

# Bundle for regulating the body temperature of newborns over 34 weeks: Construction and validation

Bundle para regulação da temperatura corporal de recém-nascidos maiores de 34 semanas: construção e validação

Paquete para regular la temperatura corporal de recién nacidos de más de 34 semanas: construcción y validación

Ana Caroline Alves Galli<sup>1</sup> Maria Paula Custódio Silva<sup>2</sup> Flávia da Veiga Ued<sup>1</sup> Letícia Volpe Rezende Mariana Torreglosa Ruiz<sup>1</sup> Divanice Contim<sup>1</sup>

 <sup>1</sup>Universidade Federal do Triângulo Mineiro (UFTM), Uberaba, Minas Gerais, Brazil.
 <sup>2</sup>Hospital Universitário Júlio Muller (HUJM-EBSERH), Cuiabá, Mato Grosso, Brazil.

Corresponding author: Maria Paula Custódio Silva E-mail: maria\_paulacs@hotmail.com

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### ABSTRACT

**Objective:** Describe the process of building and validating a bundle to promote body temperature regulation in newborns over 34 weeks of age. **Methods:** This methodological research was carried out in three stages: a scoping review, construction of the first version of the bundle, and content validation by 15 experts, nine nurses and six physicians, selected according to criteria adapted from references in the field. A content validity index above 0.80 was considered acceptable for the agreement among the experts on each type of care. Two rounds of evaluation were required to produce the final version. **Results:** The bundle was structured into care in the delivery room, during transportation, and in the rooming-in unit, with a total of 15 items, all with agreement above 0.90 after the second round of evaluation. **Conclusion:** The bundle developed was considered valid in terms of content and establishes care based on scientific evidence in a standardized and safe way for the childbirth care team.

**Descriptors:** Validation Study; Infant, Newborn; Body Temperature Regulation; Hypothermia; Patient Care Bundles.

### RESUMO

**Objetivo:** Descrever o processo de construção e validação de um bundle para promoção da regulação da temperatura corporal de recém-nascidos maiores de 34 semanas. **Métodos:** Pesquisa metodológica executada em três etapas: revisão de escopo, construção da primeira versão do bundle e validação de conteúdo realizada por 15 experts, sendo nove enfermeiros e seis médicos, selecionados conforme critérios adaptados de referencial na área. O índice de validade de conteúdo acima de 0,80 foi considerado aceitável para a concordância entre os experts sobre cada cuidado. Foram necessárias duas rodadas de avaliação para a confecção da versão final. **Resultados:** O bundle foi estruturado em cuidados: na sala de parto, no transporte e no alojamento conjunto, com total de 15 itens, todos com concordância acima de 0,90 após a segunda rodada de avaliação. **Conclusão:** O bundle elaborado foi considerado válido quanto ao conteúdo e estabelece cuidados baseados em evidências científicas de maneira padronizada e segura para a equipe de assistência ao parto.

**Descritores:** Estudo de Validação; Recém-Nascido; Regulação da Temperatura Corporal; Hipotermia; Pacotes de Assistência ao Paciente.

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#### RESUMEN

**Objetivo:** Describir el proceso de creación y validación de un paquete para promover la regulación de la temperatura corporal en recién nacidos de más de 34 semanas de edad. **Métodos:** Investigación metodológica realizada en tres etapas: una revisión del alcance, la construcción de la primera versión del paquete y la validación del contenido llevada a cabo por 15 expertos, nueve enfermeras y seis médicos, seleccionados según criterios adaptados a partir de referencias en la materia. Se consideró aceptable un índice de validez de contenido superior a 0,80 para el acuerdo entre los expertos sobre cada tipo de atención. Fueron necesarias dos rondas de evaluación para elaborar la versión final. **Resultados:** El paquete se estructuró en cuidados: en la sala de partos, durante el transporte y en la unidad de alojamiento, con un total de 15 ítems, todos ellos con una concordancia superior a 0,90 tras la segunda ronda de evaluación. **Conclusión:** El paquete se consideró válido en cuanto a su contenido y establece una atención basada en pruebas científicas de forma estandarizada y segura para el equipo de atención al parto.

