PATIENT SAFETY IN LARGE HOSPITALS

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10.37885/210906252
ABSTRACT

Objective: to analyze the implementation of the national patient safety policy. Method: this is a quantitative, descriptive and evaluative study of multiple cases in large hospitals. Please be informed that the data collection consisted of an interview with the professional responsible for the Patient Safety Centers using a semi-structured form. Data were analyzed using simple statistics. Results: it is detailed that, of the 20 eligible hospitals, 12 (60%) participated in the study; all hospitals (100%) have centers, (91.7%) have a Patient Safety Plan and (50%) have a professional with exclusive dedication. All mandatory protocols were implemented in more than half of the centers (58.3%), with patient identification (83.3%) and hand hygiene (83.3%) being the most frequent. It is revealed that the percentages of adverse events reported were: pressure injury (88.9%); bed falls (77.8%) and medication errors (75%). Conclusion: it is concluded that the centers studied do not fully comply with the regulatory policies in force in the country, therefore deserving adjustments and effective sanitary control.

key Words: Patient Safety; Hospital Legislation; Patient Harm; Iatrogenic Disease; Public Policy; Delivery of Health Care.
INTRODUCTION

Thousands of patients suffer from damages due to diagnostic and therapeutic errors that occurred during healthcare, and the role of hospitals, regulatory agencies, managers and health professionals has been widely discussed, as well as the identification of risk factors that compromise patient safety.¹–⁴

It is warned that 421 million hospitalizations occur annually in the world, with approximately 42.7 million adverse events (AEs), conceptualized as incidents that occur during care and that result in harm to the patient, whether physical, social or psychological and may include injury, suffering, disability or death.⁵–⁷ It is estimated that care error is the third leading cause of death in the United States, behind only cardiovascular disease and cancer, with 400 thousand deaths / year.⁶,⁸

Studies on the incidence of AE began in the 1970s with The Medical Insurance Feasibility Study (MIFS) in California, but the “The Harvad Medical Practice Study” study, carried out in New York in 1984, revealed for the world the magnitude of errors occurred in hospitalized patients and, since then, the interest in patient safety grows progressively, driven by other subsequent studies that pointed to the extent of insecurity related to care care.⁸–⁹

By the publication of the book “To Error is Human”, in 1999, by the United States Institute of Medicine, the occurrence of 44 to 98 thousand deaths due to sanitation in the USA due to AE and a cost between 17 to 29 billion dollars.⁸–¹⁰

It is warned, by other studies, that 10% of patients admitted to hospitals suffer some type of adverse event. In Europe, it is estimated that one in ten inpatients are victims of AE and that 50 to 60% of these events are classified as preventable.⁹–¹¹ were related to surgery (32.3%), infections related to healthcare - HAI (24.6%), non-surgical medical procedures (29.2%) and diagnostic errors (15.3 %) as the most frequent and, of these, HAI were the AE that most impacted because they demanded an additional 226 hospitalization days for affected patients.⁸

After this study, several others followed in order to analyze adverse events in Brazilian health services, both in hospitals and in primary health care services, with different methodologies and results.

In parallel, the Ministry of Health (MH) and the National Health Surveillance Agency (ANVISA) launched, in 2013, Ordinances No. 529/2013 and RDC No. 36/2013,¹³–⁴ which institute, respectively, the National Patient Safety Program (NPSP) and actions for Patient Safety in Health Services. Decrees No. 1,377 and 2,095, of 2013, were subsequently published by the Ministry of Health,¹⁵–⁶ that approve the minimum patient safety protocols to be implemented in Brazilian hospitals.

It is mandatory, by the regulations described above, the constitution of Patient Safety Centers (PSC) in all health services in the country, which, under the supervision of Health
Surveillance (VISAs), must define and implement a Patient Safety Plan (PSP) according to the need and specificity of the service.

The Brazilian regulatory environment denotes the country’s concern with the issue of health care quality and the need to establish a culture of safety in the country’s health services and, in this context, Health Surveillance (VISA) can be a catalyst for the success of the NPSP, since it is the function of VISA to act to “eliminate or minimize the health risk involved in the production, circulation and consumption of certain products, processes and services”.17

Data on AE in developing countries is understood to be incipient. In a cross-sectional study, the point prevalence of AE in 58 hospitals located in Argentina, Colombia, Costa Rica, Mexico and Peru was identified. 11,379 inpatients were analyzed, identifying a point prevalence rate of AE of 10.5%; of these, 28% caused disability to injured patients, 6%, death and 60% of these AE were classified as preventable.10–2.

