

# National Patient Safety Program in Brazil: Incidents Reported Between 2014 and 2017

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**Objective:** The aim of the study was to analyze the patient safety incidents reported to the Brazilian National Health Surveillance System from March 2014 to March 2017.

**Method:** A documentary study that used the records of the incidents published in the Reports of Adverse Events (AE) in Brazil. The following variables were selected: number of incidents by type, type of health service, hospital unit, and degree of harm. To find whether there was a significant difference across the Brazilian regions by notifications related to general incidents, AE, and deaths, the analysis of variance and the Tukey tests were used.

**Results:** A total of 109,082 incidents were reported, of which 75,088 were AE, with 649 deaths. In relation to the types of incidents reported, there was a higher frequency in the categories other (30.04%) and failures during health care (26.72%). A total of 93.90% of the incidents occurred in hospitals, with 54,950 cases registered in hospitalization units and 30,141 cases in intensive care units. Statistically significant differences across the Brazilian regions were observed in the number of incidents ( $P = 0.004$ ), AE ( $P = 0.004$ ), and deaths ( $P = 0.024$ ).

**Conclusions:** A significant underreporting of incidents was found in Brazil, demonstrating only the tip of a giant iceberg. More than half of the incidents were reported as AE and were registered in hospitals, reiterating the importance of establishing public health policies at national, state, and municipal levels, with adequate supervision of the health service regarding the implementation of the Patient Safety Nuclei and the preparation of new protocols based on the most prevalent incidents.

**Key Words:** patient safety, notifications, incidents, adverse events, National Patient Safety Program of Brazil

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**P**atient safety, which refers to actions to reduce the risk of unnecessary harm associated with health care,<sup>1</sup> has been widely discussed in the international scenario, considering the magnitude of the repercussions caused by these incidents.

Part of the Brazilian health services (HS) has been organized to implement actions that ensure the proper management of these incidents, recognizing them as an event or circumstance that could

have resulted, or resulted, in unnecessary harm to the patient. If it causes harm, these are characterized as an adverse event (AE).<sup>1</sup>

Because the global mobilization for patient safety began, there is increased awareness that the health care activity is complex and dynamic, involving risks to patients. When solid barriers are not in place to prevent these risks from reaching patients, incidents may occur, compromising the quality of care and safety. These events can be present from basic care (primary level) to medium and high complexity health care (secondary and tertiary level).

In Brazil, the health care of the population is ordered in organizational arrangements of actions, services, and systems of different technological densities, such as Health Care Networks, which aim to respond with effectiveness, efficiency, safety, quality, and equity in the process of implementation of the Unified Health System.<sup>2</sup>

The first initiative to implement a national reporting system was the creation of the Brazilian Network of Sentinel Hospitals in 2002 to report on technical and AE complaints associated with pharmacovigilance, technosurveillance and hemovigilance.<sup>3</sup> The Brazilian Network of Sentinel Hospitals is a strategy adopted by Brazilian Health Regulatory Agency (ANVISA) to monitor and report adverse events and technical complaints related to health products.<sup>30</sup>

To expand this initiative, aiming at a specific patient safety regulation in the context of Brazilian Health Care Networks and covering all levels of health care, the National Patient Safety Program (NPSP) was established by Administrative Rule No. 529, published in April 2013 by the Ministry of Health. The main objective of the NPSP is to contribute to the qualification of health care in all HS in the national territory.<sup>4</sup>

The NPSP was complemented by regulations issued by the ANVISA, which through Resolution no. 36, published in July 2013, establishes the obligation to create the Patient Safety Nuclei (PSN) in the Brazilian HS.<sup>5</sup>

Among its functions, the PSN are responsible for the monitoring and investigation of incidents occurring in HS and for the mandatory and monthly report to the National Health Surveillance System, except in case of deaths, which must be notified within 72 hours.<sup>5</sup> These notifications are made in the National Reporting System of Sanitary Surveillance, which has, since 2014, had a specific module for notification of incidents and AE related to health care.<sup>6</sup>

In this scenario, it is observed that currently, there are approximately 300 thousand health establishments registered in Brazil<sup>7</sup> to serve a population of more than 207 million people,<sup>8</sup> evidencing the urgent need to institute measures for prevention and mitigation of incidents, both at the level of public policies and at the operational and strategic level in HS. However, despite the relevance of the topic, the studies on incidents in the Brazilian context are still scarce and incipient. Thus, this research aimed to analyze the patient safety incidents reported to the National Health Surveillance System of Brazil from March 2014 to March 2017.

