The Surgical Care Improvement Project Redux: Should CMS Revive Process of Care Measures for Prevention of Surgical Site Infections?

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The Genesis of the Surgical Care Improvement Project

Many surgical procedures are performed each day in the USA; in 2006 approximately 46 million procedures were performed in inpatient hospital settings [1] and an additional 32 million were performed in ambulatory settings [2]. Surgical site infections (SSIs) are currently one of the most common types of infections associated with care that patients receive in healthcare facilities [3]. Approximately 300,000 SSIs occur each year in the USA [4] although this is likely to be an underestimate because of the challenges around complete ascertainment of these infections, especially for SSIs that are diagnosed after hospital discharge or are sequelae of procedures performed in the ambulatory setting. Estimates of average attributable costs of SSI range from $10,433 to $25,546 per infection (2005 and 2002 dollars, respectively), with substantially higher costs associated with some types of surgery [5–7]. The considerable impact of SSI on national healthcare costs is incontrovertible.

In August of 2002, the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) established the Surgical Infection Project (SIP) with the goal of improving SSI outcomes by increasing adherence to evidence-based use of perioperative antimicrobial prophylaxis (AMP) [8]. A SIP multidisciplinary expert panel selected these three performance measures for national surveillance and quality improvement:

1. The proportion of patients who have parenteral antimicrobial prophylaxis initiated within 1 h before the surgical incision
2. The proportion of patients who are provided a prophylactic antimicrobial agent that is consistent with currently published guidelines
3. The proportion of patients whose prophylactic antimicrobial therapy is discontinued within 24 h after the end of surgery

The SIP expert panel chose to focus on subgroups of surgical procedures with clear evidence-based benefits of AMP including coronary artery bypass graft and other cardiac surgeries excluding transplantation, vascular surgery, colorectal surgery, hip and knee arthroplasty, and abdominal and vaginal hysterectomy. In 2003, this national initiative evolved into the Surgical Care Improvement Project (SCIP) [9, 10], an extension of SIP supported by multiple agencies and organizations that continued to focus on the three AMP measures described above as well as three additional SSI prevention processes:

4. No hair removal or hair removal with clippers or a depilatory agent (i.e., avoidance of shaving) at the surgical site
5. Control of blood glucose during the immediate postoperative period for patients undergoing cardiac surgery (i.e., glucose of ≤200 mg/dL at 6AM on postoperative days 1 and 2)
6. Maintenance of perioperative normothermia among patients with anesthesia duration of at least 60 min

Because the overall goal of the SCIP was to reduce preventable surgical morbidity and mortality, some additional process measures focused on improving non-SSI outcomes were also included:

7. Surgery patients on beta-blocker therapy prior to arrival who received a beta-blocker during the perioperative period
8. Surgery patients who received appropriate venous thromboembolism prophylaxis within 24 h prior to surgery to 24 h after surgery
9. Surgery patients with urinary catheters removed on postoperative day 1 or postoperative day 2

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Table 11.1 Surgical Care Improvement Project (SCIP) measures

SCIP performance measure	Performance measure description
SCIP Inf-1	Prophylactic antibiotic started within 1 h prior to surgical incision
SCIP Inf-2	Received prophylactic antibiotic consistent with recommendations
SCIP Inf-3	Prophylactic antibiotics discontinued within 24 h after surgery end time
SCIP Inf-4	Cardiac surgery patients with controlled postoperative blood glucose
SCIP Inf-6	Surgery patients with appropriate hair removal
SCIP Inf-9	Urinary catheter removed on postoperative day 1 or postoperative day 2 with day of surgery being day zero
SCIP Inf-10	Surgery patients with perioperative temperature management
SCIP Card-2	Surgery patients on beta-blocker therapy prior to arrival who received a beta-blocker during the perioperative period
SCIP VTE-2	Surgery patients who received appropriate venous thromboembolism prophylaxis within 24 h prior to surgery to 24 h after surgery

These SCIP measures (Table 11.1) were supported by a number of quality improvement organizations and endorsed by the National Quality Forum.

CMS and The Joint Commission provided the infrastructure for voluntary reporting of SCIP measures by hospitals. As part of the Deficit Reduction Act of 2005, CMS was required to collect hospital-reported performance measures and to make this information available to the public [11]. Although reporting of SCIP measure adherence by hospitals to CMS continued to be voluntary, hospitals that did not report these process measures did not receive their annual 2% CMS market basket reimbursement updates. Hospital-specific SCIP adherence rates were also made accessible to the public on the CMS Hospital Compare website [12]. The Patient Protection and Affordable Care Act of 2010 further accelerated implementation of the CMS Value-Based Purchasing (VBP) and Hospital-Acquired Conditions (HAC) Reduction programs, pay-for-performance programs with substantial potential to impact hospitals' Medicare reimbursement levels [13, 14]. Adherence to the SCIP measures along with other quality metrics was used to determine hospitals' VBP scores starting in 2013.

Evidence to Support the SCIP Measures

Perioperative Antimicrobial Prophylaxis

The evidence to support the impact of appropriate choice of antimicrobial agent(s) used for antimicrobial prophylaxis (AMP) and the importance of the timing of the start of AMP administration have been summarized in other publications including the "Clinical practice guidelines for antimicrobial prophylaxis in surgery" that was jointly developed by the American Society of Health-System Pharmacists (ASHP), the Infectious Diseases Society of America (IDSA), the Surgical Infection Society (SIS), and the Society for Healthcare Epidemiology of America (SHEA) [15].

1. Choice of AMP Agent(s)

The antimicrobial agent(s) selected for SSI prophylaxis should have activity against the most common SSI organisms associated with the specific surgical procedure. In addition, fundamental AMP principles include using an antimicrobial agent with the narrowest spectrum of activity required for SSI prevention in order to minimize the risk of adverse consequences resulting from impact on the patient's native microbial flora, including the emergence of multidrug-resistant organisms and infection due to *Clostridium difficile*. Overall, the most common organisms associated with SSI following clean procedures continue to be *Staphylococcus aureus* and coagulase-negative staphylococci [16], and therefore recommended AMP regimens for most surgical procedures include an antistaphylococcal agent such as cefazolin. Because organisms that lead to SSI are those that are likely to contaminate the operative bed during the course of the procedure, procedure-specific AMP regimens recommended by SCIP also include agents with activity against other organisms that most commonly contaminate the operative field (e.g., antistaphylococcal, Gram-negative, and anaerobic coverage for colon surgery to cover bowel flora) [15].