Descriptores: Estudio de Validación; Recién Nacido; Regulación de la Temperatura Corporal; Hipotermia; Paquetes de Atención al Paciente.

# INTRODUCTION

Newborn babies are more susceptible to variations in body temperature due to the immaturity of the central nervous system in the production and conservation of heat. Imbalances in these mechanisms can lead to hypothermia. Exposure to cold triggers compensatory responses such as chemical thermogenesis without shivering through brown fat. Hypothermia has been associated with the need for admission to a neonatal unit, respiratory support, and longer hospital stays, regardless of weight and gestational age, and with the occurrence of late-onset sepsis, hypoglycemia, respiratory disease, and intraventricular hemorrhage. When prolonged, it can result in respiratory failure, tissue hypoxia, metabolic acidosis, and neurological damage<sup>(1,2)</sup>.

In addition, hypothermia can increase the length of hospital stay for newborns over 34 gestational weeks by 20%, reinforcing the need for preventive action<sup>(1)</sup>.

In this sense, specific thermal control measures are recommended during birth. Controlling the temperature of the environment and medical equipment is essential to avoid heat loss through convection, conduction, evaporation and radiation<sup>(1,2)</sup>.

Skin-to-skin contact should be encouraged for newborns older than 34 weeks, with good vitality, to promote temperature maintenance<sup>(3)</sup>. This skin-to-skin contact can be made with the mother or father right after birth and maintained during transportation to the rooming-in unit or neonatal unit, regardless of the type of delivery<sup>(4)</sup>.

Despite the recommendations, studies show that it is difficult to maintain thermal control of newborn babies after birth<sup>(3-5)</sup>. Therefore, the development of tools to minimize this risk in care are indicated.

Among the various tools, bundles stand out because they are low-cost tools based on scientific evidence, which group together actions that, when carried out as a group, improve care and guarantee patient safety. Bundles highlight essential care to prevent certain health care problems and must be utilized associated with ongoing training and constant vigilance to ensure adherence to care<sup>(6)</sup>.

In view of the above, the aim of this study was to describe the process of building and validating a bundle to promote body temperature regulation in newborns over 34 weeks of age.

# METHODS

This is a methodological study, which was developed in three stages: a scoping review, construction of the first version of the bundle, and content validation by experts, guided by the Standards for Quality Improvement Reporting Excellence (SQUIRE) framework of the Enhancing the Quality and Transparency of Health Research (EQUATOR) network<sup>(7)</sup>.

In the first stage, for the scoping review, we followed the recommendations of the Joanna Briggs Institute, Reviewers Manual<sup>(8)</sup> and the protocol of the Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) Checklist<sup>(9)</sup>. Searches were carried out in the Medical Literature Analysis and Retrieval System Online (MEDLINE) databases, using the search engine of the National Library of Medicine of the National Institutes of Health (PubMed) of the United States of America, in the Latin American and Caribbean Health Sciences Literature (LILACS) through the Virtual Health Library (Portuguese acronym: BVS), in the Web of Science and in the Cochrane Library, including a manual search for references of the studies identified. Primary and secondary research on the subject were selected, published from 2014 onwards and excluding expert opinions and letters to the editor.

The PCP framework, in which P (participants) = newborns, C (concept) = temperature maintenance, and C (context) = birth, was used to formulate the review question: What care is essential to maintain the temperature of newborns over 34 weeks of age, with good vitality at birth, from birth to transportation to the rooming-in unit?

The searches were carried out in April 2021 and updated in January 2023, using controlled descriptors from the Medical Subject Headings (MeSH) "Infant, newborn", "Body Temperature Regulation", "Temperature", "Hypothermia" and, using the Health Sciences Descriptors (DeCS) "Recém-nascido premature", "Regulação da temperature corporal", "Temperatura", "Hipotermia". The used strategy on MED-LINE/PubMed was: ((("Infant, Newborn" [Mesh] OR (Infants, Newborn) OR (Newborn Infant) OR (Newborn Infants) OR (Newborns) OR (Newborn) OR (Neonate) Neonates) AND ("Body Temperature Regulation" [Mesh] OR (Thermoregulation) OR (Thermoregulations) OR (Regulation, Body Temperature) OR (Body Temperature Regulations) OR (Regulations, Body Temperature) OR (Temperature Regulations, Body) OR (Temperature Regulation, Body) OR (Heat Loss) OR (Heat Losses) OR (Loss, Heat) OR (Losses, Heat))) AND ("Temperature" [Mesh] OR (Temperatures)) AND ("Hypothermia" [Mesh] OR (Hypothermias) OR (Hypothermia, Accidental) OR (Accidental Hypothermia) OR (Accidental Hypothermias) OR (Hypothermias, Accidental)).

