# Colorectal Surgery Surgical Site Infection Reduction Program: A National Surgical Quality Improvement Program—Driven Multidisciplinary Single-Institution Experience

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Surgical site infections (SSI) are a major cause of morbidity in surgical patients and they
increase health care costs considerably. Colorectal surgery is consistently associated with
high SSI rates. No single intervention has demonstrated efficacy in reducing colorectal
SSIs. The American College of Surgeons National Surgical Quality Improvement Program
(ACS NSQIP) is a nationally validated system that uses clinically abstracted data on surgical
patients and their outcomes to assist participating institutions drive quality improvement.
A multidisciplinary team was assembled to develop a colorectal SSI-reduction bundle at an
academic tertiary care medical center. The ACS NSQIP data were used to identify patterns of
SSIs during a 2-year period. Multiple interventions across the entire surgical episode of care
were developed and implemented in January 2011. Monthly ACS NSQIP data were used to
track progress.
Our ACS NSQIP overall colorectal SSI rate for 2009 and 2010 was 9.8%. One year after
implementation of the SSI reduction bundle, we demonstrated a significant decline (p
< 0.05) in both overall and superficial SSIs, to 4.0% and 1.5%, respectively. Organ space
infections declined to 2.6%, which was not a significant change ( $p = 0.10$ ). During the entire
analysis period (2009 to 2011), there was no change in our colorectal-specific Surgical Care
Improvement Program performance.
Using our ACS NSQIP colorectal SSI outcomes, a multidisciplinary team designed a colorectal
SSI reduction bundle that resulted in a substantial and sustained reduction in SSIs. Our study is
not able to identify which specific elements contributed to the reduction. (J Am Coll Surg
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Surgical site infections (SSIs) are the most common hospital-acquired infection in surgical patients.<sup>1</sup> Surgical site infections result in substantial morbidity, increased mortality, prolonged hospital length of stays, hospital readmissions, and subsequent procedures.<sup>2-5</sup> Aside from the negative impact on patients, SSIs are associated with major economic costs. An evaluation of the economic impact of SSIs in the United States limited to 7 categories of surgical procedures estimated that SSIs resulted in nearly 1 million excess hospital days and >\$1.6 billion in direct costs.<sup>5</sup> For both patient and economic reasons, SSI reduction efforts are a major quality-improvement priority for surgeons, institutions, and payers.

Surgical procedures are associated with varying SSI risks. Numerous factors are associated, in general, with all types of SSIs, including type of procedure, underlying medical condition of the patient, disease process, surgical technique, and urgency of the operation.<sup>6-8</sup> Although there is considerable variability in the literature about SSI rates, colon and rectal surgery (CRS) is consistently associated with much higher SSI rates relative to other types of surgery. Colon and rectal surgery SSI rates range from 5% to 45%.<sup>9-11</sup> Nearly all the same risk factors that

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ACS	= American College of Surgeons
BMI	= body mass index
CRS	= colon and rectal surgery
LSS	= Lean Six Sigma
MBP	= mechanical bowel preparation
NSQIP	= National Surgical Quality Improvement Program
RMH	= Rochester Methodist Hospital
SCIP	= Surgical Care Improvement Project
SSI	= surgical site infection

correlate with any type of SSI are similarly identified in CRS.<sup>6,8,10</sup> Frequently identified predictive factors for CRS SSIs are obesity, diabetes, type of procedure, technique (eg, open vs laparoscopic), longer operative time, and emergency operations.<sup>6,8,10</sup> Interestingly, although these factors are commonly associated with increased CRS SSI rates, these findings are not universally identified across the CRS SSI literature based on single-institution experiences. The absence of consistent CRS SSI risk factors speaks to the complexity of the problem. This also suggests that the potential for a single intervention or small number of interventions to decrease CRS SSI rates substantially is unlikely.