2. Timing of the Start of AMP Administration

In order to optimize the impact of AMP, serum and tissue concentrations exceeding the minimal inhibitory concentrations of the agent(s) being used should be achieved prior to the initial surgical incision (i.e., before contamination occurs). Support for the importance of the SCIP recommendation to begin administering the first dose of the AMP agent(s) within 60 min prior to the initial surgical incision (or within 120 min before incision for antimicrobial agents with longer infusion times such as vancomycin and fluoroquinolones) is mainly based on observational study data, including the study by Classen et al. that assessed SSI outcomes for patients who underwent a variety of surgical procedures and found SSI rates to be significantly lower for patients who received AMP starting within 2 h before surgical incision compared to any time after incision (0.59% vs. 3.3%) [17]. When the results were stratified according to the timing of the start of prophylaxis administration in relation to incision time, a statistically significant trend was observed demonstrating increasing risk of SSI with each successive hour that the start of AMP was delayed. Although some

studies have demonstrated lower SSI rates associated with shorter time intervals between the start of AMP and start of surgery (e.g., within 30 min prior to incision) [18, 19], the generalizability of those results is unresolved.

3. Minimize the Duration of AMP

Studies assessing the impact of varying durations of AMP strongly indicate that continuation of AMP after incision closure is not associated with added benefit compared with receipt of AMP limited to the procedure duration. Prolonged AMP administration, however, has been associated with adverse consequences including the emergence of resistant organisms [20] and increased risk for *Clostridium difficile* infection [21]. Although minimizing the duration of AMP is unlikely to impact patients' SSI risk, adherence to this antimicrobial stewardship-focused recommendation is important to reduce the risk of unintended adverse consequences associated with unnecessary exposure to antimicrobial agents.

Hair Removal Technique

There is limited high-quality data addressing the impact of hair removal or hair removal techniques on SSI risk. Theoretically, shaving using razors may lead to microabrasions of the skin that can increase the bioburden of microorganisms and therefore the risk for subsequent development of SSI. A Cochrane systematic review [22] demonstrated no significant difference in SSI risk between patients who were shaved and those who had no hair removal (relative risk of 1.75, 95% confidence interval 0.93–3.28) but did find a significantly higher risk of SSI associated with shaving compared with hair removal using clippers (relative risk of 2.03, 95% confidence interval 1.14–3.61). Although the evidence is limited, these results have been used to support the SCIP recommendation for no hair removal or, if hair removal is needed to perform the procedure, to avoid use of razors.

Perioperative Glucose Control

Although SCIP measures focus on blood glucose control in patients undergoing cardiac surgery during the immediate postoperative period [23, 24], beneficial impact of glucose control has also been demonstrated for patients undergoing other types of operative procedures [25–29]. Both the SHEA/IDSA "Strategies to prevent surgical site infections in acute care hospitals: 2014 update" [30] and the recently revised Healthcare Infection Control Practices Advisory Committee (HICPAC) "Guideline for prevention of surgical site infections, 2017" [31] recommend perioperative glycemic control for diabetic and nondiabetic patients undergoing cardiac and noncardiac procedures. Guideline recommendations regarding blood glucose target levels typically range from <180 to <200. Studies comparing these blood glucose targets to stricter glucose targets (e.g., 80–100 mg/dL or 80–130 mg/dL) suggest that tighter glucose control does not significantly improve SSI risk compared to standard glucose control [32, 33].

Normothermia

High-quality, randomized controlled trial results suggest that maintenance of perioperative normothermia reduces SSI risk for a variety of surgical procedures [34, 35]. The most effective strategies and temperature targets needed to optimize benefit are unclear based on existing literature although some practice guidelines [30, 36] recommend maintaining a temperature of ≥36° or ≥35.5°.

Did the SCIP Improve SSI Outcomes?

Despite evidence-based support for the beneficial impact of individual SCIP measures on SSI risk and despite national data demonstrating improved adherence to SCIP measures over time, a clear association between adherence to SCIP measures and improvements in SSI outcomes has been difficult to demonstrate [37, 38]. A retrospective cohort study from an inpatient administrative database (Premier, Inc's Perspective Database) that included information from discharges between July 1, 2006, and March 31, 2008, for over 400,000 patients used administrative data to identify surgical patients with probable SSI using an algorithm based on discharge diagnosis codes. The investigators assessed the association between risk of SSI and adherence to individual and composite SCIP measures [39]. Although adherence measured through a global all-or-none composite infection-prevention score was associated with a lower probability of developing a postoperative infection, adherence to individual SCIP measures was not significantly associated with SSI risk. Limitations of this study included dependence on International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes to identify patients with SSI and restriction of these discharge codes to the hospitalizations when the surgical procedures took place (i.e., no readmission data); this may have substantially limited SSI ascertainment since many SSIs are diagnosed after hospital discharge [40]. A retrospective cohort study by Hawn et al. used National Veteran's Affairs SCIP adherence data and SSI outcomes collected through the Veteran's Affairs Surgical Quality Improvement Program to assess the relationship between SCIP adherence and SSI risk. They found that although adherence to all SCIP measures significantly improved between 2006 and 2009, risk-adjusted SSI

rates remained unchanged, and SCIP adherence was not associated with lower SSI risk at the hospital level [41].

Why Is It So Challenging to Demonstrate a Significant Impact on SSI Risk?

There are a number of possible reasons for the apparent limited impact of improvements in adherence to SCIP measures on national SSI rates.

1. Some SCIP measures were not designed to impact SSI risk.

As discussed, the goal of the SCIP program was to improve postoperative outcomes, and several of the SCIP measures are focused on non-SSI complications. For example, limiting the duration of AMP would not be expected to reduce an individual patient's SSI risk. The goal was instead to prevent the emergence of multidrug-resistant organisms and other complications of unnecessary exposure to antimicrobial agents through improved antimicrobial stewardship. Other SCIP measures are focused on preventing cardiac and venous thromboembolism-associated complications and catheter-associated urinary tract infections.

