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IMPLEMENTATION RESEARCH

Interdisciplinary clinical protocol of therapeutic hypothermia for newborns withasphyxia: implementation research*

Protocolo clínico interdisciplinar de hipotermia terapêutica para recém-nascidos com asfixia: pesquisa de implementação

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ABSTRACT

Objective: To describe the process of implementing an interdisciplinary protocol for the management of therapeutic hypothermia. **Method:** Implementation research with a participatory approach, which used the Consolidated Reference Framework for Implementation Science for the elaboration and implementation of the protocol, carried out in the Neonatal Intensive Care Unit of a university hospital in southeastern Brazil, with the participation of the interprofessional team and managers. **Results:** The first protocol for therapeutic hypothermia was developed and implemented in the institution. Training was carried out that improved the team knowledge. Flowcharts and infographics were designed to direct interprofessional work in this process and translate knowledge to the user population. **Conclusion:** The interdisciplinary protocol for the management of therapeutic hypothermia was built in a participatory way by the team. The training in cycles involving the different professionals brought great interaction between them and engagement to achieve improvements, with exchange of experiences and increased knowledge about therapeutic hypothermia.

Descriptors: Clinical protocols; Induced Hypothermia; Implementation Science; Asphyxia; Newborn; Neonatal Nursing.

RESUMO

Objetivo: Descrever o processo de implantação de protocolo interdisciplinar para manejo da hipotermia terapêutica. **Método:** Pesquisa de implementação com abordagem participativa, que utilizou o Marco de Referência Consolidado para a Ciência da Implementação para elaboração e implementação do protocolo, realizada na Unidade de Terapia Intensiva Neonatal de um hospital universitário, no sudeste do Brasil, com a participação da equipe interprofissional e gestores. **Resultados:** Foi elaborado e implantado o primeiro protocolo para hipotermia terapêutica na instituição. Foram realizados treinamentos que melhoraram o conhecimento da equipe. Fluxogramas e infográficos foram elaborados para direcionar o trabalho interprofissional nesse processo e transladar o conhecimento para a população usuária. **Conclusão:** O protocolo interdisciplinar para manejo da hipotermia terapêutica foi construído participativamente pela equipe. As capacitações em ciclos envolvendo os diferentes profissionais trouxeram grande interação entre eles e engajamento para obtenção de melhorias, com troca de experiências e aumento de conhecimento sobre hipotermia terapêutica.

Descritores: Protocolos Clínicos; Hipotermia Induzida; Ciência da Implementação; Asfixia; Recém-Nascido; Enfermagem Neonatal.

INTRODUCTION

Perinatal asphyxia is a serious global public health problem, being the third leading cause of death in children under five years of age, preceded only by prematurity and congenital malformations. Each year, around 1 million newborns die of perinatal asphyxia worldwide, which means 30 to 35% of neonatal deaths[1-2] .

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Hypoxic-ischemic encephalopathy is a serious consequence of perinatal asphyxia. Neurological alterations and their evolution depend on the duration of the hypoxic-ischemic incident, which may occur before, during or after delivery[3-4]. This clinical condition causes brain inflammation and immunosuppression, and can be classified, by means of scale, in three stages: mild, moderate and severe[5].

Currently, the application of therapeutic hypothermia is the only form of treatment used in ischemic hypoxic encephalopathy. The effectiveness in preventing brain injury and improving the neurological outcome occurs the sooner therapeutic hypothermia is initiated, in an orderly manner in the first six hours of life [6-7]. This therapeutic technique aims to cool the newborn at an ideal body temperature of 33.5ºC for a period of 72 hours, and has as its role neuroprotection, with interruption or reduction of the process of brain injury[2,8-9].

Therapeutic hypothermia is a complex process that triggers effects on the circulatory, cardiovascular, urinary, immune and gastrointestinal systems of the newborn. An interdisciplinary team capable of maintaining constant surveillance of the newborn submitted to therapeutic hypothermia is necessary; performing care uninterrupted, safe and individualized, according to the clinical complexity of the newborn[3-5,9-10].