The descriptors and their synonyms were checked in the dictionaries of each database, and if there was any divergence, the terms were modified to meet the specific requirements. The Rayyan<sup>®</sup> (version 2016, Qatar Foundation, Qatar) software was used to remove duplicates and screen titles and abstracts. The entire search, screening and extraction process was carried out independently by two researchers (Figure 1). Disagreements were examined by a third researcher.

Data from the articles eligible to be read in full were extracted into an Excel<sup>®</sup> spreadsheet (version 365, 2017, Microsoft Corporation, United States of America) including: author, year, title, journal, type of study, level of evidence, and recommended care. The level of evidence was based on the type of study, considering I for systematic reviews and meta-analysis of randomized clinical trials; II for randomized clinical trials; III for non-randomized controlled trials; IV for case-control or cohort studies; V for systematic reviews of qualitative or descriptive studies; VI for qualitative or descriptive studies, and VII for opinions from authorities and/or expert committee reports. This classification ranks levels

#### Identification of studies in databases Studies identified (n= 602) in: Identification PubMed/Medline\* (n =349) Duplicated studies Embase (n = 87) $BVS/LILACS^{\dagger}$ (n = 51) removed (n = 216)Web of Science (n = 1)Cochrane Library (114) Excluded studies (n = 302): Selected studies: Did not approach the review (n = 386)theme/subject Screening Studies searched for Unretrieved studies: retrieval: (n = 84)(n = 0)Studies evaluated for Excluded studies (n = 23). eligibility: (n = 40)Did not approach the review theme/subject Studies included in the review: (n = 17)Inclus

Note: Prepared according to the model recommended by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for scoping reviews (PRISMA-ScR). \*US National Library of Medicine National Institutes of Health (PubMed)/Literature Analysis and Retrieval System Online (MEDLINE); 'Virtual Health Library (Portuguese acronym: BVS)/Latin American and Caribbean Health Sciences Literature (LILACS)

I and II as strong, III to V as moderate and VI to VII as weak $^{(10)}$ .

The first version of the bundle was inserted into Google Forms<sup>®</sup>, in HyperText Markup Language standard, for later evaluation by the experts. The first part of the form included professional identification data: training, highest degree, place and unit of work and the second part included the care listed to make up the bundle. This care was assessed using a Likert scale with five attributes in terms of agreement with the representativeness/pertinence of the item: totally disagree, partially disagree, partially agree, agree, and totally agree. A blank field after each item was indicated for suggestions and changes.

The experts were selected based on the résumés of research nurses and physicians in the areas of obstetrics and/or neonatology, available on the Lattes Platform of the National Council for Scientific and Technological Development (Portuguese acronym: CNPq). For the screening, the "professional activity" filter was activated to select the major area, specific area, and sub-area. Those who obtained a minimum of five points from the criteria evaluated were selected non-probabilistically: a master's degree (four points); a master's degree with a dissertation in the areas of obstetrics and/or neonatology (one point); a doctoral thesis in the areas of obstetrics and/or neonatology (two points); at least

Figure 1 - Flowchart for selecting the identified studies, 2023

one year of experience in the areas of obstetrics and/ or neonatology (one point); specialization in obstetrics and/or neonatology (two points) and published studies in the areas of obstetrics and/or neonatology with relevance to this study (two points)<sup>(11)</sup>. Following these criteria, potential evaluators were contacted from September/2021 to November/2021 via e-mail, totaling 25 professionals (nurses and physicians). Of these, 15 agreed to participate in the first round (nine nurses and six physicians).

The body of the e-mail sent to the evaluators contained the objectives of the study, the informed consent form and the link to access the form. It should be noted that when access to the evaluation form was released, the participant had to click on the "agree to participate in the study" icon.