The first large-scale attempt to decrease SSIs, including CRS SSIs, evolved from a Center for Medicaid and Medicare Services and Center for Disease Control and Prevention demonstration project in Washington State.<sup>12</sup> This multi-institution effort reduced SSIs in 56 hospitals by 27%, from an overall of 2.3% to 1.7% after 1 year. Initially focused on appropriate timing, selection, and discontinuation of perioperative antibiotics, the eventual Surgical Care Improvement Project (SCIP) expanded to include perioperative skin clipping, glucose control in cardiac surgery patients, and normothermia in CRS patients. These performance metrics will be linked to Center for Medicaid and Medicare Services payments starting in 2013.13 Unfortunately, subsequent studies demonstrated that even high compliance with SCIP measures is not directly associated with reducing SSI rates.<sup>14,15</sup> These findings speak to the complexity of the problem and most likely the institution-specific nature of SSIs. A number of institutions have reported additional "bundles" of interventions directed at reducing CRS SSIs with varying success.<sup>16-19</sup> Unfortunately, in some cases the intervention bundle actually resulted in an increase in SSIs.11

In this report, we describe a Lean Six Sigma (LSS) approach to reducing CRS SSIs at a single high-volume tertiary care academic hospital.<sup>20</sup> Lean Six Sigma is a process-improvement methodology that evaluates all the steps in a process and focuses on eliminating waste

or inefficiency and improving the quality of the process. A multidisciplinary team designed and implemented a bundle of interventions across the entire surgical episode from preoperative preparation, intraoperative, postoperative management, and postdismissal care. Performance was monitored by the team and feedback was provided to the team and staff on a monthly basis using our CRS-specific outcomes from the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) dataset. The ACS NSQIP dataset is composed of patient demographic, clinical, intraoperative elements, and postoperative occurrences/complications for 30 days after surgery. Data collection and analysis is performed in a proscribed manner and aggregated with other participating institutions. Once analyzed, the data are returned to the individual institutions as both raw performance and risk-adjusted comparisons to help drive quality improvement for surgical patients.<sup>21</sup>

## **METHODS**

## Study setting

The Mayo Clinic, Rochester campus has two tertiary care hospitals. The Division of Colon and Rectal Surgery is based at Rochester Methodist Hospital (RMH) and is composed of 8 board-certified colon and rectal surgeons. General surgery residents or colon and rectal surgery fellows participate in all procedures. This practice performs >95% of all colon and rectal surgery at the Mayo Clinic, Rochester. From 2009 to 2011, 5,120 inpatient abdominal colon and rectal surgical procedures were performed. The Mayo Clinic participates in ACS NSQIP, which evaluates a sample of the colon and rectal surgery practice each month using the standard ACS NSQIP procedure sampling methodology. This sample varies in size between 13% and 18% of the monthly CRS procedures performed at RMH.

# **Project design**

A multidisciplinary team was established to evaluate the colorectal SSI outcomes. This team was part of Mayo Clinic's participation in a multi-institution collaborative coordinated by the Joint Commission's Center for Transforming Healthcare (http://www.centerfortrans forminghealthcare.org/) and the ACS to reduce colorectal SSIs. The collaborative design was to use LSS techniques combined with ACS NSQIP data to evaluate institutional practices and processes to reduce colorectal SSIs by >50% from baseline for each institution. Here we only discuss the Mayo Clinic team, process redesign, and outcomes. The team composition is presented in Table 1.

Table 1. Composition of the Mayo Clinic Colorectal Surgery Surgical Site Infection Reduction Team by Role and Department

Role	Department
Surgeon, project leader	Surgery, Division of Colon and Rectal Surgery
Quality advisor	Systems and Procedures
Infection preventionist	Nursing
Nurse managers on colon and rectal surgery patient care units	Nursing
Clinical administrator	Nursing
Clinical nurse specialist	Nursing
Wound, ostomy, continence nurse	Nursing
Operating room nursing managers supporting colon and rectal surgery	Nursing-Hospital Surgical Services
Quality improvement advisor	Nursing–Hospital Surgical Services
ACS NSQIP data abstraction and analysis	Surgery Clinical Research Office
Pharmacist	Pharmacy
Process engineer	Systems and Procedures
Extended nurse practitioner	Colon and Rectal Surgery
Research fellow	Surgery, Division of Colon and Rectal Surgery

ACS NSQIP, American College of Surgeons National Surgical Quality Improvement Program.

