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Prospective Cohort Study

# An interventional nationwide surveillance program lowers postoperative infection rates in elective colorectal surgery. A cohort study (2008–2019)

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#### ABSTRACT

*Background:* Colorectal surgery is associated with the highest rate of surgical site infection (SSI). This study analyses the effectiveness of an interventional surveillance program on SSI rates after elective colorectal surgery. *Material and methods:* Cohort study showing temporal trends of SSI rates and Standardized Infection Ratio (SIR) in elective colorectal surgery over a 12-year period. Prospectively collected data of a national SSI surveillance program was analysed and the effect of specific interventions was evaluated. Patient and procedure characteristics, as well as SIR and SSI rates were stratified by risk categories and type of SSI analysed using stepwise multivariate logistic regression models.

*Results*: In a cohort of 42,330 operations, overall cumulative SSI incidence was 16.31%, and organ-space SSI (O/S–SSI) was 8.59%. There was a 61.63% relative decrease in SSI rates (rho = -0.95804). The intervention which achieved the greatest SSI reduction was a bundle of 6 measures. SSI in pre-bundle period was 19.73% vs. 11.10% in post-bundle period (OR 1.969; IC 95% 1.860–2.085; p < 0.0001). O/S–SSI were 9.08% vs. 6.06%, respectively (OR 1.547; IC 95% 1.433–1.670; p < 0.0001). Median length of stay was 7 days, with a significant decrease over the studied period (rho = -0.98414). Mortality of the series was 1.08%, ranging from 0.35% to 2.0%, but a highly significant decrease was observed (rho = -0.67133).

*Conclusions*: Detailed analysis of risk factors and postoperative infection in colorectal surgery allows strategies for reducing SSI incidence to be designed. An interventional surveillance program has been effective in decreasing SIR and SSI rates.

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#### 1. Introduction

Surgical site infections (SSIs) are among the most common health care-related infections [1], and colorectal surgery has the highest incidence of SSIs after elective abdominal procedures, ranging from 9% to 20% [2–4]. SSI is associated with increased length of stay (LOS), morbidity and mortality, and places considerable financial strain on healthcare systems [5]. In colorectal surgery, organ/space SSI (O/S–SSI) triples LOS and is associated with a 23% rate of readmissions, 60% reoperations and 29% need for intensive care [6].

About half of SSIs are believed to be preventable [7,8], and epidemiological surveillance with feedback to providers has been shown to be an excellent means of reducing their rates [9–13], but SSI surveillance programs that dynamically include interventions may achieve superior results [14].

This nationwide pragmatic cohort study aims to determine the effectiveness of a national surveillance program in the SSI rate after elective colorectal surgery, both at the incisional and organ/space levels, and to investigate the impact of the interventions applied over a period of 12 years, mainly the implementation of a specific bundle of care.

#### 2. Material and methods

#### 2.1. Study design, setting and patients

Pragmatic cohort study analysing a SSI surveillance database from a national network. The VINCat Program performs prospective active surveillance of SSI in elective colorectal surgery in public and private hospitals in Catalonia, Spain [15]. The structure of the program is described in detail elsewhere [16] and on its website [17]. Sixty-one hospitals contributed cases in the analysis. The results of this quality improvement project, from 2008 to 2019, are analysed.

#### 2.2. Surveillance

Prospective surveillance was performed by the infection control team (ICT) of each hospital to ensure appropriate data collection. The standardized methodology of the program is described in Table 1. Elective wound class 2 and 3 cases were followed. Table 2 shows the inclusion and exclusion criteria for colorectal surgery. Participating hospitals recorded the data in an Internet-based database. At various times during the development of the program, audits of the data provided by the hospitals were carried out to ensure their accuracy.

Hospitals were classified according to number of hospital beds and complexity into three groups: (type 1) >500 beds; (type 2) 200–500 beds; (type 3)  $\leq$ 200 beds. The ICT staff performing surveillance had received training in the surveillance methodology to ensure the

#### Table 1

Methodology of colorectal surgery monitoring in the VINCat Program.

#### During hospitalization

- From the day of surgery until hospital discharge: active monitoring of surgical site infection signs by a periodic visit (every 2–3 days) and review of the following items:
- •Nursing clinical courses/oral information provided to doctors and nurses
- •Temperature chart of patient
- Antibiotic treatments
- Appropriate surgical wound condition

- Comprises a period of 30 days from the intervention. The post-discharge follow-up includes:
- •Control of readmissions (Required)
- •Control of the consultations at the Emergency Department (Required)
- •Review of outpatient clinical course of the surgical team (Required)

#### Table 2

Inclusion and exclusion criteria for colorectal surgery surveillance in the VINCat Program.

