American Journal of Infection Control 47 (2019) 1112–1117

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major Article

Effect of surgical safety checklist on colorectal surgical site infection rates in 2 countries: Brazil and Canada

Camila Sarmento Gama RN, MSc [a,*], Chantal Backman RN, PhD [b], Adriana Cristina de Oliveira RN, PhD [a]

[a] *Nursing School, Universidade Federal de Minas Gerais, Belo Horizonte, Minas Gerais, Brazil*
[b] *Nursing School, University of Ottawa, Ottawa, Ontario, Canada*

Key Words:
Patient safety
Surgery
Surgical wound
World Health Organization

Background: The effectiveness of the surgical safety checklist (SSC) in countries with different socioeconomic backgrounds is uncertain. To evaluate the effect of the SSC in 2 different socioeconomic settings, we compared surgical site infection (SSI) rates before and after its implementation in colorectal procedures.
Methods: An epidemiological retrospective study was conducted in the university hospitals in Ottawa, Canada, and Belo Horizonte, Brazil. Data were collected through chart review from the period before and after the SSC implementation.
Results: The SSI rate decreased from 27.7%-25.9% ($P = .625$) and from 17.0%-14.4% in Canada and Brazil, respectively ($P = .448$) after the SSC implementation. In Canada, there was no SSI in incomplete SSC, and in Brazil, SSI was 20.0% ($P = .026$).
Discussion: Despite high and regular completion of the SSC in the Canadian and Brazilian hospitals, respectively, there was no significant reduction of SSI after the SSC implementation in any setting. However, in Brazil, the association between incomplete SSC and higher SSI rates demonstrated the potential impact of the SSC in developing countries.
Conclusions: The effect of the SSC on SSI may be greater in developing countries due to minor investment and consolidation of policies in SSI prevention.

The quality of health care in surgical procedures has been a constant concern worldwide owing to the high rates of adverse events (AEs) related to these procedures. In 2008, the World Health Organization (WHO) launched the Second Global Patient Safety Challenge, “Safe Surgery Saves Lives,” to improve surgical care and reduce morbidity and mortality resulting from surgical interventions, including the prevention of surgical site infections (SSIs), an important AE.[1]

Despite being largely preventable, SSIs are the most common and studied health care–associated infection (HAI). They are of great concern considering that 77% of deaths in patients with SSI are directly attributable to SSI. In the United States, 160,000-300,000 SSIs occur each year, which represents 2%-5% of patients undergoing inpatient surgery and contributes anywhere from $3.5-$10 billion in medical costs.[2] In Brazil, SSIs make up 14%-16% of all HAIs,[3] whereas in Canada, SSIs make up 13%-30% of all HAIs.[4]

SSIs are the most frequent complication for patients undergoing colorectal procedures associated with substantial morbidity, and the rates of SSIs are higher in these procedures compared with others, impacting an increased length of hospital stay and health care costs.[5,6] The incidence of SSIs in colorectal surgery is an indicator of health care quality. Therefore, surveillance and prevention of SSIs are essential in improving the effectiveness and safety of colorectal surgery.[6]

As part of the WHO Second Global Patient Safety Challenge, the adoption of a 19-item surgical safety checklist (SSC) was proposed in an attempt to raise awareness among surgical teams (surgeons, anesthesiologists, and nursing staff) around the world to the critical steps aiming at SSI prevention, safe anesthesia, safe surgical teams, and measurement of surgical services. These steps in the surgical procedure were divided

* Address correspondence to Camila Sarmento Gama, RN, MSc, Nursing School, Universidade Federal de Minas Gerais, 190 Professor Alfredo Balena Ave, Belo Horizonte, Minas Gerais, 30130-100, Brazil.
E-mail address: camilasarmentogama@gmail.com (C.S. Gama).
Funding/support: This study was supported by the Coordination for the Improvement of Higher Education Personnel (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior [CAPES]/Process: Programa de Doutorado Sanduíche no Exterior-88881.132298/2016-01) that granted a doctoral sandwich scholarship to one of the authors, Foundation for Research Support of Minas Gerais (Fundação de Amparo a Pesquisa de Minas Gerais [FAPEMIG]/Edital de Programa de Pesquisa para o SUS-PPSUS Process N: APQ-03537-13), and National Council for Scientific and Technological Development (Conselho Nacional de Desenvolvimento Científico e Tecnológico/Process: 304870/2011-0 da Modalidade: Edital: PQ 2011-Produtividade em Pesquisa).
Conflicts of interest: None to report.