#### **Data capture**

Procedures included in the data analysis were defined by the Current Procedural Terminology code used by the ACS NSQIP abstraction guidelines for selecting CRS procedures (Appendix). The 34 Current Procedural Terminology codes include open and laparoscopic small bowel, colon, and rectal resections, as well as procedures involving ostomy construction. Analysis of patient demographics and patient- and procedure-related factors commonly thought to contribute to SSIs were analyzed during the 2 time periods of this study: preintervention (2009 and 2010) and postintervention (2011). Surgical site infections were classified according to the site (superficial, deep, and organ space) using the ACS NSQIP abstraction guidelines. No substantial changes in the ACS NSQIP sampling methodology occurred during the 3-year study period. The ACS NSQIP SSIs were tracked monthly. Control charts were created and statistical analysis on the monthly rates was performed using Minitab Statistical Software (version 16.2.2, Minitab, Inc). Statistical significance was set at the p < 0.05 level with comparative statistics performed using Pearson chi-square. A control chart is graphical representation of how a variable of interest changes over time. The events, in this case SSI rates, are plotted over time. A central line represents the mean performance, an upper line is the upper control limit and a lower line is the lower control limit. Control limits are determined from historical data and represent the significance of variations in the plotted data. By comparing current data with these lines, you can draw conclusions about whether the process is consistent, unpredictable, or has been influenced by some intervention.

Compliance data with the SCIP elements related to colorectal and abdominal surgery (ie, SCIP 1, 2, 3, 6,

7, and 10) during the same period were obtained from the Institutional Quality Office. Performance metrics on items in the reduction bundle were collected during random audits. This quality-improvement project was deemed exempt by the Institutional Review Board.

#### Intervention bundle design

The intervention bundle design was conducted in 3 stages. The first stage consisted of team meetings focused on reviewing available literature about colorectal SSI risk factors and prevention techniques, analysis of our RMH ACS NSQIP data, and development of a current state process map for the care of the colorectal surgical patient. This process map covered the entire episode of surgical care from the initial consultation to care recommendations postdischarge. The second stage focused on enhancing current process steps with a specific goal of reducing variation between the surgeons. All elements were evaluated for scientific evidence, workflow issues, and economic impact. Although some elements lacked strong evidence for SSI reduction, they were included because they fit easily into the workflow and/or were acceptable on economic terms. The final stage included establishing the infrastructure to support the process changes and staff education. Individual element implementation was evaluated to ensure reproducibility, appropriate process flow, and compliance once implemented.<sup>22</sup>

The surgical episode of care was divided into the following phases: preoperative, intraoperative, postoperative, and postdischarge. The specific elements of the SSIreduction bundle were built into these phases and are presented in Figure 1. All elements were implemented as a single bundle starting January 1, 2011 and were