The records of the experts' responses in Google Forms<sup>®</sup> were exported to an Excel<sup>®</sup> spreadsheet and after the suggestions were added, the material was organized into a new electronic form for the second round. The Content Validity Index (CVI) was used to analyze the agreement between the experts, in which the calculation is the sum of the answers "agree; partially agree, and totally agree" divided by the total number of answers. For the inclusion of care, indices above 0.80 were adopted as the cut-off point<sup>(12)</sup>. The suggestions provided by the experts were incorporated and a second round of

evaluation was carried out to verify the new inclusions, following the precepts of the Delphi technique. In the second round, which took place between November and December 2021, all 15 initial experts were invited and, of these, 14 responded to the invitation and evaluated the second version of the bundle.

This study complied with the precepts established in Resolution No. 466/2012 (BR) and its complementary norms. It was approved by the Research Ethics Committee linked to the Brazil Platform, with Certificate of Submission for Ethical Appraisal No. 40339620.8.0000.866.

# RESULTS

The scoping review included 17 studies on care to promote the maintenance of the temperature of newborns older than 34 weeks, with good vitality at birth, from birth until their transfer to rooming-in. Of these, six studies were randomized clinical trials that resulted in evidence for strongly recommended care, such as skin-to-skin contact, controlling the temperature of the environment, preheating fabrics and equipment that would come into contact with the newborn, breastfeeding, drying the skin, wearing a cotton cap, and postponing routine procedures and the first bath (Chart 1)<sup>(13-29)</sup>.

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Author	Title/Journal	Type of study/ Level of evidence	Recommended care
Lunze et al. <sup>(13)</sup>	Prevention and management of neonatal hypothermia in rural Zambia/PLoS One	Qualitative study/ VI	- Skin-to-skin contact at birth. - Use appropriate, low-cost newborn warmers. - Postpone the first bath for 24 hours.
Nimbalkar et al. <sup>(14)</sup>	Effect of early skin-to-skin contact following normal delivery on incidence of hypothermia in neonates more than 1800 g: randomized control trial/J Perinatol	Randomized clinical trial/II	- Early skin-to-skin contact for 24 hours after birth.
Srivastava et al. <sup>(15)</sup>	Effect of very early skin to skin contact on success at breastfeeding and preventing early hypothermia in neonates/Indian J Public Health	Randomized clinical trial/II	- Skin-to-skin contact at birth. - Skin-to-skin contact during transportation. - Skin-to-skin contact in the rooming-in unit.
George et al. <sup>(16)</sup>	A pragmatic descriptive study of rewarming the newborn after the first bath/J Obstet Gynecol Neonatal Nurs	Randomized clinical trial/II	- Skin-to-skin contact to rewarm the newborn after the first bath.
Perlman and Kjaer <sup>(17)</sup>	Neonatal and maternal temperature regulation during and after delivery/ Anesth Analg	Narrative review/V	<ul> <li>Implement strategies to mitigate maternal hypothermia, including controlling the temperature (21 to 26°C) of the delivery room and monitoring maternal temperature.</li> </ul>

Continue...

