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SSIs in Italy: Prevention and Surveillance during the Last Five Years

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Abstract

Surgical site infections (SSIs) are recognized as a common surgical complication, occurring in about 2% - 5% of all surgical procedures. For this reason, it is the second most common nosocomial infection, representing the 19.6% of all infections observed in hospitalized patients and 38% of those observed among surgical patients. Among SSIs prevention strategies, surveillance has been proved to be very incisive. The most recent surveillance study carried out at a national level in Italy is SNICh protocol (National Surveillance System of Surgical Site Infections), which analyses data received from 127 Italian hospitals, from the 2009 to 2011 and the entire 2013. The only application of a surveillance strategy, observing the recommended prophylaxis protocols, brought to a reduction of SSIs: their incidence has been shown to be comparable to European or American one. Furthermore, recent studies have brought strong evidence that the development of new devices, such as dressings impregnated with silver nanoparticles or triclosan-coated sutures, is strongly connected with the reduction of incidence of SSIs. In conclusion, if common preventive techniques were applied to all surgical procedures performed in the country, about 14,000 SSIs per year could be avoided with a possible savings after three years between 50 million and EUR 175 million euro.

Keywords

Surgical Site Infections (SSIs), General Surgery, Infections, Antibiotic Prophylaxis, Prevention, Surveillance

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1. Introduction

Over the last 30 years the medicine is facing a new challenge: reducing of healthcare-associated infections (HAIs), which include surgical site infections (SSIs); this definition was introduced into medicine literature in 1992 to replace the previous "infection of the surgical wound" [1].

According to CDC and NHSN a SSI to be considered as such, must have some characteristics reported in **Table 1** [2].

As can be seen SSIs are classified in incisional and organ-space infections; the former can be superficial if only skin and subcutaneous tissue of the incision are involved, or deep when they involve fascial and/or muscle layers.

Organ-space infections occur in any anatomical site that has been opened or manipulated during surgery.

Through this review we want to show how techniques of prevention, control and treatment of SSIs have changed over the years both in Italy and in Europe, stressing the importance of these infections on economic and clinical budget.

2. Wound and Intervention Classification

Before to talk about SSI epidemiology, it is necessary to introduce the classification of interventions and wounds, **Table 2** [3].

This classification, only based on the grade of contamination during surgical procedure, has been improved from the National Nosocomial Infections Surveillance System (NNISS), adding two more important parameters:
- Clinical conditions (measured with ASA score).
- Surgical procedure duration (if >3 hours it is considered at a major rick of intraoperative contamination).
- The age of the patient [3].

In the case of long lasting surgical procedures, many guidelines suggest the use of an intra-operative dose, if the operation is still in course after a period equal to the doubles of the antibiotic half-life time. In order of the possible contaminating factor occurring during surgical intervention, it should be added a long list of risk factors for the infection of the surgical wound and for the post-operative infection usually connected to the patient and/or the hospital environment.

3. Epidemiology

The epidemiology of SSI is very difficult to establish because of their highly heterogeneous nature, moreover their incidence not only depend on type of surgical procedure but also on hospital, patient and surgeon.

In 2010, an estimated 16 million operative procedures were performed in acute care hospitals in the United States [4] and an American recent prevalence study found that SSIs were the most common healthcare-associated

Table 1. Main characteristic of each SSIs type according to CDC/NHSN [2].

	Superficial incisional surgical site infection (SIP/SIS)	Deep incisional surgical site infection (DIP/DIS)	Organ/space surgical site infection
Time of occurrence	Within 30 days after the operative procedure	Within 30 days after the operative procedure if no implant is left in place. Within 1 year if implant is in place	Within 30 days after the operative procedure if no implant is left in place. Within 1 year if implant is in place
Anatomic area involved	Only skin and subcutaneous tissue of the incision	Deep soft tissues (e.g. fascial and muscle layers) of the incision	Any part of the body that is opened or manipulated during the operative procedure (excluding skin incision, fascia or muscle layers)
Medical findings of infection	Purulent drainage from the superficial incision Organism isolated from an aseptically obtained culture of fluid or tissue from the superficial incision	Purulent drainage from the superficial incision (but not from the organ/space component of the surgical site) A deep incision spontaneously dehisces or is deliberately opened by surgeon and is culture-positive.	Purulent drainage from a drain that is placed through a stab wound into the organ/space Organism isolated from an aseptically obtained culture of fluid or tissue in the organ/space
Other signs and symptoms (at least 1)	Pain or tenderness Localized swelling Redness or heat	Fever (>38˚C) Localized pain or tenderness Abscess or other evidence of infection involving the deep incision	Abscess or other evidence of infection involving the organ/space

Table 2. Classification of wounds and intervention according NNISS [3].

