



Self-assessment of Patient Safety Centers in a state in Northern Brazil

Autoavaliação dos Núcleos de Segurança do Paciente em um estado do Norte do Brasil

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ABSTRACT

This study aimed to evaluate the organizational structure of Patient Safety Units in hospitals in Rondônia. A cross-sectional study was conducted between November and December 2020, involving 25 out of 40 patient safety units registered with the National Health Surveillance Agency. Data were collected using an instrument containing indicators of structure, process, and outcomes. The results showed a higher adherence to structural indicators, with almost all institutions having fully implemented safety units. However, weaknesses were identified in the execution of certain actions, particularly in risk management. Only six organizations reported notifications of adverse events, demonstrating a direct relationship with high adherence to good safety practices ($p = 0.04$) and the type of institution ($p = 0.02$). It is concluded that, although the units are fully implemented, process and outcome indicators indicate the need for qualification of members and closer monitoring by the state patient safety coordination.

Keywords: Evaluation of health services. Patient safety. Organizational culture

RESUMO

Este estudo teve como objetivo avaliar a estrutura organizacional dos Núcleos de Segurança do Paciente em hospitais de Rondônia. Foi realizado um estudo transversal entre novembro e dezembro de 2020, envolvendo 25 dos 40 núcleos de segurança do paciente cadastrados na Agência Nacional de Vigilância Sanitária. Os dados foram coletados por meio de um instrumento que continha indicadores de estrutura, processo e resultados. Os resultados mostraram que houve uma maior adesão aos indicadores de estrutura e que quase todas as instituições possuíam núcleos de segurança totalmente implantados. No entanto, foram identificadas fragilidades na execução de algumas ações, principalmente no gerenciamento de riscos. Apenas seis organizações realizaram notificações de eventos adversos, o que demonstrou uma relação direta com a alta adesão às boas práticas de segurança ($p = 0,04$) e o tipo de instituição ($p = 0,02$). Conclui-se que, embora os núcleos estejam totalmente implantados, os indicadores de processo e resultados apontam a necessidade de qualificação dos membros e um acompanhamento mais próximo por parte da coordenação estadual de segurança do paciente.

Palavras-chave: Evaluation of health services. Patient safety. Organizational culture.

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INTRODUCTION

Patient safety is a worldwide premise in health institutions since the encouragement of a safety culture must be transversal in health care, that is, considered by all those involved and in all stages of care¹. Patient safety aims to improve processes and quality management in services based on the principle of first do no harm to the user².

The movement in favor of patient safety became more evident from the report "To err is Human" dated 1999, which evidenced the occurrence of deaths resulting from assistance care in the United States³. In 2004, the World Alliance was formed after the 57th World Health Assembly to establish regulations aimed at patient safety in several countries⁴.

In Brazil, the Resolution of the Collegiate Board number 63 of 2010 is the first document related to the theme in the country and was later complemented by Resolution of the Collegiate Board number 36 of 2013 and Ordinance number 529 of 2013^{5,6,7}. These documents were the basis for the creation of the Patient Safety Centers, whose actions are based on risk management to mitigate adverse health events.

Thus, the Patient Safety Centers significantly acts in the management of quality in services considering the Donabedian Triad, which consists of indicators of structure, process, and outcomes performed by a multidisciplinary team and supports studies that aim to understand the organizational structure⁸. It is up to the centers to choose their indicators or those validated in the literature⁹.

The self-assessment is an evaluation method that allows professionals to have autonomy, independence, and active participation in understanding the current health situation of their organizations and critically reflect on their actions, to minimize possible harm to the user¹⁰.

Despite the mandatory implementation of Patient Safety Centers in hospitals with

intensive care beds, this regulatory requirement does not guarantee patient safety^{11,12}. In the Self-Assessment of Patient Safety Practices in Health Services carried out by the National Health Surveillance Agency in 2020, in the North region, only the state of Pará with two hospitals received 100% compliance in the indicators, in the Northeast region, Ceará with three institutions, in the Central-West, Mato Grosso, two services, Minas Gerais, in the Southeast with twelve institutions, and the South, the state of Paraná, with seven hospitals¹³. This year, the Southeast region had the highest number of hospitals with high compliance. In Rondônia, only five hospitals were classified as highly compliant with good practices in the state¹³.