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## METHODS

This is a documentary study that used the patient safety incidents records reported to the Brazilian ANVISA, covering notifications from March 2014 to March 2017.

Data were collected from the General Report of AE of Brazil and the AE Reports from the 26 federate units of the country, except for the State of Amapá, which did not present incidents reports. It should be noted that this document covers all incidents, including those in the “no-harm” category. Brazil has continental dimensions, being the largest country in Latin America. It is divided into 26 states and the federal district, and these are grouped into the following five regions: North, Northeast, Midwest, South, and Southeast.

The data presented in these reports were notified by the PSN through the National Reporting System of Sanitary Surveillance Web platform. The following variables were selected in these documents: number of incidents by type; number of incidents by HS type; number of incidents by hospital unit; and number of incidents by harm degree. After recording these variables, the data were compiled by Brazilian geographic region. The data were arranged on Microsoft Excel 2016, using descriptive statistics to analyze the profile of the reported incidents. Analysis of variance was used to determine whether there was a significant difference between the Brazilian regions by reports related to incidents in general, AE, and deaths, and the Tukey test was used for pairwise comparisons. Statistical significance was 5%. All statistical procedures were performed on SigmaPlot 11.0 software.

There was no need to request approval of this study by a research ethics committee, because the reports used are available

for consultation at ANVISA's electronic address, being in the public domain. These reports do not present the identification of the notifying PSN, neither of the victims of the incidents.

## RESULTS

In the investigation period, 2392 PSN were registered and 109,082 incidents were reported in Brazil. Considering that only 882 (36.87%) PSN made at least one notification in the period, the national average of incidents per notifying PSN was 123.67. Table 1 shows the types of incidents reported by region, with a higher frequency in the categories other (32,766/30.04%) and failures during health care (29,146/26.72%). In the category other, the five most frequent reported incidents are the following: loss and obstruction of probes ( $n = 8033$ ); phlebitis ( $n = 6006$ ); notifications involving venous catheters ( $n = 4043$ ); and notifications involving medications ( $n = 3250$ ) (See online supplementary appendix Table A1, <http://links.lww.com/JPS/A154>). In the category failures during health care, the most prevalent were failures during procedure/treatment/intervention ( $n = 19,326$ ) and during general care ( $n = 8189$ ) (See online supplementary appendix Tables A2 and A3, <http://links.lww.com/JPS/A155>).

Figure 1 shows the frequency of reported incidents per degree of harm in each Brazilian geographic region.

Regarding the notifying health service (Table 2), 93.90% (102,428) of the incidents occurred in hospitals, of which 54,950 cases (53.65%) were reported in patients in hospitalization units and 30,141 cases (29.43%) in intensive care units (ICUs).

**TABLE 1.** Types of Incidents Reported in Brazil From March 2014 to March 2017, by Geographic Region

	Southeast	South	Northeast	Midwest	North	Total in Brazil
Incidents by Type	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Failures during health care*	20,440 (70.13)	4366 (14.98)	1446 (4.96)	2077 (7.13)	817 (2.80)	29,146 (26.72)
Pressure injury	7793 (40.61)	4217 (21.98)	4511 (23.51)	1702 (8.87)	966 (5.03)	19,189 (17.59)
Fall	6653 (53.72)	3266 (26.37)	1152 (9.30)	994 (8.03)	320 (2.58)	12,385 (11.35)
Patient identification failures	2482 (34.31)	1154 (15.95)	2644 (36.55)	452 (6.25)	502 (6.94)	7234 (6.63)
Documentation failures	811 (39.79)	277 (13.59)	212 (10.40)	332 (16.29)	406 (19.92)	2038 (1.87)
Burns	123 (29.71)	77 (18.60)	135 (32.61)	66 (15.94)	13 (3.14)	414 (0.38)
Failures in administrative activities	1051 (61.75)	253 (14.86)	165 (9.69)	126 (7.40)	107 (6.29)	1702 (1.56)
Failures during surgical procedure	139 (33.82)	75 (18.25)	85 (20.68)	81 (19.71)	31 (7.94)	411 (0.38)
Failure to administer diets	1145 (53.45)	492 (22.97)	109 (5.09)	315 (14.71)	81 (3.78)	2142 (1.96)
Accidents of the patient	357 (52.89)	160 (23.70)	46 (6.81)	98 (14.52)	14 (2.07)	618 (0.60)
Failures in patient care/protection	16 (42.10)	4 (10.53)	10 (26.32)	7 (18.42)	1 (2.63)	38 (0.04)
Failure to administer O <sub>2</sub> or medical gases	36 (40.45)	16 (17.98)	11 (12.36)	22 (24.72)	4 (4.49)	89 (0.08)
Failures in clinical or pathology laboratories	619 (73.69)	116 (13.81)	39 (4.64)	47 (5.60)	19 (2.26)	840 (0.77)
Failures in radiologic assistance	—	1 (11.11)	4 (44.44)	4 (44.44)	—	9 (0.01)
Failures in transplant or graft procedure	3 (75.00)	—	—	1 (25.00)	—	4 (<0.01)
Other†	16,606 (50.68)	5863 (17.89)	5114 (15.61)	4278 (13.06)	905 (2.76)	32,766 (30.04)
Total	58,274 (53.42)	20,337 (18.64)	15,683 (14.38)	10,602 (9.72)	4186 (3.84)	109,082 (100.00)

