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The Surgical Care Improvement Project Antibiotic Guidelines: Should We Expect More than Good Intentions?

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Abstract

Since 2006, the Surgical Care Improvement Project (SCIP) has promoted three perioperative antibiotic recommendations designed to reduce the incidence of surgical-site infections. Despite good evidence for the efficacy of these recommendations, SCIP's efforts have not measurably improved rates of surgical site-infections. We offer three arguments as to why SCIP has fallen short of expectations. We then suggest a reorientation of quality improvement efforts to focus less on reporting, and incentivizing adherence to imperfect metrics, and more on creating local and regional quality collaboratives to educate clinicians about how to improve practice. Ultimately, successful quality improvement projects are behavioral interventions that will only succeed to the degree that they motivate individual clinicians, practicing within a particular context, to do the difficult work of identifying failures and iteratively working toward excellence.

Since its inception in 2006, the Surgical Care Improvement Project (SCIP) promoted three perioperative antibiotic recommendations as one component of an ambitious goal to reduce overall surgical complication rates by 25% before 2011.¹ Although SCIP based its antibiotic recommendations on several high-quality studies demonstrating good efficacy, the project fell short. Indeed, a 2011 paper concluded that far from contributing to a portion of the hoped for 25% reduction in complications, "SCIP infection prevention measures did not

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yield measurable improvement in [surgical-site infections].”² In the present article, we begin with a brief overview of SCIP's historical development and then explore why its perioperative prophylactic antibiotic recommendations have failed to provide improved surgical outcomes. Although SCIP began with a set of well-validated patient-care guidelines, numerous factors likely contributed to its failure to meet its own benchmark. Contributing factors may have included an aging population with greater comorbid burdens, increases in antibiotic resistance, and individual practitioners' resistance to adopt best practices. However, amidst the multitude of explanations for SCIP's failure, we believe that three factors in particular have been important determinants of its limited achievement:

- 1) SCIP's delayed launch in relation to the initial adoption by clinicians of the underlying care measures.
- 2) SCIP's inability to quantify the true spectrum of quality care through dichotomous (i.e. all-or-none) process measures.
- 3) SCIP's dependence on unvalidated performance data subject to corruption by pay-for-performance incentives.

Each of these factors has impaired SCIP's effectiveness. Taken together, SCIP's ongoing costs and limited ability to improve outcomes provide a cautionary tale regarding national top-down quality improvement efforts in general. We will conclude with some suggestions about ways of reconceiving future quality improvement programs with a focus on a) local and regional specificity and b) the critical importance of inspiring a culture of improvement among institutions with an ethic of care and among the individuals who work in them.

The origins of perioperative antibiotic guidelines

In 1999, the Centers for Disease Control and Prevention (CDC), as part of a multi-pronged effort to reduce the public health burden of surgical-site infections (SSIs), published a 30-page guideline that included recommendations for targeted perioperative antibiotic prophylaxis.³ The small proportion of the 1999 CDC guidelines that discussed perioperative antibiotics emerged out of a rich scientific literature that included multiple randomized controlled trials, prospective observational trials, and meta-analyses.⁴⁻⁸ This literature established the efficacy of preoperative antibiotic administration in the two hours prior to incision as one important component of reducing SSIs in selected populations. The clinical data were buttressed by laboratory data offering additional scientific rationale for the importance of achieving therapeutic levels of antibiotics in a timely manner when treating tissues with a high risk of surgical infection.⁹⁻¹¹ In the ensuing years, CDC joined with the Centers for Medicare and Medicaid Services (CMS) to create the Surgical Infection Prevention (SIP) Project in 2002, leading to the Surgical Care Improvement Project (SCIP) in 2006. In 2004, the SIP Project included appropriate perioperative antibiotic administration in its core recommendations to reduce surgical morbidity. The CDC's original perioperative guidelines regarding perioperative antibiotics continue to this day in the form of SCIP's present prophylactic antibiotic recommendations (Table 1). The studies on which the CDC guidelines were based included a variety of populations and outcome measures. A representative subset of the CDC's evidence is listed in Table 2. As would be expected, baseline rates of infection and the absolute reduction in rates of SSIs were wide-ranging, but

all of the listed studies showed that timely antibiotic prophylaxis was superior to no antibiotic prophylaxis. The number needed to treat, a measure frequently favored in evidence-based medicine and throughout the present manuscript to help understand the clinical relevance of a given intervention,¹² ranged between 5.3 and 37 patients to prevent one SSI across the different surgical populations. This evidence led to well-intended SCIP recommendations, but at least three factors have markedly impaired the apparent effectiveness of SCIP's implementation.

