

RECONSIDERING PATIENT SAFETY AT NEONATAL INTENSIVE CARE UNITS: A SYSTEMATIC REVIEW

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ABSTRACT: The objective was to get to know adverse events and care practices for the purpose of patient safety at a Neonatal Intensive Care Unit. Systematic review using the following descriptors: Patient Safety; Intensive Care Units, Neonatal; Adverse events. Study developed between September 2015 and February 2016. Eighty-four articles were found in three databases between 2006 and 2015. After applying the screening and eligibility criteria, nine articles were selected. The analysis of the articles revealed that adverse events take place at the Neonatal Intensive Care Units, which are attributed to different factors. The actions mentioned to prevent the adverse events were continuing education, training and an increasing number of professionals, support from management, knowledge strengthening and team commitment. In conclusion, the most noteworthy adverse events were related to medication, respiratory infections and non-programmed extubations. The main factors contributing to error were excessive workloads, lack of professionals and resources and an unfavorable work environment.

DESCRIPTORS: Patient Safety; Intensive Care Units, Neonatal; Quality of Health Care.

REPENSANDO A SEGURANÇA DO PACIENTE EM UNIDADE DE TERAPIA INTENSIVA NEONATAL: REVISÃO SISTEMÁTICA

RESUMO: Objetivou-se conhecer eventos adversos e práticas assistenciais realizadas para segurança do paciente em Unidade de Terapia Intensiva Neonatal. Revisão sistemática utilizando descritores: *Patient Safety; Intensive Care Units, Neonatal; Adverse events*. Estudo realizado entre setembro de 2015 e fevereiro de 2016, encontrados 84 artigos, em três bases de dados, entre 2006 e 2015. Após critérios de triagem e elegibilidades, foram selecionados 9 artigos. A análise dos artigos revelou eventos adversos presentes nas Unidades de Terapia Intensiva Neonatal, atribuídos a diversos fatores. As ações citadas para prevenção dos eventos adversos foram educação continuada, treinamentos e aumento dos profissionais, apoio da gestão, fortalecendo conhecimento e comprometimento da equipe. Conclui-se que os eventos adversos de maior destaque foram os relacionados às medicações, infecções respiratórias e extubações não programadas, cujos principais fatores contribuintes para o erro foram as cargas excessivas de trabalho, falta de profissionais e de recursos e o ambiente de trabalho desfavorável.

DESCRIPTORES: Segurança do paciente; Unidades de Terapia Intensiva Neonatal; Qualidade da Assistência à Saúde.

REPENSANDO LA SEGURIDAD DEL PACIENTE EN UNIDAD DE TERAPIA INTENSIVA NEONATAL: REVISIÓN SISTEMÁTICA

RESUMEN: La finalidad fue conocer eventos adversos y prácticas asistenciales efectuadas para seguridad del paciente en Unidad de Terapia Intensiva Neonatal. Revisión sistemática utilizando descriptores: *Patient Safety; Intensive Care Units, Neonatal; Adverse events*. Estudio desarrollado entre septiembre del 2015 y febrero del 2016, encontrando 84 artículos en tres bases de datos, entre 2006 y 2015. Tras la aplicación de los criterios de tamizaje y elegibilidades, fueron seleccionados 9 artículos. El análisis de los artículos reveló eventos adversos presentes en las Unidades de Terapia Intensiva Neonatal, atribuidos a diversos factores. Las acciones citadas para prevención de los eventos adversos fueron educación continuada, capacitaciones y aumento de los profesionales, fortaleciendo conocimiento y comprometimiento del equipo. En conclusión, los eventos adversos de mayor destaque fueron los relacionados a las medicaciones, infecciones respiratorias y extubaciones no programadas, cuyos principales factores contribuyentes al error fueron las cargas excesivas de trabajo, falta de profesionales y de recursos y el ambiente de trabajo desfavorable.

DESCRIPTORES: Seguridad del paciente; Unidades de Cuidado Intensivo Neonatal; Calidad de la Atención de Salud.