Given the low number of hospitals that responded to the National Assessment on good safety practices in the state of Rondônia, this study is justified by the opportunity to evaluate the organizational structure of Patient Safety Centers of hospitals in the state of Rondônia.

In view of this, this analysis sought to answer whether the state's patient safety centers are implemented, active, and effectively fulfilling patient safety through their main action, that is, risk mitigation through the notification of Adverse Events. Therefore, the present study aimed to evaluate the organizational structure of Patient Safety Centers of hospitals in the state of Rondônia.

METHODOLOGY

A quantitative, observational, cross-sectional study, was carried out between November 25 and December 26, 2020, in the municipality of Porto Velho, state of Rondônia, through a field survey. In 2015, the state of Rondônia had just over one and a half million individuals, representing the third most populous state in the Northern region¹⁴. The state has 52 municipalities and, in 2010, 73.5% Rondônia

residents lived in urban areas, 10.3% were less than five years old and 7% were elderly¹⁵.

The population of this study was composed with the support of the Patient Safety Coordination of the Health Surveillance Agency of the state of Rondônia, which made available a nominal list of the 45 Coordinators of the Patient Safety Centers out of the 55 with updated registration in the National Health Surveillance Agency database. Five individuals who did not have a telephone number or e-mail record in the system, making contact impossible, were excluded. Attempts were made to communicate via the institution but without success. The invitation was sent to the 40 Coordinators of the Patient Safety Centers of the hospitals in the state of Rondônia via e-mail, providing information about the research, of which 25 Coordinators of the Center, all nursing professionals, accepted to participate in the research. After acceptance, a new e-mail was sent with the instrument and guidance script for filling out and returning the answers.

Data were collected for the situational diagnosis of the Patient Safety Centers at hospitals in Rondônia using the validated self-assessment instrument proposed by Macedo and Bohomol⁸. The questionnaire and the Informed Consent were made available to the participants via google forms and sent by email. The instrument contains 69 items that assess six dimensions of two structure and process domains: 1) Human and material resources; 2) Implementation of the Patient Safety Centers; 3) Main activities of the Patient Safety Centers; 4) Sentinel Event prevention guidelines and actions; 5) Strategies and actions for risk management; 6) Training of professionals.

The answers for the structure domain can be: a) has, b) intends to have, c) does not intend to have, and d) uses another sector/ share with another sector. For the process domain, the options are: a) implemented, b) partially implemented, c) plans to implement, d) will not be implemented, or e) not applicable.

To assess compliance with Good Patient Safety Practices, the Health Surveillance Agency assessment score provided for in the Integrated Plan for Sanitary Management of Patient Safety in Health Services was used, which considers positive responses above 67% as a metric for high adherence to the self-assessment form¹⁷. Given the limitation of the instrument used in terms of evaluating the results, the notification of adverse events made to the Health Surveillance Notification System during the collection period was used as an indicator.

A descriptive analysis was carried out to characterize the study participants regarding the characteristics of the hospital institution. For quantitative variables, percentage measurements and central tendency analysis (mean, median, percentiles, standard deviation) were used. For inferential analysis, Fisher's Exact test was applied using the STATA 16.0 statistical package (College Station, Texas, USA).

This study is part of the matrix project "Good Practices in patient care, infection control and Processing of health products in the state of Rondônia" approved by the Health Ethics Committee of the Federal University of Rondônia under number 3771377. All participants signed the Informed Consent and the ethical principles for research involving human beings were respected by resolution 466/2012 of the National Health Council¹⁸.

