INSTITUTO POLITÉCNICO DE SANTARÉM
Escola Superior de Gestão e Tecnologia de Santarém

QUALITY IN NEONATAL CARE: SAFETY CHECKLIST VALIDATION

Dissertation

Master's in Health Unit Management

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July 2024

Recognition and gratitude
to those who have always been by my side, they know who they are

Dedicated to you, T.C.

QUALITY IN NEONATAL CARE VALIDATION OF THE SAFETY CHECHLIST

Resumo

A implementação da Checklist de Segurança do Doente Neonatal (CSDN) tem como objetivo promover uma avaliação rigorosa dos pontos sensíveis e/ou críticos no continuum de cuidados, contribuindo de forma significativa para o clima organizacional, ao incutir um sentido crítico sobre os cuidados prestados aos doentes neonatais nas Unidades de Cuidados Intensivos Neonatais (UCIN), potenciando assim a qualidade e a segurança. Este instrumento de qualidade foi concebido para avaliar a conformidade das intervenções de cuidados, assegurando o cumprimento das directrizes, normas e protocolos estabelecidos. Para além disso, define e operacionaliza um conjunto de indicadores de qualidade e segurança neonatal, promovendo uma prática de cuidados consciente e intencionalmente terapêutica, ao mesmo tempo que aumenta a segurança e a qualidade de vida do doente neonatal e da sua família.

Assim, é fundamental dispor de um instrumento que reflicta a complexidade da prática de cuidados na UCIN em toda a sua abrangência e intervenção. Para tal, é essencial chegar a um consenso sobre o seu conteúdo e objetivo, através da validação por peritos na área. A metodologia adoptada inclui a obtenção de feedback e avaliação de peritos em cuidados neonatais no contexto da UCIN. Procura-se uma construção colectiva através do método Delphi, que envolve um conjunto de questionários respondidos sequencial e individualmente pelos participantes (peritos), os quais são analisados e sistematizados pelos investigadores. Posteriormente, é dado um feedback com informação que sintetiza as respostas do grupo aos questionários anteriores, com o objetivo de construir uma resposta colectiva gradual.
A aplicação deste método resulta na consolidação de um instrumento cujo desenho está intrinsecamente relacionado com a qualidade e segurança da saúde, bem como promove o desenvolvimento de indicadores de saúde sensíveis às necessidades dos doentes neonatais e suas famílias.

Keywords: cuidados intensivos neonatais, segurança do doente, indicadores de qualidade, checklist.

QUALITY IN NEONATAL CARE: SAFETY CHECKLIST VALIDATION

Abstract

The implementation of the Neonatal Patient Safety Checklist (CSDN) aims to facilitate a comprehensive evaluation of critical aspects of patient care, thereby enhancing the organizational climate and fostering heightened awareness of care quality and safety in Neonatal Intensive Care Units (NICUs). This quality tool is designed to assess the conformity of care interventions, ensuring adherence to established guidelines, standards, and protocols. Moreover, it defines and operationalizes a set of neonatal quality and safety indicators, promoting conscious and intentional therapeutic care practices while enhancing the safety and quality of life for neonatal patients and their families.

It is imperative to have an instrument that accurately reflects the complexity of NICU care practices in all their aspects and interventions. To achieve this, consensus on the checklist's content and purpose through expert validation is essential. The methodology employed involves soliciting feedback and evaluation from experts in neonatal care within the NICU context. The Delphi method is utilized to facilitate collective construction. This method entails a series of questionnaires answered sequentially and individually by the participants (experts). The responses are then analyzed and systematized by researchers. Subsequently, feedback is provided in the form of a summary of the group's responses to previous questionnaires, with the objective of developing a cumulative collective response.

The implementation of this methodology culminates in the establishment of an instrument inherently linked to health quality and safety. It also facilitates the advancement of health indicators responsive to the needs of neonatal patients and their families.

Key-words: intensive care, neonatal; quality indicator, health care; patient safety; checklist.

CONTENTS

LIST OF FIGURES

LIST OF TABLES

ACRONYMS

IQA: Interquartile Range
BAPM: British Association of Perinatal Medicine
CCD: Development Centred Care
CSDN: Neonatal Patient Safety Checklist
DALY's: Disability Adjusted Life Year
DGS: General Directorate of Health
EFCNI: European Foundation for the Care of Newborn Infants
FINE:
HESE EPE: Hospital do Espírito Santo de Évora E.P.E.
HAIs: Healthcare Associated Infections
IHI: Institute for Healthcare Improvement
CVI: Content Validity Index
JCI: Join Commission International
NIDCAP:
OECD: Organisation for Economic Co-operation and Development
OE: Order of Nurses
WHO: World Health Organisation
PNSD: National Patient Safety Plan
ADR: Adverse Drug Reactions
NB: Newborn
NICU: Neonatal Intensive Care Unit
EU: European Union

INTRODUCTION

The safety and quality of healthcare are of increasing importance in the field of public health and hospital management. The intricate nature of the care provided and the rising demand for effective and secure health services have prompted the necessity for the development of methodologies and instruments that ensure the uninterrupted enhancement of this care.

The Institute for Healthcare Improvement (IHI) emphasises the necessity of a comprehensive approach that encompasses all stages of the patient care process. This approach is designed to reduce discrepancies between the quality of care received and the quality desired. This is achieved through an integrated planning and control system that implements continuous quality improvement activities at various levels of the healthcare system (Sampath, 2021).

The quality of healthcare is a complex concept, encompassing multiple dimensions such as effectiveness, efficiency, accessibility, acceptability, patient-centredness, equity and safety. The concept of patient safety, defined as the absence of avoidable harm and the minimisation of risks inherent in healthcare, has emerged as a crucial component of quality. As indicated by data from the World Health Organisation (WHO), safety incidents continue to occur in significant numbers, with direct impacts on mortality, morbidity and economic costs (WHO, 2021). It is estimated that in developed countries, the direct cost of treating patients who have suffered harm during care is approximately 13% of healthcare expenditure (Slawomirski & Klazinga, 2022). Indeed, the financial implications of safety incidents are considerable and impact the efficiency of healthcare resources. The provision of care to patients whose condition has been worsened by safety incidents results in the diversion of resources, such as diagnostic equipment and healthcare professionals' time, increasing opportunity costs and impacting on the ability to care for other patients (Slawomirski & Klazinga, 2022).

The evolution of these concepts has prompted healthcare organisations to implement comprehensive programmes aimed at enhancing safety and quality standards. This has necessitated the appointment of leaders and stakeholders to formal roles within these domains. Despite the advancement of methodologies for the comprehension of quality

and safety, the interrelationship between these two concepts remains unclear. These concepts are interlinked and largely synonymous; they are driven by systems of care, and thus achieving either will require an organisational commitment to developing a culture based on learning and continuous improvement (Shenoy, 2021; Slawomirski & Klazinga, 2022).

In its 2020 report, the WHO defines high-quality care as being safe, effective, person-centred, timely, efficient, equitable and integrated. The term "patient safety" is more specifically defined as the absence of avoidable harm and the reduction of the risk of unnecessary harm to an acceptable minimum. There are currently ongoing efforts to enhance the safety and quality of care, with the utilisation of analogous theories and instruments. The implementation of quality instruments, such as safety checklists, has been demonstrated to be an efficacious strategy for the reduction of safety incidents and associated complications, the promotion of a culture of safety, and the enhancement of the consistency of the care provided. The structure-process-result triad proposed by Donabedian (1968) is a widely used model for assessing quality in healthcare. In accordance with this model, the utilisation of quality tools, such as checklists, serves to enhance the quality of care processes, which subsequently improves patient outcomes.

In Portugal, the National Patient Safety Plan (PNSD) serves to reinforce patient safety, encompassing strategies and objectives that are designed to promote safety and quality in healthcare. The plan, which is aligned with the targets set by the World Health Organisation (WHO), places great emphasis on the importance of a culture of safety, effective communication and the continuous implementation of safe practices. The PNSD 2021-2026 emphasises the mobilisation and action of the different health stakeholders, including political decision-makers, managers of health institutions, health professionals, users, patients, families and carers (DGS, 2022). The culture of safety has been driven by healthcare organisations and their professionals, reflecting a commitment to the implementation of strategies aimed at the continuous promotion of the quality of care.

A substantial body of evidence suggests that safety incidents in neonatal intensive care units (NICUs) have the potential to cause significant harm, affecting length of stay, mortality and institutional costs. In 2015, the Neonatal Patient Safety Checklist (CSDN) was adapted to the specific context of the NICU at Hospital Espírito Santo de Évora,

E.P.E., with the objective of identifying and addressing potential shortcomings that could increase the likelihood of safety incidents occurring. By the end of 2021, it had become apparent that the tool required an additional component, namely the therapeutic environment, in order to avoid any reduction in the quality of neonatal patient care while simultaneously guaranteeing quality improvement. The utilisation of quality instruments, such as the aforementioned checklist, is of paramount importance to guarantee that critical safety concerns are neither overlooked nor omitted during the provision of care across the entire continuum of care.

Three international checklists for neonatal intensive care units (NICUs) were identified (Silva, 2019; Saraiva et al., 2022; Manzo et al., 2023). However, no CCD indicators were identified in the instrument under consideration. CCD indicators are those that are specific to neonatal care and are operationalised in isolation in various related initiatives and/or programmes (for example, NIDCAP®). It is this author's intention to integrate these indicators into quality and safety programmes within the NICU context, given their pivotal role in neonatal care and the outcomes they facilitate.

The objective of this study is to validate the CSDN indicators using the Delphi method, thereby ensuring their representativeness and relevance to the context of neonatal care. Through consultation with experts in the field, it will be possible to consolidate a robust instrument that can serve as a guide for care practices and contribute to improvements in neonatal outcomes. The Delphi methodology, which has been demonstrated to be an effective approach for reaching consensus among experts, will be fundamental for the development of a theoretical and empirical framework to support the practical application of the CSDN.

The study employs the Delphi method, a structured technique for obtaining consensus among a group of experts through the administration of questionnaires in multiple rounds. This method is employed in the context of complex topics where consensus is required. A panel of experts comprising health professionals with extensive experience in neonatology and patient safety was selected for this purpose. The initial questionnaire round will be employed to ascertain the relevance and clarity of the indicators proposed in the CSDN. Subsequently, the results will be subjected to analysis and returned to the experts for review, thereby allowing for adjustments and refinements based on the feedback received.

The utilisation of the Delphi method is predicated on the necessity for an interactive process that guarantees the anonymity of the experts, circumventing the potential influence of dominant figures and fostering the autonomy of each expert's expression. The responses were subjected to statistical analysis, employing measures of central tendency, such as the median, and dispersion, such as the interquartile range, in order to ascertain the level of consensus. A Content Validity Index (CVI) will be calculated for each indicator, with a CVI value of 80% or greater serving as the acceptance criterion.

The objective of this study is to validate the CSDN indicators through the input of experts in order to ensure that the construct is robust and capable of fulfilling its intended purpose. The necessity for this is underscored by the imperative to ensure the safety and quality of healthcare for neonatal patients. The CSDN will facilitate the identification of deficiencies and foster a culture of safety, thereby enabling the continuous enhancement of the quality of care. It is the intention of this work to provide an invaluable tool for clinical practice, with the objective of achieving excellence in neonatal care and ensuring the safety of the most vulnerable patients. The adoption of evidence-based practices and the rigorous validation of the CSDN indicators are pivotal steps in guaranteeing that the care provided is effective, efficient and safe, thus promoting the health and well-being of neonates and their families.

Dissertation Structure: Chapter I: This chapter establishes the theoretical foundation of the study through an extensive literature review on quality and safety in neonatal care.

Chapter II: It presents the methodological design of the Delphi method and the subsequent sampling, data collection, data analysis and interpretation, thereby ensuring the reliability of the results. Chapter III presents the findings of the research, which are presented and interpreted through the analysis of the data obtained from the subjects in the various rounds. These findings are then related to the theoretical context. In conclusion, the findings of the research are presented, along with an analysis of the limitations of the study and recommendations for future work.

CHAPTER I: LITERATURE REVIEW

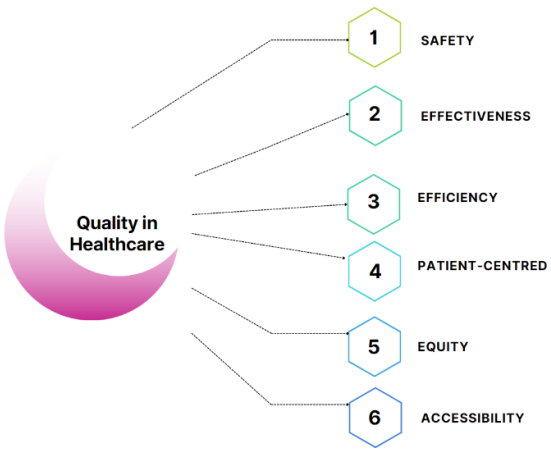
The aim of this chapter is to methodically build a theoretical and empirical framework through a review of concepts, theories or ideas produced on the subject under study, providing a solid basis for existing knowledge, identifying gaps in research and contextualising the investigation.

1.1 QUALITY AND SAFETY

> The quality of care the patient receives is a difficult concept to define either conceptually or operationally" (Donabedian, 1968, p. 118).

Quality in healthcare is a complex, multifactorial and multidimensional concept. The World Health Organisation (WHO) defined the basic concepts of quality by stating that care should be effective, efficient, accessible, acceptable, patient-centred, equitable and safe. More recently, it has taken on integrated, people-centred care by describing "high-quality care" as care that is safe, effective, people-centred, timely, efficient, equitable and integrated (World Health Organization (WHO), 2020a) (Figure 1).

Figure 1. *Key Characteristics of High Quality Health Care* (WHO, 2020a)



The concept of quality in healthcare is inherently complex, comprising a multitude of interrelated factors and dimensions. The World Health Organisation (WHO) has defined the fundamental principles of quality in healthcare as follows: care should be effective, efficient, accessible, acceptable, patient-centred, equitable and safe (WHO, 2020a). In more recent times, the WHO has advanced the concept of integrated, people-centred care, characterising it as "high-quality care" (WHO, 2020a).

Patient safety is defined as the absence of avoidable harm and the reduction of the risk of unnecessary harm related to healthcare to an acceptable minimum (WHO, 2021). In the broader context of the healthcare system, patient safety can be defined as a framework of organised activities that promote a culture of safety, as well as processes, procedures, behaviours, technologies and environments in healthcare that are designed to reduce risks in a consistent and sustainable way. This approach aims to reduce the incidence of adverse events and the occurrence of avoidable harm, to make errors less likely and to reduce the impact of harm when it does occur (WHO, 2021).

There is a close and overlapping relationship between quality and safety. Although safety can be regarded as one of the constituent elements of healthcare quality, it is also possible to conceptualise healthcare quality in terms of its safety. Theoretical frameworks and tools used to enhance safety and quality are largely consistent (Gupta et al., 2019). The evolution of these concepts has compelled healthcare organisations to implement robust programmes to enhance safety and quality, prompting leaders and stakeholders to assume formal roles in these domains. Despite efforts to recognise the evolution and sophistication of the concepts of quality and safety, the relationship between them remains unclear. These concepts are intertwined and largely synonymous; both are driven by systems of care, and achieving either requires an organisational commitment to developing a culture based on learning and improvement (Gupta et al., 2019).

Consequently, patient safety has been identified as a pivotal aspect in enhancing the quality of care. Its applicability and adaptation to the nuances of care delivery serve as a gauge for improving quality (WHO, 2020a; Slawomirski & Klazinga, 2020; IHI, 2022).

It is crucial to recognise that safe and high-quality care are two aspects of the same entity. To achieve this type of healthcare, it will be necessary to employ a range of common tools centred on care systems. Safety and quality are two complementary

assumptions of care. Furthermore, quality improvement is the discipline that provides the set of implementation tools to achieve these goals (Gupta et al., 2019).

Figure 2. *Quality Improvement: quality and safety process*

It is now evident that while healthcare, which is becoming increasingly complex and demanding, is associated with positive outcomes for the patient, such as improved health, it is not without adverse events.

As evidenced by the findings presented in the report by Slawomirski and Klazinga (2020) on behalf of the Organisation for Economic Co-operation and Development (OECD) concerning the economic impact of patient safety, it is estimated that over one in ten patients are adversely affected by safety failures during the course of their healthcare. Furthermore, recent estimates suggest that four in a thousand people die as a consequence of unsafe care. The provision of unsafe care is associated with significant financial and economic costs. In developed countries, the direct cost of treating patients who have suffered harm during care is approximately 13% of healthcare expenditure. Excluding safety lapses that may not be preventable, this figure represents 8.7 per cent of healthcare expenditure, which is equivalent to 606 billion dollars a year. This equates

to just over 1 per cent of the combined economic output of OECD countries (Slawomirski and Klazinga, 2020).

Over time, the culture of safety has been promoted and has gained prominence, reflecting the commitment of healthcare organisations and their professionals to implement strategies aimed at continuously promoting quality care. It thus follows that the assurance of enhanced patient safety is contingent upon the promotion of a favourable culture within healthcare organisations. This entails a collective responsibility for the patient and the encouragement of open and effective discourse concerning errors and events, with a view to facilitating learning (Sousa, 2019; Slawomirski & Klazinga, 2020).

In Portugal, the Basic Health Law and the National Patient Safety Plan (PNSD) of the Directorate-General for Health (DGS) serve to reinforce the role of the state in the promotion of patient safety. The 2019 Basic Health Law (Law No. 95/2019) emphasises that patient safety is one of the fundamental dimensions of healthcare, as set out in Order No. 9390/2021. The PNSD 2021-2026 establishes strategic objectives and promotes safety in the provision of healthcare, in alignment with the objectives set forth by the WHO. This plan synthesizes the latest knowledge on patient safety, engaging political decision-makers, leaders, and managers of healthcare institutions and structures responsible for quality, patient safety, and risk management, clinical audit, healthcare professionals, users, patients, families, and carers (Order no. 9390/2021).

In alignment with the WHO objectives, the PNSD 2021-2026, as the National Strategy for Quality in Health, "(...) assembles the most contemporary knowledge in the domain of patient safety, invoking and integrating the engagement and action of the diverse health In particular, the stakeholders in question are policymakers, leaders, and managers of health institutions and structures with responsibility in the area of quality, patient safety, and risk management, clinical auditing, health professionals, users, patients, families, and carers (Order no. 9390/2021, p. 97). The objective is to build upon the achievements of the previous PNSD (2015-2020) and is supported by five pillars: The strategic objectives are to be defined, the promotion of safety in the provision of healthcare consolidated, the basic principles that underpin the area of patient safety emphasised, a safety culture established, communication facilitated, and safe practices

continued to be implemented in increasingly complex environments, with more modern scenarios such as home hospitalisation also being addressed.

