Received: 20 September 2019 | Revised: 22 November 2019 | Accepted: 18 December 2019

DOI: 10.1002/pne2.12012

ORIGINAL ARTICLE

Paediatric & Neonatal Pain | WILEY

# A complex interprofessional intervention to improve the management of painful procedures in neonates

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**Funding information**
This study was funded by the Scientific Research Advisory Board of the Ente Ospedaliero Cantonale (ABREOC).

## Abstract

During hospitalization, neonates are exposed to a stressful environment and a high number of painful procedures. If pain is not treated adequately, short- and long-term complications may develop. Despite evidence about neonatal pain and available guidelines, procedural pain remains undertreated. This gap between research and practice is mostly due to limited implementation of evidence-based knowledge and time constraints. This study describes in detail the development process of a complex interprofessional intervention to improve the management of procedural pain in neonates called NEODOL© (NEOnato DOLore). The framework of the Medical Research Council (MRC) for the development and evaluation of complex interventions was used as a methodological guide for the design of the NEODOL© intervention. The development of the intervention is based on several steps and multiple methods. To report this process, we used the Criteria for Reporting the Development of Complex Interventions in Healthcare (CReDECI 2). Additionally, we evaluated the content of the intervention using a Delphi method to obtain consensus from experts, stakeholders, and parents. The complex interprofessional intervention, NEODOL©, is developed and designed for three groups: healthcare professionals, parents, and neonates for a level IIb neonatal unit at a regional hospital in southern Switzerland. A total of 16 panelists participated in the Delphi process. At the end of the Delphi process, the panelists endorsed the NEODOL© intervention as important and feasible. Following the MRC guidelines, a multimethod process was used to develop a complex interprofessional intervention to improve the management of painful procedures in newborns. Complex interprofessional interventions need theoretical bases, careful development, and integration of stakeholders to provide a comprehensive approach. The NEODOL intervention consists of promising components and has the potential to improve the management of painful procedures and should facilitate the knowledge translation into practice.

KEYWORDS
bundle of care, complex interventions, interprofessional relations, knowledge translation, neonate, procedural pain

## 1 | BACKGROUND

The evolution of neonatal intensive care has led to an increase in premature survival. In Switzerland, in 2017, births at less than 37 weeks' gestation represented 7% of all births. Newborns hospitalized in neonatal care are exposed to a stressful environment (noise, light)[1] and to many painful procedures such as capillary sampling.[2,3] It has been shown that during the first 14 days of life, newborns undergo an average of 7.5-17.3 procedures per neonate per day.[4-6] If pain is not adequately treated, short- and long-term complications may develop, particularly in premature infants, and may be associated with abnormal brain development such as changes in brain microstructure and function, stress systems, and neurodevelopment.[5,7-10] Parental involvement as well as developmental or environmental care can protect the neonate's brain and are described to reduce stress.[11-14] Many systematic reviews[15-17] and guidelines[18-20] have been developed and recommend good practices in neonatal analgesia. Many nonpharmacological or pharmacological interventions have proven their effectiveness.[15-17] Despite many efforts in recent years to improve the management of painful procedures, the frequency of procedures remains high and the use of analgesia is not yet routinely practiced.[2,3,21-23] Often, guidelines or adequate interventions are not implemented systematically and regularly.[24,25] Newborns in neonatal units continue to be exposed to procedural pain. This shows that there is still a gap between recommendations and practice.[26] Knowledge transfer among health professionals remains complex and difficult. Cultural, clinical, and organizational factors are identified as barriers to the implementation of good practices.[6] In particular, the roles of context and environment as well as interprofessional collaboration associated with erroneous beliefs and attitudes about pain management present challenges.[27,28] Strategies for evidence implementation are primarily directed at health professionals such as the introduction of a nurse pain champion or training of health professionals on pain management, thereby forgetting the parents who are key stakeholders.[26] The involvement of parents is recommended to improve outcomes of interventions.[22,23,29] This implies finding solutions to improve knowledge translation along with parent involvement to eventually improve the management of painful procedures.[30]

Implementing research findings requires multiple approaches at different levels. Craig's Social Communication Model of Pain[31,32] indicates that for pain management not only the person who suffers from pain but also his/her entourage (caregivers, parents) and environment as well as the respective interactions need to be considered. In order to facilitate the transfer of research results into practice, complex interventions as proposed by the Medical Research Council (MRC) guidelines should be considered.[33] Complex interventions contain a variety of types of interventions or components that interact. They are widely used in health sciences because they can improve patient health outcomes.[34] Therefore, a complex interprofessional intervention may significantly improve pain management. The purpose of this study was to develop a complex interprofessional intervention to improve the management of painful neonatal procedures that includes all partners, that is, health professionals, parents, and neonates, for a level IIb neonatal unit at a regional hospital in Southern Switzerland. This paper describes the development process of this intervention in detail, involving the MRC guideline, to allow for replication.

