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The Surgical Care Improvement Project and Prevention of Post-Operative Infection, Including Surgical Site Infection

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Abstract

Background: In response to inconsistent compliance with infection prevention measures, the Centers for Medicare & Medicaid Services collaborated with the U.S. Centers for Disease Control and Prevention on the Surgical Infection Prevention (SIP) project, introduced in 2002.
Methods: Quality improvement measures were developed to standardize processes to increase compliance. In 2006, the Surgical Care Improvement Project (SCIP) developed out of the SIP project and its process measures. These initiatives, published in the *Specifications Manual for National Inpatient Quality Measures*, outline process and outcome measures. This continually evolving manual is intended to provide standard quality measures to unify documentation and track standards of care.
Results: Seven of the SCIP initiatives apply to the peri-operative period: Prophylactic antibiotics should be received within 1 h prior to surgical incision (1), be selected for activity against the most probable antimicrobial contaminants (2), and be discontinued within 24 h after the surgery end-time (3); (4) euglycemia should be maintained, with well-controlled morning blood glucose concentrations on the first two post-operative days, especially in cardiac surgery patients; (6) hair at the surgical site should be removed with clippers or by depilatory methods, not with a blade; (9) urinary catheters are to be removed within the first two post-operative days; and (10) normothermia should be maintained peri-operatively.
Conclusions: There is strong evidence that implementation of protocols that standardize practices reduce the risk of surgical infection. The SCIP initiative targets complications that account for a significant portion of preventable morbidity as well as cost. One of the goals of the SCIP guidelines was a 25% reduction in the incidence of surgical site infections from implementation through 2010. Process measures are becoming routine, and as we practice more evidence-based medicine, it falls to us, the surgeons and scientists, to be active, not only in the implementation and execution of these measures, but in the investigation of clinical questions and the writing of protocols. We are responsible for ensuring that out-of-date practices are removed from use and that new practices are appropriate, achievable, and effective.

In 1970, the U.S. Centers for Disease Control and Prevention (CDC) established a system to monitor the rates of and trends in nosocomial infections that is called the National Nosocomial Infections Surveillance (NNIS) System. Their 1999 *Guideline for Prevention of Surgical Site Infection* reported that surgical site infections (SSIs) were the third most frequently reported nosocomial infections. In addition, they were the most common nosocomial infections among surgical patients and of the deaths among SSI patients, 77% were related to infection [1].

Many hospitals are not yet adhering adequately to national standards of peri-operative practices proved to reduce surgical morbidity, including appropriate selection, timing, and discontinuation of prophylactic antibiotics. This was revealed by a retrospective study of 34,133 Medicare patients undergoing surgery at 2,965 hospitals. Three main outcome measures were evaluated, namely, the percentage of patients who received prophylactic antibiotics within 1 h before surgery, who received an antibiotic selected in accordance with current guidelines, and who had the antibiotic discontinued within

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24 h after surgery. The results were unsatisfactory, with only 55.7% of patients receiving antibiotics on time and only 40.7% having antibiotics discontinued after 24 h. On the other hand, the selection of antibiotic was consistent with current standards 92.6% of the time [2].

In response to inconsistent compliance with infection prevention measures, in 2002, the Centers for Medicare & Medicaid Services (CMS) collaborated with the CDC on the *Surgical Infection Prevention* (SIP) project [3]. The purpose of this initiative was to develop quality improvement measures to standardize processes to increase compliance that could be extended and applied nationally. These measures included the timeliness, selection, and duration of peri-operative antibiotics. The investigators found both clinically and statistically significant reductions in post-operative infection rates after implementation of these measures [3].

In 2006, the *Surgical Care Improvement Project* (SCIP) developed out of the SIP project and its process measures. The specific SCIP initiatives are published in the *Specifications Manual for National Inpatient Quality Measures* (*Specifications Manual*). This continually evolving manual (available online at www.qualitynet.org) was created by the CMS and the Joint Commission to provide a standard form of quality measures in order to unify documentation and track various standards of care.

