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# Do surgical care bundles reduce the risk of surgical site infections in patients undergoing colorectal surgery? A systematic review and cohort meta-analysis of 8,515 patients

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**Background.** Care bundles are a strategy that can be used to reduce the risk of surgical site infection (SSI), but individual studies of care bundles report conflicting outcomes. This study assesses the effectiveness of care bundles to reduce SSI among patients undergoing colorectal surgery.

**Methods.** We performed a systematic review and meta-analysis of randomized controlled trials, quasi-experimental studies, and cohort studies of care bundles to reduce SSI. The search strategy included database and clinical trials register searches from 2012 until June 2014, searching reference lists of retrieved studies and contacting study authors to obtain missing data. The Downs and Black checklist was used to assess the quality of all studies. Raw data were used to calculate pooled relative risk (RR) estimates using Cochrane Review Manager. The  $I^2$  statistic and funnel plots were performed to identify publication bias. Sensitivity analysis was carried out to examine the influence of individual data sets on pooled RRs.

**Results.** Sixteen studies were included in the analysis, with 13 providing sufficient data for a meta-analysis. Most study bundles included core interventions such as antibiotic administration, appropriate hair removal, glycemic control, and normothermia. The SSI rate in the bundle group was 7.0% (328/4,649) compared with 15.1% (585/3,866) in a standard care group. The pooled effect of 13 studies with a total sample of 8,515 patients shows that surgical care bundles have a clinically important impact on reducing the risk of SSI compared to standard care with a CI of 0.55 (0.39–0.77;  $P = .0005$ ).

**Conclusion.** The systematic review and meta-analysis documents that use of an evidence-based, surgical care bundle in patients undergoing colorectal surgery significantly reduced the risk of SSI. (Surgery 2015;158:66-77.)

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SURGICAL SITE INFECTIONS (SSIs) are associated with increased morbidity, increased duration of hospitalization, re-admission, and excess utilization of health care resources. Each year >600,000

operative procedures are performed in the United States to treat colon-related diseases; as a surgical specialty, colorectal surgery has one of the highest rates of SSI. This rate as measured by several independent investigators is highly variable, ranging from 15 to 30%.<sup>1-4</sup> A recent collaborative study by the Joint Commission Center for Transforming Healthcare and the American College of Surgeons (ACS) found a baseline rate of 15.8% among 7 US institutions participating in a multidisciplinary effort to reduce the risk of infections after colorectal surgery.<sup>5</sup> The financial cost of treating SSIs can be substantial. The Joint Commission/ACS

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collaborative study estimated that the use of evidence-based practices can prevent >30,000 infections, with an estimated collective saving of \$834 million.<sup>5</sup> After discharge, patients who develop an SSI often experience an impairment of both physical and mental well-being.<sup>6</sup> This process is exacerbated in patients undergoing colorectal resection of cancer, further impacting their health-related quality of life.

Numerous clinical interventions with varying levels of supporting evidence have been implemented to reduce SSIs among colorectal patients. A recent approach to improving patient outcomes is the use of care bundles. Care bundles were first introduced by the Institute for Healthcare Improvement (IHI) in 2001 to improve clinical outcomes in the critical care population.<sup>7</sup> The concept of a care bundle was developed from evidence documenting that a structured approach to performing 3–5 evidence-based collective interventions could lead to an improved patient outcome. While specific interventions may vary between bundles, it is the bundle approach that ensures consistent implementation of all measures that is claimed to be successful. Surgical care bundles have been developed to reduce SSI after the success of care bundles in reducing catheter-related bacteremia and ventilator-associated pneumonia.<sup>8,9</sup>

To date, there has been no systematic review of the effect of care bundles to reduce SSIs, and individual studies report conflicting findings of successes and failures.<sup>10–13</sup> Our analysis represents the first systematic review of the effectiveness of surgical care bundles to reduce SSIs among patients undergoing colorectal surgery.

## METHODS

This systematic review was conducted and is reported in accordance with the PRISMA statement.<sup>14</sup>

**Research question.** The aim of this study was to determine if implementation of an SSI care bundle reduced the rate of SSIs among patients having colorectal surgery.

**Inclusion and exclusion criteria.** We included all studies that compared a care bundle designed to reduce SSI against a control group, baseline group, or early implementation group, and reported SSIs among colorectal patients as an outcome for both groups. While randomized trials are usually the focus of a meta-analysis, meta-analysis can also be applied to cohort studies. This is a common practice, although the Cochrane Collaboration cautions that meta-analyses of

cohort studies are more likely to be subject to selection bias where not all patients receive the intervention.<sup>15</sup> We decided to extend the inclusion criterion beyond randomized trials, because care bundles comprise existing best practice interventions such as appropriate antibiotic management and implementing a non-intervention group may be unethical. The inclusion of cohort studies also added to the breadth of clinical data.

The IHI defines care bundles as  $\geq 3$  evidence-based interventions with the potential to prevent SSI that are implemented in a consistent manner for all patients. Importance is placed on the consistent and systematic application of all elements within a bundle rather than on individual selective elements. For this reason, all bundles designed to reduce SSI were included in this review, despite variations among individual interventions. Only patients undergoing colorectal surgery were included. No constraints were placed on language of the publication.

