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Patient safety in the neonatal intensive care unit: nursing assessment according to the Donabedian model

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Patient safety in the neonatal intensive care unit: nursing evaluation according to the Donabedian model

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ABSTRACT

Objective: To evaluate patient safety in the neonatal intensive care unit, according to the Donabedian model, considering the performance of the nursing team.

Method: Cross-sectional study. The sample consisted of 28 nursing professionals. Data collection was carried out through systematic observation, performed by two independent evaluators, using two instruments: the Patient Safety Assessment Checklist in the Neonatal Intensive Care Unit, which includes the dimensions of Structure, Processes, and Outcomes; and the Graphic Protocol. Descriptive statistics were applied for analysis, and the Kappa coefficient was calculated.

Results: The Kappa coefficient indicated a perfect degree of agreement between the evaluators (k=1). The overall assessment showed a conformity rate of 86.48%. The Structure category obtained 88.46%; Process reached 82.69%; and Outcome, 85.71%. The main deficiencies are concentrated in the dimensions of the care process, such as patient identification, communication with the family, and prevention of infections and falls.

Conclusion: The Neonatal Intensive Care Unit was classified as a provider of partially safe care, with greater compliance in the Structure category, followed by the Outcome category, and lower performance in the Process category, highlighting weaknesses in the execution of care practices.

Descriptors: Patient Safety; Infant, Newborn; Intensive Care Units, Neonatal. Nursing, Team. Observational Study. Outcome and Process Assessment, Health Care.

RESUMO

Objetivo: Avaliar a segurança do paciente na unidade de terapia intensiva neonatal, segundo o modelo de Donabedian, considerando a atuação da equipe de enfermagem.

Método: Estudo transversal. A amostra foi composta por 28 profissionais de enfermagem. A coleta de dados ocorreu por meio da observação sistemática, realizada por duas avaliadoras independentes, utilizando dois instrumentos: Checklist de Avaliação da Segurança do Paciente na Unidade de Terapia Intensiva Neonatal, que contempla as dimensões Estrutura, Processos e Resultados; e o Protocolo Gráfico. Para a análise, foram aplicadas estatísticas descritivas e calculado o coeficiente Kappa.

Resultados: O coeficiente Kappa indicou grau de concordância perfeita entre os avaliadores (*k*=1). A avaliação global evidenciou percentual de 86,48% de conformidades. A categoria Estrutura obteve 88,46%; Processo alcançou 82,69%; e Resultado, 85,71%. As principais deficiências concentram-se nas dimensões de processo assistencial, como identificação do paciente, comunicação com a família e prevenção de infecções e quedas.

Conclusão: A Unidade de Terapia Intensiva Neonatal foi classificada como prestadora de cuidado parcialmente seguro, com maior conformidade na categoria Estrutura, seguida pela categoria Resultado, e menor desempenho no Processo, evidenciando fragilidades na execução das práticas assistenciais.

Descritores: Segurança do paciente; Recém-nascido; Unidades de terapia intensiva neonatal; Equipe de enfermagem; Estudo observacional; Avaliação de processos e resultados em cuidados de saúde.

RESUMEN

Objetivo: Evaluar la seguridad del paciente en la unidad de cuidados intensivos neonatales, según el modelo de Donabedian, considerando el desempeño del equipo de enfermería.

Método: Estudio transversal. La muestra estuvo compuesta por 28 profesionales de enfermería. La recolección de datos se realizó mediante observación sistemática, llevada a cabo por dos evaluadores independientes, utilizando dos instrumentos: la Lista de

Verificación de Evaluación de la Seguridad del Paciente en la Unidad de Cuidados Intensivos Neonatales, que incluye las dimensiones de Estructura, Procesos y Resultados; y el Protocolo Gráfico. Se aplicaron estadísticas descriptivas para el análisis y se calculó el coeficiente Kappa.
Resultados: El coeficiente Kappa indicó un grado perfecto de acuerdo entre los evaluadores (k=1). La evaluación general mostró una tasa de conformidad del 86,48%. La categoría Estructura obtuvo el 88,46%; Proceso alcanzó el 82,69%; y Resultado, el 85,71%. Las principales deficiencias se concentran en las dimensiones del proceso de atención, como la identificación del paciente, la comunicación con la familia y la prevención de infecciones y caídas.
Conclusión: La Unidad de Cuidados Intensivos Neonatales fue clasificada como proveedora de atención parcialmente segura, con mayor cumplimiento en la categoría de Estructura, seguida de la categoría de Resultado, y menor desempeño en la categoría de Proceso, lo que pone de manifiesto deficiencias en la ejecución de las prácticas de atención.
Descriptores: Seguridad del Paciente; Recién Nacido; Unidades de Cuidado Intensivo Neonatal; Grupo de Enfermería; Estudio Observacional; Evaluación de Procesos y Resultados en Atención de Salud.

