

PEDIATRIC PATIENT SAFETY INCIDENTS BEFORE AND DURING COVID-19: A MIXED-METHODS STUDY

Ananda Rosa Borges¹ 
Ana Maria Muller de Magalhães¹ 
Gabrielli de Oliveira Lima² 
Thiago da Silva¹ 
Dinara Dornfeld¹ 
Deise Vacario de Quadros¹ 
William Wegner¹ 

¹Universidade Federal do Rio Grande do Sul, Programa de Pós-graduação em Enfermagem. Porto Alegre, Rio Grande do Sul, Brasil.

²Universidade Federal do Rio Grande do Sul, Escola de Enfermagem. Porto Alegre, Rio Grande do Sul, Brasil.

ABSTRACT

Objective: to analyze the profile of pediatric patient safety incidents in a university hospital, with a particular focus on comparing notifications before and during the COVID-19 pandemic and on Nursing professionals' perception.

Method: a mixed-methods and convergent strategy study conducted at a university hospital from southern Brazil. The data were collected from a database with 1,663 notifications between March and September 2021. After applying the inclusion criteria, a total of 418 records of patient safety incidents occurred between January 2019 and December 2020 were found, which were analyzed by descriptive statistics with SPSS 18.0; semi-structured interviews were carried out with 18 Nursing professionals, using thematic content analysis.

Results: the safety incidents recorded in the pediatric units were more related to intravenous medications and fluids, male gender and infant age group. There were no relevant differences when comparing the notifications from 2019 (219) with those from 2020 (199), with a reduction of only 20 (-9.13%). In the professionals' perception, there was also no expressive change in this situation.

Conclusions: the characteristics of the patient safety incidents that occurred in pediatric units showed few statistically significant differences in the periods investigated, corroborating the Nursing professionals' perception that there was no significant change in the institution's scenario regarding incidents. Strategies to encourage notifications and improvements in this system are still required to provide a safe environment to pediatric patients.

DESCRIPTORS: Patient safety. Pediatrics. Safety management. COVID-19. Pediatric Nursing.

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INCIDENTES DE SEGURANÇA DO PACIENTE PEDIÁTRICO ANTES E DURANTE A COVID-19: ESTUDO DE MÉTODOS MISTOS

RESUMO

Objetivo: analisar o perfil de incidentes de segurança do paciente pediátrico em hospital universitário, com foco particular na comparação das notificações antes e durante a pandemia de COVID-19 e na percepção de profissionais de enfermagem.

Método: estudo de método misto e estratégia convergente, realizado em hospital universitário, no sul do Brasil. Os dados foram coletados de um banco de dados de 1.663 notificações entre março e setembro de 2021. Após critérios de inclusão, totalizaram 418 registros de incidentes de segurança do paciente, ocorridos entre janeiro de 2019 a dezembro de 2020, que foram analisados por estatística descritiva com o SPSS 18.0; foram realizadas entrevistas semiestruturadas com 18 profissionais de enfermagem, sendo empregada a análise de conteúdo temática.

Resultados: os incidentes de segurança ocorridos nas unidades pediátricas foram mais relacionados a medicações e fluidos intravenosos, sexo masculino e faixa etária dos lactentes. Não houve diferenças relevantes comparando as notificações de 2019 (219) com as de 2020 (199), havendo redução de apenas 20 (-9,13%) notificações. Na percepção dos profissionais, também não houve mudança expressiva nesse panorama.

Conclusões: as características dos incidentes de segurança do paciente ocorridos em unidades pediátricas apresentaram poucas diferenças estatisticamente significativas nos períodos investigados, corroborando a percepção dos profissionais de enfermagem de que não houve mudança expressiva no panorama de incidentes da instituição. Estratégias de incentivo às notificações e aprimoramento desse sistema ainda são necessários para proporcionar um ambiente seguro ao paciente pediátrico.

DESCRITORES: Segurança do paciente. Pediatria. Gestão da segurança. COVID-19. Enfermagem pediátrica.

INCIDENTES DE SEGURIDAD EN PACIENTES PEDIÁTRICOS ANTES Y DURANTE COVID-19: ESTUDIO DE MÉTODOS MISTOS

RESUMEN

Objetivo: analizar el perfil de los incidentes de seguridad en pacientes pediátricos de un hospital universitario, con especial énfasis en la comparación de las notificaciones antes y durante la pandemia de COVID-19 y en la percepción de los profesionales de Enfermería.

Método: estudio de métodos mixtos y estrategia convergente realizado en un hospital universitario del sur de Brasil. Los datos se recolectaron de una base de datos con 1663 notificaciones entre marzo y septiembre de 2021. Después de aplicar los criterios de inclusión, se obtuvo un total de 418 registros de incidentes de seguridad del paciente entre enero de 2019 y diciembre de 2020, que fueron analizados por medio de estadística descriptiva con el programa SPSS 18.0; además, se realizaron entrevistas semiestruturadas con 18 profesionales de Enfermería, empleando análisis temático de contenido.

Resultados: los incidentes de seguridad que tuvieron lugar en las unidades pediátricas estuvieron más relacionados con medicamentos y fluidos intravenosos, con el sexo masculino y con el grupo etario de lactantes. No se registraron diferencias relevantes al comparar las notificaciones de 2019 (219) con las de 2020 (199), con una reducción de apenas 20 (-9,13%) notificaciones. De acuerdo con la percepción de los profesionales, tampoco hubo ningún cambio significativo en este panorama.

