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Major Article

Ten-year-long implementation of a bundle for the prevention of surgical site infections: A cohort study of the temporal trend and factors influencing compliance

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Key Words:

Infection prevention and control
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Background: Many bundles have proven effective at preventing surgical site infections (SSIs), but little is known about factors influencing compliance to such bundles.

Methods: This cohort study includes 41,400 surgeries performed in 47 hospitals throughout a decade. The outcome of interest was binary compliance with a 4-element bundle for SSI prevention. A multivariable logistic regression model was computed with 12 predictor variables: patient sex, age, American Society of Anesthesiologists score, surgical specialty, length of preoperative stay, procedure year, procedure duration, surgical technique, presence of a prosthetic implant, elective versus emergent procedure, hospital type, and hospital size.

Results: Bundle compliance has increased significantly since its implementation, reaching 67.1% in the latest year. Lower odds of bundle compliance are correlated with emergent procedures (OR 0.3697), procedure duration above the first tertile (0.8597), age above the first quartile (0.7365), absence of a prosthetic implant, open surgical technique, and preoperative stay above 1 day (0.7920).

Discussion: Older age, longer procedure duration, longer preoperative stay, and an open surgical technique all correlate negatively with bundle compliance and are also known risk factors for SSIs.

Conclusions: Certain patient subgroups are at higher risk for bundle noncompliance, and thus show greater margins for improvement.

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BACKGROUND

Rationale

Surgical site infections (SSIs) are a common complication following surgical procedures.

These infections may involve the incision site or deeper tissues, resulting in various consequences, ranging from mild to life-threatening, and complicating the healing process.

In 2016, the Italian National Surveillance System for SSIs (Sistema Nazionale Sorveglianza delle Infezioni del Sito Chirurgico, SNICH)

estimated an SSI rate of 1.4 SSIs every 100 surgeries, representing one of the most common types of health care-associated infection (HAI) following an invasive procedure.¹

SSIs are associated with an important burden in the clinical, economic, and social-care fields.

As far as the clinical aspect is concerned, SSIs prolong the patient's healing course, resulting in an increase in the average length of hospital stay and in the number of readmissions.

Quantifying the precise cost of SSIs is difficult due to differing methodologies. However, the real cost is likely to be high because it represents the sum of many expenses, such as additional days of hospital stay, increased work of the health care staff, and additional diagnostic procedures and treatments required. In 2019, Turner et al reported that the additional cost of a patient with an SSI could range from \$1,400 to \$40,500 (superficial SSI requiring less cost than deep infection).² Consistently, a meta-analysis by Zimlichman et al estimated the average additional cost of SSI to be \$20,785 per case in the US context.³

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¹ See Appendix A for Members of the working group.

All of this is reflected on the social-care side leading to an increase in the patient's needs, especially during hospital stay, as well as to a reduction in the capacity of the health care system to provide other additional services.

Furthermore, as all other HAIs, SSIs play a role in the growing phenomenon of antimicrobial resistance.

For all these reasons, it is imperative to implement effective infection-prevention-and-control measures against SSIs, such as structured surveillance^{4,5} and the bundle protocol presented in this study.

The Institute of Healthcare Improvement defined a bundle as a small set (from 3 to 5) of evidence-based interventions for a specific patient segment/population and care setting that, when implemented together, will result in significantly better outcomes than when implemented individually.⁶

Many bundles already exist, with proven effectiveness in reducing the risk of SSIs, especially in the fields of abdominal^{7,8} and orthopedic surgery,⁹ while the evidence is still scarce regarding the likelihood of compliance with such bundles.

Gilhooley et al have shown that, in general, the number of elements included correlates negatively with the faithful application of bundles of all kinds.¹⁰

Deslarzes et al have found that compliance with a bundle for the prevention of SSIs decreased significantly with the length of the surgical procedure and during nighttime operations, while the age of the patient did not appear to have an influence¹¹; however, their study included only 3 types of surgeries performed in a single hospital.

Objectives

Our study presents data from a regional surveillance system in North-Western Italy. It also aims at identifying possible factors, pertaining to characteristics of the patients, the surgery, and the hospital, that may influence compliance with a bundled intervention (comprising 4 elements) for the prevention of SSIs, applied across a wide range of hospitals and surgical specialties.