INTRODUCTION

Neonatal Intensive Care Units (NICUs) are high-tech environments[1], designed for the care of extremely vulnerable newborns (NB), which requires a high level of expertise from the nursing team[2]. In these services, patient safety is a central component of care, defined as the reduction, to the minimum possible extent, of avoidable harm associated with care, through continuous processes of identification, analysis and mitigation of adverse events (AE) [3].

It is estimated that at least one adverse event occurs in 50.0% of newborns admitted to NICUs, with adverse drug reactions (40.8%) being the leading causes of morbidity and mortality in this group[4]. Given this magnitude, the World Health Organization (WHO) announced “Safe care for every newborn and every child” as the theme for World Patient Safety Day 2025, aiming to increase global awareness of safety risks in pediatric and neonatal care in all healthcare settings, emphasizing the specific needs of children, families and caregivers[5].

In the neonatal context, patient safety is a multidimensional phenomenon, influenced by structural factors, such as resource availability, staffing levels and environmental conditions[6], and by procedural aspects, including interprofessional communication, adherence to protocols and safety culture[7]. These components are directly linked to nursing practice, which acts at the interface between service organization and direct care of the newborn[8]. From this perspective, nursing has a strategic position, since it is involved in

continuous surveillance, the execution of procedures and the coordination of care, contributing decisively to the prevention and early detection of risks[9].

In many NICUs, there is a scarcity of information on patient safety[7], and research addressing this phenomenon comprehensively is limited[10]. Although it is an intrinsically complex environment, marked by the interaction between structure, care processes and clinical outcomes, studies with fragmented approaches predominate, focusing on specific dimensions, such as professional skills, physical environment or isolated quality indicators. This limitation compromises the understanding of neonatal care as a complex system, by not considering the experience of care, along with other domains of quality[11].

Therefore, it is necessary to use validated and reliable instruments to assess patient safety in the NICU, sensitive to its specificities, considering all its complexity and capable of contributing to the continuous improvement of the quality of care[7]. Health Quality Assessment (HQA) stands out as a relevant strategy, as it allows the identification of weaknesses in care processes, the monitoring of service performance and the direction of nursing interventions aimed at reducing risks.

Among the available references, the Donabedian model is the most widely used internationally[12], being considered by the WHO an appropriate structure to evaluate and improve the quality of care[13]. It is an investigation that monitors the performance of services and verifies compliance with acceptable standards[14]. The model is composed of three categories: structure (physical, human and organizational resources), process (care actions performed) and outcome (clinical outcomes such as discharge or death)[12].

Considering that, despite extensive research, there is still no consensus on the factors that influence the quality of care in the NICU and that the complexity of care makes isolated approaches insufficient, highlighting gaps resulting from fragmented analyses and the limited adoption of integrated models[10], this investigation advances by adopting Donabedian's framework to analyze the safety of neonatal care in a coordinated way between structure, process and outcome, with emphasis on nursing practice. From this theoretical-methodological framework, the following research question was formulated: how is the safety of newborns admitted to a neonatal intensive care unit configured? Thus, the present study aimed to evaluate patient safety in the NICU, according to Donabedian's model, considering the performance of the nursing team.

METHOD

This is a cross-sectional, structured, and self-reported study, in accordance with the recommendations of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.

The study was conducted in the NICU of a regional hospital located in the inland of the state of Piauí, Brazil. This is a medium- to high-complexity general hospital, with services primarily provided through the Unified Health System (SUS). The institution offers outpatient, inpatient, emergency, and diagnostic and therapeutic support services. In 2023, it had 745 beds catalogued in the National Registry of Health Establishments (CNES) (citation omitted to avoid compromising peer review).