Conclusiones: las características de los incidentes de seguridad del paciente que tuvieron lugar en unidades pediátricas presentaron escasas diferencias estadísticamente significativas en los períodos investigados, lo que corrobora la percepción de los profesionales de Enfermería de que no se registró ningún cambio significativo en el panorama relacionado con incidentes de la institución. Todavía se necesitan estrategias para incentivar las notificaciones y mejorar este sistema, a fin de proporcionar un ambiente seguro a los pacientes pediátricos.

DESCRIPTORES: Seguridad del paciente. Pediatría. Gestión de la seguridad. COVID-19. Enfermería pediátrica.

INTRODUCTION

The National Patient Safety Program advocates a safety culture in which health professionals are responsible for their safety, as well as for that of their colleagues, patients and family members, emphasizing that safety is a priority and that there is promotion of learning in the face of episodes related to incidents¹. An incident is any event that caused or could have caused unnecessary harm to a patient, being subdivided as follows: notifiable circumstances, when the incident does not occur but there is significant potential for harm; near miss, when the incident does not reach the patient; incident without harm, when it reaches the patient but there is no harm; and adverse event, when there is harm to the patient².

A multicenter study carried out in pediatric units of North American hospitals revealed that for every 1,000 patients/day, 19.1 suffer some adverse event, with 52.7% of the events contributing to temporary harm to the patients and requiring intervention; 35.3% with temporary harm and prolonged hospitalization; 1.2% resulting in permanent harm; 10.1% were life-threatening and 0.7% leading to death³. In Brazil, between May 2019 and April 2020, the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, ANVISA) reported 153,126 healthcare-related incidents in all the age groups⁴.

In relation to the incidents in the pediatric age group, from November 2019 to October 2020, a total of 17,543 incidents were reported in the age group from zero to 17 years old, of which 11,256 were in children under two years of age, with the state of Rio Grande do Sul having a record of 181 incidents⁵. Physiological, psychological and developmental differences make children more susceptible to harms in hospital environments, and potential risks are intrinsic to care complexity⁶.

The occurrence of adverse events and other patient safety incidents is associated with the quality of the assistance provided to pediatric patients. To this end, it is of utmost important that the work environment is favorable and safe; however, maintaining this work environment in the COVID-19 pandemic context can become difficult⁷.

In this way, the efforts made by the professionals as a result of the situations generated by the pandemic contributed to wear out in them, which may have caused a decrease in care quality and resulted in the occurrence of adverse events⁸⁻⁹. Thus, it is fundamental that these events be identified, seeking to determine the risks in order to implement mitigation strategies.

Given the above, the following research question was formulated: which are the characteristics of the pediatric patient safety incidents notified in the comparison between the previous year and the first year of the COVID-19 pandemic and which is the Nursing professionals' perception in this context? The study objective was to analyze the profile of pediatric patient safety incidents in a university hospital, with a particular focus on comparing notifications before and during the COVID-19 pandemic and on Nursing professionals' perception.

METHOD

This study is part of a matrix research project entitled "Work environment and health during the COVID-19 pandemic: Absenteeism, burnout, management and work organization among Nursing professionals", approved by the institution's Research Ethics Committee, which uses a mixed research method with convergent strategy, combining quantitative and qualitative approaches. In the quantitative stage, conducted from March to September 2021, the participants were 150 Nursing professionals who develop care activities in pediatric units, which consist of five units with 114 beds at a university hospital in southern Brazil, which has all 836 beds divided into clinical, surgical, intensive care and emergency units, being a reference in the state for the treatment of various pathologies, including COVID-19. Secondary data on the notifications of safety

incidents, in the units surveyed, were collected from January 2019 to December 2020, in order to compare the incidents that occurred in the first year of the pandemic with the previous year. In the qualitative stage, sampling was intentional, selecting as participants those individuals who expressed interest in discussing the theme, having participation in the quantitative stage of the research as inclusion criterion.

For this manuscript, the incident notification forms were used for the quantitative stage, being a documentary study with retrospective analysis, and interviews were employed for the qualitative stage, being an exploratory-descriptive study. The method is justified by the fact that the quantitative data regarding pediatric patient safety incidents are not enough to understand the changes caused by the pandemic in the care processes, which had direct implications for risk management and patient safety.

The notifications came from the database extracted from the institutional system for reporting incidents, conducted by the Patient Safety Center, and made available by the hospital's Risk Management area, through tables in Excel[®]. At a first moment there were 1,663 notifications of safety incidents. The following inclusion criteria were defined: incidents reported in 2018 and 2020, in children aged from 0 to 18 years old hospitalized in the pediatric units. The exclusion criteria were the following: incidents reported more than once (duplicates) and those recorded as adverse drug reactions or transfusion reactions that were related to expected side effects, resulting in 418 notifications to be analyzed.

The variables were extracted from the unprocessed data of the tables: gender, age, month and year of notification, shift, unit, whether assistance was involved, whether it reached the patient, preventable event, type of incident, harm severity and whether any immediate action was taken. The variables were classified by the researchers based on the diverse information described in the notifications: development stage, actors involved, notifier, incident classification, contributing factors, improvement actions and whether there is a direct relationship with COVID-19. In addition, the variables with lack of information were classified as missing.