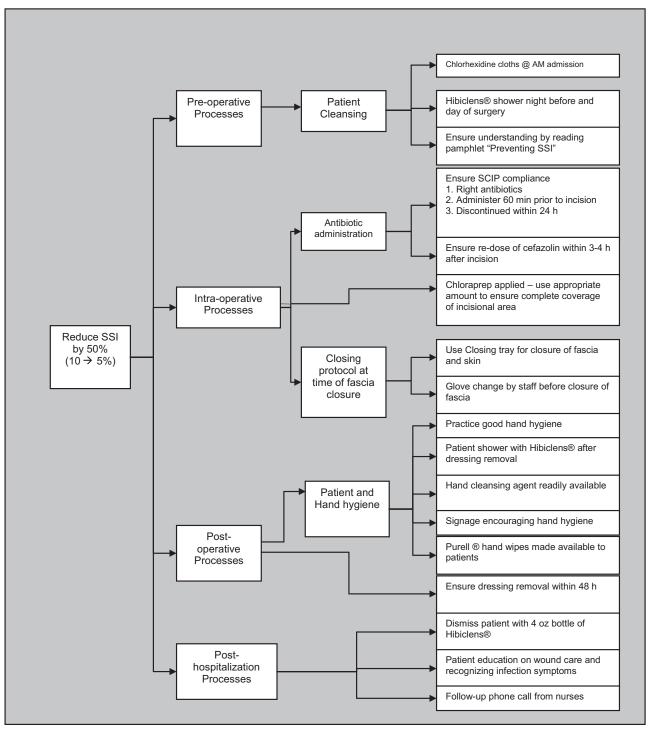


Figure 1. The critical to quality tree diagram for the different elements of the colorectal surgical site infection bundle and the phases of surgical care where they were instituted.

maintained throughout the year. No mandated changes were made in the technical approaches selected by our surgeons relative to the conduct of operation or wound closure. Our standard practice is to close all abdominal wounds with a subcuticular closure except for type IV cases, in which the skin is left partially open.

#### RESULTS

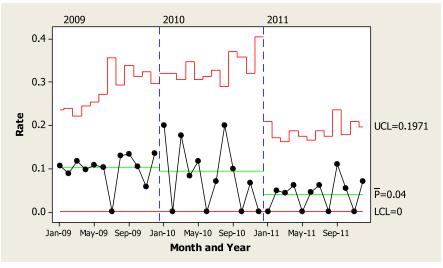
The ACS NSQIP RMH colorectal surgery SSI rate for the 2 years (2009 and 2010) before reduction-bundle implementation was 9.8%. After implementation in 2011, the overall SSI rate declined significantly to 4.0% (p < 0.05; Fig. 2). Superficial and organ space SSI rates both declined in the intervention period (Figs. 3, 4). Superficial SSIs declined significantly from 4.9% before the interventions to 1.5% (p < 0.05). Organ space infections also declined to 2.5%, but this reduction did not reach statistical significance (p = 0.10). The patient characteristics during the 2 periods are reported in Table 2. A total of 729 patients were analyzed in the ACS NSQIP sample, with 531 patients in the pre-reduction bundle group (2009 to 2010) and 198 patients in 2011 after implementation of the SSI reduction bundle. The majority of patient demographics and characteristics that might influence SSI were not different in the 2 periods. However, the following factors were significantly different: wound classification, American Society of Anesthesiologists' class, and the number of operations coded with a Current Procedural Terminology code indicating a rectal resection or a rectal resection with an anastomosis. During the implementation period (2011), there were more high-risk wounds according to the woundtype classification and more patients with higher American Society of Anesthesiologists' class. However, there were fewer cases involving surgery on the rectum. Exactly how these differences influenced our overall results is uncertain.

The SCIP measure performance for colorectal surgery was unchanged between the preintervention (2009 and 2010) and postintervention (2011) period (Fig. 5).

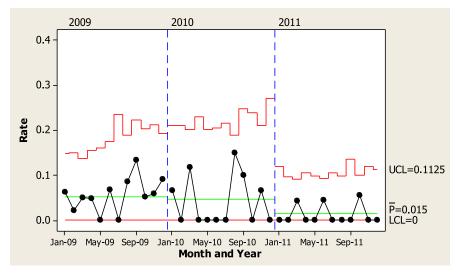
#### DISCUSSION

Surgical site infections cause considerable morbidity in surgical patients. Colorectal surgery, in particular, is a major contributor to institutional SSI rates.<sup>23</sup> In our experience and that of others, the nationally implemented SCIP measures have not impacted colorectal SSI rates appreciably.<sup>24,25</sup> However, using an LSS approach, a multidisciplinary team at the Mayo Clinic, Rochester developed a number of interventions across the entire surgical episode that resulted in a substantial and sustained reduction in the colorectal SSI rate based on our ACS NSQIP performance.

