

NOTIFICATION OF ADVERSE EVENTS IN A NEONATAL INTENSIVE CARE UNIT
NOTIFICAÇÃO DE EVENTOS ADVERSOS EM UMA UNIDADE DE TERAPIA INTENSIVA
NEONATAL
NOTIFICACIÓN DE DE EVENTOS ADVERSOS EN UNA UNIDAD DE CUIDADO INTENSIVO
NEONATAL

Marisa Utzig Cossul^{ID}, Lia Esther Corrêa de Paula Neiva^{ID}, Aline Oliveira Silveira

ABSTRACT

Objective: To identify and analyze the notifications of adverse events in 2015 in a Neonatal Intensive Care Unit (NICU).

Method: An observational, retrospective, descriptive and cross-sectional study with a quantitative approach. Data was collected from the adverse events (AEs) notification form, electronic medical records, Hospital Infection Control Center records and NICU medical head. **Results:** Approximately 70% of the patients experienced some kind of adverse event. HAIs occurred in 45.6% of the population. The most affected population was preterm infants and babies with BW < 2,500 g. Unplanned extubation was the most notified event. Moderate events occurred the most. **Conclusion:** The analysis of adverse events visualized their high occurrence. Preterm infants and babies with low birth weight are more likely to suffer AEs. HAIs and unplanned extubation are the main adverse events occurring in the NICU. **Descriptors:** patient safety; intensive care units; neonatal; notice; newborn.

RESUMO

Objetivo: Identificar e analisar as notificações de eventos adversos no ano de 2015 em uma Unidade de Terapia Intensiva Neonatal (UTIN). **Método:** Estudo observacional, retrospectivo, descritivo de abordagem quantitativa e corte transversal. Os dados foram coletados do formulário de notificação de eventos adversos (EAs), do prontuário eletrônico, dos registros do Núcleo de Controle de Infecção Hospitalar e da chefia médica da UTIN. **Resultados:** Aproximadamente 70% dos pacientes sofreram algum tipo de evento adverso. Ocorreram IRAS em 45,6% da população. A população mais atingida foi a de prematuros e bebês com PN < 2500g. A extubação não planejada foi o evento mais notificado. Eventos moderados foram os que mais ocorreram. **Conclusão:** A análise dos eventos adversos visualizou a grande ocorrência de eventos adversos. Prematuros e bebês com baixo peso de nascimento tem maiores chances de sofrerem EAs. IRAS e extubação não planejada são os principais eventos adversos que ocorrem na UTIN. **Descritores:** segurança do paciente; unidade de terapia intensiva neonatal; notificação; recém-nascido.

RESUMEN

Objetivo: Identificar y analizar las notificaciones de eventos adversos registradas en el año 2015 en una Unidad de Cuidado Intensivo Neonatal (UCIN). **Método:** Estudio observacional, retrospectivo, descriptivo y transversal con enfoque

cuantitativo. Los datos se recolectaron del formulario de notificación de eventos adversos (EA), de registros médicos electrónicos, de los registros del Centro de Control de Infecciones Hospitalarias y de la dirección de la UCIN. **Resultados:** Aproximadamente el 70% de los pacientes sufrió alguna clase de evento adverso. Se registraron IRAS en el 45,6% de la población. La población más afectada fue la de bebés prematuras y con un peso al nacer < 2500 g. La extubación no planificada fue el evento más notificado. Los eventos moderados fueron los más frecuentes. **Conclusión:** El análisis de los eventos adversos permitió visualizar su alta incidencia. Los bebés prematuros y con bajo peso al nacer presentaron más probabilidades de sufrir EA. Las IRAS y la extubación no planificada son los principales efectos adversos que tienen lugar en la UNCI. **Descriptores:** seguridad del paciente; unidades de cuidado intensivo neonatal; notificación; recién nacido.

¹Universidade de Brasília/UnB. Brasília (DF), Brazil. ¹<https://orcid.org/0000-0002-4849-6186>
²Escola Superior de Ciências da Saúde/ESCS. Brasília (DF), Brazil. ²<https://orcid.org/0000-0001-8181-4214>
³Universidade de Brasília/UnB. Brasília (DF), Brazil. ³<https://orcid.org/0000-0003-4470-7529>

How to cite this article
Cossul MU, Neiva LECP, Silveira AO. Notification of adverse events in a neonatal intensive care unit. J Nurs UFPE on line. 2021;15:e246969 DOI: <https://doi.org/10.5205/1981-8963.2021.246969>

INTRODUCTION

Safe patient care has gained relevance from the release of the report of the Institute of Medicine (IOM) entitled *To Err is Human: Building a Safer Health System* in 1999, which evidenced the impact of adverse events on the mortality rates and on the prolongation of hospital stay. Consequently, concerns about the occurrence of errors and their interference in quality of care have gained worldwide proportions.¹⁻³

Following recommendations from the World Health Organization (WHO), the National Patient Safety Program (*Programa Nacional de Segurança do Paciente*, PNSP) was established in Brazil in 2013 with the general objective of collaborating for the qualification of health care in health facilities in the national territory.⁴ Immediately after that, the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, ANVISA) launched RDC/Anvisa No. 36/2013 that establishes actions, regulates and discriminates basic points for patient safety, such as: the patient safety centers, mandatory notification of adverse events, and the elaboration of the patient safety plan.⁵