METHODS

Bundle protocol

Starting from January 1, 2012, a 4-element bundled intervention for the prevention of SSIs was introduced in the Piedmont region (North-Western Italy); implementation is voluntary, but incentivized through the regional performance-indicator system for public and private hospitals alike. The intervention was designed based on the principle that, when compliance is measured for a core set of accepted elements of care for a clinical process, the necessary teamwork and cooperation required will result in high levels of sustained performance (reliability), not observed when working to improve individual elements.⁶

Each item of the bundle represents an effective preventive measure against the onset of SSIs, supported by level 1 evidence.¹²

Preoperative shower

This item requires that the patient takes a shower with soap during the 24 hours prior to incision, either at home or in the hospital, in order to minimize the bacterial load on the skin.¹² Either regular or antiseptic soap is acceptable, because the evidence is insufficient to demonstrate a superior effectiveness of the latter over the former.¹³ It is considered as noncompliant if the shower was performed more than 24 hours before the incision, or with water only.

Appropriate hair removal

This item requires that body hair be removed only when necessary, immediately before the incision, and only by means of an electric clipper or depilatory cream; manual razors are not allowed.

The rationale is that the presence of hair can hinder the application of sutures and of dressings. On the other hand, the shaving, especially by a razor, creates microscopic skin lesions that promote the development of SSIs.^{12,13} Therefore, this item is considered as compliant if hair removal is performed with a clipper or with cream, or avoided altogether.

Intraoperative normothermia

This item requires that the core body temperature of the patient be measured prior to extubation, limited to procedures lasting longer than 60 minutes, or performed on newborns or elderly patients, or involving ample laparotomies. Procedures performed without general anesthesia are exempt from this requirement. The rationale is that hypothermia (defined as core body temperature < 36 °C) is a common occurrence following major surgeries, and it is facilitated by general anesthesia; it also represents a risk factor for impaired wound healing and SSI development.^{12,13} Therefore, this item is considered as compliant if the procedure does not pose a risk of hypothermia, or—if it does—if the patient's temperature stays above 36 °C until the end of the procedure, prior to extubation.

Antibiotic prophylaxis

This item requires that the surgical antibiotic prophylaxis be appropriate in regard to the agent, the timing, the intraoperative redosing, and the duration; it is thus composed of 4 subitems, and it is considered as compliant only if all the 4 are compliant.

1. The agent used must have an antimicrobial spectrum that is effective against the pathogens likely to contaminate the procedure.¹² Since the prevalence of pathogens can vary locally, each hospital must establish their own protocol for surgical antibiotic prophylaxis; the agent used in each case is considered compliant if it complies with the local protocol.
2. The timing of administration must allow for the presence of an effective tissue concentration at the surgical site at the moment of incision. Therefore, the timing is considered compliant if the agent is administered within the 60 minutes prior to incision¹²; alternative timings can be allowed for drugs with different kinetic properties, provided that they are detailed in the local protocol.
3. An intraoperative redosing of the agent can be necessary to maintain a minimal inhibitory concentration at the surgical site throughout the procedure, depending on the duration and the half-life of the drug. It is considered compliant according to the criteria that must be specified in the local protocol.
4. The duration must be limited to the perioperative period; thus, it is considered compliant only if the prophylaxis is discontinued within 24 hours after the procedure.¹²

Included procedures

Out of 63,063 surgical procedures monitored through the regional surveillance system from 2012 to 2021, 41,400 (65.71%) were reported as having applied the bundle and included data about compliance to the single elements, and were therefore included in this prospective cohort study. Monitored procedures are listed in the SNICH protocol and are grouped into National Healthcare Safety Network operative procedure categories according to International Classification of Diseases, 9th revision - Clinical Modification (ICD-9-CM) codes.¹⁴

Data collection

Data pertaining to patient and surgery characteristics and to bundle implementation were collected through Piedmont's regional surveillance system for SSIs; the system applies the national SNICH protocol,¹⁴ which is based on the ECDC's (European Centre for

Disease Prevention and Control) HAIS protocol.¹⁵ From 2012 to 2021, 51 hospitals took part in the regional surveillance system and among them, 47 (92.16%) implemented the bundle and tracked compliance for at least 1 surveillance year. In accordance with the surveillance protocol, patients are followed up for 30 days after the surgery (or 90 days if they receive a prosthetic implant) to detect the eventual development of an SSI.¹⁴

When the bundle is applied, data collection instruments include the monitoring of compliance for each bundle element, with 3 possible responses:

- Compliant, if the individual element has been applied to the case in exam in accordance with the standard;
- Noncompliant, if the individual element has not been applied in accordance with the standard;
- Unknown, if the data on that element are missing.

Records not including data on the bundle were labeled as “bundle not applied” and excluded from the current analysis; records that were marked as “unknown” on all questions were likewise considered as not having implemented the intervention. With regard to surgical antibiotic prophylaxis, a record was considered compliant only if all 4 answers (agent, timing, intraoperative dose, and duration) were “compliant.” Conversely, a record was considered noncompliant if it had at least 1 “noncompliant” or “not known” answer.

