Action-Research for the development of care technology: protocol for the management of pain and stress of the newborn in intensive care.

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Abstract: Surveys show a gap in health professionals’ knowledge for the management of neonatal pain and their daily practice. To minimize this dichotomy a participatory development of a protocol for pain and stress management in the Neonatal Intensive Care Unit was proposed, based on scientific evidence, at a public children’s hospital, Paraná state, Brazil. The theoretical-methodological framework used was the action research, with the participation of 65 health professionals. The protocol was developed in three stages, by means of a structured questionnaire applied to all professionals and by discussions and theorising that occurred in seven workshops. The Action-Research development led to a positive movement of reflective interaction among the team, with a view to its application for qualification of neonatal care.

Keywords: Qualitative Research; Neonatal Nursing; Stakeholder Participation; Pain Measurement; Pain Management.

1 Introduction

The hospitalization at a Neonatal Intensive Care Unit (NICU) exposes newborns (NB) to a large number of painful procedures, many of them necessary for diagnostic and therapeutic purposes (Kyolo, Stevens, Gastaldo & Gisore, 2014).

Researches also quantify, beyond painful procedures, stressful procedures to which newborns are submitted (Cruz, Fernandes, Oliveira, 2016; Bonutti et al. 2017). Moreover, some harm can be generated to the NB by small-, médium- and long-term hospitalization (Brummelte et al., 2012; Valeri, Holsti & Linhares, 2015).

There are significant advances for assessing and treating neonatal pain, such as the development of new scales, effectiveness of non-pharmacological measures for its relief. However, the development and deployment of evidence-based clinical protocols for the proper management of neonatal pain is a weakness. (Deindl et al., 2013; Santos, Ribeiro & Santana, 2016).

There is a gap between the knowledge and practice of professionals in the management of neonatal pain. This is due to: lack of protocols for systematic and careful measurement; its treatment; and the shortage of strategies and actions for continuing education for health care professionals (Aymar, Lima, Santos, Moreno & Coutinho, 2014; Britto et al., 2014; Costa et al., 2017).
This study is relevant once it describes the process of participatory development of a multidisciplinary protocol for pain and stress management in newborns in the Neonatal ICU, based on scientific evidence, at a children's hospital, in the Brazilian Southern region.

2 Material and Method

2.1 Type of study

This is an intervention survey in the perspective of the theoretical-methodological framework of action-research, with the steps proposed by Thiollent. It is a type of social research, with empirical basis, performed through action or resolution of a collective problem, which involves both the research participants as the researcher. The action should occur in a cooperative and participatory way, with planned actions to contribute to the improvement of professional practice and quality of care. (Thiollent, 2011).

Specialist groups draw up guidelines for the action that will be tested in their practice (Thiollent, 2011). Thus, the meetings, here called workshops, proposed reflections on important aspects for elaborating the protocol for adequate pain and stress management in the Neonatal ICU.

2.2 Scenario

The scenario was the Neonatal ICU of a hospital which is a unit of Paraná state, located in the municipality of the metropolitan region of Curitiba, Brazil. It meets children aged 0-18 years. At the time of the survey, the hospitalization units contained 22 beds in pediatric surgery, 34 in pediatric clinic, 10 in the Pediatric ICU, 20 in the Neonatal ICU, in addition to an outpatient clinic for Medical Specialties. In the Neonatal ICU, there, in 2017, 232 hospitalizations of NB from the municipality itself, and neighboring municipalities, by transfer from other hospitals or by the center for beds adjustment in the state of Paraná.

In this unit, professionals from the nursing, neonatology and physiotherapy areas work. They all work under work scale regime.

2.3 Inclusion and Exclusion Criteria, Research Phases, Participants

The inclusion criteria for participants were: being a health care professional of the Neonatal ICU of the hospital for more than six months; being of professional category under work scale regime, and working directly with the NB during 24 hours. Exclusion criteria: professionals who were away due to vacation, leaves, or absent due to another reason during the data collection period. The research was carried out in three phases, with specific approaches, as shown in Table 1.