The NICU at this hospital was inaugurated in 2017 and has 10 beds dedicated to the care of high-risk newborns from the southern and southwestern regions of Piauí, as well as from surrounding municipalities in the state of Maranhão. Its implementation aimed to reduce travel to the capital, Teresina, and expand specialized neonatal coverage in the interior of the state. The unit has a multidisciplinary team of 48 professionals who work directly with patients, including a nursing coordinator, six nurses, 28 nursing technicians, six physicians, six physiotherapists, and a speech therapist (citation redacted to avoid compromising peer review). At the time of data collection, the institution participating in the study did not have a formally structured Patient Safety Center (PSC).

The study population consisted of the nursing staff, using a census sample. All eligible professionals were invited to participate, including one coordinating nurse, six assistant nurses, and 28 nursing technicians. The decision to include all available participants is justified by the small number of professionals in the investigated setting, being methodologically more appropriate for this context, as it eliminates the need for sample size calculation and reduces potential selection biases. However, because this study was conducted in a single service with a limited sample size, statistical generalization of the findings is not possible; they should be interpreted contextually and with potential for analytical transferability. The exclusive focus on the nursing staff is based on the fact that these professionals remain continuously with the critically ill newborn, being directly responsible for the execution, monitoring, and evaluation of care practices, especially those related to patient safety and the quality of neonatal care.

The inclusion criteria considered being a nursing professional for at least one year, in order to ensure minimum prior experience in neonatal care, and being included in the NICU work schedule during the data collection period. Seven professionals were excluded due to

absences for different reasons: two on maternity leave, four on vacation, and one in the process of institutional termination. Considering those who met the established criteria and were active during the data collection period, 28 professionals from the nursing team effectively participated in the study, corresponding to one coordinating nurse, four assistant nurses, and 23 nursing technicians.

Data collection took place between May and June 2024, conducted in a naturalistic environment, through direct systematic observation of the structure and care practices developed in the NICU. Systematic observation consists of a planned, structured and controlled technique, carried out using standardized instruments for objective data collection, without interference from the observer in the phenomenon analyzed. This is a relevant method in nursing research, as it allows for the rigorous capture of the complexity of practice in dynamic clinical contexts[15].

The observations were conducted by two independent evaluators, previously trained and calibrated, both undergraduate nursing students. The training consisted of theoretical and practical sessions in which the study objectives, the operational concepts of the variables, and the data collection instrument were presented, with a detailed explanation of each item and evaluation criteria. Following this, the evaluators participated in simulated and pilot field application sessions, with joint discussion of interpretations and standardization of observational procedures. The calibration stage was conducted by comparing the independently performed evaluations, analyzing the degree of agreement between the evaluators. Identified discrepancies were discussed until consensus was reached, aiming to standardize the application of the instrument and reduce interpretation biases, ensuring greater reliability, consistency of the collected data, and internal validity of the measures.

Data collection comprised eight visits to the sector, with an average duration of 120 minutes each, distributed between day and night shifts, totaling 16 hours of observation. This period was defined based on consolidated methodological strategies of structured observation and time-motion type studies, widely used in the analysis of care processes in complex environments[16-17]. This design does not aim to exhaust all variations of the phenomenon, but to systematically capture work patterns, activity distribution, and critical events in real-world practice conditions. International evidence indicates that observational sessions of delimited duration, when associated with standardized instruments and intentional sampling, are capable of generating robust data on care dynamics and patient safety[18].

In observational studies, obtaining Informed Consent after the start of observation may be ethically justified, according to the guidelines of the National Health Council (Resolutions

No. 466/2012 and No. 510/2016), especially when prior interaction may interfere with the natural behavior of participants. In these cases, it must be ensured that participants are duly informed as soon as possible, and that they are guaranteed full freedom to refuse participation or withdraw consent at any stage of the research, without any penalty, including the exclusion of collected data, as recommended by the aforementioned resolutions, which was included in the aforementioned document.

After the observation phase was completed, the evaluated items were presented to the participants, who then signed the informed consent form for the ethical inclusion of the data in the research. There were no refusals or withdrawals from the study, and no sociodemographic or professional characterization of the participants was performed, since the investigation focused exclusively on evaluating patient safety, the physical structure, and the care processes of the unit.

The observation phase followed a structured protocol, with simultaneous and independent recording by both evaluators, without communication between them during the process, in order to guarantee impartiality. For this, the Patient Safety Assessment Checklist in the Neonatal Intensive Care Unit and the Graphic Protocol, previously constructed and validated instruments[12] were used. Validation was conducted using the Delphi technique with experts, presenting a Content Validity Coefficient of 0.97 and a global face validity index of 0.99, indicating high adequacy and representativeness of the items for assessing patient safety in a neonatal context[12]. The checklist was developed based on the health assessment model proposed by Donabedian[14], distributed in the categories structure, process and outcome, allowing a comprehensive analysis of patient safety from multiple care perspectives.

