Original Research Article

**ANALYSIS OF NOTIFICATIONS OF INCIDENTS RELATED TO HEALTH CARE IN THE STATE OF PARÁ, DURING THE COVID**

**19 PANDEMIC**

**ABSTRACT**

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| **Objective:** to analyze the incidents and adverse events related to health care in the State of Pará in the period from 2020 to 2021, registered in the National Notification Program for Health Surveillance (NOTIVISA). **Method:** This is a cross-sectional study with a quantitative approach, using secondary data recorded in NOTIVISA, published and made available on the ANVISA website. **Results:** it was possible to verify during the study period that the state of Pará recorded 498 notifications of incidents related to health care in the period from 2020 to 2021 to NOTIVISA. The most notified and highlighted types of events were during health care with 201 notifications (40.36%). Of the incidents recorded, the majority occurred in hospitals, with 199 (42.16%) notifications involving failures during health care. Regarding the outpatient service, we highlight the incident Patients Accidents (3) (0.64%) and Patient Fall (2) (0.42%). In other types of services, failures during health care were the most notified event, with 2 records (0.42%). In the clinics, the reported incidents were Bronchoaspiration and Failures in the administration of O2 or medicinal gases, both with 1 notification (0.21%). In the types of damage, Light Damage stood out with 288 notifications (57.83%), followed by No damage with 82 notifications (16.47%), Moderate damage with 77 records (15.46%), Death with 28 records (5.62%) and Severe with 23 notifications (4.62%). Incidents by age group show that adults aged 56 to 65 years were the most affected, with 85 records (17.07%). In relation to pediatrics, the age group of less than 28 days was the one that obtained the highest number of notifications, with 33 records (6.63%). Reported deaths were highlighted in Failures during Health Care (23) (82.14%). The most notified never events were Stage III Pressure Injury (PPL), with 7 notifications (87.50%). **Conclusion**: between 2020 and 2021, NOTIVISA recorded only 498 notifications of health-related incidents in the state. Being a problem of great proportion in Pará, due to the deficit in the recognition of injuries and limitation in the practice of notifying, consequently, the number of records is well below expected. |

**Keywords**: incidents; adverse events; health care; patient safety.

**1. INTRODUCION**

Unsafe healthcare practices are considered a problem in healthcare processes in healthcare establishments around the world. Therefore, promoting the safety of patients receiving care in healthcare services is one of the biggest challenges for workers and managers. Health services must provide care that is effective and safe, with user satisfaction throughout the care process (CUNHA; GOMES, 2019).

Based on the importance of the quality of care provided, the Ministry of Health established the National Patient Safety Program (PNSP) with Ordinance No. 529 of April 1, 2013, with the aim of contributing to the qualification of health care in all health establishments across the country (BRASIL, 2013a).

In order to achieve the objectives of the program, the National Health Surveillance Agency (ANVISA) established, through RDC No. 36 of July 25, 2013, actions for patient safety with the aim of improving the quality of care in health services, whether public, private, philanthropic, civil or military, including those that carry out teaching and research actions, in addition to establishing the mandatory implementation of the Patient Safety Center (NSP), which plays a fundamental role in the entire process of implementing the Patient Safety Plan (PSP) (BRASIL, 2013b; BRASIL, 2016a).

ANVISA, aiming to receive notifications of incidents and Adverse Events (AEs) that occur in healthcare services and establishments in the country, developed a computerized system called the Health Surveillance Notification System (NOTIVISA) (SILVA et al., 2020). The detected incidents highlight characteristics of the structure, environment, conditions and care process, becoming a source of research and guide for improving security policies (LANZILLOTTI et al., 2016). As a consequence of unsafe assistance, users are also subject to never events, which commonly occur in healthcare establishments. For Brazil (2016c), never events are defined as events that should never happen in health services, being considered as an indicator of quality and safety in which just one case is enough to signal problems in the health service and indicate the need for investigation and analysis.

