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Original article

The feature of preventable adverse events in hospitals in the State of Rio de Janeiro, Brazil[☆]

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Objective: To analyze the features of preventable adverse events (AEs) in hospitals inpatient in the state of Rio de Janeiro, in Brazil, in order to identify elements to serve as a substrate for priority actions aimed at improving patient safety.

Methods: Analysis of data from a baseline retrospective cohort study to assess the incidence of AEs in a sample of records in three teaching hospitals in the State of Rio de Janeiro to describe the features of preventable AEs.

Results: In a sample of 1,103 patients, were identified 65 preventable AEs of 56 patients who suffered preventable AEs. The healthcare associated infections (HAI) accounted for 24.6% of preventable AEs; surgical complications and/or anesthetic, 20.0%; damages arising from delay or failure in diagnosis and/or treatment, 18.4%; pressure ulcers, 18.4%; damage from complications of venipuncture, 7.7%; damage due to falls, 6.2%; damage as a result of the use of drugs, 4.6%. The preventable AEs were responsible for additional 373 days of hospital stay. **Conclusion:** The HAI is the major preventable AE, as observed in other developing countries. Despite the limitations of the study, the characterization of preventable AEs indicates that known and effective actions available to reduce HAI, such as hand hygiene, to prevent pressure ulcers, to encourage adherence to protocol and clinical guidelines and to create continuing education programs for health professionals, should compose the list of priorities of hospital managers and health professionals involved in the care of hospitalized patients.

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Características de eventos adversos evitáveis em hospitais do Rio de Janeiro

R E S U M O

Palavras-chave:

Evento adverso evitável
Qualidade da assistência à saúde
Segurança do paciente
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Objetivo: Analisar as características dos eventos adversos (EAs) evitáveis em pacientes internados em hospitais do Rio de Janeiro, com vista a identificar elementos que sirvam de substrato à ações prioritariamente voltadas para melhoria da segurança do paciente.

Métodos: Análise de dados coletados no estudo de base de coorte retrospectivo para avaliação da ocorrência de EAs em uma amostra de prontuários em três hospitais de ensino do estado do Rio de Janeiro para descrever as características dos EAs evitáveis.

Resultados: Na amostra de 1.103 pacientes foram identificados 65 EAs evitáveis dos 56 pacientes que sofreram EAs evitáveis. As infecções associadas aos cuidados da saúde (IACS) representaram 24,6%; complicações cirúrgicas e/ou anestésicas, 20,0%; danos decorrentes do atraso ou falha no diagnóstico e/ou tratamento, 18,4%; úlceras por pressão, 18,4%; danos de complicações na punção venosa, 7,7%; danos devido a quedas, 6,2%; danos em consequência do emprego de medicamentos, 4,6%. EAs evitáveis foram responsáveis por 373 dias adicionais de permanência no hospital.

Conclusão: O estudo mostrou que os EAs mais frequentes são as IACS, tal como observado em outros países em desenvolvimento. Apesar das limitações do estudo, a descrição da caracterização dos EAs evitáveis indica que ações disponíveis e consagradas voltadas para diminuir as IACS, como a higienização das mãos, a prevenção a úlcera por pressão, o estímulo a adesão a protocolo e diretrizes clínicas e o estabelecimento de programas de educação continuada de profissionais de saúde, devem compor a lista de prioridades dos gestores hospitalares e dos profissionais de saúde envolvidos no cuidado ao paciente hospitalizado.

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Introduction

The first study to use the method of retrospective chart review of medical records to assess the incidence of adverse events (AEs) in hospitals was the Medical Insurance Feasibility Study (MIFS), conducted in California, United States in 1974.¹ However, the study that brought to light the magnitude of the inpatient safety issues was the Harvard Medical Practice Study² (HMPS), conducted in 1984 in hospitals of the state of New York, United States. This study contributed to the publication of the book "To err is human",³ which had a major impact on the American society and, subsequently, on the world. Sequentially, other investigations were conducted in the United States,⁴ Canada,⁵ Denmark,⁶ France,⁷ Australia,⁸ New Zealand,⁹ United Kingdom,¹⁰ Brazil,¹¹ Spain,¹² Sweden,¹³ Netherlands,¹⁴ Portugal,¹⁵ and Tunisia.¹⁶ These studies considered that AE, pursuant to the HMPS² definition, an unintended injury resulting in temporary or permanent disability and/or prolonged length of stay as a consequence of health care management. Based on published empirical evidence, it is estimated that the incidence of inpatients that experience AE is approximately 10%, and that the proportion of preventable AEs is around 50% of the total AEs.¹⁷⁻¹⁹ Therefore, the occurrence of an AE is a serious problem related to the safety of patients, reflecting on the quality of the care provided worldwide.

