

ORIGINAL ARTICLE

OVERVIEW OF SAFETY INCIDENTS INVOLVING PEDIATRIC PATIENTS AT A UNIVERSITY HOSPITAL*

HIGHLIGHTS

1. ICUs and Inpatient wards had a higher risk of pediatric incidents.
2. Infants were more likely to suffer mild/moderate harm.
3. The most frequent pediatric incidents were related to medications/intravenous fluids.
4. The preventability of reported pediatric incidents was 93.5%.

Dinara Dornfeld¹ 

Letícia Maria Hoffmann¹ 

Marina Scherer Silveira¹ 

Sabrina dos Santos Pinheiro¹ 

Thatianny Tanferri de Brito Paranaguá² 

Márcia Koja Breigeiron¹ 

William Wegner¹ 

ABSTRACT

Objective: To analyze the profile and characteristics of safety incidents that occurred between 2015 and 2019 with pediatric patients reported in the computerized system of a university hospital. **Method:** quantitative, descriptive, cross-sectional study with 2,558 notifications at an institution in southern Brazil. Descriptive statistics and the chi-square test were used to analyze the data. **Results:** higher occurrence of safety incidents related to medications/intravenous fluids (n = 643; 25.1%), diet/food (n = 448; 17.5%), clinical process/procedure (n = 384; 15.0%), medical devices/equipment (n = 304; 11.9%), and patient accidents (n = 273; 10.7%). Inpatient and intensive care units are more related to the occurrence of incidents; work shifts were not related to the type of incident reported. **Conclusion:** The overview of safety incidents can guide strategies for improving care in the institution under study and collaborate with other health services in identifying risk situations for hospitalized children.

DESCRIPTORS: Patient Safety; Pediatrics; Child, Hospitalized; Safety Management; Risk Management.

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*Universidade Federal do Rio Grande do Sul, Escola de Enfermagem, Programa de Pós-Graduação, Porto Alegre, RS, Brasil.

²Universidade de Brasília, Faculdade de Ciências da Saúde, Departamento de Enfermagem, Brasília, DF, Brasil.

INTRODUCTION

The quality of hospital care is directly linked to the organizational culture of patient safety. Thus, recognizing the possibility of errors and failures, with the implementation of measures to identify and monitor them, represents an important institutional attitude with the aim of developing strategies to prevent and minimize adverse events resulting from healthcare¹⁻².

It is estimated that serious incidents occur more frequently in intensive care units, including pediatric and neonatal units. In addition, pediatric patients are three times more susceptible to adverse drug events compared to adult patients³⁻⁴. A retrospective study which analyzed 3,790 medical records from 16 US pediatric hospitals identified 414 adverse events (19.1 adverse events per 1,000 patients/day), 210 of which (9.5 adverse events per 1,000 patients/day) were preventable. The study also found that chronic patients, who required more complex care, were at greater risk of harm⁵.

Brazilian studies show a range of 3.4% to 4.5% of adverse events reported in pediatric units. These estimates can vary according to the child's age group and can reach 4.7% in children under one-year-old. The most recurrent adverse events are related to falls, medications, infections, among others⁶⁻⁸. Internationally, studies portray a reality that is different from Brazil's, where the rates of identification of adverse events during a child's hospitalization can vary from 10.9 to 15.4%, with incident notification rates considerably higher than the national parameters^{3,5,9-10}.

Although studies related to Patient Safety have intensified recently - especially after the launch of the National Patient Safety Program (PNSP, in Portuguese) in 2013 - producing scientific evidence relevant to care practice, the field of pediatrics still receives secondary attention given the complexity of the issue. Furthermore, publications generally approach pediatric patient safety with a single focus, such as failures in the medication process. A few studies deal with safety incidents, providing an overview of occurrences, who the affected patients are, what the outcomes are and how to avoid further events^{4,6,8,11}.

