# Implementation of Evidence-Based Practices for Surgical Site Infection Prophylaxis: Results of a Pre- and Postintervention Study

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BACKGROUND:	Although evidence-based guidelines for best practices pertaining to surgical site infection (SSI)
	prophylaxis exist, the feasibility of implementing such practices remains to be demonstrated outside of a controlled clinical trial. This study was designed to assess the safety and feasibility
	of implementing evidence-based care practices to prevent SSIs.
STUDY DESIGN:	A prospective, double-cohort (pre- and postintervention) trial in elective, general surgery patients was conducted. All patients undergoing elective, major colorectal or hepatobiliary operations were
	enrolled. Postintervention cohort patients were exposed to new strategies to improve antibiotic administration times, perioperative normothermia rates, and perioperative glucose control. They
	were compared with the preintervention cohort, which received standard practice at the time. Outcomes evaluated include timing of antibiotic administration, perioperative temperatures,
RESULTS:	and postoperative glucose levels. SSI rates between cohorts were also compared. A total of 208 patients were enrolled. The proportion of patients receiving their preoperative antibiotics within 60 minutes improved from 5.9% to 92.6% ( $p < 0.001$ ); perioperative normothermia rates improved from 60.5% to 97.6% ( $p < 0.001$ ) between cohorts. There was no improvement in rates of hyperglycemia. SSI rates improved but did not reach statistical
CONCLUSIONS:	significance (14.3% versus 8.7%; $p = 0.21$ ). Implementation of evidence-based care practices to prevent SSI is both safe and practical outside the setting of a randomized, controlled trial. Sustained compliance remains to be demonstrated, although practice audits at our institution suggest ongoing success is possible. (J Am Coll Surg 2008;207:336–341. © 2008 by the American College of Surgeons)

Despite many changes in the field of surgery during the past 20 years, very little has changed with respect to the occurrence of surgical site infections (SSIs) after major abdominal operations. SSIs continue to occur in up to 22% of patients, depending on patient and operative factors.<sup>1,2</sup> Overall, SSIs account for 38% of all nosocomial infections in surgical patients.<sup>3</sup> These infections are a substantial

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burden in terms of cost and surgical morbidity and mortality.<sup>4-7</sup>

Appropriate antibiotic timing, perioperative normothermia, and perioperative euglycemia have all been associated with a substantial reduction in SSIs.<sup>4,8-11</sup> Consequently, The Institute for Healthcare Improvement's "100K Lives Campaign" and the "Safer Healthcare Now!" initiatives in Canada have identified them as part of their recommended bundle for reducing SSIs.12,13 Although evidence-based guidelines exist to support these practices, there remains a substantial gap in the translation of evidence into practice.<sup>14</sup> A multicenter audit of hospitals in the Netherlands highlights this phenomenon, where only 28% of patients examined were found to have all aspects of their perioperative antibiotic use meet institutional guidelines.<sup>15</sup> A Canadian institution demonstrated that only 5% of patients met guidelines with respect to antibiotic prophylaxis.<sup>16</sup> At our own center and elsewhere, barriers to successful implementation of evidence-based practice strategies have included lack of awareness of the problem, lim-

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#### Abbreviations and Acronyms

OR	=	operating room
PACU	=	postanesthesia care unit
RR	=	relative risk
SSI	=	surgical site infection

ited funding, and clinician resistance to a change in practice or disagreement with established guidelines. The paucity of strategies to facilitate translation of evidence into practice continues to hinder change. The Surgical Site Infection Working Group at McMaster University performed a prospective, pre- and postintervention cohort study to assess the feasibility, safety, and effectiveness of introducing a bundle of interventions designed to improve the timing of perioperative antibiotic administration, rate of perioperative normothermia, and perioperative glucose control. Presented is a novel strategy demonstrating multidisciplinary involvement in the planning, implementation, and evaluation aspects of developing new care pathways. These particular interventions, ie, proper antibiotic timing and selection, perioperative normothermia, and perioperative euglycemia, were chosen because of the strong evidence to support these practices and the perceived lack of adherence to their use.