The checklist consists of 111 items, distributed across 10 dimensions, three related to structure (infrastructure, materials and equipment, human resources), six to process (patient identification, safety in the use of medications, effective communication, prevention of healthcare-associated infections, fall prevention and prevention of skin injuries) and one related to results (patient safety indicators). The items are answered with “yes” or “no”, indicating the presence or absence of the minimum safety requirements[12].

The items related to the "structure" dimension were evaluated through a single measurement, as these are relatively stable characteristics of the service, such as the availability of equipment, supplies, and physical resources, which do not undergo significant variations throughout the observation period. The items related to the "process" and "outcome" categories were evaluated through direct observation of care practice, being

applied repeatedly to each member of the nursing team observed (n = 28), with the aim of capturing the variability of conduct and increasing the reliability of the measurements.

The checklist dimensions are numbered from 1 to 10 and each has a certain number of items, depending on the particularities. The items are in the form of questions, directed only to the researcher. These items were developed in accordance with national regulations on patient safety, legislation dealing with the minimum operating conditions of a NICU and scientific evidence concerning safe care for newborns[12].

The study variables corresponded to the items on the NICU patient safety assessment checklist, adopted as the unit of analysis. The primary outcome was the level of compliance with these items, distributed across the categories of structure, process, and outcome, as well as the respective dimensions of the instrument, allowing for an integrated analysis of neonatal care safety.

Next, the analysis was carried out using the Graphic Protocol of the score for each dimension, which was obtained by the proportion of compliant items on the checklist , being categorized as adequate (100%), partially adequate (50–99.9%) or inadequate (<50%). For overall assessment, the dimensions obtained a score of 0 (inadequate), 1 (partially adequate) or 2 (adequate), with the unit's final classification as safe (14 to 20 points), partially safe (7 to 13 points) or unsafe (0 to 6 points)[12].

Data analysis was descriptive and evaluative in nature, and was carried out using absolute and relative frequencies. Inter-rater reliability was measured using Cohen's Kappa coefficient, categorized as mild (k < 0.4), moderate (k between 0.4 and 0.8), strong (k between 0.8 and <1.0) and perfect (k = 1.00), with respective 95% confidence intervals[19]. The data were organized in a Microsoft Excel® spreadsheet, with double entry and validation for quality control.

No inferential analyses or control for confounding factors were performed, since the study did not aim to establish causal relationships, but to evaluate the conformity of care practices. Among the potential biases, the Hawthorne effect and observer bias stand out, which were minimized through training, standardization, and independent evaluation. There were no missing data, since all items of the instrument were fully observed and recorded. Another potential bias concerned the possibility of errors in data entry and tabulation during the analyses. To minimize this risk, a double-entry strategy was adopted, performed by two different researchers, followed by validation of the records.

The study was conducted in accordance with national and international ethical guidelines, in compliance with Resolutions No. 466/12 and 580/2018 of the National Health

Council, and approved by the Research Ethics Committee of Universidade Federal do Piauí (Protocol no. 6.625.225, CAAE no. 76768023.0.0000.5660), whose opinion is attached to this submission.

RESULTS

The overall assessment of care provided in the NICU reached a compliance rate of 85.59%, equivalent to 95 positively evaluated items out of a total of 111 items. Analysis by category indicated that Structure had the highest compliance rate (88.46%), suggesting adequate physical and organizational conditions for safe neonatal care. The Outcome category reached 85.71%, demonstrating that the effects of care on the patient tend to be positive. Process was the category with the lowest compliance (82.69%) and the highest rate of non-conformities (17.31%), revealing weaknesses in the procedures performed during care (Table 1).

Table 1 - Evaluation of conformity and nonconformity of the categories Structure, Process, Outcome and Overall Evaluation of the categories, according to the Patient Safety Assessment Checklist in the Neonatal Intensive Care Unit. Piauí, Brazil, 2024

Categories	**Number of items**	**NC***	**NC (%) †**	**NI ‡**	**NI (%) §**
Structure	52	46	88.46%	06	11.54%
Process	52	43	82.69%	09	17.31%
Result	07	06	81.71%	01	14.29%
Overall evaluation of the categories	111	95	85.59%	16	14.41%

Source: Authors' database, 2024.
*NC = Number of compliant items, † NC (%) = Percentage of compliant items, ‡ NI = Number of non-compliant items, § NI (%) = Percentage of items with nonconformities.

