ORIGINAL ARTICLE

Assessment of healthcare-associated infection control programs: a critical perspective of ANVISA's RDC Nº 48/2000

Avaliação de programas de controle de infecções relacionadas à assistência à saúde: perspectiva crítica da RDC N°48/2000 da ANVISA

Evaluación de los programas de control de las infecciones asociadas a la atención de salud: perspectiva crítica del RDC Nº 48/2000 de la ANVISA

Charlise Fortunato Pedroso[1]
Rafael Alves Guimarães[2]
Karla de Aleluia Batista[1,2]
Paula Regina de Souza Hermann[3]
Lyriane Apolinário de Araújo[1]
Ingrid Aline de Jesus Gonçalves[1]
Thaís Augusto Marinho[1]
Hélio de Souza Júnior[4]
Jeane Kelly Silva de Carvalho[4]
Geraldo Andrade de Oliveira[5]
Raquel Silva Pinheiro[1]

[1] Instituto Federal de Educação, Ciência e Tecnologia de Goiás (IFG), Goiânia, Goiás, Brasil.

[2] Universidade Federal de Goiás (UFG), Goiânia, Goiás, Brasil.

[3] Universidade de Brasília (UnB), Ceilândia Sul, Distrito Federal, Brasil.

[4] Instituto Federal de Educação, Ciência e Tecnologia de Goiás (IFG), Águas Lindas, Goiás, Brasil.

[5] Instituto Federal de Educação, Ciência e Tecnologia de Goiás (IFG), Valparaíso, Goiás, Brasil.

Corresponding author:
Raquel Silva Pinheiro
E-mail: raquel.pinheiro@ifg.edu.br

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ABSTRACT

Objective: to critically evaluate Healthcare-Associated Infection Control Programs (HAICP) in medium to extra-large hospitals, as to compliance with national health criteria. **Methods:** cross-sectional study conducted in 18 hospitals with Healthcare-Associated Infection Control Committees (HAICC) in the states of Goiás and São Paulo, Brazil. Data were collected using online form based on the evaluation items from Directors' Collegiate Resolution (RDC) Nº 48/2000 – ANVISA. For statistical analysis, frequency, and distribution of variables (mean; standard deviation - SD) were examined. **Results:** HAICC met 100% of the indispensable items, 93.0% (SD = 5.8) of the required, and 64.8% (SD = 32.5) of the recommended. Healthcare-Associated Infection Control Services complied with 90.2% (SD = 16.1) of the necessary items, and 77.8% (SD = 19.2) of those recommended. **Conclusion:** indispensable items were met, but the necessary and recommended ones present different degrees of noncompliance, which may compromise the prevention and control of healthcare-associated infections. The application of a script based on the RDC Nº 48/2000 contributes to identify the reality of the hospitals' HAICP, however, this normative does not establish a minimum percentage of compliance, making it difficult to interpret the results. It is necessary to update it in order to provide tools to surveillance agencies.

Descriptors: Hospital Infection Control Program; Cross Infection; Epidemiological Monitoring; Quality of Health Care.

RESUMO

Objetivo: *avaliar criticamente Programas de Controle de Infecções Relacionadas à Assistência à Saúde (PCIRAS) em hospitais de médio-extra portes, quanto ao cumprimento dos critérios sanitários nacionais.* ***Métodos:*** *estudo transversal realizado em 18 hospitais com Comissões de Controle de Infecções Relacionadas à Assistência à Saúde (CCIRAS) dos estados de Goiás e São Paulo, Brasil. Para coleta de dados aplicou-se formulário online fundamentado nos itens de avaliação preconizados pela Resolução de Diretoria Colegiada (RDC) Nº 48/2000 - ANVISA. Para análise estatística utilizou-se exame da frequência e distribuição das variáveis (média e desvio padrão - DP).* ***Resultados:*** *as CCIRAS atenderam 100% dos itens imprescindíveis, 93,0% (DP = 5,8) dos necessários e 64,8% (DP = 32,5) dos recomendados. Os Serviços de Controle de IRAS atenderam 90,2% (DP = 16,1) dos itens necessários, e 77,8% (DP = 19,2) dos recomendáveis.* ***Conclusão:*** *itens imprescindíveis foram cumpridos, porém os necessários e recomendados apresentam diferentes graus de inconformidades, podendo comprometer a prevenção e controle de IRAS. A aplicação de roteiro baseado na RDC N° 48/2000 contribui para conhecer a realidade dos PCIRAS dos hospitais, contudo, essa normativa não estabelece percentual*

mínimo de conformidade, dificultando a interpretação dos resultados. Há necessidade de atualizá-la para instrumentalizar os órgãos fiscalizadores.