Never events and deaths, considered very serious adverse events, were established as priorities for the notification and investigation of adverse events related to healthcare, at a national level (CUNHA;

GOMES, 2019).

The care process is not risk-free and healthcare institutions are characterized as complex services, where several factors can contribute to the occurrence of incidents related to healthcare (LANZILLOTTI et al., 2015). However, the complexity of healthcare work increases risks, which require the application of a set of measures to prevent incidents related to care and high-quality care in favor of a patient safety culture in healthcare services (SIMAN et al., 2019). Health services increasingly seek to maintain safe quality behaviors and minimize vulnerabilities in care, however, the magnitude of the occurrence of adverse events in work processes is recurrent in health systems around the world, and has compromised the quality of care and produced impacts on patient safety (OLIVEIRA et al., 2014).

WHO studies estimate that for every ten patients hospitalized in developed countries, one suffers when receiving assistance (BRASIL, 2016b). In Brazil, around 330,536 incidents were reported to Anvisa from March 2014 to June 2019 (SILVA et al., 2020). Among the most frequently reported adverse events in Brazil are: pressure injuries and failures during healthcare, which, in turn, are guided by errors that result in the highest rate of deaths in hospitals (ANVISA, 2021a). However, failures interfere with care, causing injuries to users and interfering with assistance. Therefore, to mitigate the occurrence of damages, the NOTIVISA system, as an important tool for generating information on processes accompanied by errors, allows the provision and analysis of data that enable the improvement and reduction of As in health services (FIGUEIREDO et al., 2018; SILVA et al., 2020). Therefore, it is necessary to analyze the data entered into the system in the State of Pará during the period of this study. This research becomes relevant because it allows us to understand the main flaws in health care reported in the state of Pará, which generate results that favor the creation of barriers against harm to patients, minimizing risks and strengthening actions to prevent harm (SILVA et al., 2020), and 18 consequently, reducing the period of hospitalization. Thus, enabling the promotion of quality and safe patient care.

**2. METHODOLOGY**

This is a cross-sectional study with a quantitative approach, using secondary data registered in NOTIVISA, published and made available on the ANVISA website.

For the development of this study, incident notifications made by the Patient Safety Centers (NSP) of health institutions in the State of Pará to the Health Surveillance Notification System (NOTIVISA) were investigated.

Reports of incidents related to health care in the state of Pará, in the period from 2020 to 2021, were used as secondary data sources. All data collected from notification bulletins were recorded using the Microsoft Office Excel 2013 platform as an instrument to gather research data. Based on the analysis, the profile of incident notifications carried out in the state of Pará was drawn up.

For analysis, the results were tabulated and projected using graphs and tables, in which the variables of interest to the research were grouped and then the number and percentage were calculated using the resources available in this spreadsheet. Therefore, all quantitative elements were analyzed and discussed based on the incident notification report for the period under study.

**3. RESULTS**

Through data collection, it was possible to verify in the period under study that the state of Pará registered 498 notifications of incidents related to health care to NOTIVISA in the period from 2020 to 2021.

The incident “failures during healthcare” stands out with 201 notifications (40.36%), followed by “failures involving venous catheter” with 78 notifications (15.66%), “pressure ulcer” with 62 (12.45%) and “failure to identify the patient” with 54 records (10.84%), these being the most frequently reported types of events, as shown in table 1.

Table 1 – Types of incidents most reported in the period, NOTIVISA, Pará, 07/2020 to 06/2021.