Inclusion criteria
--------------------

- Minimum of 100 procedures per year per hospital or continuous monitoring
- throughout the year for those centres that perform less than 100 procedures per year Exclusion criteria
- Peritonitis at the time of intervention (patients who underwent type 4 surgery are excluded)
- Patients who underwent multiple procedures during the same surgery, for example resection of liver metastases (until 2015)
- Centres that performed less than 10 surgical procedures annually

Centres that have not been able to ensure prospective surveillance during	
hospitalization or effective monitoring of cases within 30 days of the intervention	

collection of homogeneous, accurate data. Active mandatory postdischarge surveillance was performed up to day 30 post surgery by a multimodal approach including electronic review of clinical records (primary and secondary care), checking readmissions, checking emergency visits, and reviewing microbiological and radiological data.

A detailed operational definition document was generated and shared with all network hospitals [17]. The structure and process of SSI surveillance, as well as of SSI outcomes, were periodically validated through on site visits by two specifically trained investigators with full knowledge of the methodology.

#### 2.3. Interventions

The timeline of when interventions were carried out is shown in Fig. 1. In 2010, a specific interdisciplinary group, including specialists in infectious diseases, infection control personnel, and surgeons was created to oversee the colorectal surgery program. During the first 3 years of the program, data of colon and rectal surgery were aggregated, but from 2011, surveillance was separated for each type of surgery, colonic and rectal. Starting in June 2016, a 6-measure bundle of SSI preventative measures was voluntarily implemented by the participating hospitals. These measures are shown in Table 3.

#### 2.4. Study outcomes, variables, definitions and data source

The primary study end point was the development of an SSI within 30 days of operation, according to the Centres for Disease Control and Prevention (CDC) [18,19] definitions. SSI were defined as superficial incisional (S–SSI), deep incisional (D-SSI) or organ-space (O/S–SSI). SSI were stratified into categories of surgical procedures (-1 to 3) according to the risk of surgical infection defined by the NHSN. The incidence of SSI was measured as events per 100 included procedures. A modified NHSN standardized infection ratio (SIR) was also used to investigate the trends in the outcomes during the period of the study. SIR compares the actual number of SSI reported with the number that would be predicted, given the standard population and adjusting for several risk factors that have been found to be significantly associated with SSI incidence [20].

Secondary variables included reintervention, readmission, postoperative 30-day mortality, and length of hospital stay (LOS). Basic demographic data were recorded, along with the following information on patient comorbidities and surgical procedures: information on surgical procedures, including the American Society of Anesthesiologists (ASA) classification, whether adequate antibiotic prophylaxis was administered, duration of surgery, and bacterial aetiology of infections.

Participating hospitals with <10 cases per year were excluded from the analysis. Data on process and outcomes were collected locally and submitted on using a web-based form.

<sup>•</sup>Review of microbiology cultures and complementary radiological examinations Post-discharge surveillance

<sup>•</sup>Review of the radiological procedures and microbiological cultures (Required) •Phone control

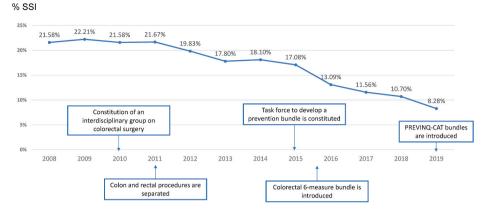


Fig. 1. Colorectal SSI and Organ/space-SSI rates during the surveillance period of the VINCat Program (2008-2019).

#### Table 3

Measures included in the VINCat colorectal bundle.

	Element	Comments
<i>✓</i>	Adequate antibiotic prophylaxis	Cefuroxime 1,5 g + Metronidazole 15 mg/kg or Gentamicin 5 mg/kg + Metronidazole 15 mg/ kg Start 30–60 min before incision. Full doses, adjusted for weight and kidney function. Redosification if blood loss >1500 ml or duration of surgery >2 times the half-life of the antibiotic. Preoperative single dose. Do not prolong prophylaxis with postoperative doses >24 h.
1	Mechanical bowel preparation	Day before the procedure
1	Oral antibiotic prophylaxis	Neomycin 1 g + Metronidazole 750 mg (3 doses) Day before the procedure
1	Laparoscopic surgery	, I
1	Maintenance of normothermia	Goal: ${>}36^\circ$ at the end of operation
1	Use of double-ring plastic wound edge retractor	In open or laparoscopic surgery

#### 2.5. Statistical analysis

Data were summarized as frequencies and proportions for categorical variables. For continuous variables, medians and interquartile range (IQR) or mean and standard deviation were presented. Infection rates were expressed as cumulative incidence, that is, the crude percentage of operations resulting in SSI/number of surgical procedures. Some analyses were stratified by year, risk index category, hospital group and SSI type. To describe the evolution of infection rates and mortality over years, we performed a Spearman correlation (rho).

To describe the relationship between two qualitative variables, contingency tables have been used. To characterize the infection, we performed a logistic regression model. The results are presented in terms of odds ratio (OR) or estimated infection rates, with the corresponding 95% confidence intervals (CI<sub>95</sub>).