SCIP Performance Measures

The *Specifications Manual* outlines seven specific SCIP process and outcome measures applicable in the peri-operative period, as listed in Table 1. Each of these measures was designed to track the compliance of hospitals with national standards of care. Studies have confirmed the benefit of each outcome measure, although the measures were derived from the recommendations of appropriate societies and not based on the primary literature.

SCIP-INF 1

The first three SCIP infection measures pertain to the timing, type, and discontinuation of prophylactic antibiotics. In 1985, a prospective study conducted on non-emergency surgical patients concluded that a computer-generated prompt regarding the timing of antibiotics significantly reduced SSI by providing an automated reminder regarding pre-operative antibiotic dosing [4]. This study was conducted over a two-year period, in which the first year was observational, to monitor current practice patterns and track baseline SSI outcomes; and during the second year, a computer-assisted prompt was placed in a patient's medical record to facilitate compliance with this standard for infection prevention. In the study period, compliance with the rule that antibiotics should be administered within 2 h pre-operatively improved significantly (40% [638/3,263] vs. 58% [1,070/3,568]; $p < 0.03$). Corresponding to the improvement in compliance was a reduction in the post-operative SSI rate (1.8% [28/1,621] vs. 0.9% [16/1,830]; $p < 0.03$). That is, better compliance with antibiotic timing significantly reduced post-operative infectious complications [4].

SCIP-INF 2

The SCIP initiative number two relates to selection of the appropriate antibiotic for the particular operation and, specifically, the most likely antimicrobial contaminants. The antibiotic chosen should be consistent with current guidelines from the Hospital Infection Control Practices Advisory Committee, the American Society of Health-System Pharmacists, the *Medical Letter*, the Infectious Diseases Society of America, the *Sanford Guide to Antimicrobial Therapy*, and the Surgical Infection Society.

The antibiotic selected should provide coverage for the pathogens most likely to be encountered during the operation, have pharmacokinetics that will ensure adequate serum and tissue concentrations, have demonstrated safety, and be cost-effective. The class of antibiotics used most commonly and studied most thoroughly for peri-operative prophylaxis is the cephalosporins [1, 5]. This class is effective against the gram-positive and gram-negative pathogens commonly encountered in general surgery and meets the criteria of an appropriate prophylactic antibiotic described above. Cefazolin generally is the agent of choice for clean operations and also provides adequate coverage for many clean-contaminated cases [1]. For colon operations, a second-generation cephalosporin is recommended to provide anaerobic coverage; cefoxitin is selected frequently. For patients with a cephalosporin allergy, clindamycin or vancomycin can be used for gram-positive coverage, whereas clindamycin or metronidazole can be used for anaerobic coverage [1, 5].

For specific cases or classes of operations such as transplantation and cardiac or orthopedic surgery, antibiotic selection becomes more complex. It is recommended the surgeon consult microorganism reference tables to determine likely pathogens, listed by operation, with references for antimicrobial prophylaxis. An example is the *Guideline for Prevention of Surgical Site Infection, 1999* by Mangram et al. [1].

Table 1. Surgical Care Improvement Project (SCIP) Performance Measures Applicable to the Peri-Operative Period

SCIP infection measure designator	*Performance measure title*
INF-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision
INF-2	Prophylactic Antibiotic Selection for Surgical Patients
INF-3	Prophylactic Antibiotics Discontinued Within 24 H after Surgery End-Time
INF-4	Cardiac Surgery Patients With Controlled 6 AM Postoperative Blood Glucose
INF-6	Surgery Patients with Appropriate Hair Removal
INF-9	Urinary Catheter Removed on Postoperative Day 1 or Postoperative Day 2 with Day of Surgery being Day 0
INF-10	Surgery Patients with Peri-operative Temperature Management

SCIP-INF 3

The discontinuation of prophylactic antibiotics post-operatively defines SCIP initiative three, because there is significant evidence demonstrating no additional benefit to lengthening the course beyond 24 h. This observation is consistent with the rationale that peri-operative antibiotics are not meant to sterilize tissues but rather to reduce the bacterial burden to an inoculum that may be controlled by the patient's defenses. Further administration of antibiotics increases the risk of drug resistance and secondary infections, such as *Clostridium difficile*-related disease. A review of randomized and other prospective clinical trials that compared single-dose with multi-dose prophylactic antibiotics concluded there was no SSI reduction benefit when administering more than a single dose and thus a single dose is appropriate [6].