Thus, considering the complexity of the subject in question, the breadth of concepts and situations that characterize patient safety, as well as the scarcity of studies in the area focusing on pediatric patients, the research question that guided this study was: what is the panorama of safety incidents involving pediatric patients reported to the risk management department of a university hospital? Identifying these elements helps us take precise, targeted action in areas of care where there are gaps, as well as plan improvements or revise care protocols. To answer the research question, the study aimed to analyze the profile and characteristics of safety incidents that occurred between 2015 and 2019 with pediatric patients reported in the computerized system of a university hospital.

METHOD

This is a quantitative, descriptive, cross-sectional study based on pediatric incident reports from 2015 to 2019, made available by the Hospital Risk Management (HRM) incident reporting system at a public university in southern Brazil. The service is predominantly for patients from the Unified Health System, with beds for private and health insurance patients.

The study population consisted of all incident reports involving patients aged between zero and 18, admitted to pediatric beds in the pediatric intensive care unit (13 beds), neonatal intensive care unit (20 beds), clinical inpatient unit (65 beds), surgical inpatient unit (5 beds), psychiatric inpatient unit (4 beds), oncology treatment unit (24 beds) and emergency department (9 beds), totaling 140 beds. Notifications of pediatric incidents

involving outpatient units and diagnostic sectors were also included.

Consideration was given to analyzing notifications from 2015 onward, even though the Patient Safety Center had already been implemented at the institution in 2013. This choice is justified by the fact that a period was needed to adapt to the notification process and the implementation of the computerized system, which could influence the quantity and quality of notifications at the institution under study.

To collect the data, a survey was carried out to determine the number of notifications that occurred between 2015 and 2019 in children and adolescents aged 0 to 18 in pediatric units. The sample calculation considered previous studies that determined the number of adverse event reports to be analyzed. Thus, considering 95% confidence, a margin of error of 3%, and a prevalence of 50% to include estimates of categorical outcomes, we arrived at a sample size of 1,068 incident reports. Adding 10% for possible losses, the sample size should have been 1,175 incident reports. However, considering the importance of the study in outlining the panorama of these events in pediatrics, it was decided not to consider the sample calculation and to analyze all the notifications that occurred between 2015 and 2019, excluding those that did not have the minimum information necessary to characterize them.

Notifications of safety incidents that did not have the age informed in the specific field or that could not identify the hospitalization unit in which the event occurred were excluded. Notifications of incidents from obstetric services were also discarded, except for incidents involving neonates. Duplicate reports were only included once. Notifications of healthcare-related infections were not made available by the HRM, as they were received, analyzed, and followed up by the institution's Hospital Infection Control Committee. These notifications were not requested to be included in the study due to their high number and the need to include new variables to build the final database.

The data from the database was made available in Excel® tables, automatically generated by the notification system, with the notifications for each year. The variables analyzed in this study were: patient characteristics (gender and age group), year of notification, sector, and work shift where the incident occurred. The other variables were categorized according to the Conceptual Framework of the International Classification of Patient Safety (ICPS) of the World Health Organization (WHO)¹²: type of incident; categorization of the type of incident; consequences for the patient and outcome. Notifications were categorized according to events that reached or did not reach the patient; events that reached the patient can be classified as incidents with or without harm, while incidents that almost reached the patient are called near miss.

Quantitative data were analyzed using descriptive and analytical statistics using SPSS software version 18.0. Categorical variables were described with absolute and relative frequencies; continuous variables with mean and standard deviation, considering interquartile ranges of 25 and 75. The chi-square test was used to verify the association between categorical variables. After checking the overall association between the variables, the local association between the categories was checked by calculating the adjusted residuals, which showed the variables that showed a significant association, considering a p -value ≤ 0.05 .

This study was approved by the Research Ethics Committee of the Federal University of Rio Grande do Sul, under opinion no. 1.072.189.

RESULTS

We analyzed 2,558 notifications distributed between 2015 and 2019. Among outpatients, the majority of incidents involved the chemotherapy outpatient clinic, which was responsible for most of the events, followed by the surgical outpatient clinic.