**Outcomes of interest.** SSI among patients having colorectal surgery was the primary outcome.

**Search strategy.** A member of the research team (W.P.) performed a comprehensive literature search using terms identified and agreed by the authors. PubMed, Embase, CINAHL, Scopus, the Cochrane Database of Systematic Reviews, the Central Register of Controlled Trials, Academic Search Premier, and [clinicaltrials.gov](http://clinicaltrials.gov) were searched from 2002 to June 2014 using the keywords: “surgical site infection,” “compliance” or “adherence,” “care bundle,” “care package,” “care checklist,” “care pathway,” “care intervention,” “prevention bundle,” “surgical care improvement,” “5 million lives,” “SCIP,” “100000 lives,” and “colorectal.” We also reviewed the reference lists of retrieved studies to identify studies that had not been identified by the search strategy. If studies were identified as potentially able to answer the study question but contained missing data, authors were contacted in an attempt to fill in the missing variables.

**Data extraction and risk of bias assessment.** Two review authors independently assessed the titles and abstracts of 518 potentially relevant studies. If it was unclear from the title or abstract whether a study met the criteria or there was a disagreement over eligibility, the study was retrieved in full and assessed further by all 6 review authors independently. Two review authors independently extracted details from eligible studies onto data extraction forms which were cross-checked and used to create [Tables I](#) and [II](#). The Downs and Black quality checklist was used to assess all

**Table I.** Study description

<i>First author and year</i>	<i>Study design</i>	<i>Data collection period</i>	<i>Sample group</i>	<i>Sample size (patients)</i>	<i>Compliance with interventions</i>	<i>SSI data and surveillance</i>	<i>SSI outcome</i>
Anthony 2011	RCT	2 y, 8 months	Colorectal Single center	Baseline 97 Cohort 100	Compliance data for composite bundle in both groups	CDC definition. Surveillance at 30 days.	Control 24.7% Intervention 45%
Berenguer 2010	Cohort (before and after implementation)	Baseline 1 y Cohort 1 y	Colorectal Single center	Baseline 113 Cohort 84	Compliance data for composite bundle in baseline and cohort	Superficial SSIs only. NSQIP definition, collected by dedicated nurse	Superficial SSI data only Baseline 13.3% Cohort 8.3%
Bull 2011*	Cohort (before and after implementation)	Baseline 1 y Cohort 1 y	Colorectal Single center	Baseline 180 Cohort 275	Compliance data for composite bundle and quarterly for individual interventions for cohort	Australian NHSN definition. No additional information.	Baseline 15% Cohort 7%
Cima 2013	Cohort (before and after implementation)	Baseline 1 y Cohort 2 y	Colorectal Single center	Baseline 531 Cohort 198	Compliance data for individual interventions for baseline and cohort	NSQIP defined outcomes	Baseline 9.8% Cohort 4.0%
Crolla 2012†	Cohort (before and after implementation)	Baseline 1.5 y Cohort 2.5 y	Colorectal Single center	Baseline 394 Cohort 377	Compliance data for composite bundle and individual interventions for baseline and cohort	CDC definition. Surveillance by dedicated infection control staff until 30 days	Baseline 21.5% Cohort 16.1%
Hawn 2011‡,§	Cohort	Baseline 1 y Cohort 3 y	Colorectal, CABG, cardiac, orthopedic. Multicenter	Baseline not known Cohort 15,444	Compliance data for composite bundle and individual interventions for cohort only	CDC definition. Surveillance at 30 days.	No baseline data Cohort 14.2%

(continued)

**Table I.** (continued)

<i>First author and year</i>	<i>Study design</i>	<i>Data collection period</i>	<i>Sample group</i>	<i>Sample size (patients)</i>	<i>Compliance with interventions</i>	<i>SSI data and surveillance</i>	<i>SSI outcome</i>
Hedrick 2007	Cohort (before and after implementation)	Baseline 2 y Cohort 6 months	Colorectal Single center	Baseline 175 Cohort 132	Compliance data for individual interventions for baseline and cohort	CDC definition. 90 days follow-up	Baseline 25.6% Cohort 15.9%
Keenan 2014	Cohort (before and after implementation)	Baseline 3 y Cohort 1.5 y	Colorectal Single center	Baseline 212 Cohort 212	No data presented. Narrative reports that 'compliance with some interventions approached 100%'	NSQIP defined outcomes. Surveillance at 30 days.	Baseline 25.9% Cohort 8.4%
Larochelle 2011§	Cohort (before and after implementation)	Baseline 2 y Cohort 4 y	Colorectal Single center	706 Not clear if this is Cohort only or Baseline and Cohort combined	Compliance data for individual interventions for baseline and cohort	International Classification of Diseases. Follow- up performed by surgeon (time of surveillance unknown).	No baseline data Cohort 12.3%
Liau 2010*	Cohort (before and after implementation)	Baseline 1 y Cohort 2 y	Gastrointestinal Single center	Baseline 1,040 Cohort 2,408	Compliance data for individual interventions for cohort only	CDC definition. In patient case note review, clinic review, post discharge phone calls.	Baseline 3.1% Cohort 0.5%
Lutfiyya 2012	Cohort (before and after implementation)	Baseline 4 y Cohort 1.5 y	Colorectal Single center	Baseline 430 Cohort 195	No information on compliance data	NSQIP definition. Data collected by trained nurses	Baseline 21% Cohort 6.6%
Pastor 2010	Cohort (early implementation versus late implementation)	Early 14 months Late 14 months	Colorectal Single center	Early 238 Late 243	Compliance data for composite bundle and individual interventions for early and late	CDC definition.	Early 18.9% Late 19.4%

