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Surgical Site Infections in Italy, 2009-2015: Incidence, Trends, and Impact of Surveillance Duration on Infection Risk

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3 **Surgical Site Infections in Italy, 2009 to 2015: incidence trends and impact of**
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5 **surveillance duration on infection risk.**
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46
47

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Abstract

Background. Surveillance programmes have proven to be effective in reducing SSI rates. In 2008 the region of Piedmont, in the north-west of Italy, joined the Italian national surveillance system (SNICH). The aims of this study were to evaluate SSI rates and trends in Piedmont from 2009 to 2015 for the two most frequently performed surgical procedures, hip arthroplasty and colon surgery, and to estimate whether the number of years of participation in a surveillance programme and the number of monitored surgical procedures have an impact on the incidence of SSIs.

Methods. Data were collected through the national surveillance system. Procedure-specific SSI rates were calculated, overall and by year of participation in the network. Trends in SSI rates were evaluated in relation to the duration of surveillance and the number of monitored procedures using Poisson regression analysis.

Results. A total of 16 288 procedures were monitored from 37 hospitals. The overall adjusted SSI rates were 8.61% after 6050 colon surgery procedures and 1.16% after 10 238 hip arthroplasty procedures. Each year of increase in participation was associated with a significant risk reduction for SSI in both procedure categories: 7% for colon surgery (Risk Ratio, RR 0.93; 95% Confidence Interval, CI 0.89-0.97) and 20% (RR 0.80; 95% CI 0.73-0.88) for hip arthroplasty. Conversely, an increase in the number of monitored procedures was not associated with a significant decrease in SSI risk: an overall RR of 0.99 (95% CI 0.98-1.00) and 1.00 (95% CI 0.99-1.00) was found for every one unit increase in the number of monitored procedures for colon surgery and hip arthroplasty respectively.

Conclusions. These results support the efficacy of systematic surveillance in reducing SSIs, increasing with the number of years of participation, and suggest the volume of monitored procedures has no significant impact on SSI risk.

Introduction

Surgical Site Infections (SSIs) significantly increase morbidity, mortality¹, duration of hospital stay and healthcare costs.² The incidence of SSIs is recognized by the European Council as one of the main indicators of healthcare quality in surgical wards.³ According to recent European literature, SSIs affect 0.7% to 9.5% of operated patients, varying according to surgical procedure⁴. SSIs are considered to be among the most preventable healthcare-associated infections (HCAIs).⁵⁻⁷

Surveillance programmes have proven to be an effective preventive measure for SSIs.^{8,9} Over the past four decades, several national and international surveillance systems have been established and most, although not all, have shown a significant decrease in SSI rates.¹⁰⁻¹² The Italian surveillance system for SSIs (Sistema Nazionale Sorveglianza Infezioni del Sito Chirurgico, SNICH¹³) was funded and implemented in 2005 by the Italian Centre for Disease Control and Prevention. Piedmont, a north-western region of Italy with around 4 million inhabitants, joined the national surveillance system in 2008 and additionally introduced a performance indicator system to allow an objective assessment of HCAI surveillance, infection prevention and control activities and structural and organizational resources.

The aims of this study were (1) to evaluate the epidemiologic features of SSIs in Piedmont from 2009 to 2015 and (2) to estimate whether the number of years of participation in a surveillance programme and the number of monitored procedures have an impact on the incidence of SSIs.

Methods

A prospective study was conducted in 37 primary, secondary and tertiary hospitals participating in the national surveillance system. The Department of Public Health and Paediatrics of the University of Turin coordinated data collection for the region of Piedmont. For the current study, data collected between January 1st, 2009, and December 31st, 2015 were analysed.

Participating Hospitals

Participating in the SNICH programme is voluntary. According to the national protocol¹³, surveillance must be carried out for at least three months each year and continuous surveillance is encouraged. In Piedmont, the regional indicator system additionally requires participating hospitals to monitor a minimum of 50 procedures and/or to perform surveillance for a minimum of six months each year. Participating hospitals in Piedmont are required to include the following procedure categories: colorectal surgery or hip arthroplasty and a third category, depending on the surgical activities performed in the specific hospital.