It is a support tool at an achievable level for leaders, whether at the top or middle management level, which requires active involvement and shared responsibility for its implementation in care practice. It also implies coordination and operationalisation at the various levels of care provision, increasing the safety of the care provided, focusing on the patient, family and their carers, and extending to society in general.

1.2 QUALITY TOOL: SAFETY CHECKLIST

> "What is measured, evaluated and recognised evolves. Without the fulfilment of this premise, there is no management worthy of the name." (Santos, cited in Frederico & Sousa, 2022, p. 42)

The intricate and multifaceted nature of healthcare, characterised by interactions between diverse sectors and individuals, elevates the likelihood of incidents, errors, and failures, which can have a pervasive and enduring impact on the quality of care.

In accordance with James Reason's theory of active and latent failures (Reason, 2000), the occurrence of safety incidents within the intricate systems that constitute healthcare settings can be attributed to a deficiency or absence of safety barriers at four distinct levels of a socio-organisational system. The application of the Swiss Cheese Model can facilitate improvements in patient safety within healthcare settings in a number of ways. By identifying failures at each level of the system, or at the very least, searching for them during each safety audit, more opportunities for improvement with regard to the safety of the system are created. Moreover, the classification of the failure, whether active (the consequence of interpersonal dynamics and/or the practitioner's relationship with structures or equipment) or latent (associated with deficiencies in organisational design), has a substantial impact on the safety of the system, as it can be addressed (Reason, 2000; Emanuel et al., 2008).

This model facilitates the identification of the trajectory of safety incidents and the exploration of the potential contributions of factors at all levels of the system. It is crucial

to recognise that the majority of harmful events for patients are frequently associated with multiple active and latent failures. By grasping these failures and their interconnections, healthcare organisations can implement targeted measures to mitigate risks and enhance patient safety by assuming joint accountability for the matter (Chatziioannidis et al., 2017; Seshia, 2018; Wiegmann et al., 2022).

In essence, patient safety necessitates a comprehensive approach to the entire care process, encompassing a collective accountability for the patient. This entails acknowledging potential errors, identifying their underlying causes, and implementing measures to prevent their recurrence. This cyclical process of continuous improvement is essential for ensuring patient safety. The objective of achieving the safest and highest quality healthcare for the patient and family necessitates an understanding of the tools required to improve both safety and quality. This entails the promotion of a favourable culture within healthcare organisations, the assumption of collective responsibility for the patient, and the facilitation of open and effective discussions regarding safety incidents, with the aim of enhancing learning (Gupta et al., 2019; Sousa, 2019; WHO, 2021).

It is therefore crucial to employ tools that facilitate the definition, measurement and reliable analysis of the functional reality of organisations in terms of the care provided to patients. These tools should serve as a foundation for effective safety barriers and consistently drive quality improvement across the continuum of care (Frederico, cited in Frederico & Sousa, 2022).

The theoretical framework used to understand the impact of the various checklists, most of which are applied to the context of surgical patient safety and quality improvement, is that proposed by Donabedian (1968). This framework posits that the implementation of structural quality tools, such as checklists, enhances the quality of care processes, which in turn improves outcomes (Haugen et al., 2019). It is the most widely used model globally for assessing quality in healthcare, comprising a systematic structure that establishes the "structure-process-result" triad. The "structure" encompasses the context of infrastructure analysis and organisational characteristics; the "process" pertains to the actual delivery of care; and the "outcome" represents the effect of care on the health status of patients or populations (Saraiva et al., 2022).

The introduction of quality tools such as the checklist has been demonstrated to promote safe care by reducing the likelihood of safety incidents and associated complications. This is achieved through the promotion of better teamwork, communication and consistency of care (Mckelvie et al., 2016; Haugen et al., 2019; Slawomirski & Klazinga, 2020; McNally, 2023). These instruments are designed to be straightforward and adaptable to local practices. Their implementation has been demonstrated to have a favourable impact on selected safety process measures related to items on the checklist (Haugen et al., 2019; Slawomirski & Klazinga, 2020).

1.3 NEONATAL PATIENT SAFETY CHECKLIST (CSDN)

The NICU environment is distinguished by the necessity for highly specialised care and sophisticated technology, which is a consequence of the unique characteristics of neonatal patients. It is estimated that the target population is at a risk of safety incidents three times greater than that of adult patients. The incidence of safety incidents is 74 per 100 newborns. These incidents have the potential to cause significant harm and have consequences such as increased length of stay, higher mortality rates and greater institutional burden, which collectively increase the human and economic impact that these incidents have on patient safety (Chatziioannidis et al., 2017; Mueller et al., 2019; Brado, 2021; Cossul et al., 2021). In the United States, the incidence of medical errors in paediatric settings is approximately 9%, with estimates suggesting a similar prevalence in Portugal (Lage, 2010; Fragata & Martins, 2014; Silva et al., 2018). Nevertheless, despite the paramount importance of safety, the neonatal context is characterised by a dearth of investment, a finding that is corroborated by scientific studies (Chatziioannidis et al., 2017; Babaie et al., 2023).

The Neonatal Patient Safety Checklist (CSDN), adapted for the Neonatal Intensive Care Unit (NICU) at HESE, E.P.E., in 2015, was modified in 2021 to include the therapeutic environment. This modification was made with the aim of identifying and mitigating failures that could lead to safety incidents (Chatziioannidis et al., 2017; Mueller et al., 2019; Brado, 2021; Cossul et al., 2021).

It is acknowledged that the intricate operational environment of the NICU is susceptible to a multitude of potential failures, including active failures (occurring in operational tasks

related to human behaviour), latent failures (introduced during the design, construction or maintenance of the system), ineffective procedures, lack of adequate training and communication problems), and precondition failures (trigger factors for failures to occur). If these failures are aligned with the inherent risks of the care process, they can form a pathway for safety incidents to occur, which, when reaching the patient, can have devastating consequences (Chatziioannidis et al., 2017). Consequently, the neonatal safety checklist serves as a defensive barrier, with the objective of preventing and/or mitigating the consequences of these failures, thereby contributing to a culture of safety within the NICU context.

The aforementioned tool is based on the definition and operationalisation of a set of quality and safety indicators. Health quality indicators encompass a range of stratified dimensions that facilitate the measurement and improvement of the quality of care and outcomes (Chatziioannidis et al., 2017; Saturno et al., 2018). However, for them to be effective in monitoring progress, they must be measurable and clearly defined, accurate, reliable, valid, useful, relevant, accessible, specific and time-bound (Larson & Mercer, cited in Benova et al., 2020).

1.4 QUALITY AND SAFETY DIMENSIONS AND INDICATORS CSDN

Quality indicators are indispensable instruments for the surveillance, assessment and enhancement of the quality of care. In order to facilitate progress, quality indicators must be measurable, clearly defined, precise, reliable, relevant and adapted to the specific context (WHO, 2016; Benova et al., 2019).

In the context of the PNSD, a series of patient safety indicators have been defined, including the assessment of safety culture, the implementation of auditing processes, the reporting of safety incidents, the transition of care, the issue of informed consent, the unequivocal identification of patients, the occurrence of falls, pressure ulcers, medication safety and healthcare-associated infections (HAIs) (DGS, 2022). However, these remain almost generic and, as a result, some of them are not transferable to the neonatal patient.

Despite the scientific community's investment in identifying indicators that are sensitive to the practice of care in the NICU context, there is a gap with regard to the specificity

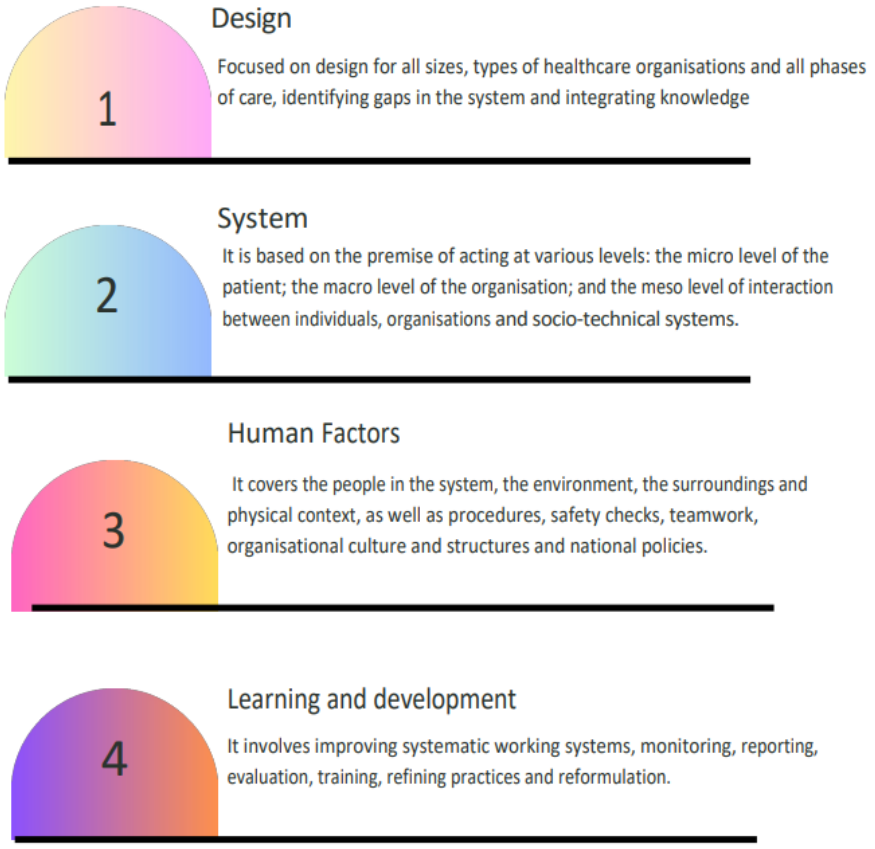
and complexity of neonatal care. This has resulted in few specific indicators being defined (Wang et al., 2023). It is therefore imperative to validate the indicators that make up the CSDN by including indicators centred on the specificity of the neonatal patient.

1.4.1 SAFETY CULTURE

The concept of patient safety culture is of paramount importance in healthcare settings, encompassing values, beliefs and norms that inform the delivery of care and the actions of key stakeholders (Sorra & Dyer, 2010; Camacho-Rodríguez et al., 2022). The World Health Organization (WHO) emphasizes the necessity for a unified and multifaceted safety culture to minimize the likelihood of errors and mitigate the adverse effects of adverse events (WHO, 2021). Clinical governance guarantees that healthcare organisations are held accountable for ensuring patient safety, thereby promoting the delivery of safe, effective, integrated and quality healthcare (Rodrigues, cited in Frederico & Sousa, 2022, p. 39).

This requires the integration and interaction of all relevant parties to ensure the timely and appropriate resolution of issues in the healthcare design and decision-making process (Figure 3), thus creating a resilient patient safety system (WHO, 2021).

Figure 3. *Healthcare design and decision-making process*



It is imperative that leaders reinforce and empower the information infrastructure, enabling the monitoring of patient safety through audits and incident reporting processes. This will facilitate the analysis of the causes of harm and the identification of strategies to mitigate it (WHO, 2021; Babaie et al., 2023). In order to achieve this, it is essential that healthcare professionals receive adequate training and education, and that the relevant authorities designate individuals or teams with responsibility for patient safety and risk management. Furthermore, international and national directives must be adapted, implemented and aligned with the local healthcare context (WHO, 2021). In terms of safety culture, the indicators are included in the CSDN are explained in more detail in Table).

Table1. *Safety Culture: indicators*

1	The risk management liaison organises and/or replicates training activities in the area of patient safety for the NICU's multidisciplinary team.
2	The risk management liaison promotes multidisciplinary teamwork in the implementation of processes relating to NB Safety.
3	The Risk Management Liaison is involved in supervising and monitoring all stages of the clinical risk management process, mediating communication and liaising between all those involved.
4	The Risk Management Liaison Officer draws up the report resulting from the audit carried out in accordance with current regulations and makes the results available to the multidisciplinary team.
5	Safe appropriations in nursing care are ensured in accordance with Opinion 19/2019 of the Order of Nurses.
6	Safety prevention plans are in place: NICU Emergency Plan.
7	There are safety prevention plans: standards and protocols for aspects related to the safety of NB care.
8	Procedures for checking the emergency car on a monthly basis have been implemented and are complied with.
9	It has implemented and complies with procedures for carrying out tests on the emergency car's defibrillator;
10	It has implemented and complies with procedures for auditing the transport bag, which is checked every time a newborn is transferred/transported;
11	Professionals are trained and sensitised to reporting, communicating the occurrence of incidents in the Notifica, Pharmacovigilance/RAM and Haemovigilance systems.
12	The Standards in force are disseminated across the board, guaranteeing/confirming the multidisciplinary team's access to information by means of a signature and mechanographic number.
13	There is information and training on safety procedures (Welcome Guide, Discharge Guide, Training/Information Actions and Safety Systems Audits).

1.4.2. COMMUNICATION SECURITY

Effective communication is a vital component in enhancing patient safety across diverse healthcare settings (Figure 4). It can facilitate enhanced coordination between healthcare providers, curtail safety incidents, and ultimately optimise patient outcomes (Slawomirski & Klazinga, 2021). The Joint Commission International (JCI) posits that ineffective communication is a primary cause of safety incidents with the potential to cause harm to patients in hospital settings, accounting for 80% of such incidents (JCI, 2018a).

In this context, the objective is to establish a culture of open and non-punitive communication, encouraging healthcare providers to report safety incidents. This enables the monitoring and analysis of such incidents, facilitating the identification of root causes and the implementation of corrective actions from a learning perspective (Muller, 2018; WHO, 2021; DGS, 2022).

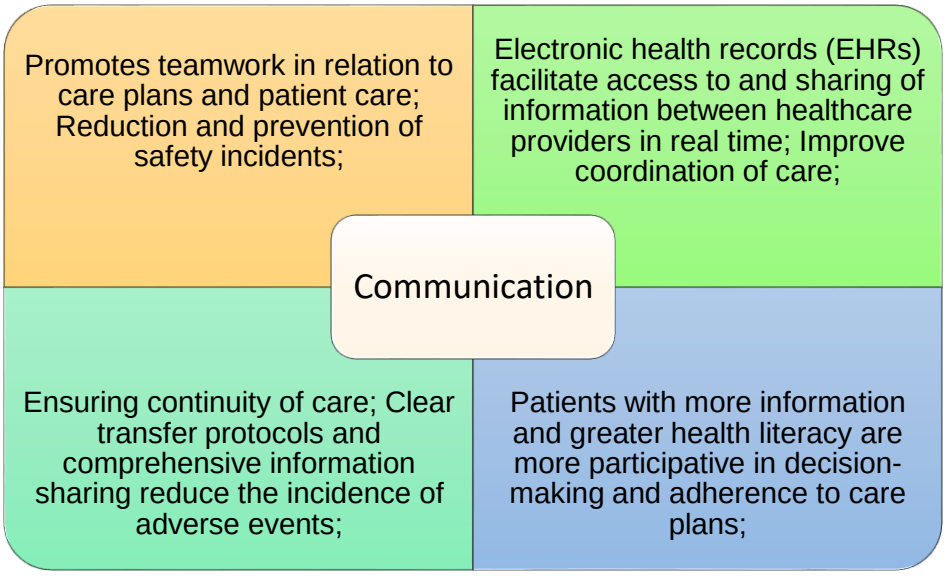
It is therefore important to enhance and optimise communication in the various care settings, ensuring that it is a fundamental aspect of the transition and continuity of care. The utilisation of well-structured strategies and/or tools by healthcare organisations and professionals, such as electronic health records and ISBAR, facilitates and simplifies the transition of care in a patient-centred approach (Muller, 2018; WHO, 2021; Chien, et al., 2022; DGS, 2022). Furthermore, the consolidation of interoperability between electronic health systems and records is planned, with the objective of aggregating patients' clinical information and enabling the timely accessibility of this information to health professionals (DGS, 2022).

Despite the significance of communication between healthcare professionals, it is of paramount importance in the relationship with the patient. Indeed, it is regarded as one of the principal predictors of quality of care in the NICU context (Labrie et al., 2021). It is imperative that patients are informed so that they can participate in their own care, thereby enhancing the management of their care and actively taking responsibility for the safety of their care (WHO, 2021; DGS, 2022). It is incumbent upon healthcare organisations to ensure the implementation of policies that promote transparency with patients. These policies must include, but are not limited to, informed consent, patient

access to medical records and access to all information in a transparent manner (WHO, 2021).

In the context of neonatal care, effective communication tailored to the specific needs of caregivers (parents and family) fosters collaboration between parents and healthcare professionals, with significant clinical implications. It facilitates the transfer of information, the acquisition of consent, and the formulation of decisions (Labrie et al., 2021).

Figure 4. Communication at the various levels of care



For this purpose, the following indicators are used in CSDN (Table 2).

Table 2. *Communication Security: Indicators*

14	Has forms for internal reporting of adverse events and/or incidents.
15	Procedures are in place to ensure accurate and timely communication.
16	Informed and informed consent is guaranteed.
17	The limits of health communication are respected, guaranteeing the ISBAR mnemonic.

1.4.3. UNEQUIVOCAL IDENTIFICATION OF THE NEONATAL PATIENT

The unequivocal identification of patients is a fundamental element in the delivery of secure and suitable care, assisting in the prevention of potential safety incidents. The implementation of robust patient identification protocols contributes to the significant enhancement of the safety of healthcare organisations, reducing the risk of errors and improving the overall quality of patient care (Slawomirski & Klazinga, 2021; Kendir et al., 2023).

The identification of patients is an international patient safety goal that requires a simple process and an effective method (WHO, 2021; DGS, 2022).

It is widely accepted that unambiguous patient identification is a fundamental aspect of preventing errors that could potentially lead to significant harm to the recipient of care. Consequently, healthcare organisations should:

It is imperative that strict patient identification procedures are adopted in order to minimise deviations related to the human aspects involved in the transfusion process. Furthermore, the means of identifying patients must be utilised, in a manner that is appropriate to the transfusion movement of each institution and specific to the transfusion process. This can serve to minimise the identified risk (Order no. 20730/2008).

Neonatal patients are particularly vulnerable to safety incidents related to patient identification. In the context of neonatal care, the risks are amplified due to the distinctive characteristics of the patient, the intricate nature of the care provided, and the prolonged duration of hospitalization. Correct and unambiguous identification of the patient is essential to guarantee safe care, with a reduced likelihood of errors and damage to the patient. This is why unambiguous identification with a wristband should be applied to all newborns in hospital (DGS, 2011a; Souza Gomes et al., 2017).

It is imperative that NICUs are equipped with a coded access door or doors, with the respective code being made available only to service professionals and changed at irregular intervals, without prejudice to the safeguarding of security conditions required in special situations (accidents or catastrophes).