## 2 | METHODS

For the development of the intervention, the Medical Research Council (MRC) guideline on developing and evaluating complex interventions, revised in 2008,[34,35] was employed. This procedure consists of three steps: identifying existing evidence, identifying and developing a theory, and modeling the process and outcomes. To report this process, we used the Criteria for Reporting the Development and Evaluation of Complex Interventions in Healthcare 2 (CReDECI 2) guidelines for transparent and comprehensive reporting of complex interventions.[36,37] These criteria are also enhanced by specific elements proposed by Bleijenberg et al.[38] These elements—namely problem identification and definition, identification of beneficiaries' and providers' needs, review of current practices and context, and design of interventions—enriched the development phase of the MRC framework and, thus, improved the chances of success and relevance to clinical practice.[38]

Additionally, we evaluated the content of the intervention using a Delphi method to obtain consensus from experts, stakeholders, and parents.[39,40] The content of the intervention will be described in the results section. Then, the choices made for the design of the intervention will be briefly described. Figure 1 depicts the flow of study.

### 2.1 | Identifying existing evidence

In order to identify relevant and existing evidence,[34,35] a systematic review of guidelines on procedural pain management in neonates was carried out.[41] This systematic review aimed at determining the quality of existing guidelines on the management of procedural pain in neonates and at summarizing the recommendations provided by these guidelines. Among others, it was elicited that procedural pain management in neonates needs to involve not only healthcare

