco use is an established risk factor for surgical complications, including SSIs. Smoking causes vasoconstriction and endothelial dysfunction. It leads to reduced inflammatory response, impaired innate immune system, and attenuation of reparative cell functions including collagen synthesis and deposition. In tissues especially with compromised blood supply, all these processes may lead to critical tissue hypoxia, necrosis, and infection [36]. Current or past smokers have twice the risk of developing SSI compared to those who never used tobacco [37].

Hypoalbuminemia, a surrogate marker for malnutrition, is associated with increased risk for SSI [38–40]. Malnutrition impairs wound healing by decreased collagen synthesis and granuloma formation [41, 42]. It also leads to reduced innate immune response by impairing macrophage activation [42] and inducing macrophage apoptosis [43]. These mechanisms predispose patients with hypoalbuminemia to infection. An albumin level < 3.5 g/dL is associated with nearly 2.5 times higher risk of SSI [44].

SSI Prevention

The CDC [7•], Society of Healthcare Epidemiology of America (SHEA) [45•], United Kingdom National Institute for Health and Care Excellence (NICE) [46•], World Health Organization (WHO) [4•], and American College of Surgeons (ACS) and Surgical Infection Society (SIS) [14•] have guidance on the prevention of SSIs.

In 1982, the CDC published its first guideline [47] on the prevention of then called surgical wound infections and revised it in 1985 [48]. The 1999 update by the CDC and the Hospital Infection Control Practices Advisory Committee (HICPAC) [10] led to the creation of the Surgical Infection Prevention (SIP) Project by the US Centers for Medicare and Medicaid Services (CMS) in 2002. In 2003, the Surgical Care Improvement Project (SCIP) was created as an extension of the SIP. While the SIP monitored adherence to three performance measures related to antimicrobial prophylaxis, SCIP also monitored three other measures: proper hair removal, postoperative glucose control, and maintenance of perioperative normothermia. These performance metrics would be linked to CMS payments later. In 2008, SHEA and the NICE released their guidelines [49, 50]. In 2016, the WHO published the first global guideline for SSI prevention [51, 52]. In the same year, the ACS and SIS had their guideline [14•].

SSI rates are one of the major hospital quality metrics used in pay-for-performance programs. Publicly reported, they are used to determine reimbursement since up to 60% of SSIs may be considered preventable when evidence-based recommendations are applied [13]. Procedures commonly reported to NHSN include cardiac surgery, neurosurgery, orthopedic surgery, colorectal surgery, and abdominal hysterectomy. Since 2008, the CMS no longer reimburses hospitals for HAIs like SSI [53]. Specifically, CMS uses data for SSI following colorectal surgery and abdominal hysterectomy in repayment programs.

The following core recommendations are considered best practices in the prevention of SSI according to expert society guidelines.

Decolonization with antistaphylococcal agent reduces SSI risk. In order to suppress *S. aureus* colonization, patients are given intranasal antimicrobial, skin antiseptic agent, or both prior to surgery. Current evidence is most supportive of use of twice daily 2% intranasal mupirocin and daily chlorhexidine gluconate (CHG) bathing for up to 5 days prior to surgery, especially cardiothoracic and orthopedic procedures, and other procedures at high risk of staphylococcal SSI (e.g., involvement of prosthetic material) [54].

Preparation of the operative site involves antisepsis and, if necessary, hair removal. Surgical skin preparation with an alcohol-based agent and antiseptic reduces SSI risk. Though alcohol is highly bactericidal, it does not have persistent activity when used alone. Combining alcohol with an antiseptic (e.g., CHG or povidone iodine) has a rapid, cumulative, and residual activity [55]. CHG-alcohol combination is associated with lower rates of SSI compared with povidone iodine-alcohol [18, 56, 57]. Hair removal at the operative site should only be performed if absolutely necessary. Preoperative hair removal with shaving is associated with higher risk of SSI compared with either use of depilatory agents or no hair removal [58]. Shaving creates microscopic cuts in the skin which can later serve as niduses for bacterial growth [10]. If hair will interfere with the surgical procedure, clipping or use of a depilatory agent is recommended outside of the operating room [45•].

Administration of antimicrobial prophylaxis within 60 min prior to incision is recommended to maximize tissue concentration of the antibiotic [59, 60]. Aside from timing, the dose and redosing of antimicrobials are important. Dosing should be based on the patient's weight. For long surgeries as well as those with excessive blood loss, redosing helps maintain adequate serum and tissue concentration levels of the antimicrobial agent. After incisional closure, prophylactic antibiotic should be discontinued because it does not further reduce the SSI risk and, moreover, it is associated with increased risk of adverse events.

Maintenance of normothermia during the perioperative period decreases the SSI risk [61–64]. Skin warming, warmed intravenous fluids, forced warm air, or their combinations are utilized to keep the core body temperature at least 35.5 °C. Hypothermia may impair neutrophil function directly or indirectly by triggering subcutaneous vasoconstriction and tissue hypoxia [65].