In addition to a coded identification bracelet, hospitalised newborn babies (NB) must also be fitted with an electronic bracelet (TAG), with an alarm and automatic closing system for access doors. This is without prejudice to the safeguarding of safety conditions required in the event of an accident or disaster (Order no. 20730/2008). The placement of the bracelet must be tailored to the individual, with consideration given to factors such as gestational age and the potential risk to the skin.

The following indicators that make up the CSDN have been shown to provide safe patient identification in the neonatal context (Table 3)

Table 3. *Unequivocal Identification of the Neonatal Patient: Indicators*

18	Identification of hospitalised NBs by means of a coded identification bracelet and/or electronic bracelet (Tag)
19	The method used to identify the NB before procedures is based on the positive identification of at least two of these: name and surname (NB and/or mother's), date of birth, unique case number)
20	No abbreviations, acronyms and/or symbols are used to identify the NB
21	The unequivocal identification of the NB always takes place before any intervention
22	There is a procedure in place to guarantee the traceability of complementary diagnostic tests (including labelling of samples with unequivocal identification of the NB and a two-person verification process).
23	Are there any procedures, protocols or other guidelines regarding the discharge/transfer of the NB in order to guarantee continuity of care with the delivery of discharge/transfer documentation?
24	Accompaniment of the NB and carer (parents or guardians) to the gate is carried out by Health Assistant Technicians where the discharge documentation is checked, together with the carer's identification document.

1.4.4.SAFE USE OF THE MEDICINE

Medication-related safety incidents represent one of the main causes of harm associated with healthcare, with a prevalence of 5% (1 in 20 patients), where a quarter of harm is considered serious or life-threatening (WHO, 2023). The OECD estimated that the annual cost of harm associated with medication safety incidents amounted to more than 54 million dollars, equivalent to 11 per cent of total pharmaceutical expenditure in 31 OECD countries (de Bienassis, K., et al., 2022).

Inadequate practices in terms of prescribing, transliterating, dispensing or selling, administering and monitoring, combined with weaknesses in drug administration systems, enhanced by poor professional training and poor working conditions and the environment for harm-free healthcare compromise care (WHO, 2022b; WHO, 2023).

The vulnerability of the neonatal patient translates into an increase in safety incidents related to medication, being inversely proportional to gestational age and Apgar score at the 5th minute of life, accentuated by the complexity of care and the need to adjust drug dosage based on body weight (Leopoldino et al., 2019; Alghamdi, 2019; Manzo et al., 2019; Palmero et al., 2019; Brennan-Bourdon et al., 2020; Alghamdi et al., 2021).

In order to reduce the occurrence of incidents and boost the safe use of medicines, organisations must seek a multifactorial approach supported by a robust safety culture, in which the integration of technology parameterisation, the education and training of healthcare professionals related to reporting and learning from errors (Table 4), the standardisation of therapeutic processes, the design and simplification of medication use systems and processes represent important strategic axes (Alghamdi et al., 2019; Palmero et al., 2019; Alghamdi et al., 2021; WHO, 2023).

Table 4. *Safe Use of Medicines: Indicators*

25	**The organisation uses electronic prescription of medicines**
26	A set of procedures has been implemented for the verbal prescription of medication (in exceptional situations, emergencies or failure of the computer system), guaranteeing double verbal confirmation by the professional who prepares and administers the medication (drug, dose, route).

27	Therapeutic reconciliation is guaranteed in accordance with current regulations.
28	It has implemented standardised practices for the storage and labelling of all medicines, safeguarding packaging requirements.
29	Labelling of medicines is guaranteed when they are transported outside their original packaging.
30	Medicines containing psychotropic drugs and narcotics are kept separate and in restricted áreas.
31	Safe concentrations, (in)compatibilities and safe dilutions are standardised in order to reduce the likelihood of medication-related errors.
32	High-risk medicines are identified and specific strategies are implemented to ensure the safe use of the Maximum Alert Medicine throughout the circuit.

1.4.5. RISK OF PRESSURE ULCERS/SKIN INTEGRITY

A pressure ulcer is defined as a localised injury to the skin and/or underlying tissue resulting from pressure, or pressure in combination with mechanical tension (shear), with varying degrees of severity (European Pressure Ulcer Advisory Panel, 2019). It is estimated that the financial burden of pressure ulcers represents between 2 and 4 per cent of total healthcare expenditure (de Bienassis et al., 2020), with no studies other than those applied to the adult population (Kottner et al., 2013).

Recent studies have indicated that pressure ulcers are a common occurrence in the neonatal population, with prevalence rates ranging from 3% to 43.1% (Kottner, 2013; Broom et al., 2019). Neonatal patients are at an elevated risk due to intrinsic and extrinsic factors associated with their condition and/or iatrogenic factors to which they may be exposed during their admission to the NICU (Broom et al., 2019).

It is therefore recommended that patients at risk of developing pressure ulcers are identified through structured risk assessments as a first step towards prevention. Such assessments are based on risk scales, which represent a central and highly cost-effective approach, offering a return on investment that is seven times greater than that applied (Kottner, 2013; Broom et al., 2019; Slawomirski & Klazinga, 2022).

In Portugal, the Neonatal Skin Injury Risk Observation Scale (NSRAS) is currently undergoing validation by the DGS for use with neonatal patients. Once validated, the NSRAS will be a valuable tool for measuring, assessing, planning and implementing preventive measures and treatment regarding the risk of skin injury (Martins & Curado, 2017; Ferreira et al., 2023). However, it has been demonstrated to have limitations in that it does not include the presence of medical equipment and/or devices, which have been identified as important risk factors. Therefore, there is an urgent need to invest in and standardise a reliable and complete instrument for the NICU context.

With regard to the risk of pressure ulcers/skin integrity, two indicators have been defined in the CSDN (Table 5).

Table 5. *Risk of Pressure Ulcers/Skin Integrity*

33	Regular monitoring of skin integrity is carried out and this assessment is recorded in the NB's file.
34	A tool for assessing the risk of skin damage in the neonatal population has been implemented.

1.4.6. RISK OF NEONATAL FALLS

Although there is a paucity of data on falls in the NICU context, they represent a significant clinical problem, given the vulnerability of the neonatal patient. It is assumed that they are a sudden, unintentional fall against a surface, which may or may not result in damage. They are mostly associated with parental risk factors, such as physical exhaustion, type of delivery, maternal medication and breastfeeding (JCI, 2018b; Carr et al., 2019; Duthie, 2020; Hofstaedter et al., 2023). Such incidents have consequences that extend beyond adverse clinical outcomes, resulting in increased parental emotional stress (Duthie, 2020; Mitchell et al., 2023).

It is established that falls contribute to a high prevalence of comorbidities and/or mortality, which is undoubtedly associated with increased costs (de Bienassis et al., 2020).

Therefore, the implementation of fall prevention programmes and broader quality improvement initiatives within an organisational culture that promotes education, monitoring and environmental risk reduction could reduce the occurrence of fall safety incidents (Table 6), thereby contributing to cost savings in the intensive care setting (de Bienassis et al., 2020; WHO, 2021).

The monitoring of the risk of falls in neonatal patients has become a crucial aspect of care, with the implementation of a Newborn Falls Risk Assessment tool that proposes risk stratification and the identification of preventive interventions (Ainsworth et al., 2016; JCI, 2018b).

Table 6. *Neonatal Fall Risk: Indicators*

35	Intervention strategies are in place to prevent and reduce falls.
36	A fall risk assessment scale has been implemented.
37	There are regulations aimed at preventing and reducing the occurrence of falls.

1.4.7 HEALTHCARE-ASSOCIATED INFECTIONS (HAIS)

Healthcare-associated infections (HAIs) generate an annual burden of 501 Disability-Adjusted Life Years (DALYs[1]) per 100,000 inhabitants (Cassini et al., 2018; Slawomirski & Klazinga, 2022), which represents a cost of between 135 and 230 billion dollars per year in EU countries (Slawomirski & Klazinga, 2022).

In the NICU, HAIs represent a significant complication due to the vulnerability of the neonatal patient, prolonged hospitalisation and the frequency of invasive procedures

[1] A DALY represents the loss of the equivalent of one year of full health. DALYs for a disease or health condition are the sum of years of life lost due to premature mortality (YLLs) and years lived with a disability (YLDs) due to prevalent cases of the disease or health condition in a population. Source WHO (2019) (https://cdn.who.int/media/docs/default-source/gho-documents/global-health-estimates/ghe2019_daly-methods.pdf?sfvrsn=31b25009_7)

associated with clinical practice. This complication is associated with compromised neurodevelopment, increased mortality, and an elevated risk of prolonged hospitalisation consequently, an increase in the financial costs of care (Hsu et al., 2020; Liu et al., 2020; WHO, 2020b; Johnson et al., 2021).

To this end, there has been a focus on multimodal interventions and rigorous measures (Table 7) based on scientific evidence for the prevention and control of associated infections, with these interventions involving simple but effective aspects such as environmental cleaning, hand hygiene, patient isolation and contact precautions, testing and surveillance, education and training of healthcare professionals (WHO, 2021; Slawomirski & Klazinga, 2022, DRE, 2022). This investment provides a return of 7 times the amount invested (Slawomirski & Klazinga, 2022).

Table 7. *HAIs: Indicators*

38	There is a person defined as being responsible for infection prevention and control and antimicrobial resistance in accordance with the standard in force.
39	The unit has implemented hand hygiene measures in accordance with the WHO's 5 moments.
40	The use of a mask is recommended as a measure to prevent respiratory infection.
41	Isolation measures have been implemented to prevent infection.

1.4.8. DEVELOPMENT-CENTRED CARE

There is a growing interest in the benefits of the human factors approach for health systems, due to its potential gains in terms of patient safety (WHO, 2021). The Global Action Plan for Patient Safety seeks to emphasise this significant contribution by ensuring that the incorporation of essential elements of human factors into all healthcare contexts is operationalised through a person-centred approach, where patient

participation and empowerment emerge as the most powerful tool for improving patient safety (WHO, 2021).

The NICU environment is distinguished by the necessity for comprehensive and multifaceted attention, which can potentially be harmful and stressful for the neonatal patient. Such stimuli have been linked to alterations in brain structure and function, as well as disturbances in psychomotor development. These risk factors include exposure to various stressors in the NICU, such as light and noise, exposure to serious infections, a high risk of accidental extubations and invasive procedures, all of which have a detrimental effect on the growth and neurodevelopment of these newborns (El-Atawi et al., 2019; Babaie et al., 2023).

The polyvagal theory is associated with the concept of safety, as it provides a conceptual framework for understanding the influence of the autonomic nervous system (ANS), particularly the vagus nerve, on physiological and behavioural responses to perceived threats and safety, thereby shaping our nervous system's involvement with the environment. The behavioural responses resulting from neuroception (i.e., the feeling of safety) in the context of neonatal intensive care have the potential to either promote or impede co-regulation between the mother-baby dyad and the feeling of safety and security that is essential for the health and well-being of both (Sanders & Hall, 2018; Porges, 2022).

An understanding of Polyvagal Theory in the context of safety is of value in a number of fields, including mental health, trauma therapy and education (Porges, 2022). The creation of environments that promote a sense of safety has been demonstrated to exert a beneficial influence on a number of levels, including the physiological state of individuals, their emotional well-being and their capacity to engage socially and to learn effectively. This perspective on safety is aligned with the notion that a supportive and secure environment is vital for the promotion of general health and resilience. The identification and comprehension of safety-seeking behaviours between parents and children will facilitate the implementation of trauma-informed interventions and individualised care (Babaie et al., 2023).

This approach to neonatal care, which emphasises partnership between healthcare professionals and families, has the potential to facilitate development-centred care

(DCC). This, in turn, has the capacity to reduce the length of stays in the neonatal intensive care unit (NICU), enhance satisfaction for both healthcare professionals and parents, and improve neurodevelopmental outcomes for the neonatal patient (Altimier & Phillips, 2016; Chatziioannidis et al., 2017; Coughlin, 2020; EFCNI, 2021).

It is crucial to underscore the significance of integrating sensory modalities in the care of neonatal patients. Doing so will ensure that this care yields positive physiological outcomes and, in a less reductionist manner, beneficial effects on their neurodevelopment and their relationship with the environment and caregivers. The implementation of individualised interventions has been demonstrated to exert a significant influence on the surrounding environment, thereby promoting enhanced neurodevelopment in neonatal patients and facilitating their attachment process with their caregivers. It is of the utmost importance to recognise that the neonatal patient is an active participant in their care, striving to complete the trajectory of foetal development. Individualised attention to the care environment is therefore essential (Altimier & Phillips, 2016; WHO, 2020b; Coughlin, 2020; EFCNI, 2021).

The role of parents and kangaroo care are also crucial in maintaining neonatal neurodevelopment. Kangaroo care is the optimal trauma-informed care intervention for fostering the bond between parents and babies, as it increases oxytocin levels and reduces stress (Babaie et al., 2023).

At present, the focus of intervention in the NICU has shifted towards the protection and prevention of incidents. This approach is underpinned by a holistic view of the neonatal patient and their active relationship with their physical and social environment, including their family. It is therefore essential that the range of CCD interventions be evaluated in accordance with specific outcome indicators related to the interventions themselves (Table 8).

***Table 8**. Development Centred Care: Indicators*

42	NB care is grouped in such a way as to minimise unnecessary manipulation.
43	A peaceful environment is promoted to ensure uninterrupted sleep, respecting a sound level of 45db-65db.

44	Technological devices (mobile phones and the like) are used in silent mode.
45	A separate room is used for preparing medication/serums outside the unit/room, in order to keep noise and light levels within the recommended parameters.
46	A blanket or protective cover is used to cover the incubator.
47	The NB's eyes are protected from excessive lighting at all times, ensuring that adjustable intensity lights are used when assessing the NB.
48	Dim ambient lighting is maintained between RN manipulations.
49	A neutral thermal environment is promoted in order to maintain a normal core temperature, with minimal oxygen consumption and calorific expenditure (36.5ºC-37º).
50	Promote Positive Touch.
51	Promote positioning and containment.
52	Encourage/educate/integrate the participation of parents/carers in care.
53	Promote/support/encourage breastfeeding.
54	Promote pleasant/neutral olfactory sensations.
55	NB is sensitised to maternal odour.
56	The scale of self-perceived parenting skills (Discharge Guide) is provided.

CHAPTER II: RESEARCH PROBLEM AND STUDY OBJECTIVES

> "Scientific research is the construction and search for knowledge that takes place when we recognise the ineffectiveness of existing knowledge, which is incapable of providing consistent and justifiable answers to the questions and doubts raised. It is recognising the limitations of established knowledge and the need to produce it in order to clarify and provide an understanding of a doubt. In this sense, to start a scientific investigation is to recognise the crisis of existing knowledge and try to modify, expand or replace it, creating a new one that answers the existing question." Köche (2016, p.30).

2.1 RESEARCH PROBLEM

The CSDN is a notable tool that, through the operationalisation of a set of indicators, gauges, systematises and guides the actions of professionals, thereby promoting safety and quality across the entire continuum of care. While there is a set of indicators that have been widely validated by the scientific community and implemented in various international safety checklists, this checklist is unique in that it includes safety indicators for CCDs. This is in order to guarantee the quality and safety dimensions that person-centred care advocates.

Only three international checklists for neonatal intensive care were identified (Silva, 2019; Saraiva et al., 2022; Manzo et al., 2023). No indicators related to the range of CCDs that make up the CSDN were identified, which makes it unique.

The range of indicators related to Development-Centred Care is supported by a substantial body of scientific evidence; however, they have never been associated with or grouped together in an instrument designed to enhance safety in neonatal care. It is therefore imperative to ascertain whether these indicators are capable of measuring the construct they are designed to assess. To this end, they must be validated so that they can be incorporated into programmes aimed at improving quality and safety in the NICU context, given their pivotal role in neonatal care and the outcomes that this care produces.

2.1.1 GENERAL OBJECTIVE

- Validate the indicators of the Neonatal Safety Checklist by experts to ensure that the construct is robust and capable of fulfilling its purpose.

2.1.2. SPECIFIC OBJECTIVES

- Identify experts in the field of the NICU in order to validate the construct;
- Recognise and fill in gaps in the checklist;
- Ensure that the indicators in the Checklist explain the specific nature of neonatal care;
- To disseminate results in order to promote improvements and leverage quality in neonatal care.

CHAPTER III: METHODOLOGY

The consolidation of the methodological stages of research is represented by a systematic and organised design that the researcher proposes to follow in order to answer the question and/or objective of the study, including the methods and procedures used. The choice of methodology depends on the nature of the research problem, the objectives, the theoretical approach adopted and the resources available.

3.1 METHODOLOGICAL DESIGN

The CSDN is presented in this study as a quality tool with the strategic objective of measuring, systematising and guiding the promotion of safety throughout the care continuum, thereby enhancing quality.

The implementation of this tool is intended to guarantee compliance with the standards set forth for neonatal patient safety, ensuring that these standards are reflected in the care provided and that the care is effective, efficient, and of the highest quality and safety standards. The objective is to provide guidance to healthcare professionals throughout the neonatal patient's journey, from admission to discharge. This enables the identification of the various safety mechanisms in place and fosters a culture of safety in the care provided through critical thinking about all care activities and a commitment to utilising the tools in order to achieve continuous improvement (Marshall Junior et al., 2008).

The tool was constructed and introduced to the HESE NICU in 2015 and has since undergone recent conceptual enhancements following an analysis of the safety targets and indicators made available by the Health Regulatory Authority (2022) and the National Plan for Patient Safety 2021-2026 as part of the National Strategy for Health Quality, supported by the WHO (2021). Furthermore, the instrument was subjected to several phases of pre-testing, benchmarking, and improvements as a result of review and adaptation to reality. This ensured that the indicators were meaningful to the neonatal patient and strengthened their validity (Boateng et al., 2018).

The rigour of its design is intended to result in a reliable and transparent instrument that can be relied upon to provide accurate measurement and facilitate progress in understanding health outcomes (Boateng et al., 2018). It is thus intended that the design be complemented by means of validating the instrument, with a view to consolidating its purpose.

As posited by Hulley et al. (2003), cited by Aguiar et al. (2011), the concept of validity is related to the degree of accuracy of a given phenomenon. The most common validity tests are content validity, which requires evidence of content relevance, representativeness and technical quality, assessed by experts (Boateng et al., 2018).

In the field of healthcare, a variety of criteria are employed to select and determine new quality indicators through the Delphi method. Accordingly, indicators selected through consensus methods, such as the Delphi technique, are deemed to possess a high degree of validity, which is a fundamental prerequisite for any quality indicator (Stereiner et al., 1995, cited in Boulkedid et al., 2011; Zarili et al., 2021).