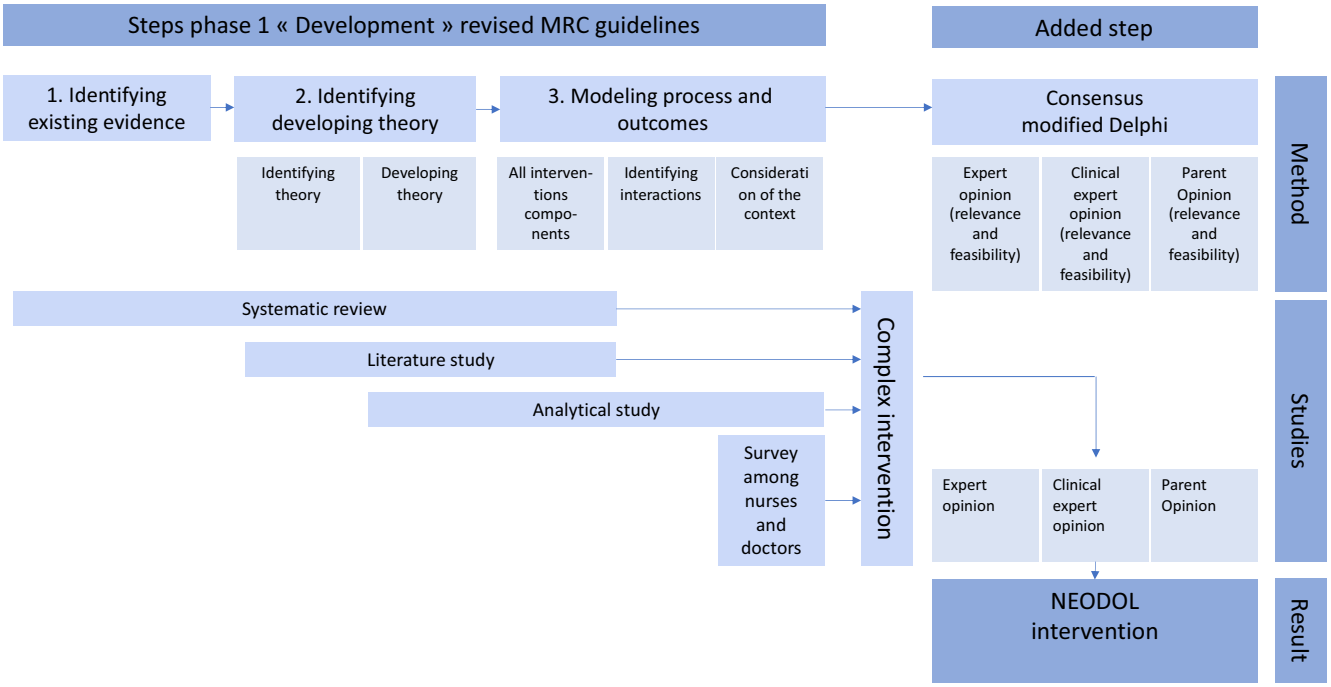


**FIGURE 1** Flow of study (adapted from Ettema[80])

professionals, but also the parents. Subsequently, we compiled all the recommendations to improve pain management in such procedures. The results served as an evidence-based starting point for the development of the intervention.

## 2.2 | Identifying and developing a theory

The identification of the theory that underpins the intervention is essential.[42] In order to determine the rationale for a complex intervention, elements that may interact with pain management in newborns were identified in the literature. First, Craig's Social Communication Model of Pain conceptual framework[31,32] provided a holistic view of pain and a detailed framework for understanding the complex interactions of biological, psychological, and social factors as well as interpersonal and intrapersonal variables (Appendix S1). Second, the bundle of care approach shows that a small set of evidence-based interventions, when implemented together, will yield better results than when implemented individually.[43-45] There is growing evidence for the benefits of care bundles in improving the application of evidence in practice in a variety of areas.[46-49] Indeed, some studies show the benefits of combining the use of different nonpharmacological interventions.[50,51] In contrast, most studies describing pain management methods generally focus on a single element and therefore do not identify the interactions between the different elements that could have an impact on the management of painful procedures. Third, the interprofessional approach[52,53] that integrates the knowledge, skills, and expertise of different professionals, as well as the experience and needs of parents, is essential to improve pain management. These approaches all provide valuable elements of theoretical understanding that could be included in a complex intervention.[37]

## 2.3 | Modeled process and outcomes

In this third step, it is necessary to understand the intervention and its likely effects: (a) describe all the components of the intervention; (b) illustrate the interactions between the different components; and (c) consider the characteristics of the context.[34,37] First, to define the components of the intervention, we combined the recommendations identified in the systematic review of the guidelines with the elements of the Craig's Social Communication Model of Pain.[31,32] This first draft of the intervention was produced by the first author (CBB) and subdivided the intervention into three targets to be taken into account in order to improve the management of painful procedures, that is, newborns, parents, and health professionals. Then, this intervention was discussed, improved, and validated by the other authors (CJN, GDS, and MZS). Second, to illustrate the interactions between the different components, we relied on the social communication model of pain[31,32] in which the focus is on interactions between the child and the people who care for him or her (parents and health professionals). The process is dynamic because each component of the model has an impact on the others. This is particularly important in the case of the newborn, who is particularly vulnerable because it depends on the judgments and measures taken by adults.[54] Third, we studied the characteristics of the context, that is, the care unit for which the intervention is being developed. Information about the implementation context and providers offered essential information to optimize the intervention. For this

purpose, all professionals (ie, nurses and physicians) of the level IIb unit were surveyed concerning their knowledge on and attitudes toward painful procedures, interprofessional collaboration, and demographic information. To determine knowledge and attitudes of physicians and nurses regarding pain management in neonates, the questionnaire by Akuma and Jordan[55] was employed. This questionnaire comprises four gestational age categories and seven painful procedures. We included another four painful procedures (ie, eye control, CPAP prongs insertion/reinsertion, insertion of a nasogastric tube, and removal of a tape). In addition, the Akuma and Jordan questionnaire includes eight open-ended questions and 24 fixed-choice questions formatted as numeric analogue scales (ranging from 0, no pain, to 10, worst pain) or as Likert-type response categories (true/false; less than/same/more than; never/rarely/often/often/usually/always). The questionnaire was translated and validated according to Wild.[55] The second questionnaire "Assessment of Interprofessional Team Collaboration Scale" (AICTS-II) was used to assess the level of interprofessional collaboration.[56] The original version of this questionnaire was developed in 2012 by Orchard et al[57] and updated into a shorter version in 2018.[56] The Italian version of AICTS-II was used for this study.[58] The questionnaire consists of 23 items that are arranged into three domains to measure partnership (8 items), cooperation (8 items), and coordination (7 items). Each item is rated using a 5-point Likert scale (from never = 1 to always = 5). The scores for the 3 domains were calculated by averaging the items in each domain, where values less than or equal to four indicate an inadequate perception of the domain. Socio-demographic information was also obtained. For both questionnaires, permission for use was obtained from the authors.[56-58]