1) SCIP's delayed launch in relation to the widespread adoption by clinicians of the underlying care measures

In the case of antibiotic prophylaxis, clinical practice by anesthesiologists began to change before the formation of SCIP's quality partnership. By the time SCIP was inaugurated in 2006, the original 1999 CDC guidelines, and the studies on which they were based, had already led to a fairly high rate of adoption of clinical standards for perioperative antibiotic prophylaxis. In 2001, 55.7% adherence to SCIP INF-1 (infection measure 1, regarding timely antibiotic administration) was documented, rising to as high as 76% in 2002.^{13,14} Regarding SCIP INF-2 (infection measure 2, regarding appropriate antibiotic selection), studies found that adherence ranged from 90-92.6% in the early 2000s. Although the numbers left room for improvement, these high baseline adherence rates inevitably diluted the apparent benefit of improved adherence to SCIP antibiotic prophylaxis recommendations in follow-up effectiveness trials. By illustration, assuming that effect sizes for reduction in SSIs remain constant in Table 2, an increase in adherence to timely antibiotic administration (SCIP INF-1) from 0% to 76% among control groups across the five studies,^{13,14} would markedly increase the number of patients needed to treat in order to prevent one additional SSI from the range of 5.3-37 to the range of 21.9-154. This dilution of apparent effectiveness is likely to have been compounded by high compliance with other SCIP INF recommendations, specifically a greater than 90% adherence to appropriate antibiotic selection (SCIP INF-2).

As might be expected, based on the assumption that good baseline clinical practice already existed, intensive efforts to increase adherence to the SCIP recommendations succeeded at improving reported adherence rates, but the marginal benefit experienced by patients proved vanishingly small. In one prospective study, for example, Dellinger, et al. found that the absolute reduction in the incidence of surgical site infections after increasing the already substantial adherence to the SCIP INF recommendations was 0.6% ($p=0.10$).¹⁴ The paradoxical disconnect between the well-documented efficacy of appropriate prophylactic perioperative antibiotic administration and the repeated reports of lack of effectiveness of the SCIP INF recommendations may not be so paradoxical at all, despite continuing to confound many in the medical and health policy community.¹⁵⁻¹⁷

To strengthen the argument that SCIP's antibiotic guidelines were well-founded but that they were enacted too slowly to make a large difference in observed outcomes, it is instructive to look at a study of an infection-reduction bundle that stretched from 2000-2006, and which thus spanned an extended adoption period of the CDC guidelines prior to the establishment of SCIP.¹⁸ Hedrick, et al. showed an effectiveness of increased adherence to an infection-

reduction bundle with an absolute reduction in rates of SSI following colorectal surgery of almost 10% (number needed to treat 10.3).¹⁸ This represents an effect-size over 16 times the that seen in the Dellinger, et al. study that began just two years later in 2002.¹⁴ Even if relative reductions in SSIs had remained steady, they would have corresponded to progressively smaller and harder-to-detect absolute reductions. The association between marginal improvements in care and better outcomes becomes increasingly difficult to detect as baseline care improves.

2) SCIP's inability to quantify quality of care with dichotomous (i.e. all-or-none) process measures

