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RESEARCH

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DEVELOPMENT OF "CARE FOR SKIN INTEGRITY IN THE NEONATAL PERIOD": DOCUMENTATION TOOL FOR SKIN CONDITIONS

Desenvolvimento do "cuidado com a integridade da pele neonatal": instrumento para documentação das condições da pele

Desarrollo del "cuidado de la integridad de la piel neonatal": instrumento para documentar condiciones de piel

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ABSTRACT

Objective: to develop tool for documenting skin conditions and wound management in neonatal patients's records. **Method:** methodological study conducted into stages: development of the tool based on literature; content validation by a committee of experts and testing with 50 newborns. Kappa coefficient was used to evaluate qualitative items, and Intraclass Correlation Coefficient (ICC) for quantitative items. **Findings:** the content of Care for Skin Integrity in the Neonatal Period (CIPNeo) were validated by 9 experts. **Conclusion:** the content of CIPNeo was validated. It showed satisfactory reliability when administered by nurses to patients, and is adequate for promoting documentation about skin conditions and wound management. Daily records are essential for continuous evaluation of factors for wound prevention, assessment, monitoring and treatment, and for providing support to nurses' clinical reasoning.

DESCRIPTORS: Skin care; Wounds and injuries; Validation study; Newborn; Neonatal intensive care units.

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RESUMO

Objetivo: desenvolver instrumento para documentar as condições da pele e o manejo de feridas de pacientes neonatais. Método: estudo metodológico realizado em etapas: desenvolvimento de instrumento para registro, com base na literatura; validação de conteúdo por comitê de especialistas e teste com 50 recém-nascidos com feridas. O coeficiente Kappa foi utilizado para avaliar itens qualitativos e o Coeficiente de Correlação Intraclasse (ICC) para quantitativos. Resultados: o conteúdo do Cuidado para a Integridade da Pele Neonatal (CIPNeo) foi validado por 9 especialistas. Conclusão: o conteúdo do CIPNeo foi validado. Apresentou confiabilidade satisfatória quando administrado por enfermeiras aos pacientes, sendo adequado para promover documentação sobre condições de pele e manejo de feridas. Os registros diários são essenciais para avaliação contínua quanto a prevenção, monitoramento e tratamento de feridas, assim como para fornecer suporte ao raciocínio clínico dos enfermeiros.

DESCRITORES: Higiene da pele; Ferimentos e lesões; Estudo de validação; Recém-nascido; Unidades de terapia intensiva neonatal.

RESUMEN

Objetivo: desarrollar herramienta para documentar condiciones de la piel y manejo de heridas en pacientes neonatales. **Método:** estudio metodológico realizado en etapas: desarrollo de la herramienta con base en la literatura; validación de contenido por un comité de expertos y pruebas con 50 recién nacidos. Se utilizó el coeficiente Kappa para evaluar los ítems cualitativos y el coeficiente de correlación intraclase (CCI) para los ítems cuantitativos. **Hallazgos:** el contenido de *Cuidado para integridade da pele neonatal* (CIPNeo) fue validado por 9 expertos. **Conclusión:** se validó el contenido de CIPNeo. Mostró una confiabilidad satisfactoria cuando fue administrado por enfermeras a los pacientes y es adecuado para promover la documentación sobre las condiciones de la piel y el manejo de heridas. Los registros diarios son esenciales para la evaluación continua de los factores de prevención, evaluación, seguimiento y tratamiento de las heridas, y para brindar apoyo al razonamiento clínico de las enfermeras.

DESCRIPTORES: Cuidados de la piel; Heridas y lesiones; Estudio de validación; Recién nascido; Unidades de cuidado intensivo neonatal.

