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PATIENT SAFETY AND THE CORRELATION WITH THE CEARENSE HOSPITAL INCENTIVE POLICY

SEGURANÇA DO PACIENTE E A CORRELAÇÃO COM A POLÍTICA DE INCENTIVO HOSPITALAR CEARENSE

SEGURIDAD DEL PACIENTE Y LA CORRELACIÓN CON LA POLÍTICA DE INCENTIVOS DEL HOSPITAL DE CEARA

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ABSTRACT
Patient safety must be present at all points in the health care network. The objective of this study was to outline the profile of the hospitals inserted in the State Policy of Hospital Incentive of Ceará and its correlation with the Patient Safety Centers implanted and registered with the National Health Surveillance Agency. This was a descriptive, cross-sectional, and quantitative study that used secondary data from the registration and implementation of these security centers in Ceará, obtained from the agency's analytical information database. It was identified a total of 136 hospitals with profiles of regional, strategic, and small reference hospitals were identified and distributed in the five health regions of Ceará. Of these, only 37 hospitals (27.20%) had a patient safety center implemented. Demonstrating the need to qualify and make available instruments for the implementation of these centers, improving the quality of services, and reducing the occurrence of avoidable damage.
Descriptors: *Hospital Care; Health Surveillance of Health Services; Quality of Health Care; Patient Safety; Patient Harm.*

RESUMO
A segurança do paciente deve estar presente nos diversos pontos da rede de atenção à saúde. O objetivo deste estudo foi traçar o perfil dos hospitais inseridos na Política Estadual de Incentivo Hospitalar do Ceará e sua correlação com os núcleos de segurança do paciente implantados e cadastrados junto à Agência Nacional de Vigilância Sanitária. Foi um estudo descritivo, transversal e quantitativo, que se utilizou de dados secundários de cadastramento e implantação desses núcleos de segurança no Ceará, obtidos do banco de dados de informações analíticas dessa agência. Foram identificados 136 hospitais com perfis de hospitais de referência regional, estratégicos e de pequeno porte, distribuídos nas cinco regiões de saúde do Ceará. Destes, apenas 37 hospitais (27,20%) possuíam núcleos de segurança do paciente implantados, demonstrando a necessidade de qualificar e disponibilizar instrumentos para a implantação desses núcleos para melhorar a qualidade dos serviços e reduzir a ocorrência de danos evitáveis.
Descritores: *Assistência Hospitalar. Vigilância Sanitária de Serviços de Saúde. Qualidade da Assistência à Saúde. Segurança do Paciente. Dano ao Paciente.*

RESUMEN
La seguridad del paciente debe estar en toda la red asistencial. El objetivo de este estudio fue delinear el perfil de los hospitales insertos en la Política Estatal de Incentivo Hospitalario de Ceará y su correlación con los Centros de Seguridad del Paciente implantados y registrados en la Agencia Nacional de Vigilancia Sanitaria. Fue un estudio descriptivo, transversal y cuantitativo, que utilizó datos secundarios del registro e implementación de estos centros de seguridad en Ceará, obtenidos de la base de datos de la Agencia. Fueron identificados un total de 136 hospitales con perfiles de hospitales regionales, estratégicos y pequeños de referencia distribuidos en las 05 Regiones de Salud de Ceará. Solo 37 hospitales (27,20%) tenían implantado un Centro de Seguridad del Paciente. Demostrando la necesidad de cualificar y disponer de instrumentos para la implementación de estos Centros, mejorando la calidad de los servicios y reduciendo la ocurrencia de daños evitables.
Descriptores: *Atención Hospitalaria; Vigilancia Sanitaria de Servicios de Salud; Calidad de la Atención de Salud; Seguridad del Paciente; Daño del Paciente.*

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INTRODUCTION

Patient safety, according to the World Health Organization (WHO), is defined as a set of activities that, in an organized way, enables the creation of cultures, processes, procedures, behaviors, technologies and environments in health that aim to reduce risks in a consistent and sustainable way. With this we have the reduction in the occurrence of errors and avoidable damages and the impact of the damage when it happens[1]. This safety should be sought in all health units, from primary care, so that we can have an environment that takes care of the patient without causing damage and offers a quality service.

Since May 2002, the World Health Assembly has prioritized patient safety. In May 2004, the *World Alliance for Patient* Safety[1] was created, which established the six international Patient Safety guidelines: identify patients correctly; improve the effectiveness of communication and the safety of high-surveillance medications; ensure correct patient surgeries, intervention site and procedure; reduce the risk of healthcare-associated infections and the risk of injury to patients due to falls[2].