<table>
<thead>
<tr>
<th>Phases</th>
<th>Objective</th>
<th>Used instruments/strategies</th>
<th>Participants</th>
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<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt;</td>
<td>To characterize knowledge and practices of the multiprofessional team in neonatal pain and stress management.</td>
<td>Structured questionnaire, distributed and returned after completion</td>
<td>65 people: 10 nurses, 10 physical therapists, 08 physicians, and 37 nursing technicians</td>
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<td>2&lt;sup&gt;nd&lt;/sup&gt;</td>
<td>To theorize knowledge and practices manifested by interviewees in the first phase.</td>
<td>Workshops (n=5) with previous and presente reading of a theoretical material on pain and stress in the NB</td>
<td>13 people: 3 nurses, 3 physical therapists, 1 physician, and</td>
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To elaborate a Protocol based on evidence adequate to the service Workshops (n=2) for consensus of scientific evidence adequate to the practical scenario for pain and stress prevention and management in the neonate.

The same as above

Source: The authors.

### 2.4 Data collection and organization

The organization and recording of each workshop was held by the research coordinator, with the support of a participating professional volunteer, to detailed records in the book of minutes of the discussions.

The participants defined dates, times and locations of meetings at the end of each workshop. The meetings were weekly or fortnightly, between April and May 2017, with the latest, in July 2017, with the consolidation of the Protocol. The number of meetings was not pre-defined, but established with the professionals, according to the progress of activities, following the recommendations of Thiollent.

### 2.5 Data analysis

The data collected in PHASE I were entered in a spreadsheet in Excel Program (2013), analyzed with the statistical package GRAPHPAD PRISM, with a significance level of 5% ($\alpha = 0.05$). Then, they were submitted to descriptive analysis with presentation of results in tables. The different variables were described as means and standard deviations or frequencies, separated according to the categories of professional training - nurse, physical therapist, physician or nursing technician.

Data analysis in PHASES II and III, arising from the discussions and theorizations during the workshops comprised the Protocol for Pain and Stress Management in newborns. The researcher, after the meetings, transcribed her entire perception and events, records that were presented as a report of each workshop in the final product, together with the assessment by the group.

### 2.6 Ethical aspects

The researcher provided the materials for the workshops. The participants had no expense. The research composes the thematic project entitled “Infant hospitalization & Care technologies: contributing to the practice of a children’s hospital”. The study followed the requirements of Resolution 466/2012 of the Brazilian National Health Council, and was approved by the Ethics Committee of the Health Secretariat of Paraná/SESA, on 25 August 2016, with opinion 1.618.264, and Certificate of submission for Ethical Consideration (CAAE) 56162516.4.0000.0102.

### 3 Results

The research was carried out in three phases with the development of Workshops (Table 2). In the first workshop, some results of the first stage of the research (data collection) were presented, which analyzed the knowledge and practices of the multiprofessional team on the assessment and treatment of pain and stress in the Neonatal ICU.

The following aspects stood out from the results:

- The professional training in neonatal pain, in which most professionals reported any participation in courses or scientific events in the last five years, nor trainings in the last 12 months;
The difference between the Pain Management Protocol and Pain Treatment Routines isolated, reported by the research participants;

The observation made by all participants that the nursing technician is responsible for assessing the pain in the newborn, although they could have listed other categories;

The fact that procedures considered painful by everybody (adhesive removal, venipuncture, arterial puncture, lumbar puncture and thoracic drainage) presented few pharmacological or non-pharmacological interventions.

For the theorization of the 1st Workshop (Phase 2), the result of an integrative review on the State of the Art in the Neonatal Pain Management was presented, in addition to the data analyzed in Phase 1. Some information from the analysis of the Phase 1 were similar to those already found in other review studies, and the discussion developed on the existing gap between knowledge about neonatal pain and the practice of health professionals. In this perspective, pointing to the strategy of the development of the institutional protocol for the neonatal pain management, containing validated scales for systemized assessment of pain. Furthermore, the importance of the permanent education process to minimize the gaps and lack of knowledge were evidenced. At the end of this reflective-exploratory process, the researcher asked the group: “Are changes in the pain management necessary in our neonatal ICU? Which ones? How to promote them?”