# METHODS

# Study design and data collection

This study was conducted in three stages. The first stage (preintervention; patient cohort I) was designed to collect data on the performance of our current perioperative practices for antibiotic prophylaxis, normothermia, and glucose control. The second stage used three working groups made up of relevant stakeholders (surgeons, anesthesiologists, nurses, and pharmacists from the involved patient-care areas) to evaluate data from cohort I and, using expert guidance and evidence from the literature, develop new practice algorithms. The multidisciplinary nature of the working groups facilitated the evolution of practical care pathways by incorporating the clinical experience and expertise of all caregivers. The final stage of this study (postintervention; patient cohort II) implemented the new protocols designed by the working groups and collected performance data for comparison. The research ethics board of McMaster University approved the study, and all patients provided written informed consent before participating.

Data were collected prospectively pre- (cohort I) and post- (cohort II) intervention on 100 consecutive adult patients undergoing elective, "clean-contaminated," major hepatobiliary or colorectal surgery at McMaster University Medical Centre, a 365-bed tertiary care center in Hamilton, Ontario, with a catchment area of > 1.3 million people, performing > 850 elective general surgery procedures a year. Patients were enrolled during 2 time periods: cohort I: October 2004 to April 2005; cohort II: April 2006 to February 2007. Patients were excluded if they were not admitted postoperatively or presented with clinical signs of infection of any kind. Previously published criteria from the CDC were used to diagnose a wound infection.<sup>3</sup> Patients were enrolled preoperatively by a research nurse and followed until their first outpatient visit 4 weeks after discharge, where they were assessed by the treating surgeon for the presence of an SSI. Data collected included patient characteristics, variables pertaining to preoperative antibiotic administration, temperature control, glucose control, and presence of an SSI.

## Interventions

Three working groups, meeting during a period of 1 year, April 2005 to April 2006, designed new practice protocols for each of the interventions. They reviewed the baseline data from cohort I and through a collaborative, multidisciplinary approach developed new processes for implementation. Recommendations from the antibiotic working group included changing the location of antibiotic administration from the admissions unit to the operating room (OR) suite and preprinted, preoperative order forms designed to standardize the antibiotics selected. The standardized antibiotic regimen included cephazolin and metronidazole (cephazolin alone for hepatobiliary patients) limited to 24 hours of postoperative use based on the CDC and National Surgical Infection Prevention Project Guidelines.<sup>17</sup> Gentamicin was the proposed alternative for patients with a documented penicillin allergy. A new system for maintenance of perioperative normothermia included warming the OR suite to 22°C during induction and emergence of anesthesia, standardizing the use of IV-fluid warmers and 2 forced-air devices per patient, 1 each over the chest and legs when supine, and 1 forced-air device over the chest for patients in lithotomy, with clear plastic bags wrapped around their legs to prevent evaporative heat loss. Finally, a new program for perioperative glucose control was also introduced. All patients were screened with a random venous blood glucose at their preoperative assessment. Patients identified as diabetic were entered into the glycemic control program. The practice of using the "sliding scale" for postoperative glucose control was replaced with a new weight-based regimen administering NPH insulin at 0.1 U/kg 3 times per day with adjustments every 24 hours to keep glucose levels within Canadian Diabetes Association guidelines of 5.0 to 11.0 mmol/L.18 Patients were restarted on

their home regimen once resuming a regular diet. Before implementing the previously mentioned interventions, each working group conducted independent tests of change. Members of the departments of surgery, anesthesia, and perioperative nursing services took part in tests on both mock and real patients to ensure the feasibility of the practices to be implemented and provide feedback before going live in cohort II.

The new care plan was introduced to the clinical staff through academic rounds for attending and house staff and a series of in-services for nurses where input could be sought and concerns could be addressed. An OR nurse and a nurse from our same-day surgery unit involved with protocol development acted as the study champions, resources for nurses and clinicians to inquire about protocol implementation, and provided direction and confirmed compliance. Standardized order sheets for antibiotic prophylaxis and glucose control were developed to aid the transition into the new care plan. Monthly performance figures for the entire population were posted in the OR during cohort II to provide feedback to the staff, although individual surgeon and anesthesiologist performance data were not reported.