3.1.1 DELPHI METHOD

The Delphi method permits a blended approach between qualitative and quantitative techniques, and when employed with methodological rigour, it is an effective method. The Delphi method is defined as a systematic process whose aim is to structure a system of effective collective communication. This allows a group of experts as a whole to deal with a complex problem and reach a measurable consensus (Marques & Freitas, 2018; Humphrey-Murto et al., 2020; Niederberger & Spranger, 2020; Barrios et al., 2021). The objective is thus the collective construction of a consensus, which entails multiple rounds of questionnaires and subsequent feedback to the experts to encourage reflection and enhance the instrument's quality (Figure 5).

The aforementioned authors recommend the inclusion of four main characteristics: the guarantee of anonymity, the use of a standardised questionnaire that can be adapted for each new round of questions, the interactive process with controlled feedback between the researcher and experts, and statistical aggregation.

This collective construction could entail at least two rounds of questionnaires, with subsequent feedback, thereby encouraging a period of reflection before commencing a new round, which serves to enhance the instrument's evaluation (Marques & Freitas, 2018; Barrett & Heale, 2020; Lacasta, 2022; Spranger et al., 2022).

This method has been extensively investigated in the field of health, particularly in the development of health indicators, consensus-building on treatment guidelines, and the creation of tools to inform health design in relation to safety. Despite its relevance, the process is complex and demanding, and therefore it is essential to describe, substantiate and reflect methodologically in order to enhance the reliability of the results (Boulkedid et al., 2011; Niederberger & Spranger, 2020; Taylor, 2020; Barrios et al., 2021; Spranger et al., 2022).

A standardised questionnaire in electronic format was therefore administered sequentially and individually to the experts, ensuring their anonymity. To ensure the questionnaire's objectivity, issues of semantics and clarity of information were considered. The time required to complete the questionnaire was analysed, with an estimated response time of between 15 and 20 minutes. This was done in order to prevent experts from abandoning the questionnaire due to slow responses. These were tested in advance of each round with the experts in order to ascertain their vulnerability.

Each expert was requested to analyse the various indicators that constitute the CSDN, as presented in the questionnaire, using a Likert scale with a score of one to four, in order to assess their representativeness and relevance (Alexandre & Coluci, 2011; Campbell et al., 2018).

- 1 = not relevant or not representative,
- 2 = item needs major revision to be representative,
- 3 = item needs minor revision to be representative,
- 4= relevant or representative item.

In this sense, the sum of the agreement of the indicators scored 3 or 4 reflects the percentage of agreement of the experts. It is therefore necessary to revise and/or

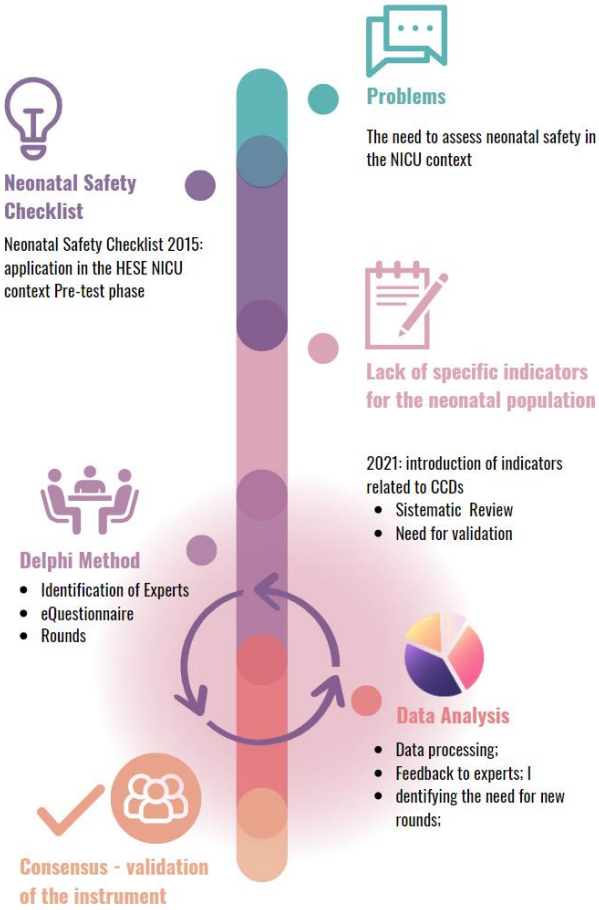
eliminate those indicators which have been scored 1 or 2 (Alexandre & Coluci, 2011; Benevides et al., 2016; Campbell et al., 2018; Storesund et al., 2019; Harris et al., 2022).

The utilisation of Microsoft Excel 2016 enabled the aggregation of data and the subsequent description of its principal characteristics, including the calculation of measures of central tendency. This approach facilitated the attainment of an objective understanding of the data. The median is less susceptible to the influence of outliers than other measures of central tendency. In contrast, the interquartile range (IQR) represents the dispersion of the middle 50 per cent of observations and is employed to ascertain consensus. Accordingly, on a four-item Likert scale, an interquartile range (IQR) of 1 or less can be considered indicative of consensus (Shang, 2023).

Similarly, the representativeness of an indicator enabled the calculation of the Content Validity Index (CVI), with a threshold of 80% or above (Pedreira et al., 2016; Martins et al., 2017; Lacasta et al., 2022; Shang, 2023).

It is important to note that the contributions of the experts were not solely quantitative; they also had the option of suggesting modifications to the structure of the indicators. This input was considered to be of significant value due to its potential for advancing arguments and reasoning in the development of the indicators (Spranger et al., 2022).

Figure 5. *CSDN Methodological Design*



3.1.2. POPULATION AND SAMPLE OF EXPERTS

This methodology is associated with the specificity of experts, who are expected to make a significant and crucial contribution to a topic that has been little explored thus far: consensus. Accordingly, experts are individuals who possess considerable expertise and knowledge in the subject matter under investigation (Lacasta, 2022).

It is established that competence encompasses the individual's responsible, effective and proven knowledge in a given professional context, taking into account their educational background (knowledge, values and attitudes) and professional experience (Roldão, cited in Amaral & Figueiredo, 2021). The concept of expertise is inextricably

linked to both practical experience and theoretical expertise in a given field (Benner, cited in Amaral & Figueiredo, 2021; Shang, 2023). Despite the lack of consensus regarding the criteria for defining experts, educational level and years of experience are the most commonly used metrics for classifying experts (Aguiar et al., 2011; Shang, 2023).

The cognitive heterogeneity of the expert panel is essential for the generation of more robust and valid results, which in turn support innovative discussion processes as well as the individual skills, knowledge and competences of the panel members. Heterogeneity can exert a significant impact on data quality, credibility, and the acceptance of quality indicators (Boulkedid et al., 2011; Niederberger & Spranger, 2020; Spranger et al., 2022).

Conversely, patients and their families are the ultimate consumers of healthcare services and possess a comprehensive and distinctive understanding of the outcome, making their insights on how to enhance safety standards invaluable. It is therefore imperative that they be involved in patient safety planning, as this allows all strategies to be viewed from the patient's perspective (WHO, 2021).

In conclusion, the utilisation of experts in this study resulted in the formation of a convenience sample comprising healthcare professionals (doctors and nurses) identified within the field of the NICU and patient safety (Table 9). An invitation to participate in this study was extended to representatives of the neonatal patient, specifically to carers representing a parent support association. Although there was no consensus on this aspect, a panel of between 15 and 20 experts was deemed appropriate, whose inclusion criteria are outlined in Table 10 (Alexandre & Coluci, 2011; Marques & Freitas, 2018; Nora et al., 2017; Taylor, 2019; Böhmdorfer-McNair et al., 2021; Zarili, 2021; Lacasta et al., 2022; Shang, 2023).

Table9. *Inclusion criteria for expert panel*

Health professionals working in the NICU (> 5 years)	Competence encompasses the individual's responsible, effective and proven knowledge in a given professional context (OE, 2017; Amaral & Figueiredo, 2021; Lacasta et al., 2022).

Training in Health Risk Management/Patient Safety	The acquisition and development of expert competences is based on lived experiences, knowledge and know-how, strengthened symbiotically through research and clinical practice (Taylor, 2019; Niederberger & Spranger, 2020).
Member of the Quality and Safety Committee	These committees are responsible for promoting, monitoring, facilitating and integrating all the activities provided for in the National Strategy for Quality in Health and the PNSD (Order No. 3635/2013).
Training in the field of CCD	Skills related to the assessment, intervention and promotion of the therapeutic environment in the NICU with the implementation of developmental care and family inclusion (Coughlin, 2020).
Neonatal patient representative	A care partnership requires active participation in decision-making processes about their children's healthcare (Hagen et al., 2018; Niederberger & Spranger, 2020).
Clinical supervision	The safety and quality of care justifies shared teaching about the method to be adopted, the steps that make it up and its implementation (Carvalho et al., 2019).
Higher education lecturer in the area of intervention	Heterogeneous groups tend to generate deliberations of higher quality and acceptance (Marques & Freitas, 2018, Taylor (2019, Lacasta et al., 2022).

3.1.2.1. CHARACTERISATION OF THE SAMPLE

Following the identification of potential experts in the field of neonatology and neonatal patient safety through a range of professional organisations, scientific societies in the field of neonatology, higher education institutions and associations of health professionals, as well as parents/carers of premature newborns admitted to the NICU, the experts were contacted via email. They were invited to participate in the validation of the Quality in Neonatal Care initiative as part of a panel of experts. The Safety Checklist Validation instrument was validated through the use of an informed consent form, which

provided general information and was supported by a consent support document that clarified the study's objective, the instrument to be validated, and the method used. The researcher's contact details were provided for any further clarification or additional information that the experts might require (see Appendix I).

A total of 30 invitations were sent to potential experts via email, with a seven-day window for consideration of the responses. A total of 19 experts expressed their willingness to participate in the study. Given the distinctive characteristics of the expert groups, a cluster analysis will be employed to examine their demographic profiles. This approach will facilitate the characterisation of the groups in a manner that reflects the unique contributions of their members.Table 10 presents de demographics of the panel of experts.

Table 10. *Demographic characterisation of the panel of experts*

		Frequency	**Percentage**
Sample of experts (n = 19)	Doctor	3	15,7%
	Nurse	15	78,9%
	1 Parent representative	1	5,3%
Sex (n=19)	Female	17	89 %
	Male	2	11 %
Location (n=19)	Almada	1	5,3
	Angra do Heroísmo	1	5,3
	Beja	2	10,6
	Bragança	1	5,3
	Covilhã	1	5,3
	Évora	3	15,6

	Faro	1	5,3
	Lisboa	2	10,6
	Porto	2	10,6
	Funchal	1	5,3
	Setúbal	2	10,6
	Viseu	2	10,6
Professional experience and formation			
Professional experience and field of work (health professional experts n= 18)	≥ 10 years	17	94,4%
	> 5 e ≤	1	5,6%
	NICU	16	88,9%
	CQS / Clinical Risk Management	11	61,1%
	Clinical Supervision	18	100%
	Teaching in Higher Education Institutions	3	16,7%
Training (health professional experts n= 18)	Paediatrics/ Neonatology	18	100%
	CDD (NIDCAP and FINE)	11	61,1%
	Patient safety	11	61,1%

Note: QQS: Quality and Safety Committee; NIDCAP: Newborn Individualised Developmental Care and Assessment Program; FINE: Family and Infant Neurodevelopmental Education.

In order to encompass the diverse organisational realities that exist, an attempt was made to broaden the diversity of perspectives and representativeness through the geographical dispersion of the experts. This approach was taken in order to prevent

biases and guarantee more robust data, greater rigour and reliability of the results, with greater future applicability of the CSDN (Figure 6).

With regard to the expert representing the patient, questions were posed to ascertain his experience as a NICU user, with a view to evaluating the value of his contribution. It is noteworthy that the expert was a NICU user on two separate occasions following the birth of his two children, at 27 and 32 weeks gestational age, with a birth weight of 980 grams and 1485 grams, respectively. This resulted in 75 and 29 days of hospitalisation, respectively. Despite his assertion that he was unaware of the concept of Developmental Care in the NICU, he stated that he had collaborated with the multidisciplinary NICU team in the care of his children, and that factors such as sound, light, and manipulation had been taken into account. In response to a question regarding the elements he considered essential for safe hospitalisation in the neonatal context, he identified infection prevention measures as a key priority.

3.1.3 DATA COLLECTION PROCEDURES

Data analysis is a fundamental component of research, providing the descriptive and exploratory basis for decision-making, transforming empirical data into useful information, enabling decision-making and the construction of knowledge based on concrete evidence.

Consequently, this phase was conducted in parallel with the overall methodology. The data obtained in the initial round of data collection, after undergoing processing and analysis, informed the design of a second questionnaire. This questionnaire aimed to address areas of contention regarding indicators that had not reached consensus in the initial round or had been suggested in open response format.

In addition to the quantitative data, textual suggestions were incorporated, and their analysis enabled the identification of indicators that required revision in terms of concept, wording, or even the removal of those that did not meet consensus. Some inconsequential suggestions were excluded on the grounds that they were not aligned with the expert's input.

In light of the aforementioned considerations, the initial phase of the study commenced on 6 May 2024 (Table 11). This involved the distribution of an electronic questionnaire via email, with the access link provided on the Google Forms platform. This was made available for completion over a period of 15 days (see Appendix II).

A second questionnaire was dispatched to the experts on 27 May 2024, accompanied by a summary of the principal data and levels of compliance achieved. It was intended that this questionnaire would be completed in accordance with the same principles as the previous one (see Appendix III). The data obtained enabled the conclusion of the initial stages of the study and the preparation of a third and final instrument, which will be presented in due course.

In the initial phase of the study, 19 questionnaires were distributed to experts who had consented to participate. Of these, 16 were completed within the specified timeframe, while one was not submitted within the allotted 15 days. Consequently, this response was not included in the analysis, representing 84.2% of the initial expert population.

The second phase of the study commenced on 27 May, with the provision of feedback on the data collected in the preceding phase and the dissemination of a new electronic questionnaire to the 16 experts who had participated in the previous round. A total of 14 questionnaires were returned, representing a response rate of 73.7% among the initial population of experts who had accepted the invitation to join the panel. A total of 12.5% of participants withdrew from the study between the first and second rounds.

Table 11. *Rounds; Duration and number of participating experts*

Rounds	Chronological frieze (days)	Initial Experts	No. of answers	No Reply
Round #1	06/05/24 a 21/05/24 (15 days)	19	16	3
Round #2	27/05/24 a 11/06/24 (15 days)	16	14	2

It is acknowledged that one of the constraints associated with this methodology pertains to the attrition of experts across the requisite number of rounds for the study, with such departures potentially linked to divergent perspectives (Shang, 2023). To address this limitation, the research team sent reminders 10 and 13 days after the link to access the questionnaire was sent, encouraging experts to complete it and reiterating the importance of their contribution.

It is worth noting that the expert whose input was intended to inform the instrument's end user (neonatal patients in the form of carers) contacted the researcher to express reservations about the questionnaire, citing its technical language and complexity as reasons for declining to join the panel of experts. It is important to note that the instrument was not accessible to all those involved, which is a limitation of the study.

3.1.4. MAIN STATISTICAL PROCEDURES

The measures of central tendency and dispersion considered relevant to this study are the median (Me) and the interquartile range (IQR), due to their sample characteristics of being less susceptible to outliers. All the indicators were also investigated in terms of their content validity index. It will therefore be considered cumulatively for each CSDN indicator:

- AIQ ≤ 1, consensus reached for the indicator;
- IVC ≥ 80%, indicator with representativeness.

In considering qualitative data in the form of suggestions, only those relating to the indicator itself were taken into account, with those that explained individual or collective professional experiences in relation to the organisation in which the expert was working excluded. Only one instance of each suggestion was taken into consideration.

In order to facilitate the reading and interpretation of the results, they will be presented in a single table format, divided into the various dimensions that comprise the CSDN. To facilitate consultation and identification, the indicators will be associated with a numerical and sequential form.

- The suggestions put forth by the experts (identified as P#) were acknowledged and found to be beneficial in enhancing the comprehension of the quantitative data, subsequently facilitating the linguistic textual reconstruction with a view to achieving a cohesive and coherent structure. It should be noted that the provision of suggestions was optional and that not all indicators were accompanied by suggestions.

3.1.5 ETHICAL CONSIDERATIONS

With regard to the conceptual construction that supports research, it is known that this involves a specific set of ethical considerations in order to guarantee the integrity of the process and the reliability of the results (Vilelas, 2020). Thus, the implicit ethical considerations approved and recommended by the ethics committee of the Polytechnic Institute of Santarém (Appendix IV) include:

- Guaranteed transparency and reproducibility;
- Ensuring the impartial and inclusive selection of studies in order to minimise publication bias;
- Respect copyright by properly citing sources;
- Confidentiality and anonymity with regard to research participants;
- Disclosure of Conflicts of Interest, if any;
- Responsibility in interpreting the results, recognising the limitations of the review and avoiding undue extrapolations;
- Transparent disclosure: providing clear information on the methodology used, including inclusion and exclusion criteria, so that readers can assess the validity and reliability of the research.

- The data collected will be kept and stored securely for a period of five years, after which it will be destroyed in accordance with the applicable ethical and legal requirements.

CHAPTER IV: PRESENTATION AND DISCUSSION OF RESULTS

Presenting and analysing data is a crucial phase of research. Through careful organisation and rigorous interpretation of the data, the results will enable relevant conclusions to be drawn.

4.1 ROUND #1

The indicators that comprise the safety culture dimension exhibited consensus-guaranteeing overall scores, with a mean of 4 across 92.3% of the indicators and an AIQ ranging from 0 to 1. Approximately 69.2% exhibited an AIQ of nearly zero, indicating the absence of dispersion in relation to the centrality measure (Me = 4). Furthermore, the representativeness of the indicators was fully guaranteed in this dimension, with a CVI ranging from 81.25% to 100%. Notably, six indicators achieved a CVI of 100%.

The CVI of 81.25% attributed to indicators #5, #11 and #12 suggests alignment with data from the DGS (2020 and 2022). This data indicates that, at the national level, the results of the pilot study and evaluations carried out between 2014 and 2020 demonstrate the necessity for intervention and clarification with regard to aspects related to patient safety culture. These aspects include the response to non-punitive errors, notification, staffing, and others.

In regard to the Communication Security dimension, the initial round of questionnaires yielded feedback on all indicators, with a mean of 4 and an AIQ of 1 or below. The CVI ranged from 81.25% to 93.75%. The aforementioned values permit the validation of all the indicators that constitute this dimension.

The DGS has sought to enhance the security of communication in healthcare, as this is a principal predictor of quality and is explained by actions aimed at effective and efficient communication between the various stakeholders. This can only be achieved through the implementation of clearly defined standards and procedures that guarantee effective communication during transitions or transfers of responsibility in care. This should be accompanied by the adoption of best practices and the active involvement of patients and carers in the process (DGS, 2022).