2. Adherence to many of the SCIP measures quickly became "topped off."

Hospitals attained high adherence to many of the SCIP measures shortly after SCIP implementation, and by 2009 national adherence rates exceeded 90% for all SCIP measures [12]. Because of this, further incremental improvements in adherence rates were unlikely to result in substantial improvements in SSI outcomes [42].

3. Reported adherence may not always reflect true practice.

Because CMS relied on self-reporting of SCIP adherence rates by hospitals with minimal data validation and because of pressure on hospitals to demonstrate good performance on publicly reported measures, the potential exists for "gaming" the system by inflating self-reported adherence rates.

4. SCIP recommendations may not be nuanced enough to impact outcomes.

Although AMP has been shown to reduce SSI risk for a wide variety of surgical procedures, it is possible that the specific aspects of AMP that are highlighted by SCIP were not nuanced enough to optimize impact. For example, although a menu of AMP choices for procedure categories was provided by the SCIP [43], a hospital's specific distribution of antimicrobial resistance (i.e., the hospital's "antibiogram") may suggest the need for broader or differing coverage than that recommended by the SCIP technical expert panel.

The effectiveness of AMP also depends on achieving adequate antimicrobial concentrations throughout the period of risk when the surgical incision is open. In order to achieve this, weight-based dosing may be required for some antimicrobial agents, including commonly used antimicrobials such as cefazolin and vancomycin. In addition, re-dosing of AMP agents for long surgical procedures is likely to be important for sustaining the protective effect of AMP during the period of risk [15]. Data from some studies suggest that repeat dosing of AMP agents for procedures lasting more than approximately two half-lives of the agent(s) is associated with lower SSI risk compared to procedures without re-dosing [18].

5. SCIP recommendations may constitute minimal requirements, but additional SSI prevention strategies may be needed for further improvements in outcomes.

The practices highlighted by SCIP may reflect minimum requirements for SSI prevention, but optimizing SSI prevention may require adherence to one or more additional interventions. Some of these interventions are discussed below (Table 11.2).

Preoperative Skin Preparation Using a Long-Acting Antiseptic Agent Plus Alcohol

A systematic review by Kamel et al. [44] included data from five randomized controlled trials, two cohort studies, and two case-control studies, including a randomized controlled trial [45] that compared the impact of chlorhexidine-alcohol versus povidone-iodine for preoperative skin preparation prior to clean-contaminated surgical procedures and demonstrated significantly lower SSI risk for patients randomized to receive skin preparation with chlorhexidine-alcohol. The overall conclusion of this systematic review was that conclusive evidence demonstrating the benefit of one

Table 11.2 Examples of supplemental surgical site infection prevention strategies

Use an antiseptic that includes a long-acting agent plus alcohol for preoperative skin preparation
Administer preoperative oral antimicrobial prophylaxis to patients undergoing colorectal surgery
Use hemodynamic goal-directed therapy
Use supplemental oxygenation for patients with normal pulmonary function who undergo general anesthesia with endotracheal intubation
Screen patients for *Staphylococcus aureus* (SA) carriage and decolonize SA carriers for selected surgical procedures
Implement surgical site infection prevention bundles

skin preparation agent over another was lacking but that this should be a high priority topic for further research. A Cochrane systematic review and meta-analysis evaluating the impact of preoperative skin antiseptics on SSI prevention following clean procedures also concluded that there was insufficient evidence to recommend the use of one preoperative skin preparation agent over another, but in a mixed treatment comparison, meta-analysis found that alcohol-containing products had the highest probability of being effective [46].

Administering Preoperative Oral Antimicrobial Prophylaxis to Patients Undergoing Colorectal Surgery

For patients undergoing colorectal surgery, the utility of preoperative oral antimicrobial agents with or without preoperative mechanical bowel preparation remains controversial. Interpreting the results of studies on this topic is challenging because of lack of clarity around the impact of the interaction between mechanical bowel preparation and oral antimicrobial prophylaxis on SSI risk. The results of a Cochrane systematic review and meta-analysis showed no significant difference in SSI risk between patients who did and did not receive mechanical bowel preparation prior to colorectal surgery [47], supporting the NICE surgical site infection guideline recommendation to not use mechanical bowel preparation routinely as a strategy to reduce the risk of surgical site infection for colorectal surgery [36]. Despite this, preoperative mechanical bowel preparation is still commonly favored by colorectal surgeons [48]. Among patients who undergo mechanical bowel preparation, receipt of preoperative oral antimicrobial agents, usually consisting of oral neomycin plus erythromycin or metronidazole given two or three times during the day prior to surgery, has been associated with significant reductions in SSI risk following colorectal surgery [49, 50]. Most studies demonstrating improved SSI outcomes associated with oral antimicrobial prophylaxis also utilized mechanical bowel preparations, making it difficult to extrapolate results to patients who receive oral AMP without mechanical bowel preparation prior to colorectal surgery. Overall, study results suggest a benefit to preoperative oral antimicrobial prophylaxis when provided in conjunction with mechanical bowel preparation.

Hemodynamic Goal-Directed Therapy

A systematic review and meta-analysis by Dalfino et al. [51] evaluated the impact of hemodynamic goal-directed therapy on SSI risk. Goal-directed therapy was defined as perioperative monitoring and manipulation of hemodynamic parameters to reach normal or supraoptimal values by fluid infusion alone or in combination with inotropic therapy within 8 h after surgery. In this meta-analysis of 18 randomized controlled trials, standard therapy was associated with significantly higher SSI risk compared with goal-directed therapy (odds ratio of 5.8, 95% confidence interval 0.46–0.74). Hemodynamic goal-directed therapy is a component of "Enhanced Recovery After Surgery" protocols (see below).

Supplemental Oxygenation

Although studies evaluating the impact of supplemental oxygenation on SSI risk have had varying results, overall they provide support for the benefit of administering increased fraction of inspired oxygen (FiO2) both intraoperatively and post-extubation in the immediate postoperative period for patients with normal pulmonary function who undergo general anesthesia with endotracheal intubation. Benefit was seen in studies in which normothermia and adequate volume replacement were monitored and maintained [52, 53, 54], suggesting the importance of optimizing parameters needed to ensure tissue oxygen delivery in order to maximize the impact of supplemental oxygenation on SSI prevention.