Blood glucose should be monitored and controlled during the perioperative period in all patients, regardless of diabetes status. Hyperglycemia impairs leukocyte function and potentiates procoagulant responses. Since postoperative hyperglycemia is associated with increased SSI risk [66–68], blood glucose level of 110–150 mg/dL is recommended. Stricter blood glucose control of < 110 mg/dL has not consistently shown benefit and is associated with increased episodes of hypoglycemia and other adverse events [69].

Use of impervious plastic wound protectors during gastrointestinal and biliary tract surgery decreases risk for SSI [70, 71]. These plastic sheaths facilitate retraction of incision without requiring additional mechanical retractors.

Intraoperative wound lavage with an antiseptic, not saline, decreases SSI risk [72, 73]. Sterile dilute povidone iodine lavage is recommended over nonantiseptic lavage [74–77].

Negative pressure wound therapy also reduces the SSI risk [78, 79]. Reduction of fluid accumulation promotes faster primary wound healing.

Use of checklist improves adherence with best practices in SSI prevention. The use of the 19-item WHO Surgical Safety Checklist [80] decreases surgical complications such as SSI and death [81–83]. Despite this, variation in the practices included in checklists exists.

Bundles in SSI Prevention

The concept of care bundles was introduced by the Institute for Healthcare Improvement (IHI) in 2001. A care bundle is a set of practices that, when implemented together, lead to better patient outcomes than when implemented individually [84•]. Numerous factors before, during, and after surgery influence the patient's risk of SSI. Because the prevention of SSIs is complex, bundles ensure compliance and improve patient safety. Although interventions in a bundle are evidence-informed, some are supported by randomized trials while others are derived from cohort studies or expert consensus.

Colorectal Surgery

Bundles have been used extensively in colorectal surgery. A meta-analysis including 2 randomized controlled trials (RCT) and 28 cohort studies involving 20 701 patients showed lower colorectal SSI rate of 8.4% (894 of 10 627) in groups that received bundle compared with those that did not (15.5%) (1561 of 10 074) (risk ratio [RR] 0.56 [95% confidence interval [CI] 0.48 – 0.65]) [85]. The most frequently used interventions in the studies included multidisciplinary collaborative team or steering committee led by a colorectal surgery champion; hospital administration leadership support; educational meetings with relevant frontline clinicians; use of checklist; use of electronic order sets and automatic reminders; standardization of clinical practices and protocols; performance feedback to staff and clinicians; and overall promotion of culture and safety and openness to change [85]. Compared to an earlier meta-analysis [86] of 23 studies (17 557 patients) which found that bundles with sterile closure trays, mechanical bowel preparation with oral antibiotics, and pre-closure glove changes led to greater colorectal SSI risk reduction, this recent meta-analysis that included 3 additional studies found preoperative bathing with CHG and standardized postoperative wound dressing changes at 48 h were also associated with significant SSI reduction [85]. Interestingly, the highest SSI reduction in the meta-analysis was associated with the largest bundle size [85]. These systematic reviews and meta-analyses [85–87] show the heterogeneity in the bundle interventions included in studies of colorectal SSI prevention.

Orthopedic Surgery

SSIs following arthroplasties decline with bundle use according to multiple studies [88–91]. A multicenter study involving 18 791 hip arthroplasties showed a decrease in SSI rates from 2.9% to 1.4% after bundle implementation [88]. A 92.3% reduction in periprosthetic joint infection (PJI) following knee arthroplasties was seen after bundle use from 1.43% (13 of 908) to 0.11% (1 of 890) [89]. PJI rates following primary or revision total joint arthroplasties dropped from 12.9% (9 of 70) pre-bundle to 1.9% (2 of 108) post-bundle [90]. A bundle with interventions implemented one after the other within the study period led to a decline in PJI rates after total joint arthroplasties from 1.7% (20 of 1150) to 0.4% (4 of 1053) [91]. Interventions included staff education, preoperative patient optimization, antimicrobial prophylaxis, nasal/skin decolonization, venous thromboembolism prophylaxis modification, and povidone iodine wound irrigation [91].

Vascular Surgery

Bundle use decreased vascular SSI in contaminated surgeries from 33.3% to 13.9% [92]. A 97% reduction in SSI rate after lower extremity vascular bypass surgeries was seen from 18% (43 of 234) to 4% (3 of 73) when a bundle consisting of preoperative and postoperative CHG showers and transverse groin incision was implemented [93]. In another before-after study, SSI following lower extremity revascularization decreased from 14 to 7% after bundle implementation [94].