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● INTRODUCTION

Discussions about patient safety during hospitalization gained momentum after the publication of the American report "To err is human: building a safer healthcare system" in the year 2000, which appointed that, around the globe, millions of people are victims of injuries and death as a result of health practices^(1,2). Epidemiological studies in developed countries evidence that the environment, culture, relationships and complexity of the system culminate in countless errors and adverse events that could be avoided and end up compromising patient safety, causing sequelae and even deaths⁽³⁾.

Referring to patient safety in the context of Neonatal Intensive Care Units (NICUs) and relating it with the infants' particularities, the safety risks can be larger in this situation. In a study at the NICU of a Brazilian philanthropic hospital showed that, out of 218 infants admitted over five months, 183 (84%) were victims of adverse events (AEs) and the majority of more than one AE, with an average rate of 2.6 AEs per patient, during an average hospitalization of 13.5 days^(1,4). It should also be taken into account that adverse events may be underreported, and this can be attributed to several factors, such as: health professionals' lack of knowledge, neglect or even fear of sanctions.

Demonstrating concern with this situation, in 2004, the World Health Organization (WHO) created the World Alliance for Patient Safety, later called the "Patient Safety Program", aiming to organize the concepts and definitions about patient safety and to propose measures to reduce the risks and mitigate the AEs⁽⁵⁻⁷⁾. Thus, in Brazil, the Ministry of Health established the National Patient Safety Program (PNSP) in 2013, aiming to contribute to the qualification of care in all health institutions across the national territory, whether public or private, according to the priority granted to patient safety⁽⁸⁻⁹⁾. Beyond the knowledge inherent in the health practices, an environment is needed that motivates the professionals and grants appropriate support to accomplish the different procedures, which are essential for the recovery and promotion of the patients' health.

Patient safety at the NICUs is a delicate issue, revealing that different cultural factors need to be reconsidered as, although research indicates the main causes that interfere in safety, errors are still judged as professional incompetency, which entails resistance to report AEs. According to nursing and medical professionals, hospital management does not prioritize patient safety and does not provide for a work climate that motivates its promotion, making it difficult to establish such a climate at the different health institutions⁽¹⁾.

The health institutions are taking care of people going through disease, treatments and complex technologies, which requires efforts towards a patient safety culture system. Among these spaces, the NICUs stand out, as they treat children in the most vulnerable age of childhood, which can imply their survival and impose limitations in the development of their potential. In view of the importance of safer care, which contributes to improve the quality of work and the recovery of the client's health, studies are needed that expand this discussion.

In this context, this research aimed to understand the main adverse events and care practices developed for the sake of patient safety at NICUs.

● METHOD

A systematic review was undertaken to answer the following question: which are the main adverse events and the care practices developed for the purpose of patient safety at a neonatal intensive care unit?

The study was developed between September 2015 and February 2016. In the search for scientific evidence, the following descriptors were used: Patient Safety; Intensive Care Units, Neonatal; Adverse events; linked with the Boolean operators (AND, OR) to identify the articles in accordance with the research theme. The inclusion criteria were original articles published in the following databases: (BDENF), Medical Literature Analysis and Retrieval System Online (MEDLINE) and Scientific Electronic Library Online (SCIELO), between 2006 and 2015, which discussed the main adverse events at the NICUs and the patient safety practices to try and avoid them. Articles published before 2006, reviews,

experience reports and articles beyond the proposed objective were excluded, as they did not add information on the theme at the NICUs.

To select the studies, first, the titles and abstracts were read to assess the theme. Next, the articles were selected that fit into the inclusion criteria and objective established in this study. Finally, the articles were again assessed based on a full reading, with a view to a critical synthesis of the carefully selected studies. The main theme of all articles submitted to the analysis process is patient safety at Neonatal Intensive Care Units. The main results were critical summarized in response to the guiding question.

Figure 1 schematically represents these steps in accordance with the methodological recommendations of the “Preferred Reporting Items for Systematic Reviews and Meta” (PRISMA) Flow Diagram^(10,11).