Preoperative *Staphylococcus aureus* Screening and Decolonization

A number of recent studies have assessed the impact of a variety of strategies that include *Staphylococcus aureus* (SA) decolonization, including a randomized controlled trial performed in the Netherlands in which patients were screened for SA carriage on hospital admission and patients found to be SA carriers were then randomized to receive either 5 days of intranasal mupirocin and chlorhexidine bathing or placebo. In this study, SA carriers who received intranasal mupirocin and chlorhexidine bathing had significantly lower SSI risk [55]. A systematic review and meta-analysis evaluating studies that assessed the effectiveness of nasal SA decolonization and inclusion of a glycopeptide for AMP on SSI risk for patients undergoing cardiac surgery and orthopedic total joint replacement surgery concluded that a bundled intervention including nasal decolonization for all SA carriers and glycopeptide prophylaxis for methicillin-resistant SA (MRSA) carriers may decrease rates of SSI caused by SA or other Gram-positive bacteria [56]. A subsequent prospective, observational multicenter study involving patients who underwent cardiac surgery and hip or knee replacement procedures demonstrated that a bundled intervention that included preoperative SA screening, decolonization of SA carriers with intranasal mupirocin and topical chlorhexidine, and targeted addition of vancomycin to cefazolin or cefuroxime AMP for MRSA carriers was associated with a significantly lower deep incisional and organ/space SSI risk (rate ratio 0.58, 95% confidence interval 0.37–0.92) [57].

SSI Prevention Bundles

During recent years, there has been increasing interest in using bundled protocols to prevent healthcare-associated infections. A "bundle" is usually defined as a grouping of evidence-based practices that individually improve care.

Central line-associated bloodstream infection (CLABSI) prevention bundles, for example, have been shown to result in significant improvements in CLABSI outcomes [58]. Some examples of SSI prevention bundles that merit attention are discussed below.

1. Surgical Safety Checklist

Haynes et al. in collaboration with the World Health Organization evaluated a Surgical Safety Checklist in a multinational, multicenter observational study. Their checklist consisted of questions assessing adherence to practices aimed at preventing surgical complications. The checklist questions were administered at three perioperative time points (before induction of anesthesia, before skin incision, and before patient left the operating room). Implementation of the checklist was associated with significant improvements in SSI and mortality rates in a before-after comparison [59].

2. Other SSI Prevention Bundles

A variety of other SSI prevention bundles have been evaluated. These typically include SCIP-recommended practices in addition to varying combinations of supplemental practices including many of those discussed above. A systematic review and meta-analysis by Tanner et al. assessed the impact of SSI prevention bundles for colorectal surgery using results from 13 studies and concluded that the use of evidence-based surgical care bundles significantly reduced the risk of SSI compared with standard care (risk ratio of 0.55, 95% confidence interval of 0.39–0.77) [60].

3. Enhanced Recovery After Surgery

The use of a bundle of perioperative practices aimed at improving surgical recovery following colorectal procedures referred to as Enhanced Recovery After Surgery (ERAS) has been gaining support in the surgical community based on a growing body of literature suggesting beneficial impact of ERAS bundles on postoperative outcomes, including SSI [61–64]. ERAS protocols typically include administration of a carbohydrate beverage prior to surgery, avoidance of sedatives, goal-directed fluid administration, multimodal pain control minimizing the use of narcotics, and postoperative immediate diet and mobilization. ERAS protocols have been implemented with and without additional bundles of practices specifically aimed at SSI prevention. For example, a study by Keenan et al. evaluated sequential implementation of an ERAS pathway followed by a SSI prevention bundle and found that introduction of the ERAS pathway alone resulted in reduced length of stay and improved superficial and organ/space SSI rates, while subsequent addition of an SSI bundle that included mechanical bowel preparation with oral antibiotics, preoperative chlorhexidine cleansing of patient, chlorhexidine-alcohol preoperative skin preparation, standardized AMP, maintenance of euglycemia and normothermia, fascial wound protectors, gown and glove change prior to fascial and skin closure, and a dedicated wound closure tray led to further significant reductions in SSI and sepsis rates [65].

The impact of SSI bundles likely depends on adherence to bundle elements, and some studies demonstrated that the number of bundle processes that were adhered to correlated with patients' SSI risk, suggesting an additive effect for each SSI prevention element [66].

Change of Focus from Process to Outcome Measures Used for Pay for Performance

Over the past several years, CMS's approach to assessing the quality of care provided by hospitals has undergone a major shift in focus from process to outcome measures. In the area of SSI prevention, the shift toward focus on SSI outcomes was reflected by a change in CMS reimbursement practices implemented in October of 2008 in which CMS ceased additional payment for hospital-acquired conditions not present on admission (POA), including some specific types of SSI [67]. Beginning in 2012, acute care hospitals were required to either report SSI outcomes following abdominal hysterectomy and colon surgery in addition to other healthcare-associated infection outcomes to CMS as part of the Hospital Inpatient Quality Reporting Program or receive a 2% penalty on Medicare reimbursement. As part of the CMS HAC Reduction program, beginning in fiscal year 2016, CMS reimbursement was tied to hospital performance around SSI and other healthcare-associated infection outcomes. Hospitals with HAC scores that fall within the lowest-performing quartile are subject to a 1% loss in total Medicare inpatient prospective payment system (IPPS) reimbursement [68].

Metrics used to determine a hospital's VBP score are divided into domains that include clinical process of care (including the SCIP measures), patient experience, and outcome measures (including SSI outcomes following colon surgery and abdominal hysterectomy procedures). In fiscal year 2013, process of care measures accounted for 70% of a hospital's VBP score, but by fiscal year 2016, process of care measures accounted for only 20% of VBP scores compared to a 40% weight for outcome measures. Starting in fiscal year 2017, VBP will no longer include SCIP process of care measures. By fiscal year 2017, a hospital's VBP performance will have the potential to result in forfeit of up to a 2% withhold in Medicare IPPS base operating payments.

Limitations of SSI Outcome Measures for Pay for Performance

Although judging the performance of hospitals based on SSI outcomes makes intuitive sense since the goal of quality improvement efforts is ultimately to prevent postoperative complications, utilizing SSI outcomes as pay-for-performance metrics has led to a number of major challenges.