Descritores: *Programa de Controle de Infecção Hospitalar; Infecção Hospitalar; Monitoramento Epidemiológico; Qualidade da Assistência à Saúde.*

RESUMEN

Objetivo: *evaluar críticamente los Programas de Control de Infecciones Relacionadas con la Atención de Salud (PCIRAA) en hospitales medianos y grandes para determinar si cumplen con los criterios nacionales de salud.* ***Métodos:*** *estudio transversal realizado en 18 hospitales con Comisiones de Control de las Infecciones Asociadas a la Atención de Salud (CCIAAS) en los estados de Goiás y São Paulo, Brasil. Para la recolección de datos se aplicó un formulario online, desarrollado con base en los ítems de evaluación recomendados por la Resolución Directiva Colegiada (RDC) Nº 48/2000 de la ANVISA. Para el análisis estadístico, se utilizó el examen de la frecuencia y distribución de las variables (media y desvío estándar - DE).* ***Resultados:*** *las CCIAAS cumplieron en promedio el 100% de los ítems indispensables, el 93,0% (DE = 5,8) de los necesarios y el 64,8% (DE = 32,5) de los recomendados. Los Servicios de Control de las Infecciones Asociadas a la Atención de Salud cumplieron en promedio el 90,2% (DE = 16,1) de los ítems necesarios y el 77,8% (DE = 19,2) de los recomendados.* ***Conclusión:*** *se cumplieron los ítems imprescindibles, pero los necesarios y los recomendados presentan diferentes grados de disconformidad, que pueden comprometer la prevención y el control de las infecciones asociadas a la atención de salud. La aplicación de la rutina basada en la RDC Nº 48/2000 contribuyó a conocer la realidad de los PCIRAA en los hospitales, pero esta normativa no establece un porcentaje mínimo de conformidad, lo que dificulta la interpretación de los resultados. Se hace necesario actualizarla para dotar de herramientas a los organismos supervisores.*

Descriptores: *Programa de Control de Infecciones Hospitalarias; Infección Hospitalaria; Monitoreo Epidemiológico; Calidad de la Atención de Salud.*

INTRODUCTION

Healthcare-associated infections (HAIs) are an important public health problem, since they increase the length of hospital stay, treatment costs, microbial resistance and morbidity and mortality, with negative implications for the quality of care and patient safety[1].

In developing countries, the rates of HAIs are estimated to be 60 times higher when compared to developed countries. This difference is caused mainly by the deficiency or absence of effective programs and surveillance systems for the prevention and control of this condition[2].

In Brazil, the National Program for Prevention and Control of HAIs became mandatory in 1997 and in the following year its work process was regulated by Ordinance Nº 2616/1998[3]. Subsequently, in view of the need to improve the quality of the actions of the Healthcare-Associated Infection Control Programs (HAICPs), an inspection script was established by the Collegiate Directive Resolution (RDC) Nº 48/2000 of the National Health Surveillance Agency (ANVISA)[4].

Despite its limitations regarding validation and time lag, this inspection script, still in force, is one of the legal landmarks used in inspections by surveillance agencies. In addition, it enables the knowledge of the physical structure, human and material resources, rules, and routines adopted for the control and monitoring of HAIs, and is an important tool for evaluating the performance of HAICPs in hospitals[4].

In the international scenario, there are eight minimum components for evaluation of HAICPs proposed by the World Health Organization[1] and an assessment tool for low- and middle-income countries, which was translated and validated for Brazilian Portuguese[5]. A second validated tool has been available in Brazil since 2021, based on process, structure, and outcome indicators[6]. However, these instruments have not yet been adopted by supervisory agency of healthcare services or by healthcare facilities in Brazil.

The mandatory preparation of HAICPs by Decree Nº 2616/1998[3] does not guarantee its implementation in Brazilian health care services, besides being adapted according to the service care profile. In addition, few studies have evaluated the implementation of HAICPs by means of validated instruments[7-10], which did not include health care services in the state of Goiás or in the capital of the state of São Paulo.

Therefore, it is necessary to know the organizational and functional structure of the Healthcare-Associated Infection Control Committees (HIACCs) of different Brazilian regions, the adequacies of the actions included in their HAICPs, as well as to identify the weaknesses present in the sanitary inspection script, RDC Nº 48/2000[4], in order to contribute to better practices of prevention and control of HAIs in Brazilian healthcare services. Thus, the present study aimed to evaluate the HAICPs of medium to extra-large hospitals in terms of compliance with national health criteria.