(continued)

**Table I.** (continued)

<i>First author and year</i>	<i>Study design</i>	<i>Data collection period</i>	<i>Sample group</i>	<i>Sample size (patients)</i>	<i>Compliance with interventions</i>	<i>SSI data and surveillance</i>	<i>SSI outcome</i>
Tillman 2013 <sup>‡</sup>	Cohort (before and after implementation)	Baseline 1 y Cohort 1 y	Cardiac, colorectal, general, gynecologic, orthopedic, thoracic, vascular Single center	Baseline 79 Cohort 104	Compliance data for individual interventions for baseline and cohort	SSI definition unclear but presumably based on NSQIP.	Baseline 24.0% Cohort 11.5%
Waits 2014	Cohort (comparison of increasing number of interventions within bundle)	Cohort 3 y	Colorectal Multicenter	1 intervention, 99; 2 interventions, 552; 3 interventions, 1,179; 4 interventions, 1,438; 5 interventions, 730; 6 interventions, 87	Compliance data for individual interventions and composite bundle	International Classification of Diseases. Surveillance at 30 days	1 17.1% 2 14.1% 3 8.3% 4 6.1% 5 2.6% 6 2.1%
Wick 2008 <sup>§</sup>	Cohort	Cohort 11 months	Colorectal Single center	Cohort 298	Compliance data for individual interventions for baseline and cohort	CDC definition. Surveillance at 30 days by attending surgeon	No baseline data Cohort 20%
Wick 2012	Cohort (before and after implementation)	Baseline 1 y Cohort 1 y	Colorectal Single center	Baseline 278 Cohort 324	Compliance data for individual interventions for baseline and cohort	NSQIP defined outcomes Surveillance unknown	Baseline 27.3% Cohort 18.2%

\*Study authors provided additional information.

<sup>†</sup>Data from 2009 and 2010 was excluded as bundle implementation was incomplete during this time.

<sup>‡</sup>Colorectal data extracted.

<sup>§</sup>Insufficient data to be included in the meta-analysis.

CABG, Coronary artery bypass grafting; CDC, Centers for Disease Control and Prevention; NHSN, National Healthcare Safety Network; NSQIP, National Surgical Quality Improvement Program; RCT, randomized, controlled trial; SSI, surgical site infection.

**Table II.** Bundle interventions

<i>SSI bundle interventions</i>	<i>Anthony 2011</i>	<i>Berenguer 2010</i>	<i>Bull 2011</i>	<i>Cima 2013</i>	<i>Crolla 2012</i>	<i>Hawn 2011</i>	<i>Hedrick 2007</i>	<i>Keenan 2014</i>	<i>Larochelle 2011</i>	<i>Liau 2010</i>	<i>Lutfiyya 2012</i>	<i>Pastor 2010</i>	<i>Tillman 2013</i>	<i>Waits 2014</i>	<i>Wick 2008</i>	<i>Wick 2012</i>
Appropriate antibiotic selection/dose		✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
Prophylactic antibiotics within 60 min before surgery	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	
Prophylactic antibiotics discontinued within 24 h		✓		✓		✓	✓		✓		✓	✓	✓		✓	
Antibiotic re-dose within 3–4 h after incision				✓							✓	✓			✓	
Glycemic control			✓				✓	✓		✓	✓	✓		✓	✓	
Normothermia pre-operatively	✓		✓		✓						✓					✓
Normothermia intra-operatively	✓		✓		✓		✓	✓		✓	✓		✓		✓	
Normothermia post-operatively		✓	✓		✓	✓		✓	✓	✓	✓	✓		✓	✓	
Appropriate hair removal		✓			✓	✓	✓			✓		✓	✓		✓	
Supplemental oxygen	✓		✓								✓					
Systolic pressure ≥90 mmHg			✓													
Reduction in intravenous fluids during operation	✓															
Wound edge protector	✓							✓								
CHG cloths on admission				✓												
Preoperative CHG wipes or shower				✓				✓			✓					✓
CHG in alcohol skin preparation				✓				✓			✓					✓
Double gloving											✓					
Glove and/or gown change				✓				✓								
Theatre discipline/restricted traffic					✓			✓								
Smoking cessation											✓					
Patient SSI education				✓				✓			✓					
Tray for closure of fascia and skin				✓				✓								✓
Omission of mechanical bowel preparation	✓															*
Mechanical bowel preparation plus oral antibiotics								✓			✓					✓*
Oral antibiotics given with mechanical bowel prep if used														✓		

(continued)

Table II. (continued)