In Brazil, Ordinance No. 529/2013[3] of the Ministry of Health, which is a milestone for patient safety, established the National Patient Safety Program (NPSP-PNSP) and was based on the relevance and magnitude that adverse events have in our country[3]. Among Ordinances, Resolutions and Norms issued to prioritize the issue of patient safety, the Collegiate Board Resolution (CBR-RDC) No. 36/2013 stands out, which made mandatory the implementation of Patient Safety Centers (PSC-NSP) in health services in the country[4].

In Ceará, there is the strategy of the State Policy of Hospital Incentive for Regional, Strategic and Small Local Hospital Reference Hospitals, which prioritizes the State Health System[5]. This policy provides financial support for the strengthening of hospital care at the regional level, expanding the population's access to hospital services closer to the citizen[6]. Thus, it is important to have an overview of patient safety in these hospitals, since it seeks to offer a quality service and that values patient safety.

It is noteworthy that this state policy was endorsed by the Bipartite Interagency Commission of Ceará (BIC-CIB/CE), by the State Health Council of Ceará (SHC-CESAU/CE)[6,7] and by Law No. 17,006/2019, which established that the health care network should be located in the health region[8].

As one of the criteria for adherence of hospitals to this policy is the requirement of sanitary license[5.7], according to Law No. 6,437 / 1977[9], RDC 63/2011 [10] and RDC 36/2013[4]. To comply with this requirement, the hospital must prove that it has the registration of the Patient Safety Center with the National Health Surveillance Agency (ANVISA)[11]. Thus, patient safety is one of the factors considered for adherence to the Hospital Incentive Policy, since in order to obtain the sanitary license, the hospital needs to have the NPS implanted and registered with ANVISA. It is also worth remembering that the NPS are responsible for the notification of adverse events (AE) related to care with the National Health Surveillance System (SNVS). This notification takes place through the Health Care module of the Health Surveillance Notification System (NOTIVISA)[12].

The implementation and implementation of the NPS presupposes improvement in the care and quality of care provided to the user of the Unified Health System (UHS-SUS), since protocols are created to protect the patient. It is observed worldwide that failures in processes that lead to adverse events can result in mild, moderate, severe damage or even death of the patient. Despite all efforts, in 2016, WHO recognized that the amount of preventable harm to health and health systems around the world was unacceptably high and with few signs of improvement.

Based on these premises, identifying the hospitals that have NPS implanted or not, by itself, already presupposes identifying those that have a greater commitment to this safety and that comply with the legislation in force. For those who have not yet implemented the NPS, identifying them will allow an overview of the need to qualify and make available instruments for the implementation of these centers.

This work, therefore, aims to outline the profile of the hospitals included in the State Policy of Hospital Incentive of Ceará and its correlation with the Patient Safety Centers implanted and registered with ANVISA.

METHODS

This is a descriptive, transversal study, with a quantitative approach, related to the patient safety centers implanted and registered with ANVISA in the hospitals of the state of Ceará, where it was sought to know where they were implanted, what the number and size of these hospitals and to which health region they belonged.

The State of Ceará is politically and administratively divided into 184 municipalities and 5 Health Regions, especially the Metropolitan Regions of Fortaleza, Cariri and Sobral and which had an estimated population for 2021 of approximately 9,240,580 people[13,14].

The research had as inclusion criteria all hospitals, both public and private, with the possibility of adhering to the State Policy of Hospital Incentive for Regional, Strategic and Small Local Hospital Reference Hospitals for the period 2021-2023, contained in Resolution No. 53/2021 of CESAU/CE[7]. The other hospitals not included in this resolution were not included in this research.

The data collection instrument consisted of Microsoft® Excel® 2019 MSO spreadsheets (Version 2206 Build 16.0.15330.20216), in which the hospitals included in the research were arranged according to the variables that mattered: type of hospital and size (regional reference hospitals of size III and IV, strategic and small location), city and health region to which they belonged. Next, the hospitals that had the patient safety center implanted were identified, using the data obtained from ANVISA, which included all the health units in the state of Ceará with implanted patient safety centers. After this identification, the number and percentage of hospitals with patient safety core were calculated using the resources available in this spreadsheet, according to the health region, type and size of the hospital.

