

PATIENT SAFETY IN HEALTH SERVICES: AN ANALYSIS IN THE CITY OF SALVADOR, BAHIA

Segurança do paciente em serviços de saúde: uma análise na cidade de Salvador, Bahia

Seguridad del paciente en servicios de salud: un análisis en la ciudad de Salvador, Bahia

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ABSTRACT: Objective: To evaluate the national policy of patient safety in large hospitals in Salvador. **Method:** Study of multiple cases in tertiary hospitals. Data collection occurred between October 2017 and October 2018, with professionals from a Center for Patient Safety (CPS). Four independent variables were analyzed: composition of CPS; action plan for management of adverse events (AE); technical and operational activities developed by the CPS; and monitoring of AE in the hospital. **Results:** In a sample of 20 CPS, 12 (60%) were studied. All hospitals have a CPS established, 91.7% have patient safety plan, and 50% have a professional exclusively dedicated to it. Among the institutions, 58.3% implement all required protocols. The most frequent are patient identification (83.3%) and hand hygiene (83.3%). Percentages of AE identified were: pressure wound (88.9%), bed fall (77.8%) and medication errors (75.0%). **Conclusion:** The AE mentioned here signal the need for adjustments for patient safety. The CPS do not fully meet Brazil's current regulatory policies, thus lacking adequacies and effective sanitary control.

Keywords: Patient safety. Patient harm. Hospital legislation. Healthcare quality assurance.

RESUMO: Objetivo: Avaliar a política nacional de segurança do paciente em hospitais de grande porte de Salvador. **Método:** Estudo de casos múltiplos em hospitais terciários. A coleta de dados ocorreu entre outubro de 2017 e outubro de 2018, com profissionais dos núcleos de segurança do paciente (NSP). Foram analisadas quatro variáveis independentes: constituição dos NSP; ações de planejamento do controle dos eventos adversos (EA); atividades técnico-operacionais desenvolvidas pelos NSP; e ações de monitoramento dos EA no hospital. **Resultados:** Dos 20 NSP existentes, estudaram-se 12 (60%). Todos os hospitais possuem NSP constituídos, 91,7% têm plano de segurança do paciente, e 50% contam com profissional com dedicação exclusiva. Das instituições, 58,3% implementam todos os protocolos obrigatórios, sendo identificação do paciente (83,3%) e higienização das mãos (83,3%) os mais frequentes. Os percentuais de EA identificados foram: lesão por pressão (88,9%), queda do leito (77,8%) e erros de medicamentos (75,0%). **Conclusão:** Os EA aqui referidos sinalizam a necessidade de adequações em prol da segurança do paciente. Os NSP não atendem totalmente às políticas regulatórias vigentes no país, carecendo, portanto, de adequações e de controle sanitário efetivo.

Palavras-chave: Segurança do paciente. Dano ao paciente. Legislação hospitalar. Garantia da qualidade dos cuidados de saúde.

RESUMEN: Objetivo: evaluar la política nacional de seguridad del paciente en grandes hospitales de Salvador. **Método:** estudio de caso múltiple en hospitales terciarios. La recopilación de datos tuvo lugar entre octubre de 2017 y octubre de 2018, con profesionales de los núcleos de seguridad del paciente (NSP). Se analizaron cuatro variables independientes: constitución de la NSP; planificación de acciones para controlar eventos adversos (EA); actividades técnico-operativas desarrolladas por NSP; y acciones de monitoreo de AE en el hospital. **Resultados:** De los 20 NSP existentes, 12 (60%) fueron estudiados. Todos los hospitales tienen un NSP establecido, el 91.7% tiene un plan de seguridad del paciente y el 50% tiene un profesional con dedicación exclusiva. De las instituciones, el 58.3% implementa todos los protocolos obligatorios, siendo la identificación del paciente (83.3%) y la higiene de las manos (83.3%) las más frecuentes. Los porcentajes de EA identificados fueron: lesión por presión (88.9%), caída de la cama (77.8%) y errores de medicación (75.0%). **Conclusión:** El AE al que se hace referencia aquí indica la necesidad de ajustes a favor de la seguridad del paciente. Los NSP no cumplen totalmente con las políticas regulatorias vigentes en el país, por lo tanto, necesitan ajustes y un control sanitario efectivo.