As for overall SSI and O/S–SSI estimated SIRs, a logistic regression model was used to model the probability of acquiring an SSI and O/S SSI given some risk factors such as the hospital group, ASA score, procedure (colon or rectal), gender, 10-years increase, 10-min increase, adequate antibiotic prophylaxis or exposure to laparoscopy surgery. In order to estimate the expected number of SSI, the standard population selected for the model comes from the period 2008–2015. SIR 95% confidence intervals were calculated as from exact Poisson test.

The significance level was set at 0.05 in all tests. The results were

analysed using two statistical packages of software: SAS v9.4, SAS Institute Inc., Cary, NC, USA; and R-Gui v4.0.4, The R Foundation, Vienna, Austria.

#### 3. Ethical issues

The study was conducted by the VINCat colorectal coordination team as a performance improvement project. The need for informed consent and the provision of an information sheet were waived because data were routinely collected as part of hospitals surveillance and quality improvement. Anonymity and data confidentiality (access to records, data encryption, and archiving of information) were maintained throughout the research process. Patients' confidential information was protected in accordance with European regulations. Data extraction was approved by the Institutional Research Board with code 20166009, and the study was approved by the Clinical Research Ethics Committee of Hospital General de Granollers with code 2021006. The work has been reported in line with the STROCSS 2021 criteria [21].

The project was registered with the ClinicalTrials.gov Identifier: NCT04496635 (https://clinicaltrials.gov/ct2/show/NCT04496635), and at www.researchregistry.com, with Research Registry UIN: researchregistry7728 (https://www.researchregistry.com/browse-the-regist ry#home/registrationdetails/6229c003839239001e2e45f0/).

#### 4. Results

#### 4.1. Characteristics of patients and procedures

During the period 2008–2019, 42,330 elective colorectal procedures from 61 centres were recorded. The characteristics of the procedures included are described in Table 4. The use of laparoscopic technique increased from around 40% in the first half of the analysed period to 75% in the last half. Duration of surgery and ASA score, remained stable.

#### 4.2. Incidence of colorectal SSI rates and trends over time

Table 5 and Fig. 1 show the annual incidence of SSI in colorectal surgery. There were 6904 SSI, which represents a cumulative incidence of 16.31%. According to the space involved, 2439 (6.18%) infections were S–SSI, 1117 (2.83%) D-SSI, and 3336 (8.45%) O/S–SSI.

The surveillance and successive interventions were associated with a 61.63% relative decrease in SSI rates over the study period, from 21.58% in 2008 to 8.28% in 2019. In the three surgical spaces the SSI incidence significantly decreased, with Spearman rho = -0.95804 for overall SSI, and rho = -0.69930 for O/S–SSI (Figs. 2 and 3).

SSI was diagnosed at median postoperative day (POD) 8 (IQR 5–12). S–SSI occurred at a median POD 8 (6–13), D-SSI at a median POD 8 (6–13), and O/S–SSI at a median POD 7 (4–11).

Characteristics of the patients included in the colorectal surgery program (2008-2019)	ts included in	the colorectal	surgery progra	am (2008–2019	.(6								
	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Overall
Cases	2335	2720	2854	3309	3348	3467	3480	4039	4521	4557	4355	3345	42330
Participating hospitals													61
Hospital group 1	7	8	6	6	6	8	8	6	6	6	6	7	6
Hospital group 2	14	14	16	17	17	17	18	18	18	18	17	15	19
Hospital group 3	22	24	25	27	26	28	28	28	27	29	30	24	33
Age, years (SD)	69.04	69.24	69.14	68.79	68.77	68.90	69.29	68.60	67.85	68.36	68.73	69.07	68.75
	(12.52)	(12.16)	(12.15)	(12.38)	(12.36)	(12.22)	(12.07)	(12.76)	(12.44)	(12.26)	(12.39)	(12.68)	(12.38)
Sex, male/female (%)	1364	1624	1654	2009	2017	2073	2140	2464	2684	2732	2593	1997	25351
	(58.42%)	(59.71%)	(57.95%)	(60.71%)	(60.24%)	(20.79%)	(61.49%)	(61.01%)	(59.37%)	(20.95%)	(59.54%)	(26.70%)	(29.89%)
Adequate surgical	2161	2496	2627	2948	3005	2881	3001	3234	3636	3639	3640	2816	36084
prophylaxis (%)	(92.79%)	(92.07%)	(92.05%)	(89.17%)	(89.81%)	(86.31%)	(86.31%)	(80.09%)	(80.55%)	(79.94%)	(83.72%)	(84.41)	(85.37%)
Mean duration of	168.14	165.77	169.11	170.93	175.05	175.13	176.45	178.47	177.15	180.08	181.14	180.99	175.66
intervention, minutes (SD)	(71.42)	(69.86)	(68.34)	(74.87)	(77.16)	(74.02)	(75.55)	(78.42)	(77.03)	(77.29)	(74.57)	(74.85)	(75.08)
ASA score $>1$ (%)	2187	2516	2657	3123	3165	3274	3282	3785	4264	4256	4118	3176	39803
	(94.27%)	(93.12%)	(93.20%)	(94.52%)	(94.56%)	(94.62)	(94.45%)	(93.90%)	(94.50%)	(94.24%)	(95.35%)	(95.58%)	(94.41%)
Laparoscopy (%)	783	1064	1265	1610	1803	2045	2176	2546	3014	3281	3331	2609	25527
	(38.51%)	(40.77%)	(44.91%)	(48.88%)	(54.03%)	(59.16%)	(62.67%)	(63.29%)	(%66.99%)	(72.44%)	(76.79)	(78.32%)	(61.16%)
NNISS $\geq 1$ (%)	1111	1142	1180	1315	1155	1168	1106	1300	1308	1187	1109	884	13965
	(47.58%)	(41.99%)	(41.35%)	(39.74%)	(34.50%)	(33.69%)	(31.78%)	(32.19%)	(28.93%)	(26.05%)	(25.46%)	(26.43%)	(32.99%)
ASA: physical status classification score; NNISS: National Nosocomial Infection Surveillance System risk index; SD: standard deviation; SSI: surgical site infection.	ation score; N	VNISS: Nations	ul Nosocomial I	Infection Surve	illance System	risk index; SL	): standard dev	riation; SSI: su	rgical site infe	ction.			