#### Chart 1 - Continuation

Author	Title/Journal	Type of study/ Level of evidence	Recommended care
Duryea et al. <sup>(18)</sup>	The impact of ambient operating room temperature on neonatal and maternal hypothermia and associated morbidities: a randomized controlled trial/Am J Obstet Gynecol	Randomized clinical trial/II	- Control the temperature of the delivery room at 23°C, as temperatures below 20°C increase the rate of neonatal and maternal hypothermia.
Cleveland et al. <sup>(19)</sup>	Systematic review of skin-to-skin care for full-term, healthy newborns/J Obstet Gynecol Neonatal Nurs	Literature review/V	- Skin-to-skin contact for all healthy full-term newborns at birth and in the rooming-in unit.
Sharma et al. <sup>(20)</sup>	Golden 60 minutes of newborn's life: part 2: term neonate/J Matern Fetal Neonatal Med	Literature review/V	<ul> <li>Raise the temperature of the delivery room (26-28°C).</li> <li>Use radiant heaters, pre-warmed drapes and sheets in the delivery room.</li> <li>Perform early skin-to-skin contact or kangaroo care.</li> <li>Use polyethylene bags.</li> </ul>
Ramani et al. <sup>(21)</sup>	Kangaroo mother care for the prevention of neonatal hypothermia: a randomised controlled trial in term neonates/Arch Dis Child	Randomized clinical trial/II	- Skin-to-skin contact for at least 80% of the time or for at least 9 hours during the day of birth.
Ruschel et al. <sup>(22)</sup>	Hipotermia e banho do recém-nascido nas primeiras horas de vida/Rev Gaúcha Enferm	Observational study/VI	- Postpone the first bath.
Trevisanuto et al. <sup>(23)</sup>	Maintaining normothermia: why and how?/Semin Fetal Neonatal Med	Narrative review/V	<ul> <li>Maintain the temperature of newborns between 36.5 and 37.5°C, from birth to rooming-in.</li> <li>Keep the room temperature between 23 and 25°C.</li> <li>Use radiant heaters, thermal mattresses, wool or plastic caps, plastic wraps, and heated humidified gases.</li> <li>Skin-to-skin contact in the delivery room.</li> <li>Combinations of these interventions applied to initiatives to improve the quality of care, including ongoing staff education, the use of checklists and continuous feedback with the team involved in newborn care.</li> </ul>
Gözen et al. <sup>(24)</sup>	First bathing time of newborn infants after birth: a comparative analysis/J Spec Pediatr Nurs	Observational study/VI	- Postpone newborns' first bath until 48 hours after birth.
Lima et al. <sup>(25)</sup>	Nursing intervention-first bath of the NB: a randomized study on neonatal behavior neonatal/Acta Paul Enferm	Randomized clinical trial/II	- Monitor the temperature of the water and the newborn during the first bath (38°C) as well as the temperature of the environment, which should not be below 26°C.
Kardum et al. <sup>(26)*</sup>	Duration of skin-to-skin care and rectal temperatures in late preterm and term infants/BMC Pregnancy and Childbirth	Retrospective review of medical records/V	- Skin-to-skin contact at birth - Skin-to-skin contact in rooming-in.
Wood et al. <sup>(27)*</sup>	Thermoneutral environment for neonates: back to the basics/Neonatal Netw	Narrative review/V	- Maintain a thermo-neutral environment.
Dubos et al. <sup>(28)*</sup>	The newborn infant's thermal environment in the delivery room when skin-to-skin care has to be interrupted/J Matern Fetal Neonatal Med	Observational study/VI	- Maintain a thermo-neutral environment - Skin-to-skin contact at birth - Skin-to-skin contact in rooming-in.
Priyadarshi et al. <sup>(29)*</sup>	Timing of first bath in term healthy newborns: a systematic review/J Glob Health	Systematic review/l	- Postpone the first shower for at least 24 hours.

Note: \*These studies were included in the update of the review, but were not used for the construction of the bundle, since the form was sent to the experts at the end of 2021. It should be noted that no new actions have emerged to promote temperature regulation in the extended period.

The identification of these studies made it possible to list precautions for the construction of the first version of the bundle, with 15 items, divided into three stages: delivery room, transportation, and rooming-in, with five items each. In addition, current national and international guidelines on the subject were consulted and considered<sup>(30,31)</sup>.

Fifteen experts participated in the first round of content validation, nine of whom held a master's degree and five a doctorate, aged between 26 and 50 years old (mean = 37.4), 81% were female, 93% worked in federal educational institutions, and 44.0% worked in neonatal intensive care units. The five experts with a doctorate obtained the maximum score for the criteria established (12 points) and among those with only a master's degree, the average was 10 points.

The first version of the bundle and the experts' evaluation is shown in Table 1.

In the first round, all the items were evaluated with indices higher than 0.80, with suggestions for adjustments that were accepted. The first moment, the delivery room, contained five items. They were reworded to detail the care and a new item was added in line with the experts' recommendation "Take maternal temperature and ensure that it is >36.2°C before referral to the delivery room and >36°C after birth". At the second moment, transportation, two items were grouped together for better intelligibility: "Keep the newborn in warm spaces" and "Maintain skin-to-skin contact with the mother". In the third moment, rooming-in, the number of items was maintained, but in item 15, about bathing, additional information was added about thermal control in this procedure (Chart 2).