These data were organized in Excel[®] and, subsequently, they were analyzed by means of descriptive and inferential statistics in the *Statistical Package for Social Sciences (SPSS/PASW)*, version 18.0. Following the Conceptual Framework of the International Classification on Patient Safety (ICPS) recommended by the World Health Organization, they were categorized as follows: patient accidents, clinical management, behavior, diet/feeding, medical device/equipment, documentation, infrastructure/building/facilities, intravenous (IV) medications/fluids, oxygen/gas/vapor, clinical process/procedure, resources/organizational management, and blood/blood products¹⁰. The inferential statistics technique was used, with performance of Chi-Square and Mann-Whitney tests and calculation of adjusted residuals, adopting a 95% confidence level and a two-tailed p-value less than or equal to 0.05 considered statistically significant.

The qualitative data were obtained through semi-structured interviews, concomitantly with the quantitative data collection. An invitation was emailed to the professionals who expressed interest in taking part of the research, scheduling the interviews individually in Google Meet[®]. Of the 18 Nursing professionals interviewed, 10 were nurses and eight were nursing technicians. The interviews were conducted by the main author and lasted a mean of 40 minutes. They were audio-recorded and transcribed in full, and the transcripts were forwarded to the participants for possible corrections and comments. Thematic categorical content analysis as described by Minayo was used, with data pre-analysis, exploration of the material and treatment of the results¹¹, with the aid of the QSR Nvivo software, version 16.1. Maintenance of anonymity was addressed by identifying the participants by the letters N (nurses) and NT (nursing technicians), followed by the Arabic numbers corresponding to the order in which interviews were conducted.

Data integration was performed by means of data incorporation, so that the qualitative data could support, complement or explain aspects of the quantitative results¹².

This study meets the ethical assumptions set forth in resolutions No. 466/12 and No. 510/2016.

RESULTS

All 418 notifications of safety incidents that occurred in the institution's pediatric units during 2019 and 2020 were stratified by year to compare the profile of the notifications in the year of the pandemic and in the previous year. The monthly mean number of notifications was 18.25 in 2019 and 16.58 in 2020, presenting a 9.13% reduction. The most significant reductions were noticed in April (-74.07%), May (-42.10%) and August (-37.03%), whereas the highest increase was recorded in October (+45%).

The categories are distributed according to year of occurrence, in Table 1, where it can be seen that there was an increase in incidents related to intravenous medications and fluids and a decrease in those related to documentation, although no statistically significant difference was found ($p=0.123$) in relation to the categories from one year to the other.

The data related to the characteristics of the patients and incidents are described in Table 2, as well as those related to the notifier. It is observed that, in 2020, there was a statistically significant increase ($p=0.016$) in the number of incidents in the night shift, among the valid data. There was also statistical significance regarding age ($p=0.043$), increasing the median value, and regarding the development phase ($p=0.008$), decreasing among preschoolers and increasing among adolescents in 2020.

Table 3 describes the characteristics related to the incident, the harm, the contributing factors and the actions taken.

In some variables, it can be observed that there was no data completeness in more than half of the notifications, which indicates certain weakness in the data filling process when a safety incident occurs.

In addition, a search was carried out for events that mentioned COVID-19 and that process errors had occurred as a result of the pandemic in the descriptions of events corresponding to the 418 notifications of safety incidents, having been found in eight(1.9%) notifications. One incident was classified in the "intravenous medications/fluids" category and seven in "clinical administration".

Table 1 – Distribution of the number of safety incidents recorded in 2019 and 2020, according to the categorization of the ICPS conceptual structure. Porto Alegre, RS, Brazil, 2021. (n=418).

Variables	2019 (n=219) f (%)	2020 (n=199) f (%)	Total (n=418) f (%)
IV medications/fluids	59 (26.9)	80 (40.2)	139 (33.3)
Patient-related accidents	35 (16)	29 (14.6)	64 (15.3)
Diet/Feeding	37 (16.9)	23 (11.6)	60 (14.4)
Clinical process/procedure	25 (11.4)	24 (12.1)	49 (11.7)
Clinical administration	15 (6.8)	16 (8)	31 (7.4)
Behavior	10 (4.6)	8 (4)	18 (4.3)
Resources/Organizational management	10 (4.6)	7 (3.5)	17 (4.1)
Medical device/equipment	11 (5)	5 (2.5)	16 (3.8)
Documentation	9 (4.1)	2 (1)	11 (2.6)
Blood/Blood products	5 (2.3)	2 (1)	7 (1.7)
Oxygen/Gas/Vapor	3 (1.4)	2 (1)	5 (1.2)
Infrastructure/Building/Facilities	0 (0)	1 (0.5)	1 (0.2)

Table 2 – Sociodemographic data of the patients with notifications of safety incidents in 2019 and 2020. Porto Alegre, RS, Brazil, 2021. (n=418).

