Surgical Site Infection Prevention

Time to Move Beyond the Surgical Care Improvement Program

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Objectives: The objective of this study was to evaluate whether the Surgical Care Improvement Project (SCIP) improved surgical site infection (SSI) rates using national data at the patient level for both SCIP adherence and SSI occurrence.

Background: The SCIP was established in 2006 with the goal of reducing surgical complications by 25% in 2010.

Methods: National Veterans' Affairs (VA) data from 2005 to 2009 on adherence to 5 SCIP SSI prevention measures were linked to Veterans' Affairs Surgical Quality Improvement Program SSI outcome data. Effect of SCIP adherence and year of surgery on SSI outcome were assessed with logistic regression using generalized estimating equations, adjusting for procedure type and variables known to predict SSI. Correlation between hospital SCIP adherence and SSI rate was assessed using linear regression.

Results: There were 60,853 surgeries at 112 VA hospitals analyzed. SCIP adherence ranged from 75% for normothermia to 99% for hair removal and all significantly improved over the study period ($P < 0.001$). Surgical site infection occurred after 6.2% of surgeries (1.6% for orthopedic surgeries to 11.3% for colorectal surgeries). None of the 5 SCIP measures were significantly associated with lower odds of SSI after adjusting for variables known to predict SSI and procedure type. Year was not associated with SSI ($P = 0.71$). Hospital SCIP performance was not correlated with hospital SSI rates ($r = -0.06$, $P = 0.54$).

Conclusions: Adherence to SCIP measures improved whereas risk-adjusted SSI rates remained stable. SCIP adherence was neither associated with a lower SSI rate at the patient level, nor associated with hospital SSI rates. Policies regarding continued SCIP measurement and reporting should be reassessed.

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The Surgical Care Improvement Project (SCIP) was implemented in 2006 with the goal of reducing surgical complications by 25% in the year 2010.[1] The SCIP is a nationwide quality improvement effort focused on reducing postoperative surgical site infections (SSI), thromboembolic and cardiac events. Performance measures aimed at preventing these complications were developed based on national consensus and best available evidence. The SCIP has been implemented by the Center for Medicare and Medicaid Services (CMS) and endorsed by numerous stakeholders as a valid measure of surgical quality. Hospital adherence to SCIP measures is publically reported with the intent to guide patients and payers to the best hospitals for their surgical care.[2]

Surgical site infection complicates up to 5% of clean procedures and 30% of clean contaminated procedures and is the most common nosocomial infection among surgical patients.[3] SSI leads to significant increase in readmissions, ICU admissions, long-term surgical site complications and death. It is estimated that 40% to 60% of surgical site infections are preventable.[4] On the basis of the frequency of this postoperative complication and that it can complicate almost every surgical procedure, most of the SCIP measures are aimed at reducing postoperative SSI. The predecessor to SCIP, the National Surgical Infection Prevention (SIP) project began in 2002 and collected adherence to 3 performance measures for appropriate timing, selection, and discontinuation of prophylactic antibiotics.[1] A national collaborative of 56 hospitals demonstrated improved adherence to these 3 measures and a mean reduction in their SSI rates over the implementation period.[5] These analyses were at the hospital level and did not evaluate whether patients who received the intended care had lower SSI rates compared with those who did not receive the care. When the SCIP was implemented, 3 additional measures on appropriate hair removal, postoperative normothermia in patients undergoing colorectal surgery and blood glucose control in cardiac surgery patients were collected. The SCIP measures and the specified surgical population they target are shown in Table 1.[1]

Numerous studies have demonstrated that adherence to the SCIP measures has improved over the implementation period, but only a few assessed whether adherence has resulted in improved surgical outcomes.[6–10] Although these studies demonstrate that SCIP implementation has achieved substantial improvements in adherence, there is minimal evidence to support that SCIP adherence improves surgical outcomes at the patient or hospital level. The current literature is limited by lack of patient level data for both adherence and the outcome as well as a valid measure for SSI outcome. We undertook this study to evaluate whether the SCIP improved SSI rates at the patient or hospital level, using National Veterans' Affairs (VA) linked data at the patient level for both SCIP adherence and SSI occurrence.

METHODS

Study Design

This is a National VA retrospective cohort study of surgical procedures meeting criteria for the SCIP measurement from 2005 to 2009. Cases with the SCIP measures were obtained from the VA Office of Quality and Performance (OQP) and matched with patient demographic and risk variables, surgical variables, and 30-day outcomes from the Veterans' Affairs Surgical Quality Improvement Program (VASQIP). Data for SCIP adherence and VASQIP are prospectively collected by independent reviewers with strict observation of SCIP definitions and CDC surveillance criteria and definition for SSI. The

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TABLE 1. SCIP Infection Prevention Measures Available During the Study Period

