



New barrier attire regulations in the operating room: A mandate without basis?



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ABSTRACT

Background: Recent AHRQ/Joint Commission guidelines mandate additional barrier attire for all operating room personnel to target infection. The scientific basis for this is unclear.

Study design: Patients undergoing abdominal surgery at our institution were identified from institutional NSQIP database before and after March 2016, when guidelines were implemented. Patient-level variables were compared for the pre- and post-implementation groups. Multivariable regression evaluated associations between implementation and surgical site infection (SSI) and other outcomes.

Results: 1122 patients (including 60.9% laparoscopic and 16.4% bowel resection procedures) were included. There were 607 patients post-implementation and 515 pre-implementation; cohorts were similar in risk factors for SSI. Fifty-seven patients developed SSI. On multivariable analysis, laparoscopy, bowel resection and operating duration, but not barrier attire, were associated with SSI. Implementation of attire did not significantly impact SSI ($p = 0.4$), hospital readmission ($p = 0.4$), or reoperation ($p = 0.9$).

Conclusions: These data question the rationale for the new more stringent operating room attire guidelines which burden hospitals with additional cost, time and resources, and could detract efforts to target important factors that really influence outcomes.

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Introduction

Despite advances in infection control measures, surgical site infections (SSI) remain a leading source of post-operative morbidity, mortality, and cost.^{1–4} A recent study of the Veterans Affairs Surgical Quality Improvement Program (VASQIP) found that 3.2% of all patients undergoing surgery suffered an SSI; the risk-adjusted cost difference per hospital admission was \$11,876 greater for patients who had an SSI.⁵

Commonly accepted perioperative measures to reduce the risk of SSI include the appropriate use of preoperative skin preparatory agents, antimicrobial prophylaxis, operating room ventilation, and

postoperative glucose control; such measures are broadly supported by scientific evidence, and are advocated by Centers for Disease Control and Prevention (CDC), Infectious Disease Society of America, and World Health Organization.^{6–8} Barrier measures, including operating room attire, such as surgical masks, scrub caps, and shoe covers, to reduce potential exposure of the surgical wound to pathogens carried by the operating team are also frequently employed. But although live microorganisms are shed into the environment from exposed skin, mucous membranes, and hair,^{9–12} the evidence illustrating the effectiveness of operating room attire in preventing SSI is limited.^{13–15}

In 2014, the Agency for Healthcare Research and Quality (AHRQ), a division of the United States Department of Health and Human Services, adopted new guidelines for surgical attire,^{16,17} recommending that non-scrubbed operating room staff wear long-sleeve “warm-up” jackets while in the operating room, and that “skull caps” be replaced with caps that completely cover head and facial hair (e.g., “bouffant” caps); the authors cited no evidence

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for this recommendation. These guidelines were subsequently adopted by the Joint Commission, the not-for-profit organization that accredits and certifies most hospitals and other healthcare organizations in the United States; thus, use of such attire is now effectively mandated at hospitals throughout the country. Whether the new attire is effective at reducing the risk of SSI remains unclear.

The present study retrospectively examines the effect of the new attire regulations on the incidence of SSI at our institution.

Methods

Patients aged ≥ 18 years undergoing elective abdominal surgery at Columbia University Medical Center between March 2015–March 2017 were identified from the institution-specific, non-risk adjusted NSQIP database; this sample includes all cases that were submitted by CUMC to NSQIP, prior to institutional de-identification. CUMC implemented the new operating room attire regulations on March 9, 2016, with immediate and complete compliance, as overseen by supervisory staff present in each operating room. Patients who underwent surgery on or after March 9, 2016 were thus designated as “post-implementation,” whereas those who underwent surgery prior to March 9, 2016 were designated “pre-implementation.” Patients were excluded if they underwent endovascular, ear-nose-throat, breast, or anorectal procedures, or inguinal herniorrhaphy; if the procedure was an emergency; if the patient had evidence of SSI, systemic inflammatory response syndrome (SIRS), or sepsis present at time of surgery; or if outcome variables were not available.