6904 (16.31%) 2439 (6.18%) 1117 (2.83%) 3336 (8.59%) Overall 277 (8.28%) 87 (2.81%) 32 (1.03) 2019 466 (10.70%) 136 (3.36%) 50 (1.23%) 2018 527 (11.56%) 181 (4.25%) 81 (1.90%) 2017 (13.09%) 192 (4.52%) 81 (1.91%) 2016 592 690 (17.08%) 215 (5.70%) 106 (2.81%) 2015 630 (18.10%) 221 (6.73%) 105 (3.20%) 2014 (17.80%) 187 (5.51%) 94 (2.77%) 2013 617 664 (19.83%) 226 (7.20%) 125 (3.98%) 2012 717 (21.67%) 260 (8.66%) 136 (4.53%) 2011 Overall colorectal SSI rates during the surveillance period (2008-2019). 616 (21.58%) 260 (10.06%) 109 (4.22%) 2010 604 (22.21%) 260 (10.39%) 89 (3.56) 2009 504 (21.58%) 214 (9.92%) 109 (5.05%) 2008 SSI deep incisional (%) incisional (%) SSI superficial (%) ISS Table 5

4

Table 4

158 (5.10)

278 (6.87%)

263 (6.17%)

318 (7.48%)

369 (9.79%)

304 (9.26%)

334 (9.84%)

312 (9.94%)

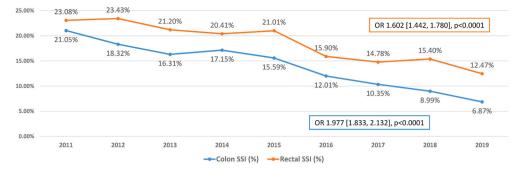
320 (10.65%)

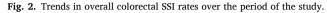
245 (9.48%)

254 (10.15%)

181 (8.39%)

Organ/space (%)





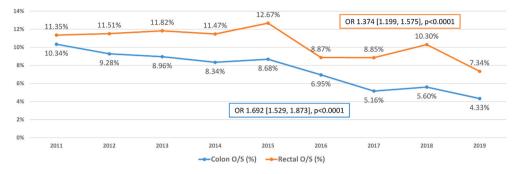


Fig. 3. Trends in colorectal O/S-SSI rates over the period of the study.

SSI was detected during the first admission in 5020 (72.77%) of cases and at post-discharge surveillance in 1878 patients (27.22%), 1012 of which (53.9%) required readmission. 2.71% of cases were diagnosed more than 30 days after surgery.

Colon and rectal data were segregated from 2011, and comprised 34,421 cases: 24,718 of them colon surgeries, and 9703 rectal surgeries. All three types of SSI fell significantly in both colon and rectal surgery during the study period (Figs. 2 and 3).

The single intervention which achieved the highest reduction in SSI rate was the introduction of a preventative bundle, which was associated with a 23% decrease during the first year of its implementation. The SSI rate before the bundle implementation (2008–2015) was 18.81%,

compared to 11.10% in the bundle period (2016–2019) (OR 1.855;  $\rm CI_{95}$  1.745–1.973; p<0.0001). For O/S–SSI, rates were 9.80% and 6.50%, respectively (OR 1.579;  $\rm CI_{95}$  1.455–1.713; p<0.0001).