Table 1 - Distribution of sociodemographic data of pediatric patients with reported safety incidents hospitalized between 2015 and 2019. Porto Alegre, RS, Brazil, 2023

Variable	n	%
Gender		
Male	1,329	51.9
Age		
Newborns	320	12.5
Infants	955	37.3
Preschoolers	190	7.4
Schoolchildren	305	11.9
Adolescents	505	19.7
Unit		
Inpatient/ICU	2,062	80.6
Surgical environment	282	11.0
Emergency	76	3.0
Outpatient	36	1.4
Diagnostic sectors	85	3.3
Other	17	0.6

Source: Authors (2023).

Key: Newborn (0 to 29 days); Infants (29 days to 2 years); Preschoolers (2 to 6 years); Schoolchildren (6 to 10 years); Adolescents (10 to 18 years).

In terms of where the events occurred, inpatient units (wards) and Pediatric and Neonatal Intensive Care Units (ICU) were grouped together in one category, representing most notifications (n=2,062; 80.6%). The "diagnostic sectors" category included records from areas where examinations were carried out and environments in common use.

Data analysis revealed an 11.3% increase in the number of notifications over time, considering 2015 (12.7%) and 2018 (24.0%).

Table 2- Distribution of the types of safety incidents reported in hospitalized pediatric patients from 2015 to 2019. Porto Alegre, RS, Brazil, 2023

Type of Incident*	2015 n. (%)	2016 n. (%)	2017 n. (%)	2018 n. (%)	2019 n. (%)	Total n. (%)
Clinical administration	12(6.4)	23(12.2)	45(24.0)	57(30.4)	45(24.0)	187(7.3)
Clinical process/procedure	51(13.2)	71(18.4)	100(26.0)	94(24.4)	68(17.7)	384(15.0)
Documentation	44(28.7)	41(26.6)	29(18.8)	19(12.3)	21(13.6)	154(6)
Medication/IV fluids	105(16.3)	113(17.5)	115(17.8)	176(27.3)	134(20.8)	643(25.1)
Blood/blood products	9(15.0)	15(25.0)	20(33.3)	6(10.0)	10(16.6)	60(2.3)
Diet/food	19(4.2)	122(27.2)	114(25.4)	106(23.6)	8(19.4)	448(17.5)
Oxygen/gas/steam	4(30.7)	1(7.6)	1(7.6)	4(30.7)	3(23.0)	13(0.5)
Medical device/equipment	25(8.2)	57(18.7)	79(25.9)	70(23)	73(24.0)	304(11.9)
Behavior	16(31.3)	9(17.6)	1(1.9)	15(29.4)	10(19.6)	51(1.9)

Patient accidents	34(12.4)	53(19.4)	77(28.2)	60(21.9)	49(17.9)	273(10.7)
Infrastructure/building/facilities	0(0)	2(16.6)	6(50.0)	1(8.3)	3(25)	12(0.5)
Resources/organizational management	6(17.6)	4(11.7)	11(32.3)	6(17.6)	7(20.5)	34(1.3)
Total	325(12.7)	511(19.9)	598(23.3)	614(24.0)	510(19.9)	2.558(100)

Source: Authors (2023).

*WHO International Classification on Patient Safety¹²

The types of incidents were classified into 12 categories according to the International Classification on Patient Safety¹². Among those reported, the most frequent occurrence was related to medications/IV fluids (n = 643; 25.1%), with the majority being classified in the "other" category (n = 419; 65.1%), which included chemotherapy, sedatives, diuretics, and antifungals, among others. The second-largest category was antibiotics (n = 102; 15.8%). As for the medication stage, the main incidents were identified in the administration phase (n = 398; 61.8%). The most recurrent medication errors were dose errors (n = 216; 33.5%), with the main error recorded in this category being the wrong time and omission of a dose.

The diets/food category (n = 448; 17.5%) was related to errors in changing the diet during preparation and dispensing or patient/bed changes during delivery, but there were also errors related to prescription/ordering, presentation, administration, and storage. The clinical process/procedure category (n = 384; 15.0%) corresponded to errors related to care procedures, general care, samples/results, and diagnosis/evaluation.

In relation to patient accidents, falls (n = 204; 74.7%) are the most recurrent events in the hospital context, followed by pressure injuries (n = 60; 21.9%) and other injuries (n = 09; 3.2%). Most of the injuries were acquired in the hospital. For these events, 92 (45.0%) reported that risk assessment scales had been applied.