### 2.4 | Consensus

A user-centered approach, composed of experts and an interdisciplinary team in direct contact with patients, can improve the feasibility, effectiveness, and efficiency of the intervention.[38] After completing the three stages of the development phase of the MRC model, we evaluated the content of the intervention from the point of view of the relevance of the different elements and of their feasibility in order to gain a consensus. To include important stakeholders, we conducted a 2-round electronic Delphi process. The Delphi panel included international pain experts (nurses and physicians), healthcare providers of the participating unit (nurses and physicians), and parents of neonates. Participants were contacted by email. Relevance and feasibility on the individual interventions were scored using a 9-point Likert scale, anchored by "highly inappropriate" (1-3), "uncertain" (4-6), and "highly appropriate" (7-9). Consensus was considered to be reached if at least 80% of panelists rated a statement as "highly appropriate".[39] Descriptive statistics were used for data analysis. Central tendencies (means, medians) and levels of dispersion (standard deviation and the interquartile range) were computed.[39] A Content Validity Index (CVI) was also calculated, with a minimum acceptable value of 0.80 for the I-CVI and 0.90 for the CVI average (Ave-CVI). We refer to the CVI process only for the purpose of determining the importance of the components of the intervention through the opinion of experts.[59] The CVI is calculated as the number of experts giving a score of 3 or 4 (4-point Likert scale), divided by the number of experts. This is the proportion of those who agree on relevance. Usually, experts use a 4-point Likert scale. Since we use a 9-point scale, the variant of labeling is as follows 1-3 = *not relevant*, 4-5 = *somewhat relevant*, 6-7 = *quite relevant*, and 8-9 = *highly relevant*.[59]

## 3 | RESULTS

### 3.1 | Identifying existing evidence

The systematic review is reported elsewhere.[41] In this systematic review, 17 guidelines were included, of which only 11 were identified as of high methodological quality. Analysis yielded a list of recommendations. Management of painful procedures in neonates must comprise nonpharmacological and pharmacological methods as well as the inclusion of parents, the training of professionals, and interprofessional collaboration. These recommendations therefore concern three target populations (ie, newborns, parents, and healthcare professionals) for whom different interventions are needed. Complex interventions are generally described as interventions that contain various components that interact.[35] In conclusion, a complex intervention, for three target groups comprising several interventions, may be more effective in preventing procedural pain in neonates.

### 3.2 | Identifying and developing a theory

To define the key components of our intervention, we drew on Craig's Social Communication Model of Pain. This model provides an overview of the interactions between the person suffering from pain (neonate) and the caregivers (ie, parents, professionals) in the respective social environment[31,32] (Appendix S1). To enrich each key component of the complex intervention, the recommendations that had emerged from the systematic guideline review were employed. In addition, the literature on bundles of care and family-centered care was included, thereby obtaining more detailed views on potential interactions and implications of each component. Based on this literature, a bundle of care[43-45] was developed to specifically address pain prevention in the newborn to improve implementation. Family-centered care literature was included to address parent support as well as interprofessional collaboration.[60-62]