Several studies have shown that implementation of standard protocols, most of which include the first three SCIP initiatives, can improve outcomes with regard to SSI. For example, Hedrick et al. found a reduction in the incidence of SSI after colorectal operations following the implementation of a peri-operative protocol focusing on the three prophylactic antibiotic measures heralded by SCIP, as well as the maintenance of normothermia and normoglycemia [7]. In this single-institution study, the SSI rate for colorectal procedures in the pre-protocol period was 25.6%, whereas after implementation of the protocol, it was 15.9%, a 39% overall improvement. During this study, compliance with timing of antibiotic administration improved (68% vs. 91%), as did discontinuation of antibiotics within 24 h (71% vs. 93%) [7].

Nguyen et al. [8] showed similar improvements in the incidence of SSI in the colorectal surgery population with the timely administration of prophylactic antibiotics (3.4% vs. 21.7% for the non-compliant time period). This significant difference in the incidence of SSI did not carry over for choice of antibiotic, measured as compliance with the 2007 SCIP-approved regimen for elective colorectal surgery, or for discontinuation of antibiotics within 24 h after the surgery end-time. During this retrospective cohort study, the institutional policy regarding administration of prophylactic antibiotics was changed such that patients received antibiotics only after they had entered the operating room. The greater compliance with timely administration was temporally related to the implementation of this policy, with 50% meeting the time administration criteria pre-policy compared with 87% post-policy [8].

A prospective analysis of patients undergoing intra-abdominal surgical procedures before and after implementation of a quality control initiative focusing on selection, timing of administration, and discontinuation of antibiotics, as well as intraoperative maintenance of normothermia and glycemic control in diabetic patients, was performed at an academic medical center. After implementation of the policy, compliance with antibiotic selection improved significantly (89% vs. 97%), as did timely antibiotic administration. There was a non-significant trend overall toward a lower incidence of SSIs with implementation of the initiative, but a significant decrease in infection rates in patients undergoing laparotomy compared with laparoscopy and upper-gastrointestinal, hepatobiliary, or colorectal procedures [9].

Awareness of these performance measures also is likely a factor in the lower rates of SSI. In a single institution during the first two years of participation in the National Surgical Quality Improvement Program (NSQIP), the rate of superficial incisional SSI in colorectal surgery patients decreased (13.3% vs. 8.3%) and compliance with SCIP guidelines improved (38% vs. 92%) [10]. Whereas the measures themselves have an effect, there is no doubt that additional benefit accrues from greater awareness of these concerns and from the availability of the database registry as a tool to identify problematic areas.

Despite numerous studies verifying the value of these SCIP measures, there are published reports of SCIP-compliant hospitals showing no significant improvement in outcomes. Stulberg et al. published a retrospective cohort study of roughly 405,000 patients from 400 SCIP-reporting hospitals [11]. Those investigators evaluated patients on the basis of two "all-or-none" composite measures. The S-INF measure included all patients with at least two recorded SCIP infection measures during their visits (any combination of INF-1, INF-2, INF-3, INF-4, INF-6, and INF-7), whereas the S-INF-Core included data on the first three infection measures only: INF-1, INF-2, and INF-3. The researchers found compliance with the S-INF was associated with a decrease in the post-operative infection rate (14.2 to 6.8 per 1,000 discharges; adjusted odds ratio [AOR] 0.85; 95% confidence interval [CI] 0.76, 0.95). However, the INF-Core composite process measure was associated with no change in the post-operative infection rate (11.5 to 5.3 per 1,000 discharges; AOR 0.86; 95% CI 0.74, 1.01) [11]. Lastly, for the individual SCIP measures, self-reported adherence was not associated with a decreased risk of post-operative infection.