According to the WHO, adverse events (AEs) are defined as an incident that causes harm to the patient, and can be classified, according to the degree of harm: none, mild, moderate, severe and death. ³ Some healthcare assistance infections (HAIs) can be considered adverse events. In neonatology, the Pan American

Health Organization (PAHO) considers that all infections occurring in the neonatal period are HAIs, excluding only those of transplacental transmission. They can be classified as early (manifestation before 48h of life) or late (manifestation after 48h of life). Among the risk factors for HAIs in newborns (NBs), the following stand out: birth weight, decreased immune defense, need for invasive procedures, and alteration of bacterial flora by acquisition of hospital flora.⁶

Neonatal intensive care units (NICUs) are a unique environment due to the characteristics of the population served, mostly consisting of premature and low birth weight newborns, who suffer excessive manipulation during hospitalization.^{2, 7-9} In addition, the length of hospitalization in the NICU is usually longer, with greater exposure to potential risks and hazards.^{2, 8} Neonatal care is one of the priority areas for actions aimed at patient safety, with fundamental importance, considering, in addition to the work process and its peculiarities, the number of patients involved and the consequent potential of adverse events that may arise in the care process.⁷

Recent studies have been describing the main adverse events occurring in the NICU,^{2, 8, 11}, being important to obtain the profile of adverse events of this NICU and its comparison with the literature, since the unit under study is a reference of the Federal District (*Distrito Federal*, DF) and its surroundings, requiring subsidies for the elaboration of interventions directed to its reality. Data regarding the occurrence of adverse events in the population served by the NICUs of the Federal District have not yet been described, emphasizing the importance of this study.

OBJECTIVE

To analyze the occurrence of adverse events in a Neonatal Intensive Care Unit (NICU) of the Federal District.

METHOD

An observational, retrospective, descriptive, quantitative and cross-sectional study. The *ex-post-facto* documentary search procedures were used.¹² The research was developed in a reference hospital for high-risk births.

Data was collected by the first author of this study from the database of AEs notified throughout 2015 from the Patient Quality and Safety Center (*Núcleo de Qualidade e Segurança do Paciente*, NQSP) of the referred hospital. Thus, the database was revisited and reanalyzed. Data from the Computerized Notification System (*Sistema de Notificação Informatizado*, SNI), the Hospital Infection Control Center (*Núcleo de Controle de Infecção Hospitalar*, NCIH) and the medical head were used, with the following sources: computerized notification form received by the NQSP; electronic medical record of the patient who suffered the adverse event;

NCIH official data for the Neonatal Intensive Care Unit (NICU) in 2015; number of appointments performed by the NICU in 2015, determined by the medical head.

Thus, the sample consisted of: NQSP SNI form data (composed of: date and time of the notification, date of the incident, place where it occurred, type of incident, if there was harm to the patient, patient data (name, date of birth, number of the electronic medical record, gender), professional category of the notifier, shift of occurrence, identification of the notifier - not required), event classification, status, Health Surveillance Notification System (NOTIVISA) and filling in the electronic FormSUS form; reading the electronic medical record of the patient who suffered the adverse event in the following cases: incomplete or confused information present on the SNI form and doubt as to the classification of the harm caused; report with the HAI outcome indicators in the neonatal ICU in 2015 from the Hospital Infection Control Center (NCIH) for the year 2015; numbers of total appointments performed by the NICU medical chief in 2015. It is noted that the data collected by the NCIH are not part of the NQSP SNI.

The criteria for inclusion in the study were the following: data referring to the NICU in 2015 and adverse events reported to the NQSP, occurring in the Neonatal Intensive Care Unit. Adverse events with incomplete notifications that could not be complemented by analysis of the medical records, such as BW and GA, and notifications that are not characterized as adverse events were excluded from the sample.

For data analysis, the following steps were used: establishment of categories, coding and tabulation, and statistical analysis of the data.¹² Data analysis occurred through descriptive and inferential statistical analysis, with the aid of the *Statistical Package for the Social Science (SPSS®) program*, version 21.0, and the *R* software.

For the inferential analyses between birth weight, gestational age and classification of the adverse event, the *Kruskal Wallis* test was applied. This test is used for nonparametric situations, where the data do not fit a normal distribution. The test aimed to verify whether the “birth weight”, “gestational age” and “occurrence shift” variables influence the classification of the adverse events. In the inferential analysis between notification shift and classification of the adverse event, the Chi-Square Test of Independence was applied.

In order to characterize the care provided in the NICU, the total number of appointments performed by the unit in 2015 was collected.

In order to optimize data analysis, nine categories of adverse events were elaborated, described below:

- 1 – Technical complaint: Referring to hospital articles and equipment;
- 2 – Medication: Various types of medication errors;
- 3 – Skin lesion: Various types of skin injury – chemical, pressure ulcer and burn;

4 – Mechanical ventilation: Unplanned extubation, endotracheal tube obstruction, pneumothorax, and poorly positioned endotracheal tube.