Neurosurgery

Rates of cranial neurosurgery SSI decreased by 53%, from 7.8% (25 of 322) to 3.7% (11 of 296) after implementation of bundle consisting of 10 interventions [95]. In a before-after study of cerebrospinal fluid (CSF) shunt surgeries, no SSIs were recorded (0 of 52) after a bundle was implemented compared to 7.3% (9 of 124) prior to the implementation [96]. Reduction in extraventricular drain-related infections (EVDRI) after surgery was seen in another study, from 29.1% (41 of 141) to 4.8% (10 of 208) [97]. A study involving 261 extraventricular drain catheter placements that implemented updates on its bundle showed a decline in EVDRI from 13.4 to 2.5 per 1000 days of catheter use [98]. The updated bundle included glove changes, use of CHG dressing, head washing with CHG soap, and changes in CSF sampling protocol in case of suspected infection [98]. Combined craniotomy and shunt procedure SSI rates decreased after bundle implementation from 3.2% (132 of 4137) to 2.1% (26 of 1250), a 37.5% reduction [99]. SSI after cranioplasties also decreased from 23.8% (5 of 21) to 2.8% (1 of 36) with bundle implementation [100].

Obstetrics and Gynecology

Obstetrics and gynecology bundles have decreased SSI rates. A systematic review and meta-analysis of 14 pre- and postintervention studies involving 17 399 women showed lower rates of infection following cesarean section from baseline of 6.2% to 2.0% after bundle implementation (RR 0.33 [95% CI 0.25 – 0.43]) [101]. Bundles in these studies involved interventions on antimicrobial prophylaxis, hair removal with clipping, CHG skin preparation (wipes/shower), enhancements to aseptic surgical technique, placental removal with gentle traction, patient and staff education, and wound dressing specification [101]. In a before-after study of 2099 hysterectomies, SSI rates declined from 4.5% (61 of 1352) to 1.9% (14 of 747) (adjusted odds ratio [aOR] 0.46 [95% CI 0.25 – 0.82]) after use of bundle [102].

Pediatric Surgery

Bundles have been useful in pediatric surgeries similarly to studies focused on adult patients. Several before-after studies in pediatric cardiothoracic surgery showed reduced SSIs after use of bundles. One study that focused on a postoperative bundle on top of an existing pre- and intraoperative bundle for pediatric patients undergoing cardiac surgery showed 74% decline in SSI rates from 3.4 per 100 procedures (27 of 799) to 0.9 per 100 procedures (5 of 570) [103]. A bundle decreased SSI in cardiothoracic surgeries among pediatric patients from 7.4% (23 of 310) to 1.7% (16 of 971) [104]. A study of 1768 cardiothoracic procedures that utilized a bundle of 14 interventions showed a reduction in SSI from 2.6% (24 of 931) to 1.4% (12 of 837) [105]. For the first time, negative pressure dressing after sternotomy especially in neonates was included in a pediatric bundle [105]. In pediatric orthopedic surgeries, SSI rates dropped from 4% to zero following implementation of two types of bundles, one for patients with high risk (e.g., those who required large amounts of instrumentation needed and those with neuromuscular condition) and with low risk (e.g., no nutritional deficiencies, no implants required) [106]. SSIs following pediatric spine surgeries decreased from an average of 5.8% to 2.2% (RR 0.41 [95% CI 0.18 – 0.94]) after bundle implementation [107]. A study on pediatric neurosurgeries demonstrated a 79% reduction in SSIs after bundle implementation from 2.9 per 100 procedures to 0.62 per 100 procedures (RR 0.21 [95% CI 0.08 – 0.56]) [108]. CSF shunt infection rates in children also decreased from 8.8% to 5.7%, a 36% reduction when a bundle was implemented [109].

Mixed/Combined Surgeries

Several studies combined different surgeries in their analyses. A study performed separate meta-analyses of 5 RCTs and 19 observational studies of 28 887 patients who underwent cardiac or orthopedic surgery [110]. The RCTs demonstrated a trend of 41% decrease in the *S. aureus* SSI risk in bundle group vs standard group (RR 0.59 [95% CI 0.33 – 1.06]) while the observational studies showed that bundle use was associated with 51% reduction in the staphylococcal SSI risk (RR 0.49 [95% CI 0.41 – 0.59]). Interventions in the bundles focused on nasal and/or skin decolonization. In a before-after study of 1672 procedures in general surgery or orthopedic surgery, the overall SSI risk declined from 3.4% (28 of 828) to 1.0% (9 of 844) after implementation of a bundle consisting of 11 interventions [111].