Variables	2019 (n=219) f (%)	2020 (n=199) f (%)	Total (n=418) f (%)	p-value
Gender				
Female	84 (38.4)	86 (43.2)	170 (40.7)	0.320†
Male	134 (61.2)	112 (56.3)	246 (58.9)	
Missing	1 (0.5)	1 (0.5)	2 (0.5)	
Development Phase				
Newborn	0 (0)	1 (0.5)	1 (0.2)	0.008†
Infant	80 (36.5)	67 (33.7)	147 (35.2)	
Preschool child	62 (28.3)	34 (17.1)	96 (23)	
Schoolchild	36 (16.4)	40 (20.1)	76 (18.2)	
Adolescent	39 (17.8)	57 (28.6)	96 (23)	
Missing	2 (0.9)	0 (0)	2 (0.5)	
Age*	2 (1-7)	4 (1-11)	3 (1-10)	0.043‡
People involved				
Patient	207 (94.5)	191 (96)	398 (95.2)	0.961†
Patient and Family member	4 (1.8)	3 (1.5)	7 (1.7)	
Patient and Employee	2 (0.9)	3 (1.5)	5 (1.2)	
Employee	2 (0.9)	1 (0.5)	3 (0.7)	
Missing	4 (1.8)	1 (0.5)	5 (1.2)	
Inpatient unit				
Pediatric Hospitalization, North	51 (23.3)	35 (17.6)	86 (20.6)	0.177†
Pediatric Hospitalization, South	52 (23.7)	45 (22.6)	97 (23.2)	
Pediatric Oncology	75 (34.2)	64 (32.2)	139 (33.3)	
Pediatric ICU	21 (9.6)	32 (16.1)	53 (12.7)	
Pediatric Emergency	13 (5.9)	17 (8.5)	30 (7.2)	
Missing	7 (3.2)	6 (3)	13 (3.1)	
Work Shift				
Night	28 (12.8)	48 (24.1)	76 (18.2)	0.016†
Afternoon	35 (16)	26 (13.1)	61 (14.6)	
Morning	30 (13.7)	20 (10.1)	50 (12)	
Missing	126 (57.5)	231 (55.3)	231 (55.3)	
Notifier				
Health professional	216 (96.6)	199 (100)	415 (99.3)	0.500†
Family member	2 (0.9)	0 (0)	2 (0.5)	
Missing	1 (0.5)	0 (0)	1 (0.2)	

*Numbers expressed as Median (Percentiles 25-75). †Value obtained by means of Fisher's Exact Test.
‡Value obtained by means of the Mann-Whitney test.

Four (50%) incidents were classified as "risk circumstance", two (25%) as "incidents without harm", one (12.5%) as a "Near Miss", and one (12.5%) event was not classified. All the contributing factors were related to personal and professional factors, and seven (87.5%) improvement actions were related to organization.

Table 3 – Characterization of the Safety Incidents notified in 2019 and 2020. Porto Alegre, RS, Brazil, 2021. (n=418).

Variables	2019 (n=219) f (%)	2020 (n=199) f (%)	Total (n=418) f (%)	p-value*
Type of Incident				
Risk Circumstance	30 (13.7)	28 (14.1)	58 (13.9)	0.274
Near Miss†	13 (5.9)	17 (8.5)	30 (7.2)	
Incident without harm	100 (45.7)	103 (51.8)	203 (48.6)	
Incident with harm (Adverse event)	48 (21.9)	31 (15.6)	79 (18.9)	
Missing	28 (12.8)	20 (10.1)	48 (11.5)	
It involves the assistance provided and reaches the patient				
Yes	189 (86.3)	172 (86.4)	361 (86.4)	-
Missing	30 (13.7)	27 (13.6)	57 (13.6)	
Preventable Event				
Yes	97 (44.3)	68 (34.2)	165 (39.5)	0.198
No	19 (8.7)	7 (3.5)	26 (6.2)	
Missing	103 (47)	124 (62.3)	227 (54.3)	
Harm Severity				
None	113 (60.7)	132 (66.3)	265 (63.4)	0.544
Mild	43 (19.6)	39 (19.6)	82 (19.6)	
Moderate	12 (5.5)	6 (3)	18 (4.3)	
Severe	1 (0.5)	2 (1)	3 (0.7)	
Missing	30 (13.7)	20 (12.1)	50 (12)	
Contributing Factors				
Factors related to the patient/ companion†	40 (18.3)	41 (20.6)	81 (19.4)	0.851
Institutional factors‡	14 (6.4)	12 (6)	26 (6.2)	
Personal/Professional factors§	165 (75.3)	146 (73.4)	311 (74.4)	
An immediate action was taken				
Yes	101 (46.1)	102 (51.3)	203 (48.6)	-
Missing	118 (53.9)	97 (48.7)	215 (51.4)	
Improvement Actions				
Related to the patient/companion	131 (59.8)	133 (66.8)	264 (63.2)	0.155
Related to organization	88 (40.2)	66 (33.2)	154 (36.8)	

*Value obtained by means of Fisher's Exact Test. †Patient severity, presence of comorbidities, agitation, others; ‡Lack of resources, inadequate staffing, high demand, others; §Stress, overload, lack of attention, others.

The qualitative data were combined to the quantitative results seeking convergence, divergence or complementation of the findings.

The following categories emerged from the qualitative data analysis: "The professionals' perception in relation to the occurrence of safety incidents"; "Under-reporting of incidents"; and "The institution's safety culture".

Regarding the professionals' perception in relation to the occurrence of safety incidents, eight professionals believe that there was no influence of the pandemic, six believe that there was an increase in safety incidents, two that there was a reduction and, in addition, two professionals did not know how to give an opinion on the question.

One of the explanations for those who reported not having noticed changes in the occurrence of safety incidents as a result of the pandemic is related to the fact that these variations also occurred at other times: [...] *The events that happen are things that I see which, routinely, at other times, had already happened* (NE8).

The reasons that could have led to the increase in these incidents were related to fear, stress and new work routines, increased demands and work overload, hiring new employees and employees who have no experience in pediatric units:

[...] *Stress and fear ended up leading to some adverse events, which ended up influencing people not to get too close, [...] there was a lot more equipment, the patients were more severely ill, there were more medications. Sometimes, a person who was in support ended up preparing the medication and the other ended up administering it* (NT3).

[...] *It's precisely this fact that overloads the professionals. [...] New employees that we ended up training very quickly, [...] so there were employees who were placed to take on patients without being in due conditions, and then we had adverse events* (N1).