It is nevertheless important to analyse the representativeness of the indicator related to Informed and Clarified Consent (IVC 81.25%), recommended by the DGS as a strategy for adapting the communication of clinical information to patients and caregivers. This standard is currently being updated and is expected to be monitored through audits of its use (DGS, 2022).

In the context of the NICU, family-centred communication serves important clinical objectives, as it allows information to be conveyed, consent to be obtained and joint decisions to be made (Labrie et al., 2021). Furthermore, the inability of the neonatal patient to assert the principle of autonomy results in the duty of legal representation being transferable to the parents. It is then incumbent upon the parents to give informed consent for certain medical, therapeutic and research procedures to be carried out (OE, 2015).

The intricacies of evolving neonatal care may justify the use of presumed consent, whereby the obligation to act is derived from the principle of beneficence, rather than the withholding of information from the caregiver (DGS, 2015). A review of the literature revealed no studies on this subject. Consequently, the conclusions presented by the researcher are his own responsibility. Despite the legal and ethical framework that supports informed consent, it remains an imperfect practice in the context of NICU care. Presumed consent continues to prevail.

Of the seven indicators that constituted the CSDN dimension of Unequivocal Identification of the Neonatal Patient, six achieved a CVI of ≥87.5% with a variable QIA between 0 and 1. This data elucidates the investment and positive evolution of professional and organisational practices in raising awareness and implementing strategies for the unequivocal identification of patients (DGS, 2022).

The risk of safety incidents related to the unequivocal identification of neonatal patients is heightened. It is therefore essential to implement standardised and well-defined rules and strategies, which are subject to audits (Souza Gomes et al., 2017; DGS, 2022; JCI, 2023). However, the placement of the wristband on the neonatal patient should be meticulously examined, with due consideration for their particular characteristics, gestational age, and clinical status.

Indicator #24 exhibited a low trend value (mean = 2.5) and considerable dispersion (acceptable interval = 3), with a CVI of 43.75%, and thus was excluded from the CSDN questionnaire for the subsequent iteration.

The Safe Use of Medicines dimension is constituted by eight indicators, all of which exhibited a mean value of 4 and an AIQ variability between 0 and 1, thereby ensuring consensus. With regard to the CVI, however, indicator #27 was deemed to be unrepresentative, with a value of 75%. While the group of experts considers the indicator to be relevant with an ME of 4 and an AIQ of 1 (within the limits of consensus), they also consider it to be unrepresentative. The indicator concerns a facet of drug safety pertaining to the process of therapeutic reconciliation. This has been a standardised procedure since 2016, as set forth in Standard No. 018/2016 (DGS, 2016). Furthermore, the PNSD has consistently advocated for the implementation of this standard (DGS, 2022). It was thus resolved to restate the indicator and advance it to the subsequent phase of questionnaires.

With regard to the dimensions of risk, namely Pressure Ulcers/Skin Integrity and Neonatal Falls, the indicators reached consensus through the analysis of both the measures of central tendency and dispersion, as well as the CVI (81.25% - 93.75%). In both dimensions, the indicators with the lowest scores relate to the utilisation of risk assessment instruments.

With regard to the risk of pressure ulcers, the instrument adopted by the DGS is reductive in nature and requires updating, as it is not parameterised for neonatal patients (Braden Q Scale), given that it covers individuals over 28 days old (DGS, 2011b). A number of studies have been conducted with the aim of validating assessment scales for skin integrity risk. These include the Neonate Skin Injury Risk Observation Scale (NSRAS), which is currently being validated by the DGS (Martins & Curado, 2017; Ferreira et al., 2023).

The HCAI safety dimension demonstrated the highest level of expert consensus, indicating that financial investment (Slawomirski and Klazinga, 2022) and the numerous national and international initiatives have resulted in enhanced educational training and increased awareness, which have contributed to a reduction in HCAIs (WHO, 2021; DGS, 2022). Notwithstanding these levels of consensus, the indicators underwent a

safety round following a review of semantic issues with the objective of validating the result.

The final dimension for analysis is that of Development-Centred Care indicators, which is the most extensive of the dimensions and contains a total of fifteen indicators. This dimension introduces innovation to the instrument, differentiating it from those identified in the literature (Silva, 2019; Saraiva et al., 2022; Manzo et al., 2023) by examining a range of safety indicators pertaining to the creation of secure and regulated environments for neonatal patients.

CCD represents a strategic approach that prioritises the advancement of cognitive and behavioural development in neonatal patients. This care comprises a variety of approaches, including environmental reorganization in the NICU, individualization of care, family-centered care, non-nutritive sucking, proper positioning and restraint, early initiation of breastfeeding, pain control, and kangaroo care (Raghu & Vatsa, 2021).

Of the fifteen indicators associated with the CCD, only two were found to lack consensus regarding their representativeness. The first of these, indicator #45, pertains to the physical design of the NICU, with the objective of identifying a space that is separate from the neonatal patient area, in which non-emergency therapies can be prepared. Compliance with this indicator would result in a reduction in the level of noise and movement in the vicinity of the patient, thereby creating a more tranquil environment with a reduction in potentially stressful stimuli. Furthermore, it would facilitate the attention of the healthcare professional during the preparation phase of the therapeutic intervention, thereby promoting the safe administration of the medication. Although this did not achieve consensus, it was reformulated and presented in the second round. This approach was endorsed by the EFCNI (2022), which stated:

> "NICU design is a very important and rapidly evolving area. Originally, NICUs weren't built so that parents could be present 24 hours a day, 7 days a week, and we still see huge differences in the quality and facilities of NICUs in different European countries. So it's a question of rebuilding, rethinking and using architecture as a kind of medicine." (EFCNI 2022, p.21).

Another indicator that did not reach a consensus on its representativeness, #56, is related to parental competencies and empowerment for caring for their child, especially

at a time of transition of care and gaining parental autonomy. This can be enhanced by using a scale of self-perceived competencies (Marques & Sá, 2004; Rodrigues, 2010; Wittkowski et al., 2017; Monteiro et al., 2022; Schneider et al., 2024).

The scale comprises items designed to assess the perceived parenting capacity of mothers who have experienced the hospitalisation of their children in the neonatal context (Schneider et al., 2024). The utilisation of this indicator could facilitate the desired informed and empowered involvement of parents, thereby ensuring a safe discharge (EFCNI, 2021).

In light of its pivotal role and in accordance with the previously established criteria, the indicator was not dismissed but rather reframed, incorporating the expert recommendations to substantiate the findings.

The initial round of testing demonstrated that the CSDN is a reliable and comprehensive instrument, comprising a set of representative indicators for evaluating the safety of neonatal patients throughout their stay in the NICU, with overall positive outcomes (Table 12). Of the 56 indicators, only four exhibited a CVI below the 80% threshold, suggesting that they may not represent reliable operationalisations of the construct (Pedreira et al., 2016; Martins et al., 2017; Lacasta et al., 2022; Shang, 2023). Those indicators with negative scores were removed, and the remainder were reformulated, always with due consideration of the input provided by the experts.

Following the analysis of the data (Table 12), the reformulation and deletion of indicators, the experts were invited to participate in a second round of the study. The objective of this second phase was to corroborate the results obtained and the changes made.

Table 12. *Results Round 1*

	Security Culture Dimension: CSDN Indicators	Me	AIQ	IVC	Suggestions
1	The risk management liaison organises and/or replicates training activities in the area of patient safety for the NICU's multidisciplinary team.	4	0	100%	"Implement an **annual training** plan in this area." **(P1; P5)**
2	The risk management liaison promotes multidisciplinary teamwork in the implementation of processes relating to NB safety	4	0	100%	"**discussing** ideas between team members" (P5)
3	The Risk Management Liaison is involved in supervising and monitoring all stages of the clinical risk management process, mediating communication and liaising between all those involved	4	0	100%	"Clinical Risk and Non-Clinical Risk fundamental to **Global Risk Management**" (P9) "**Analysis of** adverse events and **feedback**" (P16)
4	The Risk Management Liaison Officer draws up the report resulting from the audit carried out in accordance with current regulations and makes the results available to the multidisciplinary team.	4	0	93,75%	"Report that should include **Clinical Risk and Non-Clinical Risk data**" (P9) "presenting a summary to the nurse manager" (P5)
5	Safe appropriations in nursing care are ensured in accordance with Opinion 19/2019 of the Order of Nurses;	4	1	81,25%	"Nurse managers **calculate safe allocations annually**" (P5)
6	Safety prevention plans are in place: NICU Emergency Plan;	4	0,25	100%	
7	There are safety prevention plans: standards and protocols for aspects related to the safety of NB care;	4	0	100%	"Prevention specifically of **patient injury by healthcare**" (P16)

8	Procedures for checking the emergency car on a monthly basis have been implemented and are complied with	4	0	100%	"Within the framework of **the institution's** certification and **directive**" (P12) "Checking the **seal on** each car" (P9) "Activity **distribution** plan" (P5) "It has implemented and complies with procedures..." (P2) "checking **other equipment**" (P9;P11)
9	It has implemented and complies with procedures for carrying out tests on the emergency car's defibrillator;	4	0	93,75%	"define the **frequency of** this verification?" (P5; P9; P10)
10	It has implemented and complies with procedures for auditing the transport bag, which is checked every time a newborn is transferred/transported;	3	1	81,25%	"...**whenever** a transfer takes place..." (P2) "periodic and **recorded** reviews" (P12; P14) "reference to the **checklist** for uniformity in the materials present in it" (P2; P4 P11)
11	Professionals are trained and sensitised to reporting, communicating the occurrence of incidents in the Notifica, Pharmacovigilance/RAM and Haemovigilance systems;	4	1	81,25%	Professionals having training and being sensitised to reporting could be **separate items.** (P2)

12	The Standards in force are disseminated across the board, guaranteeing/confirming the multidisciplinary team's access to information by means of a signature and mechanographic number;	4	1	81,25%	
13	There is information and training on safety procedures (Welcome Guide, Discharge Guide, Training/Information Actions and Safety Systems Audits).	4	0	93,75%	"Is the reception guide a safety procedure?" (P16) "in the context of **in-service training**" (P5)

Communication Security Dimension: CSDN Indicators		**Me**	**AIQ**	**IVC**	**Suggestions**
14	Has forms for internal reporting of adverse events and/or incidents	4	0	93,75%	
15	Procedures are in place to ensure accurate and timely communication	4	1	93,75%	"**Subjective**" (P2; P16) "**ISBAR** language and **organisational methodology**" (P5)
16	Informed and informed consent is guaranteed	4	1	81,25%	
17	The limits of health communication are respected, guaranteeing the ISBAR mnemonic	4	1	87,5%	"**ISBAR as a structure**" (P16)

Dimension Unequivocal Identification of the Neonatal Patient: CSDN Indicators	**Me**	**AIQ**	**IVC**	**Suggestions**

18	Identification of hospitalised NBs by means of a coded identification bracelet and/or electronic bracelet (Tag)	4	1	87,5%	"Tag or Hugs" (P9) "Identification is important, but should extremely premature NBs have wristbands?" (P10) "placed in the respective cradle or incubator and not directly on the NB" P(12)
19	The method used to identify the NB before procedures is based on the positive identification of at least two of these: name and surname (NB and/or mother's), date of birth, unique case number)	4	0,25	87,5%	Identification should be based on the **first and last name of the NB** "AND" the mother's "**unique medical file number**" (P2).
20	No abbreviations, acronyms and/or symbols are used to identify the NB	4	0	93,75%	
21	The unequivocal identification of the NB always takes place before any intervention	4	0,25	93,75%	
22	There is a procedure in place to guarantee the traceability of complementary diagnostic tests (including labelling of samples with unequivocal identification of the NB and a two-person verification process).	4	1	87,5%	
23	There is a procedure in place to guarantee the traceability of complementary diagnostic tests (including labelling of samples with unequivocal identification of the NB and a two-person verification process).	4	0,25	100%	

24	Accompaniment of the NB and carer (parents or guardians) to the gate is carried out by Health Auxiliary Technicians where the discharge documentation is checked, together with the carer's identification document.	2,5	3	43,75%	"checks should also be carried out **before leaving** the service, and by a **more specialised team**, such as nurses" (P2) **"You don't understand"** (P16)

Safe Use of Medicines Dimension: CSDN Indicators		**Me**	**AIQ**	**IVC**	**Suggestions**
25	The organisation uses electronic prescription of medicines	4	0	93,75%	
26	A set of procedures has been implemented for the verbal prescription of medication (in exceptional situations, emergencies or failure of the computer system), guaranteeing double verbal confirmation by the professional who prepares and administers the medication (drug, dose, route).	4	0	87,5%	
27	Therapeutic reconciliation is guaranteed in accordance with current regulations	4	1	75%%	
28	It has implemented standardised practices for the storage and labelling of all medicines, safeguarding packaging requirements	4	0	87,5%	"**Evaluating** whether these practices are being **followed**" (P2)
29	Labelling of medicines is guaranteed when they are transported outside their original packaging	4	0,25	93,75%	

30	Medicines containing psychotropic drugs and narcotics are kept separate and in restricted areas	4	0	100%	
31	Safe concentrations, (in)compatibilities and safe dilutions are standardised in order to reduce the likelihood of medication-related errors	4	0	93,75%	
32	High-risk medicines are identified and specific strategies are implemented to ensure the safe use of the Maximum Alert Medicine throughout the circuit	4	1	87,5%	**high risk** (P2, P9, P16)

Pressure Ulcer Risk / Skin Integrity Dimension: CSDN Indicators		**Me**	**AIQ**	**IVC**	**Suggestions**
33	Regular monitoring of skin integrity is carried out and this assessment is recorded in the NB's file	4	0	93,75%	
34	A tool for assessing the risk of skin damage in the neonatal population has been implemented	4	1	81,25%	

Neonatal Fall Risk Dimension: CSDN Indicators		**Me**	**AIQ**	**IVC**	**Suggestions**
35	Intervention strategies are in place to prevent and reduce falls	4	0	93,75%	

36	A fall risk assessment scale has been implemented	4	0	87,5%	"there needs to be a **specific falls scale for Neonatology**" (P9)
37	There are regulations aimed at preventing and reducing the occurrence of falls	4	0	87,5%	

HCAI dimension: CSDN indicators		**Me**	**AIQ**	**IVC**	**Suggestions**
38	There is a person defined as responsible for infection prevention and control issues and antimicrobial resistance in accordance with the standard in force.	4	0	100%	
39	The unit has implemented hand hygiene measures in accordance with the WHO's 5 steps	4	0	100%	
40	The use of a mask is recommended as a measure to prevent respiratory infection	4	0	100%	
41	Isolation measures have been implemented to prevent infection	4	0	100%	

Development-Centred Care Dimension: CSDN Indicators		**Me**	**AIQ**	**IVC**	**Suggestions**
42	NB care is grouped in such a way as to minimise unnecessary manipulation	4	1	93,75%	"**Individualised** care, not grouped together" (P3)

					"according to the baby's **signs of stress and disorganisation in an individualised way"** (P14)
43	A peaceful environment is promoted to ensure uninterrupted sleep, respecting a sound level of 45db-65db.	4	1	87,5%	"**baseline less than 45 db** (**max** peak **65 db**) P14 "impossible to quantify" P12.
44	Technological devices (mobile phones and the like) are used in silent mode	3,5	1	81,25%	**"**Use in the NICU is **not recommended**, only by the emergency doctor" P3 "The use of technological devices (mobile phones and the like) in silent mode is **encouraged** when possible" (P11) "The medical team's emergency beepers **should be used with sound to ensure timely verification in urgent/emergency situations**" (P11) "limits on the **sound of controlled alarms** so that they can be **heard while minimising the noise level to acceptable values in terms of safety**" (P12)
45	A separate room is used for preparing medication/serums outside the unit/room, in order to keep noise and light levels within the recommended parameters.	4	1,25	75%	"In intensives with **open space** it's difficult" (P16)
46	A blanket or protective cover is used to cover the incubator	4	0	93,75%	"Partially ensuring the supervision of the NB and their abilities and integrating stimuli" (P3)

47	The NB's eyes are protected from excessive lighting at all times, ensuring that adjustable intensity lights are used when assessing the NB	4	1	87,5%	"The newborn's eyes are protected **when direct artificial or intense natural light is required**. **Natural light adjusted according to the newborn's ability to integrate**. At **night, 10 lux"** (P3) "Associated with the support of **the NB**, with the support of the parents or another professional" (P12)
48	Dim ambient lighting is maintained between RN manipulations	4	1	81,25%	"you should **specify the intensity in lux**: 180 to 200 lux when the baby is awake (the maximum peak light will be 200 to 600 lux)" (P14) "**Always** dim ambient lighting **and natural light**" (P12)
49	A neutral thermal environment is promoted in order to maintain a normal core temperature, with minimal oxygen consumption and calorific expenditure (36.5ºC-37º).	4	0	100%	
50	Promote Positive Touch	4	0	87,5%	**"It's** promotion" (P8)
51	Promote positioning and containment	4	0	93,75%	**"It's** promotion" (P8) "**Specifying**, positioning and elastic containment" P3
52	Encourage/educate/integrate the participation of parents/carers in care	4	0	100%	"Parents and NBs are **active participants** (P12) **"It's** encouraged" (P8)

53	Promote/support/encourage breastfeeding	4	0	100%	"**It's** promoted" P8
54	Promote pleasant/neutral olfactory sensations	4	0,25	87,5%	"Promoting will always be with positive stimuli. Neutral is not stimulation. **Avoid unpleasant and intense stimuli**" (P14). "Neutral? Pleasant, **which ones**? and **avoid aggressive odours from alcoholic or other solutions**" (P3)
55	NB is sensitised to maternal odour	4	1	93,75%	"The NB is already sensitised to the mother's odour in the womb, **rephrase with perhaps exposed**" (P3)
56	The scale of self-perceived parenting skills (Discharge Guide) is provided.	4	2	68,75%	"A **discharge preparation checklist** can be **used**. **Which scales to use**?" (P7) "A discharge guide is provided and parents/carers are given time and space to resolve doubts and ask questions regarding self-perceived parenting skills" (P8). "A Discharge Guide is provided but **without an** effective scale of self-perceived parenting skills" (P11)

4.2 ROUND #2

In this second phase of the study, the experts were tasked with evaluating the instrument in terms of its clarity, relevance, and representativeness of the underlying construct. The results confirmed the soundness, validity and representativeness of 48 of the 51 CSDN indicators analysed in the first round, which corresponds to approximately 94% (Table 13). The panel of experts validated the instrument by measuring AIQ between 0 and 1 and a variable CVI between 85.71% and 100%. Following this, textual adjustments were made.

Notwithstanding the favourable overall outcome, it is imperative to investigate the indicators that did not attain a CVI of at least 80% and/or a QAI of 1.