A recent meta-analysis of 4 RCTs and 14 before-after studies (1 controlled and 13 uncontrolled) reanalyzed uncontrolled before-after studies as interrupted time series studies (ITS) [112•]. General, colorectal, gynecologic, orthopedic, cardiovascular, and pediatric surgical procedures were included. The most common interventions in the bundles were skin preparation with alcohol-based CHG, antimicrobial prophylaxis, hair removal with clippers, and use of separate closing tray of surgical instruments for wound closure. The results of the RCTs were mixed. One showed lower SSI risk [113], another a higher SSI risk [114], and 2 did not show effect [115, 116]. The higher SSI risk with bundle implementation seen in one RCT [114] was likely due to the inclusion of potentially harmful intervention of fluid restriction and the omission of mechanical bowel preparation and oral antibiotics which could be beneficial and was given to the control group. The controlled before-after study showed reduction in SSI risk following knee surgery (aOR

0.88 [95% CI 0.78 – 0.99]) and hip surgery (aOR 0.85 [95% CI 0.75 – 0.96]) [117]. In the 13 uncontrolled before-after studies, 12 [118–129] originally showed significant decline in SSI rates after bundle use and 1 [130] reported an increase in SSI rate. Reanalysis of these studies demonstrated that only 4 [118, 120, 121, 129] had robust decline in SSI incidence after bundle implementation. Meta-analysis of the ITSs showed a significant decrease in SSI rates after bundle implementation (pooled effect estimate of level change -1.16 [95% CI -1.78 – -0.53]). Unlike in other systematic reviews [85–87, 101, 131] that suggested that larger bundle size had larger reduction in SSI incidence, meta-regression of ITSs in this study did not demonstrate an association between SSI reduction and the bundle size. However, bundles with more evidence-based interventions were associated with a larger SSI risk reduction [112•].

Enhanced Recovery After Surgery

Enhanced recovery after surgery (ERAS) is a bundled approach to perioperative care of surgical patients. Based on the philosophy that patients do better when emotional and physiologic stresses are minimized during surgery, it is a multidisciplinary care improvement initiative that promotes return of patients to normal functional status as quickly as possible. In 2001, the ERAS Study Group was established. Soon after its formation, it discovered wide variations in surgical practice and huge discrepancy between actual practices and what were considered best practices [132]. This led to the development of evidence-based protocol to optimize patient outcomes. Initially developed for colorectal surgery, ERAS programs are now used in many surgical specialties. ERAS bundles or protocols have been associated with reduction in overall complications and length of stay, as well as readmissions and cost.

A meta-analysis of 42 RCTs of different surgeries (gastrointestinal, genitourinary, thoracic, vascular and orthopedic) involving 5241 patients showed that ERAS programs led to 38% reduction in postoperative complications (RR 0.62 [95% CI 0.55 – 0.70]) which included a 27% reduction in SSIs (RR 0.73 [95% CI 0.56 – 0.95]) [133•]. Average length of hospital stay decreased by 2.4 days (95% CI -2.74 – -1.96), total cost of hospitalization decreased by $639 (95% CI -933.85 – -344.28), and time to first flatus (measure of return of gastrointestinal function) decreased by 13.1 h (95% CI -17.98 – -8.26) [133•]. Most common elements in the programs were preadmission counseling, fluid and carbohydrate loading, no prolonged fasting, no/selective bowel preparation, midthoracic epidural analgesia, no drains and nasogastric tubes, early catheter removal, early oral nutrition, early mobilization, and use of non-opioid oral analgesia or nonsteroidal anti-inflammatory drugs [133•]. ERAS protocol implementation for colorectal surgery was associated with 59% SSI risk reduction from 12.3% (26 of 212) to 5.0% (13 of 258) [134]. A 58% decline in SSI rates was seen with ERAS program for cesarean deliveries (OR 0.42 [95% CI 0.19– 0.96]) [135].

Conclusion

The impact of a bundle depends on the evidence behind a recommendation and on its consistent implementation. Heterogeneity in bundle components exists and there is likely no best bundle for all. Though interventions in a bundle for SSI prevention should involve all phases of care—preoperative, intraoperative, and postoperative, the components of the most effective bundle will depend on an institution and should be tailored to its context. Bundles should evolve overtime. As new evidence becomes available, outdated interventions and potentially harmful practices should be reviewed and replaced.

As IHI conceived them, bundles were not intended to be comprehensive care. Moreover, bundles on their own do not improve care. It is the cooperation and teamwork needed for bundles that lead to high levels of performance not seen on individual components. The synergy resulting from collaboration and communication must be sustained by multidisciplinary efforts to deliver high quality care. Since understanding of habits and processes is important, all stakeholders must be involved from bundle conceptualization to implementation. Culture change involves everyone: frontline staff, leadership, and patients.

SSI prevention is complex. Since various factors influence a patient's journey through surgery, integration of interventions before, during, and after surgery is essential. Even when best practices are known, implementation of measures is difficult to standardize. Care bundles aid in reliable implementation of evidence-based practices into routine care for all patients to prevent SSIs. We expect to see more care bundles in perioperative pathways for SSI prevention.

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Compliance with Ethical Standards

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