Patient-level characteristics, including demographics, comorbidity, operative variables, and post-operative outcomes were extracted from the institutional NSQIP database. The primary outcome was any SSI at 30 days post-operatively, defined as a composite of superficial, deep, and organ space infection, using standard Centers for Disease Control and Prevention definitions.¹⁸ Secondary 30-day outcomes included sub-categories of SSI, readmission, reoperation, and mortality.

Continuous variables are presented as mean (standard deviation), and were compared using Student's t-test, and categorical variables were evaluated with Pearson's Chi-squared test or Fisher's exact test, as appropriate. Two-tailed p-values < 0.05 were considered to be statistically significant. Multiple logistic regression models were constructed using simultaneous entry of variables to determine whether implementation of the attire guidelines was independently associated with risk of SSI or any secondary endpoint. Potential explanatory covariates adjusted for included age, gender, American Society of Anesthesiology physical status classification ≥ 3 (at least severe systemic illness), obesity (defined as body mass index (BMI) ≥ 30 kg/m²), diabetes mellitus, tobacco use, preoperative steroid use, preoperative serum albumin ≥ 3.5 g/dL laparoscopy, bowel resection, and operating time ≥ 3 h, using standard definitions. Statistical analyses were performed using SPSS[®] version 23.0 (IBM, Armonk, NY, USA) and SAS[®] version 9.4 (SAS Institute, Cary, NC, USA).

This study was approved by the CUMC Institutional Review Board with waiver of informed consent.

Results

A total of 3921 patients who underwent surgery during the study period were evaluated, of whom 1464 met inclusion criteria. A further 342 patients were excluded, leaving 1122 patients in the final study population (Fig. 1). Of these, 515 underwent surgery prior to implementation of the new operating room attire guidelines (“pre-implementation”), and 607 underwent surgery

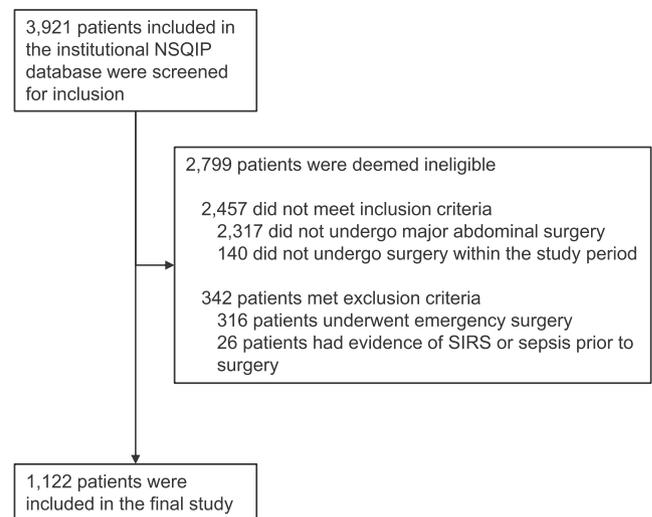


Fig. 1. Attrition diagram.

Legend: NSQIP, National Surgical Quality Improvement Program; SIRS, systemic inflammatory response syndrome.

afterward (“post-implementation”). Baseline demographics, comorbidity, and intra-operative variables were similar between pre- and post-implementation groups (Table 1). The mean age was 52.7 ± 16.7 years, and 62.1% of patients (n = 697) were female. Mean BMI was 32.9 ± 10.0 kg/m², and 52.9% (n = 593) were obese (BMI ≥ 30 kg/m²). The most common procedure by Current Procedural Terminology[®] (CPT) code was laparoscopic sleeve gastrectomy (CPT 43775, n = 242, 21.6%), followed by laparoscopic cholecystectomy (CPT 47562, n = 130, 11.6%), and pancreaticoduodenectomy (CPT 48150, n = 92, 8.2%) (Table 2). The distribution of procedures in the pre- and post-implementation groups was not significantly different (p = 0.6). One thousand fifty-six operations (94.1%) were performed under general endotracheal anesthesia, 684 operations (61.0%) were laparoscopic, and 184 (16.4%) involved either small or large bowel resection.