In addition to the relative decline in effectiveness over time, as illustrated above, the effectiveness of the evidenced-based SCIP INF recommendations was likely further diluted by the inability to grade adherence along a continuum by means of all-or-none process measures. Regarding SCIP INF-1, the process measure treats the continuous variable of antibiotic time-before-incision as a dichotomous variable, sharply demarcated at 60 minutes (or 120 minutes in the case of vancomycin and fluoroquinolones). The discontinuous treatment of time by the SCIP INF-1 process measure naturally means that the difference between adherence and non-adherence to timely antibiotic administration may have a tenuous relationship to improved outcomes or to the original evidentiary foundations for the measure.² One of the few interventional studies that discussed the limitations of a dichotomous measure of time, noted that procedures with a long set-up (e.g. cardiac surgery cases or prone-position cases) sometimes demonstrated non-adherence because correct antibiotics had been given shortly before the 60- minute window.¹⁹ In 1992, Classen, et al.⁶ demonstrated the importance of timely antibiotics on rates of SSIs, but their principle finding was to show a significant difference in the efficacy of prophylactic antibiotics given *in reasonable proximity* to the time of incision versus long-before or long-after incision. The difference in efficacy between adjacent time periods was extremely modest. Interestingly, antibiotics given within the hour prior to incision versus the hour after incision demonstrated a non-significant absolute reduction in SSI rates of 0.6% ($p>0.05$). On a similar note, in our post hoc analysis comparing the one-hour preoperative window versus the two hour preoperative window, the observed absolute reduction in the rate of SSIs was 0.2% ($p>0.05$).⁶ In 2013, Hawn, et al. correctly noted, “The empirical superiority of the 60-minute timing metric has yet to be substantiated.”² Unfortunately, a dichotomous process measure such as SCIP INF-1 is insensitive to the difference between antibiotics given 61 minutes prior to incision as compared to antibiotics never given at all. Subtle changes along the continuum of care that have no effect on surgical site infections may receive inappropriate weight in effectiveness trials using SCIP measures. Invalid judgments about quality have been shown to result when dichotomous care metrics are used to evaluate a continuum of care in other medical environments.²⁰ By failing to differentiate meaningful adherence from strict adherence, SCIP's care metrics further diluted their apparent effectiveness.

3) Pay-for-performance - regulation, accreditation, and reimbursement incentives have corrupted the reporting of process measures

Starting with the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, CMS began to incentivize the reporting of quality metrics. With the Deficit Reduction Act of 2005, CMS increased its penalty for institutions that did not report quality metrics and made the metrics available to the public.²¹ Hospitals responded predictably, as the number of hospitals reporting data increased by a factor of 50 between 2002 and 2005. The number of hospitals reporting almost doubled again in 2006, coincident with the increasing financial incentives for reporting that accompanied passage of the Deficit Reduction Act.²² The move toward pay-for-performance may have been well-intended, and a number of investigators have demonstrated this technique as a valid means to induce behavior change in medical providers.^{23,24} But despite these good intentions, subsequent studies have demonstrated that improvements in outcomes associated with pay-for-performance are no greater than improvements seen in the absence of such incentives.²⁵ Indeed, the unintended consequences of the financial incentives imposed by CMS have likely further impaired SCIP's utility more than they have helped.

To see the harm in pay-for-performance, it is important to differentiate between incentives for increasing reported adherence and incentives that require actual adherence. This difference has been underemphasized in the public square while the drumbeat to increase reported adherence has grown steadily louder.

Incentives that reward the reported adherence to SCIP INF process measures have led to the creation of several decision support tools within multiple anesthesia-specific Electronic Health Record (EHR) environments that succeeded in improving apparent adherence to SCIP INF-1 and 2.^{19,26} But as improved compliance reporting has become a selling point in a crowded EHR marketplace, some EHRs make checking the correct boxes almost impossible not to do via creative user interfaces. For example, an EHR designed so that the electronic checkbox indicating a "surgical incision" appears behind the electronic checkbox indicating "antibiotics administered" *might* increase provider awareness, but it would *certainly* assure an increase in reported adherence. When facing such a "hard-stop" in EHR workflow, a provider might conceivably administer antibiotics within seconds of the incision, click the correct boxes in the correct order, satisfy the SCIP INF-1 metric, and fail to achieve optimal antibiotic prophylaxis. In another example, an EHR with increasing national penetrance includes a SCIP compliance section to be filled out by the anesthesia provider after the surgery has been completed but before the bill can be submitted; it reads "SCIP – Antibiotics Administered?" (Figure 1). The EHR in this case, although epic in its ambitions, remains unable to adjust patient outcomes depending on whether the provider clicks the YES box or the NO box, but it can certainly affect local performance incentives and public opinion. The two EHR examples above, while anecdotal examples of user interfaces, lead to predictable discordance between documented and meaningful adherence that is consistent with what has been documented in the peer-reviewed literature. For example, Hawkins, et al. in a study of actual-versus-apparent adherence to a pediatric perioperative antibiotic protocol found 100% nurse-documented adherence despite 48%