Definitions

The included procedures are listed in the national protocol and are grouped into NHSN (National Healthcare Safety Network) operative procedure categories according to ICD-9-CM codes. The main outcome of the surveillance programme is the occurrence of infection within 30 days or one year (for surgeries involving the implant of prosthetic material) of the operation. From January 1st, 2017, follow-up duration was reduced from one year to 90 days for surgeries involving the implant of prosthetic material; but for data presented in the current study, the previous follow-up period of one year was implemented. The definition of SSI is

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2
3 consistent with NHSN and European Centre for Disease Prevention and Control (ECDC)
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5 criteria. SSIs are classified according to severity (superficial incisional, deep incisional,
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7 organ/space) following the definitions provided by the ECDC HAISSI protocol.¹⁴ The SSI
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9 risk index is calculated following NHSN methodology¹⁵ and applying ECDC definitions,
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11 according to the duration of the procedure, the patient's American Society of
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13 Anaesthesiology (ASA) physical status score and the wound contamination class (clean,
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15 clean-contaminated, contaminated, dirty).
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20 *Data Collection*

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23 SNICH is a patient-based surveillance system. Infection control staff identify included
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25 procedures and gather data for each patient upon admission. Demographic and clinical data
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27 are collected, including whether the operation is scheduled at least twenty-four hours in
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29 advance (elective procedure) or less than twenty-four hours in advance (emergency
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31 procedure), whether an endoscopic or laparoscopic technique is employed, whether surgical
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33 antimicrobial prophylaxis is administered. The national protocol defines surgical
34
35 antimicrobial prophylaxis as the administration of systemic antibiotics within two hours prior
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37 to the surgical incision, with the objective of preventing the occurrence of a SSI.
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42 Patients are monitored for the occurrence of infection until discharge. Post-discharge
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44 information on the occurrence of infection is collected (1) during ambulatory post-operative
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46 visits in the same hospital or (2) by phone at the end of the follow-up period, using a standard
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48 interview form.
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52 Data are submitted by each hospital via a standardized collection tool to the regional
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54 coordinating centre, which validates and forwards collected data to the national coordinating
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56 centre, the Regional Health Agency of the Emilia-Romagna Region. Regional and national
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3 reports are published once a year by each centre respectively. National data are further
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5 transmitted to the ECDC surveillance network for SSIs, HAISSEI.
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8 *Statistical analysis*

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11 **Cumulative** SSI rates were calculated for colon surgery and hip **arthroplasty and were**
12
13 **stratified by type of SSI (superficial incisional, deep incisional, organ/space) and Infection**
14
15 **Risk Index.** Following the methodology proposed by Manniën *et al* ¹⁶, the number of years
16
17 of participation in the surveillance programme for each hospital was determined for both
18
19 procedure categories and surveillance time **from the first year of participation until the date of**
20
21 **each operation** was stratified into one year periods. **The number of procedures monitored**
22
23 **each year in each hospital was also determined.** Hospitals in which surveillance was carried
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25 out for less than two consecutive years or in which less than 100 procedures of both
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27 categories were monitored in the considered time frame were excluded **from the analysis.**
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33 Rates per 1000 person-days and 95% confidence intervals (CI) were estimated from date of
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35 operation to end of follow-up for each procedure. Trends in SSI incidence rates over
36
37 surveillance **time and number of monitored interventions** were estimated as the annual
38
39 percent change in the SSI incidence rate using Poisson regression analysis. **Two different**
40
41 **univariate models were calculated: one for the number of years of participation in the**
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43 **programme and one for the number of monitored procedures, to evaluate the crude**
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45 **relationship with SSI risk. A single multivariable model was then estimated,** adjusted for
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47 known independent risk factors for SSI: age, sex, emergency procedure,
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49 endoscopic/laparoscopic technique, NHSN risk index, antimicrobial prophylaxis.¹⁷⁻²⁰ **Effect**
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51 **size was quantified as the Risk Ratio (RR).** The level of statistical significance was set at 5%
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60 (two-tailed test). All analyses were performed using STATA/SE version 14.2.

Results

A total of 16 288 procedures performed in 37 hospitals between 2009 and 2015 were monitored. The number of monitored procedures increased from 990 in 2009 to 3371 in 2015.

An SSI occurred in 786 (4.83%) procedures. Table 1 shows the characteristics of the study population.