https://doi.org/10.1016/j.ajic.2019.03.002
0196-6553/

into the following 3 stages: before the induction of anesthesia, before skin incision, and before the patient leaves the operating room (OR).[1]

Although the development of SSIs is multifactorial, and its prevention requires multimodal and multidisciplinary strategies,[7] the SSC is an important tool for the control of SSIs, contributing to the organization and standardization of minimal but essential steps for the safety of the surgical procedures that cannot be forgotten or neglected. This includes the administration of antimicrobial prophylaxis with the right drug at the right time, a critical point raised by several authors and with low compliance among health care professionals despite evidence of its importance,[7,8] and the confirmation of the sterility of equipment, which can directly influence the risk for SSIs.[1]

In this sense, despite its relevance in any surgical center around the world, there are only a few studies showing that the SSC has a higher impact in developing countries,[9,10] where often SSIs are the most common complication in surgical patients[7,11] and where there are less resources and investment in safety culture.[12] However, most studies that evaluate SSC use and impact on clinical outcomes such as SSIs and improvement in clinical practice are from developed countries, with controversial results.[10,13]

Ten years after the worldwide dissemination of the Second Global Challenge by the WHO, the applicability, impact, and effectiveness of the adoption of the SSC in different socioeconomic climates are still unclear,[10,13] with a few studies comparing the impact of the SSC in distinct socioeconomic realities.[10] Therefore, the present study aimed to compare SSI rates before and after the implementation of an SSC for colorectal procedures in 2 different socioeconomic settings: Brazil (developing country) and Canada (developed country).

METHODS

An epidemiological retrospective study was conducted in a large 1,122-bed university hospital in Ottawa, Canada, and a 504-bed university hospital in Belo Horizonte, Brazil, where elective and emergency surgeries are performed at surgical centers in both institutions during working hours from Monday to Friday, with only emergency procedures performed at night and on weekends. The Brazilian surgical center performed approximately 10,088 surgeries in 2015-2016, and the Canadian surgical center performed 49,618 surgeries during the same period.

Despite the difference in sizes, the institutions were selected because they are public, teaching, and research hospitals that deal with critically ill patients and complex clinical cases, contributing to the formation of health care professionals.

The SSC was initially introduced in April 2010 in the Canadian facility and on January 2014 in the Brazilian institution; the SSC was revised at both hospitals. The latest SSC policy in Canada was updated on March 2017 resulting in a 45-item checklist and in Brazil in 2016 resulting in a 24-item checklist. The modification of the SSC was along the lines of the suggestions by the WHO, which divide the checklist into distinct sections such as: "Sign in," the period before the induction of anesthesia; "Time out," the period after the induction and before surgical incision; and "Sign out," the period during or immediately after wound closure but before the patient leaves from the OR.[1]

Data were retrospectively collected through chart review in both health care institutions. In Canada, the principal investigator was responsible for data collection, and in Brazil, 2 other collaborators assisted the principal investigator.

Patients aged >18 years who underwent colorectal procedures (operations on the appendix, colon, and rectum) before the SSC implementation in the hospitals (time periods, April 1, 2008, to March 31, 2010, in Canada and January 1, 2013, to December 31, 2013, in Brazil) and after the SSC implementation (time periods, January 1, 2014, to July 31, 2017, in both institutions) were included.

Data regarding SSIs were retrieved for 30 days. For the diagnosis of SSIs, the criteria of the National Healthcare Safety Network/Centers for Disease Control and Prevention 2017[14] was adopted, which defines an SSI as superficial SSI, deep SSI, or organ/space SSI. The presence of purulent drainage was considered a "gold standard" to SSI diagnosis. In case of early discharge (before 30 days), postdischarge follow-up included any register of visits to an emergency department and outpatient clinic or readmission to the same hospital.

To better characterize the patients and the procedure, additional data such as sex, age, name of the procedure, date of operation, American Society of Anesthesiologists (ASA) score, wound classification, surgical length, and SSC completion in Sign in, Time out, and Sign out were collected.

The exclusion criteria were as follows: patients with infected colorectal surgeries or in emergency cases that presented a life-threatening condition requiring a <45-minute approach according to a 5-level urgency classification (A, <45 minutes; B, <2 hours; C, <4 hours; D, <8 hours; E, <24 hours),[15] ASA score VI, laparoscopic procedures, patients who previously received therapeutic antibiotics before the surgery, and charts without the SSC in the period after its implementation.