5 – Central access: Related to the various types of central catheter – umbilical venous catheter (UVC), peripherally inserted central catheter (PICC) and central venous catheter (CVC);

6 – Peripheral access: Adverse events related to peripheral venous access – phlebitis and peripheral infiltration);

7 – Fractures;

8 – Surgical site infection;

9 – Others: It includes patient identification error, NB without adequate assistance, inadequate appliances, opening of sterile closed system, and breaking of the hand hygiene protocol.

To classify the degree of the harms caused to the patient resulting from the AEs, the following definitions were used: none; mild (mild symptoms, minimal or intermediate short-term harms without minimal intervention); moderate (required some intervention, prolonged hospitalization, loss of function, permanent or long-term harms); severe (life-saving intervention was required, major medical/surgical intervention or caused major permanent or long-term harms, fetal disturbance/risk or congenital anomaly) and death (caused by the adverse event).³

Based on other studies,^{2, 13} the assessment of the quality of the data found in the computerized notification forms was performed using the criterion of "incompleteness", which has the following scores for evaluation: excellent (less than 5% unfilled fields), good (between 5% and 10%), regular (between 10% and 20%), bad (between 20% and 50%) and very bad (50% or more).

The ethical aspects of the research were ensured during all stages of the study, with approval Certificate of Presentation for Ethical Appreciation (*Certificado de Apresentação para Apreciação Ética*, CAAE) number 56209216.2.0000.5553. The Free and Informed Consent Form (FICF) waiver was requested and granted by the CEP, as it was impossible to obtain the signed form⁽¹⁴⁾ for this being a retrospective study, where contact with those responsible for the NBs was not possible, since they were no longer on site at the collection date.

RESULTS

During 2015, 613 newborns (NB) were treated in the NICU under study and there were 280 cases of healthcare assistance infections (HAIs), 78.0% (N=218) of hospital origin and the remainder with maternal origin.

The most prominent HAI was Primary Bloodstream Infection (clinical or laboratory, with or without catheter) occurring in 60.0% of the sample.

Regarding the total number of hospitalizations in the NICU, 35.5% had HAIs of hospital origin and 10.1% of maternal origin. Thus, HAIs occurred in 45.6% of the patients treated in the NICU, considering maternal and hospital origin.

Adverse events notified in the Neonatal Intensive Care Unit

A total of 144 adverse events were notified in 2015. However, during data analysis, 149 adverse events were found, a fact that occurred due to some reports describing more than one adverse event. Two notifications were excluded from the study because they are not characterized as an adverse event. Thus, the results presented are based on a total of 147 adverse events. Regarding the total number of hospitalizations in the NICU, 24.0% of the patients suffered some AE, excluding HAIs.

Figure 1 represents the adverse events notified, according to the categories of adverse events defined previously.

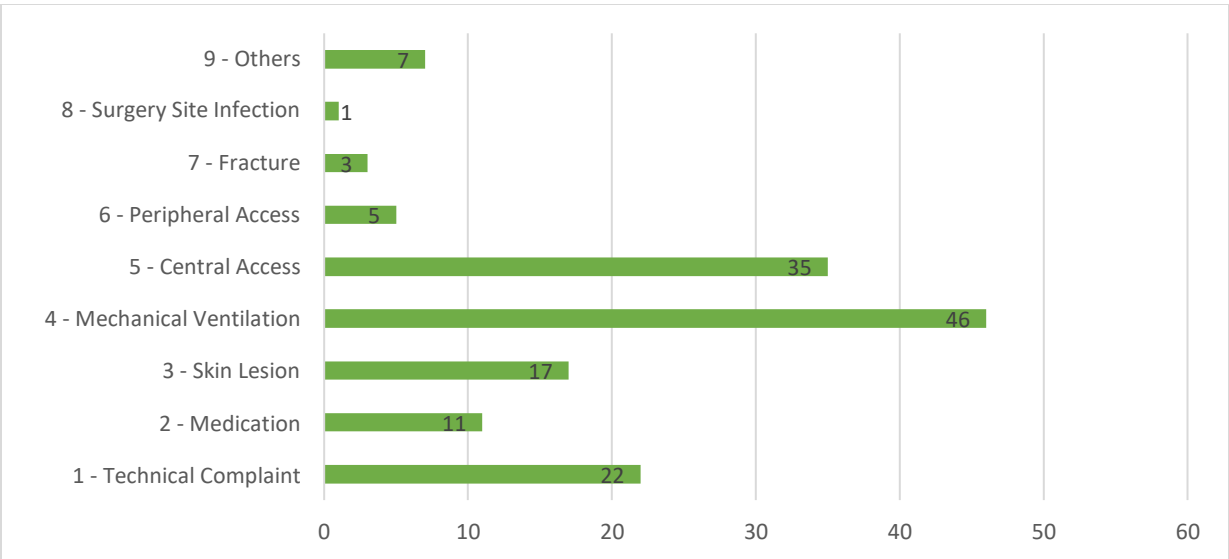


Figure 1 - Distribution of the number of adverse events notified by category of adverse event. Brasília (DF), Brazil, 2015.