Fifty-seven out of 1122 patients (5.1%) developed SSI within 30 days of operation. Of these, 17 (29.8%) were classified as superficial (i.e., limited to the skin and subcutaneous tissue, superficial to the fascia), 7 (12.3%) were deep (i.e., involving the fascial or muscle layers of the incision), and 35 (61.4%) were organ/space (i.e., deeper than the fascial or muscle layers) infection. Patients who developed SSI were significantly more likely to require reoperation [25/57 (43.9%) vs. 39/1065 (3.7%), p < 0.001] and readmission [5/57 (8.8%) vs. 10/1065 (0.9%), p < 0.001]. The incidence of 30-day complications was similar between the pre- and post-implementation groups (Table 3).

Of 515 patients in the pre-implementation group, 22 (4.3%) developed SSI post-operatively, compared with 35 out of 607 patients in the post-implementation group (5.8%, unadjusted p = 0.3). After adjusting for potential confounders, pre-implementation status remained not significantly associated with risk of SSI [odds ratio (OR) 0.76, 95% confidence interval (CI), 0.42–1.38, p-value = 0.4]. Laparoscopy was associated with significantly reduced risk, whereas bowel resection, and operative duration ≥ 3 h with significantly increased risk of SSI in multi-variable analysis (Table 4). Pre-implementation status was not significantly associated with any secondary outcome, including superficial SSI (OR 1.17, 95% CI, 0.43–3.14, p = 0.8), deep SSI (OR 1.00, 95% CI, 0.21–4.66, p = 1.0), organ space SSI (OR 0.53, 95% CI, 0.24–1.16, p = 0.1), reoperation (OR 0.99, 95% CI, 0.35–2.77, p = 1.0), or readmission (OR 0.80, 95% CI, 0.47–1.36, p = 0.4) (Table 3).

Table 1
Demographic, comorbidity, and operative characteristics.

	Overall (n, %) n = 1122	Pre-implementation (n, %) n = 515	Post-implementation (n, %) n = 607	Univariable p-value*
Age (mean, std. dev.)	52.7 (16.7)	52.7 (16.2)	52.7 (17.1)	1.0
Female gender	697 (62.1)	325 (63.1)	372 (61.3)	0.5
BMI \geq 30 kg/m ²	593 (52.9)	274 (53.2)	319 (52.6)	0.8
ASA class \geq 3	452 (40.3)	214 (41.6)	238 (39.2)	0.4
Diabetes mellitus	231 (20.6)	109 (21.2)	122 (20.1)	0.7
Recent weight loss	31 (2.8)	15 (2.9)	16 (2.6)	0.8
Chronic steroid use	31 (2.8)	22 (4.3)	19 (3.1)	0.3
Tobacco use	123 (11)	59 (11.5)	64 (10.5)	0.6
Laparoscopy	684 (61)	316 (61.4)	368 (60.6)	0.8
Bowel resection	184 (16.4)	78 (15.1)	106 (17.5)	0.3
Operative duration \geq 3 h	236 (21)	100 (19.4)	136 (22.4)	0.2

Std. dev., standard deviation; BMI, body mass index; ASA, American Society of Anesthesiology physical status classification. *P-values generated from Student's t-test or Pearson Chi-squared test, as appropriate; $p < 0.05$ deemed statistically significant.

Discussion

SSI remains a persistent source of morbidity, mortality, and cost in the contemporary era. In the wake of the Affordable Care Act, hospitals have faced increasing financial and regulatory pressure to reduce SSI and similar adverse events. Currently, the Hospital-Acquired Conditions Reduction Program (HACRP) assesses the risk-adjusted performance of hospitals against benchmark quality measures, including SSI, catheter-associated urinary tract infection, and central line-associated blood stream infection; the worst-performing hospitals face possible reductions in their Medicare reimbursement rates.^{19,20} Many efforts by hospitals to limit such adverse events, including the use of enhanced aseptic technique in the operating room,^{21,22} and implementation of central line insertion bundles,²³ have proved effective at reducing patient harm.

However, the new operating room attire guidelines endorsed by AHRQ and the Joint Commission, by contrast, do not appear to be effective at reducing SSI. The present study finds that strict implementation of the attire guidelines resulted in no significant difference in the incidence of SSI, or any other postoperative complication, including superficial or deep SSI, at a tertiary medical center. These results are consistent with previously reported findings by Farach et al.,²⁴ in a general surgery population, as well as in the neurosurgical literature,²⁵ that additional or more restrictive barrier attire does not reduce the risk of SSI.