After making the changes suggested by the experts, the bundle was submitted to a second round of evaluation, in which only one of the nurse experts did not answer, totaling 14 experts, and with no new suggestions (Table 2).

## DISCUSSION

The bundle developed and validated in this study considered three moments to list care for maintaining

Table 1 - Content validation	on of the bundle to	promote temperature	maintenance in ne	wborns older than	34 weeks, with good
vitality at birth, according	to the moment of (	care, round 1, 2022			

Bundle content according to the moments of newborn care (Round 1)	CVI*
Delivery room	
1. Neutral thermal environment, at least 26°C	0.93
2. Receive and dry the NB in preheated fields.	0.94
3. Wear double cotton caps.	0.86
4. Ensure skin-to-skin contact with the mother immediately after delivery.	0.93
5. Avoid procedures that are not considered immediate.	0.98
Partial CVI* for the bundle of care to be developed in the delivery room	0.92
Transportation	
6. Only start transportation if the temperature is > $36^{\circ}$ C.	0.89
7. Keep in warm fields.	0.98
8. Maintain skin-to-skin contact with the mother.	0.85
9. Watch for signs of physiological or clinical deterioration	0.98
10. Take axillary temperature every 30 minutes.	0.82
Partial CVI* for the care bundle to be developed when transporting the newborn to the rooming-in unit	0.90
Rooming-in unit	
11. Maintain body temperature between 36.5-37°C.	0.97
12. Stay together after giving birth in a rooming-in system and encourage skin-to-skin contact.	0.98
13. Dress the newborn in temperature-appropriate clothing.	1.0
14. Avoid bathing for the first 24 hours.	0.94
15. Baths lasting a maximum of 10 minutes.	1.0
Partial CVI* for the care bundle to be developed when transporting the newborn to the rooming-in unit	0.97
Overall CVI*	0.94

Note: \*CVI: Content Validity Index.

Chart i	2 - Suggestio	ns from the expe	erts according to the	moments in the t	oundle, the resea	arch team's decisio	ons, and the app	0-
priate	reasons							

Suggestions	Decision and reason
1st moment	
"1 - Keep the environment thermally neutral, with room temperature control at a minimum of 26°C, 3 - Use caps - replace with wear caps, 4 - Promote contact on the mother's chest for at least 30 minutes, 5 - Describe - weighing, Konakion"	Agreed. Improves the clarity of the text.
"Add mother's temperature assessment"	Agreed. Improves the clarity of the text.
"Correct the terms and specify the procedures according to the cutoff greater than or equal to 34 weeks and less than 34 weeks. They are very different!"	Accepted. It was identified in the title that the bundle is for newborns older than 34 weeks, with good vitality at birth.
"Make it clear whether the delivery room in question is for term or pre-term babies; in the double cotton cap field, in my assistance/experience, we put on a plastic cap with the cotton cap."	Accepted. Plastic not included as it is recommended for those over 34 weeks.
"Skin-to-skin contact if there is clinical stability"	Accepted. It was identified in the title that the bundle is for newborns over 34 weeks of age, with good vitality at birth, so they can make skin-to-skin contact.
2nd moment	
"1 - Add - temperature taken in the armpit, 2 - Clinical signs (add), 3 - Until transport?"; "Maybe keep skin-to-skin contact with the mother or in heated fields. And indicate where they would be transported, for example, the mother on a stretcher. If they cannot be transported together, suggest a common crib? Incubator? Think about it later."	Agreed. Improves the clarity of the text.
"Adapt items. For example, in an asphyxiated newborn who will be starting a therapeutic hypothermia protocol, the temperature should be taken every 15 minutes."	Agreed. Improves the clarity of the text.
"I suggest making it clear where the baby is being transported to and the baby's health condition."	Agreed. Improves the clarity of the text.
3rd moment	
"1 - How do you keep it? Room temperature?, 4 - remove - bathe after at least 6 hours, depending on temperature, Add: The temperature should be measured before the bath, if the temperature is less than 36°C, check the conditions, warm the baby up, and evaluate after 30 minutes. If the temperature remains below 36°C, do not bathe the baby and ask the pediatrician for an assessment. Measure the water temperature before starting the bath with a thermometer or the back of your forearm. 5 - Add: close windows and doors during bathing and separate all materials before bathing, including clothes, to optimize time."	Agreed. Improves the clarity of the text.
"Maybe just encourage skin-to-skin contact and have them stay in a rooming-in system."	Agreed. Improves the clarity of the text.

the temperature of newborns over 34 weeks: delivery room, transportation and rooming-in.