#### 4.3. Trends in the standardized infection ratio

Fig. 4 shows the predicted and observed values for overall SSI and the trend in SIR over the period of the study. A significant decrease was observed, with Spearman rho = -0.951049. SIR for O/S–SSI also diminished over time, with rho = -0.6923077 (Fig. 5). A similar decrease in SIR was seen when the results of colon and rectal surgery were separated (Figs. 6 and 7).

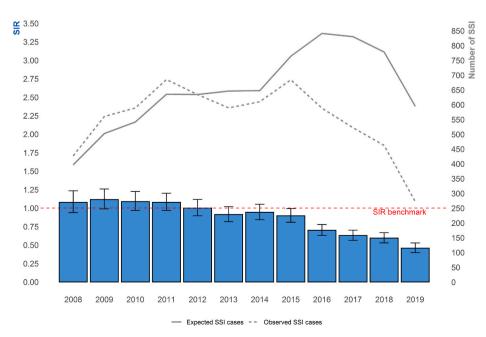


Fig. 4. Trends in the colorectal overall Standardized Infection Ratio (SIR).

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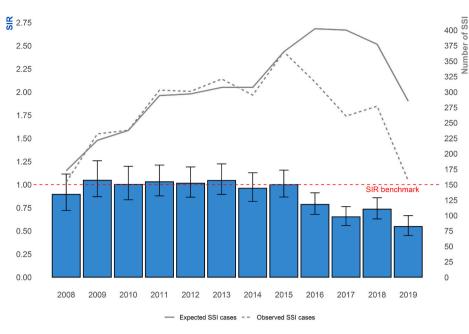


Fig. 5. Trends in the colorectal organ/space Standardized Infection Ratio (SIR).

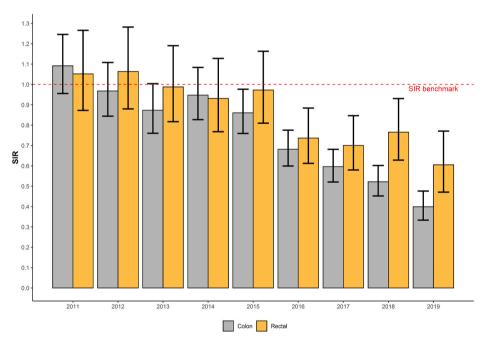


Fig. 6. Overall Standardized Infection Ratio (SIR) for colon and rectal surgery.

#### 4.4. Risk factors for SSI in colorectal surgery

The risk factors for developing an SSI, both when using univariate or multivariate logistic regression analysis were: age of the patient; male sex; duration of the intervention; ASA score >1; and a NNIS score >1; while laparoscopy had a protective effect (Table 6).

#### 4.5. Risk factors associated with O/S-SSI in colorectal surgery

Similarly, the risk factors to develop an O/S–SSI at the univariate analysis were: increasing age of the patient; male sex; duration of the intervention; ASA score>1; no use of laparoscopic surgery; and NNIS score >1. The multivariate logistic regression analysis showed that male sex, ASA score >1, length of surgery, no use of laparoscopy and NNIS

score >1 were statistically significant risk factors for overall SSI (Table 6).

#### 4.6. Incidence of SSI according to size of hospital

Fig. 8 shows the overall colorectal SSI rate distribution and odds ratio according to hospital size. Significant differences by hospital type were found, but a homogeneous decrease in overall SSI was also observed in all three types of institutions.

O/S–SSI rates also show significant differences, with the highest in type 1 hospitals (9.19%). Only type 2 hospitals showed a significant decrease over time. The decrease in incisional SSI was significant and similar among the three hospital groups during the period studied. However, there was a high variability in SSI rates within each hospital

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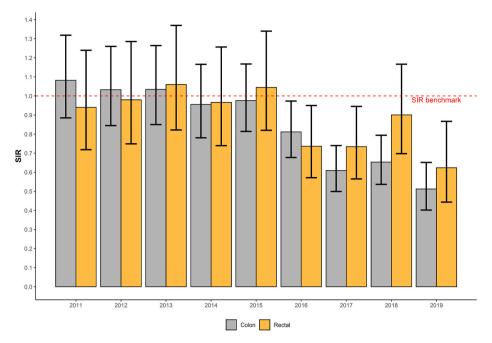


Fig. 7. Organ/space Standardized Infection Ratio (SIR) for colon and rectal surgery.

Table 6
Risk factors for SSI and O/S SSI in colorectal surgery.