The use of systematic clinical protocols applied by a team of qualified health professionals with continuous audit can generate a significant change in the life of newborns with perinatal asphyxia[11-12].

Although there are national and international protocols[5,13-18] for therapeutic hypothermia, the research scenario hospital has not yet implemented an evidence-based protocol. In view of the above, the implementation of a protocol adapted to the needs of the institution aims to promote the integration between the team, the organization of the work process and contribute to patient safety and sustained improvement of the quality of care. Thus, this study aims to describe the implementation process of the interdisciplinary protocol for the management of therapeutic hypothermia.

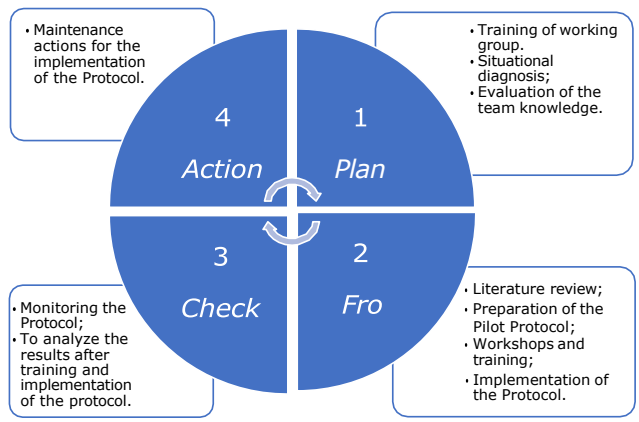
METHOD

Implementation research with a participatory approach, which used the "Consolidated Reference *Framework for Implementation Science" - Consolidated Framework for Implementation* Research (CFIR), version 2009, as a guide to the elaboration and implementation of the protocol, the following CFIR domains were used: characteristics of the intervention, characteristics of the individuals, internal scenario and implementation process (http://www.CFIRguide.org/constructs.html).

The study was conducted at the Neonatal Intensive Care Unit (NICU) of the Cassiano Antonio Morais University Hospital belonging to Empresa Brasileira de Serviços Hospitalares (EBSERH), located in Espirito Santo, Brazil.

The interprofessional team composed of doctors, nurses, nursing technicians, physiotherapists, speech therapists, occupational therapist, social worker and psychologist, responsible for the assistance of asphyxiated newborns submitted to therapeutic hypothermia. Professionals who were, for any reason, away from the assistance during the research period were excluded. The research followed four steps using the PDCA cycle, as shown in Figure 1.

Figure 1 - PDCA cycle and stages of the design and implementation of the interdisciplinary protocol of therapeutic hypothermia. Vitoria, ES, Brazil, 2024



A Working Group was responsible for the elaboration, training of the team and implementation of the protocol. This Group was composed of NICU professionals who hold leadership positions, routine doctors, day and night shift nursing professionals, physiotherapists, psychologist and social worker. As inclusion criteria, professionals should have more than five years of experience in NICU and post-graduation in neonatology.

In the "Plan" stage, the situational diagnosis was made with data from newborns with asphyxia, hospitalized at the NICU from January

2018 to December 2022. For this stage, an instrument was developed by the researchers with the data: inclusion criteria for treatment, intercurrences during the hospitalization period, sex, births with perinatal asphyxia, and newborns from other institutions admitted for treatment with therapeutic hypothermia. The researchers collected the data in the electronic medical record in November and December 2022.

Then, an online questionnaire was prepared by the research team on the *Google* Forms platform, containing 26 questions to evaluate the team's knowledge about hypoxic-ischemic encephalopathy and treatment with therapeutic hypothermia. The questionnaire was validated by the Working Group. The questionnaire was available for 30 days to complete.

In the "Execute/do" stage, a search was carried out in the literature recovering national and international guidelines and recommendations on therapeutic hypothermia. Documents from the Ministry of Health, the Brazilian Society of Pediatrics, recommendations from the Portal of Good Practices of the Fernandes Figueira National Institute / Oswaldo Cruz Foundation (Fiocruz) were identified;Protocol of *Protecting Brains & Saving Futures ,*and in the nursing guidelines of *The Royal Children's Hospital* Melbourne[5,13-18]. From these documents, the best practices based on evidence were selected and the main researcher organized the first version of the pilot protocol to be adapted to local reality.