actual adherence to all aspects of the protocol.²⁷ Many of the discrepancies in the Hawkins study were “innocent errors,” but our point is not to define reasons for discordance between the documentation of care-measures and actual care. Rather, in our opinion, what matters is that the discordance between documentation and reality – no matter the cause – will no doubt serve to mask deficiencies and impair the effectiveness of quality improvement interventions. In this regard, well-designed decision-support tools should play an important role in contributing to antibiotic guideline adherence, especially when paired with effective, if still somewhat cumbersome medication-scanning technologies.^{28,29} However, SCIP's national pay-for-performance incentives, as presently formulated, pay for correctly checking boxes without a concerted effort to validate actual care delivery. As a recent editorial in JAMA Internal Medicine argued, “...public reporting and pay-for-performance systems shift the focus of quality improvement to documentation.” Hospitals must invest in “...actual performance improvement rather than in merely creating its appearance.”³⁰

In parallel with regulators and the deficit reduction efforts of Congress, accrediting organizations have been party to further incentivizing apparent adherence by encouraging the public reporting of poorly validated data. In 1997, The Joint Commission – or the Joint Commission on Accreditation of Healthcare Organizations, as it was then known, began its ORYX initiative. ORYX was an effort to require healthcare organizations to measure and submit a list of specific performance metrics as part of the accreditation process.³¹ By compelling hospitals to submit performance metrics and publicly reporting the results through ORYX, the Joint Commission further incited gamesmanship surrounding SCIP measures. Gaming performance metrics is by no means unique to SCIP, and it has recently received extensive publicity in other healthcare contexts such as in the Veterans Health Administration, where which methods of validation regarding patient wait times were found lacking.^{32,33}

As expected with so many incentives in place, public reporting of SCIP INF-1-3 adherence has become almost universally high across the nation, with very little variation. Using hospital referral regions (HRRs) from the Dartmouth Atlas of Healthcare,³⁴ a recent study found median reported adherence rates to SCIP INF-1 across the majority of HRRs to be above 95% (Figure 2) with most HRRs containing either zero or one negative outlier hospital.³⁵ As our system continues to incentivize the appearance of adherence, it should come as no surprise that almost all hospitals have started to look pretty good. But most positive changes in perioperative antibiotic practice likely already occurred in response to the CDC guidelines, and in the early years of SIP, before SCIP established its goal to reduce surgical complications by 25% and CMS began its pay-for-reporting efforts. The heartening truth may be that care improved not as a result of public reporting and the Deficit Reduction Act, but because anesthesiologists were intent upon providing good care to their patients.

Can the move toward accountability measures redeem SCIP?

We have so far argued that three factors have contributed substantially to the apparent failure of SCIP's antibiotic guidelines: 1) SCIP's delayed launch in relation to the initial adoption of the underlying care measures by clinicians, 2) SCIP's inability to quantify the spectrum of quality of care using dichotomous process measures, and 3) SCIP's reliance on

unvalidated performance data that have been corrupted by pay-for-performance incentives. In an effort to improve the value of hospital accreditation, The Joint Commission has been engaged in trying to reform and expand the scope of their performance metrics. Recently, the former head of The Joint Commission, Dr. Mark Chassin, attempted to create a new framework for considering performance metrics by advocating for a focus on so-called “Accountability Measures.” Accountability Measures were promoted as the subset of performance measures deemed to convey the most direct and significant health benefits to patients.³⁶ Four criteria were offered to determine whether process-of-care metrics should be considered as accountability measures:

- 1) Strong evidence shows that the care process leads to improved outcomes.
- 2) The measure accurately captures whether the care process was, in fact, provided.
- 3) The measure has few intervening care processes that must occur prior to the realized outcome improvement.
- 4) Implementation has minimal chance to induce unintended adverse consequences

In 2010, shortly after Dr. Chassin published his framework,³⁶ The Joint Commission added the SCIP measures to its newly rarefied list of Accountability Measures. However, comparing the four criteria required of accountability measures to the attributes of SCIP INF-1-3, the decision to incorporate the SCIP INF process measures seems unjustified (Table 3).