Palabras clave: Seguridad del paciente. Daño del paciente. Legislación hospitalaria. Garantía de la calidad de atención de salud.

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INTRODUCTION

Technological advances incorporated into health care have provided benefits for health recovery and life span increase. However, the use of these technologies has also brought serious risks to patients, raising theoretical-practical issues of safety and effectiveness of processes. In this context, thousands of patients are harmed by diagnostic and therapeutic errors that occurred during health care, and the role of hospitals, regulatory agencies and health service managers has been widely discussed, as well as the identification of risk factors that compromise patient safety¹⁻³.

Recognizing that patient safety is a global public health problem, the World Health Organization (WHO) launched in 2004 the World Alliance for Patient Safety, aiming to develop universal norms and standards to promote evidence-based policies, to support countries in several key areas and to contribute to a global agenda for research in this field⁴. To this end, this alliance has launched three global challenges: the first in 2005, focusing on preventing Health care-associated infections (HAIs); the second, in 2008, focused on safety in surgical procedures⁵; and the third, launched in 2017, to reduce the level of severe avoidable harm related to medications⁶.

In Brazil, the Ministry of Health (*Ministério da Saúde* – MS) and the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária* – ANVISA), meeting the global challenges of WHO, launched, in 2013, Report No. 529/2013⁷ and the Collegiate Board Resolution (*Resolução de Diretoria Colegiada* – RDC) No. 36/2013⁸, which establish, respectively, the National Patient Safety Program (NPSP) and actions for patient safety in health services.

Subsequently, the MH published the ministerial decrees No. 1,377 and No. 2,095, of 2013^{9,10}, which approve patient safety basic protocols to be implemented in Brazilian hospitals:

- Safety surgery;
- Hand hygiene practice in health services;
- Prevention of pressure wounds;
- Prevention of falls in hospitalized patients;
- Patient identification;
- Safety in prescription, use and administration of medications.

Due to these ministerial decrees, all health services in the country must establish centers for patient safety (CPS) to define and implement a patient safety plan (PSP), according to the need and specificities of the service.

Besides regulatory issues, the development of a patient safety culture as a health service framework should promote the implementation of safe practices that seek the improvement of organizational processes, to reduce the incidence of adverse events (AE) and to promote the continuous improvement of quality care¹¹.

Hence, this study seeks to answer the following central question: how the hospitals of the City of Salvador are implementing the NPSP? This central question leads to the underlying questions: how CSP are composed in these hospitals? What are the most frequent adverse events in hospitals in the capital of Bahia?

OBJECTIVE

To assess the implementation of the NPSP through CSP of hospitals in the city of Salvador, considering the health protection of patients hospitalized in the institutions studied.

METHOD

This is an evaluation descriptive multiple-case study, whose unit of analysis was the implementation of actions of CPS of hospitals evaluated and mentioned in this case study methodology¹².

The research project was approved by the Committee for Ethical Compliance in Research Involving Human Beings at *Universidade Estadual da Bahia* (UNEB), registered on *Plataforma Brasil* (Certificate of Presentation for Ethical Consideration – CPEC: 84683315.0.0000.0057), final opinion 2,574,463; and received financial support from the National Council for Scientific and Technological Development (*Conselho Nacional de Desenvolvimento Científico e Tecnológico* – CNPQ) (case 400316/2016-1).

The study included large public and private hospitals (with more than 150 beds) located in the metropolitan region of Salvador (BA), selected through data from the Health Secretariat of the State of Bahia – twenty hospitals were identified. These hospitals were selected because they provide care to numerous patients in a wide range of medical specialties, resulting in a higher level of care complexity, and due to the high turnover rate of patients and professionals¹³⁻¹⁵, which may imply an increase in probability of occurrence of AE in patients hospitalized in these institutions.