An important point to AE assessment and to the design strategies directed to improve the quality of care is the identification and awareness of the characteristics and factors that contribute to the occurrence of AEs deemed preventable.²⁰ However, the enhancement of knowledge and the improvement in patient safety practices are restricted by the great proliferation of definitions and terminologies. Twenty-four different definitions of the term "error" and 14 definitions of AE were found in various studies.²¹ A recent systematic review described seven different definitions of preventable AE.²² In order to standardize the definitions of the main concepts in the literature on patient safety, the World Health Organization²¹ (WHO), through the Patient Safety Program, developed the International Classification for Patient Safety (ICPS), in which an incident is defined as any event or circumstance that could have resulted, or did result, in unnecessary harm to a patient.²² In this classification, harmful incidents correspond to AEs. However, the ICPS is subsequent to and differs from most of the aforementioned studies on incidence of AE, which adopted concepts similar to those prepared in the HMPS.²

The occurrence of an AE does not necessarily mean that there was error in the patient care. Patients may suffer harms inherent to the health care that may not be avoided (e.g., side effects resulting from chemotherapy).

Conversely, a preventable AE is a harm to the patient due to an active or latent failure, or even to a violation of rules and standards.^{23,24}

Regarding the Brazilian reality, academic production is still scarce. In addition to few studies,^{11,25-27} until now there are no studies with a broad geographic scope, which is important considering the great variability of the characteristics of Brazilian hospitals. A study conducted in hospitals of Rio de Janeiro indicated an incidence of preventable AE of 5.1% (56/1,103; 95% CI: 3.8-6.4), with a proportion of 66.7% (56/84; 95% CI: 56.4-77) of preventable AE.¹¹ The same study verified that the association between hospital death and preventable AE and the odds ratio adjusted by the patient risk factors was very high (OR: 8.23; 95% CI: 4.02-16.82.²⁸ In international studies that used the retrospective chart review as a method for collection of data, the proportion of preventable AE was as follows: Canada, 36.9%⁵; Portugal, 53.2%¹⁵; Sweden, 70%¹³; Tunisia, 60.0%¹⁶; Netherlands, 39.6%¹⁴; and Spain¹², (42.8%).

These findings draw attention to the importance of understanding the contributing characteristics and factors associated with the occurrence of preventable AEs. These are undesirable outcomes that should not occur in a health organization, and whose severity may even cause death. Continuing a series of Brazilian studies,^{11,28-31} the present study describes in detail the characteristics of preventable AEs in inpatients of Rio de Janeiro, with the purpose of identifying elements that may be used as a basis for action, primarily focused on improving patient safety.

Methodology

Design and scope of the study

This was a descriptive analysis, based on data obtained from a baseline study,¹¹ a retrospective cohort that assessed the occurrence of AEs in a sample of 1,103 adult patients hospitalized for over 24 hours in three general, public teaching hospitals located in the state of Rio de Janeiro, Brazil, in 2003.¹¹ Fifty-six patients who experienced preventable AEs were analyzed.

Baseline study – some methodological information

The hospitals selected for the baseline study were large-scale, high-complexity facilities that attended to acute patients; two of the hospitals provided obstetric care.^{11,32} In the baseline study, a simple random sample of the total of 27,350 hospitalizations of adults in 2003 in the study hospitals was used.¹¹ In order to identify the occurrence of AE and its preventability, the retrospective chart review developed by the Canadian Adverse Event Study (CAES) was adopted.⁵

The retrospective chart review was performed in two stages of assessment: (1) explicit review – nurse practitioners searched for potential AEs; (2) structured implicit review – a physician evaluated the occurrence of AEs and their preventability. The team of reviewers was composed of four nurse practitioners and one physician, with over 20 years of professional

experience and submitted to a specific training. The physician judged whether there was evidence of harm attributable to healthcare, i.e., the presence of AE (preventable or not), based on the analysis of the information described in the patient medical records through a six-level scale. In order to maintain similarity with other international studies, a score > 3 in this scale characterized the presence of AE and its preventability. The doubtful cases were reviewed by the physician together with a specialist.^{11,32}

The research project was approved by the Research Ethics Committee of the Escola Nacional de Saúde Pública Sérgio Arouca of the Fundação Oswaldo Cruz.