In keeping with these observational data, a recent Cochrane meta-analysis of three randomized controlled trials comparing the use of surgical face masks with the use of no mask during clean surgical procedures found that face masks had no significant effect on the incidence of SSI.¹³ Similarly, a study examining the utility of shoe covers found that they also failed to reduce SSI, or even floor bacterial counts.¹⁴ Indeed, no study published to date has found

that barrier attire worn by non-sterile operating room staff reduces the risk of SSI.

There are several plausible explanations for why barrier attire may fail to reduce SSI rates. Conceivably, the effect of barrier attire on the SSI rate may be too small to measure in a contemporary, general surgical population. Airborne bacteria are the predominant source of contamination in clean procedures,²⁶ and barrier attire is designed to catch desquamating skin cells and reduce bacterial shedding from operating room personnel. As a point of comparison, mobile laminar airflow units (MLAF) are capable of reducing airborne bacterial load by as much as 40-fold as compared with conventional ventilation.²⁶ However, a recent trial of patients undergoing procedures with high risk for SSI (e.g., hip arthroplasty), randomized to use of MLAF or not, found no difference in the risk of SSI between the groups despite significantly lower airborne bacterial burden in the MLAF group.²⁷ Numerous other investigations of MLAF, and also a recently published meta-analysis, have similarly demonstrated that the devices are effective at reducing airborne bacterial counts, but not SSI.^{28–31} It may be that, as with MLAF, barrier attire reduce bacterial shedding, while still failing to offer a meaningful advantage in infection control, given the relative efficacy of perioperative antibiotics, antibacterial skin prep agents, and other measures.

But barrier attire may not reduce airborne bacterial counts, after all. As Bartek et al., noted in their recent review, several studies have demonstrated that clothing appears to increase – not decrease – bacterial shedding and airborne bacterial counts; in fact, the authors write, naked surgeons shed fewer bacteria than those wearing street clothes or surgical scrubs.³² Meanwhile, SSI outbreaks have been traced definitively to the scalps of operating room staff despite appropriate use of the recommended barrier attire.¹⁵ Thus, barrier attire may not provide an effective “barrier” against skin desquamation and bacterial shedding, and may even worsen those phenomena.

Table 2
Most common procedures, by Current Procedural Terminology (CPT) code.

	CPT code	Overall (n, %) n = 1122	Pre-implementation (n, %) n = 515	Post-implementation (n, %) n = 607
Laparoscopic sleeve gastrectomy	43775	242 (21.6)	121 (23.5)	121 (19.9)
Laparoscopic cholecystectomy	47562	130 (11.6)	57 (11.1)	73 (12)
Pancreatico-duodenectomy	48150	92 (8.2)	36 (7)	56 (9.2)
Complex ventral hernia repair	49560	64 (5.7)	25 (4.9)	39 (6.4)
Distal pancreatectomy	48140	61 (5.4)	26 (5)	35 (5.8)
Laparoscopic appendectomy	44970	52 (4.6)	20 (3.9)	32 (5.3)
Umbilical hernia repair	49585	50 (4.5)	25 (4.9)	25 (4.1)
Laparoscopic Roux-en-Y gastric bypass	43644	38 (3.4)	19 (3.7)	19 (3.1)
Laparoscopic adrenalectomy	60650	31 (2.8)	14 (2.7)	17 (2.8)
Laparoscopic incisional hernia repair	49654	30 (2.7)	15 (2.9)	15 (2.5)

CPT, Current Procedural Terminology.

Table 3
Post-operative complications in pre- and post-implementation groups.