INTRODUCTION

Newborns at neonatal intensive care units (NICUs) are at risk of skin breakdown due the need for invasive procedures, use of medical devices, as they have a delicate skin structure, especially when premature. Skin injuries increase neonates' hospital stay, causing complications, such as pain, sepsis, scars, and can even lead to death. In addition to evaluating the risk of skin injuries, there must be a plan of standardized care for wound prevention and avoidance of or decrease in possible complications. Hence, adequate strategies and equipment are crucial for care, along with knowledgeable nurses with updated training.¹⁻⁴

Wound management aims to control or eliminate factors that cause injuries and/or retard wound healing. Identifying and registering risk factors for skin injury contributes to care management. It is important to consider patient characteristics that may interfere in this process, such as cardiopulmonary function, nutritional issues, and other aspects that may retard wound healing, such as the use of corticosteroids, as well as medical devices. ²⁻⁵ Skin characteristics of preterm infants put them at greater risk of complications than full term infants. There are many issues that contribute to the potential for undesirable skin events: use of medical devices; systemic toxicity from topic agents; increased skin permeability leading to loss of heat and fluids; greater risk of traumatic injury; vulnerability to invasion by microorganisms and infection; use and removal of adhesive materials; nutritional deficiencies; increased risk of edema; and

reduced blood flow to the epidermis.⁶⁻⁷ All of these aspects are relevant and must be considered in daily neonatal care.

For the best approach in skin care, it is indispensable to consider: recognition of skin conditions; knowledge about the healing process and factors that affect it; knowledge about different types of available treatment and their safety; proper pain management; and, effective documentation to facilitate health professionals' communication and support for standardizing intervention. ^{1,5,8} Records must be clear, with relevant data for management and monitoring, ⁹ including information that can direct and justify professional interventions.

No specific tools for documentating skin and wound assessment for hospitalized newborns were found in the literature. However, scales were proposed to assess skin condition (Neonatal Skin Condition Scale)¹⁰ and risk for skin injury (Braden Q. Scale, Braden Q.D., Starkid Skin Scale, Neonatal Skin Risk Assessment Scale, Glamorgan Pediatric Pressure Ulcer Risk Assessment Scale, Seton Infant Skin Risk Assessment Tool).¹ Of these scales, only two are validated to Brazilian Portuguese language: Neonatal Skin Condition Scale¹¹ and Braden Q Pediatric Skin Risk Assessment Scale.¹ However, the later does not include the premature newborn. In addition, risk assessment may be insufficient to direct interventions. Therefore, a tool to document neonatal skin should include risk factors, skin assessment information, and treatment, as well as to allow analysis over time.

Considering the relevance of these aspects, the lack of validated tools for the specific needs of this population, as well as

Grise et al. 3

the absence of electronic health records within many NICUs in developing countries, a strategy was developed for supporting standardized nursing care for maintaining skin integrity and wound treatment in the neonatal period. Thus, the objective of this study was to develop tool for documenting skin conditions and wound management in neonatal patients's records.

METHOD

This was a methodological study to develop and validate a tool for recording skin conditions and wound management, conducted in two stages. During the first stage, the tool Care for Skin Integrity in the Neonatal Period (in Portuguese, Cuidados para Integridade da Pele Neonatal, abbreviated as CIPNeo) was developed, considering specific requirements of hospitalized newborns and hospitals without electronic records. The proposed content relied on the clinical experience of authors as well as a narrative literature review. Thus, CIPNeo was developed to facilitate documentation of the presence of skin injury risk factors, conditions that may interfere in cicatrization processes, types of wounds, wound localization, and wound treatment. 1,4-8 Outcomes are included: cicatrization stages, dimensions (length, width, depth), detachment, tunneling, tissue type, exudation (volume, aspects, color, odor), signs of infection, periwound skin condition, and wound edge. 6-15 Additionally, it has place to record products used for wound treatment or prevention. The CIPNeo also contains the Neonatal Skin Condition Score (NSCS), 10 validated in Brazilian Portuguese.¹¹ A guide for completion was developed, organized based on the CIPNeo items, including their definitions, and information on how to complete each item.