	Infection percentage	Description	Antibiotic prophylaxis
Clean (I)	1.5% - 4.2%	Usually non traumatic. It presume that respiratory, genitourinary and digestive tract are not opened and the lack of technical mistakes.	Not necessary, except for the presence of risk factors and comorbidities.
Clean-contaminated (II)	<10%	Surgical procedures in which there is the opening of respiratory, genitourinary and digestive tract in the absence of an evident contamination, or the opening of the oropharynx, genitor-urinary tract or biliary tract, unless clearly infected. It is also included in this category also any minor technical mistake.	Recommended.
Contaminated (III)	10% - 20%	Procedures following a frank contamination of gastrointestinal tract or after the opening of genitor-urinary or biliary tract with the presence of urine or infected bile. It is also included in this category also any major technical mistake.	Necessary (wide spectrum).
Dirty (IV)	20% - 40%	Procedures with a frank contamination, clinical infection in course, visceral perforation, purulent collections.	The usage of antibiotics is necessary for healing a pre-existing infections.

infection, accounting for 31% of all HAIs among hospitalized patients [5]; the CDC found that there were about 157,500 surgical site infections associated with surgeries in 2011 [6].

In Europe, according to ECDC's annual report, from 2011 to 2012 were reported 15000 HAIs, among which the most frequently were respiratory tract infections (23.5%), surgical site infections (19.6%), urinary tract infections (19.0%), bloodstream infections (10.7%), and gastro-intestinal infections (7.7%) [7].

During last years, some European studies have pointed out the reduction of SSIs' incidence due to the increase of mini-invasive surgery procedures, indeed patients who underwent open cholecystectomy has a greater chance of SSIs compared to those who underwent laparoscopic cholecystectomy (4% vs 1.1%). Similarly, in patients with acute appendicitis the laparoscopic surgery granted a lower infection's rate in comparison to open surgery (2% vs 8%) [8]-[10].

These results are compatible with all features of mini-invasive surgery such as: small surgical site incisions, early patient discharge, reduction of post-surgical pain, preservation of immune system and the absence of a central venous catheter [8].

Overall, the incidence of SSI was significantly lower in laparoscopic (0.5%) than in open (1.8%) surgery ($p < 0.01$) [11]-[14].

4. Clinical and Economic Burden

The economic impact of SSIs on the health care system's budget is remarkable: for each patient with an SSI is frequently required a rehospitalisation or a hospitalisation in the intensive care unit (ICU) so they are known to be associated with increased length of stay (LOS) and additional cost.

An English study, performed at Derriford Hospital between April 2010 and March 2012, has analysed 14300 surgical procedures and 282 related SSIs (98% - 34.8%—were deep or organ-space and 184% - 65.2%—were superficial infections) [15].

The results show that the median additional LOS attributable to SSI for all surgical categories over the two-year period was 10 days (95% Confidence Interval—CI: 7 - 13 days). In patients who developed a superficial or deep or organ space SSI postoperative LOS was significantly increased to 17 days (95% CI: 13 - 18 days) and 24 days (95% CI: 21 - 29 days) respectively compared with 5 days for those who did not develop an infection ($p < 0.01$); while the median additional postoperative LOS attributable to superficial SSIs and deep or organ space SSIs was 8 days (95% CI: 7 - 11.5 days) and 15 days (95% CI: 11 - 22 days) respectively [15].

Over this two-year period, a total of 4694 bed-days were lost by the hospital due SSIs (equivalent to 6.4 beds per day) and the median additional cost attributable to SSI for all surgical categories was £5,239 (95% CI: 4.622 - 6.719), for a total of £2,491,424 [15].