Regarding SCIP INF-1 and SCIP INF-2, there is strong evidence that giving an appropriate prophylactic antibiotic within a limited window of time prior to the surgical incision represents good clinical practice, that the steps themselves are likely to improve outcomes, and that adverse consequences are unlikely. As shown, however, it is simply false to assert that the measures accurately capture whether the care actually happened.

On this point, it is worth noting that smoking cessation counseling, a longstanding ORYX quality metric, did not make the cut as an accountability measure. This occurred even though smoking cessation efforts received increasing attention as a component of critical public health efforts to reduce cardiovascular morbidity, including their being prominently featured in the widely publicized Million Hearts Initiative.³⁷ Dr. Chassin and colleagues argued that smoking cessation counseling should not be an accountability measure because such a metric could appear to be satisfied by simply checking a box that did not necessarily reflect whether the counseling had, in fact, occurred.³⁷ Clearly, in our world of electronic checkboxes, SCIP INF-1 and SCIP INF-2 fail as accountability measures by ORYX's own standards for the very same reason that smoking cessation counseling did not make the list.

Regarding SCIP INF-3, its failure to meet the standards of an accountability measure is even easier to see, as there remains little evidence that stopping antibiotics within 24-hours postoperatively in a general patient population directly improves outcomes to any appreciable extent. It is not bad care to do so, but it certainly pales in comparison to smoking cessation counseling in its potential to improve an individual patient's life and the broader public health. Indeed, The Joint Commission recently announced that as of January 2015,

both SCIP INF-2 and SCIP INF-3 are retired from the ORYX initiative along with several other performance measures that have fallen out of favor.³⁸

Rather than discarding the concept of Accountability Measures altogether, ORYX's questionable inclusion of SCIP INF-1-3 could serve as an inspiration for anesthesiologists to adopt a similar framework, but one based solely on the magnitude of the potential health benefit that the suggested care could bring to patients' lives. Imagine, for example, if in support of the Million Hearts Initiative,³⁷ anesthesiologists resolved to counsel their patients regarding smoking-cessation,³⁹⁻⁴² or, as perioperative physicians, anesthesiologists pursued education and follow-up for patients with suspected poorly-controlled hypertension.⁴³⁻⁴⁵ Although the move toward accountability measures is unlikely to redeem SCIP, a similar framework could lead to improved patient care if it focused on inspiring clinicians to engage in a broader, more comprehensive concern for surgical patients' long-term well-being.

Conclusion: What can be done to redeem SCIP?

Should we expect more than good intentions from SCIP antibiotic measures? Perhaps, on the contrary, SCIP INF-1-3 have fallen short to some degree because they have been adopted by CMS and The Joint Commission in a way that ignores the necessary role of good intentions among individual caregivers. Pay-for-performance incentives and accreditation mandates may seem attractive, but in the era of the modern EHR, they can become a costly and alienating distraction for institutions and individuals. Although good processes should positively associate with good outcomes, it does not follow that imperfect metrics of good processes will share the same relationship. The amount of care, skill, and attention to detail required for truly excellent perioperative care can be daunting. In contrast, the amount of effort that goes into the appearance of fulfilling an imperfect metric of good care may be reduced to a triviality.

This is not to say that “accountable care” and “countable care” are inherently at odds; rather, they never succeed without the final common denominator of the clinician practicing within an institutional culture of safety. A manifestation of this need for individual and institutional sincerity is that quality partnerships tend to do best as local or regional collaboratives that include tracking of risk-adjusted outcomes.⁴⁶ When an institution is interested in quality, it will highlight its deficiencies and address them. When an institution is motivated by pay-for-performance and public reporting, it will tend to highlight its successes. The consequence is that top-down national reporting efforts focused on poorly validated metrics are unlikely to lead to improvement,⁴⁷ whereas regional collaboratives with the flexibility to respond to local lapses in quality allow institutions to focus on deficiencies and eventually to surpass their peers in achieving desired outcomes.⁴⁸