|  |  |  |
| --- | --- | --- |
| **INCIDENT** | **N** | **%** |
| Failures during health care  | 201 | 40,36% |
| Failures involving venous catheter | 78 | 15,66% |
| Pressure ulcer | 62 | 12,45% |
| Failures to identification the patient | 54 | 10,84% |
| Patient fall | 31 | 6,22% |
| Patient accidents | 28 | 5,62% |
| Documentation failure  | 16 | 3,21% |
| Accidental endotrocheal extubation | 7 | 1,41% |
| Failures in administrative activities  | 6 | 1,20% |
| Failures during surgical procedure  | 3 | 0,60% |
| Failures in diet administration | 3 | 0,60% |
| Bronchoaspiration | 2 | 0,40% |
| Failures in the administration of O2 and medical gases | 2 | 0,40% |
| Burns | 2 | 0,40% |
| Patient evasion | 1 | 0,20% |
| Failures involving probes  | 1 | 0,20% |
| Patient burn | 1 | 0,20% |
| **TOTAL**   | 498  | 100% |

It can be seen that the months that received the most notifications for incidents during healthcare in Pará were the months of January and May 2021, both with 61 notifications to NOTIVISA. On the other hand, the month of February 2021 had the fewest notifications, with only 16 records (graph 1).

Graph 1 – Frequency of incidents reported per month, NOTIVISA, Pará, 07/2020 to 06/2021.

It is clear that the majority of incidents related to health care reported to NOTIVISA occurred in hospitals, with emphasis on notifications in Failures during health care (199) (42.16%), followed by Failures involving venous catheter (78) (16.53%), Pressure ulcer (62) (13.14%), Failure to identify the patient (54) (11.44%), Patient fall (29) (6.14%), Patient accidents (25) (5.30%) and Documentation failure (16) (3.39%).

Regarding the outpatient service, the incidents of patient accidents (5) (1.06%) and Patient falls (2) (0.42%) stand out. In other types of services, failures during healthcare were the most reported event, with 2 records (0.42%).

In clinics, the incidents that stand out most are Bronchoaspiration and Failures in the administration of O₂ or medicinal gases, both with 1 notification (0.21%).

In this variable, the notification of 26 incidents was not specified. They are: Accidental endotracheal extubation (7), Failures in administrative activities (6), Failures in administering diets (3), Failures during surgical procedures (3), Bronchoaspiration (1), Failures in the administration of O2 or medicinal gases (1), Burns (2), Patient evasion (1), Failures involving probes (1) and Patient burns (1), as described in table 2.

Table 2 – Incidents reported according to type of health service, NOTIVISA, Pará, 07/2020 to 06/2021.

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| --- | --- | --- | --- |
| **SERVICE** | **INCIDENT** | **N** | **%** |
| Hospital | Failures during health care | 199 | 42,16% |
| Hospital | Failures involving venous catheter | 78 | 16,53% |
| Hospital | Pressure ulcer | 62 | 13,14% |
| Hospital | Failures to identification the patient | 54 | 11,44% |
| Hospital | Patient fall | 29 | 6,14% |
| Hospital | Patient accidents | 25 | 5,30% |
| Hospital | Documentation failure | 16 | 3,39% |
| Outpatient | Patient fall | 5 | 1,06% |
| Others | Failure during assistance | 2 | 0,42% |
| Clinics | Bronchoaspiration | 1 | 0,21% |
| Clinics | Failures in the administration of O2 and medical gases | 1 | 0,21% |
| **Not specified** |  | 26 | 5,22% |
|  |  |  |  |
| **TOTAL:**  |  | 498 | 100% |

3.4 Number of incidents according to degree of damage.

In the total of 498 incident notifications, it was observed that Mild Damage stood out with 288 notifications (57.83%), followed by No damage with 82 notifications (16.47%), Moderate damage with 77 records (15.46%), Death with 28 incident records (5.62%) and Serious with 23 notifications (4.62%) (graph 2).

Graph 2 – Number of incidents according to degree of damage, NOTIVISA, Pará, 2020 to 2021.

The distribution of notifications of incidents related to healthcare, by age group, shows that adults aged 56 to 65 years were the most affected, with 85 records (17.07%), followed by adults aged 36 to 45 years, with 78 notifications (15.66%). In relation to pediatrics, the age group of less than 28 days was the one with the highest number of notifications, with 33 records (6.63%), followed by the age group of 29 days to 1 year with 15 notifications (3.01%) (graph 3).