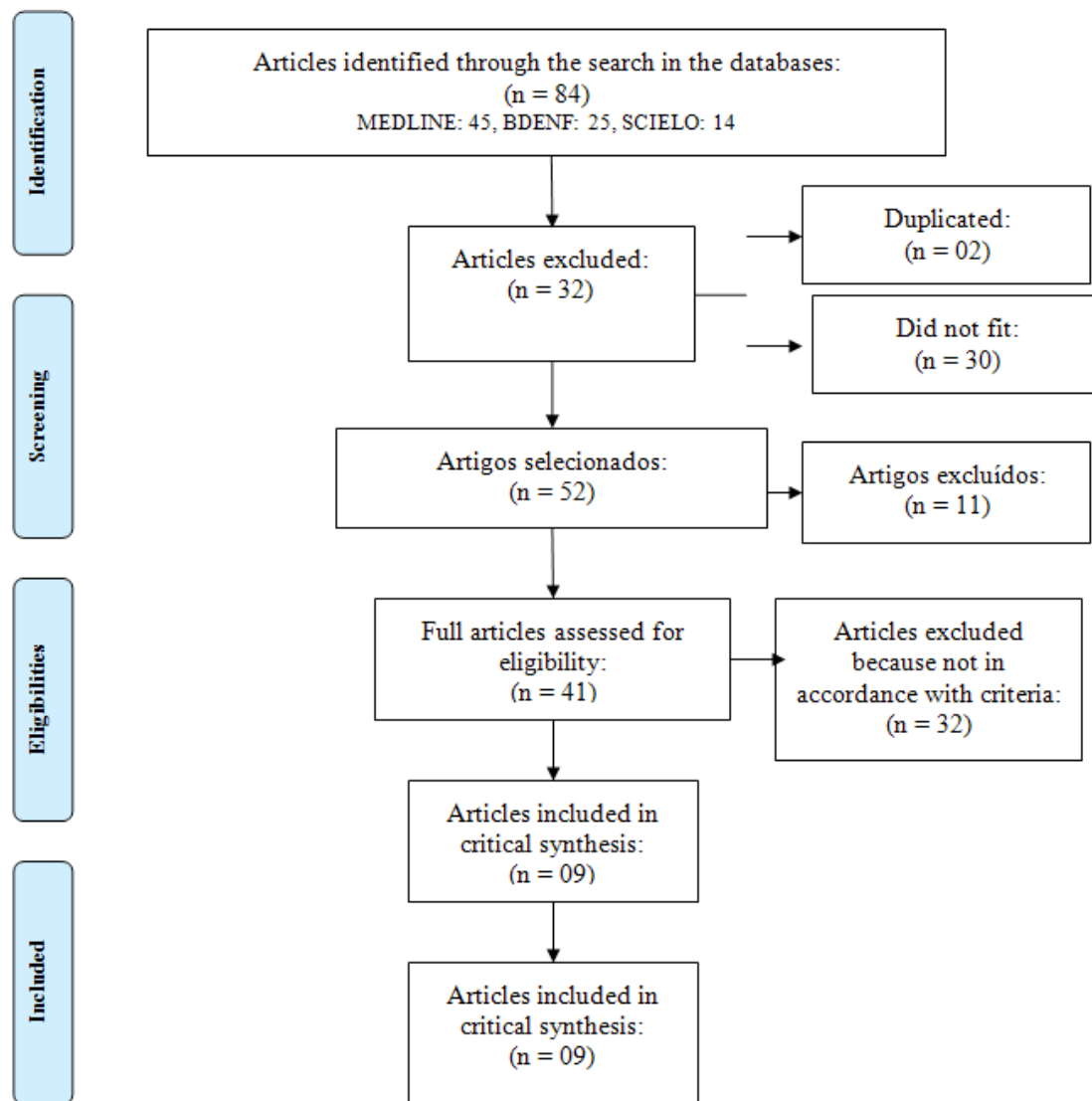


Figure 1 – Flow chart of the identification, screening, eligibility and inclusion methods of the articles according to the PRISMA Flow Diagram^(10,11). Cachoeira, BA, Brazil, 2016

● RESULTS

Among the nine articles selected, three were taken from MEDLINE, being two from international journals in English (articles No. 02 and 03), one from BDENF and five from SCIELO. The most prevalent journal was *Jornal de Pediatria* with two publications (articles 05 and 06). In addition, the articles are displayed in order of publication, with more publications in 2014 and 2015.