Three meetings with the Working Group were held in January 2023 to prepare the protocol. At the first meeting, the research objectives, the situational diagnosis and the first version of the protocol were presented. In the second and third meetings, each of the protocol's topics were analyzed, the alignment of care, adaptations of acti0vities to the local reality and the pilot protocol was finalized, as recommended in the items of the CFIR domains: characteristics of the intervention, characteristics of the individuals and internal scenario. The meetings lasted about 90 minutes and were coordinated by the main researcher, with the help of another researcher, both nurses specialized in neonatology with experience in group coordination.

The protocol structure followed the standardization of the quality sector of the hospital research institution. After the conclusion of the protocol by the Working Group, the training and application workshops of the protocol were held. To reach the highest number of professionals in the different scales of duty, 14 workshops were held. The training and application workshops took place in the months of January and February 2023, lasting 90 to 120 minutes. The main data of the workshops were recorded in a field diary by the researchers.

During the workshops the professionals had the opportunity to make suggestions and criticisms of the protocol. At the end of the workshops, the Working Group made the adjustments to the protocol according to the suggestions of the professionals, and the protocol was implemented in the unit in March 2023.

In the "Check" step, after protocol implementation, in July 2023 the online questionnaire was applied again by *Google* Forms. The purpo- se of the questionnaire was to evaluate if there was an increase in the team knowledge after the workshops. A semi-structured questionnaire was also applied to identify barriers and facilitators in the protocol implementation process. The questionnaire was structured based on the CFIR[19] and the domains were used: characteristics of the intervention, characteristics of the individuals, internal scenario and implementation process.

Based on the responses of health professionals about barriers and facilitators in the protocol implementation process, and based on the questionnaire on team knowledge, the Working Group discussed the results and decided on maintenance, alteration or adaptation in the protocol. After the adjustments, the protocol was sent to the quality sector, for approval and routine use in the sector.

In the "Acting Correctively/Action" stage, for the sustainability of the result, it was proposed to carry out periodic update of the protocol and maintenance of training workshops as simulation activities and permanent education.

Quantitative data were analyzed by descriptive statistics.

The project was approved by the Research Ethics Committee. The participants were informed about the study and, after reading, signed the Free and Informed Consent Form. In order to ensure greater reliability, validity and quality in the elaboration of the research, this study used as a support tool the *Revised Standards for Quality Improvement Reporting* Excellence (SQUIRE 2.0).

RESULTS

The situational diagnosis delineated the profile of newborns, describing perinatal characteris-

tics, clinical complications during therapeutic hypothermia and outcomes.

From 2018 to 2022, 14 newborns were admitted to the treatment of therapeutic hypothermia, 57.14% male and 64.29% was born through vaginal delivery. All newborns were resuscitated with positive pressure ventilation, and 92.5% evolved to orotracheal intubation; 50% needed chest compression; and 42.85% used drugs as adrenaline in resuscitation. Most newborns (71.43%) had gestational age between 38 and 40.6 weeks. There was no difference in the diagnosis of moderate or severe encephalopathy, with 50% each type. The mean birth weight was 3,197g (2,206g – 4760g). The apgar fashion of newborns submitted to therapeutic hypothermia was 0, 4 and 4, in the 1st, 5th and 10th minute. The hospitalization period had an average of 27 days (16 to 100 days).

As for the main clinical complications, 100% had dystermia with temperatures outside the target, and 87.71% had convulsion; and 28.57% had renal failure.

In the knowledge evaluation before training workshops, 88 professionals answered the online questionnaire, 31% nurses, 27.6% nursing technicians, 20.7% doctors, 12.6% physiotherapists, 2.3% speech therapists and 1.1% psychologists, social workers, nutritionists, occupational therapists and neonatal residents. While, in the second knowledge evaluation after the workshops, 46 professionals answered, being 34.8% nursing technicians, 28.3% nurses, 15.2% physiotherapists, 13% physicians, 4.3% speech therapists, and 2.2% psychologists and social workers.