Graph 3 – Number of incidents by age group, NOTIVISA, Pará, 07/2020 to 06/2021

Of the deaths resulting from health care-related AEs reported, it is observed that the most frequent in the period observed occurred due to failures during health care (23) (82.14%), patient accidents (2) (7.14%), bronchoaspiration (1) (3.57%), failures involving probes (1) (3.57%) and failures in the administration of O₂ or medicinal gases (1) (3.57%) (Graph 4).

Graph 4 – Types of incidents that resulted in death, NOTIVISA, Pará, 2020 to 2021.

The never events that occurred during the study period were: Pressure injury (PU) stage III, with 7 reports (87.50%) and unintentional retention of a foreign body in a patient after surgery, with 1 report (12.50%), as described in graph 5. It can therefore be seen that the data relating to this category are limited.

Graph 5 – Notification of incidents considered never events, NOTIVISA, Pará, 2020 to 2021

 **4. DISCUSSION**

Through the analysis of incident reports related to health care in the state of Pará, it can be observed that the years presented in the research made it possible to identify the dimension and understanding of the reported data, awakening the culture of reporting the harm to which users are subjected.

The culture of patient safety listed with the practice of recording incidents has focused on the context and professional conduct in the face of harm (FIGUEIREDO *et al*., 2018) and cooperated in the protection and safety of users for effective health care and transformation of the reality in hospital institutions (LANZILLOTTI *et al*., 2016).

In 2017, Brazil recorded a total of 75,296 notifications of incidents related to healthcare, but the distribution of incidents reported by the state of Pará in the same year reached only 100 notifications, ahead only of the states of Tocantins and Roraima (ANVISA, 2018a).

Based on the research carried out, it is possible to state that there is a shortage of notifications in the State and of studies that aim to show the results of the number of health-related incidents that occur in Pará, which could assist in incident prevention actions.

Therefore, it is seen that the NOTIVISA system reports show a low number of incidents that are reported in the State, which means that there is still a deficit in the reporting of incidents by health professionals.

According to the reports analyzed from 2020 to 2021, it is possible to observe that incidents are reported according to type and category, and the numbers differ according to each type of incident reported. Data from reports distributed into 7 categories were studied. They are: types of incidents most reported in the period; frequency of incidents reported per month; incidents reported according to type of health service; number of incidents according to degree of damage; number of incidents by age group; types of incidents that resulted in deaths and reports of incidents considered *never events.*

Among the data obtained, it was possible to observe that there is a significant number of incidents registered in the State of Pará, with a predominance of the incident “failures during health care” (Table 1), which stands out both in the number of records with 201 cases reported in the period described, and in the count of incidents that resulted in death. This incident occurs when the professional makes an error during the care provided to the user (SILVA *et al*., 2020).

Regarding reports of incidents considered “failures during healthcare provision” received by NOTIVISA in 2017, 18,349 reports were verified in Brazil (ANVISA, 2018a).

These data corroborate those presented at the Brazilian level by SILVA *et al*., (2020) between 2014 and 2019, showing that 25% of the most frequently reported incidents in the country are related to failures during healthcare provision. Therefore, the performance of procedures, treatments and interventions incompletely, inadequately or outside the indicated time stands out.

Because it is an incident with a generic term, it hinders interventions, the development of strategies and more specific improvements in health services. Therefore, it generates uncertainty regarding representativeness, quality of records and complexity (MAIA *et al*., 2018). Analyzing previous studies, it is possible to observe that the types of incidents most reported change over the years. According to Vilar, Martins and Rabelo (2021), the incidents and adverse events that had the highest frequency of reports from 2014 to 2018 were those related to the use of medications (50.8%), patient falls (7.5%) and infections related to health care (7.2%).