SSI Surveillance Relies on Subjective Interpretation of Medical Information and Is Vulnerable to Gaming

There are a number of studies that demonstrate substantial variation in the completeness of SSI data reported by hospitals [69, 70]. Even when using standardized CDC National Healthcare Safety Network (NHSN) surveillance definitions [71], application of SSI surveillance definitions requires some subjective interpretation of clinical information. For example, assessing the presence of "purulent drainage," a criterion for both deep incisional and organ/space SSIs, requires both highly subjective interpretation of the quality of drainage material and documentation in the medical record. Some SSI criteria also depend on provider practices that may vary between hospitals; for example, facilities that are more aggressive about aspirating and culturing postoperative intra-abdominal fluid collections are more likely to fulfill microbiology-based SSI criteria.

Ascertainment of SSI diagnosed after hospital discharge can be particularly challenging, especially for postoperative infections diagnosed and treated solely in the ambulatory setting or SSI diagnosed and treated at healthcare facilities other than the hospital where the original surgical procedure took place. The proportion of patients with SSI who are readmitted to the same hospital where the index surgery took place can vary considerably among healthcare facilities, and this can impact the completeness of SSI ascertainment and relative ranking of hospitals based on SSI outcomes [72].

Surveillance Bias and Accessibility to Data

The completeness of hospitals' SSI ascertainment is highly dependent on the intensity of resources focused on SSI surveillance. Healthcare facilities with robust electronic health records or surveillance processes that effectively utilize automated medical data will be more likely to capture information that can be used to determine the presence of postoperative infections. These hospitals are therefore likely to report more SSI events than healthcare facilities with limited access to electronic health data and can be erroneously characterized and penalized as poor performers. Variability in infection preventionist access to electronic surveillance systems is reflected in the finding by Stone et al. that only 34.3% of NHSN facilities reported using an electronic surveillance system for identifying healthcare-associated infections [73]. In addition, SSI surveillance is resource intensive, requiring review of a broad range of clinical information in order to apply surveillance definitions, and the effort available for surveillance can vary substantially between facilities, affecting the completeness of SSI ascertainment [74].

Using SSI Outcomes to Judge the Performance of Hospitals Requires Adequate Risk Adjustment

In order to meaningfully compare hospitals' SSI outcomes, adequate risk adjustment is critically important in order to take account of intrinsic differences in patient risk factors that are not modifiable through improvements in hospitals' practices. Currently, the standardized infection ratio for complex SSI used for CMS submission utilizes only a small number of variables for SSI risk adjustment. For example, for patients undergoing colon surgery and abdominal hysterectomy procedures, only age, gender, body mass index, American Society of Anesthesiologists (ASA) score, presence or absence of diabetes, and wound closure technique are included in the logistic regression model used for risk adjustment [75]. Other potentially important risk factors including medical comorbidities that increase SSI risk (e.g., active malignancies) are not currently taken into account, and hospitals with more complex patient populations at higher intrinsic risk for SSI may be more likely to receive lower performance rankings and to incur financial penalties. The possibility of inadequate risk adjustment was highlighted in a recent study examining Medicare fiscal year 2015 payments that found that major teaching hospitals were four times more likely to receive the HAC Reduction penalty compared to nonteaching hospitals [76].

Outcome Measures Are Challenging to Apply to Small-Volume Hospitals

Because SSIs are relatively rare events and because of limitations in the stability and reliability of SSI outcome measures for hospitals that perform relatively few surgical procedures, SSI data for all hospitals with <1 expected SSI per year based on procedure volume are excluded from metrics contributing to that hospital's HAC score and ranking. Based on CMS Hospital Compare data, this meant that SSI

outcome measures from over 30% of hospitals performing colon surgery and over 60% of hospitals performing abdominal hysterectomy procedures were excluded from metrics used to determine those hospitals' HAC scores during the performance period of April 2014 through March 2015 [77]. This is problematic for a number of reasons. First, it means absence of SSI performance measures for a large proportion of hospitals that perform the targeted surgical procedures. Secondly, there is evidence that hospitals that perform a lower volume of surgical procedures may have higher postoperative complication rates [78–80]; this means that the hospitals that are most likely to benefit from SSI-related quality improvement efforts are excluded from submitting SSI metrics and that some larger-volume hospitals may consequently receive undeserved financial penalties. The study by Kahn et al. described above found that hospitals with 400 or more beds were almost twice as likely to receive the HAC penalty and more than twice as likely to be penalized under VBP compared to hospitals with fewer than 100 beds [76].

The limitations of using SSI outcome measures for interhospital comparisons are underscored by studies that suggest that hospitals' performance around healthcare-associated infection metrics may not adequately reflect the quality of care provided. A study by Rajaram et al. evaluated hospitals that were penalized based on HAC Reduction program performance data used for fiscal year 2015 assessments and examined the association between those hospitals' HAC scores and other quality metrics. The investigators found that hospitals that were penalized under the HAC program were more likely to have quality accreditations, to offer advanced services, to be major teaching institutions, and to have better performance on other process and outcome measures, suggesting a disconnect between hospitals' HAC scores and the quality of care provided [81].

Going Forward: Back to the Future?

CMS incentives and penalties have the potential to exert powerful motivating forces on hospital decision-makers and can result in major changes in prioritization of hospital resources. For this reason, thoughtful alignment of incentives and penalties with performance metrics that are likely to promote adherence to processes that result in improved patient outcomes is critically important. As discussed above, CMS is in the process of transitioning from using process measures to outcome measures as pay-for-performance SSI metrics. Limitations around the ability to standardize application of SSI surveillance definitions and methods and to adequately risk adjust SSI outcomes may unfairly penalize some high-performing hospitals with robust surveillance processes or complex, intrinsically high-risk patients and excludes low-volume hospitals from evaluation. For these reasons, investing research into improving our ability to perform adequate SSI outcome risk adjustment is essential.

Until these challenges are resolved, it may also be worth considering shifting the focus of pay-for-performance programs back toward SSI process measures. In order to optimize the impact of SSI process of care measures, it will be important to choose processes that are evidence-based and that augment fundamental SSI prevention practices already in place at most hospitals, to consider procedure-specific modifications of recommendations, and to take into consideration the additive effects of bundled approaches to SSI prevention.