		SSI		O/S SSI	
		OR [95% CI]	р	OR [95% CI]	р
Univariate	Age	1007 [1.004,1.009]	< 0.0001	1.004 [1.001,1.007]	0.0036
	Sex (male)	1.463 [1.385,1.545]	< 0.0001	1.662 [1.539,1.796]	< 0.0001
	Adequate antibiotic prophylaxis	1		1.045 [0.943,1.159]	0.4009
	Duration	1.003 [1.003,1.003]	< 0.0001	1.003 [1.003,1.003]	< 0.0001
	ASA >1	1.430 [1.261,1.623]	< 0.0001	1.407 [1.179,1.678]	0.0001
	Laparoscopy	0.558 [0.530,0.588]	< 0.0001	0.749 [0.696,0.804]	< 0.0001
	NNISS >1	1.884 [1.787,1.985]	< 0.0001	1.603 [1.492,1.722]	< 0.0001
Multivariate	Age	1.004 [1.002,1.007]	0.0004	1.003 [0.999,1.006]	0.1088
	Sex (male)	1.368 [1.292,1.448]	< 0.0001	1.573 [1.452,1.704]	< 0.0001
	Adequate antibiotic prophylaxis	0.989 [0.915,1.070]	0.7870	1.035 [0.932,1.149]	0.5217
	Duration	1.003 [1.003,1.003]	< 0.0001	1.003 [1.002,1.003]	< 0.0001
	ASA >1	1.195 [1.045,1.367]	0.0092	1.230 [1.022,1.481]	0.0287
	Laparoscopy	0.598 [0.560,0.638]	< 0.0001	0.814 [0.745,0.817]	< 0.000
	NNISS >1	1.212 [1.130,1.299]	< 0.0001	1.221 [1.110,1.342]	< 0.0001

OR: odds ratio; 95% CI: 95% Wald Confidence limits; ASA: American Society of Anesthesiology physical status classification score; O/S: Organ space; NNISS: National Nosocomial Infection Surveillance System risk index; SSI: Surgical site infection.

<sup>1</sup> No modelling is performed since the percentage of adequate and inadequate antibiotic prophylaxis is the same whether or not there is a SSI.

group throughout all the period of surveillance, with differences of up to 25 points in cumulative incidence rates among hospitals.

#### 4.7. Pathogens detected in SSI

An etiological diagnosis was achieved in 5456 patients with SSI (79.03%), and 53 different organisms were detected (Table 7). When comparing the flora of the incisional space (including S–SSI and D-SSI) and the O/S–SSI, a significant difference in the spectrum of pathogens was found. In O/S–SSI, there was a significantly higher isolation of *Enterococcus faecalis, Enterococcus faecium, Enterococcus* spp., *Klebsiella* spp., *Clostridium* spp. and Candida spp. (Table 7).

#### 4.8. Outcomes of patients

Median postoperative LOS for the whole group was 7 days (IQR 5–11), and a significant decrease was noted, with Spearman rho = -0.98414, ranging from 19 days in 2008 to 6 days in 2019. Median LOS

was significantly higher when SSI was diagnosed (7 vs 15 days, p> 0.001). Patients with O/S–SSI had a LOS of 20 days (IQR 12–30), almost double that of those with incisional SSI (p< 0.001).

Mortality of the series is 1.08%, ranging from 0.35% to 2.0%. A highly significant decrease in mortality was observed over the years (Spearman rho = -0.67133).

#### 5. Discussion

This large multicentre cohort study found a significant reduction in the incidence of SSI and other adverse outcomes in elective colorectal surgery over a surveillance period of twelve years.

Surveillance programs with feed-back of results to providers are the cornerstone of infection prevention and are associated with a decrease in SSI rates by themselves. However, it has been demonstrated that specific interventions, modifying and complementing the programs, can further improve results [22,23].

This national surveillance project became progressively



Fig. 8. Distribution of overall SSI rates and odds ratio according to hospital size.

 Table 7

 Actiology of Incisional (I–SSI) and organ/space (O/S–SSI) surgical site infection.

Isolates	Overall (N = 6497)	Incisional SSI (N = 3384	Organ/space SSI (N = 3113)	P-value
Gram-positive	2086	1103 (32.6%)	983 (31.6%)	0.3803
bacteria	(32.1%)			
Enterococcus faecalis	689 (10.6%)	329 (9.7%)	360 (11.6%)	0.0160
Enterococcus faecium	416 (6.4%)	118 (3.5%)	298 (9.6%)	<.0001
Enterococcus spp.	92 (1.4%)	32 (1.0%)	60 (1.9%)	0.0008
SARM	58 (0.9%)	42 (1.2%)	16 (0.5%)	0.0019
others	831 (12.8%)	582 (17.2%)	249 (8.0%)	<.0001
Gram-negative	3942	2075 (61.3%)	1867 (60.0%)	0.2680
bacteria	(60.7%)			
Escherichia coli	2285 (35.2%)	1206 (35.6%)	1079 (34.7%)	0.4099
Klebsiella spp.	336 (5.2%)	145 (4.3%)	191 (6.1%)	0.0008
Pseudomonas spp.	484 (7.4%)	255 (7.5%)	229 (7.4%)	0.7834
Enterobacter spp.	293 (4.5%)	153 (4.5%)	140 (4.5%)	0.9628
others	544 (8.4%)	316 (9.3%)	228 (7.3%)	0.0034
Anaerobes	325 (5.0%)	177 (5.2%)	148 (4.8%)	0.3790
Clostridium spp.	37 (0.6%)	11 (0.3%)	26 (0.8%)	0.0063
Bacteroides spp.	288 (4.4 5)	166 (4.9%)	122 (3.9%)	0.0536
Yeasts	144 (2.2%)	29 (0.9%)	115 (3.7%)	<.0001
Candida albicans	144	29 (0.9%)	115 (3.7%)	<.0001

Incisional surgical site infection includes Superficial and Deep SSI.

interventional and introduced adjustments to increase its efficacy. Accordingly, the goals of this study were to determine the effectiveness of the program, and its main modifications, on the evolution of postoperative infection in colorectal surgery.