Measure	Definition	Population	Years with Measure	Number with Measure
SCIP-inf 1	Prophylactic antibiotic given within 60 minutes before incision (120 minutes for Vancomycin or Floroquinolones	CABG and cardiac surgery hip and knee arthroplasty colon surgery hysterectomy arterial vascular surgery	2005–2010	39,149
SCIP-inf 2	Appropriate antibiotic selection	CABG and cardiac surgery hip and knee arthroplasty colon surgery hysterectomy arterial vascular surgery	2007–2010	30,873
SCIP-inf 3	Discontinuation of prophylactic antibiotic within 24 hours after surgery (48 hours for cardiac cases)	CABG and cardiac surgery hip and knee arthroplasty colon surgery hysterectomy arterial vascular surgery	2005–2010	34,746
SCIP-inf 4	Cardiac surgery patients with controlled (<200 mg/dL) 6 gm glucose	CABG and cardiac surgery	Not evaluated	Not evaluated
SCIP-inf 6	Surgery patients with appropriate hair removal	CABG and cardiac surgery hip and knee arthroplasty colon surgery hysterectomy arterial vascular surgery other major surgery	2007–2010	48,508
SCIP-inf 7	Normothermia (postoperative tempurature > 96.8°F)	Colon Surgery	2007–2010	8566

Specifications Manual for National Hospital Inpatient Quality Measures. *Measure Information: Surgical Care Improvement Project (SCIP)*: Centers for Medicare and Medicaid Services (CMS), The Joint Commission Version 3.3; 2011.

study protocol was reviewed and approved by the local VA Research and Development Committee and the Institutional Review Board at the institution of each co-author, as well as by the Surgical Quality Data Use Group (SQDUG) and the Office of Quality and Performance in Patient Care Services in VA Central Office, Washington, DC.

Study Databases

The VHA Office of Quality and Performance's External Peer Review Program SCIP Module. The VA contracts with the West Virginia Medical Institute to collect information for OQP's External Peer Review Program. The VA began collecting data on SCIP measures for all eligible surgical procedures in 2005 according to guidelines set forth by the Joint Commission on Accreditation of Healthcare Organizations and the Centers for Medicaid and Medicare Services,[11] and abstractor reliability is regularly assessed.

The VASQIP started in 1991 to analyze risk-adjusted 30-day morbidity and mortality data within VA.[12,13] The methods of the noncardiac VASQIP have been previously published.[14] The VASQIP collects demographic, preoperative risk and laboratory data, operative data, and 30-day postoperative mortality and morbidity outcomes on most patients undergoing major surgery in the VA Healthcare System. Trained in clinical medicine and quality assurance, clinical nurse reviewers complete in-depth training on the data collection procedures and detailed definitions of each of the variables. A manual of operations specifies all aspects of the data collection, including selection of patients, definitions of the variables, and methods for entering the data into the computer system. A recent study of the quality of the data at a sample of VA Medical Centers showed that the data were complete and had high reliability.[15]

Study Population

The SCIP population (Table 1) for the SCIP Inf 1-3 includes patients undergoing five types of surgical procedures: (1) cardiac, (2) hip or knee arthroplasty, (3) colorectal, (4) arterial vascular, and (5) hysterectomy.[16] SCIP Inf-4 applies only to cardiac procedures and SCIP Inf-7 applies only to colorectal procedures. During this study period, only the SCIP Inf-6 applies to an extended group of major surgical procedures including, but not limited to thoracic, urologic, and neurosurgical procedures.[16] Cardiac cases were excluded as the VASQIP only collects risk and outcome information on noncardiac surgical procedures.

Study Variables

The independent variable of interest was adherence to the SCIP infection prevention performance measures as reported by OQP. Adherence was examined for each of the 5 SCIP measures individually, as well as a composite measure defined as adherence to all of the individual SCIP measures applicable (yes, no). The dependent variable of interest was the occurrence of a SSI at 30 days postoperatively as reported by VASQIP. Superficial and deep SSI were combined to create a composite SSI outcome variable. Patient level covariates of interest include demographics, functional status, lifestyle variables (eg, tobacco and alcohol use), and cardiovascular, pulmonary, renal, hepatobiliary, nutritional, and immune comorbidities. Serum albumin and bilirubin laboratory values closest to the time of the operation were also assessed. Operative variables surgical specialty, emergency operation, ASA status, wound classification, and operative times were also obtained from VASQIP. To account for the complexity of the operation, the work RVU from the Resource Based Relative Value Units system for each CPT code was used.

Statistical Analyses

Adherence rates to SCIP measures and SSI rates were compared between categories of patient characteristics using the χ^2-test. The unadjusted odds of developing a SSI related to adherence on each SCIP measure were examined. An adjusted odds ratio was then calculated using multivariable, multilevel logistic regression, adjusting for patient and operative characteristics known to be predictive of SSI, including age, work RVU, operation time, albumin, surgical specialty, diabetes, COPD, steroid use, ASA class, wound classification, smoking status, and gender. Generalized estimating equations were used to account for clustering of patients by VA medical center. Separate models were used to examine the association between each SCIP measure, including the all or none composite measure and surgical site infection at the patient level with adjustment for patient level covariates.

