ORIGINAL ARTICLE

Brazilian adaptation and validation of the Empowerment of Parents in the Intensive Care-Neonatology (EMPATHIC-N) questionnaire

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Abstract

Objectives: Considering the lack of questionnaires that propose to evaluate parental satisfaction with the Neonatal Intensive Care Unit (NICU) in Brazil, this study aimed to carry out the translation of the EMPATHIC-N questionnaire into Brazilian Portuguese, the cross-cultural adaptation and validation of its contents.

Method: The translation and cultural adaptation of the questionnaire was carried out according to the protocol established by the Translation and Cross-Cultural Adaptation Group of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) in 2005. The validation of the content was carried out by a panel of experts, who evaluated each item from “very irrelevant” to “very relevant”. Items with a mean Likert scale value <3.5 were excluded. Cronbach’s alpha of the domains was calculated.

Results: The questionnaire was submitted to two pilot tests with mothers of newborns admitted to the NICU of the study, after which some terms were modified to achieve global understanding. Cronbach’s alpha remained above 0.7 in all items.

Conclusion: The tool resulting from the translation, cultural adaptation, and validation of the EMPATHIC-N questionnaire showed to be adequate to assess satisfaction of parents of newborns admitted to the NICU in Brazil.

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Adaptação brasileira e validação do questionário Empowerment of Parents in the Intensive Care-Neonatology (EMPATHIC-N)

Resumo
Resultados: Na tradução foi invertida a ordem de algumas frases de acordo com a sintaxe do português brasileiro e alterado o tempo verbal para terceira pessoa do pretérito imperfeito. A maior parte das afirmativas manteve o sentido com a retradução, sendo as diferenças atribuídas a utilização de sinônimos pelos dois tradutores. Foi submetido a dois testes piloto com mães de recém-nascidos internados na UCIN do estudo, modificando-se alguns termos até atingir compreensão global. O alfa de Cronbach permaneceu acima de 0,7 em todos os itens.
Conclusão: O instrumento resultante da tradução, adaptação transcultural e validação do EMPATHIC-N mostra-se adequado para avaliar satisfação dos pais de recém-nascidos internados em UCIN no Brasil.

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Introduction

From the perspective of family- and patient-oriented Medicine, the parents’ perception and satisfaction about their children’s care is considered quality measures for the evaluation of care.1,2 A literature review found four tools in the English language related to parents’ satisfaction with the neonatal intensive care unit (NICU): the Neonatal Index of Parent Satisfaction (NIPS) scale, the Neonatal Intensive Care Unit—Parent Satisfaction Form (NICU—PSF) questionnaire, the Parental Stress Scale: Neonatal Intensive Care Unit (PSS:NICU) scale, and the EMpowerment of PARENT in THe Intensive Care-Neonatology (EMPATHIC-N) questionnaire.3

The NIPS is a 27-item questionnaire, divided into three areas: quality of care, communication, and attitudes in care/personality. However, this scale most often focuses on the frequency of events in the NICU rather than the parents’ opinion regarding care.4 The NICU—PSF addresses the concepts of overall satisfaction, continuous communication, information, preparation, participation in care, support for decision-making, spiritual needs and closeness in care, and monitoring. Its validity was established by content validity and internal consistency analysis in five of its nine evaluated scales, but there are questions about the quality of the sample used for validation.5 The PSS:NICO is a questionnaire adapted from experience in pediatric units, whose purpose is to evaluate the stressful experiences in the parents, rather than their satisfaction with their children’s care.6

The Dutch questionnaire EMPATHIC-N was developed from an initial list of 92 parental satisfaction indicators with neonatal intensive care, generated from a literature review and expert opinion obtained using the Delphi method in two stages. These items were evaluated by parents and caregivers, selecting 67 items, divided into five domains: information, care & treatment, organization, parental participation, and professional attitude. Each item is answered using a scale from one (1), "certainly not" to six (6), "certainly yes", in addition to the alternative "does not apply". Four open questions were also added for overall satisfaction assessment, a section for demographic information and a free space for parents to express their experiences.6 Among the satisfaction indicators regarding the provided care, communication between the NICU professionals and parents is highly valued, as it is one of the pillars of family- and patient-oriented medicine, supporting the sharing of information honestly and completely, to stimulate the participation of parents in decision-making.7

The evaluation of the EMPATHIC-N psychometric tests was carried out in two cohorts of parents of patients in a Dutch NICU; during this process, 10 items were excluded, resulting in 57 items. The internal consistency was evaluated, which showed an adequate level of reliability in all domains, with Cronbach’s α test >0.8. Spearman’s correlation test evaluated the congruent validity between the domain level and overall satisfaction, which showed to be satisfactory. Moreover, a non-differential effect was verified between the demographic variables and domains.8
Despite the importance of assessing parental satisfaction with neonatal care in any population, there are no validated instruments published in Portuguese with this purpose. This study translated the EMPATHIC-N questionnaire content into Brazilian Portuguese, and performed its cross-cultural adaptation and validation.

Method

The methodological work of translation, cross-cultural adaptation, and validation of EMPATHIC-N content was carried out from March 2013 to December 2014, in the NICU of Instituto de Medicina Integral Prof. Fernando Figueira (IMIP). IMIP is a tertiary hospital in the city of Recife, state of Pernambuco, Brazil, which has a multi-professional team, providing assistance exclusively to users of the Brazilian Public Health System (SUS). In IMIP, in 2014, there were 5846 live births and 29.3% of them were preterm newborns. The NICU has 50 beds, with a mean daily occupancy of 86.9%, mean number of admissions of 139 patients/month, and mean length of stay of 9.3 days.