A second non-supportive study, by Hawn et al. [12], evaluated SCIP INF-1, as this process initiative was proposed as a standard for public reporting as a measure in a pay-for-performance system. The investigators evaluated approximately 9,000 operations and found that incorrectly timed prophylactic antibiotics (not given within 60 min of incision) were not associated with an increase in the incidence of SSIs compared with timely dosed antibiotics (5.8% vs. 4.6%; OR 1.29; 95% CI 0.99, 1.67) [11]. Both Stulberg et al. and Hawn et al. stress the importance of recognizing studies that fail to show a relation between SCIP measures and outcomes. Hospital adherence to SCIP measures is reported publicly to assist patients in selecting centers to provide their surgical care. Thus, the implication that "adherence improves quality" is not supported uniformly.

SCIP-INF 4

Euglycemia is another objective in the prevention of SSIs. Ensuring appropriate glucose concentrations on post-operative days one and two reduces the incidence of SSI in cardiac surgery patients. Measure four of SCIP recommends well-controlled morning glucose concentrations on the first two days post-operatively in these patients.

Early data supporting strict blood glucose control as a means to decrease morbidity in critically ill patients have given way to data showing higher rates of severe hypoglycemia and adverse events with intensive insulin therapy [13–15]. The NICE-SUGAR study [16] supported conventional as opposed to intensive control of blood glucose in terms of overall morbidity and deaths among critically ill patients. On the other hand, a recent meta-analysis found no significant

mortality benefit of intensive insulin therapy in patients in medical intensive care units (ICUs), with no significant difference in hypoglycemic events, whereas a benefit was observed in surgical ICU patients [17].

Addressing the importance of glucose control in the prevention of SSI more specifically, implementation of a post-operative intravenous insulin therapy protocol in diabetic patients after open heart operations was associated with a decrease in the rate of sternal (deep incisional) SSI from 2.4% to 1.5% [18]. Another study compared deep sternal SSI rates in diabetic patients after open cardiac surgery. This second study demonstrated a reduced rate of infections for patients given a continuous insulin infusion compared with subcutaneous injections (2.0% vs. 0.8%) [19]. Finally, a retrospective cohort study of diabetic patients undergoing elective colorectal surgery demonstrated a significant decrease in the rates of SSI in those patients with a mean capillary glucose concentration $\leq 200\,mg/dL$ 48 h after surgery compared with those having concentrations $> 200\,mg/dL$ (29.7% vs. 14.3%) [20].

SCIP-INF 6

The method of hair removal at the surgical site also has been linked to significant differences in SSIs post-operatively and, therefore, became initiative six. A prospective trial completed at The New York Hospital–Cornell Medical Center randomized nearly 2,000 patients to electrical clipping or manual shaving for hair removal before open heart surgery. Electrically clipped patients had a significantly lower rate of mediastinitis than the manually shaved group (4/990 vs. 13/990; $p = 0.024$) [21]. Surgical patients may have no hair removal at all, hair removal with clippers, or removal by depilatory methods. Shaving with a blade now is considered inappropriate for removal of hair pre-operatively.

The 2006 Cochrane review by Tanner et al. [22] summarizes the evidence with regard to hair removal techniques. Again shown is a benefit of clipping or use of depilatory creams over razors for reduction of SSIs. Depilatory creams and clippers have not been compared. Clipping on the day of vs. the day before surgery does not seem to affect the rate of SSIs [22].

SCIP-INF 9

The ninth initiative addresses the prevention of urinary tract infections (UTIs) related to the use of indwelling Foley catheters. The likelihood of these infections correlates directly with duration of catheter use. The National Surgical Infection Prevention Project data were analyzed to determine the ideal duration of Foley catheter use and the optimal time for removal. Approximately 31,000 Medicare patients undergoing major operations were analyzed to determine the frequency and duration of catheter use and its relation to post-operative UTIs. Patients with catheters in place for longer than two days post-operatively had twice the probability of UTI as those with catheterization for less than two days (9.4% vs. 4.5%; $p = 0.04$) [23].