To assess association of the SCIP adherence and SSI rates at the hospital level, we used least-squares linear regression adjusting for hospital volume and case mix. Finally, we assessed whether secular trends in SCIP adherence and SSI rates existed. Secular trends for SCIP adherence and unadjusted SSI rates were tested using the Cochran-Armitage test for trend. Secular trends for adjusted SSI rates comparing the observed to expected SSI rate semiannually over the evaluation period were assessed. All analyses were completed using SAS v9.2 and R v12.2.2 with the contributed package *geepack*.[17,18]

RESULTS

A total of 60,853 surgeries performed at 112 VA hospitals with at least 1 SCIP measure are included in the study. The number of patients with information on SCIP adherence and the years the measure was collected are shown in Table 1. SCIP-inf 1 and 3 were collected by OQP before the SCIP implementation, therefore additional study years are available for these measures. Characteristics of the study population, stratified by SCIP measure adherence and SSI occurrence, are shown in Table 2. Overall adherence to the SCIP measures ranged from 75% for normothermia to 99% for hair removal. For patients with all measures assessed, the composite rate of SCIP adherence was 81%. The rate of SSI at 30 days was 6.2%. There are several patient and procedure factors associated with SCIP measure adherence, as well as whether the patient developed a postoperative SSI. In general, surgeries in patients with comorbid conditions, higher ASA class, undergoing more complex or colon procedures were less likely to have adherence to the measures and more likely to result in a SSI.

Evaluation of the association between adherence to SCIP measures and SSI is shown in Table 3. There were significant associations between SCIP 1, 2, and composite adherence score and postoperative SSI in unadjusted analyses. After adjusting for patient and procedure factors associated with SSI employing generalized estimating equations analyses, the association between SCIP adherence and SSI was no longer significant (Table 4). To confirm these findings, we performed numerous sensitivity analyses using different modeling methods and limiting the study population. We performed adjusted analyses excluding the emergent and the other major surgery population and did not find an association between the SCIP adherence and SSI. We tested different methods of modeling, including generalized estimating equations (Table 4), to account for clustering of patients within hospitals, and a fixed effect model adjusting for hospital level adherence to the composite adherence score (data not shown). None of these methods demonstrated an association between SCIP adherence and SSI.

TABLE 2. Study Population Stratified by SCIP Adherence and SSI Occurrence

		Total	Timely		Discontinued		Appropriate		Hair Removal		Normothermia		Composite		Surgical Site Infection	
		N	%	*P*	%	*P*	%	*P*	%	*P*	%	*P*	%	*P*	%	*P*
Overall			93.0		84.0		96.0		99.0		75.0		81.0		6.2	
Demographics																
Age category	<64.1	34,553	93.6	<0.0001	84.2	<0.0001	96.5	0.001	99.2	0.02	77.3	<0.0001	82.5	<0.0001	6.5	<0.0001
	≥64.1	26,300	92.3		82.1		95.8		99.0		73.5		78.4		5.7	
Gender	Male	51,745	93.0	0.13	83.0	<0.0001	96.2	0.53	99.1	0.01	75.4	0.50	80.5	0.0002	6.5	< 0.0001
	Female	3,667	93.8		88.2		96.0		98.7		73.3		83.9		4.0	
Race	White	35,143	94.3	0.13	85.4	0.20	96.1	0.60	99.2	<0.0001	76.3	<0.0001	80.9	0.24	6.5	0.05
	Black	7,490	93.9		86.1		96.3		98.9		68.1		79.7		5.7	
	Other	6,271	93.5		84.7		96.4		98.6		78.1		80.9		6.6	
Comorbidities																
Diabetes	Oral	8,496	93.2	0.90	83.7	0.48	96.8	<0.0001	99.1	0.64	75.8	0.60	80.4	0.02	6.7	<0.0001
	Insulin	5,059	92.8		84.0		94.3		99.2		73.9		78.3		9.2	
	No	47,298	93.0		83.2		96.3		99.1		75.4		81.0		5.7	
Steroid Use	Yes	1,381	92.0	0.29	80.7	0.07	95.3	0.25	99.6	0.05	77.8	0.40	76.9	0.03	8.7	<0.0001
	No	59,472	93.0		83.4		96.2		99.1		75.3		80.8		6.1	
COPD	Yes	8,732	92.4	0.07	82.7	0.24	95.8	0.17	99.1	0.75	74.5	0.40	79.6	0.07	8.2	<0.0001
	No	52,120	93.1		83.4		96.3		99.1		75.5		80.9		5.8	
CHF	Yes	568	91.6	0.40	80.1	0.22	92.0	0.01	99.6	0.28	64.5	0.03	74.2	0.07	6.3	0.74
	No	60,284	93.0		83.4		96.2		99.1		75.5		80.8		6.1	
History of radiation therapy	Yes	709	89	0.006	79.7	0.04	87.1	<0.0001	98.2	0.02	74	0.42	54.3	<0.0001	19.9	<0.0001
	No	60,143	92		83.4		96.3		99.1		72		81.0		6.0	
Dyspnea	None	52,792	93.1	0.0008	83.5	0.39	92.3	0.21	99.2	0.08	76	0.67	81.1	0.0006	5.8	<0.0001
	Minimal	7,307	92.6		82.6		95.8		98.9		75		78.4		8.3	
	At rest	615	86.2		83.9		94.4		99.1		78		73.4		8.6	
Preop Albumin	<3.5	8,390	89.7	<0.0001	81.5	<0.0001	92.1	<0.0001	99.4	0.09	73.0	0.03	70.4	<0.0001	9.8	<0.0001
	≥3.5	38,024	93.0		84.3		96.4		99.2		75.5		81.8		5.9	
Preop Bilirubin	<0.7	25,580	92.7	0.36	83.8	0.36	95.7	0.21	99.2	0.73	74.8	0.97	80.2	0.30	6.9	0.26
	≥0.7	17,549	92.4		83.5		96.0		99.2		74.9		79.6		6.7	
Smoker	Yes	20,135	92.8	0.17	83.3	0.93	95.8	0.01	99.2	0.12	73.6	0.01	80.3	0.20	7.7	<0.0001
	No	40,672	93.1		83.3		96.4		99.1		76.1		81.0		5.4	
Alcohol >2 drinks/day	Yes	5,197	93.2	0.71	84.0	0.34	95.5	0.06	99.2	0.33	75	0.91	79.6	0.16	8.0	<0.0001
	No	55,605	93		83.3		96.3		99.1		75		80.8		6.0	
ASA Class	1–2	13,851	93.9	<0.0001	84.1	0.03	97.0	<0.0001	99.1	0.40	78.4	0.01	82.9	<0.0001	4.0	<0.0001
	3	40,712	93.1		83.2		96.2		99.1		74.8		80.5		6.4	
	4	6,131	89.9		81.6		93.6		99.3		73.7		75.1		9.0	
	5	159	70.4		85.7		82.6		99.3		64.7		62.5		8.8	