Analysis of data on preventable adverse events

The described analysis of preventable AEs comprised demographic characteristics (gender and age of patients) and the type of admission (elective or emergency). The description of the preventable AEs was based on the following information: (i) additional days of hospitalization due to AE; (ii) place where the AE occurred (ward, operating room, intensive care unit, or others); (iii) timing when the AE occurred (before, during, or after hospitalization); (iv) adequacy of the procedures adopted to treat the AE (certainly appropriate, probably appropriate, possibly inappropriate, or certainly inappropriate); (v) classification of the AE according to the origin (diagnosis; surgery; fracture; anesthesia; obstetric care; drug; medical procedures; system [when the event is not attributed to an individual or specific source, e.g., miscommunication, error in registration, lack of equipment, drugs, medical and surgical equipment, etc] ; or other); (vi) description of AE (healthcare-associated infection [HAI]; harm due to falls; pressure ulcers; harm from surgical complication; harm arising from delay in the diagnosis or failure to diagnose; harm arising from delay in treatment or failure to treat; harm from complications of venipuncture; and harm associated to the use of medication); (vii) AE contributing factors (lack of knowledge by the professional when managing the case; non-compliance with the rules [did not check or follow the protocol or clinical guideline]; inattention by the medical professional; technical error [incorrect and/or non-indicated procedure]; violation [willful failure to comply with rules or protocols]; or indefinite error – the reviewing doctor had the option to choose more than one); (viii) failure to prevent the occurrence of an AE (failure to take precautions to prevent accidental injury delay in treatment; failure to take precautions to prevent accidental injuries; physician or other professional practicing outside area of expertise; failure to verify equipment and medications; misdiagnosis; failure to act based on results of the findings or tests; failure to ask for help when needed; and use of improper or obsolete examinations); (ix) complexity of the diagnosis and definition of treatment regimen, considering the patient's condition and the acceptable technical standards (high complexity, moderate complexity, low complexity, no complexity, or undefined).

The statistical analyses were performed using the statistical package STATA 10.0.

Table 1 – Neurological scoring system for fetuses through 4DUS (KANET test). Adapted from Kurjak, et al.²

Characteristics of the study population	Sample % (n)	95% CI	Patient with preventable AE % (n)	95% CI
<i>Gender</i>				
Female	61.4 (677)	58.5-64.2	60.7 (34)	47.5-73.9
Male	38.6 (426)	35.7-41.5	39.3 (22)	26.0-52.4
<i>Age group</i>				
18-30	26.5 (292)	23.8-29.1	5.4 (3)	-0.7-11.4
31-40	16.2 (179)	14.0-18.4	14.3 (8)	4.8-23.7
41-50	15.1 (166)	12.9-17.2	14.3 (8)	4.8-23.7
51-60	14.5 (160)	12.4-16.6	8.9 (5)	1.2-16.6
61-70	13.3 (147)	11.3-15.3	26.8 (15)	14.8-38.7
> 70	14.4 (159)	12.3-16.5	30.4 (17)	17.9-42.7
Average (SD)	46.8 (19.1)	—	59.5 (17.4)	—
Median (IQR)	46 (30-63)	—	64 (45-74)	—
<i>Type of admission</i>				
Emergency	55.3 (611)	52.4-58.3	66.0 (37)	53.2-78.8
Elective	44.6 (492)	41.6-47.5	33.9 (19)	21.1-46.7
Total	100.00 (1103)		100.00 (56)	

95% CI, 95% confidence interval; AE, adverse events; IQR, interquartile range; SD, standard deviation.