It should be noted that, in Brazil, 829 Brazilians die every day in public or private hospitals due to AE and supplementary health data indicate that hospital care AE consumes between 5.19 and 15.5 billion / year.6 The pioneering assessment of the incidence of adverse events in the country in 2009 is dated by authors who studied three public and teaching hospitals in Rio de Janeiro. This study evaluated 1,103 patients, identifying 56 preventable adverse events (5.1%). These events

**OBJECTIVE**

- To analyze the implementation of the national patient safety policy.

**METHOD**

This is a quantitative, descriptive, evaluative study of multiple cases whose unit of analysis was the implementation of the actions of the Patient Safety Centers (PSC) of the evaluated hospitals called in this case methodology.18

It is informed that the study included public and private hospitals considered to be large (number of beds greater than 150), located in the metropolitan region of Salvador, BA, selected from the data of the Secretariat of Health of Bahia, with the identification of 20 hospitals. One chose to study these hospitals, as they assist a large number of patients in the most diverse specialties, resulting in a higher level of care complexity, as well as the high turnover of patients and professionals, which may imply an increase in the possibility of the occurrence adverse events in patients admitted to these institutions.19–20
The hospitals were contacted, after identification, by telephone to explain the objectives of the research, obtain permission to carry it out and schedule the data collection performed in person during the months of December 2017 to October 2018.

It is detailed that the data collection consisted of an interview with the professional responsible for the PSC of each hospital using a semi-structured form and was carried out by two scholarship holders of the Nursing Course at the University of the State of Bahia, properly trained and supervised for this activity.

Four independent variables were analyzed: 1) Constitution of the Patient Safety Nucleus and its organo-functional structure (infrastructure related to human resources; responsible professional and other professionals; resources, equipment, supplies, materials destined to the PSC); 2) Actions to plan the control of adverse events in the SS (Patient Safety Plan; Safety Protocols adopted); 3) Technical-operational activities developed by NSP and 4) Actions to monitor adverse events in the hospital.

The data collected were tabulated using the EpiData® software, version 3.1, and the statistical analyzes performed using the STATA® statistical package, version 12.

The project for this study was approved by the Research Ethics Committee of the State University of Bahia - UNEB after its submission to the Brazil Platform (CAAE Protocol: 84683315.0.0000.0057). All the participants read and signed the Free and Informed Consent Term (FICT). It is added that, to guarantee the confidentiality and anonymity of the participating organizations, the proposed instrument did not contain any type of identification.

## RESULTS

It is explained that, of the 20 hospitals located in the metropolitan region of Salvador that met the inclusion criteria of the study, eight (40%) did not authorize data collection and twelve (60%) hospitals participated in this study.

Table 1. shows that all participating hospitals are large, with an average of 376 beds (range: 150 to 955; SD = 67.07) and three (25%) are teaching hospitals; in relation to the sponsoring entity, five (41.7%) are public, four (33.3%) are philanthropic, two (16.7%), private and one (8.3%), managed by a public-private; participating hospitals have, on average, four (range: 1-7; SD = 2.16) intensive care units, with an average of 68.4 beds (range: 20 124; SD = 37.2).

It is described that these institutions are mainly intended for the care of the adult population (91.7%), pediatric (66.7%) and neonatology (33.3%), attending to various medical specialties, with emphasis on medical clinic (91.7%) and surgical (83.3%), general, pediatrics
and orthopedics (41.7%). In addition to hospital assistance, these hospitals also provide outpatient care (91.7%), hemodialysis (75%) and hemodynamics (58.3%).

It is noted, regarding the notification of incidents involving patients, that, in four hospitals (36.4%), this task is still performed manually; in seven cases (63.6%), it is performed through a computerized system and in one case (5%) there is no AE notification system.