Among the 10 dimensions analyzed, as shown in Table 2, only "Prevention of Skin Injuries" was classified as adequate, reaching 100% compliance. The others were considered partially adequate, according to the established criteria, with the dimensions "Materials and Equipment" (96.6%), "Safety in the use of medications" (92.3%) and "Prevention of Healthcare-Associated Infections" (90.9%) showing high compliance, while "Patient Identification" (50%) and "Fall Prevention" (66.7%) were critical areas that indicated low compliance. Based on this, the NICU obtained a total of 11 points, being classified as a unit that offers "partially safe care".

Table 2 – Classification by dimension of compliant items observed in the Neonatal Intensive Care Unit, according to the Graphic Protocol. Piauí, Brazil, 2024

Dimensions	**NT***	**NC †**	**NC (%) ‡**	**Classification**	**Points**
Infrastructure	17 items	13	76.5%	Partially adequate	01
Materials and Equipment	30 items	29	96.6%	Partially adequate	01
Human resources	5 items	04	80%	Partially adequate	01
Patient Identification	6 items	03	50%	Partially adequate	01
Effective communication	10 items	08	80%	Partially adequate	01
Prevention of healthcare-associated infections	11 items	10	90.9%	Partially adequate	01
Safety in the use of medications	13 items	12	92.3%	Partially adequate	01
Fall prevention	6 items	04	66.7%	Partially adequate	01
Prevention of skin lesions	6 items	06	100%	Adequate	02
Patient safety indicators	7 items	06	85.71%	Partially adequate	01

Source: prepared by the authors, 2024.
*NT = Total number of items per dimension, † NC = Number of compliant items, ‡ NC (%) = Percentage of compliant items. Adequate = 100% of compliant items (02 points), Partially Adequate = 50 to 99.9% of compliant items (01 point), Inadequate = below 50% (0 point), Care Classification = Safe care (14 to 20 points), Partially safe care (7 to 13 points), Unsafe care (0 to 6 points).

Table 1 presents the items in the three categories and 10 dimensions that are non-compliant, showing weaknesses in structural, organizational, and care aspects that impact the safety of neonatal care. Regarding the Infrastructure dimension, the following absences were observed: natural lighting in the environment; a procedure room for the care and hygiene of newborns; an individual isolation room; and a human milk collection room. In the Materials and Equipment dimension, there was a lack of standardized alarm programming and noise control for the unit's electromedical equipment, while in the Nursing Human Resources dimension, no records were found of the implementation of continuing education programs for professionals working in the unit.

Regarding the Patient Identification dimension, it was observed that the service did not use wristbands with at least two identifiers (mother's full name and date of birth). Furthermore, the accompanying person/family member/caregiver was not involved in the correct identification process, and there was no explanation to the accompanying

person/family member/caregiver about the purpose of the two identifiers on the wristband, nor guidance on the mandatory verification of identification before care. In the Communication between Professionals and Family dimension, it was found that shift handover was not performed at the patient's bedside and that professionals were not trained to communicate bad news to families. In the Prevention of Healthcare-Associated Infections (HAIs) dimension, it was found that there was no protocol for the prevention of ventilator-associated pneumonia.

Table 1 – Items from the Patient Safety Assessment Checklist in the Neonatal Intensive Care Unit that presented nonconformities, by category and dimension. Piauí, Brazil, 2024.