[...] *You're exposed to risk because some things were not checked. [...] These minute things that are sometimes imperceptible for people who don't work in the unit [...] it makes a big difference* (NT6).

While the reduction in these incidents can be related to the increased attention of the Nursing team: [...] *I think that I'm more attentive, medication, vital signs, everything. We pay more attention to whether the patient has a cough, a different runny nose, we pay more attention, we certainly do, because there's the COVID issue now* (NT2).

In this way, the professionals report certain balance between negative and positive aspects during the pandemic, not causing a significant change in the institution's scenario regarding incidents.

As for the notifications of safety incidents, most of the professionals believe that there were no changes, although it was pointed out that under-reporting of incidents may have been one of the reasons. A point raised was under-reporting related to the increase in demand and to non-resoluteness of the notifications: [...] *I think that there were fewer notifications, the staff [...] was a little exhausted, because the demand increased due to the absence of the other professionals. I think that there were fewer notifications for not having some support, we had work overload* (N10).

In addition, some professionals raised the relationship between under-reporting of safety incidents with lack of process improvements and fear of judgment by co-workers:

[...] *Then you see that there was no change, the notification is made, a survey is carried out, an investigation is carried out and he dies, it doesn't improve, it's the same thing. [...] or when we receive feedback on the notification, they only seek the error in the Nursing team* (N10).

[...] *I think people are always afraid of notifying, because they are still afraid of being judged as they used to be, despite the fact that, now we have a whole structure that tells us that we have support* (NT3).

In turn, regarding the institution's safety culture, the professionals brought up points related to an educational culture and the use of safety incident notifications to improve processes:

[...] *I think that people have seen notifications as a door, a possibility for us to change things, [...] to really try to change the processes and try to improve* (N8).

[...] *We know it's not to find the culprit and punish, so we always encourage and we always do it with tranquility* (N2).

Added to this, in the following statements, unawareness about the institutional notification process and lack of autonomy in the nursing technicians are noticed:

[...] *Sometimes the person knows how to notify and what they notify. What is actually an adverse event that should be reported* (N5).

[...] *But I think so, I think that the technician who does it, at least, I think he writes, we'll tell the nurse, but I think he writes, I think he does, but the nurse, I think, does the most bureaucratic part* (NT7).

[...] *We ask the nurse, always pass it on to the nurse, there's the paper there that we could notify, I don't know if on other nights* (NT5).

Thus, it can be inferred that the patient safety culture within the institution is widespread among the professionals. However, strategies are still necessary to encourage notifications, as well as improvements in the processes of evaluation and implementation of action plans and monitoring of results.

Chart 1 presents the “Joint Display” with the integration of the quantitative and qualitative research results. It can be observed that the qualitative data converge with the quantitative ones in relation to the profile of incident notifications, confirming that there was no significant change in the institution’s scenario regarding incidents. Furthermore, the findings related to the safety culture in the institution and the strategies that promote greater knowledge of the notification system on the part of professionals converge with the numbers of missing that occurred in the notifications. In addition to that, the reasons that lead to under-reporting complement these data.

Chart 1 – Joint Display with the integration of the quantitative and qualitative results. Porto Alegre, RS, Brasil, 2022

Quantitative Results	Qualitative Results
<p>The profile of notifications of safety incidents that occurred in the institution’s pediatric units showed few significant differences when comparing the first year in which the COVID-19 pandemic occurred in Brazil to the previous year.</p>	<p>In the professionals’ perception about the influence of the COVID-19 pandemic on the occurrence of patient safety incidents, there was no significant change in the institution’s scenario regarding incidents, as there was certain balance between positive and negative aspects in the work processes during the pandemic.</p>
<p>It can be observed that there is no data completeness in more than half of the notifications, indicating a weakness in the data filling process when a safety incident occurs.</p>	<p>The patient safety culture within the institution is widespread among the professionals. However, the professionals reported that some colleagues are still unaware of how notification system works and that they lack autonomy to make them.</p>

DISCUSSION

The decreases observed in the incidents reported can be related to the reduction in the number of pediatric hospitalizations due to the lower number of cases of children who required hospitalization and the strategies adopted by the institution for the care of adult patients affected by COVID-19. The increase in the number of notifications started to be significant in October 2020.

A study carried out at a pediatric hospital in Costa Rica found that there was a 37.6% increase in reported safety incidents from 2019 to 2020, in contrast to the data found in this study. However, the same study also reports a reduction in incidents in the first months of the year, more pronounced in April, and an increase in incidents from August, also with a greater increase in October¹³. It can be inferred that the changes in the notifications are related to a decrease in pediatric hospitalizations at the beginning of the pandemic and to the peaks of the pandemic, where overcrowding in hospital institutions occurred.

However, the quantitative data of this study did not show significant changes in the profile of notifications during the pandemic, converging with the qualitative data in which, for most of the Nursing professionals interviewed, there were also no significant changes in the occurrence of incidents. Even

so, some professionals pointed out factors that contributed to the occurrence of safety incidents, such as fear, stress, new work routines, increased demands and work overload, hiring new employees and reassigning employees who have no experience in pediatric units.

Work overload is one of the most cited contributing factors in the occurrence of incidents, related to the accumulation of stress, sleep, fatigue and lack of concentration, which can exert an impact on patient care. Nursing staffing can be associated with such factors; thus, the number of professionals needs to be adequate so that safe and good quality care is offered¹⁴⁻¹⁵.