Results

In the sample of 1,103 patients, 56 experienced preventable AEs. Among these, 34 (60.7%) were females. The average age of the patients with preventable AE was different than that found in the sample of patients from the baseline study. While the average age of the patients in the sample was 46.8 years old (standard deviation, SD: 19.1) with a median of 46 years old, among the patients with preventable AE the average was 59.5 years old (SD: 17.4 years) with a median of 64 years old (Table 1). The difference between the average age of the total sample and of patients with preventable AEs was statistically significant ($p < 0.001$). Regarding the total sample, the higher the age, the higher the proportion of preventable AEs ($p < 0.001$). In general, an increasing dose-response gradient among the age group and the percentage of patients with preventable AE was observed; the highest age groups (61 to 70 years old and above 70 years old) represented approximately 21% of these events. Regarding the type of admission, 19 patients (33.9%) with preventable AEs were admitted electively and 37 (66.0%) were in an emergency.

The total preventable AEs was 65, as seven of the 56 patients experienced more than one preventable AE. Regarding the origin, the most frequent preventable AEs were related to surgery, 21 (32.3%); to non-surgical medical procedures, 19 (29.2%); to misdiagnosis, ten (15.3%); to obstetric care, four (6.15%); to the system, four (6.15%); and to medication, three (4.6%). The main preventable AEs were HAI, 16 (24.6%); surgical and/or anesthetic complications, 13 (20.0%); harm arising from delay or failure in diagnosis and/or treatment, 12 (18.5%); and pressure ulcers, 12 (18.5%) (Table 2).

Of the 16 cases of HAI, 11 (68.7%) were due to surgical site infections, three (18.7%) to urinary infections, and two (12.5%)

to respiratory infections. No bloodstream infection associated with central venous catheters was detected.

Preventable AEs were responsible for 373 additional days of hospitalization; HAI had the greater impact (226 days), followed by surgical and/or anesthetic complications (79 days) (Table 2).

In 56 (86.2%) of the preventable AEs, harm occurred during hospitalization. Suitable measures for treating the harm were adopted in 50 (79.4%) of the preventable AEs. Regarding the location preventable AEs occurred predominantly in the ward (37 patients, 56.9%) and operating room (20 patients, 30.8%) (Table 3).

Regarding the complexity of the cases in which there was a preventable AE, 13 (20.0%) were classified as high complexity, 20 (30.8%) as moderate complexity, 19 (29.2%) as low complexity, and 13 (20.0%) as no complexity. The main failures that lead to the 65 preventable AEs were: failure to take precautions in order to avoid accidental damage in 47 (72.3%) of preventable AEs, and failure to act based on test results in eight (12.3%) (Table 3).

Sixty-eight contributing factors were identified for the occurrence of 65 preventable AEs, as in three cases there was more than one factor. The most frequent contributing factor was failure to comply with the rules in 36 (55.9%) cases, technical error in nine (14.7%) cases, and inattention of the professional in seven (11.8%) cases (Table 3).

Discussion

The high proportion of Brazilian patients with preventable AEs (67%), described by Mendes et al.,¹¹ expresses the relevance of the issue and the need for actions aimed to reduce the occurrence of unnecessary and preventable harm to patients. The findings of the present study provide some indications,

Table 2 – Proportional distribution of preventable adverse events by number of additional days of hospitalization.

Preventable adverse events	Proportion of preventable AEs % (n)	Additional days of hospitalization
Healthcare-associated infections	24.6% (16)	226
Surgical and/or anesthetic complications	20.0% (13)	79
Harm arising from delay or failure in diagnosis and/or treatment	18.5% (12)	59
Pressure ulcers	18.5% (12)	9
Harm from complications of venipuncture	7.7% (5)	0
Harm due to falls	6.2% (4)	0
Harm due to medication	4.6% (3)	0
Total	100% (65)	373

AE, adverse events.

Table 3 – Proportional distribution of preventable adverse events regarding the place and moment of occurrence, contributing factors, and failure to prevent.