After identification, hospitals were contacted by telephone to be informed of the research objectives; if permission was

given and the data collection was scheduled, it was performed in person from December 2017 to October 2018.

Data collection consisted of an interview with the professional in charge of the CPS of each hospital, through a semi-structured form elaborated by the authors, and it was performed by two Nursing scholarship holders from UNEB, properly trained and supervised for this activity.

Four independent variables were analyzed:

- Composition of the CPS and its organic and functional structure (human resources associated infrastructure; professional in charge and other professionals; resources, equipment, supplies, materials to the CPS);
- Planning actions of AE control in the health service (HS) (PSP; safety protocols adopted);
- Technical and operational activities developed by the CPS;
- Actions to monitor adverse events in the hospital.

The collected data were tabulated by the software EpiData[®] version 3.1, and statistical analyses were performed by statistical package STATA[®] version 12.

RESULTS

Twenty hospitals met the inclusion criterion, 8 of which (40%) did not authorize data collection for several reasons; hence, 12 (60%) are part of this study.

All hospitals that participated in this study are large (Table 1), with a mean of 376 beds (variation=150–955; standard deviation – SD=67.07), and three (25%) are school hospitals. Regarding the board of trustees, five (41.7%) are public, four (33.3%) are philanthropic, two (16.7%) from private sector and one (8.3%) from a public-private partnership. The hospitals which participated have, on average, four intensive-care units (variation=1–7; SD=2.16), with a mean of 68.4 beds (variation=20–124; SD=37.2).

These institutions are intended mainly for the adult (11 cases/91.7%), pediatric (eight/66.7%) and neonatological populations (four/33.3%) and provide care for several medical specialties, especially medical clinic (11/91.7%) and surgical (10/83.3%), general (five/41.7%), pediatrics (five/41.7%) and orthopedics (five/41.7%). In addition to hospital care, these institutions also provide ambulatory care (11/91.7%), hemodialysis (nine/75%) and hemodynamics (seven/58.3%).

Table 1. Characterization of participating hospitals (n=12)*.

Board of trustees	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
Attendance profile	n (12)	%	Orthopedics	5	41.7
Adult	11	91.7	Cardiology	4	33.3
Pediatric	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
Ambulatory services	11	91.7	Nephrology	2	16.7
Hemodialysis	9	75	Neurosurgery	1	8.3
Hemodynamic	7	58.3	Other specialties	8	66.7
Notification system	n (12)	%	Descriptive statistics	Mean	SD
Electronic	7	63.6	Beds (150-955)	376,01	67.07
Manual	4	36.4	ICU Number (1–7)	4	2.16
Nonexistent	1	8.3	ICU beds (20-124)	64,9	37.2

*It may vary depending on the number of missing; ICU: intensive care unit; SD: standard deviation.

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

Table 2 describes the organic functional structure of CPS of the hospitals studied.

Among the 12 CPS of hospitals studied, 9 (75%), have an exclusive room for the CPS and 11 (91.7%) have the aid of computers. Eleven CPS (91.7%) have supplies and material resources, however only 4 (33.3%) have their own financial resources for the development of safety activities.

These centers were formally established by the hospital trust board in all cases, five of which (41.7%) are included in the quality service, four (33.3%) are organized as autonomous services and three CPS (25%) are in other organizational compositions of an advisory nature.

The existence of a professional in charge of and exclusively dedicated to the CPS, as recommended by legal regulations⁷, was identified in only six hospitals (50%).

In relation to the implementation period, ten CPS (90.9%) were implemented in 2013, in compliance with national regulations, and one (9.1%) before this obligation. Most hospitals (seven/63.6%) adopted the internal incident reporting system after 2013.

Almost all CPS (11/91.7%) have specific PSP for the institution: seven PSP (58.3%) have strategies to promote the participation of patients and family members in providing care; on nine PSP (75%), there are strategies to promote safety in enteral and parenteral nutritional therapies; and in ten (83.3%), there are strategies to promote safety in prescription, use and administration of blood and blood components.