Table 2. Research phases according to the Action-Research Stages proposed by Thiollent (2011).

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<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
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<tr>
<td>Characterization of knowledge and practices of the multiprofessional team on neonatal pain and stress management</td>
<td>The theory as strategy for basing the praxis</td>
<td>Protocol elaboration and implementation of the actions</td>
</tr>
<tr>
<td>Application and analysis of the semistructured questionnaire to all health professionals who accepted to participate in the research (n=65).</td>
<td>1st Workshop: The pain of NB in the Neonatal ICU. 2nd Workshop: The pain language in NB. 3rd Workshop: Scales for assessing neonatal pain. 4th Workshop: Pharmacological methods for treating neonatal pain. 5th Workshop: Non-pharmacological methods for treating neonatal pain. A carga sensorial relacionada aos procedimentos dolorosos nos RN.</td>
<td>6th Workshop: Definition of the procedures considered painful by the multiprofessional team and the methods to be used for analgesia. Participatory elaboration of the Neonatal Pain Management Protocol. 7th Workshop: Consolidation of the protocol for neonatal pain management.</td>
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There was unanimous signaling for the need to promote changes, considering that the health team of the Neonatal ICU did not assess and treat the neonate’s pain routinely. The easiest way to promote change was not expressed; however, they stated that the participatory development of the Protocol would be a mediating tool for promoting these changes.

After, they suggested themes for study and discussion in the upcoming workshops, namely: suggestive signs of pain; sensory load; sedated babies and pain; scales for pain assessment; non-pharmacological measures for pain relief.

In order to evaluate the Workshop, colored cards were distributed on the tables, with the following words: I loved it; I liked it; It was bad; It was a waist of time and It will improve my practice. The...
participants were instructed to choose one or more of them and put it (them) in a receiver box. After the workshop, the researcher counted the expressions of the participants in order to count with the evaluative subsidy for improvements or adaptations for the following workshops.

In the 2nd Workshop, the objective was to provide theoretical-reflective elements for health professionals to list the suggestive signs of pain in the newborn. To sustain the discussion, a week before, by e-mail, the scientific document “The language of pain in the newborn” for prior reading was forwarded (Guinsburg & Cuenca, 2010). The contents of the document directed the beginning of the discussion on the questioning, by the researcher: “What are the signs of pain that we can observe in infants hospitalized in Neonatal ICU?”

The health professionals readily pointed out randomly behavioral and physiological signals. The researcher welcomed the expressions and proposed the theorization supported by digital material with images that showed the behavioral parameters (facial mimicry, crying, movements of arms and legs). During the discussion, the present professionals emphasized the crying question, once they expressed difficulty identifying the crying in intubated neonates. In addition, they stressed that crying is the most common and expected of communication used by NB, and thus may result from other events, not only from the pain, namely: hunger, cold, need for nappy changing, among others. The researcher, after having heard and welcomed the expressions of doubts and questions, proposed dividing the participants into pairs for reading scientific articles that showed physiological behavior of pain in newborns.

After reading, the explanation of the content addressed in the scientific material began, and the classification of physiological and behavioral signs. The participants raised for discussion several clinical cases they remembered at that moment, which enriched the discussions. The points regarding the weeping were also discussed in the light of scientific evidence and the group expressed satisfaction with the answer to their doubts.