The references used for development of CIPNeo were: the Association of Women's Health, Obstetric and Neonatal Nurses/National Association of Neonatal Nurses (AWHONN/NANN) Neonatal Skin Care Research-Based Clinical Practice Guideline;¹³ Triangle of Wound Assessment;¹⁴TIME (tissue, infection/inflammation, moisture balance, and edge of wound),¹⁵ and articles focused on: neonatal wound care;⁸ study on the development of an infant skin breakdown risk assessment tool,¹ wound assessment tools, and nurses' needs, not specific to precise age populations.⁹

In the second stage, the content of CIPNeo was validated by a committee of experts, according to following properties: pertinence, clarity, and scope. Each expert could evaluate the criteria with scores from 1 to 4, in which: "1" = item does not meet criteria; "2" = item needs major revision to meet criteria; "3" = item requires minor revision to meet criteria; "4" = item fully meets criteria. Experts also evaluated the CIPNeo face validity, considering the following scores: "1" = inadequate; "2" = barely adequate; "3" = moderately adequate; "4" = fully adequate. When experts scored an item either as a 1 or 2, they were asked to offer suggestions. Content validity was measured using the Content Validity Index (CVI) to indicate proportion of experts who agreed with the presence of the criteria. Thus, the

CVI was calculated by summing the number of items marked by the experts as "3" or "4", then dividing this value into the total number of expert responses. A score of 0.80 or higher was considered adequate CVI. 16 Items that did not score this level were resubmitted to experts.

Considering literature recommendations of at least seven experts, 15 were invited. At this study, experts must present: at least five years of professional experience, and working in at least one of the following roles: neonatal nurse practitioner, ostomy and/or wound care nurse practitioner, neonatologist, and, physician or nurse with publications on validation studies.

The experts received an invitation letter and instructions, explaining the procedures of content validation of the CIPNeo, and the Terms of Free and Informed Consent form, which were sent by e-mail. They were instructed that they could remove, modify, and/or add items. After their evaluation, the required adjustments were made, and these changes were resubmitted to them until consensus was reached, what occurred at second round.

The reviewed CIPNeo inter-observer reliability was analyzed: two registered nurses administered the tool. The evaluation considered the agreement¹⁷ between documentation on the CIPNeon, which was administered to 50 newborns, a sample recommended in the literature.¹⁸ The administration occurred at a 30 beds neonatal unit, level III, at public teaching hospital from São Paulo, Brazil. After parental consent, it was included patients with skin injury. Newborns with vital sign instability and minimal handling were excluded.

Two trained registered nurses assessed and recorded skin and wound conditions, independent and simultaneously, without sharing their notes or perceptions during completion of the tool. The time spent was noted by each nurse, which supported evaluation of the applicability of the tool in care settings. For each newborn, the duo of nurses started collecting data on a patient's identification and clinical data, from the medical chart (item 1 of the CIPNeo). After that, they assessed the patient during routine nursing care, considering skin conditions and wound monitoring, as well as dressing change procedures. They administered the CIPNeo just once for each included newborn. The data collection was from March to September of 2018.

To evaluate the CIPNeo, the CVI total was calculated: it was performed the sum of all items' CVI, and divided into the number of items scored by experts. To be adequate, the CVI had to be greater than or equal to 0.80. 16 To measure inter-observer reliability, data were exported into the Statistical Package for the Social Science (SPSS), version 22. To evaluate agreement between the nurses on qualitative items of the instrument, the Kappa Coefficient was calculated. This coefficient was categorized as poor when scores were <0.00, slight from 0.00 to 0.20, fair from 0.21 to 0.40, moderate from 0.41 to 0.60, substantial from 0.61 to 0.80, and nearly perfect from 0.81 to 1.00. 20 Agreement on quantitative items was evaluated by means of the Intraclass Correlation Coefficient (ICC). Literature suggests that values above 0.75 indicate good

reliability.²¹ The Statistical Analysis System (SAS), version 9.4, was used for descriptive analysis, such as measures of position (medium, average, minimum and maximum) and dispersion (standard deviation) for all quantitative items of the CIPNeo. For all analysis, the adopted level of significance was p<0.05 and support of a statistical professional.

It is emphasized that this study took into consideration the ethical aspects contained in Resolution No. 466/12 of the National Health Council that regulates research with human beings, in force in the country, being approved by the Ethics and Research Committee of UNICAMP, on July 31, 2017, with consubstantiated opinion: 2.193.094 and under CAAE No. 67809317.5.0000.5404.