METHODS

Study design, population, and setting

This is a descriptive cross-sectional study linked to a larger research study entitled "Epidemiological study of the effectiveness of HAIs monitoring and control, through the use of a digital tool implemented in the context of HIACCs". This study involved hospitals in the states of Goiás (Center-West region) and São Paulo (Southeast region), Brazil.

Eligibility criteria

In August 2020, a total of 1,390 general or specialized hospitals were included in the National Registry of Healthcare Facilities (CNES), of which 421 were in Goiás and 969 in São Paulo.

Due to the nature of the matrix project, hospitals that have HIACCs and computerized laboratory, pharmacy, and electronic medical record systems in at least one direct patient care sector, except emergency units, were included. Specialized clinics, nursing homes, home care, day hospitals, health care centers, and mental health centers were excluded.

The hospitals were initially approached by telephone and the institutional e-mail registered in the CNES, in order to request direct contact with the HIACCs coordinator. Adopting a non-probabilistic sampling criterion, 20 eligible hospitals were identified (twelve in the state of São Paulo and eight in the state of Goiás). However, two institutions in the state of São Paulo refused to participate in the survey, resulting in a sample of 18 hospitals.

The institutions were classified according to the care profile (specialized or general), legal nature (public or private), management (state or municipal) and hospital size, namely: medium (51 to 150 beds), large (151 to 500 beds) and extra-large (over 500 beds).

The states of São Paulo and Goiás are two distinct geographical regions, with different densities of urban networks and compositions of public and private services. The first is one of the most economically developed states in Brazil, with numerous modern computerized health services. The second, is a state where hospitals are in the process of implementing information technology. Thus, the choice of these regions is justified as it represents the variability present in the Brazilian territories and allows us to know the diverse practices of prevention and control of HAIs implemented in the health services of these contrasting regions of the country.

Data collection

Data were collected between August and September 2020. After signing an Informed Consent, the HIACC coordinators of the 18 hospitals filled out the inspection script of the RDC Nº 48/2000[4], in a self-administered format, online, via Google Forms. The script had the following dimensions: A - identification of the hospital unit; B - inspection of the Program and the Hospital Infection Control Committee; C - inspection of the Executive Members of the Committee and the Hospital Infection Control Service; and D - conclusion (Appendices 1 and 2). The RDC Nº 48/2000[4] assesses compliance with the HAICPs actions based on the potential risk of each item, as shown in Table 1.

Table 1 - Classification of requirements for Healthcare-Associated Infection Prevention and Control according to potential risk

Items	Potential risk
1. Indispensable (I)	May influence, to a critical degree, the quality and safety of hospital care.
2. Necessary (N)	May influence, to a less critical degree, the quality and safety of hospital care.
3. Recommended (R)	May influence, to a non-critical degree, the quality and safety of hospital care.
4. Informative (INF)	Offers support for a better interpretation of the other items, without affecting the quality and safety of hospital care.

Data processing and analysis

Data were analyzed using the software Statistical Package for Social Sciences (SPSS), version 20.0 (IBM Corp, New York, The United States of America). Hospital characteristics (type of care, legal nature, management, hospital size according to the number of beds, type of intensive care unit and quality certification by the National Accreditation Organization (ONA, as per its acronym in Portuguese) were described according to the state (Goiás and São Paulo). Comparisons between proportions were made using Fisher's exact test, with p-values < 0.05 considered statistically significant.

The inspection criteria for HAICPs and HIACCs, as well as those for the executing members and the Healthcare-Associated Infection Control Service (HAICSs) were described for the total sample (N = 18). Each item was described as absolute (n) and relative (%) frequencies. In addition, the overall means were calculated to

identify compliance of the items, being defined as the percentage of responses present (yes), divided by the total number of questions[4] and the standard deviation (SD).

Ethical aspects

The matrix research and the present cutout met the standards of Resolution Nº 466/2012[11], of the National Health Council, which were approved by the National Research Ethics Committee, opinion Nº 3.979.597, dated April 18th, 2020.

RESULTS

The sample was made up of 18 hospitals, whose characteristics are shown in Table 1. Except for the type of care provided (general or specialized), and the type of ICU, no differences were found in the characteristics of these hospitals according to the state where they were located (Table 2).

The HIACCs showed all indispensable items and a mean compliance of 93.0% (SD = 5.8) in relation to the necessary items, considered of potential risk for quality and safety of care (Table 3). Among the noncompliant items, the following stand out: absence of an antimicrobial use policy defined in cooperation with the Pharmacy and Therapeutics Committee (11.0%) and a standardized form for antimicrobial prescriptions (11.0%); absence of systematic control of antimicrobial prescriptions (5.6%); absence of disclosure of reports among the hospital's clinical staff (5.6%); and absence of a mechanism to detect cases of post-discharge HAIs (16.7%%).