Overall, bundle compliance was classified into 2 categories: fully compliant, for records with 4 out of 4 compliant elements; compliance with the bundle is measured by the documentation of adherence to all elements of the bundle (“all-or-none” measurement).⁶ The second category, partially compliant, includes all records that have at least 1 element reported as “unknown” or “noncompliant.”

Considering that the purposes of the program are disease surveillance and improvement of quality of care and that it is coordinated by public entities (Italian Centre for Disease Control, CCM, Italian Ministry of Health, and Regions of Emilia-Romagna and Piedmont), the SNICH protocol states that the written consent of involved patients or any other authorization by an Ethics Committee is not requested.¹⁴ Patients are notified of their participation in the program via an information sheet and only anonymized data are collected.

The data pertaining to the hospital (type of facility and number of beds) were drawn from the third edition of the Point Prevalence Survey of HAIs and antimicrobial use in European acute care hospitals (PPS3),^{16,17} which took place in Italy from 2022 to 2023 within the European surveillance coordinated by the European Centre for Disease Prevention and Control.

Description of variables

The “surgical technique” variable includes minimally invasive procedures, that is, procedures performed with the aid of a scope (laparoscopy, arthroscopy, thoracoscopy, etc), and open procedures, that is, all other procedures.¹⁴

The definitions of basic, first-level, and second-level hospitals are specified by the Italian law,¹⁸ with second-level hospitals offering the most advanced level of care. Specialized hospitals focus on 1 sector of specialized care, such as pediatric hospitals or orthopedic clinics.¹⁷ University (teaching) hospitals are owned by, or affiliated with, a university, and they were considered as a separate category.

Statistical analysis

Due to the presence of several outliers, quantitative variables were transformed into categorical variables. Age was expressed in quartiles (I: < 61 years, II: 61–71 years, III: 72–79 years, and IV:

> 79 years), duration of the procedure was expressed in tertiles (I: < 68 minutes, II: 68–123 minutes, and III: > 123 minutes), and preoperative hospital stay was classified as “short” if ≤ 1 day or “long” if > 1 day. Descriptive statistics were used to summarize demographic and clinical characteristics; the age of the patients was described using median and interquartile range (IQR). The following nominal variables were considered: legal sex (male or female), surgical technique (minimally invasive vs open), presence of an implant, elective versus emergency procedure, surgical specialty (orthopedics, general surgery, cardiothoracic surgery, obstetrics and gynecology, neurosurgery, urology, and all remaining surgical specialties), and hospital type (basic, I level, II level, specialized, and teaching). The following ordinal variables were also included: year of surgery (ranging from 2012–2021), American Society of Anesthesiologists (ASA) score (ranging from 1–5), and hospital dimension (< 200 beds, 200–500 beds, and > 500 beds).^{14,16}

The outcome variable was the dichotomous compliance with the bundle; all the other variables were analyzed as predictors. Differences between the 2 groups (compliant vs noncompliant procedures) were first assessed using χ^2 tests of independence for nominal variables and Mantel-Haenszel trend tests for ordinal variables. The threshold for statistical significance was set at a P value < .05.

Subsequently, a binomial multivariable logistic regression model was run, with bundle compliance as the outcome, in order to control for potential confounding effects.

All statistical analyses were performed using Jamovi 2.3.¹⁹

RESULTS

In total, 63,063 surgical procedures were monitored through the regional surveillance system from 2012 to 2021. The bundle intervention for the prevention of SSIs was applied to 41,440 of these, which were considered in the analysis.

Table 1 summarizes the main demographic and surgical characteristics of the sample.

Table 2 presents the proportion of procedures, over the 10-year period, which were marked as compliant to each of the 7 items and subitems.

Out of 41,440 procedures on which the bundle was implemented, 22,519 (54.3% of the sample) reported full compliance, while 18,921 (45.7%) reported partial compliance (at least 1 of the elements was noncompliant or unknown). Graph 1 illustrates the yearly trend in the proportion of compliant procedures, by whole bundle and single items and subitems. A statistically significant increase in the proportion of fully compliant procedures (by whole bundle) throughout the surveillance period was found at the Mantel-Haenszel trend test ($P < .001$). A full breakdown of the available bundle data by year and by item can be found in Table S1, among the Supplementary Materials.

Table 1
Demographic and surgical characteristics

Sex	
Male (%)	18,801 (45.4%)
Age	
Median (IQR)	71 (60–79)
Surgical specialty	
Orthopedics (%)	19,862 (48.0%)
General surgery (%)	10,559 (25.5%)
Cardiothoracic surgery (%)	2,934 (7.1%)
Obstetrics and gynecology (%)	2,481 (6.0%)
Neurosurgery (%)	2,230 (5.4%)
Urology (%)	1,518 (3.7%)
All the remaining (< 1,000 procedures, %)	1,856 (4.5%)

IQR, interquartile range.