## Statistical analysis and sample size

A comparison of outcomes between cohorts I and II was performed. The primary objective of this study was to evaluate the effect of this multifaceted approach on changing the process of care pertaining to SSI prophylaxis. The performance of the strategies was measured by the improvement in perioperative normothermia rates, improvement in the timing of perioperative antibiotic administration, and maintenance of perioperative euglycemia. SSI rates between the two cohorts were also compared. Continuous variables were analyzed using the Student's *t*-test or Wilcoxon rank-sum test for nonnormally distributed values; categorical variables were analyzed using the chi-square test.

Sample size estimates were based on estimated change in the rates of hypothermia, as this analysis was the most limited in power and required the greatest sample size. Our objective was to reduce the rate of hypothermia from 30% to 10%, a 20% reduction in the absolute rate. With an  $\alpha$  of 0.05 and 80% power, a sample size of 93 patients per arm would allow us to detect a reduction of this magnitude.<sup>19,20</sup> Estimating a 15% dropout rate, 110 patients were to be enrolled in each cohort. This sample size would allow detection of a 20% improvement in timing of antibiotic administration ( $\alpha = 0.05$  and power = 0.80), estimating an inappropriate perioperative antibiotic administration rate of 34%.<sup>21</sup> With approximately 10% to 15% of the population having diabetes (allowing for at best 15 diabetics 
 Table 1. Comparison of Baseline Patient Characteristics
 Between Cohorts

Characteristic	Cohort I (n = 105)	Cohort II (n = 103)	p Value
Gender, male, n (%)	57 (54.3)	55 (53.4)	0.90
Age (y), mean $\pm$ SD	$58.5 \pm 15.5$	$60.8 \pm 15.7$	0.29
Body mass index,			
mean $\pm$ SD*	$27.6 \pm 8.2$	$26.1 \pm 4.0$	0.11
Type of procedure, n (%)			0.50
CRS	69 (65.7)	63 (61.2)	
HPB	36 (34.3)	40 (38.8)	
NNIS scores, n (%)			0.11
0	36 (34.3)	22 (21.4)	
1	41 (39.0)	46 (44.7)	
2	28 (26.7)	35 (34.0)	
3	0	0	
Median operative time			
(min)	157	169	0.71

\*Data available on 85 cohort I patients and 86 cohort II patients.

CRS, colorectal procedure; HPB, hepatobiliary procedure; NNIS, National Nosocomial Infection Surveillance Score.<sup>1</sup>

being enrolled in each arm of the study), this sample size would allow for the detection of a 45% reduction in the rate of perioperative hyperglycemia ( $\alpha = 0.05$  and power = 0.80).<sup>22,23</sup> Statistical analysis was performed using SAS 9.1 (SAS Institute); significance was set at p < 0.05.

# RESULTS

### **Patient demographics**

A comparison of baseline patient characteristics across cohorts is demonstrated in Table 1. The majority of patients underwent a colorectal procedure and were at low SSI risk. Patients were comparable in age and gender with no substantial differences in distribution of procedures and SSI risk between the two cohorts.

## Antibiotics

In cohort I, preoperative antibiotics were administered in the same-day surgery admissions unit of our hospital, before the patient was called to the operating room. Eight patients (7.6%) failed to receive any antibiotics and 13 (13.4%) did not have the time of drug administration recorded. Median time interval between antibiotic administration and skin incision was 116 minutes (range 30 to 415 minutes). Distribution of antibiotic administration to incision time intervals is presented in Table 2. In cohort II, 3 patients failed to receive any preoperative antibiotics (2.9%; p = 0.13). Four patients (3.8%; p = 0.02) did not have the time of drug administration recorded. There were 7 protocol violations in cohort II, where patients did not receive an antibiotic regimen recommended by the work-

Table 2.	Distribution of Antibiotic Administration	Time
Intervals	Within Cohorts	

	Antibiotic 1				Antibiotic 2			
Time	Cohort I		Cohort II		Cohort I		Cohort II	
interval (min)	n	%	n	%	n	%	n	%
≤ 60	5	5.9	88	92.6*	7	12.1	60	93.8*
61–120	41	48.2	3	3.2	29	50.0	1	1.5
121-180	31	36.5	2	2.1	17	29.3		_
> 180	8	9.4		_	5	8.6		_
Late		_	2	2.1	_	_	3	4.7