RESULTS

The sample consisted of 25 Patient Safety Centers coordinators of the state out of the 40 registered in the Health Surveillance Agency database. The Patient Safety Centers were composed of a multidisciplinary team and have an average of four members from different areas of health such as medicine, nursing, pharmacy, and biomedicine, in addition to administrative agents, general director, and clinical director,

but in all Patient Safety Centers, the nurse was the coordinator. All teams have been together for over a year, except two teams.

Most institutions provided general care and had an adult intensive care unit, and a surgical center (Table 1). The shortest time of institutionalization of the center was 15 months and the longest, 89 months.

Table 1. Profile of the hospitals participating in the study. Porto Velho, state of Rondônia, Brazil, 2020 (n=25).

(Continua)

Variable	N (%)
Location	
Porto Velho	11 (44)
Interior	14 (56)
Type	
Public	12 (48)
Private	13 (52)
Serves the SUS	
Yes	14 (56)
No	11 (44)
Level	
State	12 (48)
Municipality	13 (52)
Size	
Large	11 (44)
Medium	3 (12)
Small	11 (44)
Type of establishment	
Specialized	5 (20)
General	20 (80)
ICU	
Yes	17 (68)
No	8 (32)
Type of ICU*	
Adult	11 (64.7)
Pediatric	1 (5.9)
Adult and pediatric	5 (29.4)

(Conclusão)

Variable	N (%)
Location	
Porto Velho	11 (44)
Interior	14 (56)
Type	
Surgery Center	
Yes	20 (80)
No	5 (20)

* The hospital may have more than one type of ICU

Most had a minimal structure for the operation of the Patient Safety Centers and had human resources partially sufficient to meet the demand (Table 2).

Table 2. Presentation of the structure domain: availability of human and material resources, Porto Velho, state of Rondônia, Brazil, 2020 (n=25).

Items	Yes n (%)	No n (%)
Physical Area	17 (68)	8 (32)
Computer	22 (88)	3 (12)
Printer	17 (68)	8 (32)
Telephone	9 (36)	16 (64)
Internet access	24 (96)	1 (4)
Office supplies	25 (100)	0 (0)
Human Resources	15 (60)	10 (40)

Regarding the process of implementing the Patient Safety Centers, almost 70% were fully implemented, and most encouraged a patient safety culture, however, they have difficulty using risk management tools and establishing effective communication (Table 3). The tools 5W2H, PDCA, PDSA, Process Flowchart, Checklist, Ishikawa Diagram, Brainstorming, and Pareto Diagram were mentioned, and nine services used more than one tool

Table 3. Process domain: main activities of the Patient Safety Centers, Porto Velho, RO, Brazil, 2020 (n=25).