We have observed a significant decrease in SSI rates, both in colon and rectal surgery, in all the three surgical spaces and in all types of institutions belonging to the network. Our findings validate the important role that surveillance plays in adding epidemiological context when deciding clinical interventions and are aligned with the outcomes of other published national surveillance programs [10,24–26]. Surveillance activities by and of themselves reduce the tendency of HAIs [26], although in most of the studies it is difficult to disentangle the "surveillance effect" from the result of implementing specific interventions [10]. In our case, the surveillance effect seemed to somehow have faded after the first years of the program, but the decline in SSI rates resumed following the introduction of successive interventions, as has been found in other published experiences [14]. As the Standardized Infection Ratio has been advocated as the best statistic available for risk-adjustment purposes in infection control [27], we also used it for comparison. SIR can track Healthcare-Associated Infections (HAIs) at a local level and adjusts for patients of varying risk over time. Consequently, it has become the new standard for comparing HAI incidence. In our study, the trends in SIR over time parallel those of SSI rates and confirm the beneficial results of the program.

Apart from the specific interventions implemented by the program, some other improvements in healthcare practices may have occurred over the period studied, independently of the surveillance activity, and are likely to have contributed to lowering infection rates over time. Among them, the introduction of the laparoscopic technique in colorectal surgery stands out. It has previously been reported that laparoscopy reduces overall and incisional SSI, but has no impact on O/S-SSI [28–30]. In contrast, as in a previous publication [30], we found the progressive introduction of laparoscopy operated as a significant protective factor not only for overall and incisional SSI, but also for O/S-SSI, although to a lesser extent. This could be related to a progressive reduction (by 12%) in the number of hospitals authorized to perform complex rectal procedures, as this concentration of centres providing rectal surgery coincided with the period of this study. It could be argued that the improvement in O/S-SSI rates we have observed is to some extent the result of these high-performance surgical teams making better use of laparoscopy in rectal surgery, in turn leading to less anastomotic leakage.

Throughout the years studied, we have seen a slight increase in the duration of the interventions, which has been counterbalanced in the calculation of the NNIS index by the significant increase in the use of laparoscopic surgery. Despite this, from 2008 to 2015 there were no significant changes in the annual rates of SSI, which was around 21%. Only from 2016, with the implementation of the SSI prevention care bundle, did SSI rates start to decrease significantly. As shown by other authors, the implementation of a specific colorectal bundle of preventative measures has been the single intervention with the most significant impact on SSI rates [31–36]. Other outcomes, such as PLOS and mortality also decreased during the period studied and were probably associated with the decrease in the infection rate.

Several risk factors for SSI have been identified, among which stand out sex, ASA score, length of surgery, and NNIS score, both for SSI and O/S–SSI. This is similar to other authors' findings [30,37]. However, it has been pointed out that data-based risk models commonly used in colorectal surgery surveillance networks may not be useful in predicting individual risk of SSI [38,39], and that new models including other variables should be developed.

It may be surprising that systemic antibiotic prophylaxis was not shown to be a protective factor for SSI in our series. This may be explained by the fact that we only considered properly administered prophylaxis for the analysis. The criteria used to consider antibiotic prophylaxis "adequate" were very strict and took into account: the type of drug, the dose administered, the timing of infusion, its completion before the surgical incision, and the duration of therapy. Although prophylaxis was recorded and performed in all patients, a single deviation from the recommended guidelines was enough to consider the process inadequate. It is possible that these slight deviations from the protocol were not critically important when it came to protecting, or not, the patient from SSI, and this could explain the lack of statistical differences when comparing the groups of adequate and inadequate prophylaxis, since each group received the antimicrobials in all cases.

Differences have been detected in the infecting flora of the O/S–SSI and the incisional SSI (including the superficial-SSI and the deep SSI), with a greater isolation of *Enterococcus* spp., *Klebsiella* spp and *Candida albicans* in the former.

The differences in SSI rates according to the type of centre are noteworthy, and especially the remarkable variability within groups of hospitals with similar characteristics, a fact rarely discussed in the literature. Periodic validation of data by trained investigators, as suggested by other authors [40] did not demonstrate inter-hospital differences in the surveillance method.