In the first evaluation, 97.7% were able to respond about the indication of therapeutic hypothermia stating when there are clinical conditions of moderate or severe ischemic hypoxic encephalopathy and 65.1% said they knew the criteria and 34.9% did not know. However, when asked to mention the criteria, 45% cited, but incomplete; 40% did not know how to respond and 14% responded inappropriately.

In the second evaluation, 97.8% responded correctly after training. Regarding the inclusion criteria 95.7% answered what they were, and when asked to mention the criteria, 41.3% knew how to cite correctly, 58.8% cited inadequate criteria and 4.3% reported not knowing how to answer the question. In general, there was an improvement in the knowledge of the professionals.

In the institution under study, the technique used for therapeutic hypothermia is the passive form, in the training the team was trained to do the cooling and reheating using low cost material, such as reusable/flexible ice plates, cold compresses and use of room temperature. Regarding the question of available resources, there was an increase of 55% to 73.9% got correct and complete answers.

On how cooling is performed at the institution, in the first evaluation 53.4% described the procedure, and the materials as ice bags or cold compresses; while in the second evaluation 80.4% responded correctly.

About the time to start therapeutic hypothermia after birth there was an increase in correct responses from 72.4% to 84.8%. Regarding the period that the newborn is subjected to cooling, there was an increase in correct responses from 83.7% to 91.3% after the workshops.

On how the reheating is performed, in the first evaluation 51.65% got it correctly and in the second evaluation increased to 82.6%.

As for temperature monitoring, before training 13.64% reported the material used and should maintain the target temperature. After training, 30.4% described the procedures for monitoring.

Regarding the complications, in the first evaluation compared to the second post-workshop, there was improvement in the responses. The professionals were able to cite bradycardia (88.5% to 93.5%); active bleeding (32.2% to 41.3%) and oliguria (34.5% to 39.1%).

Regarding the need of the team to clarify the family about therapeutic hypothermia, 89.1% said they could explain the treatment and 10.9% said they could not, because they understood that the doctor along with the psychologist, were the most indicated professionals.

Regarding the criteria for suspension of the Protocol of Therapeutic Hypothermia, from the first to the second evaluation there was an increase in the correct criteria, being: 38.8% - 39.1% when there is sustained hypothermia below 33ºC; 58.8% -73.9% uncontrolled bleeding and 51.8% - 63.9% uncontrolled pulmonary hypertension.

In order to know the opinion of professionals about the intervention and its implementation process, 72 professionals answered the questionnaire based on the CFIR domains (Table 1).

Table 1 - Description of the characteristics of the intervention, the individuals, the internal scenario and the implementation process based on the CFIR domains (n=72). Vitoria, ES, Brazil, 2024

CFIR domains	I agree		I agree partially		I do not agree	
	N	%	N	%	N	%
Characteristics of the intervention						
Will the elaboration of the interdisciplinary protocol for therapeutic hypothermia bring results regarding improvements in the care provided to newborns with moderate/severe ischemic hypoxic encephalopathy?	71	98.6	1	1.4	0	0
Is the therapeutic hypothermia protocol a need for NICU?	71	98.6	1	1.4	0	0
Is the protocol adapted to meet the reality of the institution?	70	97.2	2	2.8	0	0
Is the protocol very complex, has many steps and stages that make it difficult to apply?	13	18.1	16	22.2	43	59.7
Does the protocol need high investments to be implemented?	13	18.1	12	16.7	47	65.3
Characteristics of the individual						
Do UTIN professionals support the use of the protocol?	70	97.2	2	2.8	0	0
Internal Scenario						
Does the UTIN have available resources for the implementation of the protocol?	63	87.5	8	11.1	1	1.4
Implementation Process						
Knowing the data on the use of the protocol and the role of each professional in decision making can favor the maintenance of its use.	72	100	0	0	0	0

In the evaluation of the protocol, 98.6% agreed that it will bring results regarding improvements in care provided to newborns. The protocol was considered a need for NICU by 98.6% and 97.2% agreed that the protocol is adapted to attend the institution. Among those who partially agreed mentioned the lack of equipment. As for the complexity of the protocol, 59.7% did not agree that the protocol is complex and has many steps to its application. They reported that the protocol is easy to apply and with training of the team and necessary materials it is possible to be applied in the institution.