Importantly, our ability to prevent SSI is limited by gaps in our understanding about which perioperative practices, individually or in combination, are most likely to impact SSI risk. We also have limited insight into about how best to implement and sustain adherence to those practices that have been shown to be effective. In order to optimize national efforts to improve surgical outcomes, it will be essential to allocate adequate financial resources to support high-quality SSI prevention research.

References

1. DeFrances CJ, Lucas CA, Buie VC, Golosinskiy A. 2006 National Hospital Discharge Survey. National health statistics reports; no 5. (2008); Available at: http://www.cdc.gov/nchs/data/nhsr/nhsr005.pdf. Accessed 2 Feb 2016.
2. Cullen KA, Hall MJ, Golosinskiy A. Ambulatory Surgery in the United States, 2006. National health statistics reports; no 11. Revised. (2009); Available at: http://www.cdc.gov/nchs/data/nhsr/nhsr011.pdf. Accessed 2 Feb 2016.
3. Magill SS, Edwards JR, Bamberg W, et al. Multistate point-prevalence survey of healthcare-associated infections. New Engl J Med. 2014;370:1198–208.
4. Umscheid CA, Mitchell MD, Doshi JA, Agarwal R, Williams K, Brennan PJ. Estimating the proportion of healthcare-associated infections that are reasonably preventable and the related mortality and costs. Infect Control Hosp Epidemiol. 2011;32(2):101–14.
5. Scott RD. The direct medical costs of healthcare-associated infections in U.S. hospitals and the benefits of prevention. Centers for Disease Control and Prevention (2009); Available at: http://www.cdc.gov/hai/pdfs/hai/scott_costpaper.pdf Accessed 29 Feb 2016.
6. Stone PW, Braccia D, Larson E. Systematic review of economic analyses of health care associated infections. Am J Infect Control. 2005;33(9):501–9.
7. Zimlichman E, Henderson D, Tamir O, et al. Health care-associated infections: a meta-analysis of costs and financial impact on the US health care system. JAMA Intern Med. 2013;173(22):2039–46.
8. Bratzler DW, Houck PM. Antimicrobial prophylaxis for surgery: an advisory statement from the National Surgical Infection Prevention Project. Clin Infect Dis. 2004;38:1706–15.
9. Bratzler DW, Hunt DR. The surgical infection prevention and surgical care improvement projects: national initiatives to improve outcomes for patients having surgery. Clin Infect Dis. 2006;43:322–30.
10. Dellinger EP, Hausmann SM, Bratzler DW, et al. Hospitals collaborate to decrease surgical site infections. Am J Surg. 2005;190:9–15.