Items	IT n (%)	PI n (%)	PLI n (%)	NSI n (%)	NA n (%)
Actions for risk management	10 (40)	8 (32)	6 (24)	0 (0)	1 (4)
Actions for multidisciplinary integration	14 (56)	7 (28)	4 (16)	0 (0)	0 (0)
Identifies and evaluates existing adverse events in processes and procedures	13 (52)	9 (36)	2 (8)	1 (4)	0 (0)
Elaborates, implements, disseminates, and updates the Patient Safety Plan	14 (56)	6 (24)	5 (20)	0 (0)	0 (0)
Monitor actions linked to the Patient Safety Plan	14 (56)	9 (36)	2 (8)	0 (0)	0 (0)
Implements patient safety protocols and monitors their indicators	10 (40)	12 (48)	2 (8)	1 (4)	0 (0)
Establishes accident prevention barrier	15 (60)	8 (32)	2 (8)	0 (0)	0 (0)
Develops, implements, and monitors training programs in patient safety	13 (52)	9 (36)	3 (12)	0 (0)	0 (0)
Analyzes and evaluates data on incidents and adverse events resulting from care	11 (44)	10 (40)	3 (12)	1 (4)	0 (0)
Discloses the results of the analysis to management and professionals	9 (36)	11 (44)	5 (20)	0 (0)	0 (0)
Notifies adverse events to the National Health Surveillance Service	15 (60)	5 (20)	5 (20)	0 (0)	0 (0)
Archive the notifications	21 (84)	3 (12)	1 (4)	0 (0)	0 (0)
Keep track of health alerts and other risk communications	16 (64)	7 (28)	2 (8)	0 (0)	0 (0)
Patient identification	17 (68)	6 (24)	2 (8)	0 (0)	0 (0)
Encouraging hand hygiene	24 (96)	1 (4)	0 (0)	0 (0)	0 (0)
Safe surgery	17 (68)	3 (12)	2 (8)	0 (0)	3 (12)
Safety in prescribing, using, and administering medications	15 (60)	8 (32)	2 (8)	0 (0)	0 (0)
Safety in the prescription, use, and administration of blood components	15 (60)	6 (24)	2 (8)	0 (0)	2 (8)
Encourages the patient and family to be involved in their safety	13 (52)	7 (28)	4 (16)	1 (4)	0 (0)
Effective communication	13 (52)	9 (36)	3 (12)	0 (0)	0 (0)
Pressure injury prevention	13 (52)	5 (20)	3 (12)	0 (0)	4 (16)
Fall prevention	16 (64)	6 (24)	3 (12)	0 (0)	0 (0)
Safety in the use of equipment and materials	15 (60)	6 (24)	4 (16)	0 (0)	0 (0)
Risk identification, analysis, monitoring, and communication	12 (48)	8 (32)	5 (20)	0 (0)	0 (0)
Integration of the different risk management processes developed by the service	11 (44)	8 (32)	6 (24)	0 (0)	0 (0)
Implementation of protocols established by the Ministry of Health	16 (64)	7 (28)	2 (8)	0 (0)	0 (0)
Safety in the prescription, use, and administration of enteral and parenteral nutritional therapies	14 (56)	2 (8)	5 (20)	0 (0)	4 (16)
Records the use of orthoses and prostheses, when used	7 (28)	3 (12)	6 (24)	1 (4)	8 (32)
Prevention and control of adverse events, including care-related infection	16 (64)	7 (28)	1 (4)	0 (0)	1 (4)
Actions to encourage a safe environment	15 (60)	9 (36)	1 (4)	0 (0)	0 (0)

IT: Fully implemented; PI = Partially implemented; PLI = Plan to implement; NSI = Will not be implemented; NA = Not applicable

As for coping with sentinel events, preventive actions are promoted regarding the surveillance of deaths or serious injuries associated with medication errors, patient falls, transfusion errors, use of products and devices, or environmental events of electrical, chemical, and/or biological risk (Table 5). In the process

domain related to training in patient safety and risk management strategies, twenty institutions had positive responses. However, there were negative responses about risk management, root cause analysis, and the use of the tool called Failure Modes and Effects Analysis (FMEA).

Table 5. Process domain: prevention of sentinel events and training, Porto Velho, state of Rondônia, Brazil, 2020 (n=25).

Items	IT n (%)	PI n (%)	PLI n (%)	NSI n (%)	NA n (%)
Guidelines and actions to prevent sentinel events					
Surgery procedure	6 (24)	5 (20)	7 (28)	0 (0)	7 (28)
Products and devices	10 (40)	2 (8)	10 (40)	0 (0)	3 (12)
Patient protection	6 (24)	4 (16)	10 (40)	0 (0)	5 (20)
Care management	14 (56)	5 (20)	5 (20)	0 (0)	1 (4)
Environmental events	9 (36)	2 (8)	10 (40)	0 (0)	4 (16)
Radiological events	4 (16)	3 (12)	8 (32)	0 (0)	10 (40)
Potential criminal events	4 (16)	2 (8)	9 (36)	2 (8)	8 (32)
Training of health professionals					
Quality and patient safety	15 (60)	7 (28)	3 (12)	0 (0)	0 (0)
Basic Principles in patient safety	19 (76)	5 (20)	1 (4)	0 (0)	0 (0)
Types of adverse events related to healthcare	14 (56)	9 (36)	2 (8)	0 (0)	0 (0)
Patient safety protocols	19 (76)	4 (16)	2 (8)	0 (0)	0 (0)
Patient safety indicators	9 (36)	8 (32)	8 (32)	0 (0)	0 (0)
Strategies for improving quality and safety	9 (36)	12 (48)	4 (16)	0 (0)	0 (0)
Safety culture	8 (32)	10 (40)	7 (28)	0 (0)	0 (0)
Patient safety center	18 (72)	5 (20)	2 (8)	0 (0)	0 (0)
Patient safety plan	14 (56)	8 (32)	3 (12)	0 (0)	0 (0)
Management and risk management	12 (48)	7 (28)	5 (20)	1 (4)	0 (0)
Adverse event reporting system	18 (72)	4 (16)	3 (12)	0 (0)	0 (0)
Investigation of adverse events	12 (48)	10 (40)	3 (12)	0 (0)	0 (0)
Root cause analysis	6 (24)	8 (32)	9 (36)	0 (0)	2 (8)
Failure Modes and Effects Analysis (FMEA)	6 (24)	6 (24)	11 (44)	1 (4)	1 (4)