As for the high investment for the protocol to be implemented, 65.3% did not agree. Some have reported that the investment is high in the acquisition of brain monitoring.

Regarding the characteristics of the individual, 97.2% supported the use of the protocol. And in relation to the internal scenario, 87.5% agreed that the institution has resources available for implementation.

Regarding the implementation process, 100% agreed that knowledge on the the protocol and the role of each professional in decision making can favor the maintenance of its use.

Regarding the facilitators and barriers of the protocol implementation process. The facilitators were: yam training, team engagement in the protocol process, elaborated document, training and resources that can be applied to therapeutic hypothermia, interprofessional team performance and service organization. While, the barriers were: lack of adherence of the multiprofessional team, lack of equipment and structure, low frequency of service cases, lack of interest of management, poor communication between the team with discussion of errors and difficulty in the initial indication of treatment. On the other hand, many professionals do not see barriers to implementing the protocol.

The suggestions presented by the professionals to improve the protocol and its implementation were: team training and evaluation of

results after treatment. They also highlighted the need for technology and acquisition of modern equipment to carry out the protocol. They also suggested the use of simulated cases to upgrade the team, improve integration with different sectors involved, increase the number of professionals to care for newborns in therapeutic hypothermia, develop educational material for the neonatology team on the protocol and for parents/family, facilitate the transport of newborns who need to perform treatment at the institution. Some participants did not give suggestions because they felt that the protocol is well structured and easy to apply.

The Working Group after analysis and discussion of the suggestions made the adjustments in the protocol. In addition to the protocol, some educational materials were elaborated: Folder with the step-by-step nursing care in cooling and reheating of the newborn, Warning signs; fluxograms for eligibility of the asphyxiated newborns for therapeutic hypothermia; indication of therapeutic hypothermia in the NICU; and performance of therapeutic hypothermia (Figure 2).

Figure 2 - Warning signs Cooling and reheating Therapeutic hypothermia protocol. Vitoria, ES, Brazil, 2024

DISCUSSION

Therapeutic hypothermia is a safe and beneficial intervention, which results in a significant reduction in the combined outcome of mortality or severe neurological disability. In Brazil, treatment was initiated in the last decades and at the study site approximately six years ago[11]. This justifies the lack of knowledge of professionals in some work processes.

The protocol of therapeutic hypothermia developed for the study institution was based on the best evidence, adapted to local needs, performing the treatment passively through low-cost materials[19-20]. This condition is present in more than half of the NICU of Brazil highlighting the relevance of the study, showing the feasibility and effectiveness of the use of cold compresses and ice packs as a low cost cooling alternative[21-22].

The data after the team training show that the participants acquired greater knowledge about the materials used in low cost cooling, however, it is still necessary to improve the knowledge about the complete procedure. Studies prove that both servo-controlled and passive cooling effectively reduce the rectal temperature to the target temperature within the specific time limit, although passive therapeutic hypothermia requires closer and more rigorous monitoring by the team that provides assistance to newborns[3,7,14.19].

It was remarkable the improvement of the participants' responses regarding the reheating phase detailing that the temperature should be reached slowly and the central temperature should not exceed 0.5ºC per hour. However, they still need to delve deeper into the adverse effects and complications. Studies in adults and animals indicate that rapid reheating can adversely affect the results, with rebound convulsion and that slow reheating can help preserve the benefits of cooling[4.6-7,11]. This requires more attention from the staff who provide assistance and care.

Adequate knowledge by the team of how hypothermia compromises all organic systems of asphyxiated newborns, who are already severely

weakened to prevent and avoid complications of excessive cooling[5,12-13] is essential.