11. U.S. Government Printing Office. The deficit reduction act of 2005. Available at: https://www.gpo.gov/fdsys/pkg/PLAW-109publ171/html/PLAW-109publ171.htm Accessed 26 Feb 2016.
12. Centers for Medicare & Medicaid Services. Hospital compare. Available at: https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/hospitalcompare.html. Accessed 26 Feb 2016.
13. Centers for Medicare & Medicaid Services. Medicare program: hospital inpatient prospective payment systems for acute care hospitals and the long-term care hospital prospective payment system and fiscal year 2013 rates; hospitals' resident caps for graduate medical education payment purposes; quality reporting requirements for specific providers and for ambulatory surgical centers. Final rule. Fed Regist. 2012;77(170):53257–750.
14. Centers for Medicare & Medicaid Services. Medicare program; hospital inpatient value-based purchasing program. Final rule. Fed Regist. 2011;76(88):26490–547.
15. Bratzler DW, Dellinger EP, Olsen KM, et al. Clinical practice guidelines for antimicrobial prophylaxis in surgery. Am J Health-System Pharm. 2013;70(3):195–283.
16. Sievert DM, Ricks P, Edwards JR, et al. Antimicrobial-resistant pathogens associated with healthcare-associated infections: summary of data reported to the National Healthcare Safety Network at the Centers for Disease Control and Prevention, 2009–2010. Infect Control Hosp Epidemiol. 2013;34(1):1–14.
17. Classen DC, Evans RS, Pestotnik SL, et al. The timing of prophylactic administration of antibiotics and the risk of surgical-wound infection. New Engl J Med. 1992;326:281–6.
18. Steinberg JP, Braun BI, Hellinger WC, et al. Timing of antimicrobial prophylaxis and the risk of surgical site infections: results from the trial to reduce antimicrobial prophylaxis errors. Ann Surg. 2009;205(1):10–6.
19. van Kasteren ME, Mannien J, Ott A, et al. Antibiotic prophylaxis and the risk of surgical site infections following total hip arthroplasty: timely administration is the most important factor. Clin Infect Dis. 2007;44(7):921–7.
20. Harbath S, Samore MH, Lichtenberg D, Carmeli Y. Prolonged antibiotic prophylaxis after cardiovascular surgery and its effect on surgical site infections and antimicrobial resistance. Circulation. 2000;101:2916–21.
21. Coakley BA, Sussman ES, Wolfson TS, et al. Postoperative antibiotics correlate with worse outcomes after appendectomy for nonperforated appendicitis. J A Coll Surg. 2011;213(6):778–83.
22. Tanner J, Norrie P, Melen K. Preoperative hair removal to reduce surgical site infection. (2011). Cochrane Database of Systematic Reviews issue 11: CD004122.
23. Furnary AP, Zerr KJ, Grunkemeier GL, Starr A. Continuous intravenous insulin infusion reduces the incidence of deep sternal wound infection in diabetic patients after cardiac surgical procedures. Ann Thorac Surg. 1999;67:352–60.
24. Carr JM, Sellke FW, Fey M, et al. Implementing tight glucose control after coronary artery bypass surgery. Ann Thorac Surg. 2005;80:902–9.
25. Dronge AS, Perkal MF, Kancir S, Concato J, Aslan M, Rosenthal RA. Long-term glycemic control and postoperative infectious complications. Arch Surg. 2006;141(4):375–80.
26. Golden SH, Peart-Vigilance C, Kao WH, Brancati FL. Perioperative glycemic control and the risk of infectious complications in a cohort of adults with diabetes. Diabetes Care. 1999;22(9):1408–14.
27. Olsen MA, Nepple JJ, Riew KD, et al. Risk factors for surgical site infection following orthopaedic spinal operations. J Bone Joint Surg Am. 2008;90(1):62–9.
28. Kwon S, Thompson R, Dellinger P, Yanez D, Farrohki E, Flum D. Importance of perioperative glycemic control in general surgery: a report from the surgical care and outcomes assessment program. Ann Surg. 2013;257(1):8–14.
29. Umpierrez GE, Smiley D, Jacobs S, et al. Randomized study of basal-bolus insulin therapy in the inpatient management of patients with type 2 diabetes undergoing general surgery (RABBIT 2 surgery). Diabetes Care. 2011;34(2):256–61.
30. Anderson DJ, Podgorny K, Berríos-Torres SI, et al. Strategies to prevent surgical site infections in acute care hospitals: 2014 update. Infect Control Hosp Epidemiol. 2014;35(suppl 2):S66–88.
31. Berríos-Torres SI, Umscheid CA, Bratzler DW, et al. Centers for Disease Control and Prevention guideline for the prevention of surgical site infection, 2017. JAMA Surg. 2017; [published online May 3, 2017]. JAMASurg. doi:10.1001/jamasurg.2017.0904
32. Gandhi GY, Nuttall GA, Abel MD, et al. Intensive intraoperative insulin therap versus conventional glucose management during cardiac surgery: a randomized trial. Ann Intern Med. 2007;146(4):233–43.
33. Chan RP, Galas FR, Hajjar LA, et al. Intensive perioperative glucose control does not improve outcomes of patients submitted to open-heart surgery: a randomized controlled trial. Clinics (Sao Paulo). 2009;64(1):51–60.
34. Kurz A, Sessler DI, Lenhardt R. Study of wound infection and temperature group. Perioperative normothermia to reduce the incidence of surgical wound infection and shorten hospitalization. N Engl J Med. 1996;334(19):1209–15.
35. Melling AC, Ali B, Scott EM, Leaper DJ. Effects of preoperative warming on the incidence of wound infection after clean surgery: a randomised controlled trial. Lancet. 2001;358(9285):876–80.
36. National Institute for Health and Clinical Excellence (NICE). Surgical site infection: prevention and treatment of surgical site infection. London: NICE, (2008). http:www.nice.org.uk/nicemedia/pdf/CG74NICEGuideline.pdf. Accessed Feb 26 2016.
37. Nguyen N, Yegiyants S, Kaloostian C, Abbas MA, Difronzo LA. The surgical care improvement Project (SCIP) initiative to reduce infection in elective colorectal surgery: which performance measures affect outcome? Am Surg. 2008;74(10):1012–6.
38. Hawn MT, Itani KM, Gray SH, Vick CC, Henderson W, Houston TK. Association of timely administration of prophylactic antibiotics for major surgical procedures and surgical site infection. J Am Coll Surg. 2008;206(5):814–9.
39. Stulberg JJ, Delaney CP, Neuhauser DV, Aron DC, Fu P, Koroukian SM. Adherence to surgical care improvement Project measures and the association with postoperative infections. JAMA. 2010;303(24):2479–85.
40. Sands K, Vineyard G, Platt R. Surgical site infections occurring after hospital discharge. J Infect Dis. 1996;173(4):963–70.
41. Hawn MT, Vick CC, Richman J, Holman W, Deierhoi RJ, Graham LA, Henderson WG, KMF I. Surgical site infection prevention: time to move beyond the surgical care improvement program. Ann Surg. 2011;254:494–501.
42. Bratzler DW. Surgical care improvement project performance measures: good but not perfect. Clin Infect Dis. 2013;56(3):428–9.
43. The Joint Commission. Specifications manual for national hospital inpatient quality measures. Available at: http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx. Accessed 26 Feb 2016.
44. Kamel C, McGahan L, Polisena J, et al. Preoperative skin antiseptic preparations for preventing surgical site infections: a systematic review. Infect Control Hosp Epidemiol. 2012;33:608–17.
45. Darouiche RO, Wall MJ, Itani KM, et al. Chlorhexidine-alcohol versus povidone-iodine for surgical-site antisepsis. NEJM. 2010;362:18–26.
46. Dumville JC, McFarlane E, Edwards P, Lipp A, Holmes A. Preoperative skin antiseptics for preventing surgical wound infections after clean surgery. Cochrane Database Syst Rev 2013; Issue 3. Art. No.: CD003949. doi:10.1002/14651858.CD003949.pub3