IT: Fully implemented; PI = Partially implemented; PLI = Plan to implement; NSI = Will not be implemented; NA = Not applicable

During the collection period, 248 Adverse Events records were reported to the Health Surveillance Notification System from six participating hospitals. The data showed a higher

frequency of mild adverse events compared to moderate and severe, with no death recorded (Figure 1).

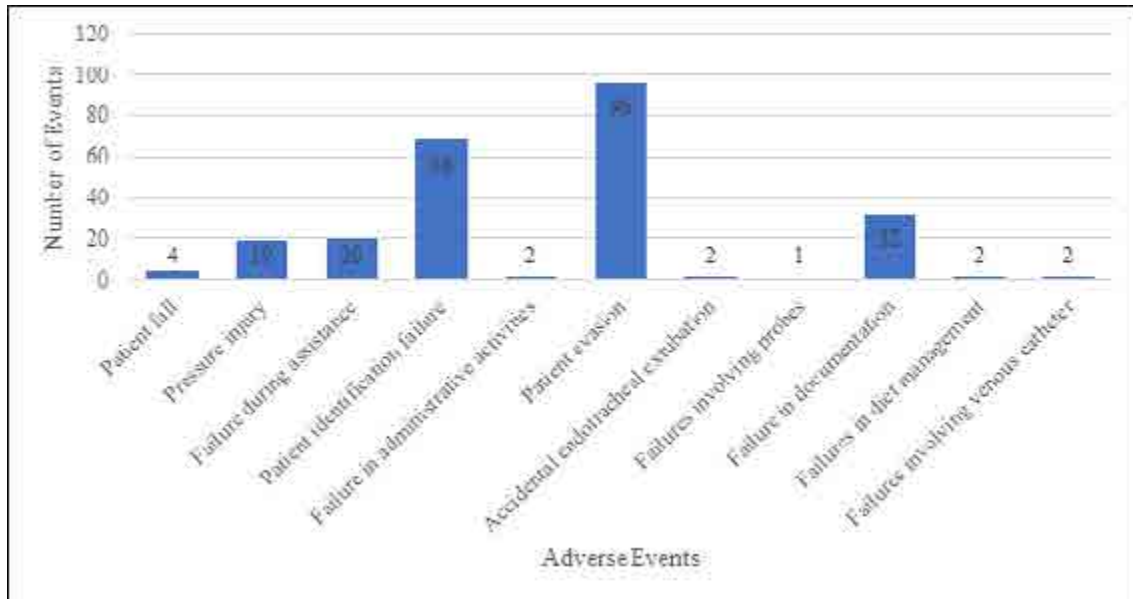


Figure 1 - Adverse events reported by the Centers in November and December, Porto Velho, state of Rondônia, Brazil, 2020 (n=248).

Out of the total Patient Safety Centers evaluated, just under half showed high adherence to good patient safety practices (48%). A significant difference was detected for the type of institution,

whether public or private (p=0.02), and whether records of adverse events were recorded during the study period (p=0.04; Table 4).