In France, during 2010, was estimated that 3% of surgical procedures performed resulted in infection, for a total annual cost of €57,892,715 and, moreover, patients who experienced a SSI had a significantly increased mortality risk (from fourfold to fifteen-fold) and an increased length of hospital stay (threefold) [16] [17].

5. Prevention Strategies

Among all strategies to adopt for the prevention of SSI, surveillance and data reporting can effectively reduce the risk of infections.

The surveillance of nosocomial infection is conducted through the collection, the analysis and the interpretation of data, which follow the implementation of preventive actions and the evaluation of effectiveness of the measures applied.

It is necessary to understand that HAIs are not an indispensable result of healthcare assistance: a well-organized surveillance & intervention system can substantially reduce the incidence of these problems and should be established in each hospital without considering economical, regulatory and organisational aspects [18] [19].

In order to prevent SSIs is important to follow a list of actions during all phases of hospitalization and surgery; recommendations of RCSI are listed and summarized in **Table 3** [20].

The operating room represent a control point that, if carefully analysed, can greatly reduce the risk of infections; furthermore many recent studies showed that new single-use materials and more efficient sterilization methods are important features in SSIs' prevention.

Table 3. Key recommendations for practice in order to prevent surgical site infections [20].

Type of prevention	Time of implementation	Grade of evidence
Avoid hair removal at the surgical site. If hair must be removed use single-patient clippers and not razors.	Preoperative phase	1A[2]
Wash the patient or ensure that has showered on day of or day before surgery.	Preoperative phase	1B[3]
Use the right drug, at the right time and for the right duration for antibiotic prophylaxis[1].	Preoperative phase	1A[2]
Use 2% chlorhexidine gluconate in 70% isopropyl alcohol solution for skin preparation.	Intraoperative phase	1A[2]
Patient's body temperature should be maintained above 36˚C during the perioperative period.	Intraoperative phase	1A[2]
Patient's haemoglobin saturation should be maintained above 95% (or as high as possible).	Intraoperative phase	1B[3]
In diabetic patient the glucose level should be kept at <200 mg/dl throughout the operation.	Intraoperative phase	1B[3]
Give one additional antibiotic dose if the surgical procedure lasts more than 4 hours or there is major intra-operative blood loss (>1.5 litres).	Intraoperative phase	1A[2]
Cover the surgical site with a sterile wound dressing before to remove drapes at the end of surgery.	Intraoperative phase	1A[2]
Do not tamper with or remove the wound dressing for 48 hours post-op, unless clinically indicated.	Postoperative phase	II
Use aseptic technique for surgical site inspection and/or wound dressing changes.	Postoperative phase	1A[2]
Hand hygiene is mandatory before and after every time the wound is inspected or the dressing is changed.	Postoperative phase	1B[3]

[1]Antibiotic prophylaxis should be prescribed according to local antimicrobial guidelines and it must be given at induction of anaesthesia, or otherwise within 60 minutes before skin incision, in single dose. [2]"Grade of evidence 1A" means this statement is a strong recommendation in which benefits clearly outweigh risk and burdens and there is a consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. [3]"Grade of evidence 1B" means this statement is a strong recommendation in which benefits clearly outweigh risk and burdens but evidence was proofed by randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate.

In this regard some studies have pointed out that an alcohol-chlorhexidine solution, used for preoperative disinfection of the skin, is more effective in reducing SSIs than the "classic" povidone-iodine solution [21] [22].

Another key feature is the role of hand hygiene in HAI prevention: in fact healthcare workers' hand are the most common vehicle for the transmission of pathogens from patient to patient and within the environment. The use of posters, focus groups, hand hygiene observation and alcohol-based rub introduction have lead to a significant reduction in HAIs' incidence (4.1 vs 1.2; $p < 0.009$) [23] [24].

Even though during last years was not yet proofed the role of triclosan-coated sutures (Vycril® Plus) in prevention of surgical-site infection [25]-[27], a recent French meta-analysis has demonstrated that the use of these sutures reduced the incidence of SSIs after clean, clean-contaminated and contaminated surgery with a strong grade of evidence (level 1a) [28].

6. First Italian Report: From 2009 to 2011

The first multicentre Italian surveillance study is performed by our national healthcare system (SSN) and contains surveillance data collected from 355 surgical wards in 12 Italian regions.