Table 1 – Identification of articles, authors, title, database, journal and year of publication. Cachoeira, BA, Brazil, 2016

Nº	Authors	Title	Base	Journal/Year
1	Ventura, Claudiane Maria Urbano; Alves, João Guilherme Bezerra; Meneses, Jucille Do Amaral.	Eventos adversos em Unidade de Terapia Intensiva Neonatal ⁽⁴⁾	MEDLINE	Revista Brasileira de Enfermagem/2012
2	Merkel, Lori; Beers, Kimberly; Lewis, Mary M; Stauffer, Joy; Muijsce, Dennis J; Kresch, Mitchell J.	Reducing Unplanned Extubations in the NICU ⁽¹²⁾	MEDLINE	Pediatrics/2014
3	Samiee-Zafarghandy, Samira; Raman, Sudha R; Anker, John N. van den McHutchison, Kerstin; Hornik, Christoph P; Clark, Reese H; Smith, P. Brian.	Safety of milrinone use in neonatal intensive care units ⁽¹³⁾	MEDLINE	Early Human Development/ 2015
4	Barbosa, Maria Teresa de Souza Rosa; Alves, Valdecyr Herdy; Rodrigues, Diego Pereira; Branco, Maria Bertilla Lutterbach Riker; Souza, Rosângela de Mattos Pereira de; Bonazzi, Vera Cristina Augusta Marques.	Quality indicators in support of intravenous therapy in a university hospital: a contribution of nursing ⁽¹⁴⁾	BDENF	Revista de Pesquisa: Cuidado é Fundamental Online/2015
5	Ferreira, Janita; Bouzada, Maria CF; de Jesus, Lenize A; Cortes, Maria da Conceição Werneck; Armond, Guilherme A; Clemente, Wanessa T; Anchieta, Lêni M; Romanelli, Roberta MC.	Evaluation of national healthcare related infection criteria for epidemiological surveillance in neonatology ⁽¹⁵⁾	SCIELO	Jornal de Pediatria/2014
6	Filho, Fernando Lamy; Silva, Antônio AM; Lopes, José MA; Lamy, Zeni C; Simões, Vanda MF; Santos, Alcione M.	Staff workload and adverse events during mechanical ventilation in neonatal intensive care units ⁽¹⁶⁾	SCIELO	Jornal de Pediatria/2011
7	Oliveira, Poliana Cardoso Ribeiro De; Cabral, Laura Alves; Schettino, Renata De Carvalho; Ribeiro, Simone Nascimento Santos.	Incidência e principais causas de extubação não planejada em unidade de terapia intensiva neonatal ⁽¹⁷⁾	SCIELO	RevBras Ter Intensiva/2012
8	Tomazoni, Andréia; Rocha, Patrícia Kuerten; Kusahara, Denise Miyuki; Souza, Ana Izabel Jatobá de; Macedo, Taise Rocha.	Avaliação da cultura de segurança do paciente em terapia intensiva neonatal ⁽¹⁾	SCIELO	Texto Contexto Enferm. Florianópolis/2015
9	Tomazoni, Andréia; Rocha, Patrícia Kuerten; Souza, Sabrina de; Anders, Jane Cristina; Malfussi, Hamilton Filipe Correia de.	Patient safety culture at neonatal intensive care units: perspectives of the nursing and medical team ⁽¹⁸⁾	SCIELO	Revista Latino-Americana de Enfermagem (RLAE)/2014

The following types of studies and approaches were used (Table 2): prospective (three), retrospective (two), descriptive (four) and cross-sectional (three). It should be highlighted that six articles (66.6%) used more than one type of methodological approach. As to the data collection tool, the “Hospital Survey on Patient Safety Culture” (HSOPSC) was used in articles 08 and 09. This tool consists of nine sections, listed from A to I, adding up to 42 items, and is structured in 12 safety culture dimensions, assessed in the individual, service and hospital contexts, assessing the professionals’ level of agreement with aspects of the patient safety culture through a Likert scale.