In the 3rd Workshop, the targets were to present, discuss and reflect the validated scales for neonatal pain evaluation. This workshop aimed at completing at least a scale model best suited to compose the Protocol for Pain and Stress Management in the Neonate. It started with the presentation of the possible results of scales known and applied by them in the Neonatal ICU. After that, there was a reflective discussion, based on a graphic presentation in Power Point, on the main validated and suitable scales for newborns, namely: NIPS (Neonatal Infant Pain Scale); NFCS (Neonatal Facial Coding System); BIIP (Behavioral Indicators of Infant Pain); CRIES (Crying, Requires of oxygen for saturation above 95%, Increased vital signs, Expression and Sleeplessness); PIIP (Premature Infant Pain Profile) e, PIIP-R (Premature Infant Pain Profile – Revised). In addition to the conception of the Scale, the intervals of evaluation were discussed, and the score for each scale according to the behavioral and physiological indicators. In this perspective, the present professionals stressed the need for a specific scale for neonatal patients in the immediate postoperative period, since they considered it a weakness in the Neonatal ICU.

To subsidise the reflections, learning and the option for the Scale(s), scientific articles about the scales of neonatal pain assessment used in various scenarios were distributed. After reading in pairs, identification of scales, discussion and resolution of doubts, the scales to compose the Protocol for Neonatal Pain and Stress Management were defined, namely: BIIP - Behavioral Indicators of Infant Pain to be used by the nursing as fifth vital sign (Holsti & Grunau, 2007). Piip-R, the Premature Infant Pain - Revised, was also chosen to be applied by nursing and medical staff in situations in which BIIP was greater than 5, and in the postoperative period; and for the physical therapists during the procedures of aspiration of endotracheal tube and upper airways (Stevens et al., 2014; Bueno & Kimura, 2013).

The multiprofessional team opted to withdraw the use of the NIPS Scale, used since 2010 in the Neonatal ICU, since they concluded it was not effective in pain assessment; however, most
professionals stated not having enough knowledge to use it. Given the rapprochement with the other scales, they realized they were more appropriate to compose the new Protocol.

The 4th Workshop took place with the objective of talking about the drugs used for analgesia in newborns, their indications and adverse effects. A medical professional, member of the group, developed it, for being drugs that must be prescribed by this professional category.

The doctor, through material with the main drugs used for analgesia in neonatology, explained their indications, adverse effects, dosage, route of administration, and intervals between doses. This workshop was one of the most interesting from the researcher’s point of view, since health professionals could understand the reasons for not keeping the NB sedated all the time. This was a disagreement and dissatisfaction point of the nursing team with the doctor, since the doctors, in some situations, denied the request of sedation, and the team did not understand the reason for this denial.

In the end, the drugs of first choice in the unit were confirmed, namely: Fentanyl, Paracetamol, Lidocaine and Midazolam.

The 5th workshop discussed the non-pharmacological methods used for treating pain in neonates and the sensory load related to painful procedures. This workshop aimed at presenting, based on scientific evidence, the consequences of painful procedures for NB, in the medium and long term, and also non-pharmacological methods used for analgesia in neonates.

After presenting the goals, professionals were requested to divide into pairs for the reading of scientific articles. After, the discussion of situations identified in the reading was raised through the problematization of known clinical cases of neonates hospitalized in the Neonatal ICU. Thus, the following aspects were discussed:

1. **Non-pharmacological methods**: facilitated containment, winding, non-nutritive sucking, parental involvement, skin-to-skin contact, breastfeeding. International researchers do not consider the use of 25% glucose as non-pharmacological analgesia, since it has an endogenous opioid action.

2. **Consequences of prolonged exposure of the newborn to painful procedures**: medium and long term, such as: increased sensitivity to pain, delayed cognitive development, among others.

3. **Stressful factors for the RN**: luminosity, noise, and excessive manipulation.

During the discussions, the professionals expressed that NBs are handled a lot and do not have time to rest. Thus, they stressed the importance of including in the Protocol: the restricted handling and grouped by all professional categories, considering the “sleep time”; with the reduction of environmental noises.

To finish, the video: “Be sweet with the babies” was presented, which demonstrates the performance of painful procedures with the non-pharmacological analgesia and their benefits provided to the newborn. This video is at the page “Painless newborn” of the social network Facebook. The participants expressed awareness with the film, and being committed to analgesia.