Currently, there are fewer data to demonstrate that implementation of SCIP has reduced the number of UTIs in surgical patients. However, awareness of the protocol has likely increased compliance with the recommendation to remove the catheter within 48 h, which should reduce the likelihood of a catheter-associated infection.

SCIP-INF 10

Maintaining normothermia peri-operatively reduces SSIs and represents the tenth initiative. In a randomized clinical trial, 200 colorectal surgery patients were assigned to either the standard temperature (non-) management or active warming intra-operatively. The intraoperative core temperature was significantly higher in the active warming group than in the standard care patients ($36.6 \pm 0.5^{\circ}C$ vs. $34.7 \pm 0.6^{\circ}C$; $p < 0.001$). This maintenance of normothermia was associated with fewer SSIs, as determined by the significantly lower rate in the active-warming group compared with the standard care group (18/96 [19%] vs. 6/104 [6%]; $p = 0.009$) [24]. It is hypothesized that peri-operative hypothermia causes peripheral vasoconstriction and impaired immune function, resulting in higher rates of SSIs.

As with Foley catheter removal, specific outcomes data for this temperature measure since the 2007 SCIP guidelines were published are lacking. However, Hedrick et al. [9] demonstrated a decrease in the incidence of hypothermia on admission to the post-anesthesia care unit from 15% to 10% following implementation of a bundle of surgical infection prevention strategies in patients undergoing intra-abdominal operations.

The trial completed by Kurz et al. is the only prospective study validating the tenth SCIP initiative; active warming during colorectal operations reduced SSIs. However, there is limited evidence that maintaining normothermia alone prevents SSIs, although mandatory reporting of normothermia is required by hospitals participating in the SCIP [5]. This tenth initiative was instituted in 2009, replacing the previous process measure (SCIP-INF 7), which required reporting of normothermia immediately after colorectal operations specifically [25].

Both SCIP-INF-7 and −10 report on the basis of a particular temperature and not on warming protocols or intra-operative temperature management, as was studied by Kurz et al. A recent study by Lehtinen et al. evaluated peri-operative normothermia and the development of SSIs in gastrointestinal surgery [26]. They completed a matched, case-control study using NSQIP data and patient medical records and identified 146 cases (who had SSI) and 323 matched controls (without SSI). Treated patients were more likely to have normothermia at the conclusion of surgery than were control patients (87.6% vs. 77.8%; $p = 0.015$) [27]. However, the rates of immediate post-operative normothermia were similar (70.6% vs. 65.3%; $p = 0.19$). Overall, no independent association was found between peri-operative normothermia and SSI (adjusted OR 1.05; 95% CI 0.48, 2.33; $p = 0.90$). The authors concluded that active warming protocols reduce SSIs in the colorectal surgery population, but that maintaining normothermia does not independently reduce the risk of SSI in general or other surgical patients.

Discussion

There is sufficient evidence that acquisition of an SSI increases morbidity (length of stay, length of ICU stay, rate of readmission), cost, and the likelihood of death [27]. There also is evidence that implementation of protocols that standardize practices reduce surgical infections. Furthermore, these measures have, generally, decreased the rate of SSIs, although not always.

The success of these measures likely is attributable to the attention being devoted to them, increasing awareness, not only of the individual measures themselves, but also of an individual's or surgical team's compliance. Observation alone may play a substantial role in the improved outcomes noted. This phenomenon, known as the Hawthorne effect, suggests that people perform differently when they know they are being observed. In the case of surgical infection prevention strategies, one test of the effectiveness of the measures being proposed will be the duration of the effect once the active campaign for awareness has ended.