Table 2 – Identification of articles, type of study, objective, results/conclusion. Cachoeira, Bahia, Brazil, 2016

Nº	Type of study	Objective	Results/Conclusion
1	Observational, prospective study.	Determine the frequency of AEs, applying the American “trigger instrument” method at an NICU of a developing country.	The most frequent adverse events were: thermoregulation disorders, glucose disorders, infection (HRI), non programmed extubation. Hence, the incidence of AEs at this NICU is high, especially among infants with very low birth weight.
2	Prospective	Reduce unplanned extubations, reaching one unplanned extubation per 100 days of extubation.	Through the development of a package of potential best practices implemented in successive Plan-Do-Study-Act (PSDA) cycles that included: 1st staff education about the frequency and importance of unprogrammed extubations, prioritizing the safety of the endotracheal tube, where nurses and physiotherapists should regularly assess the safety tape of the endotracheal tube; 2nd placement of colored cards to alert on airways at the headrest of each intubated and mechanically ventilated patient; 3rd use of a commercial device to protect the tube; 4th analysis of any unplanned extubation by a multidisciplinary team; 5th cycle resulted in a significant reduction in the unplanned extubation rate.
3	Retrospective analysis	Determine the safety of milrinone therapy among children at a neonatal intensive care unit.	In the AEs observed during the exposure to milrinone, about 42% of the patients at the NICU presented at least one. Hypotension, commonly reported at the start of milrinone therapy, and thrombocytopenia were the most reported clinical and laboratory AEs. Thus, the safety, dosage and efficacy of this drug in children can be determined in prospective clinical trials.
4	Non-experimental descriptive	Understand the quality indicators of intravenous therapy at the Neonatal Intensive Care Unit of a university hospital.	The installation of intravascular catheters is one of the most frequent interventions in infants hospitalized at NICUs. These research results evidence that repeated puncture events contributed to the infants’ exposure to pain and to AEs like phlebitis, inflammation, infection and extravasation of fluids, which can harm the venous network, thus representing inappropriate care. ON average, 1.3 catheters were installed for an average 2.1 puncture events per infant. Thus, the professionals should be trained and equipped in their care actions for the infants, favoring their safety concerning equipment maintenance errors.
5	Cross-sectional	Assess the application of national criteria for the reporting of healthcare related infections (HRI) in Neonatal Units and compare them with the criteria proposed by the National Health Care Safety Network (NHSN).	882 patients were monitored at the Neonatal Progressive Care Unit (NPCU), where about 330 infants presented at least one episode of reported infection. In total, 552 episodes of HRI were reported, independent of the criterion, with an infection density (ID) of 27.28 infections/1000 patient-day. Sepsis was the most frequent infectious complication with 58.3%, followed by skin infections (moniliasis) 15.1%, conjunctivitis 6.5% and pneumonia 6.1% as the most frequent infections.
6	Prospective cohort	Investigate a possible association between the workload of health professionals and intermediary adverse events, such as accidental extubation, obstruction of the endotracheal tube and accidental disconnection of ventilator circuit during neonatal mechanical ventilation at high-risk neonatal units.	543 infants were studied during six months, when 117 AEs related to mechanical ventilation occurred. The numbers of disconnections of ventilator circuits, accidental extubations and endotracheal tube obstructions, expressed in percentages of all patients assessed, corresponded to 9.98, 5.37 and 4.61%, respectively. The team in each shift consisted of 5.28 auxiliary nurses, 1.45 nurses and 3.54 physicians on average. The adjusted analysis demonstrated an association between the number of infants classified according to the Care Demand (RCDCs) per nurse or auxiliary and adverse events: the larger the proportion between the number of RCDCs and the number of nurses or auxiliary nurses, the higher the risk of AEs. The hypothesis of an association (...)