SSI bundle interventions	Anthony 2011	Berenguer 2010	Bull 2011	Cima 2013	Crolla 2012	Hawn 2011	Hedrick 2007	Keenan 2014	Lavochelle 2011	Liau 2010	Lutfyya 2012	Pastor 2010	Tillman 2013	Waits 2014	Wick 2008	Wick 2012
Penrose drain for patients with BMI $\geq 25$ kg/m <sup>2</sup>							✓									
Pulse lavage of subcutaneous tissue											✓					
Minimally invasive surgery														✓	✓	
Short duration of surgery																
Silver dressings for 5 days											✓					
Removal of sterile dressing within 48 h								✓								
Postoperative washing of wound with CHG				✓				✓								

\*Omission of mechanical bowel preparation was revised during study to mechanical bowel preparation plus oral antibiotics.  
BMI, Body mass index; CHG, chlorhexidine gluconate; SSI, surgical site infection.

studies.<sup>16</sup> This checklist was designed to meet the increasing demand for the use of evidence in systematic reviews and meta-analyses by enabling the quality of both randomized and non-randomized studies to be assessed. It provides an overall numeric score out of 30 points based on 5 themed sections. The 5 sections comprise study quality (overall quality), external validity (ability to generalize findings), study bias (in interventions and outcome measures), confounding and selection bias (in sampling), and power (sample size). The National Collaborating Center for Methods and Tools, Canada describes the Downs and Black system as valid, reliable, and methodologically strong.<sup>17</sup>

**Statistical analysis.** Raw data only were used to calculate pooled relative risk (RR) estimates from random effects models using Cochrane Review Manager version 5.2.

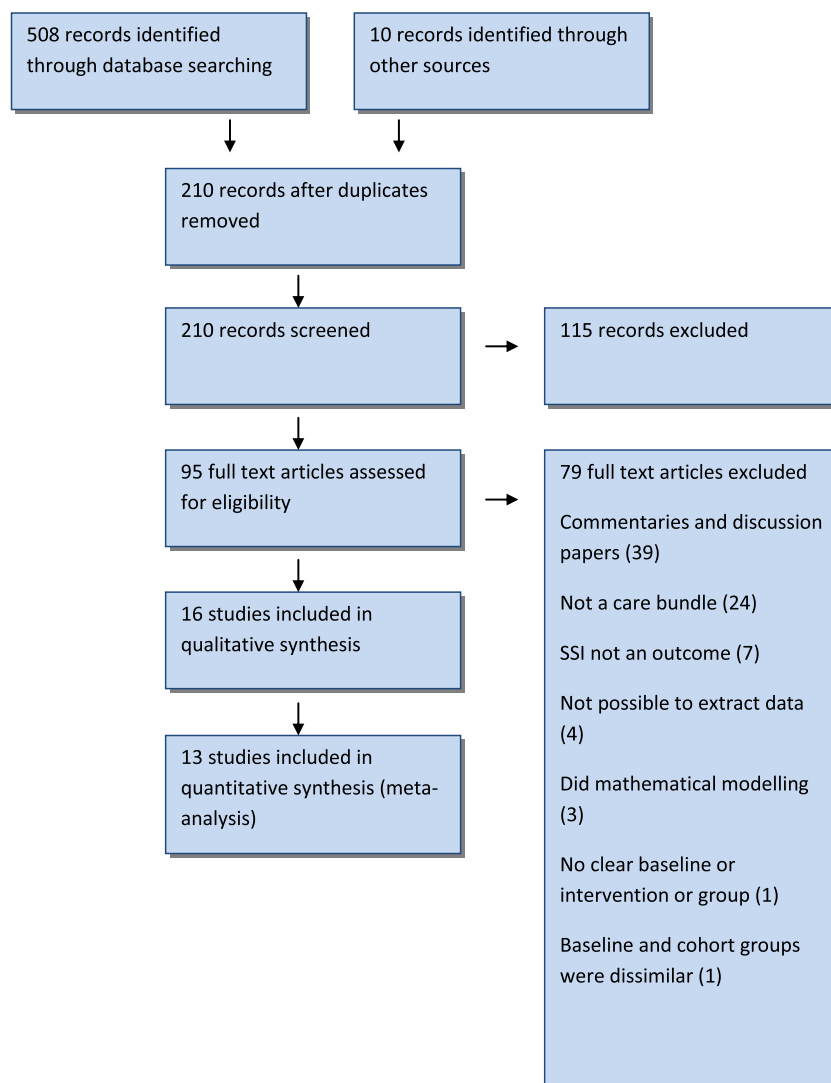
**Sensitivity analysis and publication bias assessment.** To minimize possible publication bias, the  $I^2$  statistic was used to assess heterogeneity, and funnel plots were inspected for symmetry to identify possible publication bias. A sensitivity analysis was carried out by deleting 1 study each time to examine the influence of individual data sets on the pooled RRs. The National Library of Medicine's clinical trial registry ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)) was screened to discover whether any studies had been conducted that remained unpublished. Our search did not identify any relevant "closed" studies. One study investigating the effect of bathing bundle regimens in reducing SSIs started in April 2011 and closed data collection in February 2014,<sup>18</sup> but no results have been published to date, and this study was not included in the analysis.