CATEGORIES	ITEMS WITH DIMENSIONAL INCONSISTENCIES
Structure	**Dimension – Infrastructure** **1.2** Does the room have natural lighting? **1.10** Is there a procedure room designated for the care and hygiene of newborns? **1.12** Does the unit have a private isolation room? **1.16** Is there a room for collecting human milk?
	Dimension – Materials and equipment **2.4** Are there standard programming procedures for alarms and noise controls for electromedical equipment in the NICU*?
	Dimension – Human resources in nursing **3.5** Does the technical manager implement and maintain records of a continuing education program for all professionals working in the unit?
Process	**Dimension – Patient Identification** **4.2** Does the service use wristbands to identify newborns with at least two identifiers (mother's full name and date of birth)? **4.4** Is the companion/family member/caregiver involved in the correct identification process? **4.5** Is the purpose of the two bracelet identifiers explained to the companion/family member/caregiver, and is it explained that checking the identification is mandatory before providing care?
	Dimension – Communication between professionals and the family **5.1** Does the shift handover take place at the patient's bedside? **5.8** Are professionals trained to deliver bad news to families?
	Dimension – Prevention of HAIs † **6.8** Does it have a protocol for preventing ventilator-associated pneumonia?
	Dimension – Safety in the use of medications **7.9** Do they have allergy alert systems?
	Dimension – Fall Prevention **8.2** Are newborns assessed for fall risk? **8.3** In cases of high risk, is there any visual signage indicating the risk of falls in the unit or on the patient's bed?

	Dimension – Prevention of skin injury No inadequacy whatsoever.
Result	**Dimension – Patient safety indicators** **10.7** Is user/family satisfaction research conducted?

Source: prepared by the authors, 2024.
*****NICU = Neonatal Intensive Care Unit, †HAIs = Healthcare-Associated Infections.

Inter-rater reliability analysis showed perfect agreement for all dimensions of the instrument. In the Structure dimension (52 items), Cohen's Kappa coefficient was 1.00 (95% CI: 1.00–1.00); in the Process dimension (52 items), 1.00 (95% CI: 1.00–1.00); and in the Outcome dimension (7 items), 1.00 (95% CI: 1.00–1.00). When considering the set of 111 items evaluated, the overall Kappa was also 1.00 (95% CI: 1.00–1.00), corresponding to the classification of perfect agreement.

Table 3 – Inter-rater agreement by instrument dimension, according to Cohen's Kappa coefficient. Piauí, Brazil, 2024.

Categories	Items evaluated	Kappa (k)	95% CI	Classification
Structure	52	1.00	(1.00-1.00)	Perfect
Process	52	1.00	(1.00-1.00)	Perfect
Result	7	1.00	(1.00-1.00)	Perfect
Global	111	1.00	(1.00-1.00)	Perfect

Source: prepared by the authors, 2024.

DISCUSSION

Critical analysis of the data revealed advances in the quality of care in the Neonatal Intensive Care Unit (NICU), while at the same time identifying gaps that hinder the consolidation of fully safe care. The *Structure* category showed the highest level of compliance, indicating partially adequate availability of material and human resources, a minimum condition for organizing care and obtaining better neonatal outcomes, including the prevention of avoidable AEs[20].

Despite this conformity, the inadequacies found in the infrastructure dimension, which included the absence of a procedure room and a human milk collection room, reveal a dissociation between the installed capacity and its operationalization. These findings make the unit inconsistent with WHO standards[13] and may increase the burden on the nursing staff, who then have to adapt spaces to perform procedures, increasing the risk of infections and care failures[6].

Regarding the infrastructure dimension, the absence of natural light constitutes another relevant limitation of the care environment, with implications especially for professionals and family members. Exposure to natural light is associated with the regulation of the circadian rhythm, improved mood and sleep quality, while its absence can promote fatigue, stress and biological disorganization. In addition, environments without natural lighting tend to have a higher microbial load[21].

The lack of an isolation room is another important limitation in infection control, considering the high vulnerability of newborns. Although strategies such as isolation and cohorting are widely recommended, robust evidence is still limited, as demonstrated by a systematic review from the Cochrane Library. Nevertheless, such measures continue to be adopted due to their potential to reduce cross-transmission, particularly in units with high care density[22].

These limitations extend beyond the structural dimension and directly impact the organization of care, adherence to protocols, and infection prevention strategies[11]. In environments such as the NICU, where the newborn's conditions change rapidly[2], the availability and organization of resources are crucial for team performance and for consolidating a safety culture[6]. These findings reinforce the understanding of the NICU as a complex adaptive system, in which care outcomes emerge from the dynamic interaction between structure, processes, team, and organizational context.

In the “Materials and Equipment” dimension, a significant level of compliance was observed, with the availability of essential resources for resuscitation, ventilation, monitoring and medication administration[20]. However, the absence of alarm programming and noise control systems represents a relevant gap. High noise levels are associated with sleep disruption, physiological instability and increased stress in newborns, in addition to compromising the team's working conditions, favoring distractions, communication failures and care errors[21].