Table 2

Whole-period proportion of procedures marked as “Compliant,” “Noncompliant,” and “Unknown” by single item and subitem; ordered by decreasing percentage of “Compliant” answers

Bundle items and subitems	Compliant		Noncompliant		Unknown	
	N	Row %	N	Row %	N	Row %
Antibiotic prophylaxis—timing	38,641	93.3	1,038	2.5	1,761	4.3
Appropriate hair removal	38,195	92.2	914	2.2	2,331	5.6
Antibiotic prophylaxis—choice of agent	35,090	84.7	1,954	4.7	4,396	10.6
Antibiotic prophylaxis—duration	34,209	82.6	3,057	7.4	4,174	10.1
Preoperative shower	34,068	82.2	2,506	6.1	4,866	11.7
Antibiotic prophylaxis—redosing	33,884	81.8	1,441	3.5	6,115	14.8
Intraoperative normothermia	33,494	80.8	1,528	3.7	6,418	15.5

Table 3 shows the results of the univariate and multivariate analyses conducted.

Out of all the factors considered in the analysis, the single most powerful predictor of full bundle compliance was elective surgery, as opposed to emergency surgery.

Sex appeared to influence the likelihood of full bundle compliance when considered at univariate analysis, but the effect disappeared when accounting for the other variables.

Notably, the duration of procedure presented a U-shaped relationship with bundle compliance when considered at univariate analysis, with intermediate-length procedures being disadvantaged in comparison with both shorter and longer procedures. However, the relationship became linear when accounting for all the other factors, implying a negative correlation between the duration of a procedure and the odds of full bundle compliance.

The type and size of the hospital also showed a complex and interesting interplay. Both small and big hospitals appeared to have an advantage over their medium-sized counterparts, a finding that remained significant at multivariate analysis. The hospital type showed a partially countervailing tendency, with basic and specialized hospitals—both typically small—performing worse than first-level hospitals—typically medium-sized. Second-level hospitals—typically big—showed a higher level of compliance than first-level ones in the univariate analysis, but the result reversed in the multivariable regression analysis. Finally, teaching hospitals performed about the same as first-level ones, both at univariate and multivariable analyses.

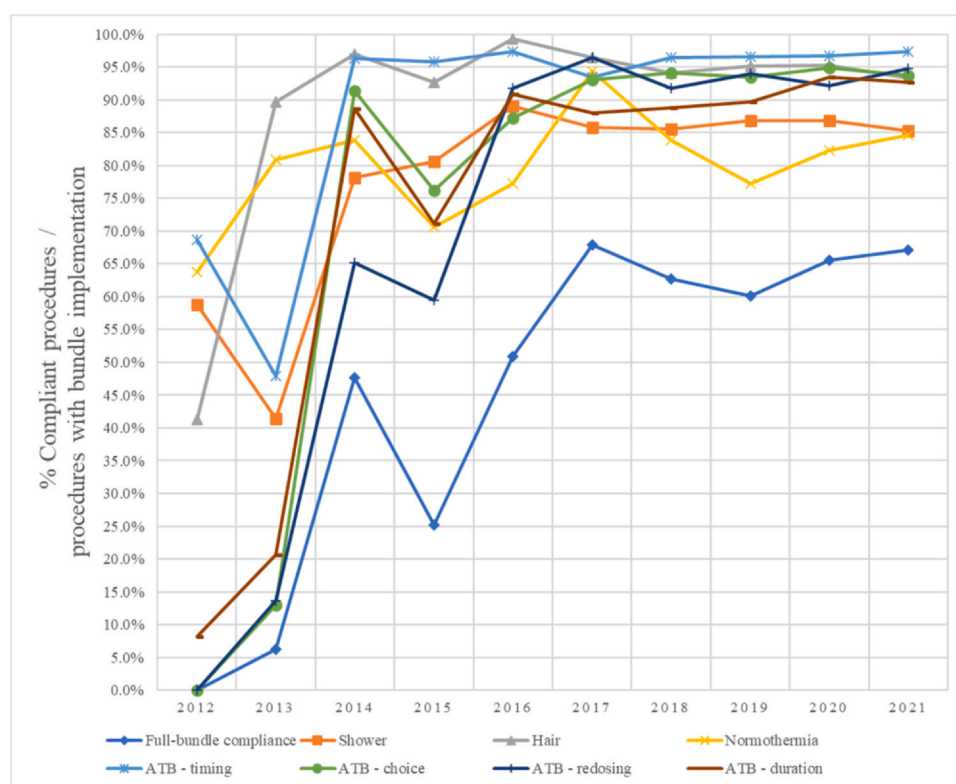
Regarding the surgical specialties involved, orthopedics appeared to perform better than general surgery, but the difference disappeared when considering the other factors. Similarly, the comparison between cardiothoracic surgery and general surgery reversed direction in the multivariable regression.