Nº	Type of study	Objective	Results/Conclusion
6			(...) between excessive work burden and AES in neonatal mechanical ventilation was confirmed in this study.
7	Retrospective and descriptive	Determine the incidence and the main causes of unplanned extubations in infants at the neonatal intensive care units of Hospital Sofia Feldmanin Belo Horizonte (MG).	Fifty-four unplanned extubations (UPE) took place, with an observed incidence of 1.0 UPE for every 100 days of intubation. The main causes of UPE analyzed were: agitated patient (30.8%); inappropriate patient handling (17.9%), during some procedures (blood collection, dressing change, lumbar puncture, x-ray and when placing the infant in the bed); inappropriate fixation of ETT (17.9%); inappropriate positioning of ETT (6.6%); infant badly positioned in the bed (9%); others, such as change of ETT fixation and vomiting (3.9%); no report (2.6%), and badly positioned MV circuit (1.3%). On average, 1.44 causes of UPE were registered for each event. To reduce the incidence of UPE, the assessment and quality of continuous care for the infants hospitalized at these NICUs, mainly through surveillance of clinical signs of possible UPE event and the adoption of measures to reduce the causes of this event.
8	Descriptive-exploratory, quantitative cross-sectional survey	Analyze the patient safety culture from the perspective of the nursing and medical teams at public hospitals in Florianópolis.	Twelve dimensions of the safety culture were analyzed, classifying the dimensions in strengths or critical areas. Mainly the dimensions "expectations and actions of the supervisor/head for patient safety promotion" (61%) and "Organizational learning – continuous improvement" (59%) demonstrate advances in the patient safety culture and have the potential to become strengths at the NICUs. The percentages of positive answers indicate that the actions of the supervisor/head and organizational learning are positive factors of the patient safety culture. In addition, the second critical area highlighted was "support from hospital management for patient safety". According to the study subjects, there is little commitment and support from management with regard to patient safety. The high work burden due to the insufficient staff numbers indicates risks for patient safety.
9	Descriptive-exploratory, quantitative cross-sectional survey	Verify the assessment of the patient safety culture according to the work burden and experience of nursing and medical teams at Neonatal Intensive Care Units.	When analyzing the burdens of the team for the safety score, a statistical difference was observed between very good and regular. In that sense, the nursing technician and the physician chose the concept very good most frequently (24 and 19%, respectively). The nurses and auxiliary nurses considered these two options of patient safety concepts less frequently. As the professionals gained experience, at the institution and at the NICU, they chose less positive concepts. Concerning the reporting of events, the professionals who chose to report fewer events had more experience. As regards the functions, the technicians and physicians chose none or between 1 and 2 events most frequently.

● DISCUSSION

The search for quality in health services is essential and the movements in favor of patient safety should be a priority route towards appropriate care delivery free from damage. Nevertheless, addressing quality in health is not an easy task, mainly in the hospital context as, for high-quality, safe and error-free care to be delivered, a range of aspects is needed, such as: suitability of service infrastructure, service articulation involving the provision of material, equipment, specialized human resources; and the reporting of AEs is fundamental. The analysis of the selected articles revealed a range of AEs at the NICUs, which makes it difficult to implement tactics to reduce the contributing factors⁽¹⁹⁾.

Article one mentions that the main AEs are thermoregulation disorders, glucose disorders, respiratory failure and unplanned extubation (UPE). The incidence rate of AEs at this NICU is high, especially among infants of very low birth weight⁽⁴⁾. In another study, it is evidenced that the most frequent types of incidents at NICUs are related to errors in medication use, healthcare-associated infection, cutaneous injury, mechanical ventilation and intravascular catheters⁽²⁰⁾, similar to the research findings.

About medication use, article three describes that 42% of the patients at the NICU studied presented at least one AE in cases of exposure to milrinone, the main AEs being hypotension and thrombocytopenia⁽¹³⁾. In another study developed in the interior of the State of São Paulo in 2012, involving nurses, it was verified that the factors that contribute to medication errors are related to work overload, lack of attention, lack of preparation or bad professional preparation, unreadable prescription, lack of professionals, care automation, lack of planning, disinterest in work and inappropriate physical environment. For these reasons, it is essential that the units have not only systemized services, focused on the organization of care, but also policies in favor of occupational health, as the work burden and deficient conditions and organization of health work can contribute to the occurrence of AEs⁽²¹⁾.

Studies have been undertaken and strategies have been defined to improve the patient safety, such as the need for continuing education, team training, increased number of employees to avoid the work overload; better organization of physical environmental and service standardization; better readability of medical prescriptions and non-punishment are fundamental to improve care in general⁽²¹⁾.

Concerning the above and highlighting the importance of continuing education, in a study developed in 2014 at three units of a teaching hospital in the South of Brazil, it is emphasized that investigating AEs permits the establishment of educative actions through in-service education, by means of technical as well as higher education courses. As the PNSP suggests the inclusion of safety contents in professional education processes, the scope of safety teaching needs to be expanded since education⁽²²⁾.