Among the professionals working in the CPS studied, it was identified that nurses are part of all centers (12/100%), physicians of 11 (91.7%), pharmacists of ten (83.3%) and other professional categories of nine (75.0%) institutions. Most staff working in these centers do not have specific training for this area of activity, although three of them have graduate studies in patient safety and one in hospital management.

The basic patient safety protocols recommended by the HM and implemented by the CPS of the hospitals studied are described in Table 3.

Among the 12 CPS studied, only seven (58.3%) implemented all six basic protocols recommended by the MH, and two CPS (16.7%) did not follow any of them. The most adopted protocols are: patient identification and hand hygiene (83.3%), safe surgery and prevention of pressure wound (75%). The least implemented protocols are: prevention of medication errors and bed fall prevention (66.7%).

Table 2. Organofunctional structure of centers for patient safety (CPS) of hospitals studied (n=12)*.

Feature	n	%
Exclusive room for CPS (n=12)	9	75
Computer (n=12)	11	91.7
Existence of own financial resources (n=12)	4	33.3
Existence of supplies and materials for development of activities (n=12)	11	91.7
CPS formally composed (n=12)	12	100
CPS inserted in quality service (n=12)	5	41.7
CPS as autonomous service (n=12)	4	33.3
CPS with other constitutions of advisory nature	3	25
Exclusive professional in charge (n=12)	6	50
Year of implementation of the center for patient safety (n=11)		
2011	1	9.1
2013	2	18.2
2014	1	9.1
2015	3	27.3
2016	2	18.2
2017	1	9.1
2018	1	9.1
Year of implementation of the internal incident notification system (n=11)		
2005	1	9.1
2010	2	18.2
2012	1	9.1
2014	1	9.1
2015	1	9.1
2016	2	18.2
2017	3	27.3
2018	1	9.1
There is written and available planning in the CPS with specific goals for controlling of adverse events in the hospital (n=12)	11	91.7
The PSP presents strategies to promote the participation of patients and family members in providing care (n=12)	7	58.3
The PSP presents strategies to promote safety in enteral and parenteral nutritional therapies (n=12)	9	75
The PSP presents strategies to promote safety in prescription, use and administration of blood and blood components (n=12)	10	83.3

*It may vary depending on the number of missing, due to the number of CPS that have not provided this information; PSP: patient safety plan.

In addition to the mandatory protocols, it was identified that eight CPS (66.7%) performed additional protocols, such as central venous catheter bundles, prevention of venous thromboembolism (three/37.5%), sepsis and bronchoaspiration (two/25%).

Technical and operational activities developed by the CPS are described in Table 4.

Regarding the training of the multidisciplinary health team on patient safety, all CPS perform this activity and have

Table 3. Patient safety protocols implemented by center of safety of the hospitals studied (n=12).

Number of protocols implemented	n	%
No	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	75.0
Pressure wound prevention	9	75.0
Prevention of medication errors	8	66.7
Fall prevention	8	66.7
Other protocols	8	66.7

Table 4. Technical and operational activities developed by center for patient safety (CPS) of the hospitals studied (n=12).

Technical and operational activities developed by the CPS	N	%
Performance of training programs about PS for health professionals	12	100
Analysis and evaluation of the data about incidents and AE in the hospital	12	100
Encouragement to employees notify incidents	11	91.7
Monitoring indicators of PS protocols	11	91.7
Monitoring of actions described in PSP	10	83.3
Sharing and disclosure of data about AE occurred in the hospital	10	83.3
Notification to the National Health Surveillance System of AE occurred in the hospital until the 15th working day	9	75
Notification of deaths to the National Health Surveillance System within 72 hours of the AE	6	50
Conducting other activities	10 (83.3)	

PS: patient safety; AE: adverse event; PSP: patient safety program.

a record of this action. To this end, they use several communication strategies: one-off campaigns, illustrated step-by-step instructions on patient safety, panels and alerts, information wheels and annual theoretical seminars.