Table 6. Bivariate analysis based on adherence to good safety practices in health services based on the theoretical model of health risk assessment, Porto Velho, state of Rondônia, Brazil, 2020 (n=25).

(Continua)

Variables	Adherence		p-value
	Intermediate or Low n (%)	High* n (%)	
Location			0.16
Porto Velho	4 (30.7)	7 (58.3)	
Interior	9 (69.2)	5 (41.7)	
Type			0.02
Public	9 (69.2)	3 (25.0)	
Private	4 (30.7)	9 (75.0)	
Serves the SUS			0.16
Yes	9 (69.2)	5 (41.7)	
No	4 (30.7)	7 (58.3)	

(Conclusão)

Variables	Adherence		p-value
	Intermediate or Low n (%)	High* n (%)	
Level			0.54
State	7 (53.8)	5 (41.7)	
Municipality	6 (46.1)	7 (58.3)	
Size			0.79
Large	6 (46.1)	5 (41.7)	
Medium	1 (7.7)	2 (16.7)	
Small	6 (46.1)	5 (41.6)	
Intensive Care Unit			0.11
Yes	7 (53.8)	10 (83.3)	
No	6 (46.1)	2 (16.7)	
Type of Intensive Care Unit			0.67
Adult	5 (71.4)	6 (60.0)	
Adult and pediatric	2 (28.6)	3 (30.0)	
Pediatric	0 (00)	1 (10.0)	
Surgery center			0.69
Yes	10 (76.9)	10 (83.3)	
No	3 (23.1)	2 (16.7)	
Adverse effects**			0.04
Yes	1 (7.7)	5 (41.7)	
No	12 (92.3)	7 (58.3)	

* Over 67% positive responses

** Registration of adverse events from November and December 2020

DISCUSSION

Out of the 55 Patient Safety Centers in the state officially registered on the Health Surveillance Agency website, 25 participated in this study. In Rondônia, the total number of centers registered at the national agency remains equal to the other states in the Northern region, led by Amazonas with 79 centers¹⁹. In Brazil, the region with the highest number of Patient Safety Centers is the Southeast with 2,679, followed by the Southern region with 1,175. In turn, the highlighted states are Minas Gerais with 1,108, São Paulo with 1,018, and Goiás with 664.

All centers are multidisciplinary, however, stands out the participation of the nursing team in all coordinations in Rondônia. Although care is a prominent field in nursing, the role of nurses in the management process is highlighted, whose leadership, communication, and teamwork are essential in promoting care and improving safety in health services²⁰.

In the self-assessment, a higher frequency of positive responses was found for the structure domain compared to the process domain. A study promoted by Health Surveillance Agency to analyze the national self-assessment process between 2016 and 2019 from the perspective of

surveillance confirms that, despite the existence of structures, the processes involved are not carried out, which leads to reflection on whether the centers are fulfilling their responsibilities²¹. Therefore, having physical, material, human, and financial resources do not guarantee patient safety.

In this way, the evaluation of practices through process indicators is essential so that the implementation of the centers does not occur for mere legal compliance. Thus, this study demonstrated that around 70% centers are fully implemented, but less than 40% use Adverse Events management tools and only five communicate their results to the teams.

A Brazilian survey points to the importance of risk management in terms of quality and safety, and the team needs to have knowledge and clarity about Adverse Events notification and the use of indicators to monitor these events²². In this study, only nine centers reported carrying out training on the use of indicators, therefore, despite national validation, their use in services is scarce.

Concerning activities of the centers, we highlight the monitoring of health alerts and risk communication. Amid the current coronavirus pandemic, this action performed by the Patient Safety Centers is of great relevance, given that disease prevention and infection control actions are highlighted and should be encouraged by the teams²³.

Of the 25, only ten centers had the basic safety protocols fully implemented, with emphasis on the six Ministry of Health protocols. Nevertheless, only seven institutions reported registering the use of orthoses and prostheses, when used. This is an alert to the centers, due to the risk of readmission for the use of implants in surgical procedures due to the formation of biofilms and the need for surgical reopening²⁴.