Perhaps the main contribution of our findings is that a healthcare "situational awareness" network is effective, but has its limits, and that the implementation of specific interventions can significantly enhance results. This would support the idea of surveillance as a first step before action. In this sense, infection surveillance offers real-time information about the local, regional and national incidence of disease, and has the potential to guide decision-making by implementing specific preventative interventions.

Our finding that surveillance combined with the implementation of minor interventions was not producing significant improvement in outcomes, led in 2016 to plan a more vigorous intervention with the design of a package of specific colorectal SSI prevention measures. Within this 6-measure bundle, we consider the reintroduction of mechanical bowel preparation and oral antibiotic prophylaxis, which had been discontinued in recent decades in most Spanish hospitals, as having had the greatest impact on the subsequent reduction in SSI.

Limitations and strengths of the study. This work has several limitations. Firstly, due to its extension over time, the results may contain various changes in the national healthcare system. Secondly, as in other national databases, the number of variables collected was restricted, and some factors such as body mass index, smoking and diabetes were not evaluated. Finally, self-reported data can contain several potential sources of bias, although several validation activities were implemented to limit this factor. Our study has also several strengths. It draws on a large population and a high number of cases followed under a consolidated reporting method. Although the program relies on voluntary adherence of hospitals, all public hospitals in the region and some private centres are included. We think that the inclusion of different types and sizes of hospitals can make the results generalizable to other settings.

In our opinion, the key to the success of an infection surveillance network is the multidisciplinary approach, in which a great variety of specialties are involved with the same objective. In our case, the collaboration of infection control teams, infectious disease specialists, microbiologists, and preventive medicine physicians, together with the perioperative nursing teams and colorectal surgeons has been fundamental for the development of the surveillance program and the design of the interventions that have been shown to be successful.

Finally, despite the good results of current SSI surveillance systems, the era of manual surveillance of postoperative infections has probably come to an end. At present, the vast quantity of data in electronic health records provides an opportunity to implement change and enhance surveillance both in terms of quality and costs. Automated surveillance based on classification algorithms will probably replace current programs based in manual review [41,42], and will fully accomplish SSI detection, or, in the case of semi-automated surveillance, will preselect high-risk patients for manual review [43,44].

#### 6. Conclusions

Awareness and detailed analysis of postoperative infection rates in colorectal surgery allows strategies for preventing and reducing SSI incidence to be designed. An interventional surveillance program resulted in a significant reduction in SIR and SSI rates for colorectal surgery over a period of twelve years.

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#### Provenance and peer review

Not commissioned, externally peer-reviewed.

#### Data statement

The research data is prospectively registered and belongs to the Nosocomial Infection Surveillance System in Catalonia (VINCat), a program from the Catalan Health Service, Department of Health, Generalitat de Catalunya. Anonymous data extraction was approved by the Institutional Research Board of the VINCat.

All data will be made available on request.

#### **Ethical approval**

Data extraction was approved by the Institutional Research Board with code 20166009, and the study was approved by the Clinical Research Ethics Committee of Hospital General de Granollers with code 2021006.

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#### Author contribution

Study conception and design: M Pujol, E Limon, J López-Contreras, JM Badia, N Arroyo. Methodology: A Vazquez, A Almendral, E Limon, JM Badia; Acquisition of data: E Limon, M Píriz, C Diez; Analysis and interpretation of data: A Vazquez, A Almendral, E Limon, JM Badia, N Arroyo. Drafting of manuscript: N Arroyo, JM Badia.Critical revision of manuscript: JM Badia, M Pujol, J López-Contreras, N Arroyo, D Parés, M Pera, M Piriz, C Diez, D Fraccalvieri, A Vazquez, A Almendral.

#### Research registration Unique Identifying number (UIN)

- 1. Name of the registry: ClinicalTrials.gov
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- Hyperlink to your specific registration (must be publicly accessible and will be checked): https://clinicaltrials.gov/ct2/show/NC T04496635

#### Guarantor

#### Guarantor: JM Badia.

#### Declaration of competing interest

- 1. Nares Arroyo-Garcia report no conflicts of interest relevant to this article
- 2. Josep M Badia report no conflicts of interest relevant to this article
- 3. Ana Vázquez report no conflicts of interest relevant to this article
- 4. Miguel Pera report no conflicts of interest relevant to this article
- 5. David Parés report no conflicts of interest relevant to this article
- 6. Enric Limón report no conflicts of interest relevant to this article
- 7. Alexander Almendral report no conflicts of interest relevant to this article
- 8. Marta Piriz report no conflicts of interest relevant to this article
- 9. Cecilia Diez report no conflicts of interest relevant to this article
- 10 Domenico Fraccalvieri report no conflicts of interest relevant to this article
- 11 Joaquín López-Contreras report no conflicts of interest relevant to this article
- 12. Miquel Pujol report no conflicts of interest relevant to this article

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#### Appendix A. Supplementary data

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