Adverse events (AEs) related to mechanical ventilation had the highest number of notifications. Among the newborns who suffered these events, it was found that 26 (56.0%) had birth weight below 1,500 g and gestational age below 30 weeks and 6 days. “Unplanned extubation” was the incident with the highest number of notifications, corresponding to 23.1% of all the events notified.

The "central access" category obtained the second highest number of notifications. The events included in the category are as follows: loss of umbilical venous catheter (UVC); infiltration at the central or peripheral level from a central venous catheter (CVC) or peripherally inserted central catheter (PICC); phlebitis originated by PICC; thrombus after central access passage and PICC obstruction. It is noted that 65.7% (N=23) of the affected NBs had birth weight below 1,500 g and 22 (62.8%) gestational age at birth below 30 weeks and 6 days.

Seventeen (11.5%) notifications were obtained in the “skin lesion” category, which includes chemical injury, pressure ulcer and burns. The birth weight range most affected was that of children under 1,500 g (82.3%). The gestational age at birth with the highest number of injuries was that of infants with GA < 30.6 weeks, with 82.3% of the total skin lesion notifications.

The classification of the degree of harms caused to the patients due to the AEs is shown in Figure 2. It is noteworthy that the events classified in the doubt category showed incomplete information on the description and outcome of the event, not allowing for classification in the other categories.

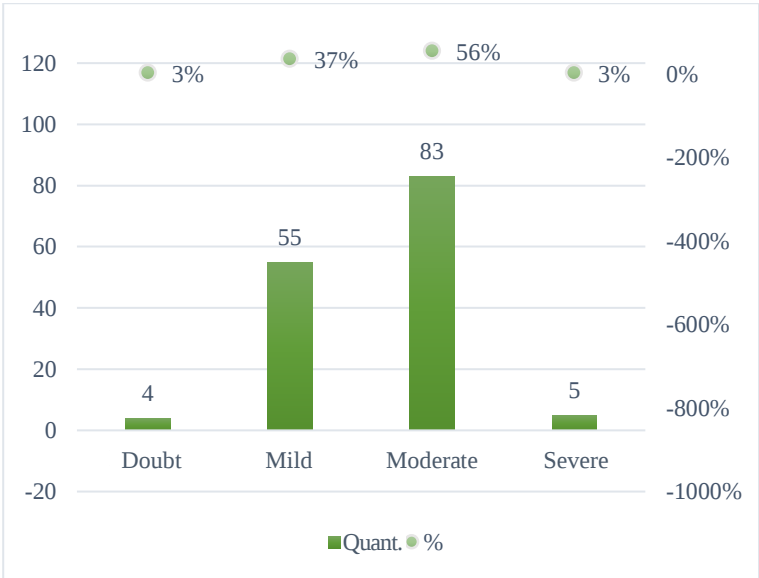


Figure 2. Classification of the AEs notified, NICU. Brasília (DF), Brazil, 2015.

Moderate adverse events were mostly suffered by neonates with birth weight < 999 g, representing 54.5% (N=48). The most prominent gestational age was < 27 weeks and 6 days, with N=42 (47.7%).

Severe adverse events were suffered by five neonates. Of these, 03 (60.0%) with BW < 999 g; 01 (20.0%) with BW between 1,500 g and 1,999 g and 01 (20.0%) with BW between 2,000 g and 2,499 g. The gestational age of these babies was represented by 40.0% (N=02) with GA < 27 weeks and 6 days, 20.0% (N=01) with GA between 28 weeks and 30 weeks and 6 days, and 40.0% (N=02) with GA between 31 weeks and 34 weeks and 6 days.

The characteristics of birth weight (BW) and gestational age (GA) of the infants who suffered some type of adverse event are shown in Table 1. It is noteworthy that, in 34 (28%) notifications, the BW and GA data were not filled out, being excluded from the analysis. Thus, Table 1 shows the characteristics of birth weight and gestational age of 113 occurrences.

Variable	n	%	% accumulated
Gestational Age Total	147	100%	100%
< 27W + 6D	44	30%	30%
28 – 30W + 6D	23	16%	46%

31 – 34W + 6D	18	12%	58%
35 – 36W + 6D	9	6%	64%
> 37W	19	13%	77%
Not filled out	34	23%	100%
Birth Weight	Total	147	100%
< 1,000 g	57	39%	39%
1,000 g-1,499 g	17	12%	50%
1,500 g-1,999 g	7	5%	55%
2,000 g-2,499 g	0	0%	55%
2,500 g <=	32	22%	77%
Not filled out	34	23%	100%

Table 1. Descriptive Statistics of the Gestational Age and Birth Weight, NICU. Brasília (DF), Brazil, 2015.

The mean weight obtained was 1,443.94 grams, with a standard deviation of 927.3. The minimum weight recorded was 530 g and the maximum was 3,720 g. The median indicated that half of the sample has a birth weight below 990 g.

Regarding gestational age, the mean was 30 weeks and 4 days, with a standard deviation of 36. The lowest gestational age was 23 weeks and 4 days, with a maximum of 41 weeks and 2 days. The median indicated that 50% of the observations had a gestational age below 29 weeks.

Regarding the notification shift, 46% (68) occurred during the morning, 31% (46) during the night and 22% (33) in the afternoon.