\*p < 0.001; comparing proportion of patients who received antibiotics within 60 minutes of skin incision to those who did not.

ing group, compared with 16 in cohort I. There was no statistically significant difference in drug selection between cohorts (p = 0.052). Median time interval between antibiotic administration and skin incision in cohort II was 30 minutes (range – 15 to 160 minutes; p < 0.001 compared with cohort I). The proportion of patients receiving their preoperative antibiotics within 60 minutes of their skin incision is significantly different between cohorts (p < 0.001; first antibiotic relative risk [RR]: 15.7; 95% CI, 6.7 to 36.9).

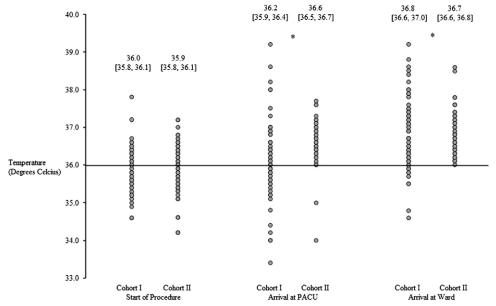
#### Temperature

In cohort I, 80 patients had temperatures recorded at the start of their operations. Mean temperature for the group was  $36.0^{\circ}$ C  $\pm 0.55^{\circ}$ C. Seventy-six patients in the cohort

had a mean temperature in the postanesthetic care unit (PACU) of  $36.2^{\circ}C \pm 0.97^{\circ}C$ , and the mean temperature on the ward was  $36.8^{\circ}C \pm 0.83^{\circ}C$  for 91 patients. In cohort II, the mean temperature for 95 patients at the start of the procedure was  $35.9^{\circ}C \pm 0.58^{\circ}C$ . On the patients' arrival to the PACU, mean temperature for 83 patients was  $36.6^{\circ}C \pm 0.50^{\circ}C$ , and mean temperature of 86 patients on patient arrival to the ward was  $36.7^{\circ}C \pm 0.53^{\circ}C$ . The proportion of patients with temperatures > 36.0°C in each cohort is summarized in Figure 1. There was no significant difference in normothermia rates between cohorts I and II at the start of operation (53.8% versus 54.7%; p = 0.90; RR: 1.01; 95% CI, 0.77 to 1.34), but normothermia rates were significantly improved both at the end of operations in the PACU (60.5% versus 97.6%; p < 0.001; RR: 1.61; 95% CI, 1.34 to 1.94) and on arrival to the ward (90.1% versus 100%; p = 0.003).

#### Glucose control

A total of 10 patients had diabetes in cohort I. Glucose levels fell below a safe level of 4.0 mmol/L in 4.8% of 462 readings between the 10 patients; levels exceeded 11.0 mmol/L 17.7% of the time. In cohort II, there were nine patients with diabetes. Glucose levels fell below 4.0 mmol/L only 0.4% of the time (p < 0.003), although levels exceeded 11.0 mmol/L 14.2% of the time in the 226 readings between the 9 patients (p = 0.23).



**Figure 1.** Distribution of patient temperatures and proportion of patients achieving normothermia (temperature  $> 36^{\circ}$ C) at various perioperative time points. Cohort means (95% CI) are reported above the plots. \*Proportion of patients achieving normothermia significantly different between cohorts (p < 0.05).

SSI rate for the population was 11.5%. The SSI rate in cohort I, according to CDC criteria, was 14.3% for superficial SSIs and 7.6% for organ space infections.<sup>3</sup> In cohort II the superficial SSI rate was 8.7% (p = 0.21; RR: 0.61; 95% CI, 0.28 to 1.33) and the organ space infection rate was 6.8% (p = 0.81; RR: 0.89; 95% CI, 0.34 to 2.37).