Of the training promoted by the center, training on the use of the Failure Modes and Effects Analysis and Root Cause Analysis tools

is negligible, despite representing an important method in the process of investigating and mitigating failures and errors. A study carried out in the state of Rio Grande do Sul in 2020, involving such administrative tools to evaluate healthcare processes, demonstrates the effectiveness of this tool in identifying and preventing potential incidents from causing damage to users²⁵.

High adherence to good patient safety practices was found in private hospitals. A report published by ANVISA in 2021 based on the Integrated Plan for Health Management found that in Rondônia, out of the five hospitals with high compliance, four were private institutions¹³. That is, private services have better indicators regarding patient safety. This result may be due to several factors, ranging from the lack of rigor and surveillance in public hospitals to the lack of adequate incentives on the part of managers to complete the questionnaire or the integrability of the assessment instrument for people with low functional health literacy²¹.

Among the main activities of the Patient Safety Centers, the notification of adverse events to the National Health Surveillance Service is a not consolidated activity, and this directly influences the construction of the state health surveillance database, which will provide subsidies for the development of future actions related to surveillance and monitoring.

Only six institutions were identified in NOTIVISA that were notified during the collection period, although 15 centers reported that the notification process was fully implemented. There was a total of 248 records within one month, most of them classified as mild, with emphasis on patient evasion, failure to identify the patient, and failure in documentation. On the other hand, in a survey carried out in Salvador, state of Bahia, of the 12 hospitals with Patient Safety Centers, nine registered Adverse Events in which pressure injuries, bed falls, and medication errors predominated²⁶. Despite the bureaucratic nature of the records, their importance in patient

safety is highlighted, whose information must be verified and inconsistencies investigated.

The patient safety management model organized and supported based on the actions of a Patient Safety Centers composed of a multidisciplinary team is unique to Brazil. Few countries have a public patient safety policy. In most countries, patient safety is linked to good professional practices. Discussion of the topic in health organizations was intensified after the publication of the report "To err is human: building a safer health system" by the Institute of Medicine of the United States in 1999. A bibliometric study that evaluated the repercussion of this report in the academic discourse in the following two decades found 20,494 documents, narrowing the diversity of patient safety discourse instead of expanding it, often focusing only on reporting incidents²⁷. This indicates the importance of looking at patient safety far beyond its results, that is, the number of notifications made, but the value given to the topic by the different actors involved in care – users, family, health professionals, and managers.

As a limitation of this research, the sample size is considered, as the number of Patient Safety Centers officially registered with Health Surveillance Agency. Despite the efforts of researchers and the state coordination of Patient Safety for the participation of all Patient Safety Centers, it is understood that adherence is a reflection of how the members of the centers understand the opportunities to evaluate their performance.

As a strength, we highlight the importance of representing patient safety centers in promoting an effective and consolidated patient safety culture in organizations, the importance of reporting adverse events in the health situation analysis, and it is considered a study with national relevance given the importance of the subject for health institutions, and due to the scarcity of research in the area.

CONCLUSION

In Rondônia, there was an appreciation of structural resources to the detriment of processes. Just under half had high adherence to good patient safety practices. Significant differences were found between public and private hospitals in adherence to good practices, as well as in Adverse Events notification and adherence to good practices.

Thus, there is a need for closer and more frequent monitoring by the state coordination of the Patient Safety Centers, given the weaknesses of the centers in risk management. A process of training Patient Safety Centers team members is also necessary so that they can effectively implement good practices in their institutions.

Future studies are suggested to investigate which tools the centers use to manage risks and what the results obtained, which allow to simplify risk management, allow the performance of the entire multidisciplinary team, and will make effective the main action of the center, mitigation of risks. And also, to find out what the professionals' knowledge about the patient safety culture is, since the Coordination must be composed of qualified and trained individuals in the safety area, whose minimum knowledge about the subject must be a priority.

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