DISCUSSION

Key results

Looking at the yearly trends in compliance, the items of preoperative shower and intraoperative normothermia rank consistently lower than the others in the last 4 years of surveillance.

During the study period as a whole, intraoperative normothermia displays the lowest proportion of compliant procedures, at 80.8%; at the same time, it also shows the highest proportion of cases reported as “Unknown,” at 15.5%. This is probably due to the fact that complying with this item often necessitates the timely annotation of the relevant information (ie, core body temperature prior to extubation) by the anesthesiologist in the delicate setting of the operating room, where the correct completion of clinical documentation often takes the backseat to direct patient care. In the absence of a precise



Graph 1. Yearly trend in the proportion of compliant procedures, by whole bundle and single items and subitems.

Table 3
Distribution of independent variables among fully versus partially compliant procedures and results of a multivariable logistic regression

Independent variable	Mode	Univariate statistics*		Multivariable logistic regression		
		Fully compliant procedures [cumulative column %]	Partially compliant procedures (row %) (row %) cumulative column % [†]	Odds ratio [‡]	95% CI	P
Sex (missing: 1)	Male	10,420 (55.4)	8,381 (44.6)	Ref.		
	Female	12,099 (53.4)	10,539 (46.6)	1.0422	0.9924-1.0946	.098
Age (missing: 134)	First quartile	5,951 (57.3) [26.5]	4,429 (42.7) [23.5]	Ref.		
	Second quartile	5,816 (55.3) [52.4]	4,710 (44.7) [48.5,0]	0.7365	0.6874-0.7890	<.001
	Third quartile	5,680 (53.6) [77.4]	4,848 (46.4) [74.2]	0.7459	0.6949-0.8007	<.001
	Fourth quartile	5,082 (51.1) [100]	4,868 (48.9) [100]	0.7498	0.6951-0.8089	<.001
Year of surgery (missing: 0)	2012	0 (0.0) [0.0]	1,850 (100.0) [9.8]	NA [§]	NA [§]	NA [§]
	2013	106 (6.2) [0.5]	1,597 (93.8) [18.2]	0.0250	0.0201-0.0310	<.001
	2014	1,307 (47.7) [6.3]	1,435 (52.3) [25.8]	0.3614	0.3275-0.3987	<.001
	2015	712 (25.1) [9.5]	2,121 (74.9) [37.0]	0.1425	0.1281-0.1585	<.001
	2016	872 (50.9) [13.4]	842 (49.1) [41.5]	0.4374	0.3891-0.4918	<.001
	2017	1,526 (67.9) [20.2]	722 (32.1) [45.3]	0.8476	0.7571-0.9490	.004
	2018	5,147 (62.7) [43.1]	3,065 (37.3) [61.5]	0.7131	0.6629-0.7670	<.001
	2019	5,186 (60.1) [66.1]	3,443 (39.9) [79.7]	0.6300	0.5867-0.6765	<.001
	2020	2,649 (65.6) [77.9]	1,391 (34.4) [87.1]	0.9612	0.8801-1.0496	.378
	2021	5,014 (67.1) [100]	2,455 (32.9) [100]	Ref.		
Preoperative hospital stay (missing: 0)	1 d or less	16,897 (56.2)	13,159 (43.8)	Ref.		
	More than 1 d	5,622 (49.4)	5,762 (50.6)	0.7920	0.7493-0.8372	<.001
Minimally invasive procedure (missing: 12)	Yes	19,417 (53.9)	16,634 (46.1)	Ref.		
	Without	3,096 (57.6)	2,281 (42.4)	1.1595	1.0707-1.2556	<.001
Prosthetic implant (missing: 84)	With	8,512 (48.9)	8,902 (51.1)	Ref.		
	Without	13,985 (58.4)	9,957 (41.6)	2.0377	1.8414-2.2549	<.001
Emergency procedure (missing: 52)	No	19,372 (58.1)	13,970 (41.9)	Ref.		
	Yes	3,108 (38.6)	4,938 (61.4)	0.3697	0.3472-0.3937	<.001
Duration of procedure (missing: 57)	First tertile	7,601 (55.5) [33.8]	6,096 (44.5) [32.3]	Ref.		
	Second tertile	7,061 (51.8) [65.2]	6,574 (48.2) [67.1]	0.8597	0.8111-0.9112	<.001
	Third tertile	7,836 (55.8) [100]	6,215 (44.2) [100]	0.7968	0.7406-0.8572	<.001
ASA score (missing: 1,831)	1	1,620 (50.7) [7.5]	1,576 (49.3) [8.7]	Ref.		
	2	11,395 (56.0) [60.6]	8,947 (44.0) [58.0]	1.1327	1.0347-1.2399	.007
	3	7,437 (53.1) [95.2]	6,558 (46.9) [94.2]	1.0674	0.9674-1.1178	.194
	4	982 (49.7) [99.8]	995 (50.3) [99.7]	1.0891	0.9492-1.2497	.224
	5	42 (42.4) [100]	57 (57.6) [100]	1.1096	0.7022-1.7535	.656
Surgical specialty (missing: 0)	General	4,917 (46.6)	5,642 (53.4)	Ref.		
	Cardiothoracic	1,952 (66.5)	982 (33.5)	0.8650	0.7607-0.9837	.027
	Neurosurgery	1,561 (70.0)	669 (30.0)	1.2123	1.0474-1.4031	.010
	Obstetrics and gynecology	1,037 (41.8)	1,444 (58.2)	0.5959	0.5245-0.6770	<.001
	Orthopedic	11,057 (55.7)	8,805 (44.3)	0.9183	0.8127-1.0376	.171
	Urology	874 (57.6)	644 (42.4)	1.4410	1.2693-1.6361	<.001
	All the remaining	1,121 (57.6)	735 (39.6)	1.1808	1.0385-1.3425	.011
Hospital size (missing: 0)	< 200 beds	7,156 (57.3) [31.8]	5,340 (42.7) [28.2]	Ref.		
	200-500 beds	9,601 (46.2) [74.4]	11,174 (53.8) [87.3]	2.4012	2.1901-2.6327	<.001
	> 500 beds	5,762 (70.5) [100]	2,407 (29.5) [100]	0.2886	0.2461-0.3384	<.001
Hospital type (missing: 0)	Basic	353 (32.5)	733 (67.5)	Ref.		
	I level	9,187 (50.5)	9,000 (49.5)	0.9978	0.9265-1.0746	.954
	II level	4,164 (66.2)	2,126 (33.8)	0.8973	0.8075-0.9971	.044
	Specialized	2,936 (65.6)	1,542 (34.4)	0.5819	0.5304-0.6384	<.001
	Teaching	5,879 (51.6)	5,520 (48.4)	0.9978	0.9265-1.0746	.954