Although data from different hospitals can be different due to factors such as techniques and patient's characteristics, benchmarking SSI incidence between surgical wards and over time may allow identification of areas for targeted intervention and may help to better allocate resources.

Were considered 83,127 operations from 2009 to 2011 but the final number of operations for the study was 60,460 because procedures involving implants of prosthetic material were not considered due to the very different length of post-intervention follow-up that is required (one-year vs one month); moreover for 54,240 of these (89.7%) there was no missing information. Main characteristics of the operations recorded by this study were reported in **Table 4** [29].

Along with the diagnosis of surgical site infections, made by doctors or nurses during the hospitalization or in follow-up (up to 30 days after discharge), were also collected other data in order to calculate the SSI risk index such as: wound classification, ASA score and duration of intervention [29].

Were reported 1628 SSIs (2.6%) among which 544 were either deep incisional or organ/space (33% of SSIs rate) and the over 90% of them were diagnosed by day 22 from discharge.

This first analysis of the Italian SSI surveillance system had two main results:

1) SSIs occurred at a lower rate for operations performed in hospitals that participate regularly to the surveillance;

2) the total number of surgical procedures surveyed doubled over the study period.

At the same time were confirmed some of the risk factors already known to be associated with an increased or reduced risk of SSIs, also for the Italian population: longer intervention duration, an ASA score of at least three and pre-surgery hospital stay of at least two days were found to be associated with an increased risk of SSI; on the other hand, laparoscopic procedures were associated with a reduction of SSIs rate [11]-[14] [29].

Despite these results were also pointed out some limitations to this study:

- Although all physicians used the same definition throughout the country, it is possible that the clinical diagnosis varied between hospitals and even between wards of the same facility.
- Low representativeness both of all surgical procedures in our national program and the entire national healthcare systems participated in the surveillance program, indeed only 12 Italian regions sent surveillance data.
- Finally, interventions including a prosthetic implant were excluded in order of the difference in follow-up that is needed in this kind of infection.

At the end, if common preventive techniques were applied to all surgical procedures performed in the country, about 14,000 SSIs per year could be avoided with a possible savings after three years between 50 million and 175 million euro [29].

7. The Last Italian Surveillance Report: 2013

The most recent multicentre Italian study about SSIs was performed by SNICh (National Surveillance System of Surgical Site Infections), and analysed data received from 127 Italian hospitals (indexed according to NHSH operative procedure categories); conducted throughout 2013, it considered 67,502 non-orthopaedic surgeries [30].

Table 4. Main characteristics of the operations recorded in the SNICh programme (2009-2011), [29].

	Operations n (%)	Infections n (rate per 100 procedures)
Duration of operation		
Under the 75th percentile	48,438 (80%)	1108 (2.3%)
Over the 75th percentile	12,022 (20%)	520 (4.3%)
ASA score		
1	18,085 (30%)	285 (1.6%)
2	26,019 (43%)	712 (2.7%)
3	9410 (16%)	422 (4.5%)
4	1804 (3%)	116 (6.4%)
5	152 (0%)	9 (5.9%)
Unknown	4990 (8%)	84 (1.7%)
Wound class		
I—clean	29,055 (49%)	478 (1.6%)
II—clean/contaminated	23,844 (40%)	673 (2.8%)
III—contaminated	4947 (8%)	318 (6.4%)
IV—dirty	1488 (3%)	152 (10.2%)
Technique of operation		
Classic	46,911 (79%)	1414 (3%)
Videoscopic	12,125 (21%)	211 (1.7%)
Hospital stay before operation		
<2 day	28,499 (47%)	485 (1.7%)
≥2 day	31,917 (53%)	1141 (3.6%)
Sex		
Male	20,298 (34%)	668 (1.7%)
Female	40,162 (66%)	960 (2.4%)
Age		
0 - 1	399 (1%)	7 (1.8%)
2 - 5	470 (1%)	6 (1.3%)
6 - 15	955 (2%)	23 (2.4%)
16 - 45	21,778 (36%)	376 (1.7%)
46 - 65	16,262 (27%)	461 (2.8%)
66 - 85	18,533 (31%)	690 (3.7%)
≥85	1955 (3%)	65 (3.3%)
Urgent operation		
No	45,044 (75%)	1174 (2.6%)
Yes	15,006 (25%)	452 (3%)
Operative procedure category		
Caesarean section	12,970 (21%)	222 (1.7%)
Cholecystectomy	9653 (16%)	162 (1.7%)
Breast surgery	8724 (14%)	156 (1.8%)
Colon surgery	6130 (10%)	508 (8.3%)
Herniorrhaphy	4172 (7%)	50 (1.2%)
Open reduction of fracture	2365 (4%)	14 (0.6%)
Appendectomy	1957 (3%)	51 (2.6%)
Prostatectomy	1558 (3%)	49 (3.1%)
Rectal surgery	1412 (2%)	126 (8.9%)
Laminectomy	1407 (2%)	5 (0.4%)
Thoracic surgery	1010 (2%)	11 (1.1%)