Regarding the recommended evaluation criteria (Table 2), the mean of affirmative answers was 64.8% (SD = 32.5).

Regarding the evaluation of the executing members and HAICSs (Table 4), all hospitals met the indispensable criteria required by RDC Nº 48/2000[4]. Physicians and nurses were the most frequent professionals among executing members of HAICCs, followed by nursing technicians, pharmacists, and managers (non-tabular data).

Regarding the necessary items (Table 4), mean compliance was 90.2% (SD = 16.1); and noncompliance

Table 2 - Characteristics of hospitals (N = 18) according to care profile, type of Intensive Care Unit, and quality certification, Goiás and São Paulo, Brazil, 2020

Variables	Total (N = 18)		Goiás (n = 8)		São Paulo (n = 10)		*p-value**
	n	%	n	%	n	%	
Type of care							
General	9	50.0	1	12.5	8	80.0	0.02
Specialized	9	50.0	7	87.5	2	20.0	
Legal nature							
Public	9	50.0	5	62.5	4	40.0	0.64
Private	9	50.0	3	37.5	6	60.0	
Management							
Municipal	6	33.3	1	12.5	5	50.0	0.15
State	12	66.7	7	87.5	5	50.0	
Hospital size (number of beds)							
Medium (51 to 150)	7	38.9	4	50.0	3	30.0	1.00
Large (151 to 500)	9	50.0	3	37.5	6	60.0	0.35
Extra-large (> 500)	2	11.1	1	12.5	1	10.0	0.86
Type of ICU							
Adult	17	94.4	7	87.5	10	100.0	0.44
Pediatric	9	50.0	3	37.5	6	60.0	0.64
Neonatal	7	38.9	1	12.5	6	60.0	0.07
Hospital certified by ONA							
No	8	44.4	3	37.5	7	70.0	0.34
Yes	10	55.6	5	62.5	3	30.0	

Note: ICU – Intensive care unit; ONA - National Accreditation Organization; * Fisher's exact test.

Table 3 - Distribution of the indispensable, necessary, and recommended criteria for the inspection of HIACCsa and HIACPsb, according to Resolution Nº 48/2000 (N = 18), Goiás and São Paulo, Brazil, 2020

Criteria	Yes		No	
	n	%	n	%
Indispensable				
1. Is there a HAICC[a] in this hospital?	18	100.0	-	-
2. Is the HAICC formally appointed?	18	100.0	-	-
3. Are there HAICPs[b] in this hospital?	18	100.0	-	-
4. Does the HAICC[a] regularly prepare reports containing informative data and indicators of the control of HAIs[c]?	18	100.0	-	-
5. Are there norms and routines, aiming to limit the spread of microorganisms of infectious diseases in course in the hospital, by means of precaution and isolation measures?	18	100.0	-	-
6. Do all sectors of the hospital have washbasins with running water, soap and/or antiseptic and paper towels, for professionals to sanitize their hands?	18	100.0	-	-
Necessary – mean (± SDd): 93.0 (± 5.8)				
1. Are there internal regulations for this HAICC[a]?	17	94.4	1	5.6
2. Are there manuals or technical-operational routines aimed at the prevention and control of HAIs?	18	100.0	-	-
3. Is there specific, systematic, and periodic training of hospital personnel for the control of HAIs?	18	100.0	-	-
4. Does the HAICC[a] systematically control antimicrobial prescriptions?	17	94.4	1	5.6
5. Is there a standardized form for antimicrobial prescriptions?	16	88.9	2	11.1
6. Does the HAICC[a] disseminate its reports among the hospital's clinical staff?	17	94.4	1	5.6
7. Does the hospital have a mechanism to detect cases of post-discharge HAIs[c]?	15	83.3	3	16.7
8. Is there an antimicrobial use policy defined in cooperation with the Pharmacy and Therapeutics Committee?	16	88.9	2	11.1
Recommended – mean (± SD[d]): 64.8 (± 32.5)				
1. Does the HAICCa promote discussions with the hospital community about the control of HAIs[c]?	16	88.9	2	11.1
2. Is there a consortium with other hospitals for the reciprocal use of technical, material and human resources in the implementation of HAICPs[b]?	6	33.3	12	66.7
3. Does the hospital have a communication or integration mechanism with other health services for detecting cases of HAIs[c]?	14	77.8	4	22.2

Note: [a]Healthcare-associated infection control committee (HAICC); [b]Healthcare-associated infection control programs (HAICPs); [c]Healthcare-associated infections (HAIs); [d]Standard deviation..