Rates and characteristics of reported SSIs are shown in Table 2. After adjustment, the cumulative SSI rates were 8.61% (95% Confidence Interval, CI 6.4-11.5) for colon surgery and 1.16% (95% CI 0.71-1.89) for hip arthroplasty. The number of participating hospitals, of years of participation in the programme and of monitored procedures are summarized in Table 3.

Figure 1 depicts crude SSI rates with 95% CI per year of participation in the surveillance programme for colon surgery and hip arthroplasty. The results of the analysis of the effect of surveillance duration on SSI risk are shown in Table 4. Every one-year increase in surveillance time was associated with a 7% and 20% decrease in the risk for SSI respectively for colon surgery (RR 0.93; 95% CI 0.89-0.97) and hip arthroplasty (RR 0.80; 95% CI 0.73-0.88). The other independent variables included in the model with the highest impact on SSI risk were NHSN risk index and antimicrobial prophylaxis. For colon surgery, a reduced risk compared to year 0 of surveillance was observed from the third year onwards; for the first five years results were non-significant but participating in the network for over five was associated with a RR of 0.64 (95% CI 0.46-0.90). For hip arthroplasty, a significant risk reduction was present each year and progressively increased for the first three years, ranging from 0.64 (95% CI 0.42-0.97) to 0.32 (95% CI 0.20-0.53), slightly decreased for years 3-4

(RR 0.54 95%; CI 0.32-0.90) and increased again for the following two years from 0.43 (95% CI 0.23-0.80) to 0.20 (95% CI 0.80-0.50).

The effect of the number of monitored procedures on SSI risk was assessed by calculating the overall RR for every one unit increase in the number of monitored procedures. After adjustment for age, sex, emergency procedure, endoscopic or laparoscopic technique and NHSN risk index, an overall RR of 0.99 (95% CI 0.98-1.00) was found for colon surgery and 1.00 (95% CI 0.99-1.00) for hip arthroplasty.

Discussion

This study presents data prospectively collected through a surveillance programme for SSIs in a network of 37 hospitals in the north-west of Italy from 2009 to 2015. The main findings of this study were: (1) a statistically significant decreasing trend in SSI rates with increased duration of participation in the surveillance programme and (2) a negligible effect of the number of monitored procedures on SSI risk. To the best of our knowledge, this is the first study to analyse the effect of both factors.

This study had some limitations that must be addressed. First of all, the SNICH programme has intrinsic methodological issues: participation is voluntary and continuous surveillance is encouraged but not required. The most recent indicators implemented in Piedmont are taking a step towards ameliorating methodological standards: from 2018, continuous surveillance is required for a period of at least six months each year or until a minimum of fifty procedures per selected category are monitored. Secondly, other factors that may have contributed to the observed decrease in SSI rates were not taken into account, such as changes in infection