Description	Proportion of preventable AEs % (n)
<i>Place where the preventable adverse event occurred (n = 65)^a</i>	
Patient room or ward	56.9% (37)
Operating room	30.8% (20)
ICU	4.6% (3)
Outside the hospital (others)	3.1% (2)
Procedure room	1.5% (1)
Emergency room	1.5% (1)
Service area	1.5% (1)
<i>Moment when the preventable AE occurred (n = 65)</i>	
Before hospitalization	12.3% (8)
During hospitalization	86.2% (56)
After hospitalization	1.5% (1)
<i>Factors contributing to the preventable AE (n = 68)^b</i>	
Violation of rule	55.9% (38)
Technical error (did not check or follow protocol)	14.7% (10)
Indefinite	13.2% (9)
Lack of ability	11.8% (8)
Others	5.9% (4)
Lack of knowledge	4.4% (3)
Technical failure (procedure incorrect and unindicated)	1.5% (1)
<i>Failure to prevent the occurrence of the preventable AE (n = 65)</i>	
Failure to take precautions in order to avoid accidental injuries	72.3% (47)
Failure to act based on test results	12.3% (8)
Delay in treatment	7.7% (5)
Other prevention errors	3.1% (2)
Inadequacy in making the anamnesis or physical examination	1.5% (1)
Misdiagnosis	1.5% (1)
Medical malpractice or failure by other professionals not based on criteria	1.5% (1)

AE, adverse event; ICU, intensive care unit.

^a65 preventable AEs.

^bThree of the 65 preventable AEs had more than one contributing factor.

highlighting actions directed to the prevention of infections, surgical complications, and conditions sensitive to the proper nursing care.

Studies assessing the occurrence of harm caused during health care especially emphasize the frequency of AEs as the main finding.¹⁹ Nonetheless, in order to develop activities to improve quality in hospitals, it is particularly important to know the characteristics of preventable AEs. In general, the studies^{1,3-16} present AEs aggregated into groups of causes: diagnosis, surgery, fracture, anesthesia, obstetrics, medication, medical procedures, and system. However, by presenting AEs in major groups, some relevant information is hidden. The best example refers to the HAI cases, one of the main problems related to the unsafe care in hospitals,³³ which are not evidenced when classified under the groups of surgical AEs and AEs arising from medical procedures.

In this study HAIs were described as the most prevalent AEs, accounting for 25% (16/65) of the preventable AEs. HAIs also had an important impact on the increase in the length of hospital stay of the patients (226 days). A research assessing the prevalence of AE in hospitals of five countries in Latin America³⁴ evidenced that 37.1% (501/1,349) of the AEs were due to HAIs. HAIs are a major public health problem, especially in developing countries, as, in addition to harming the patient, they increase health care costs.³⁵ Studies evidence that HAIs extend the length of hospital stay by at least four days, at an additional cost of US\$1,800.00.³⁵ Unfortunately, there are no up-to-date Brazilian statistics on HAIs. A study from 1995 evidenced that in 99 Brazilian hospitals researched, respiratory infections corresponded to 28.9% of the total HAIs; surgical infections, to 15.6%; skin infections, to 15.5%; urinary infections, to 11%; and septicemia, to 10%.³⁶

Several strategies are being adopted to prevent HAIs. Regarding surgical site infections, which were the majority (68.7%) in this study, the Institute for Healthcare Improvement, through the “5 Million Lives” campaign, prioritized four actions: (i) use of prophylactic antibiotics; (ii) use of clippers instead of razors for hair removal prior to surgery; (iii) blood glucose monitoring; and (iv) control of body temperature during the postoperative period.³⁷ Respiratory infections, addressed in this study, consisted of pneumonia associated with mechanical ventilation, described in the literature as the most lethal among the HAIs.³⁸ The elevation the upper

part of the patient's bed at a 30° angle, and early weaning from mechanical ventilation have been the most widely used strategies.³⁹ The urinary infections found in this study were associated with the use of urinary catheters. In the literature, urinary infection is regarded as the most frequent HAI, and is directly proportional to the time the catheter is used.⁴⁰ Hand hygiene, especially in the case of urinary infections and those associated with central venous catheters, is the most effective measure.⁴¹

The preventable AEs resulting from surgical and anesthetic procedures were responsible for 32.3% of the AEs when including surgical site infection. The only anesthetic AE found in this study was headache after spinal anesthesia, deemed a mild-severity incident. The literature describes that anesthesia performs the best in the area in comparison with other medical specialties, since safety of the procedure has long been a concern in this field.⁴¹ Surgical AEs were mostly surgical technique errors, lack of skill, or failure to follow clinical guidelines. In this case, further qualification, including with simulators, would be the best strategy to prevent AEs.