Table 4 - Distribution of the indispensable, necessary, and recommended criteria for inspection regarding the activities developed by the Executive Members of the Hospital Infection Control Committee and Service, according to Resolution Nº 48/2000 (N = 18), Goiás, GO, and São Paulo, SP, Brazil, 2020

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Criteria	Yes		No	
	n	%	n	%
Indispensable				
1. Does the HAICC[a] have executive members?	18	100.0	-	-
2. Is there an epidemiological surveillance system for HAIs[b]?	18	100.0	-	-
3. Does the hospital have a microbiology laboratory?	18	100.0	-	-
Necessary – mean (± SD[c]): 90.2 (± 16.1)				
1. Is there a written protocol that guides hand hygiene?	18	100.0	-	-

Table 4 - Distribution of the indispensable, necessary, and recommended criteria for inspection regarding the activities developed by the Executive Members of the Hospital Infection Control Committee and Service, according to Resolution Nº 48/2000 (N = 18), Goiás, GO, and São Paulo, SP, Brazil, 2020

Conclusion...

Criteria	Yes		No	
	n	%	n	%
2. Is there a written protocol for intravascular and urinary catheter care?	18	100.0	-	-
3. Is there a written protocol that orientates dressings?	18	100.0	-	-
4. Is there a written protocol that guides the cleaning and disinfection of health products?	18	100.0	-	-
5. Is there employee training for the application of the above-mentioned procedures, performed in partnership with other teams?	18	100.0	-	-
6. Is there data collection on HAIs?	18	100.0	-	-
7. Are the indicators of HAIs collected?	18	100.0	-	-
8. Rate of hospital infection?	17	94.4	1	5.6
9. Rate of patients with hospital infection?	12	66.7	6	33.3
10. Rate of hospital infection by topography - urinary?	18	100.0	-	-
11. Rate of hospital infection rate by topography - surgical?	17	94.4	1	5.6
12. Rate of hospital infection rate by topography - respiratory?	18	100.0	-	-
13. Rate of hospital infection rate by topography - cutaneous?	9	50.0	9	50.0
14. Rate of hospital infection rate by topography - bloodstream?	18	100.0	-	-
15. Rate of hospital infection rate by procedure?	14	77.8	4	22.2
16. Rate of hospital infection rate in clean surgery?	15	83.3	3	16.7
17. Rate of lethality rate by hospital infection?	9	50.0	9	50.0
18. Is there an assessment and prioritization of problems based on these indicators?	18	100.0	-	-
19. Do the HAICCa executing members perform analysis of the epidemiological surveillance system, which allows identification of outbreak in time for control measures?	18	100.0	-	-
20. Is the use of personal protective equipment supervised by the HAICCa?	16	88.9	2	11.1
21. Are sensitivity/bacterial resistance reports issued to clinical staff and the HAICCa?	16	88.9	2	11.1
Recommended – mean (± SD[c]): 77.8 (± 19.2)				
1. Sensitivity/resistance coefficient of microorganisms to antimicrobials?	12	66.7	6	33.3
2. Is there medical guidance or consultation with HAICC[a] infectologists for prescription of antimicrobials?	18	100.0	-	-
3. Does HAICC[a] establish measures for continuing education of medical staff regarding the prescription of antimicrobials?	12	66.7	6	33.3

Note: [a]Healthcare-associated infection control committee (HAICC); [b]Healthcare-associated infections (HAIs); [c]Standard deviation.

of the requirements was found regarding the indicators used in the control of HAIs by the hospitals, such as absence of calculation of the case lethality rate by HAIs (50.0%) and of sensitivity/bacterial resistance reports for the clinical staff (11.1%).

Regarding the items with recommended risk, the mean was 77.8% (SD = 19.2), with noncompliance with the indicator of sensitivity/resistance coefficient of microorganisms to antimicrobials and lack of continuing education of the medical team regarding the prescription of antimicrobials (Table 3).

DISCUSSION

In hospitals in the states of Goiás and São Paulo, which have HAICCs and computerized laboratory, pharmacy, and electronic medical record systems in at least one direct patient care sector, the indispensable items of RDC Nº 48/2000[4] were fully met. These findings differ from those found in a study conducted in the Northeast region of Brazil[10], which also used this inspection script and found a lower rate of compliance. This difference may be associated with the local reality, hospital size, and especially the inexistence of ONA

certification in health services of the Northeast region of the country[10]. Accredited hospitals have a minimum set of quality standards and patient safety standards, indirectly interfering in the actions developed by HAICCs[12], and resulting in better rates of compliance.