\*The category “failure during health care” includes incidents involving procedures such as: procedure/treatment/intervention; assistance in general; complementary diagnosis/means of diagnosis; physical restraint; and screening/checkup. Problems in this category are incomplete or inadequate assistance; wrong procedure/treatment/intervention; assistance not given when indicated; assistance unavailable; or assistance to the wrong patient.

†The category “other” includes the following incidents: loss or obstruction of probes; phlebitis; notifications involving venous catheter; various notifications; notifications involving medications; patient injury and bruising; patient escape; accidental endotracheal extubation; notifications involving surgeries; problems in exams; bronchoaspiration; infections; notifications involving diets; notifications involving hemodialysis; notifications involving transfusions; aggression; notifications involving chemotherapy; deaths; and pulmonary thromboembolism.

Source: Brazilian Health Regulatory Agency. State Reports of AE. March 2014 to March 2017.

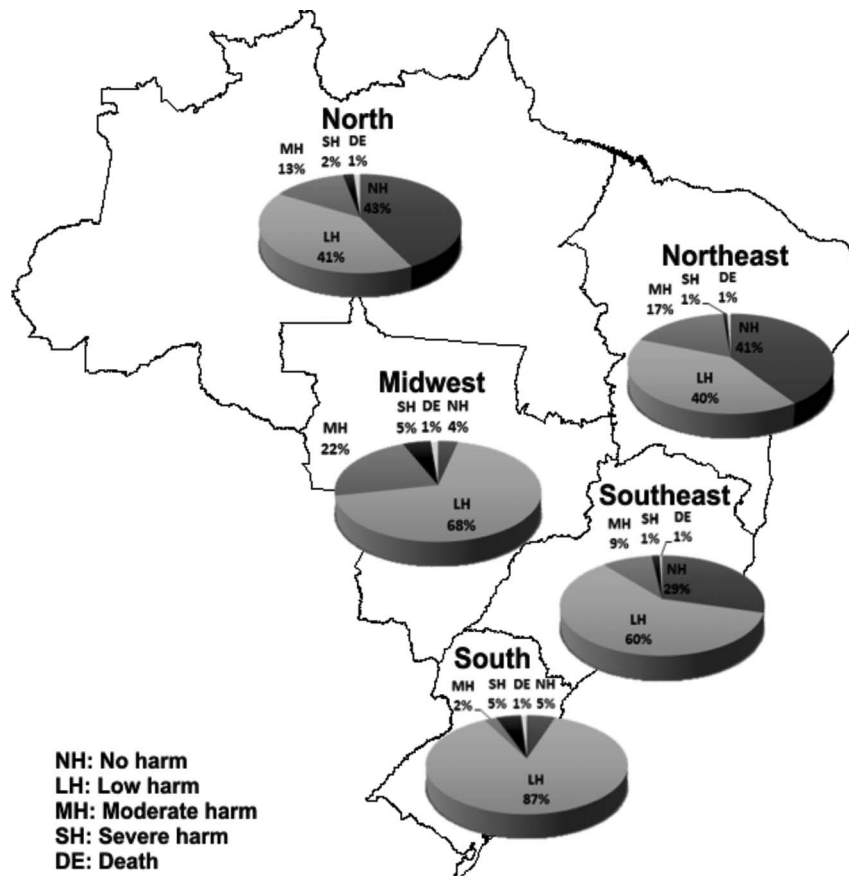


FIGURE 1. Source: Brazilian Health Regulatory Agency. State Reports of AE. March 2014 to March 2017.