ASA, American Society of Anesthesiologists.

[†]Differences were assessed using χ^2 tests of independence for nominal variables and Mantel-Haenszel trend tests for ordinal variables (age, year of surgery, duration of procedure, ASA score, and hospital size).[‡]Only for ordinal variables, cumulative column percentage is given between square brackets.[§]How to read: an OR > 1 indicates higher odds of full bundle compliance.[¶]2021 was chosen as the reference to detect subtle differences with the years immediately previous; this meant that a meaningful value could not be computed for 2012, as the number of fully compliant procedures stood at 0.

notation taken in the moment, this information is almost impossible to retrieve post hoc, which can contribute to the relatively high proportion of procedures with unknown compliance.

The relatively low compliance to the preoperative shower could be explained partly by the fact that its implementation falls wholly in the preoperative stage, and thus it can be impossible to faithfully execute in the case of very urgent procedures.

Within the antibiotic item, the choice of the correct agent and the appropriate intraoperative redosing explicitly require that hospitals equip themselves with internal protocols regulating the details of appropriate surgical prophylaxis according to their local context. The adoption of such internal protocols lagged slightly behind the introduction of the bundle, which explains why both subitems were universally marked as “Unknown” in 2012. Once in place, we speculate that the presence of these internal protocols has contributed to raise and maintain awareness of the relevance of appropriate antimicrobial prophylaxis among the surgical staff, thereby keeping compliance to all 4 antibiotic subitems above 90% throughout the second half of the study period.

The item about appropriate hair removal shows the fastest uptake of all, reaching 89.7% in compliance already in 2013, and staying consistently above 90% for all the following years.

Our study strongly suggests that minimally invasive procedures are more likely to be bundle-compliant than open ones. This could be explained by the fact that minimally invasive procedures are less likely to require hair removal and to induce perioperative hypothermia, and thus comply more easily with these 2 items of the bundle. However, this should not discourage efforts to implement the bundle more faithfully in open procedures, since previous research has shown that open procedures are more likely to lead to an SSI⁴ and to benefit from the bundled intervention.⁷

A similar reasoning goes for the duration of procedures: our study suggests that the longer the procedure, the lower the likelihood of complying with the bundle; this is to be expected because of the difficulty inherent in keeping the patient’s core temperature stable over longer operative times. At the same time, procedure duration is an independent risk factor for the development of an SSI,²⁰ so bigger reductions in the SSI rate could be obtained by focusing bundle implementation efforts on longer procedures.