Despite RDC Nº 48/2000[4] being the standard recommended by ANVISA, other instruments have been used in research to assess HAICPs in Ribeirão Preto-SP[7], Mato Grosso do Sul[8] and Paraná[9]. Although they used different methodologies[13], which were guided by RDC Nº 48/2000, the results were similar to those of this survey.

Regarding the presence of executing members in the HAICCs, an indispensable item, the hospitals presented at least two technicians with a college degree in the health area, as per Ordinance Nº 2616/1998[3], with physicians and nurses being more frequent, followed by nursing technicians, pharmacists, and managers. A multidisciplinary team is essential for the good functioning of HAICPs that, besides promoting the coordination between different services and professionals, contribute to safer and more resolutive health care in the prevention of HAIs[7].

Another conformity found in the settings of this study was the existence of a microbiology laboratory (indispensable item). This resource is indispensable for the control of HAIs, which characterizes it as one of the strengths of the evaluated HAICPs. The laboratory allows the identification of microorganisms, antimicrobial resistant strains and early detection of outbreaks, contributing to reduce the indiscriminate use of antibiotics, dissemination of multidrug-resistant microorganisms and increase the accuracy of reported data on HAIs[14].

The existence of a written protocol on hand hygiene (necessary item), washbasins, paper towel, soap, and antiseptic (indispensable items) was verified in all hospitals, characterized as strong points. Hand hygiene is one of the most effective and less expensive measures for preventing HAIs. However, in addition to infrastructure and availability of supplies, continued education of health professionals, performance feedback and positive reinforcement are necessary to improve hand hygiene compliance rates and reduce the occurrence of preventable infections[13]. Despite its great importance, this item is not present in the RDC Nº 48/2000[4], requiring adaptation of the normative with questions that enable the evaluation and monitoring of hand hygiene in Brazilian hospitals.

Among the necessary items for inspection of programs and HAICCs, one of the major gaps found in this study was the lack of active search for Surgical Site Infections (SSIs) after hospital discharge, a fact also found in hospitals in the Northeast[15] and Southeast[7,16] regions of Brazil, as well as in international literature[17]. The establishment of a post-discharge surveillance system may help in the prevention and reduction of SSIs cases, especially when this intervention occurs in a period shorter than the 15th postoperative day[17].

Failure to comply with this recommendation can lead to underreporting of HAIs, which affects the quality and reliability of the information recorded by hospitals, generating underestimated rates that are not representative of reality[16,18]. A post-discharge surveillance system is generally not adopted in Brazilian hospitals due to the lack of qualified and sufficient human resources, physical structure, and adequate financial resources for implementation, limiting the monitoring of SSI only to the period of hospitalization[16].

Although there is no reliable post-discharge surveillance system method worldwide, some strategies have been indicated as promising, among them: telehealth, which consists of monitoring the patient by telephone call/mobile devices, and outpatient return, which allows clinical evaluation of the patient and the surgical wound[16,17,19]. These are active search strategies for HAIs that can be implemented by Brazilian hospitals, contributing to the diagnosis and early treatment of surgical patients, avoiding serious complications such as death[16].

In this study, hospitals presented HAI surveillance systems (indispensable item), data collection, survey of HAI indicators, and assessment and prioritization of problems based on these indicators (necessary items). However, some epidemiological indicators were not calculated, especially the case fatality rates for HAIs and infection rates by topography. In European countries, the objectives and methods of surveillance for HAIs also vary. In general, professionals prioritize some indicators over others, taking into consideration the size of the hospital, the geographical region, and the volume of health care expenditure[20].

It is noteworthy that, in the inspection script, the predominant infection monitoring and control activities focus on surveillance and evaluation of outcome indicators, which measure the incidence or prevalence of HAIs. However, the isolated use of such estimates does not reflect the quality and safety of health care, since they do not take into account the severity of the patients and the complexity of the invasive procedures performed[9]. Therefore, the reduction or increase of a given indicator can only be understood based on structural and work process changes[1,20].

Therefore, it is of utmost importance to update and include clearer and more specific outcome indicators in the RDC Nº 48/2000[4], such as rates based on incidence density; process indicators, such as the percentage of adherence to the bundle of prevention of HAIs; and structure indicators, such as the amount of human and material resources, considered minimum requirements for building strong and effective HAICPs[21], making this tool more efficient for health surveillance by Brazilian inspection agencies.

Besides the creation and analysis of indicators, there is a need to promote debates with the hospital community about measures to prevent and control HAIs (recommended item). This study identified that two hospitals do not hold debates with the internal community. The control of HAIs is not restricted to the actions developed by the committees, but is a responsibility of all professionals involved in the institution, including the administrative staff. In this sense, programs of continuing education for professionals working in HAICSs offered by the institutions themselves, or in partnership with government entities, are fundamental, and can serve as a space for reflection, awareness, changes in attitudes and acquisition of knowledge about prevention and control of HAIs[22].