47. Guenaga KF, Matos D, Wille-Jorgensen P. Mechanical bowel preparation for elective colorectal surgery. Cochrane Database Syst Rev. 2011;9:CD001544.
48. Englesbe MJ, Brooks L, Kubus J, et al. A statewide assessment of surgical site infection following colectomy: the role of oral antibiotics. Ann Surg. 2010;252(3):514–9.
49. Englesbe; Nelson RL, Gladman E, Barbateskovic M. Antimicrobial prophylaxis for colorectal surgery. Cochrane Database of Syst Rev 2014; Issue 5. Art. No.: CD001181. doi: 10.1002/14651858.CD001181.pub4
50. Deierhoi RJ, Dawes LG, Vick C, Itani KMF, Hawn MT. Choice of intravenous antibiotic prophylaxis for colorectal surgery does matter. J Am Coll Surg. 2013;217:763–9.
51. Dalfino L, Giglio MT, Puntillo F, et al. Haemodynamic goal-directed therapy and postoperative infections: earlier is better. A systematic review and meta-analysis. Crit Care. 2011;153:R154.
52. Belda FJ, Aguilera L, Garcia de la Asuncion J, et al. Supplemental perioperative oxygen and the risk of surgical wound infection: a randomized controlled trial. JAMA. 2005;294(16):2035–2042.
53. Bickel A, Gurevits M, Vamos R, et al. Perioperative hyperoxygenation and wound site infection following surgery for acute appendicitis: a randomized, prospective, controlled trial. Arch Surg. 2011;146(4):464–470.
54. Robert Greif, Ozan Akça, Ernst-Peter Horn, Andrea Kurz, Daniel I. Sessler, (2000) Supplemental Perioperative Oxygen to Reduce the Incidence of Surgical-Wound Infection. New England Journal of Medicine 342 (3):161–167.
55. Bode LG, Kluytmans JA, Wertheim HF, et al. Preventing surgical-site infections in nasal carriers of *Staphylococcus aureus*. New Engl J Med. 2010;362:9–17.
56. Schweizer M, Perencevich E, McDanel J, et al. Effectiveness of a bundled intervention of decolonization and prophylaxis to decrease Gram positive surgical site infections after cardiac or orthopedic surgery: systematic review and meta-analysis. BMJ. 2013;346:f2743.
57. Schweizer ML, et al. Association of a bundled intervention with surgical site infections among patients undergoing cardiac, hip or knee surgery. JAMA. 2015;313(21):2162–71.
58. Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. N Engl J Med. 2006;355:2725–32.
59. Haynes AB, Weiser TG, Berry WR, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. New Engl J Med. 2009;360:491–9.
60. Tanner J, Padley W, Assadian O, Leaper D, Kiernan M, Edmiston C. Do surgical care bundles reduce the risk of surgical site infections in patients undergoing colorectal surgery? A systematic review and cohort meta-analysis of 8,515 patients. Surgery. 2015;158:66–77.
61. Gustafsson UO, Scott MJ, Schwenk W, et al. Guidelines for perioperative care in elective colonic surgery: enhanced recovery after surgery (ERAS(R)) Society recommendations. World J Surg. 2013;37:259–84.
62. Getzeiler CV, Rotramel A, Wilson C, et al. Prospective study of colorectal enhanced recovery after surgery in a community hospital. JAMA Surg. 2014;149:955–61.
63. Nicholson A, Lowe MC, Parker J, et al. Systematic review and meta-analysis of enhanced recovery programmes in surgical patients. Br J Surg. 2014;101:172–88.
64. Zhuang CL, Ye XZ, Zhang XC, et al. Enhanced recovery after surgery programs versus traditional care for colorectal surgery: a meta-analysis of randomized controlled trials. Dis Colon Rectum. 2013;56:667–78.
65. Keenan JE, Speicher PJ, Nussbaum DP, Abdelgadir Adam M, Miller TM, Mantyh CR, Thacker JKM. Improving outcomes in colorectal surgery by sequential implementation of multiple standardized care programs. J Am Coll Surg. 2015;221:404–14.
66. Waits SA, Fritze D, Banarjee M, et al. Developing an argument for bundled interventions to reduce surgical site infection in colorectal surgery. Surgery. 2014;155(4):602–6.
67. Centers for Medicare & Medicaid. Hospital-acquired conditions. Available at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html Accessed 29 Feb 2016.
68. Centers for Medicare & Medicaid Services. Medicare program; hospital inpatient prospective payment systems for acute care hospitals and the long-term care hospital prospective payment system and fiscal year 2015 rates; quality reporting requirements for specific providers; reasonable compensation equivalents for physician services in excluded hospitals and certain teaching hospitals; provider administrative appeals and judicial review; enforcement provisions for organ transplant centers; and electronic health record (EHR) incentive program. Final rule. Fed Register. 2014;79(163):49853–50536.
69. Calderwood MS, Ma A, Khan YM, et al. Use of Medicare diagnosis and procedure codes to improve detection of surgical site infections following hip arthroplasty, knee arthroplasty, and vascular surgery. Infect Control Hosp Epidemiol. 2012;33(1):40–9.
70. Yokoe DS, Khan Y, Olsen MA, et al. Enhanced surgical site infection surveillance following hysterectomy, vascular, and colorectal surgery. Infect Control Hosp Epidemiol. 2012;33(8):768–73.
71. Centers for Disease Control and Prevention. National healthcare safety network. Surgical site infection (SSI) event. Available at: www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf. Accessed 28 Feb 2016.
72. Yokoe DS, Avery TR, Platt R, Huang SS. Reporting surgical site infections following total hip and knee arthroplasty: impact of limiting surveillance to the operative hospital. Clin Infect Dis. 2013;57(9):1282–8.
73. Stone PW, Pogorzelska-Maziarz M, Herzig CT, et al. State of infection prevention in US hospitals enrolled in the National Healthcare Safety Network. Am J Infect Control. 2014;42(2):94–9.
74. Talbot TR, et al. Public reporting of healthcare-associated infection data: recommendations from the healthcare infection control practices advisory committee. Ann Intern Med. 2013;159:631–5.
75. Centers for Disease Control and Prevention. National Healthcare Safety Network. The NHSN Standardized Infection Ratio (SIR). (2017). Available at: https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/nhsn-sir-guide.pdf Accessed 17 Jul 2017.
76. Kahn CN, Ault T, Potetz L, Walke T, Chambers JH, Burch S. Assessing Medicare's hospital pay-for-performance programs and whether they are achieving their goals. Health Aff. 2015;34(8):1281–8.
77. Centers for Medicare & Medicaid Services. Hospital compare datasets. Available at: https://data.medicare.gov/data/hospital-compare Accessed 26 Feb 2016.
78. Katz JN, Losina E, Barrett J, Phillips CB, Mahomed NN, Lew RA, et al. Association between hospital and surgeon procedure volume and outcomes of total hip replacement in the United States Medicare population. J Bone Joint Surg Am. 2001;83-A(11):1622–9.
79. Birkmeyer JD, Siewers AE, Finlayson EV, Stukel TA, Lucas FL, Batista I, et al. Hospital volume and surgical mortality in the United States. N Engl J Med. 2002;346(15):1128–37.
80. Guebbels EL, Wille JC, Nagelkerke NJ, Vandenbroucke-Grauls CM, Grobbee DE, de Boer AS. Hospital-related determinants for surgical-site infection following hip arthroplasty. Infect Control Hosp Epidemiol. 2005;26(5):435–41.
81. Rajaram R, Chung JW, Kinnier CV, Barnard C, Mohanty S, Pavey ES, McHugh MC, Bilimoria KY. Hospital characteristics associated with penalties in the Center for Medicare & Medicaid services hospital-acquired condition reduction program. JAMA. 2015;314(4):375–83.