This finding is corroborated by an observational study that identified persistently high noise levels above recommended limits in an Italian NICU, with a significant association between environmental noise and the heart rate of newborns. It was also observed that for every 1 decibel increase, the probability of tachycardia increased by 6.6% (Odds Ratio = 1.066; $p < 0.001$), indicating that continuous exposure to increased noise levels can contribute to physiological instability and potential impairment of neonatal development, reinforcing the importance of adopting effective environmental control strategies in neonatology[23]. From this perspective, the NICU environment should be understood not only as a structural

component, but as an active clinical determinant, capable of directly influencing physiological stability and neonatal development.

In concluding the assessment of the *Structure* category, with regard to the dimension "Human Resources in Nursing", the absence of formal records of continuing education programs was identified, which may compromise the continuous updating of care practices. Investments in continuous training should be prioritized, given their relevance to improving quality and achieving global patient safety goals[5,11,13].

The largest gaps were observed in the *Process* category, highlighting a dissociation between the availability of resources and the effective quality of care. This finding reinforces that the structure, although necessary, is not sufficient to guarantee care safety. As emphasized by Donabedian, the process constitutes the core of care quality, as it translates available structural resources into concrete actions, with a direct impact on clinical and safety outcomes[12]. In this context, the results highlight a possible paradox, in which the availability of resources does not necessarily translate into care quality, indicating a disconnection between installed capacity and care delivery.

In light of this evidence, the importance of understanding the quality and safety of neonatal care from the operationalization of practices throughout the care continuum is highlighted. A transition is observed from a technical-structural focus to an integrated approach, which values communication, safety culture and process organization. Thus, although the structure is necessary, it is the processes effectively executed that translate resources into safe practices, indicating that quality in the NICU is more related to the execution of care than to its structural availability[20].

Poor patient identification compliance, coupled with the absence of standardized wristbands and inadequate practices, is a critical finding, considering its central role in patient safety, especially in medication administration. Identification errors remain among the most frequent and preventable events in neonatology, with repercussions such as delays, inappropriate interventions, and harm to the patient[24]. Standardization of processes and family participation are fundamental, since educational and technological interventions can reduce these failures by up to 63%[25], with the family being an important additional layer of safety in preventing adverse events.

In the "Fall Prevention" dimension, there was an absence of systematic risk assessment and bed signage, although all newborns in the NICU are considered high risk[12]. This is a preventable event, which reinforces the need for improved record keeping, staff awareness, and guidance for families[26]. The omission of these care measures can be

explained by the prioritization of more complex demands in contexts of staff shortages, being understood as a result of implicit prioritization processes of care and organizational constraints, and not just individual failures[9].

Regarding the dimension "Safety in the use of medications", the only inconsistency identified was the absence of allergy alert systems, which classified the NICU as partially adequate in this respect. Although it was the only item missing among the 13 evaluated, it is a relevant finding, as these tools are effective in identifying serious adverse events and strengthening patient safety in a high-risk environment[4]. Such systems constitute clinical decision support tools that range from traditional paper-based methods, such as records in charts, wristbands and labels, to computerized systems integrated with electronic medical records, capable of analyzing patient data and issuing real-time alerts, identifying newborns who have drug allergies[27].

The absence of this identifier therefore makes newborns even more vulnerable. This is because a prospective observational study conducted in a NICU in Natal, Brazil, found that 19.7% of newborns presented adverse reactions, with the most frequent manifestations being tachycardia (30.6%), polyuria (9.1%) and hypokalemia (8.6%); in general, it is estimated that 15% to 30% of newborns in intensive care develop adverse reactions, with about 10% being severe[28]. These findings directly relate to the previously mentioned absence of allergy alert systems, since such tools can favor the early identification of risks and the prevention of adverse events, especially in contexts of polypharmacy and high care complexity.

Also, in the *Process* category, the assessment of the "Prevention of HAIs" dimension indicated that the absence of a specific protocol for ventilator-associated pneumonia stems from limitations in neonatology, such as the lack of standardized diagnostic criteria, the nonspecificity of clinical signs, and the extrapolation of recommendations from other age groups, in addition to the lack of consensus on the most effective strategies[29]. Given this, clinical practice has prioritized prevention bundles and general infection control measures, whose effectiveness depends on the integrated action of the multidisciplinary team. In this context, the articulation between nursing, physicians, physiotherapists, pharmacists, and other professionals is essential for the consistent implementation of measures and for strengthening the safety culture[7].