The evidence for most SSI reduction interventions is quite limited and often of poor quality.<sup>26-29</sup> Our team took a multipronged approach, which included optimizing evidence-supported interventions (eg, skin preparation and appropriate antibiotic selection and weight-based dosing and re-dosing); incorporating



**Figure 2.** Overall surgical site infection (SSI) rate (2009–2011). Control chart for overall colon and rectal American College of Surgeons National Surgical Quality Improvement Program SSI infections at Mayo Clinic, Rochester Methodist Hospital during a 3-year period, preintervention (2009, 2010) and postintervention (2011). The monthly infection rate is plotted over time. The center line (green line) represents the mean performance. The upper and lower control limits (red lines) represent the statistical confidence interval for the dataset. The baseline rate (2009–2010) was 9.84% and it decreased to 4.0% after the bundle implementation (p < 0.05). Tests performed with unequal sample sizes.

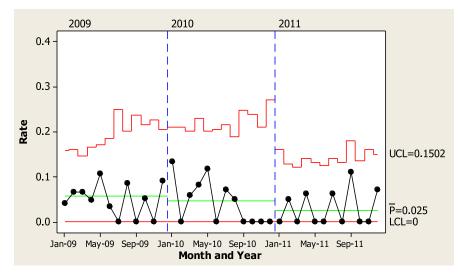


**Figure 3.** Superficial surgical site infection (SSI) rate (2009-2011). Control chart for superficial SSI colon and rectal American College of Surgeons National Surgical Quality Improvement Program SSI infections at Mayo Clinic, Rochester Methodist Hospital during a 3-year period, preintervention (2009, 2010) and postintervention (2011). The monthly infection rate is plotted over time. The center line (green line) represents the mean performance. The upper and lower control limits (red lines) represent the statistical confidence interval for the dataset. The baseline rate (2009-2010) was 5% and it decreased to 1.5% after bundle implementation (p < 0.05). Tests performed with unequal sample sizes.

simple interventions with less supporting evidence into our processes, but ensuring high compliance; and engagement of patient, families, and staff across the entire surgical episode. High-value evidence-based interventions included practice standardization to chlorhexidine-alcohol-based skin preparation for all abdominal cases, including those with an existing stoma, and weight-based antibiotic dosing preoperatively, intraoperatively, and postoperatively, was built into our electronic ordering systems.<sup>30,31</sup> In addition, weight-based intraoperative re-dosing of cefazolin for patients who were not allergic at 3-hour intervals after first administration was implemented to ensure therapeutic serum antibiotic concentrations at the time of wound closure.<sup>32</sup> To facilitate compliance with intraoperative re-dosing, electronic reminders were built into the anesthesia charting system to prompt for re-dosing at the prescribed interval.

Many of the other interventions applied in our bundle have either been reported in small series as beneficial, recommended based on expert consensus, or of possible benefit with a very low potential of adverse effect (such as preoperative chlorhexidine shower, use of chlorhexidine-impregnated cloths, and keeping dressings on for 48 hours).<sup>26,27,33,34</sup> Our goal for these interventions was to ensure high compliance with performance by building them into our care processes. For example, all patients are provided with 2 chlorhexidine soap packets at the time of scheduling surgery. They are instructed to use them during a shower the night before and morning of surgery. The morning intake process at the hospital includes a question about whether they used the packets. If they did not, there is a nurse-initiated protocol for use of chlorhexidine cloths over the entire body in the morning admission area. Additionally, any patient with a body mass index (BMI) > 30 is required to use the chlorhexidine cloths even if they used chlorhexidine with his or her shower. This BMI level was chosen because, in our institutional ACS NSQIP colorectal SSI data, a BMI >30 was an independent risk factor for superficial SSI. To assist our preoperative nursing staff in reliably identifying these patients without requiring them to search for the BMI, the electronic scheduling system was programmed to search the medical record for the patient's most recent BMI. If it was >30, then an automatic order to use the chlorhexidine cloths on the patient's arrival is activated. We believe that building these elements into the system of care rather than having staff trying to remember them ensures high compliance with performance and contributes to the overall success of the implementation bundle.