Between July 2020 and June 2021, healthcare institutions in Pará reported 498 incidents related to healthcare. However, the analysis of the reports showed that there was a higher prevalence in the count of incidents reported per month in the months of January and May 2021 (Graph 1). On the other hand, in the months described in 2020, there was a lower number compared to the rates for the period under study, in which the notification obtained an average count of 11 incidents registered in each month (ANVISA, 2020a). Data indicate that 16 records (Graph 1) were made in February 2021, being the lowest number of notifications in the year. Therefore, data show that 37 notifications were made in the same month in 2020, thus there is a discrepancy in the data in the interval of one year (ANVISA, 2020b).

Hospitals were the institutions that reported the most incidents related to healthcare, with 463 notifications, followed by outpatient clinics (5), other services (2) and clinics (2) (Table 2). According to a survey published by Anvisa (2020), in the period from December 2019 to November 2020, hospitals accounted for 299 of the incident reports, a lower value compared to the year of the period under study.

Consequently, a study carried out in referral hospitals in the state of Pará between January and December 2017 reveals that the hospital specialized in trauma recorded 985 incident reports. Meanwhile, the hospital specialized in cardiology recorded 287 reports (TYLL *et al*., 2019).

Notifications occur mainly in hospitals, highlighting the relevance of the NSP, since it is a body that is mandatorily responsible for analyzing data on incidents arising from the provision of the service and reporting adverse events to the National Health Surveillance System (SNVS) in accordance with RDC No. 36/2013 (RAIMONDI *et al*., 2019). It is noteworthy that in 2017, among hospital health units, of the 75,296 notifications across Brazil, 36,668 notifications occurred in inpatient units, 20,673 in intensive care units (adult, pediatric or neonatal) and 5,426 in emergency services (ANVISA, 2018a).

Hospitalized patients are generally subjected to various procedures and drug therapy. In addition, the ICU is a highly complex space designated for providing care to critically ill patients, which requires greater use of techniques and procedures, making it more vulnerable to incidents (FURINI *et al*., 2019). Therefore, the scope of these health service sectors and a greater demand for involved and qualified professionals can be observed, aiming to reduce incidents and the practice of reporting the occurrence of injuries.

Regarding the degree of incidents evaluated in this study, those considered mild were the most reported. In the study by SILVA *et al*., (2020), the results show that in the years 2014 to 2019, the notification system showed that 52% of the injuries were classified as mild, 12.93% moderate, 2.57% severe, 0.51% deaths and 31% were not classified as serious.

Damages considered minor are those that do not cause harm to the patient, and this large number of notifications reveals that there are weaknesses in care, therefore their notification should be encouraged, serving as a source of information and learning (SILVA *et al*., 2020).

When comparing the results from 2020 to 2021, it was observed that there was an increase in the numbers. With 57.83% of incident notifications standing out as minor damage, followed by no damage with 16.47%, moderate damage with 15.46%, deaths with 5.62% and severe damage with 4.62% (Graph 2).

The notification of incidents that are distributed by age group shows that the numbers have grown, which leads to the realization that interventions are still insufficient. The system recorded 85 notifications in adults aged 56 to 65 (Graph 3) and in the period from 2014 to 2019, the number of notifications in patients aged 18 to 55 was significant, with 33.26% of the reported cases (SILVA *et al*., 2020).

The elderly spend more time in health services and are considered a group with a higher risk of comorbidities and polypharmacy, factors that can cause harm to health, and are susceptible to side effects of medications due to physiological changes that can alter the pharmacokinetic and pharmacodynamic parameters of medications, thus generating incidents (ALMEIDA *et al*., 2017).

Pressure injuries are a conditioning factor for long stays in hospital settings due to intrinsic and extrinsic factors, showing that critical users and those with mobility difficulties are more likely to acquire possible complications (MATOZINHOS *et al*., 2017).

In pediatrics, the age group of less than 28 days has the highest number of reported incidents (Graph 3), with 33 notifications. According to Hoffmeister, Moura and Macedo (2019), newborns represent at least 10% of the population that has already suffered from at least one incident. In the period from 2015 to May 2016, newborns estimated a total of 54 incidents, which were reported in 34 newborns, that is, some have already suffered more than one incident.