### 3.3 | Modeled process and outcomes

The purpose of modeling the complex intervention is to bring together all "active components" that are known to have an effect based on empirical evidence or theory.[63] Thus, the third phase was found to consist

of three substeps: description of all intervention components, illustration of interactions between different components, and consider the characteristics of context. First, the description of all the elements of the three components of the intervention is described in Table 1. For each component of the intervention, the purpose and description of the content, as well as the theoretical bases to which we have referred, are detailed. Second, different components of the intervention are planned to support and improve direct actions with the newborn during painful procedures. In particular, the professional and parental components are essential. The contribution of a nurse pain champion promoted the use of procedural pain evidence in practice and acted as a facilitator for the development of clinical knowledge and professional practices. The staff training program for nurses and physicians aimed to improve pain assessment and knowledge of nonpharmacological and pharmacological methods and to highlight the importance of parental presence. The content of the interprofessional training is based on the "IASP Interprofessional Pain Curriculum Outline" (International Association for the Study of Pain)[64] and adapted to context as well as type of patients hospitalized in the level IIb unit. For support materials, the professionals received a pocket booklet with an overview of the elements of the complex intervention as well as the recommendations for procedural pain management. A parent information brochure was also developed based on Franck,[60,65,66] Harrison et al,[67] and Coughlin.[68] This brochure was also culturally adapted to the care context of a level IIb unit in a regional hospital in Italian-speaking region of Switzerland. Thanks to information from parents, collaboration between them and the multidisciplinary team can develop, and having received an information brochure with the different actions they can take to support their baby, parents can become more involved during painful procedures. These two components are therefore particularly relevant to facilitate the application of the bundle of care during a painful procedure. By better understanding how individual components are linked to outcomes and based on theoretical underpinnings, we can confirm the importance of a complex intervention that acts on all three target groups. Third, Interactions between context and intervention are generally considered important.[42] It is therefore crucial to adapt the intervention to the care unit. The study was conducted in a level IIb neonatal unit at a regional hospital in southern Switzerland. A total of 25 nurses and 21 doctors, which were 77% out of a total of 60 questionnaires distributed, responded to the knowledge and attitudes questionnaire.[55] Respondents generally have a good level of knowledge. There was agreement that neonates of any gestational age experience pain and need adequate analgesia. Intubation, lumbar puncture, and chest drain insertion were considered to be the most painful procedures, whereas insertion and reinsertion of CPAP prongs were considered to be the least. Both nurses and physicians reported that comfort measures and analgesics are underutilized for various painful procedures at all gestational ages for various reasons such as lack of time or lack of staff. Differences exist between physicians and nurses. 24% of participants provided suggestions for improvement and cited staff training, parent information, and the development of protocols for the care unit among others. Interprofessional education for physicians and nurses, pocket booklets with protocols as well as parental involvement, awareness, and information were identified as being of high importance. For the interprofessional collaboration questionnaire,[56] the result shows that a shift toward better collaboration between physicians and nurses as well as between parents and healthcare professionals is needed. All this information must be taken into account in the modeling of the complex intervention. As described in the flow of NEODOL© intervention (Figure 2), the first two parts of our intervention, that is, professionals and parents, are therefore based on interventions that will act in the longer term. The third part,

**TABLE 1** Components of the intervention

| Components of the NEODOL© intervention | Aims | Description | Basis of rationale |
|---|---|---|---|
| Health professionals | Training of health professionals and interprofessional collaboration | • Structured interprofessional education program<br>• «Pain champion» in the unit<br>• Creation of a recommendation booklet developed specifically for the care unit<br>• Creation of posters and reminders | • Craig's Social Communication Model of Pain[31,32]<br>• Systematic review of guidelines[41]<br>• IASP Interprofessional Pain Curriculum Outline[64]<br>• Proven evidence in other studies[22,83-86]<br>• Family-centered care theory [60-62]<br>• Bundle of care literature [43,45,87] |
| Parents | Information for parents and involvement during painful procedures | Information sheet for parents that informs them about their child's procedural pain during hospitalization in the neonatal unit and how they can collaborate during painful procedures | |
| Newborns | Implementation of a plan for the management of painful procedures (bundle procedure) | • Bundle procedures that integrate all the elements to be taken into account to perform a painful procedure:<br>• Planning the procedure<br>• Collaboration and involvement of the family<br>• Environmental measures<br>• Pain assessment<br>• Choice of analgesia<br>• Documentation in the patient's record | |