Patient age shows a negative correlation with the odds of bundle compliance. This could depend on the item of preoperative showering, which requires some patient cooperation to be accurately executed and recorded; such cooperation can be more difficult to obtain from elderly patients who suffer more often from impairments in memory and communication. Since older age is also a known risk factor for SSIs,^{12,20} stronger organizational efforts should be targeted toward ensuring full bundle compliance among older patients.

It stands to reason that emergency situations can be an independent risk factor for noncompliance, as they allow less time for the implementation of the preoperative items. Counterintuitively, a preoperative hospital stay longer than 1 day also shows a negative correlation with bundle compliance. We speculate that these 2 kinds of procedures (procedures performed in emergency and after 1 day of hospitalization) share common disadvantages—that is, they are more often not planned in advance of the patient’s admission, and they can take place on weekends and at unusual times of the day, when fewer staff are available. This can pose a problem if the correct implementation and recording of the bundle is a task assigned to a few specific individuals within a hospital organization, who might not always be on duty. By consequence, we recommend that the execution and recording of the bundle for the prevention of SSIs should be integrated into the routine workflow for all professionals involved in surgical care, to ensure a consistent implementation on all days and at all times.

Male patients seemed to benefit from a higher level of bundle compliance over females, but this effect disappeared when controlling

for other variables; this finding suggests that there is no significant sex bias at play.

The presence of a prosthetic implant appears to represent a positive factor for full bundle compliance. Since such implants are known to be prone to bacterial colonization—and consequent deep or organ/space SSI—it stands to reason that the surgical staff would implement the bundle more diligently upon procedures that involve a prosthesis.

Finally, the size and type of a hospital seem to influence the compliance with the bundle protocol in a complex fashion, that we are not able to disentangle with the present study. Further research is needed to investigate this relationship, ideally collecting data about more variables, such as the number of staff dedicated to infection prevention and control (IPC).

Implications

The current study shows that significant progress has been made in the correct application of the bundled intervention since its first introduction in the year 2012. However, in 2021, still about one-third of surveilled procedures were not fully compliant, a proportion that has not changed significantly from the previous year. We propose that, in order to increase compliance most effectively, future efforts should be targeted toward those procedures that, according to our findings, are less likely to faithfully implement the bundled intervention.

At the policy level, the performance indicators on IPC,²¹ issued yearly by the regional government, could be fine-tuned to encourage bundle compliance during such procedures. For example, a minimal compliance threshold could be set for open procedures or for procedures on patients over 60 (above our first age quartile), and slowly raised every year until the compliance gap is filled.

Regarding the item with the lowest compliance (intraoperative normothermia), we expect an improvement coming from the ongoing transition toward digital clinical records, which should be encouraged. If the act of recording the intraoperative temperature were digitized and simplified, anesthesiologists would be more likely to do it every time, and it would be easier for IPC staff to consult that information later. We expect these developments to greatly reduce the proportion of procedures with unknown compliance to intraoperative normothermia, provided that an overall high attention is kept on bundle compliance and, more generally, on SSI prevention.

On the research side, this has been the first study to research factors that systematically influence the likelihood of successful implementation of the bundled intervention in Piedmont. However, the complex web of relationships between such factors has not been fully illuminated yet, so we think further research is warranted, for example, to examine the compliance by single item, or to disentangle the interaction between the types and sizes of hospitals.

Limitations

The main limitation of this study is in the sampling method. First, participation is voluntary. Hospitals participating in the surveillance must record a continuous subset of all the procedures of a given kind that are performed every year, but the specific requirements have changed a few times over the study period. Moreover, hospitals are free to choose the surveillance period within each year and to monitor procedures in excess of the minimum number and scope required by the region. This results in a convenience sample that, although very large, may not be fully representative of all surgeries.

On the other hand, the main strength is represented by the high number and variety of centers involved, covering all the kinds of

hospital that exist in Italy, from the very big to the very small, both public and private, general and specialized, and teaching and non-teaching.

CONCLUSIONS

During the study period, we have witnessed an unmistakable trend toward growing adoption and adherence to the bundled intervention, showing that it is possible for a bundle of this kind—comprising the few most effective measures for the prevention of SSIs—to be implemented on a regional scale, across all kinds of hospitals and surgical specialties. However, compliance is still not optimal, and the present study suggests a few directions for new, targeted efforts toward improvement.

APPENDIX A

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APPENDIX B. SUPPLEMENTARY DATA

Supplementary data related to this article can be found at [doi:10.1016/j.ajic.2025.02.013](https://doi.org/10.1016/j.ajic.2025.02.013).