In addition to that, inexperience and lack of knowledge about a given area can exert a negative impact on the occurrence of these incidents. Thus, it is important that strategies are implemented targeted at promoting development and improvement in the professionals, as well as integration of work teams¹⁴.

Another determining factor pointed out by the professionals was the changes in the hospital routines as a result of the pandemic, which generated an effort by professionals and managers to contemplate the adaptations of structure and work processes¹⁶. In some places, pediatric units had mixed care; therefore, the medications were not prepared by those who administered them. Administering medications prepared by others and not checking them against the prescription before their administration diverges from good practice recommendations for safe drug administration. Associated with the interruption in the preparation process and in the checking of medications, such facts become a critical point to make professionals more vulnerable to the occurrence of a safety incident¹⁷.

In addition to that, children are conditioned to a greater risk for the occurrence of safety incidents due to physical and psychological characteristics specific to their age groups, with frequent and necessary adjustments in the doses and concentrations of the medications to be administered^{6,18}. As a result, the most frequent incidents were associated with intravenous medications and fluids (33.3%), which was also found in a study conducted with pediatric patients in Argentina, in which 48.6% of the incidents were related to medications¹⁹.

An explanation for this is due to the fact that many medications used have a pharmaceutical presentation intended for adults, and dose fractioning is a risk factor for the occurrence of errors during the drug preparation and administration processes in Pediatrics. Thus, the implementation of a unit dose system within the institutions becomes an effective strategy, minimizing the risk for the occurrence of safety incidents^{14,17}.

On the other hand, the attentive presence of the professionals throughout the care process can reduce the chance of errors. With this, it is possible to identify situations that contribute to the occurrence of errors, as well as to prevent them from occurring and causing harm to the patient^{14,20}.

Patient-related accidents were the second most reported category of incidents (15.3%), with falls as the main ones. Falls can be associated with child development factors and environmental factors, but most of these incidents might be avoided. Thus, their prevention in the hospital environment is of utmost importance, as their occurrence leads to an increase in hospitalization time and, consequently, in hospital costs²¹.

Incidents related to diet and feeding were also highly prevalent (14.4%) among the reported incidents. A study carried out at the same institution in 2017 identified that 51% of the incidents related to diet and feeding in pediatric patients occurred in the distribution and dispensation phases²².

As for the age group, the studies show that most incidents occur with children aged between 29 days and five years old^{13,19,23}; in other words, in infants and preschoolers, as identified in the current study. Thus, the child's age group is considered a risk factor for the occurrence of adverse events⁵. During the pandemic, an increase in the mean age of children who suffered some type of safety incident was noticed. This may have been a consequence of the change in the profile of pediatric

hospitalizations during the pandemic, given that, due to social isolation, diseases prevalent in younger age groups, such as bronchiolitis, decreased considerably and, at the same time, COVID-19 affected older age groups more, contributing to the change in the age profile during the period.

In turn, severity of the incidents is similar in different contexts, with no significant changes during the pandemic. A study carried out during the pandemic at a pediatric hospital in Costa Rica shows that 38% of the incidents did not cause harm to the patients, 42% caused slight harm, 18% moderate harm and 2% severe harm¹³.

In addition, an association was made between the types of incidents and the categories described by the WHO¹⁰, in which most of the risk circumstances were associated with clinical management (22.4%) and 56.3% of the incidents related to resources and organizational management were classified as risk circumstances. This can be explained by the fact that most of these incidents were situations that imposed risk to the patients but did not cause harm, such as, situations related to bed management in pediatric units.

The eight notifications that were directly related to process errors resulting from the COVID-19 pandemic were identified because they referred to the pandemic in their content. These notifications were related to the transfer of patients being screened for COVID-19 to the Oncology unit, to non-compliance with new flows and routines, and to inadequacy of the physical structure for separating family members of COVID-19 and uninfected patients. In this way, it is necessary that the institutional protocols regarding care flows, norms and routines are well established and that they are shared with all professionals through informative materials and training, providing better professional preparation given the new situations that will be faced²⁴.

It is also indispensable that the multiprofessional team works in an integrated manner, overcoming the segregation between categories and promoting defragmentation of the services. Nurses play an essential role in the reduction of incidents and adverse events, as they are professionals who stand out among the multiprofessional team for their technical-scientific knowledge, for the planning of actions and for the standardization of health processes^{20,25}.

In the professionals' statements, it can be seen that there is development and dissemination of a safety culture within the institution, promoting a fair culture in which notifications are used to improve care processes and action plans are educational and non-punitive. Thus, notifications make it possible to know the profile of the incidents and, from this starting point, create and implement learning measures that induce behavioral changes, as well as implement changes that promote improvements in the work processes¹⁴.

The professionals' lack of knowledge about the processes that involve the notification of safety incidents, the absence of feedback, work overload and insecurity regarding judgment contribute to incomplete data and under-reporting. This can untruthfully bring an overview of incidents in the institution, preventing planning of safety actions from being really focused on the highest incidence values of errors in patient care²⁶⁻²⁷.

The study limitations were related to incompleteness of the notifications, making it impossible to reliably characterize the safety incidents. In addition to that, the scarcity in the literature regarding the reporting profile of pediatric patient safety incidents during the COVID-19 pandemic made it difficult to compare data with similar studies. Thus, it is suggested that there should be greater investment in research studies that characterize the panorama of safety incidents during the pandemic, seeking to observe the differences promoted by the current context.

The study contributed to understanding the profile of the notifications made before and during the pandemic in the pediatric environment, and can be used as a subsidy in the elaboration of institutional measures aimed at improving the process of reporting incidents and, consequently, pediatric patient safety.