The indicator pertaining to Informed, Informed and Free Consent (#14) yielded an AIQ value of 0.75 and a CVI of 78.57 per cent. Consequently, the panel did not validate its representativeness in a neonatal safety instrument.

There is a paucity of research examining the decision-making processes between healthcare professionals and carers in critical care settings (Dunn et al., 2018). The perceived capacity of carers to engage in substitute decision-making is constrained by the highly specialised nature of such environments, including neonatal intensive care units (NICUs), and the emotional dimensions experienced (Parish et al., 2022). It can be hypothesised that these assumptions may be the basis for the low representativeness assumed by the experts with regard to this indicator.

A review of the literature revealed no studies in Portugal that examined the relationship between the legally required informed, informed and free consent and the quality of care provided in the NICU. On an international level, there are initiatives in place with the aim of ensuring this right is upheld and improving levels of literacy. The BAPM (British Association of Perinatal Medicine) has delineated particular guidelines for this situation, which guarantee that parents/carers are included in decision-making regarding care and that it is the responsibility of the health professional to provide consistent information that allows them to understand and favours their involvement (BAPM, 2019).

Effective communication between all relevant parties, the validation of this communication in clear clinical records and the provision of training for healthcare teams are essential strategies for obtaining valid consent. The provision of written information for common neonatal procedures, which complements verbal discussions, can positively impact these outcomes and safeguard informed consent for emergent situations (BAPM, 2019).

An alternative approach that facilitates the implementation of this best practice in healthcare is the design of integrated care documents/guidelines and other decision-making models seeking consent for an integrated package of care that is in the best interests of the neonatal patient. Consequently, in an integrated care document, by consenting, parents would authorise health professionals to perform any conventional procedures for the situation as an alternative to consenting to individual procedures (BAPM, 2019). This represents a potential avenue for future research, with the possibility of developing safer practices and more effective communication processes.

In light of the aforementioned considerations and in accordance with the established criteria for exclusion of indicators that did not meet the requisite cumulative score, the decision was taken by the researcher to retain the indicator "Informed, Informed and Free Consent is guaranteed by recording and substantiating it in the neonatal patient's clinical file" within the CSDN.

With regard to the indicator related to the implementation of a scale for assessing the risk of neonatal falls (#33), it should be noted that, despite its inclusion in the PNSD (DGS, 2022) as an indicator of safety associated with care, there is still no scale parameterised for neonatal patients and validated for the Portuguese population. In light of the aforementioned considerations, the indicator will be reformulated, with the assessment of the risk of falling completed in isolation, without any association with a scale. This represents a limitation of the indicator, as risk assessment requires the use of an instrument. However, as the CSDN is intended to be dynamic and evolving, this indicator could subsequently be associated with an instrument that has been validated for use with neonatal patients.

Finally, the Scale of Intensity of Self-Perceived Maternal Competence associated with a Discharge Guide (#51) did not achieve the requisite scores for inclusion in the CSDN.

This was due to a lack of consensus among the expert panel, with a CVI of 62.29%. Nevertheless, it was resolved that the indicator should be reformulated rather than excluded. The Discharge Guide represents a fundamental element for healthcare professionals, providing a comprehensive repository of knowledge and skills acquired during their tenure in the NICU. The objective of the scale is to validate this knowledge, thereby contributing to the safest possible transition to home (Marques and Sá, 2004; Rodrigues, 2010; Wittkowski et al., 2017; Monteiro et al., 2022; Schneider et al., 2024). These interventions are consistent with the standards of care that have been established for the neonatal context, which indicate the necessity for the implementation of structured education programmes with the objective of facilitating discharge from the NICU. These programmes must be characterised by well-defined guidelines and procedures, including a pre-discharge check (WHO, 2020b; EFCNI, 2022).

See Table 13 for a better understanding of the results.

Table 13. *Results Round 2*

	Security Culture Dimension: CSDN Indicators	Me	AIQ	IVC	Suggestions
1	The Global Risk Management liaison organises and/or replicates activities in the area of patient safety for the NICU's multidisciplinary team, as provided for in the annual training plan.	4	0	100%	"define **periodicity**" (P5) "with those **involved in areas of clinical governance** that involve **Risk Management** items" (P3)
2	The Global Risk Management Liaison promotes multidisciplinary teamwork in the implementation of neonatal patient safety processes	4	0	100%	"**involved in areas of clinical governance that involve Risk Management items**" (P3)
3	The Global Risk Management Liaison is involved in supervising and monitoring all stages of the clinical and non-clinical risk management process, mediating communication and acting as a link between all those involved.	4	0	100%	With the **nurse manager** (P3)
4	The Global Risk Management liaison draws up the report resulting from the audits and makes the results available to the heads/coordinators of the multidisciplinary team.	4	0	100%	"...Must submit an **annual report of** audits and results to the nurse manager/coordinator" (P5) "With the **Nurse Manager and Nurse responsible for** in-service **training** and **others involved in areas of clinical governance**" (P3)
5	Appropriations are calculated annually by the heads of the multidisciplinary teams in order to promote allocations that ensure safe neonatal care.	4	0,75	85,71%	"The nurse manager must present to the nursing directorate the resources and needs for the quality

					and safety of care, as well as refer to the secure resources in the service's annual plan." (P5)
6	Safety prevention plans are in place: NICU Emergency Plan	4	0	100%	
7	There are plans to prevent harm associated with healthcare: Standards and protocols for safe neonatal care	4	0	100%	
8	Procedures for checking the emergency trolley, defibrillator, resuscitator, ventilator and transport incubator have been implemented and are complied with, in accordance with the institution's directive	4	0	100%	"
9	Has implemented and complies with the material checklist for standardising procedures and carrying out safe intra- and/or inter-hospital neonatal transport	4	0	92,86%	
10	Professionals are trained in the process of reporting and communicating the occurrence of safety incidents in the Notifica, Pharmacovigilance/RAM and Haemovigilance systems.	4	0	92,86%	"...Professionals **are** aware of the process for notifying and reporting the occurrence of safety incidents in the Notifica, Pharmacovigilance/RAM and Haemovigilance systems" (P11) "held annually and be part of the institution's **compulsory training programmes**" (P5)
11	Forms for internal reporting of security incidents are available	4	0	100%	

12	Periodic training is provided for the multidisciplinary team in safety procedures for the NICU	4	0	100%	

Communication Security Dimension: CSDN Indicators		**Me**	**AIQ**	**IVC**	**Suggestions**
13	Has implemented and complies with procedures to ensure safe transition of care through effective communication, standardised by the ISBAR technique	4	0	100%	"It's a DGS standard and **should be mandatory** in all services, adapting it to the specificities of each one." (P5)
14	Informed, Informed and Free Consent is guaranteed by recording and substantiating it in the neonatal patient's clinical file.	4	0,75	78,57%	
15	Has implemented and complies with procedures to guarantee the transversal dissemination of Standards/Procedures/Circulars, through a confirmation process (e.g. signature and mechanographic number)	4	0	100%	"...There should be a file in the service with the number of each procedure and a table with the signature of each professional (mechanographic number), thus proving the reading." (P5)
16	Has implemented and complies with procedures relating to the discharge/transfer of neonatal patients in order to guarantee continuity of care with the delivery of discharge/transfer documentation	4	0	93,75%	

Dimension Unequivocal Identification of the Neonatal Patient: CSDN Indicators	**Me**	**AIQ**	**IVC**	**Suggestions**

17	Patient identification is ensured by means of a coded identification bracelet and/or an alert system (Tags or Hugs), the location of which is individualised according to the characteristics of the neonatal patient.	4	0	100%	"Patient identification is ensured" (P2) "Not necessarily a wristband" (P3)
18	The method used to identify the neonatal patient before procedures is based on the positive identification of at least two of these: name and surname (neonatal patient and mother), date of birth, unique medical file number	4	0	100%	"**At least two of these items**, and in the case of **twins, whether it's the 1st or 2nd twin**" (P8) "...The individualised, family-centred method of working with the presence of the parents 24/24 makes it even easier to ensure the safe identification of the NB" (P3).
19	No abbreviations, acronyms and/or symbols are used to identify the neonatal patient.	4	0	100%	
20	The unequivocal identification of the neonatal patient always takes place before any intervention	4	0	93,75%	
21	Has implemented and complies with a procedure to guarantee the traceability of complementary diagnostic tests (including labelling of samples with unequivocal identification of the neonatal patient and a two-person verification process)	4	0	100%	There should **always** be **double-checking** to ensure safety and prevent errors. (P5)

Safe Use of Medicines Dimension: CSDN Indicators	**Me**	**AIQ**	**IVC**	**Suggestions**

22	The NICU uses electronic prescription of medicines	4	0	92,86%	With paediatric specificity (prescription by weight and gestational age and limited by dose protocols) (P16)
23	Has implemented and complies with the procedure for verbally prescribing medication (in exceptional situations, emergencies or failure of the computer system), ensuring double verbal confirmation by the professional who prepares and administers the medication (drug, dose, route).	4	0	92,86%	
24	Has implemented and complies with therapeutic reconciliation	4	0	85,71%	
25	Has implemented and complies with standardised practices for the storage and labelling of all medicines, safeguarding packaging requirements	4	0	100%	"And **labelling** of medication trolleys and drawers" (P8)
26	Labelling of medicines is guaranteed when they are transported outside their original packaging	4	0	100%	
27	Medicines containing psychotropic drugs and narcotics are kept separate and in restricted areas	4	0	100%	
28	Safe concentrations, (in)compatibilities and safe dilutions are standardised in order to reduce the likelihood of medication-related errors	4	0	92,86%	
29	High-risk medicines are identified and specific strategies are implemented to ensure the safe use of the Maximum Alert Medicine throughout the circuit	4	0	100	

Pressure Ulcer Risk / Skin Integrity Dimension: CSDN Indicators	**Me**	**AIQ**	**IVC**	**Suggestions**

30	Has implemented and complies with regular monitoring of skin integrity with a record in the neonatal patient file	4	0	92,86%	
31	Has implemented a tool to assess the risk of skin damage in the neonatal population	4	0	85,71%	"Replace neonatal population with **neonatal patient**" (P2)

Neonatal Fall Risk Dimension: CSDN Indicators		**Me**	**AIQ**	**IVC**	**Suggestions**
32	Has implemented and complies with standards and intervention strategies for the prevention and reduction of falls	4	0	100%	"It is **compulsory to** survey the risk of falls and prescribe strategies" (P5)
33	A neonatal fall risk assessment scale has been implemented	3,5	2	62,29%	**"There is still no neonatal risk scale validated for the Portuguese population"** (P7)

HCAI dimension: CSDN indicators		**Me**	**AIQ**	**IVC**	**Suggestions**
34	There is a person defined as responsible for infection prevention and control issues and antimicrobial resistance in accordance with the standard in force.	4	0	100%	
35	The NICU has implemented hand hygiene measures in accordance with the WHO's 5 steps	4	0	100%	

36	The use of a mask is recommended as a measure to prevent respiratory infection	4	0	100%	
37	Isolation measures have been implemented to prevent infection	4	0	100%	

Development-Centred Care Dimension: CSDN Indicators		**Me**	**AIQ**	**IVC**	**Suggestions**
38	Care for neonatal patients is individualised and developmentally focused, respecting signs of stress and disorganisation	4	0	100%	
39	A quiet environment is promoted to ensure uninterrupted sleep, respecting an adequate sound level (baseline of less than 45db and maximum peak of 65db).	4	0	92,86%	"It involves a noise detection device" (P7; P8)
40	The sound limits of the alarms are controlled and promptly switched off so that they can be heard while minimising the noise level to acceptable values in terms of safety.	4	0,75	85,71%	
41	A separate room for preparing medication/serums should be used outside the unit/room, in order to keep noise and light levels within the recommended parameters.	4	0,75	85,71%	"Replace with **Is used"** (P2)
42	A neuroprotective environment is promoted through the use of a blanket or protective cover for the incubator	4	0	100%	

43	The neonatal patient's eyes are protected from excessive lighting at all times, ensuring the preferential use of natural light and/or adjustable intensity lights when assessing the patient, not exceeding 200 to 600 lux.	4	0	100%	"Light **should not be shone** into the eyes of premature NBs **under any circumstances** (national consensus on light in the SPN)" (P3) Not all units are measured (P7, P8)
44	Dim ambient lighting is maintained, with natural light whenever possible, adjusted according to the neonatal patient's ability to integrate.	4	0	100%	
45	A neutral thermal environment is promoted in order to maintain an adequate core temperature (36.5ºC-37º), with minimal oxygen consumption and calorific expenditure	4	0	100%	"Some research puts the temperature range at neutral up to 37.5º" (P3)
46	Positive touch and early skin-to-skin contact is promoted	4	0	100%	"Always use the kangaroo method" (P5)
47	Care is provided to support transitions, positioning and individualised Comfort	4	0	100%	
48	The participation/partnership of parents/carers in the care of the neonatal patient is encouraged	4	0	100%	**"Reformulate** for parents are members of the care team" (P3)
49	Protection, promotion and support for breastfeeding is guaranteed	4	0	100%	
50	Pleasant olfactory sensations are promoted through exposure to maternal/paternal aromas and access to the taste and smell of breast milk	4	0	100%	active actions are taken to protect against foreign/aggressive odours in the environment surrounding the NB/inside the incubator (P3)

51	The Discharge Guide and Self-Perceived Maternal Competence Intensity Scale are provided, allowing parents/caregivers time and space to ask questions and validate teachings.	3	2	62,29%	"The "Counselling Guide" with essential information for discharge is provided in **good** time, allowing parents/carers time and space to ask questions and validate teachings." (P11) "Would it involve the delivery of a universally accepted guide? Any specific reason why it should be this scale and not another?" (P8)

4.3. CSDN: INDICATORS VALIDATED BY A PANEL OF EXPERTS

In view of the above results and the analysis of the experts' suggestions, the rounds associated with the study methodology were closed. A final reformulation of the indicators was carried out in order to create a final instrument. See table 15.

Table 14. *CSDN validated by experts*

Security Culture Dimension: CSDN Indicators	
1	The Global Risk Management liaison organises and/or replicates activities in the area of patient safety for the NICU's multidisciplinary team, as provided for in the annual training plan.
2	The Global Risk Management Liaison promotes multidisciplinary teamwork in the implementation of neonatal patient safety processes.
3	The Global Risk Management Liaison is involved in supervising and monitoring all stages of the clinical and non-clinical risk management process, mediating communication and acting as a link between all those involved.
4	The Global Risk Management liaison draws up the report resulting from the audits and makes the results available to the heads/coordinators of the multidisciplinary team.
5	Appropriations are calculated annually by the heads of the multidisciplinary teams in order to promote allocations that ensure safe neonatal care.
6	Safety prevention plans are in place: NICU Emergency Plan.
7	There are plans to prevent harm associated with healthcare: Standards and protocols for safe neonatal care.
8	Procedures for checking the emergency trolley, defibrillator, resuscitator, ventilator and transport incubator have been implemented and are complied with, in accordance with the institution's directive.
9	Has implemented and complies with the material checklist for standardising procedures and carrying out safe intra- and/or inter-hospital neonatal transport.

10	Professionals are trained in the process of reporting and communicating the occurrence of safety incidents in the Notifica, Pharmacovigilance/RAM and Haemovigilance systems.
11	Forms for internal reporting of security incidents are available.
12	Periodic training is provided for the multidisciplinary team in safety procedures for the NICU.
Communication Security Dimension: CSDN Indicators	
13	Has implemented and complies with procedures to ensure safe transition of care through effective communication, standardised by the ISBAR technique.
14	Informed, Informed and Free Consent is guaranteed by recording and substantiating it in the neonatal patient's clinical file.
15	Has implemented and complies with procedures to guarantee the transversal dissemination of Standards/Procedures/Circulars, through a confirmation process (e.g. signature and mechanographic number).
16	Has implemented and complies with procedures relating to the discharge/transfer of neonatal patients in order to guarantee continuity of care with the delivery of discharge/transfer documentation.

Dimension Unequivocal Identification of the Neonatal Patient: CSDN Indicators	
17	Patient identification is ensured by means of a coded identification bracelet and/or an alert system (Tags or Hugs), the location of which is individualised according to the characteristics of the neonatal patient.
18	The method used to identify the neonatal patient before procedures is based on the positive identification of at least two of these: first and last name (neonatal patient and mother), date of birth, unique medical file number.
19	No abbreviations, acronyms and/or symbols are used to identify the neonatal patient.
20	The unequivocal identification of the neonatal patient always takes place before any intervention.
21	Has implemented and complies with a procedure to guarantee the traceability of complementary diagnostic tests (including labelling of samples with unequivocal identification of the neonatal patient and a two-person verification process).

Safe Use of Medicines Dimension: CSDN Indicators	
22	The NICU uses a parameterised electronic drug prescription for neonatal patients.
23	Has implemented and complies with the procedure for verbal prescription of medication (in exceptional situations, emergencies or failure of the computer system), ensuring double verbal confirmation by the professional who prepares and administers the medication (drug, dose, route).
24	Has implemented and complies with therapeutic reconciliation.
25	Has implemented and complies with standardised practices for the storage and labelling of all medicines, safeguarding packaging requirements.
26	Labelling of medicines is guaranteed when they are transported outside their original packaging.
27	Medicines containing psychotropic drugs and narcotics are kept separate and in restricted areas.
28	Safe concentrations, (in)compatibilities and safe dilutions are standardised in order to reduce the likelihood of medication-related errors.
29	High-risk medicines are identified and specific strategies are implemented to ensure the safe use of the Maximum Alert Medicine throughout the circuit.

Pressure Ulcer Risk / Skin Integrity Dimension: CSDN Indicators	
30	Has implemented and complies with regular monitoring of skin integrity with a record in the neonatal patient file.
31	Has implemented a tool to assess the risk of skin damage in neonatal patients.

Neonatal Fall Risk Dimension: CSDN Indicators	
32	Has implemented and complies with standards and intervention strategies for the prevention and reduction of falls.

33	Neonatal fall risk assessment has been implemented.

HCAI dimension: CSDN indicator	
34	There is a person defined as responsible for infection prevention and control issues and antimicrobial resistance in accordance with the standard in force.
35	The NICU has implemented hand hygiene measures in accordance with the WHO's 5 steps.
36	The use of a mask is recommended as a measure to prevent respiratory infection.
37	Isolation measures have been implemented to prevent infection.