The results of this study confirm the relevance of the Global Patient Safety Challenge program of the WHO, which established the hand hygiene campaign as a priority to prevent HAIs,³³ and subsequently, the use of a checklist in order to increase safety in surgical interventions.⁴²

Misdiagnoses are the most difficult to assess and, therefore, may be underestimated.⁴¹ Lack of knowledge is the factor that most contributes to the occurrence of AEs caused by misdiagnosis, more than in any other area regarding patient safety.⁴³ In the present study, the harms arising from delay or failure in diagnosis and/or treatment represented 18.5% of all preventable AEs. In one case of this study, a cerebrospinal fluid examination was not performed to diagnose cerebral toxoplasmosis in a patient who died with acquired immunodeficiency syndrome (AIDS), due to either the lack of knowledge or the use of a cognitive shortcut by the physician. The mitigation of AEs caused by misdiagnosis depends on the continuing education of physicians, the development of guidelines on clinical decision, and teamwork.⁴¹

Falls inside a hospital (whether from the bed, in the bathroom, or in any other hospital room) and pressure ulcer represented, in this study, approximately 25% of the preventable AEs. These AEs may only be prevented or mitigated through continuous risk evaluation and reevaluation by the nursing team. Some instruments are already used in Brazilian hospitals to assess pressure ulcer, such as the Braden scale.⁴⁴ To assess fall, several hospitals in the United States use the Stratify scale,⁴⁵ yet unknown in Brazil. Probably damage by medication (4.6%) are underestimated in this study, depending on the data collection record. In the CAES, the proportion of drug damages was 23.6%. The records had no specific field for the physician to inform whether there was harm caused by the drug treatment. The reviewing physician had difficulties assessing whether the harm was caused by medications or by the underlying disease.

Regarding the demographic characteristics, the gender of the patients did not influence the occurrence of preventable AE. Regarding age, it was observed that elderly people were more prone to preventable AEs. Several studies⁴⁶⁻⁴⁹

evidenced that elderly people are more susceptible to adverse outcomes.

The most frequent contributing factor to the occurrence of preventable AE was the non-compliance with standards. This means that the professional did not verify or follow the protocol or clinical guideline in 55.9% (36) of the cases.

Contrary to the expected, approximately half of the preventable AEs occurred in patients whose diagnostic or therapeutic clinical procedures were deemed less complex. The study evidenced that procedures required to treat the preventable AEs were not observed in 13 (20.6%) cases; thus, not only did the patient experience a preventable AE, but also he/she did not receive a proper treatment for the disease itself.

This study had the following methodological limitations:

- (i) hindsight bias. It is a limitation inherent to retrospective studies of medical records,⁵⁰ and it may have overestimated the incidence of patients with preventable AEs⁵¹;
- (ii) selection bias, which may have led to under or overestimation of the incidence of patients with preventable AEs. The criteria for choosing the hospitals – good quality of medical records and voluntary participation – may have selected the best facilities. Hospitals that have well-completed medical records provide better care compared to the average,²⁹ especially when addressing the issue on a national basis, leading to an underestimation of the outcome. Conversely, the selected hospitals were teaching hospitals, which may have led to an overestimation of the incidence of preventable AEs, since the incidence of AEs found in teaching hospitals is higher than in other hospitals⁵;
- (iii) internal and external validity issues of the study model. The first issue relates to the number of hospitals selected for the study. Only three hospitals were assessed, which represents a limited sample of institutions in the state of Rio de Janeiro. The second issue relates to the use of peer review and implied criteria, leading to a high level of subjectivity in judgment and low reliability between reviewers.^{52,53} The third issue is related to the reduced number of cases with preventable AE reviewed, which provided this study with an exploration of the factors at stake, as preventable AEs are not high-frequency events;
- (iv) the fourth limitation refers to the date of collection of data used in the study, regarding hospitalizations in 2003. The diagnostic and therapeutic technologies may have changed since then, having a repercussion on the incidence of AE.

Conclusion

Even though the limitations of the study restrict the generalization of the outcomes, the present study suggests that, while a major problem in hospital care in Brazil, preventable AEs and contributing factors may be changed by actions requiring little technological complexity.

It is important to managers, healthcare professionals, and researchers to know the characteristics of preventable AEs,

which may be mitigated by adopting interventions that reduce risk. Simpler methods may be prepared and tested aiming at monitoring and avoiding, in real-time, the incidents whose results imply physical and emotional impairments and financial losses to patients and professionals directly involved in their care.

Conflicts of interest

All authors declare to have no conflicts of interest.

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