RESULTS

The final version of CIPNeo is composed of two-sided sheet, printed as a front (Figure 1) and back (Figure 2). The content is

organized in five sections. The front page presents: 1. Identification (section for documenting patient's name, hospital identification number, gender, birth data, medical diagnosis); 2. Daily assessment (data related to risk factors for skin injury – Neonatal Skin Condition Score/NSCS, clinical condition and use of devices – and type of wound, if present). The back page presents: 3. Wound assessment and evaluation (detailed description of wound condition); 4. Treatment, and 5. Prevention (sections 4 and 5 are together and designed for documenting products used for wound treatment or skin injury prevention). Indications for which must consider protocols of each institution. There is also a section to indicate the wound location on body, in a schematic drawing, which is called "Localization".

Nine experts participated in the content validation: all of them were nurses: six experts in ostomy and wound care, two neonatal nurse practitioners, and one PhD in nursing science, with experience upon validation studies (Table 1).

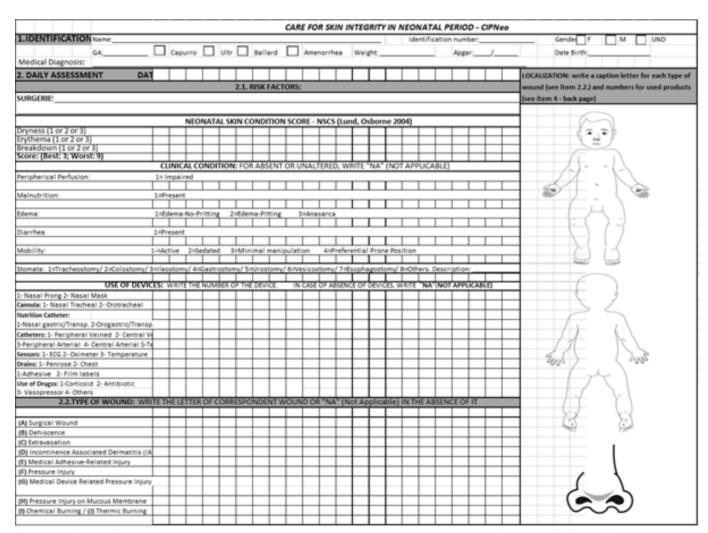


Figure 1 - CIPNeo front page: Identification and Daily assessment of risk factors and wound type - Campinas, SP, Brazil, 2018

Grise et al. 5

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Figure 2 – CIPNeo back page: Wound assessment and evaluation, treatment and prevention. – Campinas, SP, Brazil, 2018

Table 1 – Experts who validated the content of CIPNeo – Campinas, SP, Brazil, 2018 (n=9)

a	Experts											
Characteristics	1	2	3	4	5	6	7	8	9			
Years of experience in neonatal care	6	*	4	7	*	20	8	*	1			
Years of experience in ostomy and wound care	3	30	6	*	6	19	10	10	5			
Expert in ostomy and wound care	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes			
Expert in neonatal care	No	No	No	Yes	No	No	Yes	No	No			
Master's degree	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No			
Doctoral degree	No	Yes	Yes	No	No	No	No	Yes	No			

^{*} Less than one year of experience Source: Research data.

Variable	Average (SD)*	Median (IIQR)**	Minimum	Maximum 40.2	
Gestational age (weeks)	33.3 (5.1)	35.4 (28.0-37.8)	24.0		
Birth weight (grams)	2276.5 (1240.7)	2370.0 (1090.0-3275.0)	440.0	4600.0	
Apgar – 5 minute	8.4 (2.1)	9.0(8.0-10.0)	1.0	10.0	
NSCS***	4.2 (1.07)	4.0(3.00-5.00)	3.0	7.0	

Table 2 – Profile of newborns in whom the CIPNeo was applied – Campinas, SP, Brazil, 2018 (n=50)

The experts considered 11 items presented lacked clarity and suggested alterations. The CVI $_{\rm total}$ of the CIPNeo was 0.93. After minor adjustments, all CIPNeo items scored \geq 0.80, and the CVI $_{\rm total}$ was 0.95. Some newborns presented more than one wound. Therefore, data refer to 62 wounds of 50 patients. Table 2 presents patients' characteristics.