References

- Buttazzi R., Ricciardi A., Gagliotti C., Moro M.L. Sorveglianza delle infezioni del sito chirurgico in Italia Interventi ortopedici anno 2015 Interventi non ortopedici anno 2016. Published online May 2018.
- Turner MC, Migaly J. Surgical site infection: the clinical and economic impact. *Clin Colon Rectal Surg.* 2019;32:157–165.
- Zimlichman E, Henderson D, Tamir O, et al. Health care-associated infections: a meta-analysis of costs and financial impact on the US health care system. *JAMA Intern Med.* 2013;173:2039–2046.
- Marchi M, Pan A, Gagliotti C, et al. The Italian national surgical site infection surveillance programme and its positive impact, 2009 to 2011. *Euro Surveill Bull Eur Sur Mal Transm Eur Commun Dis Bull.* 2014;19:20815.
- Vicentini C, Dalmasso P, Politano G, Furmenti MF, Quattrocolo F, Zotti CM. Surgical site infections in Italy, 2009–2015: incidence, trends, and impact of surveillance duration on infection risk. *Surg Infect.* 2019;20:504–509.
- Resar R, Griffin F, Haraden C, Nolan T. Using care bundles to improve health care quality. IHI Innovation Series white paper. Published online 2012.
- Vicentini C, Scacchi A, Corradi A, et al. Interrupted time series analysis of the impact of a bundle on surgical site infections after colon surgery. *Am J Infect Control.* 2021;49:1024–1030.
- Badia JM, Arroyo-García N, Vázquez A. Leveraging a nationwide infection surveillance program to implement a colorectal surgical site infection reduction bundle. A pragmatic, prospective and multicentre cohort study. *Int J Surg.* 2023;109:737–751.
- Vicentini C, Corradi A, Scacchi A, et al. Impact of a bundle on surgical site infections after hip arthroplasty: a cohort study in Italy (2012–2019). *Int J Surg.* 2020;82:8–13.
- Gilhooly D, Green SA, McCann C, Black N, Moonesinghe SR. Barriers and facilitators to the successful development, implementation and evaluation of care bundles in acute care in hospital: a scoping review. *Implement Sci.* 2019;14:47.
- Deslarzes P, Jurt J, Hübner M, et al. Prospective compliance assessment of surgical site infection prevention measures in colorectal surgery. *BJS Open.* 2023;7:zrad013.
- World Health Organization. *WHO Guidelines for Safe Surgery 2009: Safe Surgery Saves Lives.* World Health Organization; 2009.
- World Health Organization. *Global Guidelines for the Prevention of Surgical Site Infection.* 2nd ed World Health Organization; 2018.
- Protocollo Sistema nazionale di sorveglianza delle Infezioni del Sito Chirurgico (SNiCh) - aggiornamento dicembre 2011. Innovazione sanitaria e sociale. Accessed June 17, 2024. (<https://assr.regione.emilia-romagna.it/pubblicazioni/rapporti-documenti/protocollo-snich-aggiornamento-dic2011>).
- ECDC. Surveillance of Surgical Site Infections in European Hospitals: HAISSI Protocol. Publications Office; 2011. Accessed August 9, 2024. <https://data.europa.eu/doi/10.2900/12819>.
- Vicentini C, Russotto A, Bussolino R, et al. Impact of COVID-19 on healthcare-associated infections and antimicrobial use in Italy, 2022. *J Hosp Infect.* 2024;149:14–21.
- Sorveglianza europea mediante prevalenza puntuale delle infezioni correlate all'assistenza e sull'uso di antibiotici negli ospedali per acuti - Protocollo per sorveglianza standard, versione 6.0, ECDC PPS 2022–2023. Published online 2022.
- Ministro della Salute, Ministro dell'Economia e delle Finanze. Regolamento Recante Definizione Degli Standard Qualitativi, Strutturali, Tecnologici e Quantitativi Relativi All'assistenza Ospedaliera; 2015. Accessed February 21, 2025. <https://www.normattiva.it/esporta/attoCompleto?atto.dataPubblicazioneGazzetta=2015-06-04&atto.codiceRedazionale=15G00084>.
- The jamovi project. jamovi. Published online 2022. Accessed March 8, 2025. (<https://www.jamovi.org>).
- Korol E, Johnston K, Waser N, et al. A systematic review of risk factors associated with surgical site infections among surgical patients. *PLoS One.* 2013;8:e83743.
- Regione Piemonte. Indicatori per Sorveglianza e Controllo delle Infezioni Correlate all'Assistenza (ICA) e dell'Antimicrobicoresistenza (AMR). Published online 2024. Accessed March 8, 2025. (<https://dssppunito.wixsite.com/sorveglianze/indicatori-regionali>).