SCIP's effort to reduce surgical-site infections can be redeemed, but a new orientation is required. While critical and repeated evaluation of the evidence underlying quality initiatives is of course necessary,⁴⁹ good evidence is not enough. Quality improvement must be seen as a behavioral intervention. To achieve lasting success, it requires that individual providers be motivated to care, and this most naturally happens at the local or regional level. National, financially punitive process measures, written into a deficit reduction act and

subsequently manipulated by creative EHR user-interfaces, have led physicians to the very opposite of quality care. Across every effort to improve healthcare, success will ultimately hinge on whether individual clinicians commit themselves to do the difficult work of identifying their failures and iteratively working toward excellence. Avedis Donabedian, a founder of quality improvement science, recounted shortly before his death, “It is the ethical dimension of individuals that is essential to a system's success.”⁵⁰ With that in mind, clinicians must be motivated to approach each workday with the understanding that quality improvement is difficult and happens one patient at a time. Although we may not finish the job, neither are we free to abandon the effort.⁵¹

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Figure 1.
Surgical Care Improvement Project (SCIP) Compliance reporting as seen through a creative end-user-interface.

Post

BestPractice

Procedure Info

Vitals

Allergies

Anes History

LDA Removal

I/O

SCIP

Proc/Dx Confirmati...

SCIP -

Time taken: [] [!]

Values By [] Create Note

OTHER

SCIP-Antibiotics Administered?:

SCIP-Reason for vancomycin:

Figure 2. Median Surgical Care Improvement Project (SCIP) infection measure 1 (INF-1) Adherence by Hospital Referral Region.³⁵ (Copyright John Wiley and Sons; used with permission)

Table 1**Surgical Care Improvement Project Antibiotic Prophylaxis Measures (SCIP INF-1-3)^a**

SCIP INF-1	Prophylactic antibiotic given within 60 minutes before incision (120 minutes for vancomycin or fluoroquinolones)
SCIP INF-2	Appropriate antibiotic selection
SCIP INF-3	Discontinuation of prophylactic antibiotic within 24 hours after surgery (48 hours for cardiac cases)

SCIP = Surgical Care Improvement Project

INF = infection measure

^a SCIP INF-1-3 apply to patients undergoing cardiac or vascular surgery, hip or knee arthroplasty, colon surgery, or hysterectomy.

Table 2

Effect Size and Number Needed to Treat in a Sample of Studies Referenced in the CDC's 1999 Guidelines

Article	Year	Design	Total N	Population	Infection Rate in Controls	Absolute Reduction in SSIs	Number Needed to Treat
Bernard, HR ⁴	1964	RCT	145	Mixed Abdominal	27%	19%	5.3
Classen, DC ⁶	1992	Observational	2847	Mixed Abdominal	3.30% ^a	2.7% (0-120 minutes pre-incision vs. > 3 hours post incision)	37
Tanos, V ⁸	1994	Meta-analysis	2752	Total Abdominal Hysterectomy	23.40%	13.6%	7.4
Boxma, H ⁵	1996	RCT	2195	Closed Fracture Repair	8.30%	4.7%	21.3
Da Costa, A ⁷	1998	Meta-analysis	2023	Pacemaker Insertion	3.65%	3.2%	31.3

CDC = Centers for Disease Control and Prevention

RCT = Randomized Controlled Trial

^a Baseline rate listed here refers to the rate of infection among patients in the study that failed to receive antibiotics until at least 3 hours after the surgical incision. For all other listed studies, the control group infection rate refers to the rate among patients who did not receive antibiotic prophylaxis.

Table 3Should SCIP INF-1-3 Have Qualified as Accountability Measures for ORYX?^a

Accountability Measure Criteria:	SCIP INF-1	SCIP INF-2	SCIP INF-3
1 - Strong evidence that the measure improves outcomes	✓	✓	✗
2 - The measure accurately captures whether the care actually happened	✗	✗	✓
3 - Few intervening steps between the action and improving the outcome	✓	✓	✗
4 - Minimal chance for unintended negative consequences	✓	✓	✓

SCIP = Surgical Care Improvement Project

INF = infection measure

^a As of January 2015, The Joint Commission has elected to retire SCIP INF-2 and 3 from the ORYX initiative.