TABLE 3. Surgical Characteristics of the Study Population Stratified by SCIP Adherence and SSI Occurrence

		Total	Timely		Discontinued		Appropriate		Hair Removal		Normothermia		Composite		Surgical Site Infection	
		N	%	*P*	%	*P*	%	*P*	%	*P*	%	*P*	%	*P*	%	*P*
Surgery Characteristics																
Status	Elective	57,553	93.2	<0.0001	83.5	<0.0001	96.5	<0.0001	99.1	0.8	75.8	<0.0001	81.1	<0.0001	6.0	<0.0001
	Emergent	3,300	84.4		75.3		85.1		99.2		67.7		62.9		9.8	
Type	Orthopedic	28,887	94.5	<0.0001	83.1	<0.0001	99.0	<0.0001	98.9	<0.0001			86.4	<0.0001	1.8	<0.0001
	Colorectal	15,444	89.3		83.4		87.7		99.2		73.4		60.4		14.2	
	Vascular	9,189	91.7		82.4		96.8		99.5				81.6		8.7	
	Gynecology	1,584	94.4		91.3		95.5		98.7				85.9		3.1	
	Other	4,126	100.0		44.4		85.7		99.2						3.3	
Wound Class	Clean	39,754	93.8	<0.0001	83.0	<0.0001	98.4	<0.0001	99.0	0.01	73.8	0.01	85.3	<0.0001	3.2	<0.0001
	Clean/Contam	17,566	90.5		84.8		89.8		99.2		75.6		66.2		11.5	
	Contam	2,016	90.3		80.3		86.8		99.1		76.4		62.0		13	
	Dirty	1,517	87.7		70.5		84.6		99.7		64.1		55.8		11.5	
Operation Time (hrs)	<2.8	21,434	90.7	<0.0001	80.5	<0.001	94.7	<0.0001	99.2	0.10	75.4	0.90	74.3	<0.0001	10.1	<0.0001
	≥2.8	39,419	94.1		84.6		96.9		99.1		75.3		83.5		4.0	
Work RVU	< 22.5	26,747	94.4	<0.0001	88.6	<0.0001	97.3	<0.0001	99.5	<0.0001	75.6	0.70	84.1	<0.0001	5.9	0.003
	≥22.5	34,106	92.0		79.2		95.2		98.7		75.2		76.9		6.4	

TABLE 4. Surgical Site Infection by Patient Risk Factors, Procedure Characteristics and SCIP Adherence Status