Main objectives of this study were to estimate the frequency of surgical site infections in Italy and in our districts, moreover compare this data with those obtained by the ECDC and NHSN.

A surveillance protocol has defined which operative procedures must be monitored, how long should surveillance lasts, which information must be collected and many other variables of interest (how make diagnosis of surgical site infection, class and type of surgery to include, duration of surgery, ASA score, risk index, etc.) [31].

The follow-up after discharge could be ambulatory, telephone-based or through a self-issued form given to the patient before he left the hospital.

Data were collected on regional base and then integrated in a national database. Interventions were aggregated in surgical procedure categories and each one associated to a different risk of infection. Furthermore, has been considered features of each single patient and the risk at the base of each surgical intervention [31].

In order to correctly estimate the difference in the individual risk, has been used the Infection Risk Index (IRI), that assume values of risk from M to 0, 1, 2, 3; **Table 5** shows how to calculate this score [30] [31].

The analysed population was structured according to **Table 6** [31].

During the considered period has been reported 1198 SSIs, equal to about 1.8 infections every 100 procedures, and among them the 45% has been diagnosed successively to the discharge [31].

Serious infections represent more than one third of the total: 22% interest deep tissues, 14% organs and spaces. Superficial SSIs represent the 64% of the infections. **Table 7** shows the percentage of SSIs for main surgical categories [31].

Regarding antibiotic prophylaxis, the collected data concern 23,547 intervention and in the 44% of them is not possible to state if it has been performed (but is also probable that in different cases the registration has been omitted). The using percentage is shown in **Table 8** [31].

Comparing the Italian data with those of the ECDC and NHSN, we can firmly state that SSI incidence in Italy is comparable with the American and European one.

Results of this study pointed out that SSI incidence is not significantly increased, at least regarding the quality of the collected data. Some problems have arisen in the collection of not obligatory information, invalidating the use of IRI score (in the 40% of the intervention was not possible to use this method) [31].

Our national guidelines recommend the use of a I or II generation cephalosporin and suggest the use of glycopeptides only for MRSA colonized patients or for those centres with high SSI MRSA related incidence.

This study shows how the correct use of antibiotic represent in Italy a central point in the management of the surgical patient and a primary objective in the politics of each hospital (antimicrobial stewardship) [31].

SNICh program, despite the significant increase of the supervised interventions, is still affected by a low participation, and this is even more relevant considering the demonstrated lowering SSI incidence (around the 29%) in the centres with a surveillance of at least two years [31].

8. Antibiotic Prophylaxis and Future Prospects

SSIs are a very actual and serious problem, for this reason the research is studying new methods to face them.

First of all, regarding the optimal duration of an antibiotic prophylaxis, was demonstrated the non inferiority of short-term prophylaxis compared with the long term one [32]; moreover there are no evidences of more effectiveness of antimicrobial therapy if prolonged further than 24 hours from the beginning of the procedure [2] [4].

Short-term antibiotic prophylaxis should be preferred to longer-course regimen because of:

Table 5. Calculation of IRI score [30] [31].

Considered factors	Point
Intervention class: contaminated or dirty	+1
ASA score > 2	+1
Intervention duration > 75˚ percentile of distribution[1]	+1

[1]75˚ percentile of distribution of procedure duration in that specific category. NB: for the colon surgery and the laparoscopic cholecystectomy it is removed 1 point to the IRI score (if the result is −1, category is M).