The main difficulties for the implementation of the protocol reported by the professionals were the lack of training and equipment with technology, similar to other studies in which the centers of care require more training with specific practical courses both in diagnostic and prognostic tools, how they emphasize the advantages over the use of the controlled servo system to perform therapeutic hypothermia more safely and effectively, and the examination of integrated amplitude electroencephalogram that assists in the detection of seizures and inclusion in the treatment of hypothermia. In addition, the same study points to a reduction in equipment in population terms, with the risk of not being able to apply therapeutic hypothermia or do so without appropriate follow-up[12,2].

In the clarification to the family, most professionals after the training felt able to talk with parents, because they acquired knowledge and understood the importance of all professionals to take responsibility. Communication with parents of newborns with ischemic hypoxic encephalopathy is a challenge that requires an interdisciplinary approach[6,7-18]. Maintaining good communication and sharing information are essential tools for establishing interdisciplinary cooperation. Thus, when this relationship occurs, it becomes possible to perform the treatment effectively establishing a relationship with the family to support it in this difficult experience[5,1].

It is fundamental to integrate families in the care of the NICU, with the development of educational programs that stimulate the autonomy and involvement of parents in the care of their children[23-24].

In the evaluation process of the interdisciplinary protocol, most professionals support the use of the protocol in the NICU, reporting that the sector has resources for its use and all agreed that knowing the role of each professional in decision making favors the maintenance of its use. The main facilitator was team training, as well as their engagement and availability of adequate equipment for the implementation of therapeutic hypothermia. Similarly, other studies indicate that the success of therapeutic hypothermia requires constant training of professionals, addressing the management of the newborn with ischemic hypoxic encephalopathy, monitoring, intensive care and interprofessional teamwork, which includes communication skills[11,19,21].

Research on the implementation of scientific evidence in clinical practice is challenging projects, which require a dynamic, continuous action and that cause changes in professional behavior improving the organization's culture. The science of implementation through programs, protocols, plans and intervention projects implements the best evidence in clinical practice contributing to the reduction of nonconformities and aiming to improve health outcomes[24-25].

The use of protocols with well-defined functions and responsibilities, with organized care flow that describes the integrated work among interprofessional teams, supported by frequent capabilities, are issues to standardize care and enable the implementation of the best evidence in clinical practice[25-26].

As limitations, the protocol was not evaluated by the users, as well as the preferences of the patients were not included in the elaboration of the protocol, and did not obtain a sufficient number of cases of asphyxiated newborns submitted to therapeutic hypothermia during the study period. Another limitation was that face-to-face training did not cover all NICU day and night staff, maternity and surgical center due to vacation, medical leave and employee bonds in other jobs. Given these considerations, new studies are recommended to evaluate the use of the protocol and the maintenance of long-term results and continuous team training.

CONCLUSION

The interdisciplinary protocol was built in a participatory way by the interprofessional team. The maintenance of evidence-based and protocol-recommended care requires knowledge of the team through training and clinical simulations, communication of the team and its interaction with other sectors involved.

The formation of the working group and the training in cycles involving the interprofessional team brought great interaction between professionals and engagement to achieve improvements, with rich periods of exchange of experiences among the specialties.

Educational materials with attractive and creative presentation convey information in a simplified, clear and objective way. These materials improved the communication and organization of the workflow in the service, and contributed to the translation of scientific knowledge to the population.

This study contributed to the interprofessional team in neonatal intensive care by describing how to translate and apply the best scientific

evidence in the care of the critical newborn, organizing a qualified work through the standardization of actions, based on the principles of safety and effectiveness.

The protocol and materials developed can be applied and adjusted to the reality of other health institutions. What points to the potential of this research to be applied at regional and national level, as it describes a systematic and innovative method for the implementation of the best scientific evidence in clinical practice.

*Paper extracted from the Master's Thesis entitled "Multidisciplinary protocol for therapeutic hypothermia in newborns", presented to the Postgraduate Program in Nursing, at the Federal University of Espírito Santo, Vitória, ES, Brazil, in 2023.

CONFLICT OF INTERESTS

The authors have declared that there is no conflict of interests.

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