Table 1. Characterization of participating hospitals. Salvador (BA), Brazil, 2019.

| Supporting Entity       | n (12) | %   | Specialties            | n (12) | %   |
|-------------------------|--------|-----|------------------------|--------|-----|
| Public                  | 5      | 41.7| Medical clinic         | 11     | 91.7|
| Philanthropic           | 4      | 33.3| Surgical Clinic        | 10     | 83.3|
| Private                 | 2      | 16.7| General                | 5      | 41.7|
| Public-private partnership | 1     | 8.3 | Pediatrics            | 5      | 41.7|

| Service profile         | n (12) | %   | Orthopedics            | 5      | 41.7|
| Adult                   | 11     | 91.7| Cardiology             | 4      | 33.3|
| Pediatrics              | 8      | 66.7| Urology                | 4      | 33.3|
| Neonatology             | 4      | 33.3| Angiology/Vascular surgery | 4      | 33.3|

| School Hospital         | n (12) | %   | Neurology              | 3      | 25  |
| Yes                     | 3      | 25  | Gastroenterology       | 3      | 25  |

| Additional services     | n (12) | %   | Neonatology            | 3      | 25  |
| Outpatient Serv.        | 11     | 91.7| Nephrology             | 2      | 16.7|
| Hemodialysis            | 9      | 75  | Neurosurgery           | 1      | 8.3 |
| Hemodynamics            | 7      | 58.3| Other specialties       | 8      | 66.7|

| Notification system     | n (12) | %   | Descriptive statistics | Média  | Dp  |
| Electronic              | 7      | 63.6| Beds (150-955)         | 376.0  | 67.07|
| Manual                  | 4      | 36.4| ICU Number(1-7)        | 4      | 2.16|
| Absent                  | 1      | 8.3 | ICU Beds (20-124)      | 64.9   | 37.2|

Table 2. Organo-functional structure of the security centers of the studied hospitals (n = 12 *). Salvador (BA), Brazil, 2019.

| Characteristics                     | n  | %   |
|-------------------------------------|----|-----|
| Exclusive room for the Patient Safety Unit (n=12) | 9  | 75  |
| Computer availability (n=12)        | 11 | 91.7|
| Existence of own financial resources (n=12) | 4  | 33.3|
| Existence of inputs and materials for the development of activities (n=12) | 11 | 91.7|
| Formally constituted PSC (n=12)     | 12 | 100 |
| PSC inserted in the Quality Service (n=12) | 5  | 41.7|
| PSC as a stand-alone service (n=12)  | 4  | 33.3|
| PSC with other advisory inserts      | 3  | 25  |
| Exclusive responsible professional (n=12) | 6  | 50.0|
| Professional PSC members (n=12)     | 12 | 100 |
| Nurses                              | 11 | 91.7|
| Doctors                             | 10 | 83.8|
| Pharmacist                          | 9  | 75  |

Table 2. shows the data on the organo-functional structure of the Patient Safety Centers (PSC) of the studied hospitals.
| Characteristics                                                                 | n  | %   |
|--------------------------------------------------------------------------------|----|-----|
| Other specializations                                                          | 4  | 50.0|
| Specialization in Patient Safety                                              | 3  | 37.5|
| Specialization in Hospital Management                                         | 1  | 12.5|
| Year of implementation of the Patient Safety Center (n=11)                     |    |     |
| Up to 2012                                                                    | 1  | 9.1 |
| From 2013                                                                     | 10 | 90.9|
| Year of implementation of the internal incident notification system (n=12)     |    |     |
| Up to 2012                                                                    | 4  | 33.3|
| From 2013                                                                     | 8  | 66.7|
| There is written and available planning at the PSC with specific goals for the control of adverse events in the hospital environment (n=12) | 11 | 91.7|
| The PSP ** presents strategies to encourage patient and family participation in the care provided (n=12) | 7  | 58.3|
| The PSP presents strategies for promoting safety in enteral and parenteral nutritional therapies (n=12) | 9  | 75.0|
| The PSP presents strategies to promote safety in the prescription, use and administration of blood and blood components (n=12) | 10 | 83.3|

Note: * It can vary according to the number of missing due to the number of PSC that did not provide this information; ** PSP - Patient Safety Plan

It is pointed out that most of the participating centers (75%) have an exclusive room for the service and eleven of them (91.7%) have the aid of computers; eleven NSP (91.7%) have inputs and material resources, however, only four (33.3%) have their own financial resources for the development of security activities.

These nuclei were formally constituted by the senior management of the hospital in all cases (100%), with five PSC (41.7%) within the quality service, four (33.3%) are organized as autonomous services and three PSC (25%) are in other organizational inserts of a consultative nature. The existence of a responsible professional with exclusive dedication to the PSC was identified in only six hospitals (50%).