In the categorization of events that did and did not affect the patient, the analysis indicated that most incidents affected patients (n = 2,020; 79.0%), and a few notifications could not be classified due to the lack of information for correct analysis.

Table 3 - Characterization of incidents in hospitalized pediatric patients from 2015 to 2019. Porto Alegre, RS, Brazil, 2023

Variable	n	%
Preventable event*		
Yes	2,391	93.5
No	167	6.5
Reaches the patient		
Yes	2,020	79.0
No	538	21.0
If the damage has occurred		
Yes	1,102	43.1
No	1,453	56.9

Intensity of the damage		
None	1,456	56.8
Mild/moderate	680	26.7
Severe/death	45	1.8
Not informed	377	14.8

Source: Authors (2023).

*The preventability analysis is carried out by the notifier in an item on the notification form.

Regarding the intensity of the damage, all the events that did not cause damage were classified in the "none" category ($n = 1,456$; 56.8%), which represented many incidents. The other serious incidents accounted for 28.5% of notifications. 45 (1.8%) incident notifications were categorized as serious events, with the outcomes being discharge ($n = 23$; 51.1%) and death ($n = 14$; 31.1%); and in 377 notifications (14.8%), the intensity of the damage was not reported.

In addition, for more detailed data, the association between the type of incident and the place of occurrence and between the type of incident and the work shift was checked. It was found that, regardless of the year in which the incident was reported, the pediatric and neonatal ICUs and inpatient units were the sectors in which the most incidents occurred or had the highest frequency of reporting by professionals ($p < 0.001$) compared to the other sectors. On the other hand, the analysis indicated that the work shift was not related to the type of incident reported ($p = 0.005$). Regardless of the type of incident, the severity of the damage was more associated with "no damage" or "mild/moderate" damage when compared to the occurrence of serious damage/death ($p < 0.001$).

There was an association between the intensity of the damage and the age group ($p < 0.001$), in which infants showed a greater relationship with mild/moderate damage ($n = 273$; 34.1%). No association was found between age group and the consequences of injury ($p = 0.081$). There was an association between the type of incident and the occurrence of harm ($p < 0.001$), with the highest occurrence of harm being associated with incidents involving the clinical process/procedure, medical devices/equipment, patient accidents, IV medications/fluids, diet/feeding, documentation, and oxygen, gas, or steam.

The "age group" variable was also crossed with "type of incident", showing a significant association ($p < 0.001$). It is noteworthy that in the "Newborn" age group there was a predominance of incidents related to "Clinical process/procedure" ($n = 96$; 30.0%); in "infants," the type of incident was related to "diet or feeding" ($n = 236$; 24.7%); in "Pre-schoolers" and "schoolchildren," "patient accidents" ($n = 33$; 17.4%) and ($n = 49$; 16.1%) were the most frequent, respectively; and among "adolescents," "patient accident" ($n = 76$; 15.0%) and "documentation" ($n = 62$; 12.3%) were the most frequent types of incident.

Most incidents caused minor or mild/moderate harm, representing a significant difference when compared to incidents with serious harm/death ($p < 0.001$). Mild incidents were related to documentation, medications and IV fluids, diet and food, and resources and organizational management. Serious harm/death was related to the clinical process/procedure and medications/IV fluids. Mild/moderate harm was associated with the clinical process/procedure, medical devices, patient accidents, medications/IV fluids, and oxygen, gas, or steam.

DISCUSSION

The study identified a growing increase in the number of notifications over the years.

It is believed that the health team's process of adapting to the new reporting tool, which migrated from the handwritten method to the computerized system in 2015, has some influence on this result. It should also be added that the increase in notifications may be a reflection of better understanding for professionals about the events to be recorded and changes in the organizational culture, with greater incentive to report incidents, reinforcement of the non-punitive culture, dissemination of the panorama of events that have occurred in the institution and actions that prevent these incidents, encouragement for professionals through feedback, and care changes promoted after analysis of incidents^{1,13-14}. In fact, all these actions are related to the WHO's leadership in encouraging member countries to make a commitment to safety; in Brazil, the PNSP was created, which has been unfolding in institutions, especially with the implementation of specific protocols for safe care^{2,6,13}.