In the delivery room, the first item refers to the implementation of care to maintain maternal temperature > 36.2°C. Although the uterine environment is thermoneutral, sudden changes can be related to hypothermia in the newborn. Maternal temperature can reduce the risk of hypothermia in newborns by around 40%<sup>(5)</sup>. In this sense, it is recommended to measure the temperature at 15-minute intervals and warm up with specific devices, especially during induction of anesthesia and cesarean delivery<sup>(1)</sup>.

The neutrality of the thermal environment is essential to avoid temperature imbalances in the mother-baby binomial. The entire childbirth care team should be made aware of this issue, in order to keep the delivery room at around 26°C and avoid air circulation through people coming in and out<sup>(32)</sup>. Tolerating higher temperatures is difficult for the team, which is why they should invest in protocols, bundles, and training programs<sup>(33)</sup>.

Drying off and putting on a double cotton cap prevents temperature loss through evaporation. The moisture present in the skin can lead to an abrupt loss of temperature. Due to the inability to generate an adequate response to the cold, such as shivering, this loss can reach 0.3°C per minute, around 1°C to 3°C before leaving the delivery room<sup>(34)</sup>. 

 Table 2 - Content validation of the bundle to promote temperature maintenance in newborns older than 34 weeks, with good vitality at birth, according to the moment of care, round 2, 2022

Bundle content according to the moments of newborn care (Round 2)	CVI*
Delivery room	
1. Take maternal temperature and ensure that it is > 36.2°C before referral to the delivery room and > 36°C after birth.	0.98
2. Maintain a thermally neutral environment, with temperature control between 23°C and 26°C, keep doors closed, and control the movement of people to minimize draughts.	0.90
3. Receive and dry the newborn in preheated drapes.	0.98
4. Put double cotton caps on the newborn.	0.94
5. Promote skin-to-skin contact on the mother's chest in the first hour of the newborn's life for at least 30 minutes.	1.00
6. Avoid procedures that are not considered immediate (application of vitamin K, anthropometry, bathing, complete physical examination, weighing, prevention of ophthalmia, vaccinations).	0.98
Partial CVI* for the bundle of care to be developed in the delivery room	0.96
Transportation	
7. Only start transportation if the newborn has an axillary temperature above 36.5 $^\circ$ C.	0.92
8. Keep the newborn in skin-to-skin contact with the mother on a stretcher during transportation; if this is not possible, keep the newborn in warm drapes in a common crib.	0.95
9. Be alert to signs of physiological or clinical deterioration in the newborn.	0.97
10. Take the newborn's axillary temperature every 30 minutes or continuously with a sensor.	0.94
Partial CVI* for the bundle of care to be developed when transporting the newborn to the rooming-in unit	0.94
Rooming-in unit	
11. Maintain the newborn's body temperature between 36.5°C and 37°C.	0.98
12. Encourage skin-to-skin contact.	1.0
13. Dress the newborn in temperature-appropriate clothing.	1.0
14. Avoid bathing for the first 24 hours.	0.98
15. Bathe for a maximum of 10 minutes, only if the newborn's axillary temperature is above 36.5°C, avoid draughts by closing doors and windows, leave material prepared to optimize time and measure the water temperature with a clinical thermometer (36°C to 37°C) or with the inside of the forearm.	1.0
Partial CVI* for the bundle of care to be developed when transporting the newborn to the rooming-in unit	0.99
Overall CVI*	0.97

Note: \*CVI: Content Validity Index.