Inferential analyses were performed in order to verify the influence of birth weight, gestational age and notification shift on the severity of the adverse event occurred.

The distribution of BW in each classification range of the adverse event is shown in Figure 3.

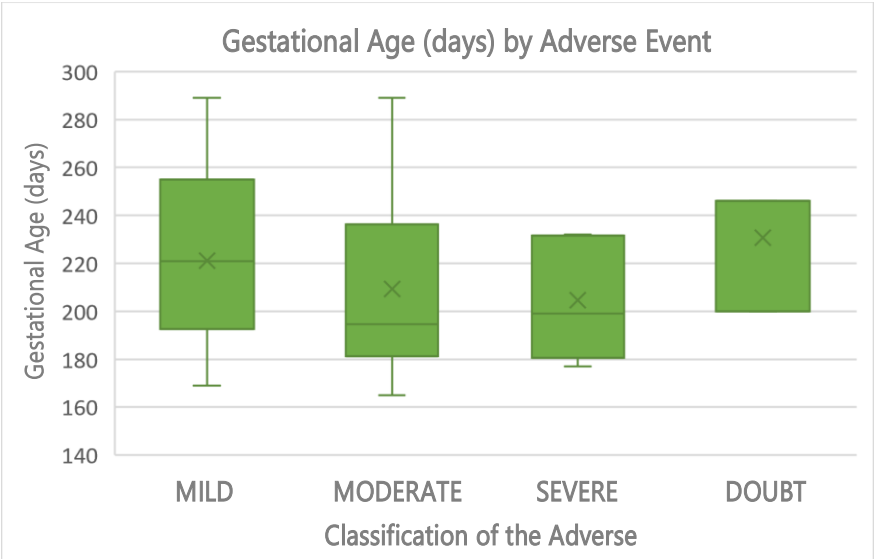


Figure 3. Distribution of birth weight by classification of the degree of harm of the Adverse Event, NICU

In order to verify the influence of the BW variable on the severity of the adverse event that occurred, the following hypothesis was developed to be tested: H_0 = Mean birth weight (g) is the same across the AE levels. A level of significance of 0.05 was adopted. When applying the Kruskal Wallis test, we obtained a p-value of 0.1565, not rejecting the hypothesis established. Thus, it is considered that BW does not influence the severity of the adverse event, as well as the mean of BW across all the AE classifications is the same.

Figure 4 represents the distribution of the various GAs according to the classification of the AE.

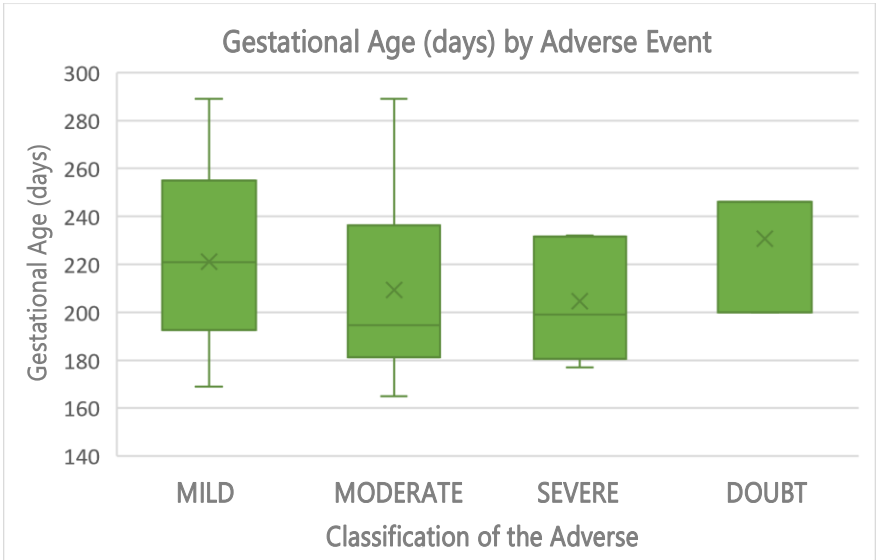


Figure 4. Distribution of gestational age by classification of the degree of harm of the Adverse Event, NICU.

Brasília (DF), Brazil, 2015.

For the GA variable, the Kruskal Wallis test was also performed and a significance level of 0.05 was considered, testing the following hypothesis: H_0 = The mean gestational age (in days) is the same across the AE levels. With the analysis, we obtained a p-value of 0.1499. Thus, it is considered that GA does not influence the severity of the adverse event, as well as the mean gestational age across all AE classifications is the same.

Regarding the notification shift, the Chi-Square test of Independence was applied and a significance level of 0.05 was considered. The p-value obtained was 0.224. Thus, we do not have enough evidence to associate the occurrence shift and classification of the adverse event variables.

Regarding data quality in this study, the following scores were obtained: 31.9% (N=47), regular; 61.2% (N=90), bad; and 6.8% (N=10), very bad. No forms with excellent or good scores were filled out.