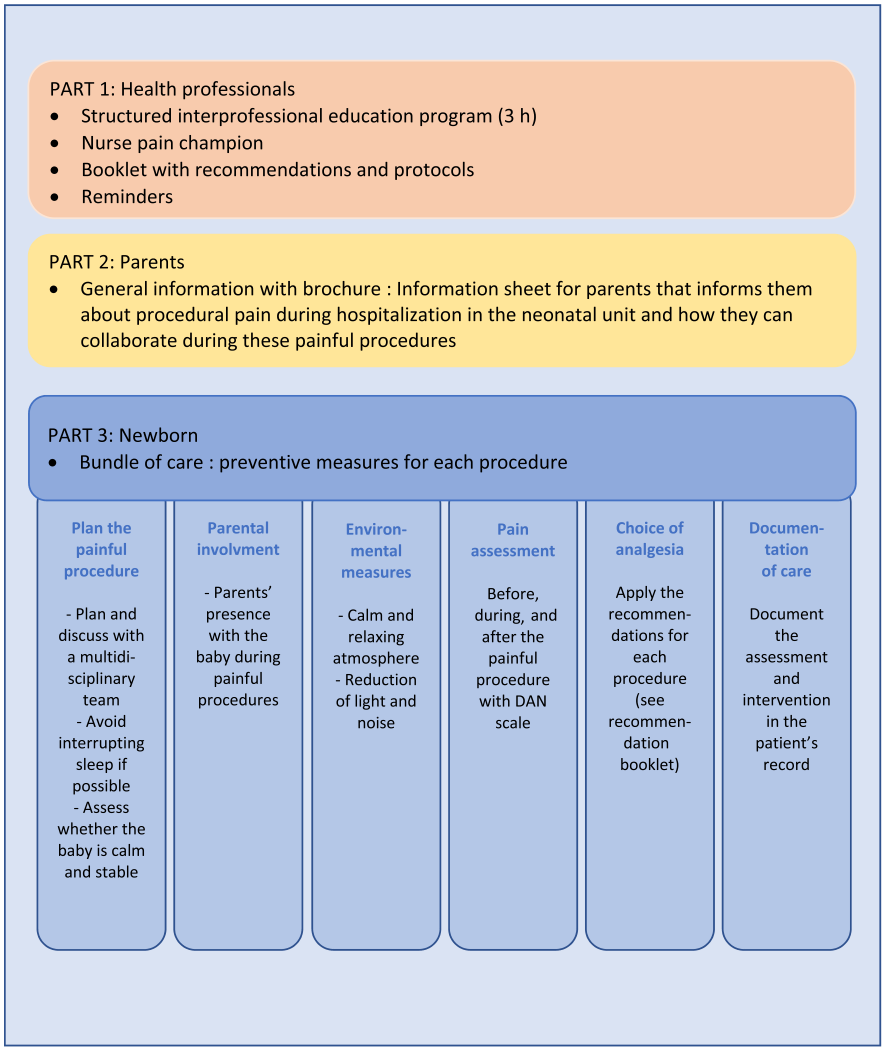


**FIGURE 2** Flow of the NEODOL© intervention

that is, the one dedicated to newborns, is more oriented toward immediate interventions that should be applied during each painful procedure. However, the implementation of these recommendations will be strongly linked to the first two steps. Our intervention therefore respects a logical flow with planned activities that will have an impact on the outcomes.

## 3.4 | Consensus

As part of the validation of the development of this complex intervention, experts, providers, and users were consulted and a Delphi study was conducted. Purposive sampling was used to constitute an interdisciplinary panel of stakeholders (N = 18), including international pain experts (n = 7), healthcare providers of the participating unit (n = 7), and parents of neonates (n = 4). International pain experts were identified by the lead author by virtue of their professional role or clinical and/or academic expertise. The Delphi panelists completed two rounds. For the first round, a structured questionnaire was used. During the first round, 88% (N = 16) of the questionnaires was completed, and during the second round also. After the first round, the panelist group agreed on the relevance of the intervention (panel median = 8.3) and on the feasibility of the intervention (panel median 7.8). Panelists clearly identified the validity of the content of the intervention for relevance (S-CVI/average = 99.03) and for feasibility (S-CVI/average = 94.21; Table 2). All the items obtain a high consensus both for relevance and for feasibility. Only the item "parent involvement" obtains a moderate consensus for feasibility. This can be explained by the panelists' comments because it is an item that is more difficult to implement depending on the emergency of the procedure, the parents' availability, or their choice to be present or not. Although panelists also had the opportunity to suggest new items, none were suggested after the first round. Only suggestions for the implementation in practice concerning two items were proposed. These comments from panelists were incorporated into the intervention. In round 2, the revised intervention was submitted for approval. A high level of consensus (99%) was reached. In conclusion, after two rounds, the panelists endorsed the NEODOL© intervention as important as well as feasible. Conducting this Delphi study was key to include important stakeholders in its development. This was an important additional step in testing this intervention.