## RESULTS

Of the 95 articles retrieved, 16 studies (1 randomised trial and 15 cohort studies) assessed the effect of implementing care bundles among patients undergoing colorectal surgery on SSIs (Fig 1).<sup>1,10-12,19-30</sup> Study characteristics are described in Table I, and bundle interventions are listed in Table II. None of the studies implemented identical SSI care bundles; however, all studies included elements from a core group of evidence-based interventions including appropriate antibiotic prophylaxis, normothermia, appropriate hair removal, and glycemic control for hyperglycemic patients. The studies were assessed as medium to high quality (Table III).

Five authors were contacted to provide additional data required for the meta-analysis. Two authors provided additional data that were included in the





**Fig 1.** PRISMA diagram.

meta-analysis.<sup>20,24</sup> One author was unable to provide the requested data, and attempts to contact the remaining 2 study authors were unsuccessful.<sup>12,23,29</sup> Thirteen studies provided sufficient raw data to be grouped together in a meta-analysis (Fig 2).<sup>1,10,11,19-22,24,28-30</sup> Baseline data were taken from the control groups, pre-implementation groups, early implementation groups, and single intervention only groups.<sup>1,10,11,19-22,24,28-30</sup> Intervention data were taken from the care bundle intervention groups, post-implementation groups, late implementation groups, and complete bundle implementation groups.<sup>1,10,11,19-22,24,28,30</sup> The meta-analysis included 8,515 patients and found an SSI rate in the surgical care bundle group of 7.0% (328/4,649) compared with 15.1% (585/3,866) in the

baseline with a CI of 0.55 (0.39 to 0.77;  $P = .0005$ ); the  $I^2$  test for homogeneity was 84%.

The 3 studies that did not provide sufficient data to be included in the meta-analysis had varying findings.<sup>12,23,29</sup> One study, which focused on improving compliance, reported a sample size that was too small to draw any definite conclusions.<sup>29</sup> The second study found no increase in compliance with any bundle interventions and found no change in SSI rates.<sup>23</sup> The third study found that, although reported adherence to core interventions increased, SSI rates remained unchanged.<sup>12</sup>

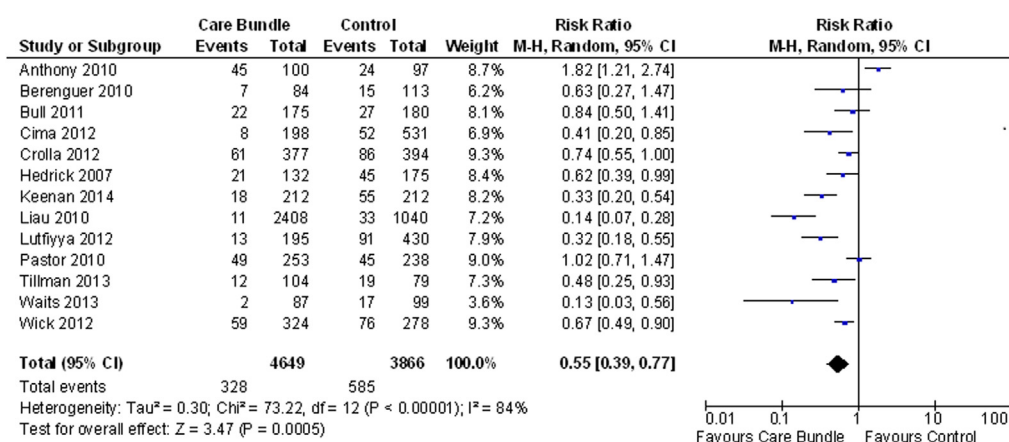
## DISCUSSION

To date, no systematic review has been published in the peer literature examining the effect of care

**Table III.** Downs and Black quality checklist

First author and year	Reporting (10)	External validity (3)	Internal validity bias (7)	Internal validity – selection bias (6)	Subtotal score (26)	Sufficiently powered?
Anthony 2011	10	3	7	5	25	Yes
Berenguer 2010	8	3	5	3	19	No
Bull 2011	7	3	4	2	16	No
Cima 2013	10	3	5	1	19	No
Crolla 2012	9	3	5	2	19	No
Hawn 2011	10	3	5	4	22	Not known
Hedrick 2007	10	3	5	3	21	No
Keenan 2014	9	3	5	5	22	Yes
Larochelle 2011	6	3	4	4	17	Not known
Liau 2010	9	3	5	2	19	Yes
Lutfiyya 2012	9	3	5	3	20	Yes
Pastor 2010	10	3	6	4	23	No
Tillman 2013	8	3	6	4	21	No
Waits 2014	9	3	6	5	23	No
Wick 2008	10	3	6	4	23	Not known
Wick 2012	10	3	4	2	19	No

Values in parentheses indicate total scores available.