In the operating room, changing surgical gloves and use of dedicated noncontaminated closing set



**Figure 4.** Organ space surgical site infection (SSI) rate (2009-2011). Control chart for organ space colon and rectal American College of Surgeons National Surgical Quality Improvement Program SSI infections at Mayo Clinic, Rochester Methodist Hospital during a 3-year period, preintervention (2009, 2010) and postintervention (2011). The monthly infection rate is plotted over time. The center line (green line) represents the mean performance. The upper and lower control limits (red lines) represent the statistical confidence interval for the dataset. The baseline rate (2009-2010) was 4% and it decreased to 2.5% after bundle implementation (p = 0.10). Tests performed with unequal sample sizes.

instruments after all the contaminated instruments are removed and the working areas are re-draped were considered common-sense interventions, but lack any strong evidence base. Meticulous postoperative wound care protocols, including leaving the operative dressing in place until the second postoperative day unless soiled and emphasizing daily patient bathing with chlorhexidine soap once the dressing is removed. Strict handhygiene policies and practices by staff, patient, and patient visitors on our CRS-dedicated patient care units were instituted. Compliance audits by independent institutional observers demonstrated staff (ie, consultant surgeons, residents, nurses, and allied health) hand hygiene at >98% for the year. Nearly all of the elements in the bundle might be expected to influence superficial SSIs rates. As our data demonstrate, the largest decline was in our superficial SSIs, with a considerable decrease from 4.9% to 1.6%. Unfortunately, because of the design of this study, we are unable to determine the contribution of each element to the observed SSI reduction.

Numerous studies have identified risk factors for SSIs after colorectal surgery.<sup>8,10,35-37</sup> Only rarely can the risk factors be modified before surgery. Especially because nearly 50% of our patients have surgery the day after the initial surgical consultation, our approach was to design interventions during the entire surgical

episode that could be applied to any colorectal abdominal surgery patient. There were some differences between our 2 patient groups that might have influenced our SSI occurrence. Interestingly, there were more contaminated wounds and higher American Society of Anesthesiologists' class patients during 2011 as compared with the previous 2 years. These factors are commonly associated with an increased risk of SSI.<sup>7,8,10</sup> On the other hand, we had fewer cases involving the rectum in 2011. In some reports, rectal cases are associated with higher SSI risk.7,8,10 Given the complexity of predicting SSI occurrence, it is hard to tell if any of these individual differences could have influenced our results. The other major SSI risk factors, BMI, diabetes, cancer diagnosis, preoperative radiation therapy, and blood transfusions, were similar between the study time periods.

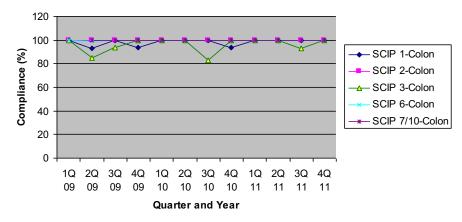
The team's goal was to standardize as many care elements that might influence SSI across the 8 surgeon practice and achieve high performance compliance with those interventions. The one exception was the use of a mechanical bowel preparation (MBP) because no practice consensus could be reached.<sup>38</sup> One surgeon uses MBP on all cases, one never uses MBP, and the remaining surgeons only selectively use MBP with the vast majority of cases not having MBP. Preoperative oral antibiotics are not used in the practice.