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3 prevention practices or in the intensity of surveillance. However, it is plausible that the
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5 experience acquired through several years of participation has improved case-finding abilities
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7 and led to an increase in sensitivity.
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11 A number of studies have evaluated the effectiveness of surveillance programmes in reducing
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13 the incidence of SSIs. An Italian study¹⁸ reported a 29% reduction in SSI risk in hospitals that
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15 performed at least two years of continuous surveillance through the SNICH programme (Odds
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17 Ratio, OR 0.71; 95% CI 0.59-0.84). The implementation of the French national programme
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19 ISO-RAISIN resulted in a relative reduction in the overall SSI incidence of 33% over eight
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21 years from 1999 to 2006.²¹ An Australian group¹² reported a 9% decrease in SSI risk with
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23 every one-year increase in surveillance between 2002 and 2013 (RR 0.91; 95% CI 0.90-0.92).
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27 Recently, Abbas *et al*²² performed a systematic review using data stratified by year of
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29 participation to determine trends in SSI rates in hospitals members of four surveillance
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31 networks, from Germany (KISS), the Netherlands (PREZIES), Switzerland (western and
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33 southern Swiss regional network) and the United States (ACS NSQIP). A significant decrease
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35 in the RR for SSI was found for the first five years of participation, ranging from 0.80 (95%
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37 CI 0.79-0.82) after the second year to 0.95 (95% CI 0.93-0.97) after the fifth year.
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43 In our study, significant decreasing trends were found for both included procedure categories,
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45 colon surgery and hip arthroplasty: the risk for SSI decreased significantly by 7% and 20%
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47 respectively for each one-year increase in surveillance for colon surgery (RR 0.93; 95% CI
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49 0.89-0.97) and hip arthroplasty (RR 0.80; 95% CI 0.73-0.88). These results are in line with
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51 those found by Abbas *et al*²² and support the effectiveness of surveillance in preventing SSIs.
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53 Furthermore, in our analysis the effect of the number of monitored procedures on SSI risk
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55 was non-significant, suggesting that the reduction in SSI risk is associated with the number of
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57 years of participation, regardless of the number of monitored procedures.
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3 The positive impact of SSI surveillance has long been demonstrated, however an
4 improvement in surveillance methods and quality and comparability of data is considered
5 necessary.^{23,24} Several countries have implemented mandatory surveillance programmes for
6 SSIs, leading to an increase in the completeness and representativeness of gathered data.²⁵
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8 However, the implementation of a mandatory system requires a considerable increase in
9 organizational and financial resources, which may not be possible in all settings.
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12 Several explanations for the positive effect of surveillance programmes have been proposed.
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14 The timely dissemination of data and feedback of SSI rates could lead to positive changes in
15 infection control practices. The occurrence of a “surveillance effect” has also been postulated,
16 which - similarly to the Hawthorne effect in clinical trials – could improve practices or
17 adherence to guidelines for the simple fact of being conscious that one is being observed.²⁶
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19 The results of the present study suggest that it is not the volume of monitored procedures that
20 determines the entity of the protective effect, but participation in itself and its duration.
21
22 Increasing surveillance coverage, be it through the implementation of mandatory surveillance
23 or through other approaches, could therefore not be essential. This finding is particularly
24 encouraging for smaller hospitals, where surveillance is often conducted in a single ward and
25 achieving high volumes of monitored procedures is challenging.
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28 Furthermore, it has been suggested that voluntary data on SSI rates may be more accurate
29 than mandatory data.⁵ Participants in voluntary systems are more invested in improving
30 patient outcomes and are more likely to produce data of higher quality. Finally, the
31 proportion of hospitals voluntarily participating in HCAI surveillance systems tends to
32 increase over time²⁵, progressively leading to an increase in representativeness.
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3 In conclusion, our results support the efficacy of systematic surveillance in reducing SSI
4 rates, increasing with the number of years of participation and regardless of the number of
5 monitored procedures. Considering the main objective of SSI surveillance is to decrease
6 infection rates in participating hospitals, other factors responsible for the decrease in SSI rates
7 found in this study and other strategies to improve quality of care through surveillance should
8 continue to be investigated and pursued.
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Table 1. Demographic characteristics.

Characteristic	Colon surgery	Hip arthroplasty
Number of procedures	6050	10,238
Patient age, years		
Median	72	75
25th percentile	63	66
75th percentile	79	82
Female sex, N (%)	2798 (46.25)	6424 (62.75)
Contaminated or dirty wound ^a , N (%)	1777 (29.37)	17 (0.17)
ASA ^b score ≥ 3 , N (%)	2617 (43.26)	3915 (38.24)
Duration of surgery >75th percentile, N (%)	1751 (28.94)	553 (5.4)
Infection Risk Index, N (%)		
0	1674 (27.67)	5493 (53.65)
1	2571 (42.5)	4006 (39.13)
2	1357 (22.43)	213 (2.08)
3	244 (4.03)	3 (0.03)
Not applicable	19 (0.31)	18 (0.18)
Emergency procedure, N (%)	1255 (20.74)	998 (9.75)
Endoscopic or laparoscopic procedure, N (%)	1377 (22.76)	0
Antimicrobial prophylaxis, N (%)	5365 (88.68)	10,033 (98)
Mean pre-operative hospital stay, days	3.12	2.45
Mean hospital stay, days		
Infection	22.22	21.7
No infection	13.54	12.46
Mean post-operative surveillance, days	30.53	327.33

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3 ^aWound contamination class according to the ECDC definition. ¹⁴
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5 ^bASA, American Society of Anaesthesiology.
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Table 2. Surgical Site Infection (SSI) incidence rates and characteristics according to surgical procedure, 2009 to 2015.