CONCLUSIONS

Pediatric patient safety incidents at the institution are more related to intravenous medications and fluids, to the male gender and to infants. Most of the incidents were classified as without harm, and the contributing factors are more associated with factors inherent to the professionals. From 2019 to 2020 there was a statistically significant increase in the incidents that occur during the night shift, in the age group and in the development stage.

The characteristics of the patient safety incidents that occurred in pediatric units showed few statistically significant differences in their profile when comparing the year in which the COVID-19 pandemic was faced to the previous year. Likewise, Nursing professionals perceive that there has been no significant change in the institution's scenario regarding incidents.

It is noticed that the safety culture within the institution is being developed and disseminated among the professionals, using notifications to carry out process improvements. However, strategies to encourage notifications, disseminate the importance of data completeness when an incident is reported, and review the processes to evaluate and implement action plans are still necessary to provide a safe environment for pediatric patients.

REFERENCES

1. Ministério da Saúde (BR). Portaria Nº 529, de 1º de abril de 2013: Institui o Programa Nacional de Segurança do Paciente (PNSP) [Internet]. Brasília, DF(BR): Ministério da Saúde; 2013. Available from: https://bvsms.saude.gov.br/bvs/saudelegis/gm/2013/prt0529_01_04_2013.html
2. Agência Nacional de Vigilância Sanitária (BR). Documento de referência para o Programa Nacional de Segurança do Paciente [Internet]. Brasília, DF(BR): ANVISA; 2014 [cited 2022 Feb 10]. 42 p. Available from: https://bvsms.saude.gov.br/bvs/publicacoes/documento_referencia_programa_nacional_seguranca.pdf
3. Stockwell DC, Landrigan CP, Toomey SL, Loren SS, Jang J, Quinn JA, et al. Adverse Events in Hospitalized Pediatric Patients. *Pediatrics* [Internet]. 2018 [cited 2022 Jan 12];142(2):e20173360. Available from: <https://doi.org/10.1542/peds.2017-3360>
4. Agência Nacional de Vigilância em Saúde (BR). Comunicado GVIMS/GGTES/DIRE1/ANVISA Nº 01/2020, de 02 de junho de 2020 [Internet]. Brasília, DF(BR): ANVISA; 2020 [cited 2022 Feb 6]. 6 p. Available from: <https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/servicosdesaude/comunicados-de-risco-1/comunicado-de-risco-no-01-2017-gvims-ggtes-anvisa/view>
5. Agência Nacional de Vigilância em Saúde (BR). Incidentes relacionados à assistência à saúde: Resultados das notificações realizadas no Notivisa – Brasil, novembro de 2019 a outubro de 2020. [Internet]. Brasília, DF(BR): ANVISA; 2020 [cited 2022 Feb 6]. Available from: https://segurancadopaciente.com.br/wp-content/uploads/2020/04/BR_2019.pdf
6. Peres MA, Wegner W, Cantarelli-Kantorski KJ, Gerhardt LM, Magalhães AMM. Perception of family members and caregivers regarding patient safety in pediatric inpatient units. *Rev Gaucha Enferm* [Internet]. 2018 [cited 2022 Jan 22];39:e2017-0195. Available from: <https://doi.org/10.1590/1983-1447.2018.2017-0195>
7. Góes FGB, Silva ACSS, Santos AST, Pereira-Ávila FMV, Silva LJ, Silva LF, Goulart MCL. Desafios de profissionais de Enfermagem Pediátrica frente à pandemia da COVID-19. *Rev Latino-Am Enferm* [Internet]. 2020 [cited 2022 Jan 28];28:e3367. Available from: <https://doi.org/10.1590/1518-8345.4550.3367>
8. Magalhães AMM, Trevilato DD, Dal Pai D, Barbosa AS, Medeiros NM, Seeger VG, et al. Professional burnout of nursing team working to fight the new coronavirus pandemic. *Rev*

Bras Enferm [Internet]. 2022 [cited 2022 Apr 16];75(1):e20210498. Available from: <https://doi.org/10.1590/0034-7167-2021-0498>