The assessment of the "Communication" dimension, in the *Process* category, revealed shortcomings, especially due to the absence of bedside shift handover, a practice associated with error reduction and greater family involvement in care[30]. This is a critical moment for patient safety, vulnerable to failures in the absence of standardization, training, and

teamwork[20]. Furthermore, it was observed that, despite the existence of protocols, nursing professionals did not receive systematized training for communicating bad news. This finding is consistent with a study that showed that 44.7% of professionals did not receive formal training, 44.2% learned empirically, and 41.2% did not have structured communication strategies[31].

Despite the critical points, in the *Process* category, total compliance in the dimension "Prevention of skin lesions" stood out as a positive result. The adoption of specific protocols, such as the proper use of sensors, prevention of nasal injuries and systematic repositioning, constitutes an important indicator of patient safety, especially considering that skin lesions in NICUs are an emerging problem, with prevalence rates between 9.3% and 43.1%[32].

The absence of inadequacies in this dimension can be explained by the greater visibility and measurability of this type of care, since physical changes are easily identified, favoring monitoring and institutional accountability. This tends to reinforce its prioritization by professionals, unlike less visible care, especially of an organizational and educational nature, which is more susceptible to omission[9]. This scenario suggests the existence of a hierarchy of care visibility, in which practices with immediate and observable outcomes tend to be prioritized, while less tangible interventions become more susceptible to omission.

When following the assessment of the NICU, based on the Donabedian model, the *Outcome* category expresses the final effects of care on the patient's health status, including clinical outcomes[14]. In this way, the results constitute the synthesis of the interaction between structure and process, being particularly sensitive to the weaknesses previously identified in these categories and their respective dimensions[12].

Specifically, the absence of systematic instruments for evaluating family satisfaction constitutes a critical gap in the *Outcome* category, since, according to Donabedian, the effectiveness of care, understood as the ability to produce health and satisfaction, is the main indicator of the quality of care[14].

Systematic measurement of parental satisfaction can contribute to patient safety and improved care, and the implementation of structured data collection, analysis and monitoring systems is recommended, with reporting to management to support decisions and promote continuous improvement in the NICU[13].

The findings of this study suggest a NICU with marked operational resilience, understood as the ability to adapt to daily pressures to maintain efficient and safe care[33]. Even though this aspect is positive, it proves unsustainable in the long term, considering that

patient safety must be anchored in robust organizational systems, since isolated and improvised actions, lacking structural support, tend to have a limited impact on outcomes[34].

The limitations of this study involve methodological and contextual aspects. The cross-sectional design and the fact that it was conducted in a single service limit external validity and prevent causal inferences, making it impossible to statistically generalize the findings, which must be interpreted according to the context. There is a possibility of biases, such as selection bias (single setting) and information bias, related to direct observation with a checklist, in addition to the possible Hawthorne effect. Although measures such as the use of the Kappa coefficient were adopted to increase reliability, subjectivity is not completely excluded. Furthermore, the presence of uncontrolled confounding factors, common in complex environments such as the NICU, may have influenced the results.

Compared to previous studies, the findings allow for targeted interventions in the most critical dimensions, such as process standardization, identification of newborns, communication with families, and infection prevention. In light of Donabedian's principles, they reinforce that the quality of care depends on the articulation between structure, process, and outcome, with the process being the main mediator of outcomes. The potential of the checklist and the need for investments in continuing education and collaborative care to promote continuous cycles of improvement and the enhancement of neonatal care are highlighted.

CONCLUSION

The Neonatal Intensive Care Unit was classified as providing partially safe care. The Structure showed greater conformity, suggesting adequate physical and organizational conditions, followed by the Outcome category, which indicated positive effects of the care. The Process obtained lower conformity, revealing weaknesses in the execution of care practices.

Among the dimensions analyzed, only "Prevention of Skin Injuries" was considered adequate, while "Patient Identification" and "Fall Prevention" represented critical areas of low compliance. Weaknesses were also found in the physical infrastructure, the use and control of equipment, the ongoing training of the team, infection prevention protocols, and communication between professionals and family members. Thus, it is concluded that although there are favorable structural conditions and positive results, the care process requires continuous improvements to achieve greater safety in neonatal care.

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Availability of data and material

Access to the dataset may be obtained by requesting it from the corresponding author.

Authors' contribution

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