**Fig 2.** Forest plot. Surgical care bundles to reduce the risk of surgical site infections.

bundles on SSI rates among any surgical patient groups. Our study represents the first systematic review of selective surgical care bundles used to reduce SSIs in patients undergoing colorectal surgery. The current collective meta-analysis comprises >8,500 patients, documenting that use of a surgical care bundle, comprising selective evidence-based interventions, results in a significant reduction in the rate of SSI in the colorectal patient population. One randomized, highly ranked, well-designed study evaluating the use of surgical care bundles found that selected care bundle elements were not effective in decreasing the risk of SSI.<sup>19</sup> A possible reason for the contrary results of this randomized trial may have been associated with the specific interventions chosen for this particular

care bundle; these interventions included the elimination of mechanical bowel preparation, removal of oral antibiotic preparation, restriction of intraoperative fluid administration, and use of wound protectors, which have limited, or conflicting, supportive documentation.<sup>31,32</sup>

The majority of the reviewed studies included a group of “core,” evidence-based interventions, comprising appropriate antibiotic management, appropriate hair removal, maintenance of normothermia, and glycemic control. The justification for inclusion of these 4 core measures, especially in US-based publications, is associated with the Centers for Medicare and Medicaid Services mandating the use of these 4 measures for all patients undergoing colorectal surgery.<sup>33</sup> These 4

interventions were also a core requirement for the statewide, surgical care bundle implemented by the Michigan Surgical Quality Collaborative.<sup>34</sup> The evidence to support these selective interventions is relatively strong, based on randomized trials and systematic reviews; however, level 1 evidence is lacking for several of the “non-core” interventions included in many of the care bundles analyzed in this review.

Assessing the reported compliance rate associated within each bundle intervention was problematic throughout this review. Compliance was particularly important as many bundle interventions were implemented already before the introduction of the full surgical care bundle. It was necessary, therefore, to know baseline and post-implementation compliance rates to determine whether uptake of the selective bundle elements had increased. Although almost all of the studies reported compliance data, 4 studies did not provide a compliance rate for both baseline and cohort groups.<sup>1,12,24,25</sup> Seven studies did report the percentage of patients who received the entire surgical care bundle<sup>10,12,19,20,22,26,28</sup>; compliance with the complete bundle was variable with reported rates ranging from 2.1 to 92%.<sup>10,28</sup> This observation suggests that, while there is recognition of the benefit of a surgical care bundle as an effective strategy to improving patient outcomes, full implementation is limited. Furthermore, in the case of the study by Waits et al,<sup>28</sup> there was a direct correlation between implementation (full versus partial) of a surgical care bundle and colorectal SSI rate.

Implementing an effective SSI surgical care bundle requires a fiscal and logistical commitment on the part of the health care institution to cover staff time, effort, and consumables. At present, there are insufficient data to conduct economic modelling to determine the cost-effectiveness of a surgical care bundle for reducing the risk of SSI among colorectal patients. Four of the studies included in this review do, however, discuss the probable cost benefits or expenses associated with executing a surgical care bundle.<sup>1,10,22,24</sup> One Dutch study identified an annual implementation cost of approximately \$50,000, although these funds were used for dedicated staff members who were involved in the project.<sup>22</sup> This bundle was deemed by the authors to be cost effective because there was an estimated annual savings of \$234,261 through a reduction in duration of hospitalization. In another study, Keenan et al<sup>1</sup> found that the reduction in superficial SSIs as a result of bundle implementation was associated with a 36% increase in variable direct costs, from \$9,779 to

\$13,253. Variable direct costs were defined as the costs incurred during hospitalization, including operating room time, equipment, drugs, and nursing and laboratory services, but excluding physician's time. Keenan et al<sup>1</sup> suggest that the increase in variable direct costs may have been influenced by inflationary health care costs or charges associated directly with post-operative care management unrelated to the care bundle process. Berenguer et al<sup>10</sup> calculated the average, in-patient cost of a superficial SSI at \$8,900 and assumed that the implementation of the bundle would result in a cost savings. Liao et al<sup>24</sup> estimated that the average cost of treating each SSI in Thailand was \$1,532 and reported an overall saving of \$147,967 during the 2-year study. Alfonso et al<sup>35</sup> suggested that the average cost of an SSI, including direct, indirect, and societal costs, has been underestimated grossly and more accurately approaches \$100,000, of which the health care cost is approximately 10%. In the effort to calculate the cost of an SSI, few authors factor into the equation the societal cost or the economic impact that an SSI may have on quality of life or economic productivity after infection. While it is difficult to arrive at a consensus of the economic benefit of embracing a strategy of surgical care bundles, enhanced compliance, especially of the core processes, will likely be cost effective for the majority of patients undergoing colorectal surgery.

The present study has 2 limitations. The first is a failure of some of the studies to report a bundle compliance rate, and the second, a failure in the consistency of SSI data collection, with studies reporting a range of methods used within active and passive programs of surveillance. These 2 limitations could have led to an underestimation of the overall clinical benefit of embracing a strategy of surgical care bundles. That said, a thoughtful and thorough review of the current peer literature suggests that implementation of an approach using surgical care bundles has a significant impact on reducing the risk of SSI in elective colorectal surgery.

A final comment worthy of consideration is: what comprised the optimal surgical care bundle for decreasing the risk of colorectal SSIs? Selective core elements such as normothermia, glycemic control, timely and appropriate antimicrobial prophylaxis, and appropriate hair removal should be viewed as representing baseline consideration. These selective elements by themselves, however, are not sufficient to provide the comprehensive risk reduction benefit required to reduce the overall risk of infection.<sup>12,26,36</sup> Additional

evidence-based interventions warrant further consideration, including supplemental oxygen, chlorhexidine gluconate pre-admission showers or cleansing, wound protectors, a separate surgical tray for fascia and skin closure, antimicrobial sutures for fascial and skin closure, and mechanical bowel preparation plus oral antibiotics. Regardless of the interventions, it is the consistent implementation of all measures within the bundle which ensures the success of the bundle. This review highlights the variation in compliance among the included studies and identifies the systematic implementation of the bundle approach as an area which warrants further study.