Essentially, the CMS has already mandated reporting of certain performance measures through the threat of reduced hospital reimbursement. In addition, the list of complications that fall under the non-payment umbrella is expanding, as has been discussed elsewhere [28]. The SCIP initiative targets complications that account for a substantial component of both morbidity and cost. As further performance measures and additional events are added to the roster of events that should be "rare" or "never" occur, reimbursement for complications resulting from lack of (or despite) adherence to such measures will hang in the balance.

Although these measures have the noble goal of requiring institutions and clinicians to be aware of and follow guidelines known to be beneficial to patient care, the question is posed of how such events will be recorded, evaluated, and reported. For example, several procedures that once mandated hospitalization now are being performed on an outpatient basis. In addition, whereas reduction in the incidence of certain complications is laudable, elimination of them may not be practical, even in the best of hospitals, as parameters such as preoperative infections and baseline patient characteristics predispose patients to such complications whatever is done at the hospital.

One of the goals of the SCIP guidelines was to effect a 25% reduction in the incidence of SSIs from implementation through 2010. It is likely that more data will appear regarding the outcomes of these initiatives. This will be instrumental, not only for patient care, but also for future policy development and, as such, need to be supported on an institutional level so that accurate results and outcomes are available to inform such decisions. Whether that goal is ever met, and what clinical and financial changes result from the data, will affect us all.

We must continue to evaluate our process measures. In a memorably titled article by Mary T. Hawn, she asked "should performance measures have performance measures?" [29]. The mandatory reporting of process measure adherence, such as SCIP reporting, focuses on narrow measures that serve as poor proxies for the overall quality of surgical care. Hawn pleaded that we limit efforts to measures that are linked directly and intimately to better outcomes, and that future quality improvement projects be evaluated clearly and be "unequivocally" measurable.

Some SCIP initiatives are founded on only a few prominent studies. As described above, some infection studies with similar endpoints have reached divergent conclusions. The design of many of these reports, a retrospective cohort study or a prospective observational study following implementation of a protocol, are not robust, and the findings therefore are not generalizable to broad populations. Future studies must have a robust design in order to provide accurate, reliable data. For protocol implementation to be effective, the focus must not be on a single intervention but rather on broad-scale efficacy. Studies designed to derive a reliable answer must be performed within a large healthcare system or region or as a multi-center trial.

A notable final point is that quality improvement measures are far simpler to implement than to cancel once adopted. One large study reporting a particular finding may prompt widespread implementation despite the absence of adequate supporting data. However, the opposite does not hold true: A single negative study should not lead to abandonment of a process measure. A prime example occurred in 2000 following a study conducted by Greif et al. [30]. The peri-operative administration of F_IO_2 0.8 was used to increase oxygen tension in tissues to decrease the incidence of SSI. This randomized trial found a significant difference in post-operative SSI with supplemental oxygen, prompting wide adoption of this practice. It was not until 2009 that this practice came to an end. Meyhoff et al. published a multi-center trial, PROXI, modeled precisely after the trial of Greif et al., and found no significant difference between the groups in terms of SSIs ($p = 0.64$) [31]. The authors highlighted a number of other studies that found no significant improvement, including one that was closed early because SSIs were more common in the increased inspired oxygen group. This example illustrates that it takes far more negative data and studies to remove inaccurate process measures and practices than it does to implement them.

Over time, process measures may reach exceptional compliance and normalcy in practice, such that mandatory reporting and close monitoring is no longer necessary. At this point, active focus on this process measure can be retired, and attentiveness to patient safety can be redirected to newer measures. New measures in infection prevention will have to display more definitive efficacy before implementation; at this time, none are on the immediate horizon with respect to SSI.

Process measures are here to stay, and as the pendulum swings ever more toward evidence-based practice, it falls to us, the surgeons and scientists caring for patients, to be active, not only in the implementation and execution of these measures, but in the investigation of clinical questions and the writing of protocols. It is our patients, our practices, and our careers that are most affected by such policies; therefore, it is only fitting that we should be responsible for molding these policies, ensuring that out-of-date practices are removed and that those that follow are appropriate, achievable, and effective.

Author Disclosure Statement

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