#### DISCUSSION

This initiative has led to substantial improvements in perioperative care at our institution. Timing of antibiotic administration has improved substantially, from only 5% of patients receiving their first drug within 60 minutes, to nearly 95% of patients. The 60-minute target interval is widely accepted as a standard for SSI prophylaxis.<sup>17</sup> Studies have shown that a delay of more than 2 hours to skin incision is associated with a 6.7-fold increase in wound infection rates.8 A Dutch multicenter audit demonstrated similar deficiencies in antibiotic prophylaxis, with only 28% of patients receiving prophylaxis that met established guidelines.<sup>15</sup> Efforts to encourage use of appropriate preoperative antibiotics with preprinted order forms proved unsuccessful in this study, although only a small proportion of patients in either cohort received antibiotics that did not meet recommendations set by the working group (15.2% in cohort I versus 6.8% in cohort II).

Perioperative normothermia rates also improved between study arms. Efforts including both active rewarming and reduction of evaporative heat-loss strategies improved perioperative normothermia from 60.5% to 97.6% in the PACU. Perioperative hypothermia, defined as temperatures < 36.0°C, has a substantial impact on wound infection rates.<sup>24</sup> Several randomized controlled studies have demonstrated the impact of active warming efforts on wound infection. A study of active warming on patients undergoing "clean" operations demonstrated a relative risk reduction of wound infections of 57%.<sup>4</sup> In a randomized study on colorectal surgery patients, use of fluid warmers and forced-air devices was able to substantially reduce wound infection rate and shorten hospital stays.<sup>9</sup> Use of these devices at our center was typically at the discretion of the anesthesiologist; standardizing their use along with other adjunctive measures, such as elevating ambient room temperature, has virtually eliminated perioperative hypothermia.

Implementation of a new glucose-management strategy proved to be the most difficult. The goal was to replace a reactive tool, the sliding scale, with a proactive model. Although there are no studies on the impact of glucose control on wound infection rates in the general surgery population, a measurable effect has been demonstrated on the rate of sternal wound infections in cardiac surgery patients.<sup>11</sup> Similarly, tight glycemic control proved effective in reducing bacteremia in the critical care population.<sup>25</sup> Despite efforts to encourage use of the new insulin protocol, without an enforcement system, clinicians tended to default back to the sliding scale. On review of nine patients in cohort II, all failed to receive the recommended insulin NPH regimen. The lack of enough patients to establish the "critical mass" required to maintain this new regimen (9 patients during 11 months) likely explains its failure. The preoperative strategy of screening all patients with random glucose levels before operation remains in effect.

SSI rate in cohort II, although improved, was not statistically different from cohort I. As this was not one of the primary outcomes of interest, we did not power the study to detect a significant difference, as the merits of these process changes are already well accepted. Our primary objective was to demonstrate the feasibility and successful implementation of our bundle. Given the trend toward significance and the proved benefit of the chosen interventions in the literature, we believe our new care pathways to be successful regardless.

This was a pragmatic assessment of perioperative care at our institution, designed to serve as a pilot study for a larger, multicenter study in the future. As a feasibility study it proved effective in assessing the practical application of evidence-based care strategies outside the setting of a randomized trial. A practice audit 6 months after data collection for cohort II was complete demonstrated that we continue to keep our patients warm and administer their antibiotics within an acceptable time frame. Although the unblinded nature of this study makes it susceptible to bias, the intent was to operate a transparent system open to critique from all members of the patient-care staff to identify process issues that could impede successful delivery of care. The multidisciplinary nature of the working groups in this study fostered the environment necessary for such participation and, in our opinion, ensured success of implementing and sustaining the interventions.

Evidence-based care pathways for prevention of SSIs can be safely and feasibly implemented in day-to-day patient care, as demonstrated with this knowledge-translation strategy. Maintenance of these strategies during the longterm remains to be seen, but, to date, internal audits of performance remain satisfactory. The continuing support of clinical and institutional administrations is critical to the longterm objectives of such an initiative.

#### Author Contributions

Study conception and design: Forbes, Stephen, Harper, Loeb, McLean

Acquisition of data: Forbes, Smith, Christoffersen

Analysis and interpretation of data: Forbes, McLean

Drafting of manuscript: Forbes, McLean

Critical revision: Forbes, Stephen, Harper, Loeb, Smith, Christoffersen, McLean

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