	Overall (n, %) n = 1122	Pre-implementation (n, %) n = 515	Post-implementation (n, %) n = 607	Univariable p-value	Adjusted OR (95% CI)	Adjusted p-value
Surgical site infection	57 (5.1)	22 (4.3)	35 (5.8)	0.3	0.76 (0.42–1.38)	0.4
Superficial	17 (1.5)	8 (1.6)	9 (1.5)	0.9	1.17 (0.43–3.14)	0.8
Deep	7 (0.6)	3 (0.6)	4 (0.7)	0.9	1.00 (0.21–4.66)	1.0
Organ/space	35 (3.1)	11 (2.1)	24 (4)	0.08	0.53 (0.24–1.16)	0.1
Readmission	64 (5.7)	26 (5)	38 (6.3)	0.4	0.99 (0.35–2.77)	1.0
Reoperation	15 (1.3)	7 (1.4)	8 (1.3)	1.0	0.80 (0.47–1.36)	0.4

OR, odds ratio; CI, confidence interval. *Univariable p-values generated from Pearson Chi-square test. **Results of multivariable logistic regression, performed with simultaneous entry of variables, and †associated adjusted p-values. P-values < 0.05 deemed statistically significant.

Table 4
Effect of new barrier attire on risk of surgical site infection: results of multivariable logistic regression.

Variable	Parameter estimate (95% CI)	p-value*	OR (95% CI)
Intercept	−4.06 (−5.65, −2.47)	<.0001	0.02 (0.004–0.08)
Pre-implementation	−0.27 (−0.86, 0.32)	0.4	0.76 (0.42–1.38)
Age	0.005 (−0.02, 0.03)	0.7	1.00 (0.98–1.03)
Female gender	−0.04 (−0.63, 0.55)	0.9	0.96 (0.53–1.73)
BMI ≥ 30 kg/m ²	0.29 (−0.35, 0.93)	0.4	1.34 (0.71–2.54)
ASA class ≥ 3	0.30 (−0.37, 0.97)	0.4	1.35 (0.69–2.63)
Diabetes mellitus	−0.13 (−0.84, 0.58)	0.7	0.88 (0.43–1.79)
Chronic steroid use	−0.92 (−3.01, 1.16)	0.4	0.40 (0.05–3.19)
Tobacco use	−0.11 (−0.99, 0.78)	0.8	0.90 (0.37–2.18)
Serum albumin ≥ 3.5 g/dL	0.34 (−0.34, 1.02)	0.3	1.41 (0.71–2.78)
Laparoscopy	−1.14 (−2.04, −0.24)	0.01	0.32 (0.13–0.79)
Bowel resection	0.79 (0.12, 1.46)	0.02	2.20 (1.13–4.3)
Operative duration ≥ 3 h	1.60 (0.80, 2.40)	<.0001	4.96 (1.00–11.01)

SSI, surgical site infection; CI, confidence interval; OR, odds ratio; BMI, body mass index; ASA, American Society of Anesthesiology physical status classification. *P-values and †odds ratios generated from multivariable logistic regression with simultaneous entry of variables; p-values < 0.05 were considered statistically significant, and are presented in bold.

The strengths of this study include the large patient population, the inclusion of only abdominal procedures at high risk of SSI, the use of standardized NSQIP variables collated by staff unaffiliated with the study team, and the crossover-style design, which permits the hospital's pre-implementation performance to serve as its own control. Moreover, unlike the Farach study, in which the studied groups were significantly different in their average age, body mass index, frequency of tobacco use, and numerous medical comorbidities,²⁴ in the present study the pre- and post-implementation groups were similar in all baseline characteristics, thereby limiting the potential effect of these confounders. Limitations of this study include its retrospective nature, and thus inability to control for unmeasured confounders, as well as the difficulty of determining the proximate cause of SSI in individual patients when using a de-identified database.

In conclusion, this study demonstrates that the new barrier attire regulations mandated by AHRQ and the Joint Commission do not reduce the incidence SSI in patients undergoing major abdominal surgery. In light of these findings, we suggest reversing this often burdensome and costly requirement, in favor of conventional practice.

Disclaimers

None.

Conflicts of interest

This manuscript has been reviewed by all authors, who declare no conflict of interest.

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What does this paper add to the literature?

This manuscript examines the impact of the new barrier attire regulations, imposed by the Agency for Healthcare Research and Quality together with the Joint Commission, on operating room personnel. Specifically we address whether these new regulations have reduced the incidence of surgical site infection. Such mandates are increasingly common, yet the evidence for their efficacy remains limited. In our series, we demonstrate that implementation of the barrier attire regulations has not been associated with any difference in the incidence of surgical site infection, or any other endpoint.

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