Statistically significant differences across the Brazilian regions were observed in the number of incidents ( $P = 0.004$ ), number of AE ( $P = 0.004$ ), and number of deaths ( $P = 0.024$ ) reported (Table 3). The comparison of multiple means by the Tukey test

indicated that there was a significantly different number of notifications in the Southeast as compared with the North ( $P = 0.004$ ), Northeast ( $P = 0.004$ ), and Midwest ( $P = 0.029$ ). When comparing the number of reported AE, the Southeast

TABLE 2. Incidents by Notifying Health Service, From March 2014 to March 2017, According to Brazilian Geographic Region

Incidents by Notifying Health Service	Southeast n (%)	South n (%)	Northeast n (%)	Midwest n (%)	North n (%)	Total in Brazil n (%)
Hospitals	55,977 (54.65)	19,625 (19.16)	12,609 (12.31)	10,197 (9.96)	4020 (3.92)	102,428 (93.90)
Outpatient clinics	765 (65.38)	273 (23.33)	51 (4.36)	43 (3.68)	38 (3.25)	1170 (1.07)
Health centers/basic health units	6 (1.04)	13 (2.25)	550 (95.16)	9 (1.56)	—	578 (0.53)
Clinics	149 (38.60)	64 (16.58)	107 (27.72)	48 (12.44)	18 (4.66)	386 (0.35)
Laboratories	100 (61.73)	43 (26.54)	10 (6.17)	7 (4.32)	2 (1.23)	162 (0.15)
Radiology	49 (24.75)	48 (24.24)	88 (44.44)	13 (6.57)	—	198 (0.18)
Exclusive urgency/emergency services	160 (6.72)	53 (2.23)	2147 (90.13)	16 (0.67)	6 (0.25)	2382 (2.18)
Pharmacies	45 (33.33)	10 (7.41)	9 (6.67)	68 (50.37)	3 (2.22)	135 (0.12)
Hemodialysis services	280 (52.53)	14 (2.63)	92 (17.26)	128 (24.02)	19 (3.56)	533 (0.49)
Psychiatric or mental health institutions	535 (98.35)	2 (0.37)	7 (1.29)	—	—	544 (0.50)
Blood banks	8 (61.54)	5 (38.46)	—	—	—	13 (0.01)
Nuclear medicine	6 (54.55)	5 (45.45)	—	—	—	11 (0.01)
Other	194 (35.79)	182 (33.58)	13 (2.40)	73 (13.47)	80 (14.76)	542 (0.50)
Total	58,274 (53.42)	20,337 (18.64)	15,683 (14.38)	10,602 (9.72)	4186 (3.84)	109,082 (100.00)

Retrieved from Brazilian Health Regulatory Agency. State Reports of Adverse. March 2014 to March 2017.

**TABLE 3.** Comparison Between the Means of Incidents, AE, and Reported Deaths From March 2014 to March 2017 in the Geographic Regions of Brazil

Variable	Southeast	South	Northeast	Midwest	North	<i>P</i> *
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	
Incidents	14,568 (12,679)	6779 (3647)	1742 (1939)	2650 (2881)	697 (938)	0.004
AE	10,285 (9203)	4685 (2617)	1077 (945)	1945 (2437)	401 (386)	0.004
Deaths	67.75 (58.89)	42.33 (46.60)	10.77 (9.20)	26.50 (24.58)	8.00 (7.45)	0.024

\*Analysis of variance test.

maintained a significantly different number of notifications as compared with the North ( $P = 0.004$ ), the Northeast ( $P = 0.004$ ), and the Midwest ( $P = 0.035$ ). Regarding reported deaths, the Southeast also had a significantly different number of notifications as compared with the North ( $P = 0.031$ ) and the Northeast ( $P = 0.026$ ).

## DISCUSSION

In Brazil, the constitution of PSN is mandatory in establishments that carry out actions to promote, protect, maintain, and recover health at all levels of complexity, whether on an inpatient basis or not. Individualized offices, clinical laboratories, mobile, and home care services were excluded from this requirement.<sup>5</sup> In this way, the Brazil has approximately 134,000 health facilities<sup>7</sup> that meet the criteria of mandatory, at least 6760 are hospitals.<sup>3,5</sup> The deadline for registering NSP and beginning notifications was, respectively, 180 and 210 days, as of November 2013.<sup>9</sup> However, the number of NSP registered is still incipient, as is the number of notifications and notifying NSP.