It is noteworthy, in relation to the implementation period, that ten (90.9%) PSC were implemented from the year 2013 in compliance with national regulations and one (9.1%), before this requirement. In most hospitals (n = 8; 66.7%), the internal incident notification system after 2013 was implemented.

Almost all PSCs (91.7%) have a Patient Safety Plan (PSP) specific to the institution; seven PSP (58.3%) have strategies to encourage the participation of the patient and family in the assistance provided; in nine PSP (75%), strategies for promoting safety in enteral and parenteral nutritional therapies are present, and in ten PSP (83.3%), there are strategies for promoting safety in the prescription, use and administration of blood and blood components.

It was identified, among the professionals who work in the PSC studied, that nurses are part of all centers (100%), doctors, 11 (91.7%) and pharmacists, ten (83.3%). It is registered that the majority of professionals working in these centers do not have specific training for this
area of activity, although three of these professionals have specialization in Patient Safety
and one in Hospital Management.

In addition, in relation to the training of the multidisciplinary health team on the subject of
patient safety, all PSC perform this activity and everyone has a record of this action. For this
purpose, several communication strategies are used by the PSC, involving specific campaig-
ns, the elaboration of mandalas with steps on patient safety, panels and alerts, educational
roulette and annual theoretical seminars.

Table 3 shows the basic patient safety protocols recommended by the Ministry of Health
and implemented by the PSC of the studied hospitals.

| Number of protocols implemented | n | %   |
|---------------------------------|---|-----|
| None                            | 2 | 16.7|
| Three                           | 1 | 8.3 |
| Four                            | 1 | 8.3 |
| Five                            | 1 | 8.3 |
| Six                             | 7 | 58.3|

| Basic Protocols implemented     | n   | %   |
|---------------------------------|-----|-----|
| Patient identification          | 10  | 83.3|
| Hand hygiene                    | 10  | 83.3|
| Safe surgery                    | 9   | 75  |
| Pressure ulcer prevention       | 9   | 75  |
| Prevention of medication errors | 8   | 66.7|
| Fall prevention                 | 8   | 66.7|
| Other protocols                 | 8   | 66.7|

It should be noted that, of the 12 PSC studied, only seven (58.3%) implement all six
basic protocols recommended by the MH and two PSC (16.7%) do not implement any of
these protocols. It should be noted that the most implemented protocols were patient identi-
fication and hand hygiene (83.3%), followed by safe surgery and pressure injury prevention
protocols (75%); the least implemented protocols were the prevention of errors in medication
administration and the prevention of falls (66.7%).

It was identified that, in addition to the mandatory protocols, eight PSC (66.7%) imple-
ment additional protocols, such as bundles of central venous catheter, prevention of venous
thromboembolism (n = 3; 37.5%), sepsis and broncho-aspiration (n = 2; 25%).

| Technical-operational activities developed by PSC | n   | %   |
|--------------------------------------------------|-----|-----|
| PSC runs PS training programs for healthcare professionals | 12  | 100 |
| PSC analyzes and evaluates data on incidents and AE in the hospital | 12  | 100 |
| PSC encourages employee notification of incidents | 11  | 91.7|
| PSC monitors the indicators of the PS protocols | 11  | 91.7|
| The PSC follows the actions described in the PSP | 10  | 83.3|

Table 3. Basic Patient Safety Protocols implemented by the Safety Centers of the studied hospitals (n = 12). Salvador (BA), Brazil, 2019.
It is verified, among the technical-operational activities developed by the PSC studied, that 100% analyze the data about the incidents and AE in the hospital; eleven (91.7%) PSC encourage the notification of incidents by hospital employees and monitor the indicators of the PS protocols. The actions described in the PSP are followed by the participating PSC for ten (83.3%), sharing and disseminating data on the AE that occurred in the hospital, however, the notification to the National Health Surveillance System of the AE that occurred in the hospital up to the 15th occurred in nine PSC (75%) and notification to the National Health Surveillance System, within 72 hours, of AEs that occurred in the hospital that evolved to death was only identified in six (50%) of the eight PSC that provided this information.