		Surgical Site Infection					Generalized Estimating Equations		
		Measured	Yes		Unadjusted		Cases Used*	Adjusted	
SCIP Measure	Met	N	N	%	Odds Ratio	95% CI	N	Odds Ratio**	95% CI
Timely	Yes	36,417	1958	5.0	0.67	0.58–0.77	29,042	0.90	0.76–1.07
	No	2732	214	7.8					
Appropriate	Yes	29,696	1582	5.3	0.36	0.30–0.43	23,244	0.89	0.72–1.09
	No	1177	158	13.4					
Discontinue	Yes	28,955	1631	5.6	1.07	0.95–1.22	25,927	1.07	0.93–1.24
	No	5791	305	5.3					
Hair Removal	Yes	48,074	3023	6.3	1.32	0.85–2.05	36,304	1.04	0.62–1.75
	No	434	21	4.8					
Normothermia	Yes	6,455	1018	15.8	1.09	0.95–1.25	7,250	1.02	0.88–1.18
	No	2111	309	14.6					
Composite	Yes	21,016	993	4.7	0.55	0.49–0.62	19,719	0.92	0.80–1.06
	No	5011	417	8.3					

*Study population for adjusted analyses excluded emergent procedures, other procedures that were only eligible for hair removal measure, but had other SCIP measures applied. Sensitivity analyses including these cases did not alter the findings.

**Adjusted for age, Work RVU, operative time, specialty, diabetes, COPD, steroid use, ASA class, wound class, smoking status, dyspnea, alcohol abuse, history of radiation therapy and gender.

Correlation between hospital composite SCIP adherence rates and SSI are shown in Figure 1. In unadjusted analyses, the hospital rate of composite SCIP adherence accounted for 2% of the variation in hospital SSI rates ($r^2 = 0.02$). The number of cases contributed by each hospital ranged from 23 to 1,379. Including hospital case mix (percent colorectal and vascular) and hospital volume improved the explanation in hospital rate of SSI variance ($r^2 = 0.25$). SCIP adherence improved over the study period for every measure evaluated ($P < 0.0001$ for each measure, respectively), however, neither the absolute nor risk adjusted SSI rates improved over the study period (Fig. 2).

DISCUSSION

Our study of national VA data assessing the SCIP effectiveness in improving SSI occurrences did not find a significant association for individual or the composite SCIP measurement methods. This study has the strength of assessing adherence and SSI at both the patient and the hospital level. Furthermore, SSI was assessed by independent abstractors based on CDC definitions within 30 days of procedure, not just within the index hospitalization. We also did not find a correlation between hospital rates of SCIP measure adherence and hospital rates of SSI, nor did we observe an improvement in absolute or risk-adjusted SSI rates over the study period.

Our study is consistent with prior assessments of the SCIP infection prevention measures and addresses some of the weaknesses of the prior studies. Our original report of no association with the timely antibiotic administration measure and SSI in a VA cohort was limited to evaluation of SCIP-inf 1. Therefore, we could not address whether the addition of multiple measures intended to guide care for infection prevention was more effective.[6] Two subsequent studies evaluating additional SCIP infection prevention measures were limited by the use of Hospital Compare hospital level SCIP adherence rates without

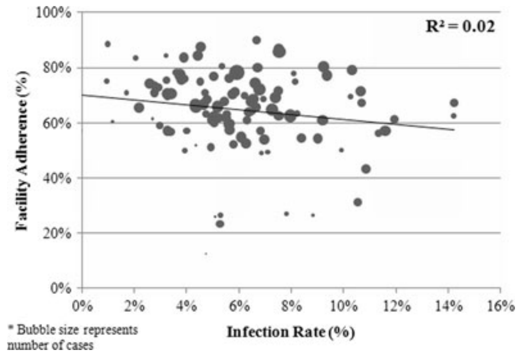

FIGURE 1. Correlation between hospital composite SCIP adherence rates and SSI.

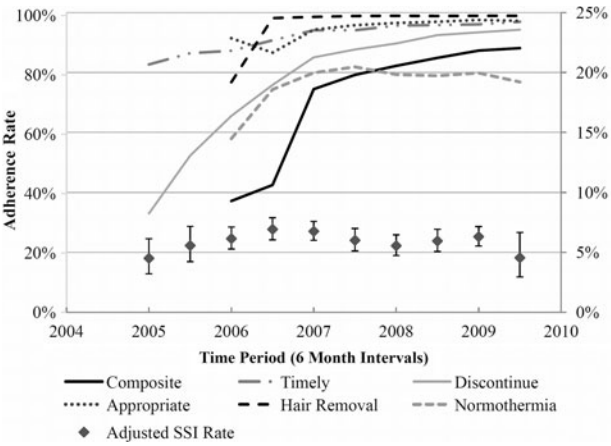

FIGURE 2. Adherence rate and risk adjusted SSI RATES over study period.