Data were typed and analyzed using the Statistical Package for the Social Sciences version 21.0 (IBM, Armonk, NY). A descriptive analysis was performed for all variables. Baseline characteristics and rates of SSIs were compared before and after the SSC implementation using the χ^2 test or the Fisher exact test. The mean time to infection from operation before and after checklist implementation was compared using the Student t test. *P* values <.05 were considered statistically significant.

This study was approved by the Canadian institution's research ethics board (20170449-01H) and by the Brazilian institution's research ethics board (037048/2017-CAAE 30783614.3.0000.5149).

RESULTS

Characterization of Canadian sample

A total of 842 charts were included in the analysis according to the inclusion and exclusion criteria adopted. Of this, 177 (21%) charts were from the period before the implementation of the SSC and 665 (79%) from the period after its implementation. From the charts reviewed post-SSC implementation, 657 (98.8%) had complete SSC, and 8 (1.2%) had incomplete SSC. The distribution of patients and procedure's characteristics with and without SSI before and after the SSC are described in Table 1.

Regarding SSC completion, 5 (62.5%) were incomplete in "Sign out" and 3 (37.5%) in "Time out." In relation to its evaluated completion per year, an increase over the years from 98% (251 of 256) in 2015 to 98.9% (270 of 273) in 2016 and 100% (136 of 136) in 2017 (*P* = .235) was observed.

Characterization of Brazilian sample

Based on the inclusion and exclusion criteria, a total of 518 charts were selected for analysis. Of this, 171 (33%) were from the period before the implementation of the SSC and 347 (67%) from the period after its implementation. For the records that contained the SSC in the postimplementation period, 222 (64.0%) SSCs were complete, and 125 (36.0%) were incomplete. The distribution of patients and procedure's characteristics with and without SSI before and after the SSC implementation is presented in Table 2.

Considering the sample in general, a total of 48 (37.5%) incomplete SSC in the "Sign in," 43 (33.6%) in the "Time out," 23 (18%) simultaneously in the "Sign in" and "Time out," 7 (5.5%) in the "Sign out," 3 (2.3%) concurrently in the "Time out" and "Sign out," 3 (2.3%)

Table 1
Distribution of patients and the procedure's characteristics with and without surgical site infection before and after the implementation of the surgical safety checklist in Canada. Ottawa, Canada, 2018.

	Period preimplementation n = 177					Period postimplementation n = 665				
	SSI n	%	No SSI n	%	P value*	SSI n	%	No SSI n	%	P value*
Sex	49	27.7	128	72.3	.119	172	25.5	493	74.2	**.028**
Female	20	40.8	69	53.9		98	57.0	233	47.3	
Male	29	59.2	59	46.1		74	43.0	260	52.7	
Age (y)					**.048**					.504
18-62 years	28	57.1	52	40.6		79	45.9	241	48.9	
≥63 years	21	42.9	76	59.4		93	54.1	252	51.1	
ASA score					.800					.243
I	0	0	0	0		1	0.6	4	0.8	
II	9	18.4	30	23.4		12	7.0	66	13.4	
III	28	57.1	66	51.6		117	68.0	316	64.1	
IV	12	24.5	31	24.2		41	23.8	103	20.9	
V	0	0	1	0.8		1	0.6	4	0.8	
Wound classification					.740					**.031**
Clean-contaminated	45	91.8	120	93.8		141	82.0	436	88.4	
Contaminated	4	8.2	8	6.3		31	18.0	57	11.6	
Type of surgery					.758					**.044**
Elective	25	51.0	62	48.4		74	43.0	256	51.9	
Urgency†	24	49.0	66	51.6		98	57.0	237	48.1	
Surgery length					**.012**					.131
60-193 min	30	61.2	102	79.7		93	54.1	299	60.6	
≥194 min	19	38.8	26	20.3		79	45.9	194	39.4	

NOTE. Bold values are statistically significant $P < .05$.
ASA, American Society of Anesthesiologists; *SSI*, surgical site infection.
*The χ^2 test or the Fisher exact test is used when there are variables with less than 5 observations.
†Emergency surgeries, life-threatening for patients, were not included in the analysis.

simultaneously in the "Sign in" and "Sign out," and 1 (0.8%) incomplete in all 3 phases were observed. Moreover, in relation to its completion by year evaluated, similar to Canada, an increase over the years from 34.4% (31 of 90) in 2015 to 71.6% (96 of 134) in 2016 and 77.2 (95 of 123) in 2017 (*P* = .000) was observed.