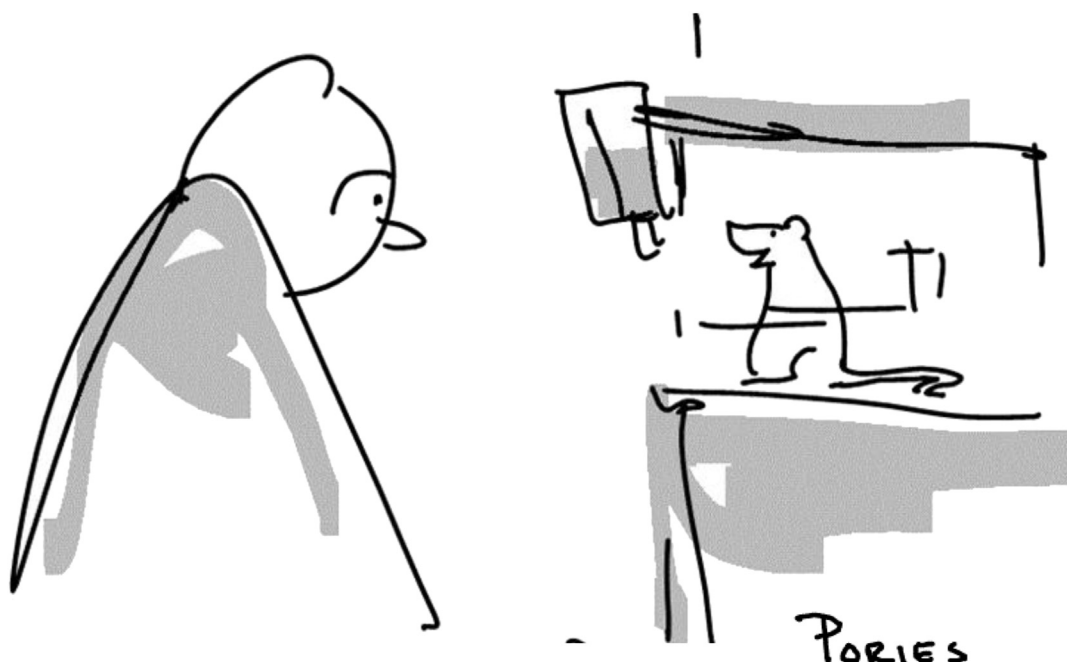
At present, there is no consensus as to what comprises the optimal colorectal surgical care bundle. However, this systematic review suggests that a multidisciplinary approach, utilizing selective, evidence-based core strategies along with adjunctive interventions that enhance wound defense mechanisms while limiting exogenous, intra-operative contamination will result in a reduced risk of infection in the colorectal patient population.