Table 5. shows the main incidents and adverse events that occurred in large hospitals in Salvador and reported by the studied PSC.

| Distribution of adverse events | n  | %   |
|-------------------------------|----|-----|
| Pressure Ulcer (n=9)          | 8  | 88.9|
| Fall from bed (n=9)           | 7  | 77.8|
| Medication errors (n=8)       | 6  | 75  |
| Phlebitis (n=8)               | 5  | 62.5|
| Accidental removal of drains and pipes (n=7) | 4  | 57.1|
| Patient identification (n=9)  | 3  | 33.3|
| Lack of hand hygiene (n=8)    | 2  | 25  |
| Surgery errors (n=8)          | 0  | 0   |
| Other adverse events (n=8)    | 4  | 50  |

Note: * May vary depending on the number of PSC that provided such information.

Only nine PSC (75%) were provided with information to analyze the percentage distribution of incidents and adverse events that occurred in large hospitals in Salvador. It is shown that the most prevalent adverse events in participating hospitals as reported by the NSP coordinators were: pressure injury (88.9%); falling of the bed (77.8%); medication errors (75%); phlebitis (62.5%); accidental removal of drains and tubes (57.1%); errors in patient identification (33.3%); non-hygiene when performing care (25%). Half of the PSC (50%) reported the occurrence of other events, such as: care-related infections - HAI (n = 1; 12.5%); skin injury caused by an oximeter (n = 1; 12.5%); adverse drug reactions (n = 1; 12.5%); change of diet (n = 1; 12.5%) and no PSC reported adverse events related to surgery.
From the 20 Patient Safety Centers in large hospitals in the city of Salvador, 12 PSC (60%) inserted in public (41.7%), philanthropic (33.3%) and private (8, 3%), being three (25%) in teaching hospitals, therefore contemplating patient safety centers in institutions with different forms of organizational management.

All nuclei were formally constituted and 91.7% have a patient safety plan prepared according to the specifics of each institution, a situation that denotes the institutionality of these services within the studied hospitals, as well as the concern with the planning of their activities.

Most PSCs (90.9%) were implanted after 2013, supposedly in compliance with the requirements defined in the regulatory frameworks on patient safety in the country, however, an institution was identified whose safety nucleus was constituted before the date of the launch of the country's national security policy, pointing out that the theme of security and risk management was already part of this organization's agenda, regardless of the mandatory nature required by current regulations.

It was identified that PSC act as an autonomous service within hospital institutions in 33.3%, are linked to quality services in 41.7% and in other consultative services in 25%, all in accordance with ANVISA’s resolution which recommends that the hospital management can use the structure of other existing services for the performance of PSC activities.

It is indicated that, of the 12 PSC studied, only six (50%) have a responsible and exclusive professional for patient safety activities, a situation that goes against the regulatory norm and that disfavors the implementation of work processes in favor of prevention of health errors in these services, as, in half of these centers, professionals act and answer for other services, fragmenting the end activity of patient safety. In addition, it was found that most professionals who “work” in these centers do not have specific training in the area of patient safety, which can be a hindering element for the performance of these professionals. These findings can challenge the implementation of a safety culture in these organizations, led by PSC and defined as individual and group behavior patterns, which determine the commitment, style and proficiency of the management of a healthy and safe organization.

In spite of these limitations, data on incidents and AE in the hospital are analyzed by all the PSC studied, and 91.7% of these stimulate the notification of incidents by hospital employees, thus establishing a culture of breaking of the fear of registration and information of health errors, in line with the understanding of the multifactorial nature of care errors, whose premise is that human beings make mistakes and that mistakes are consequences and not causes, given the knowledge that the main factors that contribute to the occurrence of adverse events are the deficiencies in the health care delivery system, both in its conception as well as in the organization and functioning.
It is believed that the notification of errors and incidents that cause or not injury to the patient is the guiding element of a health safety program, since the knowledge of the errors allows the delimitation of the magnitude of these events within the organization, in addition to the elaboration indicators and decision making. A quality indicator is defined as a quantitative measure of some aspect of patient care and the inclusion of these indicators by the PSC represents an important strategy for promoting hospital patient safety.\textsuperscript{22}

It was verified, in relation to the notification to the National Health Surveillance System (ANVISA) of AEs that occurred in the hospital until the 15th of the following month, that nine PSC (75\%) meet this recommendation, but only six (50\%) make this notification within 72 hours, when adverse events evolve to death, omitting from ANVISA, in real time, the most serious events that occurred in the institution, as well as preventing the participation of this regulatory agency in monitoring the actions proposed by hospitals to elucidate and propose strategies for the prevention of more serious events.