SSI in Brazil and Canada

Although the rates of SSIs in Canada and Brazil decreased after the implementation of the SSC, in both cases, the decrease was not statistically significant. In Canada, the rate of SSIs decreased from 27.7% before the SSC implementation to 25.9% after the SCC implementation (*P* = .625), and in Brazil, it decreased from 17.0%-14.4% after its implementation (*P* = .448). The site location of SSI in each country before and after the implementation of the SSC is presented in Figure 1.

Figure 2 presents the mean time from operation to infection diagnosis for patients with SSI before and after the SSC implementation in Brazil and Canada. The postoperative infections occurred later before the SSC implementation in both countries; however, this difference was not statistically significant.

Table 2
Distribution of patients and the procedure's characteristics with and without surgical site infection before and after the implementation of the checklist in Brazil. Belo Horizonte, Brazil, 2018

	Period preimplementation n = 171					Period postimplementation n = 347				
	SSI n	%	No SSI n	%	P value*	SSI n	%	No SSI n	%	P value*
Sex	29	17.0	142	83.0	.936	50	14.4	297	85.6	.441
Female	18	62.1	87	61.3		24	48.0	160	53.9	
Male	11	37.9	55	38.7		26	52.0	137	46.1	
Age (y)					.970					.873
18-52 years	14	48.3	68	47.9		23	46.0	133	44.8	
≥53 years	15	51.7	74	52.1		27	54.0	164	55.2	
ASA score					.576					**.004**
I	5	17.2	28	19.7		3	6.0	59	19.9	
II	17	58.6	85	59.9		28	56.0	172	57.9	
III	5	17.2	26	18.3		19	38.0	56	18.9	
IV	2	6.9	3	2.1		0	0	10	3.4	
Wound classification					.851	50		294		.739
Clean-contaminated	22	75.9	110	77.5		37	74.0	213	71.7	
Contaminated	7	24.1	32	22.5		13	26.0	84	28.3	
Type of surgery					.719					.609
Elective	20	69.0	93	65.5		32	64.0	201	67.7	
Urgency†	9	31.0	49	34.5		18	36.0	96	32.3	
Surgery Length					**.037**					.120
60-178 min	13	44.8	93	65.5		21	42.0	160	53.9	
≥179 min	16	55.2	49	34.5		29	58.0	137	46.1	

ASA, American Society of Anesthesiologists; *SSI*, surgical site infection.
*The χ^2 test or the Fisher exact test is used when there are variables with less than 5 observations.
†Emergency surgeries, life-threatening for patients, were not included in the analysis.

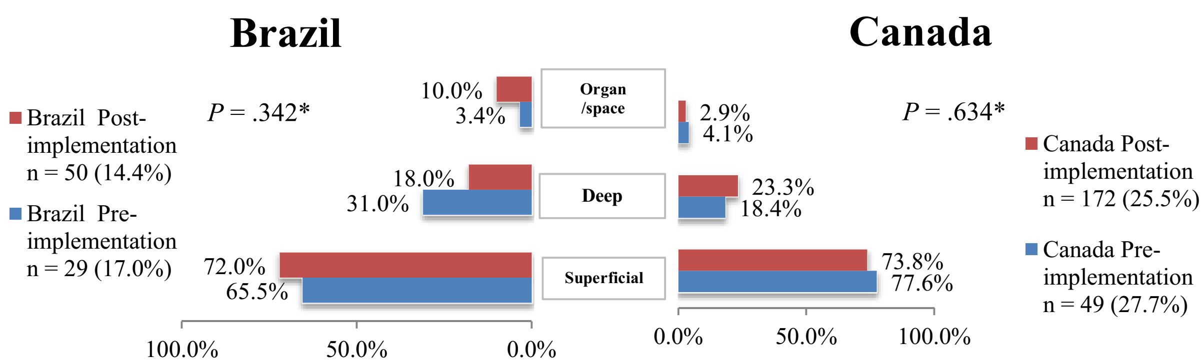

Fig 1. Distribution of surgical site infection in each country before and after the surgical safety checklist implementation. Belo Horizonte, Brazil, and Ottawa, Canada, 2018. *Fisher's exact test.