The data showed some characteristics of the patients involved, such as male children (51.9%), with a predominance of infants (37.3%), in the post-admission stage, and hospitalized (97.6%). There are studies that agree on the sex of those involved and others that differ, showing that females are the group most affected by safety incidents. The age range varies from newborns to schoolchildren, showing that children and adolescents can be recurrently affected by these events^{4,7-9,15}.

Inpatient units and pediatric and neonatal ICUs accounted for most notifications. These findings are related to the longer stay of patients in these sectors, the greater complexity of procedures, the high number of hospitalizations, and the fragile clinical state of these patients^{7,9,15}.

When analyzing the shift during which the events occurred, the highest concentration of incidents occurred during the day. Studies that have found similar results have considered that the opening hours of the outpatient clinics and the greater activity of the teams - medical and nursing consultations and visits, procedures, and care - favor safety incidents happening more frequently during the day^{4,15-16}. Furthermore, as this is a university hospital, there are numerous students and residents doing their internships during the day. The inexperience of the students or insufficient supervision by the professional/teacher could contribute to these events^{5,17}. Considering this, the topic of Patient Safety has been increasingly addressed in nursing courses since training professionals who value and understand the importance of a culture of safety guarantees safer care for pediatric patients^{2,17}.

Approximately 25% of incident reports were associated with the medication/IV fluids' category, many of which resulted in mild moderate, or severe harm. Nursing has a major role to play in the medication process, and it is the nurse's responsibility to constantly supervise the team and contribute to drawing up and adapting protocols for preparing and administering medications¹⁸. Even so, preventing errors and monitoring adverse events requires a multifaceted approach combining continuing education, management strategies and the use of technologies such as electronic prescriptions, bar codes for dispensing and administering medicines, and intelligent infusion pumps for administering intravenous drugs¹⁹.

Errors related to diet/feeding were the second most frequent type of incident. Patient safety when using enteral nutrition depends on the process, vigilance and continuous assessment of the professionals involved. Positive results were obtained by a study that used clinical simulation to address potential complications and/or adverse events related to Enteral Nutritional Therapy (ENT) and arising from care practice. Participants identified risks related to the tube (bronchoaspiration of the diet, inadvertent tube exit), contamination of the ENT (failure in hand hygiene), the diet (diet exchange between patients), and the routine of ENT care (automation of care and people outside the nursing team)²⁰.

Data analysis found a considerable number of events related to patient accidents, mainly falls and pressure injuries (PI). Although falls are considered normal in the context of a child's development and are often unavoidable, there are factors in the hospital environment that predispose to these accidents and can lead to serious injuries or death⁸.

The type of fall and the factors involved can vary according to the patient's age, stage of development and clinical factors²¹.

Studies show that in the majority of events involving falls, children are accompanied by family members, but they have not identified the risk of falling or preventive strategies have not been implemented^{10,22}. Some actions are not widely used to prevent falls in pediatrics, but they tend to bring good results, such as informing the companion if the child can walk; guiding the family member to get the child up progressively; placing the child with a history of previous falls closer to the nursing station; recording these falls and contributing factors to gather the necessary information for the patient's medical record; and adapting the beds according to the child's age²²⁻²³.

Most PIs incidents are the result of not adopting preventive measures for patients who are generally bedridden for long periods of time or continuously, or who have reduced mobility. In addition, there are other factors such as nutritional status, previous comorbidities and clinical conditions that also interfere with the occurrence of these injuries and should be considered when assessing the risk of developing PI²⁴. Another pressure injury that is still little covered in the literature is that resulting from the use of medical devices for therapeutic or diagnostic purposes. Often, these adverse events are invisible or undervalued by professionals; it is recommended that nurses systematize the early identification of these PIs, based on the recognition of the causative devices and the daily physical examination, especially during bathing, by nurses^{7,24}.