Development-Centred Care Dimension: CSDN Indicators	
38	Care for neonatal patients is individualised and developmentally focused, respecting signs of stress and disorganization.
39	A quiet environment is promoted to ensure uninterrupted sleep, respecting an adequate sound level (baseline of less than 45db and maximum peak of 65db).
40	The sound limits of the alarms are controlled and promptly switched off so that they can be heard while minimising the noise level to acceptable values in terms of safety.
41	A separate room is used for preparing medication/serums outside the unit/room, in order to keep noise and light levels within the recommended parameters.
42	A neuroprotective environment is promoted through the use of a blanket or protective cover for the incubator.
43	The neonatal patient is protected from excessive lighting at all times, ensuring the preferential use of natural light and/or lights of adjustable intensity when assessing them, not exceeding 200 to 600 lux.
44	Dim ambient lighting is maintained, with natural light whenever possible, adjusted according to the neonatal patient's ability to integrate.
45	A neutral thermal environment is promoted in order to maintain an adequate core temperature (36.5ºC-37º), with minimal oxygen consumption and calorific expenditure.

46	Positive touch, skin-to-skin contact and early kangaroo care are promoted.
47	Care is provided to support transitions, positioning and individualised comfort.
48	Parents/carers are part of the neonatal patient care team.
49	Protection, promotion and support for breastfeeding is guaranteed.
50	Pleasant olfactory sensations are promoted through exposure to maternal/paternal aromas and access to the taste and smell of breast milk.
51	Discharge is scheduled in good time, allowing parents/carers time and space to ask questions and validate teachings.

CONCLUSION

This study aimed to validate the Neonatal Patient Safety Checklist (CSDN) through the Delphi method, thereby ensuring its robustness and applicability in neonatal intensive care units (NICUs). The study highlighted the critical importance of quality and safety in neonatal care, emphasising the necessity for rigorous assessment tools to mitigate risks and enhance patient outcomes.

Key Findings

The implementation of the NPSC has demonstrated its potential as a valuable instrument for the systematic evaluation and improvement of neonatal care. The incorporation of a comprehensive set of indicators facilitates adherence to established guidelines, standards, and protocols, thereby fostering a culture of safety and continuous improvement within neonatal intensive care units (NICUs). The Delphi method facilitated an iterative refinement process, whereby expert feedback was incorporated to achieve consensus on the most relevant and representative indicators.

The study emphasised the importance of cultivating a culture of safety within neonatal intensive care units (NICUs). The indicators pertaining to safety culture were accorded high consensus by experts, thereby underscoring the necessity for uninterrupted education, efficacious communication, and a non-punitive approach to error reporting. The CSDN emphasis on these elements can play a pivotal role in fostering an environment where safety is a paramount concern and continuous learning is encouraged.

Effective communication is of paramount importance in ensuring patient safety. The validated indicators underscore the necessity for transparent, prompt, and precise communication between healthcare providers and between providers and patients' families. The utilisation of structured communication tools and protocols has the potential to mitigate misunderstandings and facilitate enhanced overall coordination of care.

The prevention of healthcare-associated infections (HCAIs) represents a crucial element of neonatal care. The NPSC includes specific indicators designed to promote rigorous infection control practices. These include hand hygiene, the use of personal protective equipment, and the regular monitoring of infection rates. The consensus among experts

on these indicators serves to emphasise their importance in reducing the incidence of infections in neonatal intensive care units (NICUs).

The study also validated indicators related to development-centred care, emphasising the significance of bespoke care plans that address the distinctive requirements of each neonate. This approach has the additional benefit of improving clinical outcomes while also supporting the developmental and emotional needs of both the neonate and their family.

Methodological Strengths and Limitations

The utilisation of the Delphi method constituted a notable strength of this study. The Delphi method facilitated the systematic collection and analysis of expert opinions, thereby ensuring that the final set of indicators was both comprehensive and reflective of best practices in neonatal care. However, it should be noted that the study was not without limitations. It proved challenging to retain experts throughout the Delphi rounds. Furthermore, the subjective nature of some indicators required careful consideration to ensure their applicability and clarity.

Practical Implications

The validated NPSC provides a robust framework for neonatal intensive care units (NICUs) to systematically evaluate and improve their care practices. It serves as a practical tool for healthcare providers, enabling them to identify deficiencies, implement optimal practices, and monitor progress over time. By fostering a culture of safety and continuous improvement, the NPSC has the potential to contribute to enhanced health outcomes for neonates and their families.

It is imperative that neonatal intensive care units (NICUs) commit to the regular use of the NPSC and integrate it into their daily routines if the tool is to be effective. It is imperative that training and education programmes for healthcare providers are implemented to ensure that all staff are conversant with the checklist and its significance.

Future Research Directions

Future research should concentrate on the long-term implementation of the NPSC in a variety of clinical settings in order to gain further insight into its impact on the quality and safety of neonatal care.

Longitudinal studies will provide valuable insights into the long-term effectiveness of the NPSC. Such studies can assist in the identification of areas for improvement and provide evidence of the impact of the checklist on patient outcomes.

Furthermore, research should investigate the applicability of the NPSC in diverse cultural and healthcare contexts. It is of paramount importance to ascertain how the checklist can be adapted to various contexts in order to facilitate its global implementation.

In conclusion, the validated CSDN represents a significant advancement in the pursuit of excellence in neonatal care. By providing a structured approach to the evaluation and improvement of safety and quality, the checklist serves as an essential tool for healthcare professionals whose primary objective is the well-being of neonatal patients. It is imperative that continued efforts are made to refine and implement this tool in order to promote a culture of safety and achieve the highest standards of care in neonatal intensive care units (NICUs). The findings of this study emphasise the value of collaborative endeavours and continuous research in the advancement of neonatal care, which will ultimately lead to improved health outcomes for the most vulnerable patients.

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APENDIX I: INFORMED CONSENT FOR EXPERT

Consentimento Livre e Esclarecido

Considero que fui informado de que o estudo “Qualidade no Cuidado Neonatal: Checklist de Segurança", tem como objetivo validar os indicadores do instrumento de forma a potenciar a qualidade e segurança no cuidado aos recém-nascidos em contexto de Neonatologia, de modo a obter uma melhoria na prestação de cuidados, assegurando a sua eficácia, eficiência e garante da qualidade e segurança.
Foi-me garantido que todos os dados relativos à minha identificação serão confidenciais e que a informação recolhida é para uso exclusivo deste projeto e estará acessível apenas à equipa de investigação.
Fui informado que posso recusar-me a participar ou suspender, a qualquer momento.
Serão requisitados dados gerais, relativos ao percurso académico e curricular, de forma a caracterizar o painel de peritos neste estudo, sendo os dados codificados, agrupados e nunca apresentados de forma individual.

Aceito participar de livre vontade no estudo acima mencionado e autorizo a divulgação dos resultados obtidos no meio científico, desde que mantida a confidencialidade e anonimato dos mesmos.

* Indica uma pergunta obrigatória

1. Email *

_____

Dados gerais

2. Sexo *

Marcar apenas uma oval.

- ◯ Feminino
- ◯ Masculino
- ◯ Prefiro não responder

3. Idade

_____

Experiência Profissional e Percurso académico

4. Experiência Profissional *

Marcar apenas uma oval.

- ◯ < 5 anos
- ◯ > 5anos e < 10 anos
- ◯ > 10 anos

5. Funções que desempenha neste momento *

_____

6. Especialidade de Enfermagem em Saúde Infantil e Pediátrica? *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

7. Desempenha funções na área da UCIN? *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

8. Em que concelho desenvolve a sua atividade profissional? *

_____

9. Possui Mestrado e/ou Pós graduação? *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

10. Se sim, em que área?

_____

11. Tem experiência como Elemento Dinamizador da Gestão de Risco e/ou Comissão de Qualidade e Segurança *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

12. Formação em Gestão do Risco em Saúde/Segurança do doente? *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

13. Formação na área dos Cuidados Centrados no Desenvolvimento *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

14. Se sim, qual? *

_____

15. Colabora na formação/orientação de alunos enfermagem *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

16. Desempenha funções como Docente em Estabelecimentos de Ensino Superior *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

Consentimento Livre e Esclarecido

Considero que fui informado de que o estudo “Qualidade no Cuidado Neonatal: Checklist de Segurança", tem como objetivo validar os indicadores do instrumento de forma a potenciar a qualidade e segurança no cuidado aos recém-nascidos em contexto de Neonatologia, de modo a obter uma melhoria na prestação de cuidados, assegurando a sua eficácia, eficiência e garante da qualidade e segurança.
Foi-me garantido que todos os dados relativos à minha identificação serão confidenciais e que a informação recolhida é para uso exclusivo deste projeto e estará acessível apenas à equipa de investigação.
Fui informado que posso recusar-me a participar ou suspender, a qualquer momento.
Serão requisitados dados gerais, relativos ao percurso académico e curricular, de forma a caracterizar o painel de peritos neste estudo, sendo os dados codificados, agrupados e nunca apresentados de forma individual.

Aceito participar de livre vontade no estudo acima mencionado e autorizo a divulgação dos resultados obtidos no meio científico, desde que mantida a confidencialidade e anonimato dos mesmos.

* Indica uma pergunta obrigatória

1. Email *

Consentimento Livre e Esclarecido

Dados gerais

2. Sexo *

Marcar apenas uma oval.

- ◯ Feminino
- ◯ Masculino
- ◯ Prefiro não responder

3. Idade

Experiência Profissional e Percurso académico

4. Experiência Profissional *

   Marcar apenas uma oval.

   - ◯ < 5 anos
   - ◯ > 5anos e < 10 anos
   - ◯ > 10 anos

5. Funções que desempenha neste momento *

   _____

6. Sub-Especialidade em Neonatologia *

   Marcar apenas uma oval.

   - ◯ Sim
   - ◯ Não

7. Desempenha funções na área da UCIN? *

   Marcar apenas uma oval.

   - ◯ Sim
   - ◯ Não

8. Em que concelho desenvolve a sua atividade profissional? *

   _____

9. Possui Mestrado e/ou Pós graduação? *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

10. Se sim, em que área?

_____

11. Tem experiência como Elemento Dinamizador da Gestão de Risco e/ou Comissão de Qualidade e Segurança *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

12. Formação em Gestão do Risco em Saúde/Segurança do doente? *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

13. Formação na área dos Cuidados Centrados no Desenvolvimento *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

14. Se sim, qual? *

_____

15. Colabora na formação/orientação em internato médico? *

Marcar apenas uma oval.

- Sim
- Não

16. Desempenha funções como Docente em Estabelecimentos de Ensino Superior *

Marcar apenas uma oval.

- Sim
- Não

Consentimento Livre e Esclarecido

Considero que fui informado de que o estudo “Qualidade no Cuidado Neonatal: Checklist de Segurança", tem como objetivo validar os indicadores do instrumento de forma a potenciar a qualidade e segurança no cuidado aos recém-nascidos em contexto de Neonatologia, de modo a obter uma melhoria na prestação de cuidados, assegurando a sua eficácia, eficiência e garante da qualidade e segurança.
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Fui informado que posso recusar-me a participar ou suspender, a qualquer momento.
Serão requisitados dados gerais, relativos ao percurso académico e curricular, de forma a caracterizar o painel de peritos neste estudo, sendo os dados codificados, agrupados e nunca apresentados de forma individual.

Aceito participar de livre vontade no estudo acima mencionado e autorizo a divulgação dos resultados obtidos no meio científico, desde que mantida a confidencialidade e anonimato dos mesmos.

* Indica uma pergunta obrigatória

1. Email *

_____

Dados gerais

2. Sexo *

Marcar apenas uma oval.

- ◯ Feminino
- ◯ Masculino
- ◯ Prefiro não responder

3. Idade

_____

Experiência Profissional e Percurso académico

4. Experiência Profissional *

Marcar apenas uma oval.

- ◯ < 5 anos
- ◯ > 5anos e < 10 anos
- ◯ > 10 anos

5. Funções que desempenha neste momento *

_____

6. Em que concelho desenvolve a sua atividade profissional? *

_____

7. Possui Mestrado e/ou Pós graduação? *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

8. Se sim, em que área?

_____

Percurso na UCIN

9. Qual a Idade Gestacional do seu filho no momento do nascimento? *

_____

10. Qual o peso do seu filho no momento do nascimento? *

_____

11. Número de dias de internamento na UCIN *

_____

12. Durante o internamento prestou cuidados ao seu filho numa perspectiva de parceria de cuidados com a equipa multidisciplinar da UCIN? *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

13. Tem conhecimento dos Cuidados Centrados no Desenvolvimento em UCIN? *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

14. Na UCIN eram tidos em conta aspetos como som, luz e manipulaçao do seu filho? *

Marcar apenas uma oval.

- ◯ Sim
- ◯ Não

15. Quais os elementos que considera importantes para um internamento seguro em contexto neonatal? *

_____

_____

_____

_____

_____

APENDIX II: QUESTIONNAIRES ROUND #1

1. Checklist de Segurança Neonatal

A Checklist de Segurança do Doente Neonatal surgiu como uma ferramenta de qualidade com o objetivo estratégico de aferir, sistematizar e nortear a promoção de segurança do doente neonatal, em todo o continuum assistencial, potenciando a qualidade.

Foi construída em 2015, adaptada à realidade dos Cuidados Intensivos Neonatais da Unidade Local de Saúde Alentejo Central (ULSAC) e alvo de melhorias progressivas (pré testes), após exaustiva análise das metas e indicadores de segurança disponibilizados pela Entidade Reguladora de Saúde (ERS), o Plano Nacional para a Segurança do Doente (PNSD), integrado na Estratégia Nacional para a Qualidade da Saúde, suportada pela Organização Mundial de Saúde (OMS), os Standards Europeus de Cuidados de Saúde ao Recém-Nascido (EFCNI) e parecer da Comissão de Qualidade e Segurança.

Não obstante, de forma a garantir a fiabilidade do instrumento e para que possa ser de uso generalizado é fundamental obter o feedback de peritos nesta área, o Método de Delphi e painel de peritos surge como o mais adequado. Pedimos a Vossa Exª que avalie a representatividade e/ou relevância de cada indicador de forma a obter consenso grupal e tornar o instrumento mais coeso.

Em caso de assinar 2 ou 3 gostaríamos do seu contributo, comentário ou sugestão adicional, uma vez que, como perito o seu envolvimento é fundamental.

Para avaliar a relevância/representatividade será utilizada uma escala tipo Likert onde:

- 1 = não relevante ou não representativo
- 2 = item necessita de grande revisão para ser representativo

- 3 = item necessita de pequena revisão para ser representativo
- 4= item relevante ou representativo

O questionário estará disponível no seguinte link durante 10 dias, sendo encerrada a ronda para análise de dados e alterações ao instrumento. Após cada ronda será dado feedback aos peritos de forma individual, de forma a manter o anonimato. Prevê-se a necessidade de mais do que uma ronda (entre 2 a 3 rondas) de forma a validar o instrumento de forma fidedigna.

Este questionário levará cerca de 10 minutos para completar.
Gratos pela sua colaboração.

Ana Malveira

* Indica uma pergunta obrigatória

1. Email *

Dimensão: Cultura de Segurança

Esta dimensão tem como objetivos estratégicos:

- Promover a formação dos profissionais de saúde no âmbito da Segurança do Doente Neonatal;
- Avaliar a Cultura de Segurança da UCIN;
- Aumentar a Literacia e a participação do doente, família, cuidador no que concerne à segurança da prestação de cuidados.

2. Ao Elo dinamizador da Gestão de Risco dinamiza e/ou replica atividades de formação na área da segurança do doente à equipa multidisciplinar da UCIN *

Marcar apenas uma oval.

1 2 3 4

3. Sugestões

4. O Elo dinamizador da Gestão de Risco promove o trabalho em equipa multidisciplinar na implementação de processos relativos à segurança do RN *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

5. Sugestões

6. O Elo dinamizador da Gestão de Risco participa na supervisão e monitorização de todas as etapas do processo de gestão do risco clínico, sendo um mediador da comunicação e um elo de ligação entre todos os intervenientes *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

7. Sugestões

8. O Elo dinamizador da Gestão de Risco elabora o relatório resultante de auditoria realizada de acordo com norma vigente e disponibiliza resultados à equipa multidisciplinar

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

9. Sugestões

10. Estão asseguradas as dotações seguras nos cuidados de enfermagem de acordo com o Parecer 19/2019 da Ordem dos Enfermeiros *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

11. Sugestões

12. Existem planos de prevenção no âmbito da segurança: Plano de Emergência da UCIN *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

13. Sugestões

14. Existem planos de prevenção no âmbito da segurança: Normas e Protocolos que visem aspetos relacionados com a segurança dos cuidados ao RN *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

15. Sugestões

16. Tem implementado e são cumpridos procedimentos de verificação mensal do carro de emergência *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

17. Sugestões

18. Tem implementado e cumpre procedimentos para a realização de testes ao desfibrilhador do carro de emergência *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

19. Sugestões

20. Tem implementado e cumpre procedimentos para auditoria do saco de transporte, sendo este verificado sempre que realiza uma transferência/transporte de recém-nascido *

Marcar apenas uma oval.

1 2 3 4

21. Sugestões

22. Os profissionais têm formação e estão sensibilizados para a notificação, comunicando a ocorrência de incidentes no sistema Notifica, de Farmacovigilância/RAM e Hemovigilância *

Marcar apenas uma oval.

1 2 3 4

23. Sugestões

Segurança na Comunicação

Um dos pilares para a promoção de cuidados seguros é a comunicação, sendo fundamental para a prevenção de eventos adversos. Assim, os objetivos estratégicos para esta dimensão são:
-Otimizar a comunicação intra e interinstitucional;
-Melhorar a comunicação e segurança no processo de transição de cuidados;
-Adequar a comunicação da informação clinica ao cuidador.

24. Estão implementados procedimentos para assegurar uma comunicação precisa e atempada *

Marcar apenas uma oval.

1 2 3 4

25. Sugestões

26. Tem formulários para a comunicação interna de eventos adversos e/ou incidentes *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

27. Sugestões

28. São divulgadas de forma transversal as Normas vigentes garantindo/confirmando o acesso da equipa multidisciplinar à informação através de assinatura e número mecanográfico *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

29. Sugestões

30. Está garantido o consentimento informado e esclarecido *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

31. Sugestões

32. São respeitados os limites da comunicação na saúde, garantindo a mnemónica ISBAR *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

33. Sugestões

34. Existe informação e formação em procedimentos de segurança (Guia de Acolhimento, Guia de Alta, Ações de Formação/Informação e Auditorias aos Sistemas de Segurança) *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

35. Sugestões

Identificação Inequívoca do RN

A identificação do recém-nascido em ambiente hospitalar é um direito legal e um objetivo importante dos programas para a segurança nas UCIN´s. Tem como objetivos estratégicos:
- Implementação de práticas padronizadas de identificação do doente;
- Procedimentos, protocolos ou orientações relativas à alta e/ou transferência de forma a garantir a continuidade dos cuidados.

36. Identificação de RN internados por meio de pulseira identificativa codificada e/ou meio de pulseira eletrónica (Tag) *

Marcar apenas uma oval.