Regarding registered PSN, it is believed that the coverage of the HS contemplated by Resolution No. 36,<sup>5</sup> the irregular distribution of these HS throughout the country, and the structural and organizational diversity they present make it difficult to apply the regulations throughout the national territory consistently. In this sense, it is believed that it is necessary to approximate state and municipal surveillance services to health institutions, to build partnerships and adaptation measures according to local reality.

Regarding the quantity of reporting PSN, the data pointed to an inexpressive number, which demonstrates that the structuring of these nuclei may have occurred just to comply with legislation, and it is not recognized as an effective instrument for the development of healthcare risk management and consolidation of patient safety culture.

To advance reporting systems and add value to their implementation, it is necessary to make them simpler to use, prioritize the events to be reported, measure the progress made through the reports, call up the various stakeholders for feedback, and analyze events and review opportunities for improvement.<sup>10</sup>

Despite the adhesion by a limited number of HS, the Brazilian strategy to make mandatory the implementation of PSN is positive inasmuch as it encouraged the institutions to be responsible for its learning and reorganization, on the basis of reported incidents, considering that the approximation with concrete reality facilitates decision-making processes.

Health services in Brazil are irregularly distributed across the regions, with a predominant concentration in the Southeast, with 58,274 establishments (53.42%), and the South, with 20,337 (18.64%), because these are the most populous and economically developed regions. Thus, there is a lack or even absence in some localities, mainly in the North and Northeast regions.<sup>11</sup> It is thus understood that the existence of a greater number of reports in the Southeast and South is related to the number of active services

and professionals who participate in accrediting companies or accredited services. In addition, it corroborates the fact that the services of these regions have a greater articulation between teaching, research, and care, increasing the intensity of the discussions on the subject.

Reporting is also associated with the reporting culture, with a greater presence in HS with quality certification. It should be noted that most organizations holding accreditation seals are in the Southeast and South regions. A study carried out in institutions certified by the National Accreditation Organization in the Southeast, South, and Midwest found that all had an implemented reporting system, regardless of the level of accreditation.<sup>12</sup>

In the model proposed by the NPSP, it is the responsibility of the PSN to articulate actions that stimulate professionals about the importance of reporting as a management tool for care risks and learning. This understanding is essential because the NPSP is configured so that the responsibility of monitoring, investigating, and analyzing the incidents is restricted to the PSN of each institution, and it is up to the municipal, district, and state management to define, among the reported incidents, those that will guide the public health goals and policies. Finally, at the national level, the measures will be focused on mitigation, especially of serious events and deaths.<sup>6</sup>

The largest reporting system in the world is the National Reporting and Learning System (NRLS), implemented in England and Wales in 2003. This British experience reinforces the use of notifications as a basis for learning and improvement of care practices.<sup>13</sup> In some countries (Germany, Italy, Norway, and Sweden), incidents reporting is mandatory, as in Brazil, and it is regulated by law or through local requirements. In others (Hungary, Slovakia, and Spain), notification is optional.<sup>14</sup>

Regarding the types of reported incidents, those of the categories “failures in care” and “other” were the most reported ( $n = 61,912$ , 56.76%).

Regarding the failures in care, these indicate that incidents occurred involving care processes such as procedures, treatments, and interventions that were not performed when they should or were incorrectly performed.

In this understanding, referring to the classic studies of Donabedian on HS quality assessment,<sup>15–17</sup> it is understood that to offer quality care, we must guarantee a complete and appropriate structure for the type of service performed, as well as efficient and effective processes to achieve good results. It can be noticed that incidents related to the failure of care reflect undesirable results that may have occurred from deficient or inadequate structures and mainly from failed processes.

The category “other” presents a range of different reported incidents and the five most frequent ones are the following: loss and obstruction of probes; phlebitis; reports involving venous catheters; and reports involving drugs.

Still on the most prevalent reported incidents, we have pressure injuries, falls, and failures in the identification of patients. About

these data, the Brazilian Ministry of Health published in 2013, with the creation of the NPSP, six basic protocols of patient safety, which include those of safety in the prescription, use and administration of pharmaceuticals, prevention of pressure injury, prevention of falls, and patient identification.<sup>18,19</sup> These protocols support decision-making about the structure and processes that must exist to prevent the occurrence of these incidents.