For data collection, three reports were considered. The first, obtained in July 2022, contains the list of Regional, Strategic and Small Local Reference Hospitals listed in Annexes I, II and VII, respectively, of Resolution No. 53/2021 of CESAU/CE. and published in the Official Gazette of the State of Ceará (DOE), No. 269, Series 3, Year XIII on December 2, 2021[6]. The second was extracted on 12/28/2022, from the ANVISA website, which contains the registered patient safety centers and constructed from the selection of the following filters: region (northeast), state (Ceará), category (everything), subcategory (patient safety core) and classification (everything)[15]. It is worth mentioning that this database is updated daily. The third, containing data regarding the number of hospitals in the State of Ceará, extracted on 02/27/2023, where the National Registry of Health Establishments (CNES), the Secretariat of Health Care and the Department of Informatics of the Unified Health System (DATASUS) was accessed, from the filters: reports (type of establishment), state (Ceará) and competence (current), Description (general hospital and specialized hospital)[16].

The search for data showed the existence of 293 hospitals described as general (241) and specialized (52) hospitals in the state of Ceará. Of these, 136 hospitals were included in the policy with the possibility of adhering to the State Policy of Hospital Incentive for Regional, Strategic and Small Local Hospital Reference Hospitals for the period 2021-2023, constituting themselves in the research sample.

It was not necessary to send it to the Research Ethics Committee (REC-CEP) for approval, due to the nature of the research that used secondary data from the public domain. Ethical procedures were observed in order not to expose the identification of the hospitals studied, as well as the commitment to make public the results of the present study.

RESULTS

The results of this research showed a quantitative of 136 hospitals inserted in the State Policy of Hospital Incentive of the state of Ceará, of these: 41 are Regional Reference Hospitals, of which 26 are Size III (above 50 beds or at least 30 when Specialized Hospital) and 15 are of size IV (above 100 beds or at least 50 when Specialized Hospital); 32 are Strategic Hospitals (hospitals of 1st level of regional reference, above 30 beds, with 24-hour medical care, habitual delivery with accommodation, therapeutic diagnostic support service (SADT) and immobilization if they have traumatology). The others, in number of 63, are Small Hospitals (HPP) with or without Stabilization Room (have between 10 and 30 beds, with 24-hour medical care, habitual delivery with accommodation, has access to SADT and observation beds) (Table 1).

It was observed that 100% of the regional reference hospitals of size IV have a patient safety center implanted and only 46.16% of those of size III have the implementation of the NSP (Table 1). Of the strategic hospitals, only 31.20% of them have NPS implanted and none of the small hospitals has NPS implanted (Table 1).

Considering all the 136 hospitals included in the policy, we can see that only 37 of them (27.20%) meet the requirement of having the safety core of the patient (Table 1).

Taking into account the Regional Reference Hospitals, regardless of size (sizes III and IV), we found that 65.85% of them have NPS implanted (Table 1).

Table 1 – Number and percentage of hospitals included in the State Hospital Incentive Policy according to the size and existence or not of the patient safety center. Ceará, 2022

All Health Regions	Types of Hospitals of the Hospital Policy d e Incentive				
	Hospital Ref. Regional Porte III	**Hospital Ref. Regional Porte IV**	**Strategic Hospital**	**Small Hospital**	**Total number of hospitals**
Size Policy Hospitals without NPS	14	0	22	63	99
	53,84%	0,00%	68,80%	100,00%	72,80%
Number and Percentage of Policy Hospitals by Size with NPS	12	15	10	0	37
	46,16%	100,00%	31,20%	0,00%	27,20%
Total Hospitals by Size	26	15	32	63	136
	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Table prepared by the author with presentation of absolute numbers and percentage. 2022

The size III hospitals are distributed in the five health regions of the state; however, the size IV hospitals are not present in the health regions East Coast Jaguaribe and Central Sertão (Table 2).

Both small and strategic hospitals are distributed in all health regions of the state of Ceará. In this case, the region of Sobral stands out, in which all the strategic hospitals of the policy do not have NPS implanted (Table 2).

We also had as a result, according to the registration in the CNES, the existence of 293 hospitals described as general (241) and specialized (52) public and private hospitals in the state of Ceará[16]. Using ANVISA data regarding the registered NPS, and using the filters: region, state (northeast, Ceará), category (hospital and sentinel hospital), classification (hospital) and subcategory (patient safety center) we arrived at 114 hospitals that have registered NPS, representing 38.90% of these hospitals.