DISCUSSION

Data analysis showed that approximately 70% of the patients seen in the unit under study suffered some type of adverse event. HAIs occurred in 45.6% of the patients seen, with emphasis on primary bloodstream infection. In numbers, the population most affected was preterm infants and babies with BW < 2,500 g. The occurrence of AEs related to mechanical ventilation, central access and skin lesions was related to the range of <http://www.ufpe.br/revistaenfermagem/>

GA < 30.6 weeks and BW < 1,500 g, that is, premature and very low weight infants. Unplanned extubation was the most notified event. Moderate events were the ones that occurred the most, mainly affecting infants with birth weight below 999 g and gestational age below 27 weeks and 6 days. No statistically significant relationships were found to relate birth weight, gestational age and notification shift to the severity of the adverse event.

The high rate of occurrence of adverse events in the NICU is reported by other studies,^{2, 8, 11, 15-6} corresponding to the findings in this search. Neonatal Intensive Care Units have a greater risk for the occurrence of AEs due to their complexity, the diversity of devices necessary for continuous monitoring of the patient, and the variety of procedures necessary for maintaining life.^{2, 11, 15} A review study showed that the main factors that contribute to the occurrence of adverse events in care are related to work overload, fragility of the health system, staff shortages, non-compliance with institutional rules and routines, lack of leadership and adequate Nursing supervision, and professional inexperience. Relationship problems among the multidisciplinary team members and communication failures also contribute to the occurrence of errors,¹⁷ the latter being identified as one of the main contributors to the occurrence of adverse events.¹⁰

The high rates for the occurrence of AEs and the possible relationships with the specificity of neonatal care, work overload and the deficit of workers described in the literature are also found in the study scenario, configuring themselves as important points of interventions aimed at preventing the occurrence of AEs. The development of a patient safety culture and the establishment of effective barriers in the direct prevention of the occurrence of AEs are essential for improving health care quality. Premature infants and newborns with birth weight below 2,500 g were those who most suffered adverse events. Such characteristics are described as risky, in addition to prematurity contributing to prolonged hospitalization, with greater exposure to potential risks and dangers.^{8, 15} The maintenance of the profile of adverse events found can be related to the specificity of neonatal intensive care, which is permeated by immaturity and the excessive handling of the multidisciplinary team.⁸ The characterization of the most affected population brings subsidies for the construction of targeted and more effective patient safety measures, which could minimize the occurrence of adverse events.

The adverse events that occur in neonatal intensive care units are related to errors or failures in drug use, infections associated with health care, skin lesions, mechanical ventilation and intravascular catheters.^{2, 8, 11} It is perceived that targeting actions to prevent such events are necessary to obtain assistance with the fewest possible failures.

Unplanned extubation (UE) was the AE most notified in this study, and was highlighted due to the short-term and long-term consequences for the newborn. UE can be defined as any unexpected extubation or performed at an unplanned time, due to the patient's agitation or to the handling of the team. The risk for this

incident to occur in the NICU is higher, due to the younger age of the NBs, the reduction in sedation, the increased number of procedures performed, and the handling profile of the multiprofessional team, especially in the care of very low birth weight preterm NBs. Among the complications resulting from UE can be respiratory failure, increased duration of mechanical ventilation and length of hospital stay, hypoxia, delayed neuropsychomotor development and increased risk of infection.^{20, 8} Safety measures must be adopted to prevent the occurrence of unplanned extubation, since the possible consequences can directly interfere with the development and growth of the newborn.

In this study, 45.6% of the total hospitalized patients had HAIs. Infections of hospital origin in premature and very low birth weight NBs can predispose to sepsis, due to the immaturity and fragility of the immune system of this population.^{2, 20} In Brazil, it is estimated that 60% of infant mortality occurs in the neonatal period, one of the main causes being neonatal sepsis. Other incidents also contribute to the risk of infections, such as problems with mechanical ventilation (UE and extubation failure) and loss of vascular catheter.^{8, 20} HAIs also foment the occurrence of temporary harms or prolonged hospital stay, in addition to being directly related to the mortality rate.^{8, 21} Infection is recognized as an avoidable adverse event due to failures at several care levels, and it is essential to provide the team with a sense of responsibility to motivate change. Actions that control the HAIs, as well as continuing education of the health professionals, are configured as incentives for conscious and safe attitudes, necessary for reducing HAI rates.

As far as data quality is concerned, we notice non-filling out of important fields, such as birth weight and gestational age. Data from self-reporting systems often have limitations, due to incompleteness and possible biases in the AE description.⁸ This may come to reflect a fragile safety culture, as the professionals did not interpret the correct completion of the notification form as important, noting the need to strengthen the patient safety fundamentals in the unit under study.

The principles of patient safety and safe practices must be carried out at all times by the health professionals.^{21, 10} In order for health care to take place with quality, a number of aspects is required, such as: strategies for continuing education and team training; effective communication among the professionals, adequacy of service infrastructure; adequate provision of specialized and sufficient materials, equipment and human resources, as well as adequate notification of AEs and a of non-punitive patient safety culture.^{2, 19, 21-2} In the context of neonatology, the involvement of the family as a companion and inspecting agent is essential for preventing the occurrence of adverse events and strengthening the safety culture.^{2, 21-2}

The study has as important limiting factors the poor data quality found in the adverse events notification forms, as well as the possible occurrence of underreporting, which was not assessed. Other limitations are

related to the characteristics of the study, retrospective and cross-sectional, with no follow-up of patients, only obtaining a snapshot of a moment from the reality of the NICU. The presence of a report issued by the Hospital Infection Control Center (NCIH) is also an important bias, since data was not collected by the researcher.