Thus, among the most reported prevalent incidents in Brazil, four of them have protocols, but others must be developed and encouraged at a national level, particularly for probes/catheters and phlebitis. It is confirmed that the HS have the autonomy to formulate and implement protocols and other strategies for the prevention of incidents; however, when there is a governmental initiative, it is possible to popularize the goal of safety as well as the execution of more profitable regulatory measures for the improvement of quality.

A study in hospitals in Catalonia showed that the most prevalent types of reported incidents are those related to medication, falls, and identification of patients,<sup>20</sup> whereas in Latin American hospitals, the most reported frequent AE were related to hospital infections and surgical procedures<sup>21</sup> and in US hospitals AE associated with surgical procedures, medication, and infections were the most common.<sup>22</sup>

Regarding the types of reported incidents by degree of harm, the results obtained show a significant number of AE. When we looked for scientific productions to compare the results found in our study, we found numerous publications focused on the occurrence of reported AE in specific assistance modalities,<sup>20–23</sup> and no articles were found evaluating patient safety incidents in the entire health system of a country, as presented in this research.

Thus, because approximately 94% of the incidents disclosed in this study were reported during hospital care, we used data from the reported AE that occurred at this level of health care and found that the percentage of reported AE in Brazil (68.84%) is significantly higher than in other countries.

This information is confirmed through research data on the incidents recorded in the *Sistema de Notificación y Aprendizaje para la Seguridad del Paciente* by hospitals in Catalonia,<sup>20</sup> in 3 years, which showed the occurrence of 26% of reported AE, whereas data of incidents reported in NRLS by hospitals in England for a decade demonstrated 29.7% of AE.<sup>24</sup> In addition, data from the 2012 and 2013 Medicare Patient Safety Monitoring System revealed the occurrence rate of reported AE of 2.3%.<sup>25</sup> In Brazil, most NSPs registered are in hospitals, which accounts for the significant number of notifications in this regard. Considering the recent implementation of the NPSP, it is understood that professionals are recognizing the damages that health care can cause, generating more notifications about AE to the detriment of the other types of incidents. As a result, higher AE reporting rates are observed than in countries where the system is already consolidated.

Regarding the degree of harm, reported AEs that led to low harm were the most frequent (77.89%), followed consecutively by moderate AE, severe AE, and those that led to death. In a study in hospitals in Latin America,<sup>21</sup> 21.5% of the reported AE were characterized as low, whereas 14% of the sample were considered as severe, data more worrisome than those for Brazil. Meanwhile, in the Dutch scenario, 5% of the reported AE resulted in permanent harm to the patients.<sup>26</sup>

There is a higher number of no-harm incidents reported in the Southeast, which can be attributed to the coverage in this region of 42.97% of the notifying PSN, 70.15% of health institutions with quality certification,<sup>27–29</sup> and 48.70% of hospitals of the Sentinel Network of the country,<sup>30</sup> strategies that contribute to the implementation and improvement of the risk management program in the HS, favoring the culture of notification of both AE and other

incidents. On the other hand, the Northeast had the largest number of reported incidents with severe harm, and it is the second most populous region, comprising 14.39% of the notifying PSN and approximately 20.32% of the Brazilian health establishments. However, of these, only 11.76% have quality certification<sup>27–29</sup> and 20.20% are sentinel hospitals.<sup>30</sup> In this way, a context with more difficulties to implement the NPSP can be noticed, making the HS less aware of incident reporting. Therefore, it is imperative that the country dedicates specific strategies according to the regional scenario.

This finding reflects on the findings reported in our article. The Tukey test allowed concluding on the existence of a statistically significant difference between the Southeast and the other regions of the country.

As for the reported AE that contributed to death, this article presents a rate of 0.89%, which is lower than in English hospitals (0.17%),<sup>24</sup> in other Latin American countries (5.8%),<sup>21</sup> and in the Netherlands (7.8%).<sup>26</sup> We believe that there is a significant underreporting in the number of deaths during health care in Brazil, which can be attributed to the recent implementation of the NPSP, the low number of PSN, associated with the probable punitive culture in many services, which hinders the reporting of AE, and, in particular, of deaths. Studies in the Brazilian context evidenced that there is a perception by health professionals of a punitive culture to errors in several HS,<sup>31–34</sup> which may reflect in the underreporting of patient safety incidents.