9. Uchmanowicz I, Karniej P, Lisiak M, Chudiak A, Lomper K, Wiśnicka A, et al. The relationship between burnout, job satisfaction and the rationing of nursing care: a cross-sectional study. *J Nurs Manag* [Internet]. 2020 [cited 2022 Mar 16];28(8):2185-95. Available from: <https://doi.org/10.1111/jonm.13135>
10. Organização Mundial da Saúde (OMS). Estrutura conceitual da classificação internacional sobre segurança do doente. Relatório técnico final. [Internet]. OMS; 2011 [cited 2022 Feb 6]. Available from: <https://proqualis.net/sites/proqualis.net/files/Estrutura%20Conceitual%20da%20Classifica%C3%A7%C3%A3o%20Int%20Seguran%C3%A7a%20do%20Paciente.pdf>
11. Minayo MCS, Gomes SFDR. *Pesquisa Social: teoria, método e criatividade*. 31st. ed. Petrópolis (BR): Editora Vozes; 2012.
12. Creswell JW, Creswell JD. *Research design: qualitative, quantitative, and mixed methods approaches*. 5th. ed. Los Angeles (US): Sage; 2018.
13. Herrera RR, Enrique MEV, Arguedas OA, Solano RB. Description of the characteristics of the clinical incidents reported in 2020 to the voluntary reporting system of a pediatric hospital in Costa Rica. *Int J Med Sci* [Internet]. 2021 [cited 2022 Jan 30];8(3):1-11. Available from: <http://doi.org/10.32457/ijmss.v8i3.1634>
14. Costa MP, Picanço CM, Batalha EMSS. Vivência de enfermeiras(os) acerca dos incidentes relacionados à administração de medicamentos em terapia intensiva. *J Nurs Health* [Internet]. 2018 [cited 2022 Feb 10];2(8):e188207. Available from: <https://doi.org/10.15210/jonah.v8i2.13458>
15. Kim CG, Kim JS. The association between nurse staffing levels and paediatric nursing-sensitive outcomes in tertiary hospitals. *J Nurs Manag* [Internet]. 2018 [cited 2022 Feb 11];26(8):1002-14. Available from: <https://doi.org/10.1111/jonm.12627>
16. Santos JLG, Menegon FHA, Andrade GB, Freitas EO, Camponogara S, Balsanelli AP, et al. Changes implemented in the work environment of nurses in the COVID-19 pandemic. *Rev Bras Enferm* [Internet]. 2022 [cited 2022 Jun 22];75(1):e20201381. Available from: <https://doi.org/10.1590/0034-7167-2020-1381>
17. Manzo BF, Brasil CLGB, Reis FFT, Correa AR, Simão DAS, Costa ACL. Safety in drug administration: Research on nursing practice and circumstances of errors. *Enferm Global* [Internet]. 2019 [cited 2022 Feb 7];18(4):19-56. Available from: <http://doi.org/10.6018/eglobal.18.4.344881>
18. Vória JO, Padula BLD, Abreu MNS, Correa AR, Rocha PK Manzo BF. Compliance to safety barriers in the medication administration process in pediatrics. *Texto Contexto Enferm* [Internet]. 2020 [cited Jun 22];29:e20180358. Available from: <https://doi.org/10.1590/1980-265X-TCE-2018-0358>
19. Fajreldines A, Schnitzler E, Torres S, Panattieri N, Pelizzari M. Measurement of the incidence of care-associated adverse events at the Department of Pediatrics of a teaching hospital. *Arch Argent Pediatr* [Internet]. 2019 [cited 2022 Jan 15];117(2):106-9. Available from: <http://doi.org/10.5546/aap.2019.eng.e106>
20. Franco LF, Bonelli MA, Wernet M, Barbieri MC, Dupas G. Patient safety: perception of family members of hospitalized children. *Rev Bras Enferm* [Internet]. 2020 [cited 2022 Jan 8];73(5):e20190525. Available from: <https://doi.org/10.1590/0034-7167-2019-0525>
21. Vieira GLC, Campos IML, Fernandes BSM, Ladeira AG, Pimenta EF. Falls among children and teenagers in hospitals: an integrative literature review. *Rev Enferm Cent Oeste Min* [Internet]. 2019 [cited 2022 Feb 16];9:1-9. Available from: <http://doi.org/10.19175/recom.v9i0.2709>
22. Silva AS, Druzian MC, Luft VC, Bosa VL, Santos ZEA, Venzke JG, et al. Analysis of the reported risk situations for the nutrition service in a hospital in southern Brazil. *Braz J Hea Rev* [Internet]. 2021 [cited 2022 Feb 21];4(1):3617-30. Available from: <http://doi.org/10.34119/bjhrv4n1-284>

23. Parra CV, López JS, Bejarano CH, Puerto AH, Galeano M.L. Eventos adversos en un hospital pediátrico de tercer nivel de Bogotá. *Rev Fac Nac Salud Pública* [Internet]. 2017 [cited 2022 Jan 19];35(2):284-92. Available from: <http://doi.org/10.17533/udea.rfnsp.v35n2a12>
24. Oliveira AC, Lucas TC, Iquiapaza RA. Health professionals' perception on the risk of contamination by COVID-19 in Brazil. *Texto Contexto Enferm* [Internet]. 2021 [cited Jun 22];30:e20210160. Available from: <https://doi.org/10.1590/1980-265X-TCE-2021-0160>
25. Casanova IA, Batista NA, Moreno LR. Interprofessional education and shared practice in multiprofessional health residency programs. *Interface* [Internet]. 2018 [cited 2022 Jan 5];22(1):1325-37. Available from: <https://doi.org/10.1590/1807-57622017.0186>
26. Lima S, Agostinho M, Mota L, Príncipe F. Health professionals' perception of the limitations to the notification of the error/adverse event. *Rev Gaucha Enferm* [Internet]. 2018 [cited 2022 Jan 5];4(19):99-106. Available from: <http://doi.org/10.12707/riv18023>
27. Costa DB, Ramos D, Gabriel CS, Bernardes A. Patient safety culture: evaluation by nursing professionals. *Texto Contexto Enferm* [Internet]. 2018 [cited 2022 Jan 8];27(3):e2670016. Available from: <http://doi.org/10.1590/0104-070720180002670016>

NOTES

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Data collection: Borges AR, Lima GO.

Data analysis and interpretation: Borges AR, Wegner W.

Discussion of the results: Borges AR, Wegner W.

Writing and/or critical review of the content: Borges AR, Wegner W, Magalhães AMM, Lima GO, Silva T, Dornfeld D, Quadros DV.

Review and final approval of the final version: Borges AR, Wegner W, Magalhães AMM, Lima GO, Silva T, Dornfeld D, Quadros DV.

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CORRESPONDING AUTHOR

Ananda Rosa Borges

anandarborges@gmail.com