Items which achieved 100% agreement by the nurses who administered the CIPNeo included: date of completion, date of birth, clinical diagnosis, and surgeries. Wound location achieved 96.77% agreement. Considering the 122 qualitative items of the CIPNeo, the Kappa Coefficient showed a large number of items with near perfect agreement: 112 items with near perfert agreement (91.8%, with Kappa Coefficiente from 1.00 to 0.80), 8 items with substantial agreement (6,56%, with Kappa Coefficiente from 0.79 to 0.60) and 2 items with moderate agreement (Kappa Coefficiente from 0.61 to 0.40). Two items could not have their values verified, due to technical limitations in the statistical test. Regarding seven quantitative items, all achieved a CCI > 0.75. Table 3 shows the application of CIPNeo, considering 50 patients with 62 evaluated skin injuries.

The administration of the CIPNeo took an average of 7.4 minutes: 4 to 23 minutes. The longest time generally occurred when the patient had more than one skin injury.

Table 3 – Interclass Correlation Coefficient values for CIPNeo's quantitative items – Campinas, SP, Brazil, 2018 (n=7)

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Item	ICC (IC 95%)						
Gestational age	1.00						
Weight	1.00						
5-minute Apgar*	1.00						
Total NSCS	0.95 (0.91-0.97)						
Wound width	1.00						
Wound depth	0.91 (0.85-0.94)						
Wound length	1.00						

^{*}Apgar was obtained from 48 patients Source: Research data.

DISCUSSION

The nursing care for skin integrity must consider a daily and careful assessment of the hospitalized newborn in order

to prevent and treat wounds.1-4 Many hospitals of developing countries do not have eletronic records, so it is essencial that printed documents show patient identification at the beginning of the form. Hence CIPNeo presents in the first section: name, identification number, birth data, gestational age, weight, gender and medical diagnoses. The next section was developed to register the daily assessment, considering risk of skin injury¹⁰⁻¹¹ such as NCSC score, the conditions of peripheral perfusion, presence of malnutrition, edema, diarrhea, as well as the level of newborn activity, and presence of stomata. In addition, other risk factors that can be documented are the use of devices (nasal devices and masks, cannulas, catheters, sensors and adhesives) and medications (corticosteroids, antibiotics, vasopressor and others).¹⁻¹³ If present, the type of wound can also be marked in this section, including: surgical wound, dehiscence, extravasation, incontinence associated dermatites, medical adhesive-related injury, pressure injury, medical device related pressure injury, pressure injury on mucous membrane, and chemical and thermal burn. 1,8-9,14-15 This section is useful to guide experienced nurses as well as beginners, designated to document commonly identified wounds in neonatal setting. 13,22

In order to increase the perspective to clinical practice, the assessment must consider factors that go beyond the skin injury itself, but rather approach the patient clinical condition, and birth history. Any comorbidities or factors that may affect skin integrity, or wound cicatrization, must be documented and considered for treatment planning.^{4,8–9,12–14} This documentation provides follow-up on the skin condition, and monitoring skin integrity and/or healing process.²²

The section for documenting assessment and evaluation of the wound includes specific data on monitoring of the evolution of the healing process: classification of the stage of a pressure injury and the degree of a burn; wound measurements; quantity, appearance and odor of the exudate; type of tissue in the wound bed; integrity of the border and periwound skin; identification of infection and pain. ¹²⁻¹⁵

CIPNeo also makes possible to record the product used for prevention and treatment of wounds. ^{2,13} The indication of products must follow institutional protocols institution and updated literature. Another relevant issue is the consensus of the staff about products, procedures, and development of protocols that drive treatment, in order to ensure continuity of care. ^{1,5,8,13} Hence, other settings can adapt the CIPNeo to their reality.

^{*}SD= standard deviation, **IIQR= interquartile range, ***NSCS = Neonatal Skin Condition Score (3 is the best score, while 9 is the worst) Source: Research data.