The verification of patterns in the occurrence of adverse events in neonatal intensive care units assists in the development of strategies aimed at preventing the occurrence of AEs, in increasing quality of care, and in strengthening the neonatal patient safety culture. This study contributes to the consolidation of the occurrence patterns of adverse events in the NICU, as well as to the characterization of risk factors.

It is suggested that a longitudinal study be carried out in the studied NICU, aimed at monitoring the outcome of each adverse event that has occurred, analyzing strategies adopted to prevent the occurrence of AEs, in addition to assessing the patient safety culture in the sector studied.

CONCLUSION

The identification of adverse events (AEs) occurring in the neonatal intensive care unit (NICU) revealed high rates for the occurrence of AEs. Analyzing the AEs, it was verified that preterm infants and babies with low birth weight are more likely to suffer AEs, but no statistically significant relationship was found between birth weight, gestational age and notification shift with the severity of the AE. Regarding the classification of such events, the occurrence of moderate events was predominant, which mainly affected infants with extremely low birth weight and extremely premature babies.

The findings corroborate the literature, contributing with diverse evidence for the development of strategies to improve quality of care and the development of patient safety in the NICU, aiming at reducing morbidity and mortality. Elaborating care protocols with neonates using mechanical ventilation, measures to prevent HAIs, and activities that make health professionals aware of the importance for the correct notification of AEs, are examples of actions that can be based on this study.

CONTRIBUTIONS

All the authors contributed equally in the design of the research project, data collection, analysis and discussion, as well as in content writing and critical review with intellectual contribution, and in approving the final version of the study.

CONFLICT OF INTERESTS

Study prepared without conflicts of interest.

REFERENCES

1. Ministério da Saúde (BR). Fundação Oswaldo Cruz. Agência Nacional de Vigilância Sanitária. Documento de referência para o Programa Nacional de Segurança do Paciente. Brasília: Ministério da Saúde; 2014a.
2. Gaíva MAM, Souza JS, Xavier JS. The Patient Safety in Neonatal Intensive Care Unit: a Literature Review. J Nurs UFPE online [Internet]. 2013 [cited 2020 jun 10]; 7: 928–64. Available from: <https://periodicos.ufpe.br/revistas/revistaenfermagem/article/view/11558>
3. World Health Organization. Final Technical Report for The Conceptual Framework for the International Classification for Patient Safety. 2009 [cited 2020 fev 03]. Available from: http://www.who.int/patientsafety/taxonomy/icps_chapter3.pdf.
4. Brasil. Ministério da Saúde. Portaria nº 529, de 1º de abril de 2013. Institui o Programa Nacional de Segurança do Paciente (PNSP). Diário Oficial [da] República Federativa do Brasil. 2013 abr; Seção 1. p. 43-46.
5. Agência Nacional de Vigilância Sanitária (BR). Nota Técnica GVIMS/GGTES/ANVISA Nº 01/2015 - Orientações gerais para a notificação de eventos adversos relacionados à assistência à saúde. 2015 [cited 2020 fev 03]. Available from: file:///C:/Users/loja/Downloads/NOTA_TECNICA_01_2015_GVIMS_NOTIFICAO_13_pdf_VERSO_FINAL.pdf.
6. Organização Pan-Americana da Saúde. Centro Latino-Americano de Perinatologia, Saúde da Mulher e Reprodutiva. Prevenção de infecções relacionadas à assistência à saúde em neonatologia. Montevideu: CLAP/SMR-OPS/ OMS, 2016 [cited 2020 fev 03]. (CLAP/SMR. Publicação Científica, 1613-03). Available from: <iris.paho.org/xmlui/bitstream/handle/123456789/34361/9789275719640-por.pdf?sequence=1&isAllowed=y>.
7. Agência Nacional de Vigilância Sanitária (BR). Serviços de atenção materna e neonatal: segurança e qualidade. Brasília: Agência Nacional de Vigilância Sanitária; 2014.
8. Lanzillotti L da S, de Seta MH, de Andrade CLT, Junior WVM. Adverse events and other incidents in neonatal intensive care units. Ciência e Saúde Coletiva. Associação Brasileira de Pós - Graduação em Saúde Coletiva [Internet]; 2015 [cited 2020 fev 03]; 20(3): 937–46. Available from: http://www.scielo.br/pdf/csc/v20n3/pt_1413-8123-csc-20-03-00937.pdf
9. Notaro KAM, Corrêa A dos R, Tomazoni A, Rocha PK, Manzo BF, Notaro KAM, et al. Safety culture of multidisciplinary teams from neonatal intensive care units of public hospitals. Rev Lat Am Enfermagem [Internet]. 2019 [cited 2020 Jan 21]; 27. Available from: https://www.scielo.br/pdf/rlae/v27/en_0104-1169-rlae-27-e3167.pdf
10. MAM Gaíva, JN Rondon, Jesus LN. Patient safety in intensive care unit newborn: perception of nursing team. Rev Soc Bras Enferm Ped [Internet]. 2017 [cited 2020 jun 10];17(1):14–20. Available from: <http://www.ufpe.br/revistaenfermagem/>

https://sobep.org.br/revista/images/stories/pdf-revista/vol17-n1/vol_17_n_1-artigo_original_2.pdf