**TABLE 2** Delphi results

| Items | Round 1 | | | | |
|---|---|---|---|---|---|
| | Mean | Median[a] | SD | IQR | CVI |
| Relevance | | | | | |
| Global relevance | 8.25 | 8 | 0.77 | 1 | 1 |
| Health professionals | | | | | |
| Structured interprofessional education program[b] | 8.37 | 8.5 | 0.72 | 1 | 1 |
| Nurse pain champion[b] | 8.5 | 8.5 | 0.52 | 1 | 1 |
| Booklet with recommendations and protocols[b] | 8.44 | 9 | 0.73 | 1 | 1 |
| Reminders[b] | 7.88 | 8 | 1.09 | 2 | 1 |
| Parents | | | | | |
| Information sheets[b] | 8.25 | 8.5 | 1.06 | 1 | 0.94 |
| Newborn | | | | | |
| Bundle of care procedure[b] | 8 | 8 | 1.21 | 1.25 | 0.94 |
| Plan the painful procedure[b] | 8.25 | 8 | 0.86 | 1 | 1 |
| Parental involvement[b] | 8.06 | 8 | 0.99 | 1 | 1 |
| Environmental measures[b] | 8.25 | 8.5 | 0.86 | 1.25 | 1 |
| Pain assessment with DAN Scale[b] | 8.25 | 8 | 0.77 | 1 | 1 |
| Choice of analgesia[b] | 8.44 | 8.5 | 0.63 | 1 | 1 |
| Documentation of care[b] | 8.44 | 8.5 | 0.63 | 1 | 1 |
| Total (mean) | 8.26 | 8.31 | 0.83 | 1.12 | 0.99[d] |
| Feasibility | | | | | |
| Global feasibility | 7.5 | 7.5 | 0.89 | 1 | 1 |
| Health professionals | | | | | |
| Structured interprofessional education program[b] | 7.5 | 7.5 | 1.09 | 1 | 0.94 |
| Nurse pain champion[b] | 7.75 | 8 | 1.24 | 2 | 0.94 |
| Booklet with recommendations and protocols[b] | 8.25 | 8.5 | 0.86 | 1.25 | 1 |
| Reminders[b] | 7.87 | 8 | 1.02 | 2 | 1 |
| Parents | | | | | |
| Information sheets[b] | 8.12 | 8.5 | 1.15 | 1.25 | 0.94 |
| Newborn | | | | | |
| Bundle of care procedure[b] | 7.44 | 8 | 1.21 | 1.25 | 0.94 |
| Plan the painful procedure[b] | 7.12 | 7 | 1.36 | 1 | 0.94 |
| Parental involvement[c] | 6.87 | 7 | 1.45 | 2 | 0.81 |
| Environmental measures[b] | 7.5 | 8 | 1.37 | 1.5 | 0.87 |
| Pain assessment with DAN Scale[b] | 7.5 | 8 | 1.41 | 2.25 | 0.87 |
| Choice of analgesia[b] | 8.06 | 8 | 0.77 | 1.25 | 1 |
| Documentation of care[b] | 7.81 | 8 | 0.99 | 1.25 | 1 |
| Total (mean) | 7.63 | 7.85 | 1.14 | 1.46 | 0.94[d] |

[a]1-9 rating scale used.
[b]High consensus.
[c]Moderate consensus.
[d]Average I-CVI.

## 4 | DISCUSSION

In this study, a complex interprofessional intervention called NEODOL© was developed to improve the management of procedural pain in newborns. The intervention was developed for a neonatal unit level IIb at a regional hospital in southern Switzerland.[69] The revised MRC guidelines (2008) were followed as a methodological guide for the development. To optimize the reporting of intervention development, we used the CReDECI 2 guideline[37] enhanced

by essential elements proposed by Bleijenberg et al (2018) to improve adequacy with clinical practice and context. The MRC guideline is widely used for the development of complex interventions.[33] However, our approach of combining the MRC guideline with elements identified by Bleijenberg et al (2018) and the CReDECI 2 facilitated intervention development. This combination has allowed us to obtain more details on the MRC development phase for which we identified the three main steps.