Characteristic	Colon surgery	Hip arthroplasty
Number of procedures	6050	10 238
Number of SSIs (rate ^a)	595 (9.83)	191 (1.87)
Type of SSI, N (%)		
Superficial incisional	370 (62.18)	97 (50.78)
Deep incisional	96 (16.13)	80 (41.88)
Organ/ space	97 (16.3)	11 (5.76)
SSI N (rate) according to Infection Risk Index ^b		
0-1	355 (8.36)	172 (1.81)
2-3	232 (14.49)	11 (5.09)
Mean time to infection, days	11.22	48.24
Post-discharge SSIs, N (%)	172 (28.9)	124 (64.92)

^a Crude SSI incidence rate for 100 operated patients.

^b N of infections for procedures in the Risk Index category / N of procedures in the Risk Index category.

Table 3. Participation in the SNICH programme, 2009 to 2015.

	Colon surgery	Hip arthroplasty
Number of participating hospitals ^a	32	35
Number of hospitals that participated for ≥ 4 years	25	13
Number of years of participation per hospital		
Median	4.5	3
25th percentile	3.75	2
75th percentile	5.25	4
Number of monitored procedures per hospital per year		
Median	166	170
25th percentile	120.5	108.5
75th percentile	213.5	345.5

^aHospitals in which surveillance was carried out for less than two consecutive years or in which less than 100 procedures of both categories were monitored between 2009 and 2015 were excluded.

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Table 4. Adjusted risk ratios (RR) and 95% confidence intervals (CI) for the association of surveillance time to operation and SSI risk, by surgical procedure.

	Colon surgery ^a			Hip arthroplasty ^b		
	SSI N	RR (95% CI)	<i>p</i>	SSI N	RR (95% CI)	<i>p</i>
0	108	1		65	1	
≤1 year	83	1.31 (0.98-1.77)	0.067	38	0.64 (0.42-0.97)	0.034
1-2 years	97	1.19 (0.92-1.60)	0.236	29	0.45 (0.29-0.71)	0.001
2-3 years	109	1.08 (0.82-1.43)	0.571	21	0.32 (0.20-0.53)	≤0.001
3-4 years	59	0.73 (0.53-1.01)	0.059	20	0.54 (0.32-0.90)	0.019
4-5 years	74	0.95 (0.70-1.29)	0.751	12	0.43 (0.23-0.80)	0.007
5-6 years	65	0.64 (0.46-0.90)	0.011	6	0.20 (0.80-0.50)	0.001
<i>Total</i>	<i>595</i>	<i>0.93 (0.89-0.97)</i>	<i>0.001</i>	<i>191</i>	<i>0.80 (0.73-0.88)</i>	<i>≤0.001</i>

^aAdjusted for age, sex, NHSN risk index, antimicrobial prophylaxis, endoscopic or laparoscopic technique, emergency procedure. Due to missing values in one or more of these variables, 529 patients were excluded from analysis.

^bAdjusted for age, sex, NHSN risk index, antimicrobial prophylaxis. Due to missing values in one or more of these variables, 204 patients were excluded from analysis.

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3 **Figure 1.** Crude SSI rates with 95% confidence intervals per surveillance year, by surgical
4 procedure.
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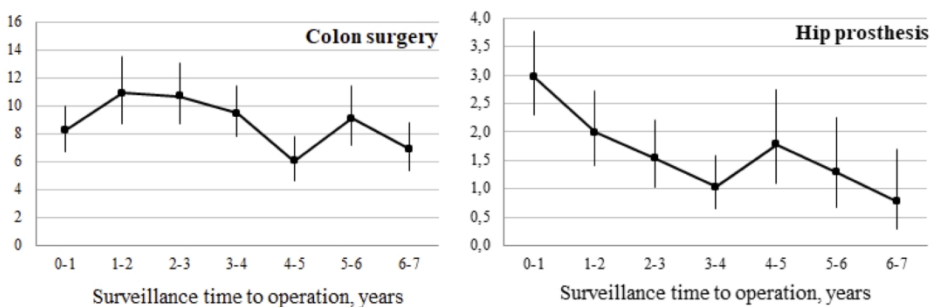


Figure 1. Crude SSI rates with 95% confidence intervals per surveillance year, by surgical procedure.

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