The influence of the SSC completion on SSIs in each country was also analyzed. In Canada, there was no SSI in incomplete SSC, and in Brazil, there was 20.0% of SSIs in incomplete SSC and 11.3% in complete SSC ($P = .026$). Regarding the completion of the SSC and the site of the SSI in Brazil, 84% (21 of 25) had superficial SSI, 12% (3 of 25) had deep SSI, and 4% (1 of 25) had organ/space SSI in patients who had incomplete SSC ($P = .150$).

DISCUSSION

In our study, the number of SSIs in colorectal procedures in both institutions was found to be consistent with other studies in this population that ranges from 3%-40%.[5,6] The higher SSI rate in the Canadian hospital compared to the Brazilian hospital apparently contradicts the literature that developed countries have lower SSI rates than developing countries[11]; however, it was proportional to its national rate of SSIs considered up to one-third of all HAIs in Canada.[4] An explanation for this difference is that developing countries have poorer surveillance systems[7] that can hinder patient follow-up and underestimate SSI cases. Another possible explanation is the sample of patients selected according to study inclusion criteria. In the Canadian hospital, the mean patient age was older than that of the Brazilian patients, there were more patients with ASA score ≥III, and also the mean time of surgery length was higher, these being important risk factors to SSI development in colorectal surgeries.[5,6]

Regarding the SSC completion, we observed higher SSC completion rate in the Canadian facility compared to the Brazilian facility, which, however, did not translate into a statistically significant improvement in SSI rates. Studies in developed countries that also did not find significant improvements in AEs after the implementation of the SSC infer that it did not add anything new to the institutional work process, which is a possible explanation for the present result.[9,10]

Another reason for the difference in SSC completion rates between these 2 institutions is the amount of time SSC has been implemented in each hospital. In Canada, the SSC has been part of the work process since 2010, and SSC completion rates are reported to provincial health authorities,[16] whereas in Brazil, the use of an SSC was only mandated by governmental policy in 2013 (Brazilian Board Resolution 36/2013),[17] and there is no governmental requirement to report SSC completion rates. The Brazilian hospital participating in this particular study did not implement the SSC until 2014. The high completion rate in the Canadian hospital and the gradual increase of this rate in the Brazilian hospital along the years demonstrated the difference of maturity of the political consolidation.

In this context, it is important to highlight that the policies differ between the settings, which may explain the distinct repercussion of the SSC in different climates. In developed countries, where there are multiple policies and multimodal strategies to infection control and prevention, and well-established and well-implemented bundles and guidelines,[7,11] the effect of the SSC in complications and SSI rates may not be evident. However, in developing countries where policies are incipient[18] and strategies for infection control and prevention are fragile,[7,11] the SSC may be 1 of the few initiatives that increases its potential impact if implemented properly.[9] In Brazil, the association between incomplete SSC and increase in SSI rate demonstrates this potential impact of SSC use in work process in a developing country.

Although the SSC is a cheap care improvement program to surgical patients that aims at reducing complications and AEs and promising for realities with limited resources,[1,9] its success depends on the institutional safety culture, credibility and involvement of the

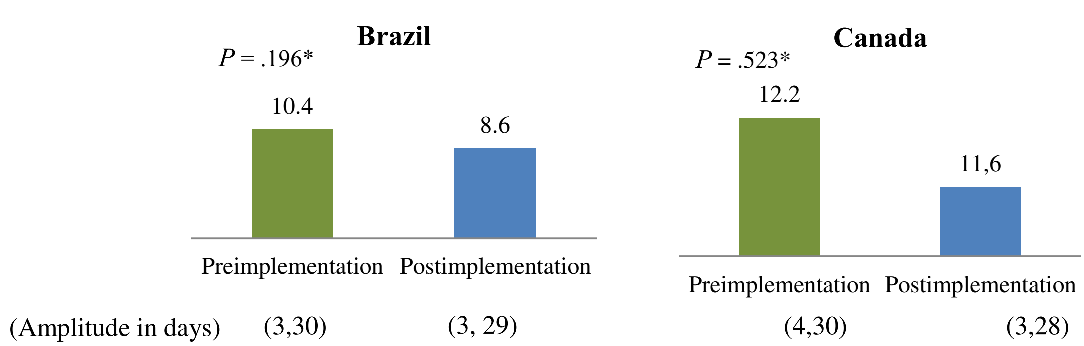

Fig 2. Mean time as days to infection from the operation before and after the surgical safety checklist implementation in Brazil and Canada within 30 days postoperatively. Belo Horizonte, Brazil, and Ottawa, Canada, 2018.
*Student's t-test.