Now, beginning **Phase III** called “implementations of actions”, two workshops were held, which defined all painful and stressful procedures that would be in the Protocol and, in the last workshop, the protocol was submitted for approval by the group and reformulations.

The goal of the 6th Workshop was defining procedures considered painful and stressful, and listing adequate analgesia to be applied in the Protocol. This carried out an outline of all the content that should be in the Protocol for Pain Management of Neonates in Neonatal ICUS.

For the optimization of time, health professionals were suggested to divide into groups corresponding to professional categories (nurses, nursing technicians, physical therapists and doctors).
Each group was responsible for listing procedures associated to measures of (pharmacological or non-pharmacological) analgesia, according to the classification of procedures of Anand (2005): mild invasive, moderate invasive and severe invasive, adopted in this Research for the Protocol.

Therefore, after presenting the consensus of each group and discussion with all participants, the preliminary draft of the protocol was defined in the following way:

1. **Measures to reduce the NB stress and discomfort**: agreement on the “sleep time” (12:30 - 14:30 and from 24h - 04h); reduced light during shifts; maintenance of incubator coverage with dark tissues to reduce direct luminosity in the NB eyes; reduction of alarm levels of incubators, infusion pumps, and cardiac monitors; restricted and grouped management to all NBs (according to the NB tolerance); days stipulated for weighing and bathing, according to gestational age and weight.

2. **Selections of painful and stressful procedures**:
   - **Mild invasive**: tracheal aspiration; aspiration of upper airways; umbilical catheter; gastric probe; extubation; adhesive removal; bath and weighing.
   - **Moderate invasive**: intramuscular injection; tracheal intubation; arterial, venous and calcaneal puncture; peripherally inserted central catheter (PICC);
   - **Severe invasive**: eye fundus examination; lumbar puncture; immediate postoperative; thoracic drainage and phlebotomy.

3. **Choice of non-pharmacological measures for each procedure**: Winding; Facilitated containment; Non-nutritive sucking; Skin-to-skin contact; Breast-feeding; Presence of family members during procedures.

4. **Choice of pharmacological measures**: 25% Glucose.

   The group stated that, due to the presence of only one medical professional, the in-depth discussion about the pharmacological analgesia was not possible, so that the first version of the Protocol will address only the 25% glucose as drug for analgesia.

   Finally, in the 7th Workshop, the multiprofessional team performed the presentation, evaluation and consolidation of the Protocol. The goal was to present, discuss together, and confirm the Protocol with the strategies developed during all the previous workshops, and that could be used for pain and stress management in neonates in the Neonatal ICU. There were less professionals due to clearances of five of them and a premium leave, a fact that did not invalidate the completion of the workshop.

   The Protocol with the final wording made by the researcher, based on the conclusions and records of all previous Workshops, was designed with multimedia, so that everyone could accompany the reading, discuss each section and suggest adjustments, which were few. And, concomitantly with the development of workshops, they were able, during the professional practice, to reflect the care to minimize Pain and Stress, a fact that has meant a great achievement of this Action-Research since this was not previously common.

   The present professionals mentioned believing that the Protocol will bring many changes to the daily professional practice, contributing to the better development of NB. They reported enjoying participating in this collective construction of knowledge, based on scientific evidence, and that the discussions linked to experiences brought major contributions.

**4 Discussion**
Professionals were interested and participative throughout the workshop period, presenting their doubts and suggestions, and that the workshops have provided a new view for the pain suffered by neonates.

Clinical protocols are technological tools for care, and professionals who work with practices that involve human care need to develop strategies to carry out this care creatively and dynamically, based on scientific evidence, to assure adequacy and full utilization of their care activities (Moraes, 2013).

Many studies have demonstrated the absence of evidence-based protocols and guidelines for pain assessment, using validated scales and pharmacological and non-pharmacological measures to alleviate neonatal pain systematically (Christoffel et al., 2017; et al., 2014). The lack of institutional protocols and adequate training for managing neonatal pain are the main barriers in the control of pain in neonatal ICUs (Schultz, Loughran-Fowlds & Spence, 2010).