Among the technical-operational activities developed by the CPS studied, it was identified that 100% analyzed the data on incidents and AE in the hospital; and 11 (91.7%) encouraged the notification of incidents by hospital employees and monitored the indicators of PS protocols.

Among participating CPS, ten (83.3%) follow the actions described in the PPS, share and disseminate data on AE occurred in the hospital. However, the notification to the National Health Surveillance System of an AE occurred in the hospital until the 15th working day occurs in nine CPS (75%), and the notification within 72 hours of an AE that evolved to death was only identified in six (50%) of the eight CPS that provide this information.

The main incidents and AE occurred in the large hospitals of Salvador reported by the CPS studied are described in Table 5.

Only nine CPS (75%) provided information for the distribution analysis of incidents and AE occurred in large hospitals in Salvador. The AE and incidents reported by CPS as the most prevalent were: pressure wound (88.9%), bed fall (77.8%), medication errors (75%), phlebitis (50%), accidental removal of drains and tubes (42.9%), patient identification errors (33.3%), lack of hand hygiene during care (25.0%) and other AE (50%), reported as: health care-associated infection, pulse oximeter-induced digital injury, bladder probe loss and diet changes. There was no notification of AE during the performance of surgical procedures among CPS that answered this research item.

Table 5. Percentage distribution of incidents and adverse events occurred in large hospitals in Salvador, BA (n=9)*.

Adverse event	n	%
Pressure wound (n=9)	8	88.9
Bed fall (n=9)	7	77.8
Medication errors (n=8)	6	75
Phlebitis (No.8)	4	50
Accidental removal of drains and tubes (n=7)	3	42.9
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

*It may vary depending on the number of missing, due to the number of centers for patient safety that have not provided this information.

DISCUSSION

Among the 20 CPS of the large hospitals of the City of Salvador, 12 (60%) were studied, the vast majority in public, philanthropic and private institutions, three (25%) in teaching hospitals; thus, encompassing CPS in institutions with different forms of organizational management.

All centers are formally established, and most have a PSP organized according to the specificities of each institution, a situation that denotes the institutional character of these services within the hospitals studied, as well as concern in planning its activities.

Most CPS were implemented after 2013, supposedly in compliance with the requirements defined in the regulatory frameworks on patient safety in the country⁷⁻¹⁰, however we identified one institution whose CPS was set up before the launching of the NPSP, pointing out that safety and risk management was already part of the organization's agenda, regardless of the obligation required by current regulations.

It was identified that CPS work with different executive models, either as autonomous service within hospital, whether in quality control services, such as advisory bodies, all in accordance with the resolution of ANVISA, which recommends that "the health service board can use the already existing structure of committees, commissions, management offices, coordination boards or nuclei for the performance of the CPS duties"⁸.

Only half of the CPS studied have an exclusive professional in charge of patient safety activities, which contradicts the regulatory norm and does not help the implementation of work processes to prevent errors in these health services, to the extent that the professionals in half of these centers work in other services and respond to them, fragmenting the patient safety activity. In addition, most professionals who work in these centers do not have specific training in the field of patient safety, which can be an obstacle to their practice. These findings can pose a challenge to the implementation of a security culture in these organizations, led by the CPS and defined as individual and group behavior patterns, which determine the commitment, style, and proficiency of the administration of a healthy and safe organization^{2,3,11,16}.

Despite these limitations, all CPS studied analyze data on incidents and AE in the hospital and 91.7% encourage hospital employees to notify incidents; thus, they foster a culture of overcoming the fear of registering and informing healthcare error, in line with the understanding of the multi factorial character of healthcare errors, whose premise is that human beings make mistakes, and that errors are consequences and

not causes. After all, it is known that the main factors that contribute to the occurrence of AE are deficiencies of the health care system in its conception, as well as in its organization and operation¹⁶.