multiprofessional team, and implementation strategies.[19,20] In the Brazilian institution, an important percentage of incomplete SSC was observed, evidencing that the process possibly is not yet consolidated. In this sense, for its consolidation, it is fundamental that the process be monitored periodically, with the exchange of feedback between professionals and managers and coordinators on the improvements achieved and the challenges and limitations to be overcome.[18,19]

Additionally, in developing countries, there are some barriers to the adoption of the SSC such as fragile or absent patient safety policy, insufficient and/or overworked health care professionals, absence or failure of training, resistance of surgical teams, and lack of infrastructure, hospital supplies, and equipment.[9,18] Therefore, although the SSC has been shown to be cost-effective in a developed country, considering the indirect costs necessary for its implementation, such as team training and use of antibiotics,[21] in developing countries, there are still few similar studies that address SSC's cost-effectiveness considering its adaptation to the reality of these countries to provide evidence of their application in different climates.

In this sense, although the SSC proposal is based on simplicity, applicability, and measurement,[1] its immediate effect may not be the same for all settings as suggested by the WHO, and consideration should be given to the consolidation and investment in infection prevention policies in these regions, which are often poorly implemented.[7] From the present study, we infer that even if the SSC is a tool with relevant objectives and goals, its success depends clearly on the consolidation of the previous policies and safety culture established and adopted by health care professionals. The result verified in the Brazilian hospital is a direct consequence of the explanation described earlier, reflecting on the scarcity of studies and investments in the prevention in the country,[22] which are often considered unnecessary owing to the absence of monitoring and feedback from the surveillance system,[7] which hinder prevention comprehension as a long-term investment.

Besides integrating one of the SSI prevention strategies, the adoption of the SSC also contributes to improve leadership, communication, and teamwork during surgeries.[10,23] ORs are a potentially stressful, complex, and pressured environment where usually there is high surgical volume and historical hierarchical issues,[10,20] being common distractions, noise, and interruption that can lead to miscommunication, surgical errors, and high rates of morbidity, such as retained surgical items, an event that often occurs in the cavities such as the abdomen and pelvis and results in pain, infection, abscess formation, sepsis, and even death.[24] In this context, communication flaws and teamwork failures are factors that similarly affect developed and developing countries, being the first root cause of many AEs.[1,23] Therefore, although the SSC did not initially demonstrate significant improvements in AEs, its use should be encouraged to develop an effective communication and teamwork and, consequently, patient safety.

As limitations of the study, it is important to highlight that as it was a retrospective study, the diagnosis of SSIs was limited to records during the hospitalization or readmission of the patient. Some of them may have sought treatment for SSI in primary care centers or treated themselves for a minor SSI, which then went unrecorded; and it was conducted in only 1 institution from each country. Furthermore, we must take into account the level of organization of SSC policy in each setting and the influence of the time that was considered for analysis. In 2015, the Canadian institution already had 5 years of experience using the SSC and the Brazilian hospital only 1 year.

Although the study considered only colorectal surgeries, it can be inferred that the result can be expanded to the other specialties of the hospitals studied as the institutional policy to implement the SSC was the same for all other departments in each facility, except for ophthalmic surgeries in Canada. According to a multicenter study from England, the use of the SSC presented large variation between hospitals, but not between surgical specialties or between elective and emergency procedures,[25] which probably is the case.

In spite of these limitations, the results may represent the reality of different developed and developing countries, whose policies and strategies to SSI control and prevention tend to differ according to the socioeconomic level. This echoes on the different effects on the reproduction of the SSC, whose employment must be part of a set of strategies and not an isolated program.

CONCLUSIONS

In the present study, it was possible to identify that the SSC, even with its adaptations to each setting, was not able to reduce SSI rates in colorectal surgeries in hospitals from countries of different socioeconomic levels or the difference of the rates between them. However, in identifying the direct association between the increase of incomplete SSC and the development of SSI in the Brazilian institution, the study showed that the effect of the SSC may be greater in middle- or low-income countries, because policies and multimodal strategies aiming at the prevention and control of SSIs, whose development is multifactorial, are scarce and fragile in these settings. However, it is questionable whether its potential impact in these scenarios would be permanent or seasonal, because the SSC alone, without the aid of other strategies for SSI prevention and control, may not have a sustained effect.

Acknowledgments

The authors thank Débora Martins and Débora Fernanda Silva for their collaboration in data collection.

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