In analyzing the incidents by notifying HS, it is noteworthy that Brazil has a significantly larger number of primary health care services than hospitals (36,020 versus 6760),<sup>7</sup> but more than 90% of the incidents were reported by the latter. Although most health care services are offered in primary care,<sup>35</sup> historically, most studies/publications in the patient safety area are focused on the occurrence of incidents in hospitals due to their complexity and high execution of procedures that can lead to immediate harm to patients, which makes the theme more widespread in this scenario and consequently the importance and necessity of reporting.

Likewise, studies show an incidence of 10.3% to 38.1% of AE in hospital admissions,<sup>22,36</sup> whereas in primary care a mean of 2 to 3 incidents per 100 visits occurs.<sup>23</sup> However, Sarkar<sup>37</sup> suggests that even though most incidents in primary care do not lead to such immediate, serious, and permanent harm or occur less frequently, this context must be explored given the high volume of these services, which translates into a weight for public health.

By relating the number of incidents reported by Brazilian hospitals to that of other countries, we find that 5,879,954 incidents were reported by 148 British hospitals along a decade,<sup>24</sup> against the 102,428 reported in the country in 3 years. These data confirm the underreporting of incidents in Brazil, considering its greater number of hospitals. In addition, the NRLS presents 14 years of functioning,<sup>13,24</sup> representing a considerable time to mobilize health professionals/services for the importance of reporting incidents, including those that did not harm the patient, and England presents strong policies aimed at promoting patient safety,<sup>13,24</sup> elements that contribute to its high reporting rates.

The hospitalization units had the highest number of reports in this study, corroborating the results from hospitals in Catalonia (54%).<sup>20</sup> Currently, there are 438,420 hospital beds in Brazil,<sup>38</sup> representing the largest amount of hospital beds, and these are available for diagnostic/therapeutic care in the most diversified medical specialties and professional categories, which increases the risk of incidents.

Brazilian ICU ranked second in the number of reported incidents (approximately 30%). Although ICU beds correspond to 8.6% of the total hospital beds in Brazil,<sup>38</sup> it is known that critical patients, due to the complexity of their clinical condition, will

be submitted to more than 170 different daily interventions, performed by a multiprofessional team and repetitively,<sup>39</sup> raising as well the possibility of incidents. However, the number of reported incidents in Brazilian ICU was exceedingly higher than in other Latin American countries (4.3%)<sup>21</sup> and Catalonia (9%).<sup>20</sup> Therefore, it is necessary to investigate such disparity in the Brazilian scenario.

## CONCLUSIONS

The results of this study show an unprecedented framework of the situation of reported incidents in the Brazilian health system. Given the low number of reporting PSN, and in view of the number of HS in Brazil, there is a significant underreporting of patient safety incidents in the country, showing only the tip of a giant iceberg. More than half of the reported incidents were defined as AE and were registered in hospitals, especially in hospitalization units and ICU. The Southeast stood out in relation to the number of incidents, AE, and deaths as compared with the North, Northeast, and Midwest regions.

In terms of limitations, failure to disclose the types and degrees of harm of incidents by type of notifying health service and hospital unit prevented a detailed analysis of events in these specific scenarios. This specificity is only available for national, state, district, and municipal surveillance services in Brazil. Likewise, it was not possible to calculate the prevalence of incidents with no harm and AE, because the number of medical visits made in the notifying HS was not disclosed either.

The information disclosed by ANVISA in its report does not allow an in-depth analysis of the causes, implications, and actions taken against reported incidents, which is a limitation of this study. This ratifies the imperative need for the country to invest in data quality, so that the reporting system can be used as an effective subsidy for learning from the incidents. Despite this, this work brings the overall requirements and structure of NPSP, as it shows the national scenario of reported incidents in the Brazil. In addition, this study presents the organizational structure of the notification system in Brazil and identifies the types of HS and the regions that participate in the notification system and incidents in which professionals and institutions more notify. Thus, it is possible to promote strategies for consolidation, not only for the notification system, but also for the NPSP.

The data herein reiterate the importance of implementing public health policies at national, state, and municipal levels, with the appropriate supervision of HS regarding the implementation of PSN and the development of new protocols based on the most prevalent incidents. In addition, it is essential to strengthen the safety culture throughout the territory, raising the awareness of the services/professionals/patients about the relevance of the reporting of incidents, regardless of the degree of harm caused, and the implementation of preventive measures to mitigate the errors and reduction of AE, with the aim of transforming this difficult reality.

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