#### Table 2. Patient Demographics and Possible Surgical Site Infection Risk Factors of Interest

Variable	January 2009–December 2010 (baseline)	January 2011–December 2011	Total/overall	p Value
Sampled cases, n	531	198	729	
Infections, n (%)				
Total	52 (9.8)	8 (4.0)	60	
Superficial	27 (5.08)	3 (1.5)	30	0.01
Organ space	27 (5.08)	5 (2.5)	32	0.03
Deep	1 (0.2)	0	1	0.13
$\overline{\text{Age, y, mean} \pm \text{SD}}$	$57.3 \pm 17.2$	$56.7 \pm 18.6$	,	0.67
Age older than 60 y, n (%)	255 (48)	96 (48.5)	351 (48.2)	0.91
Women, n (%)	259 (48.8)	90 (45.5)	349 (47.9)	0.43
Weight, kg, mean $\pm$ SD	$78.4 \pm 19.9$	$78.8 \pm 21$		0.84
BMI, mean $\pm$ SD	$27.2\pm6.1$	$26.9\pm 6.0$		0.62
BMI >30, n (%)	145 (27.4)	49 (24.8)	194 (26.7)	0.47
Wound class, n (%)				
Clean contaminated	465 (87.6)	155 (78.3)	620 (85.1)	
Contaminated	16 (3)	17 (8.6)	33 (4.5)	
Dirty/infected	50 (9.4)	26 (13.1)	76 (10.4)	0.001
ASA class, n (%)				
1 No disturb	23 (4.3)	10 (5.1)	33 (4.5)	
2 Mild disturb	330 (62.1)	127 (64.1)	457 (62.7)	
3 Severe disturb	177 (33.3)	56 (28.3)	233 (32.0)	
4 Life threat	1 (0.2)	5 (2.5)	6 (0.8)	0.01
Diabetes, yes, n (%)	48 (9.0)	23 (11.6)	71 (9.7)	0.30
Cancer diagnosis, yes, n (%)	207 (39.0)	77 (38.9)	284 (39.0)	0.99
Preoperative radiation therapy within 90 d, n (%)	43 (8.1)	16 (8.0)	59 (8.1)	0.99
Operations with CPT codes involving rectal resection with anastomosis or rectal resection, n (%)	261 (49.1)	71 (35.8)	332 (45.5)	0.001
Functional status, n (%)				
Independent	509 (95.9)	188 (95)	697 (95.6)	
Partially dependent	20 (3.8)	8 (4)	28 (3.8)	
Totally dependent	2 (0.4)	2 (1)	4 (0.7)	0.58
Sepsis, none, n (%)	510 (98.1)	192 (97)	702 (97.8)	0.37
Laparoscopic surgery, n (%)	255 (48.0)	107 (54.0)	362 (49.7)	0.15
Open surgery, n (%)	276 (52.0)	91 (46.0)	367 (50.38)	
Intra- and postoperative blood transfusion, yes, n (%)	69 (13.0)	31 (15.7)	100 (13.7)	0.35
Mean operative time, min, mean $\pm$ SD	$203.2\pm93.2$	$191.8 \pm 88.5$		0.13

ASA, American Society of Anesthesiologists; BMI, body mass index; CPT, Current Procedural Terminology.

There are a number of reported colorectal SSI reduction bundles in the literature.<sup>16-19</sup> Hedrick and colleagues reduced colorectal SSIs from 25.6% to 15.9% by ensuring high compliance with SCIP measures, as well as leaving a Penrose wound drain in patients with BMI >25.<sup>19</sup> In another study that implemented a comprehensive bundle for colorectal cancer procedures in 4 regional hospitals in Spain, an overall 24.9% SSI rate (23.2% for colon and 27.6% for rectal procedures) was reported.<sup>17</sup> Unfortunately, the authors did not report on any preintervention SSI rates, so it is difficult to determine the impact of the intervention bundle. Implementations of best-practice bundles have not always resulted in improvement. A randomized controlled trial of a bundle to reduce colorectal SSIs demonstrated a 45% SSI rate in the intervention arm, as compared with the standard care arm, which had a 24% SSI rate.<sup>11</sup> Our experience differs from these reports because we are starting with a much lower baseline colorectal SSI rate. Interventions with relatively small effects might not be seen as important if major technical or process issues are contributing to high existing SSI rates as experienced in these other reports.