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## REFERENCES

1. Keenan JE, Speicher PJ, Thacker JK, et al. The Preventative Surgical Site Infection Bundle in Colorectal Surgery: an effective approach to surgical site infection reduction and health care cost savings. *JAMA Surg* 2014;149:1045-52.
2. Petrosillo N, Drapeau CMJ, Nicastrì E, et al. Surgical site infections in Italian hospitals: a prospective multicenter study. *BMC Infect Dis* 2008;8:34.
3. Darouiche RO, Wall M, Itani KMK, et al. Chlorhexidine-alcohol versus povidone-iodine for surgical-site antisepsis. *N Engl J Med* 2010;362:18-26.
4. Tanner J, Khan D, Ball J, et al. Post discharge surveillance to identify colorectal surgical site infection rates and costs. *J Hosp Infect* 2009;72:242-50.
5. Joint Commission Center for Transforming Healthcare and American College of Surgeons Collaborative. Reducing Colorectal Infection Rates. Colorectal Surgical Site Infections Project[updated 2013 May 1; cited 2014 Nov 26]. Available from: [www.centerfortransforminghealthcare.org/assets/4/6/SSL\\_storyboard.pdf](http://www.centerfortransforminghealthcare.org/assets/4/6/SSL_storyboard.pdf).
6. Tanner J, Padley W, Davey S, et al. Patients' narratives of surgical site infection; implications for practice. *J Hosp Infect* 2013;83:41-5.
7. Institute for Healthcare Improvement (IHI). What is a bundle?[Updated 2014; cited 2014 Jan 3]. Available from: [www.ihi.org/resources/Pages/ImprovementStories/WhatIsaBundle.aspx](http://www.ihi.org/resources/Pages/ImprovementStories/WhatIsaBundle.aspx).
8. Provonost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter related bloodstream infections in the ICU. *N Engl J Med* 2006;355:2725-32.
9. Resar R, Pronovost P, Haraden C, et al. Using a bundle approach to improve ventilator care processes and reduce ventilator-associated pneumonia. *Jt Comm J Qual Patient Saf* 2005;31:243-8.
10. Berenguer CM, Ochsner MG, Lord SA, et al. Improving surgical site infections: Using national surgical quality improvement program data to institute surgical care improvement project protocols in improving surgical outcomes. *J Am Coll Surg* 2010;210:737.
11. Hedrick TL, Heckman JA, Smith RL, et al. Efficacy of protocol implementation on incidence of wound infection in colorectal operations. *J Am Coll Surg* 2007;205:432-8.
12. Hawn MT, Vick CC, Richman J, et al. Surgical site infection prevention: time to move beyond the surgical care improvement program. *Ann Surg* 2011;254:494-9.
13. Stulberg JJ, Delaney CP, Neuhauser DV, et al. Adherence to surgical care improvement project measures and the association with postoperative measures. *JAMA* 2010;303:2479-85.
14. Moher D, Liberati A, Tetzlaff J, et al. The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *BMJ* 2009;339:b2535.
15. Higgins JPT, Green S, editors. *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated 2011 Mar]: The Cochrane Collaboration; 2011 Available from: [www.cochrane-handbook.org](http://www.cochrane-handbook.org).
16. Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. *J Epidemiol Community Health* 1998;52:377-84.
17. National Collaborating Centre for Methods and Tools Quality Checklist for Health Care Intervention Studies. Hamilton, ON: McMaster University; 2008. [updated 2010 Jun 10; cited 2014 Jan 3]. Available from: [www.nccmt.ca/registry/view/eng/9.html](http://www.nccmt.ca/registry/view/eng/9.html).
18. Clinical Trials Register[cited 2014 Jul 04]. Available from: <http://clinicaltrials.gov/show/NCT01597804>.
19. Anthony T, Murray BW, Sum-Ping J, et al. Evaluating an evidence-based bundle for preventing surgical site infection: a randomized trial. *Arch Surg* 2011;246:263-9.
20. Bull A, Wilson J, Worth LJ, et al. A bundle of care to reduce colorectal surgical infections: An Australian experience. *J Hosp Infect* 2011;78:297-301.
21. Cima R, Dankbar E, Lovely J, et al. Colorectal surgery surgical site infection reduction programme: a national surgical quality improvement program-driven multidisciplinary single-institution experience. *J Am Coll Surg* 2013;216:23-33.
22. Crolla RMPH, van der Laan L, Veen EJ, et al. Reduction of surgical site infections after implementation of a bundle of care. *Plos One* 2012;7:e44599.
23. Larochelle M, Hyman N, Gruppi L, et al. Diminishing surgical site infection after colorectal surgery with surgical care improvement project: is it time to move on? *Dis Colon Rectum* 2011;54:394-400.
24. Liao K, Aung K, Chua N, et al. Outcome of a strategy to reduce surgical site infection in a tertiary-care hospital. *Surg Infect* 2010;11:151-9.
25. Lutfiyya W, Parsons D, Breen J. A colorectal "care bundle" to reduce surgical site infections in colorectal surgeries: a single-center experience. *The Permanente Journal* 2012;16:10-6.

26. Pastor C, Artinyan A, Varma MG, et al. An increase in compliance with the surgical care improvement project measures does not prevent surgical site infection in colorectal surgery. *Dis Colon Rectum* 2010;53:24-30.
27. Tillman M, Wehbe-Janek H, Hodges B, et al. Surgical care improvement project and surgical site infections: can integration in the surgical safety checklist improve quality performance and clinical outcomes? *J Surg Res* 2013;184:150-6.
28. Waits SA, Fritze D, Banerjee M, et al. Developing and argument for bundled interventions to reduce surgical site infections in colorectal surgery. *Surgery* 2014;155:602-6.
29. Wick EC, Gibbs L, Indorf LA, et al. Implementation of quality measures to reduce surgical site infection in colorectal patients. *Dis Colon Rectum* 2008;51:1004-9.
30. Wick EC, Hobson DB, Bennett JL, et al. Implementation of a surgical comprehensive unit-based safety program to reduce surgical site infections. *J Am Coll Surg* 2012;215:193-200.
31. Guenaga KF, Matos D, Wille-Jorgensen P. Mechanical bowel preparation for elective colorectal surgery. *Cochrane Database Syst Rev* 2011;9:CD001544.
32. Morris MS, Graham LA, Chu DI, et al. Oral antibiotic bowel preparation significantly reduces surgical site infection rates and readmission rates in elective colorectal surgery. *Ann Surg* 2015 Jan 20 [Epub ahead of print].
33. Fry DE. Surgical site infections and the surgical care improvement project (SCIP): evolution of national quality measures. *Surg Infect (Larchmt)* 2008;9:579-84.
34. Henke PK, Kubus J, Englesbe MJ, et al. A statewide consortium of surgical care: a longitudinal investigation of vascular operative procedures at 16 hospitals. *Surgery* 2010;148:883-9.
35. Alfonso JL, Pereperez SB, Canoves JM, et al. Are we really seeing the total costs of surgical site infections? *Wound Repair Regen* 2007;15:474-81.
36. Edmiston CE, Spencer M, Lewis BD, et al. Reducing the risk of surgical site infections: did we really think that SCIP would lead us to the promise land? *Surg Infect* 2011;12:169-77.



*"Seems to me that I should be the first author..."*