Grise et al. 7

The experts considered CIPNeo content valid, and the tool showed satisfactory reliability when administered by two trained nurses for 50 patients. CIPNeo may be considered adequate for promoting documentation on skin conditions and wound management in neonatal period at settings without electronic health records. In addition, this tool allows daily documentation that is essential for continuous assessment of risk factors for skin injury, skin condition monitoring, prevention of injuries, revision of treatment, and for providing support to nurses' clinical reasoning.

Hospitalization exposes newborns to high risk of skin injury, regardless of gestational age. Premature babies are at special risk of infection due to immaturity of their immune system, and inability of their thin skin to function as a physical barrier for microorganisms. They also present a higher risk of sepsis, when bacteria can proliferate on a wound bed.^{5,8,12–13} Therefore, it is relevant to develop a follow-up strategy to monitor and diagnose neonatal skin conditions and direct interventions precociously, which supports the development of the CIPNeo.

After a transcultural validation of the Neonatal Skin Risk Assessment Scale (NSRAS) for Brazilian Portuguese, it could replace NSCS in item 2.1 of the CIPNeo. Currently, NSRAS is validated only for Portuguese of Portugal²³ and for Spanish,²⁴ which are not adequate for use in Brazil.

CIPNeo has been conceived to provide daily records, with a column for each day, including all items that the nurse may consider suitable to patient. At the end of the daily column, there is space for professional signature. Thereby, CIPNeo offers possibility of having a longitudinal record in settings without electronic records: the printed version has been developed to be used during several consecutive days for the same patient, facilitating evaluation over time, by providing quick access to previous data. Such documentation favors communication between health professionals, collaborates for decision making process, and provides continuity of care. It is believed that the CIPNeo can be applicable for any neonatal unit, with appropriate staff training. The time spent completing the CIPNeo shows that it as a feasible strategy at neonatal unit.

Records with incomplete or inaccurate information lead to misguided decisions on newborn wound treatment. Furthermore, a careful assessment of the skin is one of the indispensable actions to promote diagnosis, and the indication of adequate therapies. Therefore, the neonatal skin particularities must be assessed, diagnosed, recorded, and monitored to implement the best care plan. Another relevant aspect of documentation is the possibility of using these data as quality indicators, by diagnosing the current situation and projecting outcomes to be achieved. The documentation helps to identify care failures and proposition of quality improvement strategies. ^{1,5,10} Thus, CIPNeo can provide data for quality management and nursing care safety. Health programs and actions must be supported by documented information, even in hospitals that do no have electronic health records. ²⁵

CIPNeo validation offered support for subsequent clinical validation, adjustments, and regular use in clinical practice. Its development can help fill gaps related to the neonatal population,

directing evaluation, diagnosis, and daily documentation of injury prevention and treatment.

In terms of future perspectives, clinical validation of CIPNeo is planned for refinement. Through its daily use in clinical practice, it will be possible to determine its useful for care and research. An electronic version of CIPNeo is currently in development, which will facilitate fulfillment, recovery, and data processing. This electronic version will include standardized nursing language, considering nursing diagnoses as Impaired integrity skin, Risk for impaired integrity skin²⁶ and, two new nursing diagnoses proposed by one of the authors of this paper and accepted by NANDA International: Neonatal pressure injury and Risk for neonatal pressure injury.

CONCLUSIONS

The CIPNeo was validated as a daily recording tool for skin conditions, wound evaluation, and treatment in neonatal period. In addition, it makes information more easily available to nurses in settings without electronic health records. This tool has the objective of improving skin care documentation, supporting data collection performed by nurses, the identification of risk factors for skin injuries, proper diagnosis, as well as monitoring wound treatments and outcomes. These daily records are essential for clinical reasoning and planning care.

Thus, CIPNeo is useful for identifying prevalence of wounds in neonatal settings, and generating data to compare outcomes of nursing care, and to develop strategies for quality improvement. Additionally, registering relevant aspects of follow-up for skin and wound conditions improves communication between health team members, and favors decision-making processes related to the treatment.

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