**Figure 5.** Reported Surgical Care Improvement Project (SCIP) performance on those measures related to colon and rectal surgery at the Rochester Methodist Hospital, Mayo Clinic during a 3-year period, preintervention (2009, 2010) and postintervention (2011). SCIP 7/10 compliance data were initiated in the second guarter of 2009.

There are a number of limitations to our study that can reduce the general applicability of our findings. First, it represents an individual specialty colon and rectal surgery practice at a high-volume academic tertiary care center. We have recently reported that our practice differs in disease mix of our patients compared with the entire ACS NSQIP colon and rectal dataset.<sup>37</sup> However, our mix was more highly weighted to high-risk patients, such as patients with inflammatory bowel disease, which should increase our SSI rate compared with the average practice. Second, the short time frame and limited numbers of patients sampled make it difficult to determine if this is a sustainable change. The ACS NSQIP sampling methodology has not changed in any meaningful manner during the 3 years that encompass this study. Increasingly, there is recognition of the importance of institutional culture and teamwork on patient safety and outcomes.<sup>39</sup>Our institution has a culture characterized by highly integrated and collaborative team-based care. All of our process-improvement projects are based on a multidisciplinary approach with extensive communication and engagement of all staff touched by the process change to gain input and compliance. This culture of cross-discipline collaboration cannot be replicated in other institutions. How this might influence our outcomes is unclear.

The substantial and sustained decline in SSIs after the bundle implementation in our institution supports that changes in our process resulted in SSI reduction. However, we cannot say what change or changes contribute to the reduction. Our study is an observational longitudinal study evaluating the impact of a practice change on SSI rates. It is not designed to elucidate the role of each specific element in SSI reduction. Because of the complex interaction between patient, their disease, the procedure, the surgeon, and institution factors that contribute to colorectal SSI, it makes it exceedingly difficult for any single trial to definitively establish a single intervention as being effective in all circumstances. This leaves open the possibility that some other process or process changes unrelated to what we have implemented and reported here have positively influenced our outcomes.

# CONCLUSIONS

A multidisciplinary team at the Mayo Clinic, Rochester using LSS methodology developed and implemented an SSI reduction bundle across the episode of care for CRS patients. The bundle resulted in a substantial and sustained decline in SSIs as measured using ACS NSQIP methodology. A significant reduction was seen in overall and superficial SSIs, although organ space infections also declined. Given the limitations of the study design, we were unable to determine which elements impacted the results. However, a coordinated approach among multiple providers across the entire episode of care using institution-specific data and standardized interventions can result in sustained reductions in colorectal SSIs.

#### Appendix

Current Procedural Terminology codes used in the American College of Surgeons National Surgical Quality Improvement Program sampling methodology for identifying colon and rectal procedures for abstraction and analysis: 44140, 44141, 44143, 44144, 44145, 44146, 44147, 44150, 44151, 44155, 44156, 44160, 44204, 44205, 44206, 44207, 44208, 44210, 44211, 44212, 45110, 45111, 45112, 45113, 45114, 45116, 45119, 45120, 45121, 45123, 45395, 45397, 45499, and 45550.

#### **Author Contributions**

- Study conception and design: Cima, Dankbar, Lovely, Nehring, Quast
- Acquisition of data: Pendlimari, Aronhalt, Nehring, Hyke, Tyndale, Rogers, Quast
- Analysis and interpretation of data: Cima, Dankbar, Lovely, Pendlimari, Aronhalt, Nehring, Hyke, Tyndale
- Drafting of manuscript: Cima, Dankbar, Lovely, Pendlimari, Aronhalt, Nehring, Rogers, Quast
- Critical revision: Cima, Dankbar, Lovely, Pendlimari, Aronhalt, Nehring, Hyke, Tyndale, Rogers, Quast

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