11. Sousa BVN, Santana RR, Santos MS, Cipriano ESV, Brito CO, Oliveira EF. Repensando a segurança do paciente em unidade de terapia intensiva neonatal: revisão sistemática. *Cogitare Enferm* [Internet]. 2016 [cited 2020 fev 03]; 21(esp): 01-10. Available from: <https://revistas.ufpr.br/cogitare/article/view/45576/pdf>
12. Gerhardt TTE, Silveira DT. Métodos de pesquisa. 1ª ed. Porto Alegre, Brasil: Editora da UFRGS [Internet]; 2009 [cited 2020 jan 23]. Available from: <http://www.ufrgs.br/cursopgdr/downloadsSerie/derad005.pdf>
13. Mendes W, Travassos C, Martins M, Noronhas JC. Revisão dos estudos de avaliação da ocorrência de eventos adversos em hospitais. *Rev. Bras. Epidemiol* [Internet]. 2005 [cited 2020 fev 03]; 8(4): 393-406. Available from: <http://www.scielo.br/pdf/rbepid/v8n4/06.pdf>
14. Ministério da Saúde (BR). Resolução CNS/MS nº 466. Diretrizes e normas regulamentadoras para pesquisas envolvendo seres humanos. Brasília: Ministério da Saúde; 2012
15. Hoffmeister LV, de Moura GMSS, Macedo APM de C. Learning from mistakes: Analyzing incidents in a neonatal care unit. *Rev Lat Am Enfermagem* [Internet]. 2019 [cited em 12 fev 2020] ;27. Available from: http://www.scielo.br/pdf/rlae/v27/pt_0104-1169-rlae-27-e3121.pdf
16. Abu-El-Noor NI, Hamdan MA, Abu-El-Noor MK, Radwan AKS, Alshaer AA. Safety Culture in Neonatal Intensive Care Units in the Gaza Strip, Palestine: A Need for Policy Change. *J of pediatric nursing* [Internet]. 2017; 33:76-82. Available from: DOI:<https://doi.org/10.1016/j.pedn.2016.12.016>
17. Duarte S da CM, Stipp MAC, Silva MM da, Oliveira FT de. Eventos adversos e segurança na assistência de enfermagem. *Rev Bras Enferm* [Internet]. 2015 [cited 2020 jan 23];68(1):144–54. Available from: <http://www.scielo.br/pdf/reben/v68n1/0034-7167-reben-68-01-0144.pdf>
18. Oliveira PCR, Cabral LA, Schettino RC, Ribeiro SNS. Incidência e principais causas de extubação não planejada em unidade de terapia intensiva neonatal. *Rev. Bras. Ter. intensiva* [Internet]. 2012 [cited 2020 fev 03]; 24(3):230-235. Available from: <http://www.scielo.br/pdf/rbti/v24n3/v24n3a05.pdf>
19. Tomazoni A, Rocha PK, Ribeiro MB, Serapião LS, Souza S de, Manzo BF. Segurança do paciente na percepção da enfermagem e medicina em unidades de terapia intensiva neonatal. *Rev Gauch Enferm* [Internet]. 2017 [cited 2020 fev 03]; 38(1):e64996. Available from: <http://www.scielo.br/pdf/rgenf/v38n1/0102-6933-rgenf-1983-144720170164996.pdf>
20. Profit J, et al. "The Correlation Between NICU Safety Culture and Quality of Care." *J Patient Saf* [Internet]. 2020 [cited 2020 out 20]: 1-21. Available from: DOI: 10.1097/PTS.0000000000000546.

21. Silva ASC, Sousa LA, Callou DRS, Cardoso JN, Macêdo ISP, Feitosa UNS, Oliveira, CRT. Segurança do neonato na unidade de terapia intensiva: desafios da enfermagem. Braz J of Develop [Internet]. 2019 [cited 2020 fev 03]; 5(10): 21331-21355. Available from: <http://www.brjd.com.br/index.php/BRJD/article/view/4033/3823>
22. Kaleci E, Arslan FT. Patient Safety Related Implementations of Nurses Working in the Neonatal Intensive Care Unit and Related Factors. J Pediatr Res [Internet]. 2020 [cited 2020 out 19]; 7(1), 18-25. Available from: 10.4274/jpr.galenos.2019.00921

Correspondence

Marisa Utzig Cossul
E-mail: marisaa.cossul@gmail.com

Submission: 07/15/2020

Accepted: 02/16/2021

Copyright© 2021 Revista de Enfermagem UFPE on line/REUOL.



This is an open access article distributed under the CC BY 4.0 Attribution [Creative Commons Attribution-ShareAlike 4.0 International License](https://creativecommons.org/licenses/by/4.0/), which allows others to distribute, remix, adapt and create from their work, even for commercial purposes, as long as they give it due credit for the original creation. It is recommended to maximize the dissemination and use of licensed materials.