To further strengthen the development of the intervention, we used a step-by-step approach combining the synthesis of knowledge gathered from different methods: a systematic review of guidelines, a literature review, and questionnaires, and then added an additional step by consulting international experts, health professionals in the care unit, and parents to assess relevance and feasibility. This modeling of the intervention within the multidisciplinary team, taking into account the opinions of parents and caregivers, is likely to increase the applicability of the intervention in practice.[38] The understanding of the context at different levels, of the target audience, of existing practices, etc, also helps to guide the implementation and knowledge translation.[70,71] Research implementation is influenced by various elements.[72,73] By drawing on Craig's Social Communication Model of Pain,[32] we were able to identify the important interactions between the person suffering from pain, the caregivers, and the context. For our purpose, we determined that the caregivers included both family members and healthcare professionals. Interestingly, the Craig's Social Communication Model of Pain is rarely used in practice.

This can be considered as another strength of our intervention that adopts a new approach to evidence translation in practice, taking into account the characteristics of the key stakeholders, namely the newborn, parents, and health professionals.

Interprofessional collaboration frequently remains limited to the healthcare professionals.[74] Parents are rarely considered to be part of the interprofessional collaboration.[75,76] However, the Canadian Interprofessional Health Collaborative (CIHC)[77] and Swiss Academy of Medical Sciences (SAMS)[78] definitions include the patient and family as a partner. The bundle of care should be seen as a directed and coordinated approach to care during painful procedures, including systematic strategies to implement care processes in the local context and collaborate more effectively as a team.[45] Providing the development of a complex intervention that takes into account all partners and not just the newborn could improve the management of painful procedures. The development of the bundle provides a systematic and coordinated approach to help health professionals involve parents in care and apply evidence. The implementation of the intervention and especially the bundle of care should improve communication between health professionals and with parents, as well as improve the quality-of-care documentation and thus ultimately interprofessional collaboration. The bundle of care created for newborns, therefore, facilitates the translation into clinical practice.[79] All these elements included in the intervention design and the Delphi study give a better chance of producing a relevant intervention, feasible in practice that is adapted to its context and is ready for testing. To our knowledge, there is currently no interprofessional intervention for the management of pain during painful procedures in newborns. We recognize that this intervention still needs to be tested; therefore, in accordance with MRC guidelines, a feasibility study is underway to evaluate the NEODOL© intervention in clinical practice. It will allow us to better adapt the intervention to maximize the chances of success in a future implementation.

A limitation of this study is that it was conducted in a level IIb neonatal unit in the Italian-speaking region of Switzerland.[69] With regard to generalization to other neonatal units, the basic elements of this intervention are literature-based and recommended. These may be used in other contexts of care. However, adaptation may be needed concerning the content of health professional education, the formatting of the pocket booklet and the information brochure for parents. Evidently, language adaptation may be necessary, too. The methodology used in this study to develop the complex intervention can be useful for other contexts.[79-82]

## 5 | CONCLUSIONS

We have developed and evaluated a theoretical interprofessional patient-centered intervention designed specifically for a neonatal unit in Italian-speaking Switzerland. The objective is to improve the management of procedural pain in newborns. Based on the literature, we propose a comprehensive approach by combining elements from the MRC development phase with model elements[37,38] to improve the design of the intervention. The content of the NEODOL© intervention was evaluated and approved by a panel of experts, healthcare providers, and parents.

### ACKNOWLEDGMENTS

We thank nurses, physicians, experts, and parents involved in the development of NEODOL© intervention. We would like to thank in particular Laura Steiner, scientific collaborator for her contribution.

### CONFLICT OF INTEREST

The authors declare that they have no competing interests.

### ETHICAL APPROVAL

The study was approved by the local committee Comitato Etico Cantonale, Bellinzona.

Reference number: CE TI 3300.

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

**How to cite this article:** Balice-Bourgois C, Newman CJ, Simonetti GD, Zumstein-Shaha M. A complex interprofessional intervention to improve the management of painful procedures in neonates. *Paediatr Neonatal Pain*. 2020;00:1–11. https://doi.org/10.1002/pne2.12012