information on adherence for assessed patients. One of these studies used Medicare data to determine patient outcomes, but the method of how they defined postoperative SSI was not reported and likely based on an unvalidated ICD-9 discharge code for postoperative infection.[19] Furthermore, they extended their study population to include patients undergoing procedures not specified for the SCIP infection prevention measures they assessed, such as esophagectomy and pancreaticoduodenectomy. Another study using Hospital Compare SCIP adherence rates correlated hospital adherence with hospital risk-adjusted SSI rates obtained from the American College of Surgeons National Surgical Quality Improvement Program. They calculated SSI rates based on the expanded SCIP population, not the population specified for SCIP-inf 1 to 3 and found a positive correlation between hospital rates of appropriate antibiotic administration and risk-adjusted SSI rates.[7] Both studies comparing Hospital Compare reported adherence rates with the expanded SCIP population infection rates have significant limitations as the assessed SSI patient population is likely widely disparate from the population measured in the hospital SCIP sample. Finally, Stuhlberg reported the largest sample of patients with SCIP adherence and postoperative infection occurrence with patient level data. However, they used an unvalidated ICD-9 code for postoperative infection as their surrogate for SSI. They found no significant association between SCIP adherence and postoperative infection when assessing individual and composite measurement and small association of a composite measure when there were 2 or more measures available.[10] Given that only 3.8% of the colorectal sample experienced a SSI based on the ICD-9 measure, further studies are warranted to validate whether the discharge code is a valid measure for postoperative SSI.

Careful analysis of the existing studies demonstrates the complexity of the SCIP measurement algorithms and highlights areas of potential confusion for abstractors and researchers. In addition to the original 3 measures deployed in 2002 (timely administration, appropriate coverage and discontinuation), 3 additional measures were added and rolled out after 2006.[1] The new measures have different denominators from each other and the original 3 SCIP measures (Table 1). The studies evaluating the SCIP adherence and infection rates using Hospital Compare data included SSIs from a broader or different group of patients than would have been included in the assessed SCIP measures, with the exception of the hair removal measure.[7,19] Potential confusion among abstractors is evidenced in our study, as well as the report from Stuhlberg.[10] Each SCIP measure has a specified population for inclusion in the sample, yet we observed that many additional procedures were included and reported for each SCIP measurement. Including additional cases in the denominator may account for differences in hospital reported adherence rates. In our study, these additional cases did alter the adjusted association between SCIP adherence and SSI in the sensitivity analysis.

Given that the SCIP processes are not intended to apply to all surgical patients, hospital strategies for ensuring that SCIP patients receive the processes may involve unintended spread of practices to non-SCIP patients. This was observed for the community acquired pneumonia (CAP) measure, timing of first antibiotic delivered. When the measure was changed from within 8 hours of evaluation to 4 hours, many errors in diagnosis of CAP occurred.[20] To meet the measure, many hospitals administered antibiotics before the diagnosis of pneumonia was confirmed, leading to antibiotic overuse in patients who ultimately did not meet diagnostic criteria for CAP.[21,22] There have not been any rigorous studies looking at whether attention focused on delivering timely antibiotics for SCIP patients has resulted in overuse or misuse of prophylactic antibiotics in non-SCIP patients.

High fidelity performance measures should be tightly linked with the intended outcome and have sufficient evidence to support that implementation of the measure will lead to the desired effect. Evaluation of the SCIP highlights the complexity of surgical care and the many moving pieces that contribute to quality improvement. Deriving measures on data that were not generated to test whether the measures were effective may explain some of the shortcomings of the SCIP measures. For example, delivery of preoperative prophylactic antibiotics improves surgical site infection rates in the appropriate clinical setting. However, the SCIP-inf 1 measures a dichotomous variable based on a continuous event (the time between antibiotic administration and surgical incision). This measure presumes that any antibiotic administered within 60 minutes before incision is effective, but that antibiotics administered outside that interval are not. This measure, although useful for reporting, likely falls short in discriminating effective antibiotic timing.

As an implementation program, SCIP has been highly successful in achieving adherence to the performance measures and highlighting the extent of the SSI problem. Both in our national VA cohort and the large Premier cohort, SCIP adherence improved over time and approached or exceeded 90% for most measures.[10] We did not specifically study the implementation, but our group assisted with a technical assistance project when the SCIP-inf 1 measure was rolled out.[23] We surveyed high and low performers, identified best practices and they were disseminated. Furthermore, the VA is a national health care system with priorities defined at the national level and implemented at the local level. Although we did not detect any improvement in risk-adjusted SSI rates over the implementation period, it could be that any improvement in SSI rates that could be achieved from improved practices for prophylactic antibiotic use occurred during the predecessor Surgical Infection Prevention program. Furthermore, once adherence for a measure reaches levels above 90%, the utility of the measure to discriminate between high and low performing hospitals markedly decreases. In 2007, the measure for whether patients were discharged on a beta blocker after admission for myocardial infarction was discontinued because adherence was greater than 90% and there was no meaningful difference between the top and bottom hospitals.[24] Other ongoing efforts in VA to address SSI include active monitoring of VASQIP occurrence data to identify outliers followed by structured site visits aimed at identifying system and processes that need improvement. To reduce the burden of data collection for SCIP measures, VA is developing the specifications for an electronic audit system.