The notification of errors and incidents that do or do not harm patients is the guiding element of a safety program in healthcare, since the knowledge of errors make it possible to delineate the magnitude of these events in the organization, and also to develop indicators and to make decisions. A quality indicator is defined as a quantitative measure on some aspect of patient care, and the inclusion of these indicators by CPS represents an important strategy for promoting safety of hospitalized patients¹⁷.

Regarding the notification to the National Health Surveillance System of AE occurred in the hospital until the 15th working day of the following month, we identified that most CPS meet this recommendation, although some do so within 72 hours, when the AE evolve to death, omitting from ANVISA, in real-time, the most serious events that occurred in the institution, as well as making it impossible to this regulatory agency to monitor the actions proposed by hospitals in order to elucidate and propose strategies to prevent more serious events.

Among the basic protocols recommended by the MH, only seven CPS (58.3%) implement them all; five (41.6%), only a few; and two centers (16.7%) do not adopt any of the mandatory protocols, configuring nonconformity and non-compliance with patient safety plans, since these protocols are essential for the minimum support of a program and an institutional security culture.

Moreover, the lack of adherence to mandatory patient safety protocols in hospitals with complex profiles such as those studied here, which provide care to patients under more serious clinical conditions, submitted to multiple interventions and, therefore, more likely to suffer unwanted effects of the care provided, evidences the gap in the health control of these health institutions that should be exercised by health surveillance.

In this sense, health surveillance, an organ of the national health system whose constitutional concept is to "control risks associated with products, processes and services relevant to human health"⁸, is thus responsible for the supervision of CPS according to the resolution in force⁸ and, in doing so, can be a catalyst for the successful implementation of the patient security policy in the country.

The most implemented safety protocols were patient identification and hand hygiene, followed by safe surgery

and pressure wound prevention protocols, and the least implemented were the ones for preventing medication errors and falling prevention. These protocols, defined as basic, are pillars of care quality for any health service, and their implementation directly interferes with health indicators, such as rates of permanence, morbidity and hospital mortality.

The most prevalent incidents and AE reported by the CPS in the hospitals surveyed were pressure wound, bed fall and medication errors. There was also the occurrence of phlebitis, as well as errors in drain and tube removal, in patient identification and lack of hand hygiene. No AE associated to surgical procedures were reported.

The AE recognized here are, *a priori*, likely to be predicted and differ from the literature data which report that most incident AE are associated to surgery, followed by those associated to medication, diagnosis, therapy, clinical procedures and falls¹⁸⁻²⁰.

The identified percentages of pressure wound, bed fall, accidental removal of drains and medication errors indicate that greater efforts of work processes for patient safety are necessary in these institutions. Additionally, the percentage of errors associated with patient identification and hand hygiene technique is noteworthy, since the most implemented protocols by the CPS studied here are patient identification and hand hygiene (both 83.3%), pointing out that implementing the protocols is not enough; it is necessary to monitor the associated practices.

CONCLUSION

This study data allowed us to analyze, in the third largest capital of the country, the implementation of the NPSP, instituted in 2013, and they contribute as a parameter for evaluating the adherence of this regulation to regulatory and supervisory bodies.

The sample, 60% of CPS of hospitals investigated, constitutes a limitation and an opportunity for future follow-up studies.

It was identified that all large hospitals studied respond positively to the NPSP. The CPS examined develop their activities in a planned manner, and most implement the basic recommended safety protocols in the country, as well as other activities associated to patient safety.

The percentages of AE found by the CPS of the hospitals surveyed ratify previous studies that indicate that Brazil has one of the highest avoidable rate of AE in the world, signaling the need for maintenance and intensification of work processes for preventing errors in health care, as well as the development of a culture of safety in health organizations, especially in the most complex, as those in this work.

We observed a gap in health control which should be performed by health surveillance in some institutions investigated and, in this sense, we believe that it is up to the State to not only regulate processes and health services imperatively, but also to have the operational capacity to enforce compliance with its regulations.

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