As determined by Ordinance Nº 2616/98, a consortium can be established among hospitals with less than 70 beds and joint formation of the HAICPs[3]. In this investigation, the consortium with other hospitals (recommended item) was not identified, possibly due to the characteristic of the sample, made up of medium and large hospitals, which have better infrastructure, financial and human resources sufficient for the execution of surveillance actions of HAIs, which was also identified by other large Brazilian hospitals[15]. Non-compliance with this item may lead to misinterpretation of results, since it does not represent the reality of the hospitals studied. In this study, this item decreased the mean compliance with the normative.

Non-compliance with the calculation of the indicator of sensitivity/resistance coefficient of microorganisms to antimicrobials and lack of continuing education of the medical team regarding the prescription of these drugs (recommended items), were present in one-third of hospitals. This finding is worrisome, since it may favor the emergence of microorganisms resistant to multiple antimicrobials.

Lack of training for physicians in antimicrobial prescribing is also a recurrent problem in other countries, including the United States of America[23], Iran[24], and Africa[25]. In this scenario, it is indispensable to design and implement an antimicrobial use management program that involves a set of actions aimed at surveillance of antimicrobial resistance patterns and consumption[21,26].

The quality assessment of HAICPs based on the criticality levels established by the RDC Nº 48/2000[4] is outdated and presents isolated, undervalued, subjective, and non-measurable results.

Given the need for better understanding of the risk, a new inspection technology was developed in 2007, called Objective Inspection Roadmap, which classifies health services into three levels: acceptable, tolerable, and unacceptable, depending on the value of potential risk calculated[27].

The unacceptable result is the one that should lead to interdiction or suspension of activities in the service. In relation to the tolerable risk, the service may receive notification for correction of non-conformities within a defined period, and if the risk is acceptable, there will certainly be the release of the health license[27].

Since 2019, this classification was incorporated by ANVISA on a recommendatory basis as part of the National Project for Harmonization of Health Inspection Actions in Health Services and of Interest to Health in 15 sectors and health services[28], but it has not yet been adopted for evaluation of HAICPs.

Therefore, it is important to highlight the urgency of re-evaluating the RDC Nº 48/2000[4] for this new methodology for classification of services, which favors risk management in sanitary surveillance and decision-making regarding the direction of its control actions based on actual and updated data, thus reducing the subjectivity of the inspection[27].

Conducting the study in a small number of hospitals, located in two Brazilian states, and using a non-probabilistic sample, consists of a limitation for generalizing the results found. In this context, stratified analyses of compliance could not be performed according to hospital size and other variables of interest due to sample size. In addition, due to restrictive measures to face the COVID-19 pandemic, it was not possible to observe some variables and to carry out the interview on-site, being the data collection carried out online and in self-reported by the coordinators of the HAICCs. However, the results contribute to the construction of knowledge about the HAICPs implemented in hospitals in the states of São Paulo and Goiás.

Finally, one should reflect on the inspection script that does not encompass important issues, such as the availability of financial budget for the operation of the HAICPs; the presence of a multidisciplinary program that considers the local situation of the unit; well-defined epidemiological indicators, action plans with objectives,

goals and clear strategies for prevention and control of HAIs; development of protocols and frequency of data feeding/analysis in the existing surveillance systems[21].

CONCLUSION

The indispensable items of RDC Nº 48/2000[4] were totally fulfilled, but the necessary and recommended ones had lower percentages. There are weaknesses regarding some important actions for the prevention and control of HAIs, such as the absence of calculation of epidemiological indicators (such as HAI's lethality rate and sensitivity/resistance coefficient of microorganisms to antimicrobials), a mechanism to detect cases of post-discharge HAI (necessary items) and management of antimicrobials (recommended item).

This current regulation does not establish a minimum percentage of compliance for the criteria, making it difficult to interpret the results. Although the RDC Nº 48/2000[4] is outdated as a tool for evaluating HAICPs, it remains an official roadmap for health inspection and its use contributed to know the local reality of the HAICPs of hospitals in the states of São Paulo and Goiás, especially the latter, whose epidemiological data on the programs are scarce. Thus, it is important to update RDC Nº 48/2000[4] in order to provide the inspection bodies with instruments during health inspections, and ANVISA is responsible for this function.

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CONFLICT OF INTEREST

None.