LIMITATIONS

Our study has several limitations. We evaluated a VA patient population, primarily comprised of men, therefore our findings may not be generalizable to women. Furthermore, we were not able to assess outcomes in patients undergoing cardiac procedures, thus we cannot draw conclusions about the effectiveness of the SCIP in the cardiac surgical cohort. Three SCIP measures were implemented and measured in the private sector beginning in 2002, and those practices may have spread to the VA before measurement began in 2005, thus limiting our ability to measure secular effects of the program before implementation in the VA.

CONCLUSIONS

Implementation of the SCIP infection prevention measures did not yield measurable improvement in SSI at the patient or hospital level, nor did we observe improvement in adjusted SSI rates over the implementation period. Although the processes measured are best practices and should continue, they might be too simplistic or blunt to discriminate hospital quality. Mandatory SCIP reporting and linkage to performance pay without proven improvement in care may lead to increased skepticism and result in physician fatigue with quality improvement endeavors. Furthermore, using these measures to guide patients to high quality hospitals may be misleading.

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DISCUSSANTS

D. Hoyt (Chicago, IL):

Healthcare reform is focused on improving the experience of care and reducing costs. The shift to quality has taken on increased importance in the last 10 years, following the Institute of Medicine report, where the difference between the health care we have and the health care we should have is described as "a chasm." In striving to narrow this gap, the quality measurement systems put in place, such as, measurement science, quality reporting, linkages of payment to quality, and comparative effectiveness, must actually correlate with an improvement in quality. This study is a critical example of how a well-intended process and improved adherence to its measures, in fact, do not reduce surgical infection. Overall, the SCIP program does not achieve its goal.

The value of the current study is that it will provoke new research and identify contributing factors that have not been considered. For instance, a current project between the American College of

Surgeons and the joint commission is designed to find other causes for surgical infection after colon surgery, using rapid cycle improvement, change management, and monitoring rates in several NSQIP hospitals. This study is also very important because the data collection burden has increased in the last several years, and unless ineffective indicators are dropped, the expense of adding new indicators cannot be accommodated. The use of individual indicators has to evolve in time and ineffective measures need to be replaced with better measures.

The first question I have for the authors is what are you doing within the VA system or at your own hospital to find alternatives to the SCIP measures that will correlate with reduced infection? Are you currently planning any projects designed to deal with this issue?

Secondly, what do you think is the essential feature that correlates with compliance? You showed very nicely that, over several years, compliance with SCIP measures reaches almost 100%, even though the measures do not work. What matters in achieving compliance? Is it leadership? Regulation?

Finally, as this is a huge cost to American hospitals to collect SCIP measures. What strategy should be pursued to redirect efforts from the SCIP program to more effective improvement strategies, such as the use of the NSQIP program?

DISCUSSANTS

D. Fry (Chicago, IL):

As a member of the 2002 Surgical Infection Prevention Project that put together the 3 antibiotic related process measures, I feel compelled to state that these measures were not meant to change the world. We hoped to provide a foundation by which we could move forward with programs that objectively tried to improve surgical site infection. Unfortunately, the Deficit Reduction Act of 2005 by the United States Congress took our process measures and made them law and required hospitals to report them. And, as we heard from Dr. Hawn today, the process measures have been about as effective as the Deficit Reduction Act itself.

The results of this study, in my view, are valid, but the SCIP surgical site infection prevention performance or process measures are also valid; the problem is that they are not inclusive. No one should walk away from here thinking that preventive antibiotics do not need to be given, or that they can be given a day before the operation, or that you do not need to have the antibiotics appropriate for the likely pathogens. As Paul Simon might say, there must be 50 ways to get a surgical site infection. Antibiotics are only a small portion of the preventive strategy.

In your analysis, were some of the emerging major risk factors, such as the presence of the patient in a nursing home before admission or prolonged hospitalization before surgery, been put into the equation? There must be hundreds of variables in the equation for the prediction of surgical site infection, but these 2 variables speak to the incredible presentation of patients with resistant organisms–organisms that fail to respond to conventional treatments.

How have you dealt with hospital variability in the equation? We use dummy variables for the hospitals in hope that the risk coefficients represent the pure impact of the hospital in question.

Finally, I did not see any C statistic, which would provide the discrimination of the model in terms of actually predicting the infection.

Response from M. T. Hawn:

The VA employed NSQIP before it employed SCIP. As part of the NSQIP process in the VA, consultative teams visit high and low outlier hospitals for surgical site infection and either make recommendations or learn best practices. These are ongoing efforts to reduce surgical site infection within the VA. We are not doing anything more specific than that at our hospital.

How was the SCIP implemented so successfully in the VA? There is a framework, when you are analyzing implementation and how effective it is, and it considers 3 factors. The first is the evidence behind the SCIP measures, which is outstanding. We all understand that prophylactic antibiotics are effective, and every patient in this study received a prophylactic antibiotic. The SCIP measures are more "Was it the right antibiotic? Was it given timely?" and the evidence behind the SCIP measures helps facilitate the implementation.