Article seven, which aimed to determine the incidence and main causes of UPE in infants, appoints that the observed incidence of this phenomenon is 1.0 UPE for every 100 days of intubation. The main causes analyzed were agitation and inappropriate handling of the patient while executing some procedures, inappropriate fixation and positioning of the endotracheal tube (ETT), among others. Therefore, according to the study, measures need to be adopted to reduce this event⁽¹⁷⁾. In the same perspective, article 02 presents a range of practices that can be implemented to diminish the UPE, such as staff education, the frequency and importance of UPE, prioritizing ETT safety, the placement of colored cards to alert on airways at intubated and/or mechanically ventilated patients' headrest, use of a commercial device to protect the tube and the analysis of any UPE by a multidisciplinary team. These measures are fundamental to significantly reduce the UPE rate, as described in the study mentioned⁽¹²⁾.

Due to their complexity, the NICUs end up presenting a greater probability of AEs, whether due to the diversity of devices needed for the continuous monitoring of the patient or to the range of procedures accomplished to maintain the patients' life and health. In that perspective, a master's thesis developed at hospitals in Rio de Janeiro in 2013 describes that the risk is involved in any and all health care, ranging from the most simple to the most complex, entailing probabilities of correct actions, errors and/or incidents. Nowadays, as a result of the development of new technologies and scientific advances in health, the care systems end up getting more complex, thus strengthening the possibilities of incidents in the care process even further⁽²³⁾.

Article four shows that the placement of intravascular catheters is one of the most frequent interventions in infants hospitalized at NICUs, whose repeated puncture attempts contribute to the exposure to pain and to different AEs, such as phlebitis, inflammation, infection and fluid extravasation. The authors mention an average 2.1 attempts per infant. Thus, the professionals need to be trained in their actions involving the infants, positively affecting their safety⁽¹⁴⁾. Besides these measures, in a study developed at the Hospital de Clínicas de Porto Alegre, other important factors are mentioned that contribute to the patient's safety and the quality of care for hospitalized children: the health professionals' intentions related to effective communication, individual care, access and attendance of information about health conditions with a view to appropriate intervention planning, strict hand washing and equipment cleaning, teamwork with critical vision and common sense⁽²⁴⁾.

In that sense, to develop a patient safety culture, the first step is to acknowledge and identify the

error and consider it as a source of teaching. It is essential to deconstruct the concept that errors are individual. Instead, the focus needs to be expanded to the team as responsible for the AE. This theme could be discussed in the health professionals' curricula as a cross-sectional theme, as the production of knowledge and the increase of research on the theme will support the socialization and expansion of the theme in all contexts⁽²⁴⁾.

Articles six and nine, which associate team workload and AEs, demonstrate that this association truly exists, mainly in AEs related to neonatal mechanical ventilation, as article six affirms⁽¹⁶⁾. The assessment in article nine involves medical and nursing team professionals from the NICUs, evidencing that, as the professionals gain further experience, they start to choose less positive reactions to the patient safety culture⁽¹⁸⁾. As another integrative review describes, including articles from the Virtual Nursing Library published between 2004 and 2012, patient safety is a theme that involves past facts and continues to challenge the researchers nowadays, despite scientific advances. To guarantee quality care, the health professionals need to adopt a holistic care view, prioritizing patient safety, considering not only the care aspects, but also education and research aspects. Professional education and training and research will certainly favor the disclosure of the patient safety culture, aiming to reduce the AEs and the unsafe practice that jeopardize the patients and professionals' health to a maximum⁽²⁵⁾.

● CONCLUSION

This review evidenced a range of AEs present at the NICUs. Among these, the events that stood out were related to medication, respiratory infections and unprogrammed extubations. Concerning the main factors contributing to error, the articles highlighted excessive workloads, lack of professionals, lack of physical and material resources and an unfavorable work environment, factors present in most Brazilian public hospitals. Making the theme even more important. The actions cited to prevent the AEs were continuing education, health team training, increased number of professionals and management support in all senses, strengthening the team's knowledge and commitment.

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