Table 6. Main characteristics of the operations recorded in the SNICh programme (2013), [31].

Characteristic	Description
Sex	**(n. 67,502)**
Female	39,990 (59%)
Male	27,512 (41%)
Age	**(n. 67,502)**
Median	54 (IQR: 37 - 70)
ASA score	
1	19,567 (29%)
2	26,372 (39%)
3	10,424 (15%)
4	1325 (2%)
5	88 (0%)
Not known	9726 (14%)
Intervention class	**(n. 67,502)**
I—clean	31,925 (47%)
II—clean-contaminated	24,011 (36%)
III—contaminated	3393 (5%)
IV—dirty-infected	1558 (2%)
Not known	6615 (10%)
Intervention duration	**(n. 65,552)**
Median	60 (IQR: 35 - 110)
Infection risk index	**(n. 67,502)**
0 - 1	34,112 (50%)
2 - 3	3343 (5%)
N.D.	30,047 (44%)
Pre-operative hospital stay (days)	**(n. 67,502)**
Median	1 (IQR: 1 - 2)
Post-operative hospital stay (days)	**(n. 56,430)**
Median	4 (IQR: 2 - 7)
Type of intervention	**(n. 67,502)**
Elective	52,224 (77%)
Urgent	14,405 (21%)
Not known	873 (1%)
Intervention technique	**(n. 67,502)**
Classic	51,054 (76%)
Not known	910 (1%)
Videoscopic	15,538 (23%)
Perioperative antibiotic prophylaxis	**(n. 23,547)**
Not performed	2,100 (9%)
Not known	10,473 (44%)
Performed	10,974 (47%)

Table 7. Description of infections incidence analysed during the study (indexed according to NHSH categories) [31].

Categories	Interventions n	Infections n (rate per 100 procedures)
Appendectomy	1837	39 (2.1%)
Breast surgery	5334	49 (0.9%)
Cholecystectomy	5505	77 (1.3%)
Colon surgery	3879	349 (9.0%)
Caesarian section	9475	166 (1.7%)
Herniorrhaphy	2919	43 (1.4%)
Abdominal hysterectomy	1027	15 (1.4%)
Others	16,555	83 (0.5%)
Ovarian surgery	1192	2 (0.1%)
Prostatectomy	1247	18 (1.4%)
Rectal surgery	776	54 (7.0%)
Thoracic surgery	1030	2 (0.2%)
Thyroid/parathyroid surgery	1479	18 (1.2%)
Laparotomy	991	31 (3.1%)

Table 8. Molecule used in antibiotic prophylaxis [31].

Active principle	Intervention	Percentage on intervention with indicated molecule (n. 9.177)
Cefazolin	3626	40%
Ampicillin and enzymatic inhibitors	1512	16%
Metronidazole	976	11%
Cefuroxime	891	10%
Ceftriaxone	804	9%
Others	528	29%

- Reduction of hospitalization costs.
- Drug toxicity.
- Emergence of resistant pathogens.

In terms of rationalize the national health system costs, it's recommended the use of short-term antibiotic regimen, since its efficacy and safety for clean plastic surgeries and most clean-contaminated surgeries. On the other hand, trials on larger scale are needed to further confirm these findings [32].

Also technology is giving a great input in medical field, for instance the production of new device like dressings impregnated with silver nanoparticles has shown an anti-biofilm and cytotoxicity activity against *P. aeruginosa*, a bacteria isolated of chronic wounds from a hospital patient, without any damage on human cells [33].

The BaFO (Bone Area Fraction Occupancy) study, analysing the difference of SSIs incidence between standard abdominal wound edge protection with surgical dressings and coverage with a sterile circular polyethylene drape, has shown that this device not only prevent displacement of skin pathogens into the surgical site such as incisional drapes do, but also effectively protect the skin, subcutaneous tissue, fascia and muscle from spillage of abdominal content during the surgical procedure; moreover it prevents hypothermia which, as demonstrated in several studies, is associated with SSI insurgence [34] [35].

9. Conclusion

In conclusion as we have analysed not only technology and progress in the search for increasingly innovative new antibiotic molecules, but also above all knowledge and good practices, both on the part of doctors that nurses and students, are important factors to prevent SSIs [23] [36]-[42].

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