According to the results of the study, the category of errors in medical devices and equipment was responsible for a wide variety of safety incidents. These included tracheal tubes, infusion pumps, and probes, among other devices and equipment that had failures related to packaging, displacement/loss of connection/removal and user error. With the advancement of technology in health care, there has been an increase in the occurrence of safety incidents involving the handling, operation, and application of these technologies by professionals. The literature dealing with incidents involving medical devices and equipment is still incipient and only touches on the subject tangentially, especially when discussing issues related to the best use of the device^{7,20}. As such, reporting this type of incident is of the utmost importance for further studies and the development of strategies to minimize its occurrence^{15-16,19}.

Incidents related to a clinical process/procedure accounted for 15.0% of notifications. The prevention of this type of incident is directly related to the existence of well-defined care protocols and routines, which guide the multi-professional team in the development of their work processes. However, for the team to work in line with these care-guiding tools, it is essential for the institution to implement a continuing education program to keep professionals up-to-date and trained to carry out their duties¹⁹⁻²⁰.

Although they don't represent a high percentage in health services^{1,4}, as confirmed by this investigation (1.8%), serious events can cause irreversible and irreparable damage to patients and their families. The causes can be multifactorial, such as lack of situational awareness, miscommunication, decision-making errors, technical errors, or process failures^{1,15-16}. Inconsistencies and weaknesses, whether institutional, patient, companion or professional, represent risks for serious events to recur and affect new patients, and it is important to detect and mitigate their consequences^{1-2,5-6,13}.

Likewise, when analyzing the incidents in general, most of the events were preventable (93.5%); in other words, they could have been anticipated but occurred due to errors or failures in patient care at an individual or systematic level^{1,5}. The high number of events considered preventable reaffirms the weaknesses of care in providing safe care^{2-3,6,15,22}. There are various reasons for this, such as work overload, lack of or non-compliance with routines/protocols, inadequate staffing levels, inexperienced/untrained staff, lack of attention/commission, communication failures, an inadequate physical environment and materials/equipment, and a lack of appropriate equipment, materials or medicines for safe care^{2,15,25}. In addition, a punitive/hierarchical culture and a lack of information about

the changes made based on incident reports are aspects pointed out by professionals as impediments to a culture of safety¹³.

Among the factors that encourage professional engagement are improving the communication process through management training and dynamic interaction between professionals¹⁴. Notification reports are also tools that enable professionals to identify risks, propose barriers and evaluate the measures implemented^{8,11,15}. The improvement of processes and care must be continuous; for this reason, professionals must be committed to changing care standards and qualifying care through ongoing and continuing education. Institutions must also provide subsidies for policies on quality of care and valuing those involved in care. To this end, the implementation and consolidation of the PNSP strengthen the proposal of institutional policies for risk management and incident monitoring in the Brazilian context.

The limitation of this study was that several of the reports presented incomplete information, making it difficult to assess whether any damage occurred to the patient, how serious it was, and what factors triggered the event. The lack of studies addressing the panorama of notifications in pediatrics, especially in the Brazilian context, was also a limiting factor in comparing and interpreting the findings of this study.

CONCLUSION

The study addressed aspects that are still little explored in the context of safety incidents reported in pediatric units in Brazil. The historical series from 2015 to 2019 showed a growing increase in notifications over time, suggesting advances in the institutional safety culture; however, its results suggest that we are still facing a range of unsafe care. The PNSP has been consolidated over the past 10 years, but there are still challenges to strengthening the safety culture in institutions.

Incident reporting should be an instrument that directs monitoring, promotes interventions, and generates positive feedback for patients, families, professionals, managers and the institution. In this way, the results presented here provide an overview of incidents, guide strategies for improving care, help other health services identify risk situations for hospitalized children, and provide a basis for further studies. With this in mind, we recommend further research into the types of incidents and contributing factors - especially those that have not yet been addressed, such as medical devices and equipment, clinical processes and procedures, clinical administration, and behavior - and their interface with nursing care.

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Corresponding author:

Dinara Dornfeld

Universidade Federal do Rio Grande do Sul

R. São Manoel, 963 - Rio Branco, Porto Alegre - RS, 90620-110

E-mail: dinara.dornfeld@gmail.com

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