In the research study, regarding the types of incidents that resulted in death, there were 23 notifications related to failures during health care (Graph 4), which was the largest number of records in the period under study and which resulted in the highest number of deaths. Such failures are due to errors, failure to perform and inadequacy of procedures, treatments and diagnoses.

According to Maia *et al*., (2018), between 2014 and 2017, most deaths resulting from failures in care occurred in adults aged 26 and over and elderly people aged 60 and over who were in hospitalization wards, mostly with diseases of the circulatory system and respiratory system, with 35.5% of diagnoses among these age groups. Perhaps, if deaths associated with hospital incidents were a group of causes of mortality, this factor would be among the main causes of deaths in the country (COUTO; PEDROSA; ROSA, 2016).

The results of the research showed that never events comprised 8 records, subdivided into 7 notifications of stage III PU (87.50%) and 1 notification of unintentional retention of a foreign body after a surgical procedure (12.50%). Despite the low number compared to other types of adverse events, these notifications are considered highly relevant given their severity.

Pressure injuries, being the most frequently reported in the period, are a multifactorial problem that interferes with the morbidity and mortality and quality of life of hospitalized patients. According to Lima and Barbosa (2015), 25.8% of patients exposed during hospitalization are at high risk for developing PU. Consequently, such incidents cause harm to the user and a longer stay under care in health services.

Regarding the number of incidents reported in the NOTIVISA System, it is possible to understand that the number of notifications is still below expectations. The North region holds 5.3% of the incidents reported in the country, being the macro-region with the lowest notification rate, reflecting the high rates of underreporting (ANVISA, 2021a). In addition, there is a lack of research focused on patient safety, delimiting records and causing a lack of incentive and misinformation regarding notifications (GOMES *et al*., 2017).

There is progress in studies aimed at patient safety, however, they still do not focus on incident notifications. These studies show which incidents occur most often and how to prevent them. The first strategy for effective safety is risk identification, followed by reporting, which aims at organizational learning. If incidents are reported accurately, it will cooperate in the change from reactive to proactive risk management (SAGAWA *et al*., 2019).

For Sagawa *et al* (2019), professionals must have a broader attitude and not limit themselves to actions to resolve the incident, but also to report it, since the simple act of reporting allows professionals to resolve the incident and reflect on the causes that led to such an error. However, for these changes to occur, the incidents that are reported must be analyzed and used as a basis for strategies to prevent and encourage professionals to reflect.

In view of this, the study presented limitations in finding reports and research from previous years that have the results of incident reports analyzed in full, since many do not have detailed results. Although the results may have been limited, they reveal the existence of a worrying situation, since the incidents that occur end up causing harm to the patient's health, causing their health condition to worsen and increasing their stay in the hospital unit.

**5. CONCLUSION**

The theme strengthens the importance of patient safety and the reduction of risks of unnecessary harm arising from healthcare, highlighting on the part of professionals the act of identification and notification, as a fundamental factor for the recognition and improvement of assistance in the country's healthcare services.

As evidenced in the research results, through the numbers of notifications, the practice of notifying incidents is not something that is rooted in the professional's culture, consequently, the number of records appears to be well below expectations. It is a major problem in Pará, due to the lack of recognition of problems and limitations in the practice of reporting.

Continuing education for healthcare professionals is essential to prevent incidents and promote quality and comprehensive customer service and care. Therefore, one of the ways for professionals to know the magnitude of the problem, stands out in the performance of reporting, so that adversities and errors are identified, to obtain a resolution of the problem and a reduction in the punitive and individual culture due to the occurrence of the reported damage, making it possible through the analysis presented to identify each reported incident, highlighting the importance that each notification brings to the professional, awakening and stimulating the practice of reporting and encouraging the perspective of comprehensive care for the user.

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