1 2 3 4

37. Sugestão

38. O método utilizado para a identificação do RN antes de procedimentos baseia-se na identificação positiva de pelo menos dois destes: nome e apelido (rn e/ou da mãe), data de nascimento, número único de processo) *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

39. Sugestão

40. Na identificação do RN não são utilizadas(os) abreviaturas, acrónimos e/ou símbolos *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

41. Sugestões

42. A identificação inequívoca do RN ocorre sempre antes de qualquer intervenção *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

43. Sugestões

44. Existe um procedimento implementado para garantir a rastreabilidade dos exames complementares de diagnóstico (incluindo a rotulagem de amostras com identificação inequívoca do RN e processo de verificação por duas pessoas) *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

45. Sugestões

46. Existem procedimentos, protocolos ou outras orientações relativos à alta/transferência do RN de forma a garantir a continuidade dos cuidados com entrega da documentação de alta/transferência *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

47. Sugestões

48. Acompanhamento do RN e cuidador (pais ou tutores) até a portaria é realizado por Técnicos Auxiliar de Saúde onde é realizada verificação da documentação de alta, em conjunto com documento de identificação do cuidador *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

49. Sugestões

Práticas seguras em ambientes seguros

A segurança do doente neonatal traduz-se num processo estrutural de atividades organizadas que promovem uma cultura, comportamentos, tecnologias e ambientes seguros nos cuidados. A sua consistência e operacionalização pretendem reduzir a ocorrência de eventos adversos, potenciando o impacto dos cuidados e ganhos em saúde. Os objetivos estratégicos são:
-Implementar e consolidar práticas seguras em ambientes de prestação de cuidados;
-Monitorizar a implementação de práticas seguras;
-Reduzir as infeções associadas aos cuidados de saúde (IACS) e as resistências aos antimicrobianos
(RAM).

50. A organização utiliza prescrição electrónica de medicamentos *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

51. Sugestões

52. Está implementada uma norma de procedimentos para Prescrição verbal de medicação (em situações de excepção, emergência ou falência do sistema informático) garantindo uma dupla confirmação verbal pelo profissional que prepara e administra a medicação (fármaco, dose, via) *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

53. Sugestões

54. A reconciliação terapêutica é garantida de acordo com norma em vigor *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

55. Sugestão

56. Tem implementado práticas uniformizadas para armazenamento e rotulagem de todos os medicamentos, salvaguardando os requisitos de acondicionamento *

Marcar apenas uma oval.

1 2 3 4

57. Sugestões

58. Está garantida a rotulagem dos medicamentos quando estes são transportados para fora da sua embalagem original *

Marcar apenas uma oval.

1 2 3 4

59. Sugestão

60. Os medicamentos que contém psicotrópicos e estupefacientes encontram-se separados e em zonas de acesso restrito *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

61. Sugestões

62. Estão padronizadas concentrações seguras, (in)compatibilidades e diluições seguras de forma a diminuir a probabilidade de erro associado à medicação *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

63. Sugestões

64. Estão identificados os medicamentos de alto e implementadas estratégias específicas que asseguram o uso seguro do Medicamento de Alerta Máximo em todo o circuito *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

65. Sugestões

66. Estão implementadas estratégias de intervenção para a prevenção e redução de quedas *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

67. Sugestões

68. Tem implementada uma escala de avaliação do risco de queda *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

69. Sugestões

70. Existem normas que visam a prevenção e redução de ocorrências de quedas *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

71. Sugestões

72. É realizada a monitorização regular da integridade da pele e registada essa avaliação no processo do RN *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

73. Sugestões

74. Está implementado um instrumento de avaliação de risco de lesão da pele na população neonatal *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

75. Sugestões

76. Existe um elemento definido como responsável pelas questões da prevenção e controlo da infeção e resistência aos antimicrobianos de acordo com a norma em vigor *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

77. Sugestões

78. A unidade tem implementadas medidas de higienização das mãos respeitando os 5 momentos da OMS

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

79. Sugestões

80. Está preconizado o uso de máscara como medida de prevenção de infeção respiratória *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

81. Sugestões

82. Tem implementadas medidas de isolamento como prevenção de infeção *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

83. Sugestões

Ambiente Terapêutico

O ambiente terapêutico, inclui o ambiente físico, humano e organizacional, influenciando a qualidade e a consistência do cuidados.
Esta combinação irá promover a neuroprotecção do RN, respeitando a dignidade humana e apoiando o ambiente socioemocional da díade RN-Pais. Tem como objetivos estratégicos:

- Promover e proteger o sono do RNP;
- Incentivar e promover ao o toque positivo e contenção;
- Adequar e utilizar corretamente o Posicionamento do RN;
- Promover Termorregulação e cuidados a pele;
- Minimizar o Stress e Dor;
- Promover o Aleitamento Materno;
- Incentivar e incluir a parceria de cuidados ;

84. Estão agrupados os cuidados do RN de forma a minimizar manipulações desnecessárias *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

85. Sugestões

86. Promove-se um ambiente tranquilo para garantir um sono ininterrupto, respeitando uma sonoridade de 45db-65db *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

87. Sugestões

88. Os aparelhos tecnológicos (telemóveis e similares) são utilizados em modo silêncio *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

89. Sugestões

90. É utilizada sala própria para preparação de medicação/soros fora da unidade/sala, de forma a manter os níveis de ruido e luminosidade reduzidos dentro dos parâmetros preconizados *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

91. Sugestões

92. É utilizada manta ou capa protetora para cobrir a incubadora *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

93. Sugestões

94. Os olhos do RN são protegidos da iluminação excessiva em todos os momentos, garantindo a utilização de luzes de intensidade ajustável, aquando da avaliação do mesmo *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

95. Sugestões

96. Está mantida a iluminação ambiente ténue entre as manipulações do RN *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

97. Sugestões

98. É promovido um ambiente térmico neutro de forma manter uma temperatura central normal, com o mínimo de consumo de oxigénio e gasto calórico (36,5ºC-37º) *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

99. Sugestões

100. Promover Toque Positivo *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

101. Sugestões

102. Promover o posicionamento e contenção *

Marcar apenas uma oval.

1 2 3 4

103. Sugestões

104. Incentivar/educar/integrar a participação dos pais/cuidadores nos cuidados *

Marcar apenas uma oval.

1 2 3 4

105. Sugestões

106. Promover/apoiar/incentivar ao aleitamento materno *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

107. Sugestões

108. Promover sensações olfativas agradáveis/neutras *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

109. Sugestões

110. O RN é sensibilizado ao odor materno *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

111. Sugestões

112. É facultada a escala de competências parentais auto-percepcionadas (Guia de Alta) *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

113. Sugestões

Google Formulários

APENDIX III: QUESTIONNAIRES ROUND #2

Ronda 2: Checklist de Segurança Neonatal

Após a análise de dados referentes à primeira ronda pode-se concluir que a maioria dos indicadores atingiu um índice de validade de conteúdo (IVC) superior a 80%, tendo sido eliminado apenas um indicador com score negativo (43,5%). Indicadores com IVC mais baixos foram alvo de reformulação de forma obter um constructo mais robusto.

Não obstante o resultado, e uma vez que são valorizadas as vossas sugestões enquanto peritos, as mesmas foram contempladas na reconstrução indicadores, pelo que pedimos a sua colaboração para a segunda ronda, prevendo que seja a última.

1 = não relevante ou não representativo
2 = item que necessita de grande revisão para ser representativo
3 = item que necessita de pequena revisão para ser representativo
4= item relevante ou representativo

Obrigado pela sua colaboração e disponibilidade.

* Indica uma pergunta obrigatória

1. Email *

2. **O Elo dinamizador da Gestão de Risco Global dinamiza e/ou replica atividades, previstas no plano anual de formação, na área da segurança do doente com equipa multidisciplinar da UCIN** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

3. Sugestões

4. **O Elo dinamizador da Gestão de Risco Global promove o trabalho em equipa multidisciplinar na implementação de processos relativos à segurança do doente neonatal** *

Marcar apenas uma oval.

1 2 3 4

5. Sugestões

6. **O Elo dinamizador da Gestão de Risco Global participa na supervisão e monitorização de todas as etapas do processo de gestão do risco clínico e não clínico, sendo um mediador da comunicação e um elo entre todos os intervenientes** *

Marcar apenas uma oval.

1 2 3 4

7. Sugestões

8. **O Elo dinamizador da Gestão de Risco Global elabora o relatório resultante de auditorias e disponibiliza os resultados aos responsáveis/coordenadores da equipa multidisciplinar**

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

9. Sugestões

10. **É realizado anualmente o cálculo das dotações, pelos responsáveis das equipas multidisciplinares de forma a promover dotações que assegurem a segurança no cuidado neonatal** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

11. Sugestões

12. **Existem planos de prevenção no âmbito da segurança: Plano de Emergência da UCIN** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

13. Sugestões

14. **Existem planos de prevenção do dano associado aos cuidados de saúde: Normas e Protocolos que visem a segurança do cuidado neonatal** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

15. Sugestões

16. **Tem implementado e cumpre procedimentos de verificação e teste do carro de emergência, desfibrilhador, reanimador, ventilador e incubadora de transporte, cumprindo diretiva da instituição** *

Marcar apenas uma oval.

1 2 3 4

17. Sugestões

18. **Tem implementada e cumpre a checklist de material para a uniformização de procedimentos e realização de transporte neonatal intra e/ou inter-hospitalar seguro** *

Marcar apenas uma oval.

1 2 3 4

19. Sugestões

20. **Os profissionais têm formação sobre o processo de notificação e comunicação da ocorrência de incidentes de segurança no sistema Notifica, de Farmacovigilância/RAM e Hemovigilância** *

Marcar apenas uma oval.

1 2 3 4

21. Sugestões

22. **Estão disponíveis formulários para a comunicação interna de incidentes de segurança** *

Marcar apenas uma oval.

1 2 3 4

23. Sugestões

24. **Tem implementado e cumpre procedimentos para garantir a transição de cuidados segura, através de uma comunicação eficaz, normalizada pela técnica do ISBAR** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

25. Sugestões

26. **Está garantido o Consentimento Informado, Esclarecido e Livre através de registo e fundamentação no processo clínico do doente neonatal** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

27. Sugestões

28. **Tem implementado e cumpre procedimentos para garantir a divulgação transversal de Normas/Procedimentos/Circulares, através de um processo de confirmação (por ex. assinatura e número mecanográfico)** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

29. Sugestões

30. **Está contemplada formação periódica para a equipa multidisciplinar em procedimentos de segurança para a UCIN** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

31. Sugestões

32. **Identificação do doente é assegurada por meio de pulseira identificativa codificada e/ou por meio de sistema de alerta (Tags ou Hugs), sendo o local de colocação dos mesmos individualizado de acordo com as caraterísticas do doente neonatal** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

33. Sugestão

34. **O método utilizado para a identificação do doente neonatal antes de procedimentos baseia-se na identificação positiva de pelo menos dois destes: nome e apelido (doente neonatal e da mãe), data de nascimento, número único de processo clínico** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

35. Sugestão

36. **Na identificação do doente neonatal não são utilizadas(os) abreviaturas, acrónimos e/ou símbolos** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

37. Sugestões

38. **A identificação inequívoca do doente neonatal ocorre sempre antes de qualquer intervenção** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

39. Sugestões

40. **Tem implementado e cumpre procedimento para garantir a rastreabilidade dos exames complementares de diagnóstico (incluindo a rotulagem de amostras com identificação inequívoca do doente neonatal e processo de verificação por duas pessoas)** *

Marcar apenas uma oval.

1 2 3 4

41. Sugestões

42. **Tem implementado e cumpre procedimentos relativos à alta/transferência do doente neonatal de forma a garantir a continuidade dos cuidados com entrega da documentação de alta/transferência** *

Marcar apenas uma oval.

1 2 3 4

43. Sugestões

44. **A UCIN utiliza prescrição eletrónica de medicamentos** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

45. Sugestões

46. **Tem implementado e cumpre procedimento para Prescrição verbal de medicação (em situações de exceção, emergência ou falência do sistema informático) garantindo uma dupla confirmação verbal pelo profissional que prepara e administra a medicação (fármaco, dose, via)** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

47. Sugestões

48. **Tem implementado e cumpre a reconciliação terapêutica** *

Marcar apenas uma oval.

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◯	◯	◯	◯

49. Sugestão

50. **Tem implementado e cumpre práticas uniformizadas para armazenamento e rotulagem de todos os medicamentos, salvaguardando os requisitos de acondicionamento** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

51. Sugestões

52. **Está garantida a rotulagem dos medicamentos quando estes são transportados para fora da sua embalagem original** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

53. Sugestão

54. **Os medicamentos que contém psicotrópicos e estupefacientes encontram-se separados e em zonas de acesso restrito** *

Marcar apenas uma oval.

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◯	◯	◯	◯

55. Sugestões

56. **Estão padronizadas concentrações seguras, (in)compatibilidades e diluições seguras de forma a diminuir a probabilidade de erro associado à medicação** *

Marcar apenas uma oval.

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◯	◯	◯	◯

57. Sugestões

58. **Estão identificados os medicamentos de alto risco e implementadas estratégias específicas que asseguram o uso seguro do Medicamento de Alerta Máximo em todo o circuito** *

Marcar apenas uma oval.

1	2	3	4
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59. Sugestões

60. **Tem implementado e cumpre normas e estratégias de intervenção para a prevenção e redução de quedas** *

Marcar apenas uma oval.

1 2 3 4

61. Sugestões

62. **Tem implementada escala de avaliação do risco de queda neonatal** *

Marcar apenas uma oval.

1 2 3 4

63. Sugestões

64. **Tem implementado e cumpre a monitorização regular da integridade da pele com registo no processo do doente neonatal** *

Marcar apenas uma oval.

1 2 3 4

65. Sugestões

66. **Tem implementado um instrumento de avaliação de risco de lesão da pele na população neonatal** *

Marcar apenas uma oval.

1 2 3 4

67. Sugestões

68. **Existe um elemento definido como responsável pelas questões da prevenção e controlo da infeção e resistência aos antimicrobianos** *

Marcar apenas uma oval.

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◯	◯	◯	◯

69. Sugestões

70. **A UCIN tem implementadas medidas de higienização das mãos respeitando os 5 momentos da OMS**

Marcar apenas uma oval.

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◯	◯	◯	◯

71. Sugestões

72. **Está preconizado o uso de máscara como medida de prevenção de infeção respiratória** *

Marcar apenas uma oval.

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◯	◯	◯	◯

73. Sugestões

74. **Tem implementado e cumpre medidas de isolamento como prevenção de infeção** *

Marcar apenas uma oval.

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75. Sugestões

76. **Os cuidados ao doente neonatal são individualizados e centrados no desenvolvimento, respeitando os sinais de stress e de desorganização** *

Marcar apenas uma oval.

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◯	◯	◯	◯

77. Sugestões

78. **É promovido um ambiente tranquilo para garantir um sono ininterrupto, respeitando uma sonoridade adequada (basal inferior a 45db e com pico máximo de 65db)** *

Marcar apenas uma oval.

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79. Sugestões

80. **Os limites de sons dos alarmes são controlados e prontamente desligados de forma a permitirem ser ouvidos mas minimizando o nível de ruido para valores aceitáveis em termos de segurança** *

Marcar apenas uma oval.

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81. Sugestões

82. **Deve ser utilizada sala própria para preparação de medicação/soros fora da unidade/sala, de forma a manter os níveis de ruido e luminosidade reduzidos dentro dos parâmetros preconizados** *

Marcar apenas uma oval.

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◯	◯	◯	◯

83. Sugestões

84. **É promovido um ambiente neuroprotetor através da utilização de manta ou capa protetora para a incubadora** *

Marcar apenas uma oval.

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85. Sugestões

86. **Os olhos do doente neonatal são protegidos da iluminação excessiva em todos os momentos, garantindo a utilização preferencial de luz natural e/ou luzes de intensidade ajustável, aquando da avaliação do mesmo, não ultrapassando os 200 a 600 lux** *

Marcar apenas uma oval.

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◯	◯	◯	◯

87. Sugestões

88. **É mantida a iluminação ambiente ténue e sempre que possível com luz natural, ajustada consoante a capacidade de integração do doente neonatal** *

Marcar apenas uma oval.

1 2 3 4

89. Sugestões

90. **É promovido um ambiente térmico neutro de forma manter uma temperatura central adequada (36,5ºC-37º), com o mínimo de consumo de oxigénio e gasto calórico** *

Marcar apenas uma oval.

1 2 3 4

91. Sugestões

92. **É promovido o toque positivo e contato pele a pele precoce** *

Marcar apenas uma oval.

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◯	◯	◯	◯

93. Sugestões

94. **São promovidos cuidados que proporcionam suporte durante transições, posicionamento e conforto individualizados** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

95. Sugestões

96. **É incentivada a participação/parceira dos pais/cuidadores nos cuidados ao doente neonatal** *

Marcar apenas uma oval.

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◯	◯	◯	◯

97. Sugestões

98. **É assegurada a proteção, promoção e apoio ao aleitamento materno** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

99. Sugestões

100. **São promovidas sensações olfativas agradáveis, através da exposição a aromas maternos/paternais e acesso ao sabor e cheiro do leite materno** *

Marcar apenas uma oval.

1	2	3	4
◯	◯	◯	◯

101. Sugestões

102. **É facultado o Guia de Alta e Escala de Intensidade da Competência Materna Auto-Percebida, permitido aos pais/cuidadores tempo e espaço para colocação de questões e validação de ensinos** *

Marcar apenas uma oval.

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◯	◯	◯	◯

103. Sugestões

APENDIX IV: OPINION OF THE ETHICS COMMITTEE

POLITÉCNICO DE SANTARÉM

PARECER

COMISSÃO DE ÉTICA DA UNIDADE DE INVESTIGAÇÃO DO IPSANTARÉM

EMISSÃO DE PARECER Nº19-2024ESSS

Identificação do Investigador | Ana Cristina Raimundo Malveira (ESSS)

Identificação do Projeto | *Quality in Neonatal Care: Safety Checklist Validation*

Constata-se que:

i. É um trabalho académico conferidor do grau de mestre;

ii. Apresenta fundamentação teórica;

iii. O cronograma é adequado considerando as diferentes etapas do desenvolvimento do projeto.

iv. Não esclarece quem assegura a salvaguarda dos dados e por quanto tempo comprometendo a garantia do anonimato;

v. Inclui o consentimento informado, livre e esclarecido embora sem a devida inclusão do logo institucional;

i. Esclarece os riscos potenciais.

Face ao exposto a Comissão de Ética emite parecer favorável condicional porquanto não cumpre o requisito ético referido no ponto iv. Solicita-se a inclusão do logo do Instituto Politécnico de Santarém nos documentos a facultar aos participantes (consentimento, questionário, etc.).

Santarém, 30 de abril de 2024

Pedro Oliveira

(Coordenador)

Rafael Oliveira

(Subcoordenador)