Table 2. Number and percentage of hospitals included in the State Policy of Hospital Incentive according to the size and existence or not of the patient safety center, by health region. Ceara, 2022

Health Region	Types of Hospitals of the Hospital Policy d e Incentive				
	Hospital Ref. Regional Porte III	**Hospital Ref. Regional Porte IV**	**Strategic Hospital**	**Hospital de Small Size**	**Total por Region**
Fortaleza hospitals without NSP	5 (1 2.82%)	0 (0%)	5 (12.82%)	19 (48,7%)	29 (74.36%)
Hospitals Fortaleza with NSP	1 (2,5%)	6 (15,38%)	3 (7,69%)	0 (0%)	10 (25.64%)
Sobral Hospitals without NPS	2 (7.70%)	0 (0%)	3 (11.54%)	16 (61,54%)	21 (89.77%)
Hospitals de Sobral with NSP	2 (7,70%)	3 (11,54%)	0 (0%)	0 (0%)	5 (19,23%)
Cariri Hospitals without NSP	4 (1 0.8%)	0 (0%)	9 (24.32%)	11 (29,73%)	24 (64.87%)
Cariri hospitals with NSP	3 (8,10%)	6 (16,2%)	4 (10,8%)	0 (0%)	13 (35,13%)
Hospitals East Coast/Jaguaribe without NSP	1 (5.55%)	0 (0%)	4 (22.22%)	8 (44,5%)	13 (72.2%)
Hospitals of the East Coast/Jaguaribe With NSP	3 (16,7%)	0 (0%)	2 (11,11%)	0 (0%)	5 (27.8%)
Central Sertão Hospitals without NPS	2 (12.5%)	0 (0%)	1 (6.25%)	9 (56,2%)	12 (75%)
Hospitals of the Central Sertão with NSP	3 (18,75%)	0 (0%)	1 (6,25%)	0 (0%)	4 (25%)
Total Hospitals by Size in all Health Regions	26 (19,12%)	15 (11,02%)	32 (23,53%)	63 (46,33%)	136 (100%)

Source: Table prepared by the author with presentation of absolute numbers and percentage. 2022

DISCUSSION

According to the WHO, unsafe care that causes harm to the patient is a growing public health challenge globally and the adverse events that occur represent one of the leading causes of death and disability worldwide. It is estimated that about 2.6 million deaths occur every year due to these events, representing a social cost that can reach 2 trillion dollars per year [1].

However, it is known that these events could be minimized if patient safety measures were adopted, such as the implementation of a patient safety center and the implementation of safety programs. It has already been verified, by policymakers and health leaders of the world, all the benefits of implementing a strategic and coordinated management in the approach to patient safety in which the causes of the damage is recognized and how to prevent them[1].

In this study, it was found that only 27.20% of the hospitals included in the hospital policy for the period 2021-2023 have NPS implemented, going against a whole Brazilian legislation that for 10 years has determined this implementation and guides this patient-oriented care: Ordinance No. 529/2013, which established the National Patient Safety Program (PNSP)[3], RDC No. 36/2013 [4], Ordinance No. 3,390/2013 [17] and Ordinance No. 3410/2013[18].

This result demonstrates that most of these hospitals do not have implanted NPS (72.80%) in contravention of the WHO guidelines, which since 2002 have prioritized patient safety to prevent the occurrence of harm and which has also obtained evidence suggesting that 134 million adverse events due to unsafe care occur in hospitals in middle- and low-income countries[1].

A study conducted in a health unit of the East Coast Health Region of Jaguaribe, demonstrated that the implementation of health commissions, including patient safety, brought technical knowledge to guide the measures and protocols to improve patient and worker safety[19]. This leads to the need to invest in knowledge

and tools to improve security and break down the laws and cultural barriers that prevent the improvement of security[20].

In 2013, the Ministry of Health published six basic patient safety protocols: the practice of hand hygiene; safety in the prescription, use and administration of medications; patient identification; prevention of falls and pressure injuries and safe surgery. These should be part of the Patient Safety Plan to be prepared by the NSP[21].

The small number of NPS implanted is also opposed to the need to ensure the quality and safety of the patient, whether at the hospital level or in other health units. A study conducted in 2021 in a Brazilian accredited hospital found that one of the safety protocols, a practice of hand hygiene, mitigated the transmission of diseases between patients. The simple act of "washing hands" represented one of the main contributions to the fight againstCOVID-19 in that hospital studied[22].

It was observed that on small hospital has NPS implanted, and currently statistics indicate that every year many patients suffer damage or die due to unsafe health care, with many events occurring in hospitals[1]. A study conducted in 2018, in Ceará, on the adverse events that occurred in the state that year showed that 3,341 adverse events were reported, of these, 29 (0.9%) were never events [23] (events that should never occur in health services)[21] and 11 (0.3%) were deaths. Pressure ulcers were the most frequent adverse event, 804 (24%)23.