It is noted that, of the basic protocols recommended by the Ministry of Health, only seven PSC (58.3\%) implement all of these, three (25\%) implement only a few and two cores (16.7\%) do not implement any of the mandatory protocols, configuring health infractions and non-compliance with patient safety plans, since these protocols are essential for the minimum support of an institutional safety program and culture.

It should also be remembered that non-compliance with mandatory patient safety protocols in complex hospitals such as those studied here, which provide assistance to patients in serious clinical conditions, undergoing multiple interventions, and, therefore, more likely to suffer events unwanted effects of the care offered, indirectly evidences a gap in the sanitary control of these health institutions to be exercised by the Health Surveillance (HS), the body responsible for inspecting the PSC according to the resolution in force.\textsuperscript{17}

It is evident that the most implemented safety protocols were patient identification and hand hygiene (83.3\%), followed by the safe surgery and pressure injury prevention protocols (75\%), and the prevention protocols of errors in medication administration and fall prevention (66.7\%) are the least implemented. These data are similar to the results of a study that aimed to verify the implantation of PSC and its relationship with healthcare-related infections, identifying that the most implemented protocols were also patient identification (66.7\%) and hand hygiene (50\%).\textsuperscript{10}

It should be noted that the most frequent incidents and adverse events reported by these hospitals were: pressure injuries (88.9\%); bed falls (77.8\%) and medication errors (75\%). The occurrence of phlebitis was also identified in 50\% of the PSC that responded to this research item, as well as errors in the removal of drains and tubes (42.9\%), in the
identification of the patient (33.3%) and absence of hand hygiene by 25%. It should be noted that no AE related to surgical procedures were reported and the adverse events identified here are, a priori, preventable and differ from the data in the literature that report that, as to nature, the AEs with the highest incidence are those related to surgery, followed by related to drugs, diagnosis, therapy, clinical procedures and falls. 8,10,12,24

It is signaled by the high incidence of pressure injuries, bed falls, accidental removal of drains and identified medication errors, that greater efforts in the work processes in favor of patient safety are necessary in these institutions. Attention is also drawn to the percentage of errors associated with patient identification and hand hygiene techniques, since the protocols most implemented by the PSC studied here are patient identification and hand hygiene (both 83.3%), pointing out that it is not enough to just implement the protocols, but to monitor the related practices.

It is known, so far, that this was the first study on the aspects of the implementation of the national patient safety policy in large hospitals in the city of Salvador - BA, contributing to the assessment of how the national safety program patient is being implemented. This study is limited by the sample of only 60% of the total of large hospitals in the city of Salvador, however, as a way to mitigate this limitation, the discussions presented here are descriptive and have no intention of universalizing the results.

■ CONCLUSION

This study achieved its objective by analyzing the implementation of the national patient safety policy through the Patient Safety Centers in large hospitals in the city of Salvador, the most frequent adverse events and their work processes, as well as the importance of HS’s performance in strengthening this policy. It is believed, as far as is known, that this was the first study that analyzed the implementation of the national patient safety policy after the mandatory provision in Brazilian legislation instituted by the Ministry of Health and ANVISA in 2013 and, thus, it also serves as a parameter of adherence of this policy to the national regulatory bodies. It was identified that all the large hospitals studied partially respond to national policy, the PSCs studied develop their activities in a planned manner and most implement the basic safety protocols recommended in the country, as well as other activities related to patient safety. Due to the high percentages of adverse events identified by the PSC of the hospitals surveyed, previous studies that point out that Brazil has one of the highest frequencies of preventable adverse events in the world, signaling the need for maintenance and intensification of work processes in favor of prevention of health errors, as well as the
constitution of a safety culture in health organizations, especially in the most complex ones, such as those in this study.

In some studied institutions, health infractions related to the patient safety policy in force in the country were observed, pointing out that it is up to the State not only the competence to regulate health processes and services, but the operational capacity to control the fulfillment of its normative obligations.

**FUNDING**

National Council for Scientific and Technological Development (CNPQ) through process number 400316/2016-1.

**ACKNOWLEDGEMENTS**

The Coordinators of the Patient Safety Centers of the participating hospitals are thanked.

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