The second factor is the structure. The VA is a national healthcare organization with national directors of surgery and anesthesia. This was a top-down implementation process to the facilities.

The third factor is how the measures are facilitated. The VA does employ pay-for-performance health care for administrators, service chiefs, and individual surgeons. In many facilities, SCIP adherence was linked to physician performance pay. Implementation and adherence were likely facilitated with dollars and were rapidly successful.

What should we do now that the evidence indicates SCIP implementation has not improved surgical site infection? We have to find a way to efficiently measure and report outcomes and work on improving the outcomes as well.

Regarding the complexity of the patient. Certainly, many patients in this cohort had significant comorbidities, had been hospitalized before the surgical intervention or had come from nursing homes, which likely brought increased risk to the table. These patients were also less likely to get the SCIP measures. We did not account for inpatient admission before surgeries specifically in this model, but that is something we can go back and look at and adjust for.

Regarding the hospital adjustment, we tested multiple models. We did put a dummy variable in for each hospital, but that puts 112 covariates into the model and makes the model less stable. There was no effect on the association between SCIP and the outcome. We also looked at putting in a covariate for the hospital, hospital adherence rate to the SCIP measure, as a way to adjust for the hospital effect. That also did not affect the relationship between the SCIP measures and the outcomes.

Finally, we used generalized estimating equations, which is a multilevel model accounting for both patient level and hospital level factors. All 3 models revealed the same results and were statistically valid, with the generalized estimating equations model being the most predictive. I do not have the C statistics with me, but I am happy to send them to you.

DISCUSSANTS

R. Fitzgibbons (Omaha, NE):

I do not think these results for the Surgical Care Improvement Program look as bad a they may have sounded here. Certainly stopping antibiotics at the appropriate time early in the postoperative course and using the cheapest antibiotic saves money.

What are we to do about operations that carry inherently high infection rates? In my own hospital, we perform complicated abdominal wall reconstructions on a referral basis under the umbrella of our center for abdominal wall reconstruction, and we have a 10% infection rate, consistent with your data and the literature as a whole. But I am getting some pressure from the powers that be because of the impact on our NSQIP numbers. A ventral hernia repair is a ventral hernia repair in the eyes of NSQIP whether there is a 1cm defect that requires 1 stitch or there is a burst abdomen in a morbidly obese patient with loss of domain. Do you have any solution for this problem?

Response from M. T. Hawn:

I wish I did. As mentioned, there must be at least 50 factors that contribute to whether or not a patient will develop a surgical site infection. My advice is to try to control as many as you can, including early recognition and treatment to prevent the potential adverse consequences if an infection develops.

DISCUSSANTS

R. Kiran (Cleveland, OH):

One of the findings here was the high rate of SSIs when compared with some other data that have been published, including the NSQIP. Did you look into potential reasons for this? Also, when evaluating a large data set like this, the individual patient-related issues may not be prominent. For example, for a patient whose colorectal surgery is deemed to be extensive, the surgeon may decide to continue the antibiotics. Is this indicated as compliance or noncompliance?

Response from M. T. Hawn:

I believe the high rate of surgical site infection in our study is the real rate of surgical site infection. First, the NSQIP data is validated and the interrater reliability is assessed. If another reviewer analyzes the data, they find the same result as the nurse who abstracted the medical record. Second, because using claims data will very much underestimate surgical site infection, we gather data on infections that are occurring after hospital discharge. As a result, our surgical site infection outcome rate is probably representative of the actual rate.

We did adjust for significant comorbidities that may be unique to the operation, like operative time, and we excluded emergent cases from the model, thinking that there may be some confounding and reasons to continue antibiotics on them. However, leaving them in or excluding them did not change our findings.

We did not go back and look at individual records, and we did not write the specification manual. So unless a reason why antibiotics were continues was documented in the medical record, they would have been counted as nonadherent to the discontinuation measure.

DISCUSSANTS

T. Sundt (Boston, MA):

I have a question about the Hawthorne effect and how we might leverage that to our advantage. Can you look between the hospitals and evaluate the quality of their quality assessment programs and the impact of these programs themselves on the surgical site infections? It may seem a little obtuse, but I wonder if we can institutionalize the Hawthorne effect to our advantage.

Response from M. T. Hawn:

Are you referring to the adherence rate or the infection rate when you are looking at hospital rates?

DISCUSSANTS

T. Sundt (Boston, MA):

One would actually need to monitor the efficacy of the monitoring mechanism. What percentage of cases actually get evaluated? In any given hospital, what is the infrastructure to monitor compliance? The rates may actually be as important as either the rates themselves or the actual details of the compliance, and a computerized electronic record captures a higher percentage.

Response from M. T. Hawn:

The VA has used computerized electronic health records since 2000, and it contracts with an external agency, an external peer review program, to assess SCIP performance measurements. That agency takes the measurements in a uniform manner for all the hospitals, and case selection follows the specification manual.