In Ceará there are 293 hospitals registered[16] in the CNES and only 114 NSP implanted in hospitals [15], this shows that only 38.90% of the total of hospitals in the state of Ceará have NSP implanted and registered. This number falls even more when we consider only the hospitals included in the hospital incentive policy (136), in which only 37 of them (27.20%) have NPS implanted[15].

When taking into account other health facilities besides hospital units, in Ceará, there are 239 NPS implanted and registered with ANVISA[15]. Making a comparison with the other regions of Brazil, in February 2023, 7,815 NPS were deployed, distributed as follows: southeast (3,386), south (1,460), northeast (1,378), midwest (1,208) and north (383)[24].

These data lead to the conclusion that there is a considerable underreporting of adverse events, since, according to ANVISA's technical note no. 05/2019, AEs related to health care must be notified to the National Health Surveillance System (SNVS) and it is the role of the NSP to make this notification[21].

In Brazil, in a report published by the General Management of Technology in Health Services (GGTES/ANVISA), in June 2022 it was observed that the Southeast region is responsible for the largest number of notifications of adverse events (37.8%). Then we have the northeast (23.1%), south (19.8%), center-west (14.6%) and north (4.7%), leading to observe that the number of notifications follows the population density of the regions[25]. These results allow the detection of risks and the application of preventive measures. When the causes of AEs are determined, safe practices can be proposed to reduce risks, thus improving patient safety in health services[12].

In Brazil, a study conducted to evaluate the incidence of adverse events in three Brazilian teaching hospitals, in the state of Rio de Janeiro, concluded that this type of event had an incidence of 7.6%, of which 66.7% were preventable events. A ratio of 0.8 events per 100 patients/day was observed. This incidence found was similar to that of international studies, but the proportion of avoidable adverse events was much higher in Brazilian hospitals[26]. This only reinforces the need to implement patient safety centers.

What is observed is a silence about these issues and it is worth remembering that despite costs, responsibilities and resistance to changes and other barriers that may arise, the health system must offer healing and comfort. The health system needs to offer this guarantee and security to the public[14]. To paraphrase Hippocrates: "first do no harm" [20].

The notification of adverse events is part of the process of improving safety, as well as serving as a source of learning. They also serve as a basis for proposing new improvement strategies. It is necessary that

institutional policies are valued, thus reducing the barriers that hinder notification and envisioning alternatives to increase the adherence of all those involved in care, making the health environment safer and more reliable[27].

Despite all the discussion around safety, a literature review study conducted in the databases in July and August 2022, using keywords related to patient safety, concluded that the literature is incipient on this topic,[28] corroborating another study, also from 2022, which observed a scarcity of studies related to patient safety in Primary Health Care (PHC), notably in relation to a notification system for this service[29].

The importance of this study for public health is evident when attention is drawn to this problem, which is the low rate of implementation of NPS in hospitals of the hospital incentive policy of Ceará (27.20%), which has as consequences the underreporting of events and the non-implementation of protocols that aim to ensure patient safety in a large portion of hospitals. This represents the great challenge to improve patient safety in these units that provide care to SUS users. In addition, it also warns about the need to seek data on how this issue of patient safety is in other health units in the state so that one can have a concrete overview of the situation of implementation of NPS and can plan and implement policies that solve these issues in order to provide a safe environment to the patient who seeks care.

CONCLUSION

The research showed that the hospitals included in the hospital incentive policy have different sizes, are located in all health regions of the state of Ceará and most do not have patient safety centers implanted. This demonstrates the need to qualify and provide instruments for the implementation of these centers, improving the quality of the services provided and reducing the occurrence of avoidable damages.

The problem of the implementation of NPS in hospitals that are inserted in the hospital incentive policy end up causing an underreporting of adverse events and the correct information can contribute to the establishment of an epidemiological profile of the State, as well as the adoption of public policies according to the reality presented.

The implementation of NPS is essential because they work as a way to improve care, since protocols are implemented that are controlled and adjusted by this nucleus.

As a limitation of this study we have the use of a sample that included only the hospitals included in the hospital incentive policy of Ceará. As potentialities we can mention the fact that this study causes a need for new studies that expands in this sample to more health units and hospitals to have a panorama of patient safety in the state of Ceará, so that care can be made safer. It also encourages a rereading of the entire planning process of health surveillance with regard to enforcing the standards that regulate the mandatory implementation of patient safety centers.

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