AUTHORS' CONTRIBUTIONS - CRediT

CFP: conception; supervision; validation; visualization and writing - original draft.
RAG: methodology; validation; visualization; writing - original draft and writing - proofreading and editing.
KAB: conception; supervision; validation; visualization and writing - original draft.
PRSH: conception; research and writing - original draft.
LAA: conception; research and writing - original draft.
IAJG: conception; research and writing - original draft.
TAM: conception; research and writing - original draft.
HSJ: conception; research and writing - original draft.
JKSC: conception; research and writing - original draft.
GAO: conception; research and writing - original draft.
RSP: conception; data selection; formal data analysis; methodology; supervision; validation; visualization; writing - original draft and writing - proofreading and editing.

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APPENDIX 1

- Evaluation Criteria for the Hospital Infection Control Program and Committee according to the Collegiate Directive Resolution Nº 48/2000, Brazil

Indispensable Criteria*
1. Is there a HAICC[a] in this hospital? 2. Is the HAICC[a] formally appointed? 3. Are there HAICPs[b] in this hospital? 4. Does the HAICC[a] regularly prepare reports containing informative data and indicators of the control of HAIs[c]? 5. Are there norms and routines, aiming to limit the spread of microorganisms of infectious diseases in course in the hospital, by means of precaution and isolation measures? 6. Do all sectors of the hospital have washbasins with running water, soap and/or antiseptic and paper towels, for professionals to sanitize their hands?
Necessary Criteria
1. Are there internal regulations for this HAICC[a]? 2. Are there manuals or technical-operational routines aimed at the prevention and control of HAIs[c]? 3. Is there specific, systematic, and periodic training of hospital personnel for the control of HAIs[c]? 4. Does the HAICC[a] systematically control antimicrobial prescriptions? 5. Is there a standardized form for antimicrobial prescriptions? 6. Does the HAICC[a] disseminate its reports among the hospital's clinical staff? 7. Does the hospital have a mechanism to detect cases of post-discharge HAIs[c]? 8. Is there an antimicrobial use policy defined in cooperation with the Pharmacy and Therapeutics Committee?
Recommended Criteria
1. Does the HAICC[a] promote discussions with the hospital community about the control of HAIs? 2. Is there a consortium with other hospitals for the reciprocal use of technical, material and human resources in the implementation of HAICPs[b]? 3. Does the hospital have a communication or integration mechanism with other health services for detecting cases of HAIs[c]?

Source: Brazil (2000)[4].
Note: [a]Healthcare-associated infection control committee (HAICC); [b]Healthcare-associated infection control programs (HAICPs); [c]Healthcare-associated infections (HAIs).

APPENDIX 2

- Inspection Criteria for Executive Members of the Hospital Infection Control Committee and Service according to the Collegiate Directive Resolution No. 48/2000, Brazil

Indispensable Criteria*
1. Does the HAICC[a] have executive members?
2. Is there an epidemiological surveillance system for HAIs[b]?
3. Does the hospital have a microbiology laboratory?
Necessary Criteria
1. Is there a written protocol that guides hand hygiene?
2. Is there a written protocol for intravascular and urinary catheter care?
3. Is there a written protocol that orientates dressings?
4. Is there a written protocol that guides the cleaning and disinfection of items?
5. Is there employee training for the application of the above-mentioned procedures, performed in partnership with other teams?
6. Is there data collection on HAIs[b]?
7. Are the indicators of HAIs[b] collected?
8. Rate of hospital infection?
9. Rate of patients with hospital infection?
10. Rate of hospital infection by topography - urinary?
11. Rate of hospital infection by topography - surgical?
12. Rate of hospital infection by topography - respiratory?
13. Rate of hospital infection by topography - cutaneous?
14. Rate of hospital infection by topography - bloodstream?
15. Rate of hospital infection by procedure?
16. Rate of hospital infection in clean surgery?
17. Rate of lethality by hospital infection?
18. Is there an assessment and prioritization of problems based on these indicators?
19. Do the HAICC executing members perform analysis of the epidemiological surveillance system, which allows identification of outbreak in time for control measures?
20. Is the use of personal protective equipment supervised by the HAICC[a]?
21. Are sensitivity/bacterial resistance reports issued to clinical staff and the HAICC[a]?
Recommended Criteria
1. Sensitivity/resistance coefficient of microorganisms to antimicrobials?
2. Is there medical guidance or consultation with HAICC[a] infectologists for prescription of antimicrobials?
3. Does HAICC[a] establish measures for continuing education of medical staff regarding the prescription of antimicrobials?

Source: Brazil (2000)[4].
Note: [a]Healthcare-associated infection control committee (HAICC); [b]Healthcare-associated infections (HAIs).