Skin-to-skin contact should be encouraged and stimulated early on in order to maintain temperature and reduce the risk of hypothermia. Stable newborns over 34 weeks placed in immediate and uninterrupted skin-to-skin contact have better thermal control. This care is considered a low-cost technology for maintaining temperature, which can save newborns in countries where technological resources are scarce<sup>(26,35)</sup>. The immediate benefits of skin-to-skin contact have been proven to help regulate and maintain body temperature and, in premature infants, improve cardiorespiratory stability, while also improving breastfeeding rates in the first days of the child's life<sup>(36,37)</sup>. It can promote normothermia in newborns with good vitality, even when the ambient temperature is below the recommended level<sup>(26)</sup>. The prevalence of newborns being placed in skin-to-skin contact is variable, and can be influenced by factors such as the presence of a companion, type of delivery and prematurity and/or neonatal complications<sup>(26,36)</sup>.

Procedures considered routine, included in the sixth item of this study's bundle, should be postponed to avoid handling the newborn and interrupting skin-toskin contact and breastfeeding. The initial assessment should be carried out with the newborn on the mother's chest/abdomen, and only if necessary should the newborn be transferred to a heated crib. Ensuring this moment, as well as contributing to thermal control, improves breastfeeding rates and helps to build the bond between the mother-baby binomial<sup>(38)</sup>. After the first hour of uninterrupted skin-to-skin contact, these procedures should be carried out with the newborn on the mother's or father's lap, to maintain temperature, relieve pain, and reduce tactile stimulation<sup>(36)</sup>.

During transportation, the second stage of the bundle, skin-to-skin contact must be ensured, with careful assessment of signs of clinical deterioration.

In rooming-in, temperature control consists of keeping the newborn in skin-to-skin contact or warmed by clothing<sup>(38)</sup>. The longer the newborn stays in skin-toskin contact, the better their temperature control will be by the time they are discharged. It should be noted that hypothermia was not identified in newborns who were in skin-to-skin contact for more than nine hours or 80% of their stay in the rooming-in unit<sup>(21)</sup>.

Bathing, when carried out before the first 24 hours of life, interrupts the newborn's adaptive process, causing insensitive temperature losses. A study evaluating the occurrence of hypothermia during the bathing of 149 newborns found that the majority received their first bath between one and two hours of life and accounted for 91.7% of the 60 cases of hypothermia identified<sup>(22)</sup>. Delaying baths to between 24 and 48 hours has been shown to be effective in preserving body temperature and is considered a positive way of avoiding hypothermia<sup>(24)</sup>.

Bundles have the potential to reduce health problems and have been effective in various health contexts, as long as they are clear, objective, undergo a validation process, and are carefully evaluated<sup>(39,40)</sup>.

The care that makes up this bundle has been recommended by the literature, by current national and international guidelines on childbirth care and the humanization of this context, and validated by experts. They should be encouraged in order to improve practices related to maintaining the temperature of newborns over 34 weeks of age, with good vitality, with a view to providing safe, quality care.

For its contribution to be effective, continuing education processes for professionals and research to verify its feasibility in each care setting will be necessary.

Although the study carefully searched the literature on the subject, considered the reference guidelines in the area and sought the opinion of experts, the number of participants is considered a limitation of this investigation, although the minimum contingent for studies of this nature was reached.

# CONCLUSION

The bundle for promoting body temperature regulation in newborns over 34 weeks of age is valid in terms of its content, as assessed by physicians and nurses who are experts in the field, backed up by the literature and guidelines from national and international reference institutions. Its organization covers 15 items divided into three moments in which birth care takes place, and specific care to be implemented by the multi-professional team, at birth, in transportation, and in rooming-in, and thermal stabilization during adaptation to extrauterine life.

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#### CONFLICT OF INTERESTS

None.

#### AUTHORS' CONTRIBUTIONS - CRediT

**ACAG:** conceptualization; data curation; formal analysis; investigation; methodology; validation; visualization; writing – original draft; writing – review & editing.

**MPCS:** conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization; writing – original draft; writing – review & editing.

**FVU:** conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization; writing – original draft; writing – review & editing.

**LVR:** conceptualization; investigation; methodology; validation; visualization; writing – original draft; writing – review & editing.

**MTR:** conceptualization; data curation; formal analysis; investigation; methodology; validation; visualization; writing – original draft; writing – review & editing.

**DC:** conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization; writing – original draft; writing – review & editing.

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