The use of protocols for neonatal pain and stress management is important to guide professional practice. A Brazilian intervention study carried out at a Neonatal ICU in Recife, Brazil, with professionals from the multiprofessional team of direct care to the NB, aimed to verify the professionals’ knowledge about neonatal pain management before and 15 months after implementing a care protocol. As a result, there was a change in pain management after implementing the protocol, reported by 79.6% of health professionals. However, the authors emphasized that many changes are still necessary for the adequate management of pain in that Neonatal ICU (Aymar et al., 2014).

In view of this, this was a pioneering study in the area of neonatal intensive care in the country, using action research as methodology for developing an instrument by the multiprofessional team for the adequate management of pain and stress in neonatal ICU. The protocol was developed by the multiprofessional team based on questions arising from the collection of information on the knowledge and practices of the team itself, since it included the procedures they considered painful with the appropriate specific recommendations of measures for pain relief (Carbajal, Gréteau, Arnaud & Guedj, 2015; Gray, Garza, Zageris, Heilman & Porges, 2015).

The implementation of actions to reduce neonatal pain and stress regarding routine procedures was relevant since discussions showed that neonatal intensive care unit is a stressful environment for the newborn due to brightness, intense noises and frequent manipulations (Jordão, Pinto, Machado, Costa & Traiano, 2016).

Even questioning the validity of that study, after learning the importance and necessity of these scales, new scales for the Neonatal ICU were necessary, in order to evaluate pain effectively, based on the best evidence. Furthermore, considering that the scale adopted in the sector was not used properly, its results were not reliable (Costa et al, 2017; Foster et al., 2013).

Pimenta, Pastana, Sichieri, Solha and Souza (2015) emphasized the importance of the validation of the protocol by the professionals who will use it, for its acceptance and incorporation into the work process. Moreover, the authors confirm the need to include these professionals in the elaboration of the instrument.

Another quite striking consideration of protocol is the degree of satisfaction achieved with it. In this sense, Leyser (2012) warns that measuring the satisfaction of teams and institutions depends on the protocol resulting from a multidisciplinary process and the active participation of professionals who will use it. Furthermore, it should have the following attributes: clarity, precision, reliability and reproducibility, achieve expected results and costs, be documented effectively and be periodically reviewed.

Thus, the elaborated protocol aimed to minimize the dichotomy between theory and practice evidenced in several studies (Lago et al., 2013; Johnston, Barrington, Taddio, Carbajal & Filion, 2011). The use of the action-reserach methodology, although consisting of several approaches of the
participants, provided a critical evaluation and reflection on the importance of the theme “neonatal pain” by the professionals involved in the care.

5 Final Thoughts

Performing a situational diagnosis allowed developing workshops for discussions and reflections on the scientific evidence that would contribute to the elaboration of a multidisciplinary protocol for pain management in the Neonatal ICU.

Some limitations of this study were the non-participation in all the workshops of the same professionals, and that the medical professional participated in only three workshops. However, the multiprofessional representation was relevant because of the limitation of studies involving health professionals from various categories in the approach of pain in neonates, a fact that may have impacted positively on data discussion.

The discussions and the participatory development of the Protocol showed that the biggest failure relates to knowledge. Although a participant had reported, in the First Phase, having the knowledge, this knowledge was inconsistent, based on the best evidence, to generate safety in professional practice focused on the management of pain in neonates.

Intitutional permanent education can systematize the care provided by health professionals to NB, to guarantee the care quality, and may favor a Multidisciplinary Protocol for Pain and Stress in newborns, as collective construct.

This research has contributed to analyze NB pain management in the research scenario, with the elaboration of the protocol based on the best evidence that catalyzed the process of reflexive interaction of the multiprofessional team about the theme. The final product, when implemented, will improve the quality of the provided care, assuring the reduction of sequels to NB caused by pain and stress during the hospitalization. The suggested continuity is the validation of the developed assessment instrument, as well as the survey and record of the difficulties, to be minimized at an opportune time.

References