The translation and cultural adaptation was carried out according to the method proposed by the Translation and Cross-Cultural Adaptation Group of the International Society for Pharmacoconomics and Outcomes Research (ISPOR) in 2005. This method was suggested by the author of the EMPATHIC-N questionnaire, after authorizing the translation and cultural adaptation. The ISPOR proposes the following steps: Preparation, Translation, Reconciliation, Back-translation, Review of Back-translation, Harmonization, Comprehension Test, Review after Comprehension Test, and Final Review (Fig. 1).

The translation consists of the creation of two translated versions, one by a Brazilian individual with knowledge of the English language (V1) and the other by a British individual (V2). V1 and V2 were analyzed by the translators, and a single version in Portuguese (V3) was created in the Reconciliation stage. In the Back-translation step, V3 was translated back into English (V4) by two translators, one Brazilian and one whose native language was English. The Review of Back-translation step was carried out by comparing the V4 with the EMPATHIC-N questionnaire. The differences were discussed in the Harmonization step, which resulted in the Portuguese version V5.

In the Comprehension Test step, V5 was applied to parents whose children had stayed for more than 48h in the NICU. The questionnaire was answered during hospitalization in the NICU and the parents were selected by consecutive sampling. Parents were excluded when they declared to be illiterate or had children who had died. The parents signed the Free and Informed Consent (FIC) form and were asked to read, answer, and interpret the questions. The analysis of all answers was carried out by the same researcher. An item was considered not understood when more than 15% of parents reported not understanding the question or mistakenly interpreted its meaning.

The items that were not understood were adjusted at the Review step, after the Comprehension Test, and the adjustments resulted in the final Portuguese version V6. In the Final Review, adjustments related to typos, grammatical, and layout errors of the questionnaire were carried out.

The Content Validation of the final version was performed by expert consensus. The sample consisted of all college/university level employees of the NICU-IMIP who were working during the study period. Employees were excluded if they were on vacation or leave, or attending a residency program. The members of the multidisciplinary team of NICU-IMIP were considered experts, consisting of 41 neonatologist physicians, nine nurses, two psychologists, one speech therapist, and 12 physical therapists, totaling 65 professionals. This number of professionals is higher than the number reported in other studies (ten to 20 professionals) to constitute the panel of experts.

After reading and signing the informed consent form, the experts answered a questionnaire evaluating the relevance of each of the 57 items of the final version (V6) included in a parental satisfaction assessment questionnaire in the NICU. A Likert scale with five points was used for the answers, with 5 being “very relevant” and 1 “very irrelevant”. Space was also provided for qualitative observations.

The data in this step were entered in duplicate using Excel 7 software (Microsoft, WA, USA) and validated in EpiInfo 3.5.3 (Centers for Disease Control and Prevention, USA). STATA software (StataCorp. 2011. Stata Statistical Software: Release 12. College Station, TX, USA) was used for data analysis, providing frequency distribution, mean, and standard deviation per item, whereas the internal consistency analysis of the items was analyzed by calculating Cronbach’s alpha coefficient for each domain. The items with mean responses higher than or equal to 3.5 were maintained in the final version of the parental satisfaction assessment tool.

The study met all ethical aspects according to Resolution No. 466/12 of the National Health Council and was...
approved by the Research Ethics Committee of the IMIP, CAE: 18419913.8.0000.5201.

Results

The translation of EMPATHIC-N was carried out as proposed. During the preparation of V3, the order of a few sentences was inverted according to the syntax of Brazilian Portuguese and the verb tense was changed to the third person singular, using the past continuous tense equivalent in Portuguese, which is more common in informal speech. The most common term was chosen for those that had synonyms. During the Review of the Back-translation of V4, the EMPATHIC-N was jointly compared by the researchers and translators regarding the semantic equivalence. Most statements retained the correct meaning after the back-translation, with differences being attributed to the use of synonyms by the two translators.

The statement “We received sympathy from the doctors and nurses” was modified after comparison with the back-translation. Considering that “Sympathy” could be translated as “compassion”, “solidarity”, or “understanding”, it was considered more appropriate to translate the phrase to “The doctors and nurses showed solidarity”. At the final evaluation, “How would you rate our performance in general?” was translated to “How would you rate the overall performance of our unit?” to make it clear to the respondent that the question was related to the work of the professionals in the NICU.

The layout, order, and division of items by topic of the EMPATHIC-N were maintained in the Portuguese version V5, which was submitted to two comprehension tests. The interviewees were mothers with a mean age of 28 years, all of mixed-race ethnicity and with more than eight years of schooling, but none had a college/university degree. After interviewing eight mothers, their interest was observed regarding the assessment of the service, with verbalization of their complaints and compliments. Most had difficulty differentiating nurses from nurse technicians, which could modify the assessment.

There was a predominance of extreme responses (1 or 6), which was attributed to the mothers’ difficulty in using the Likert scale. Thus, it was decided to add characters to the scale, with faces expressing satisfaction or dissatisfaction, which was reported to and accepted by the author of the original questionnaire.

It was observed that questions 41 and 55 were not answered coherently. Question 41 addressed the fact of receiving an explanatory leaflet, but the assessed NICU does not have this material, making it impossible to review this item. As for question 55, it addressed the “cultural background”, which was not understood by the interviewees, as it is not compatible with this context.

The difficulty in understanding some items led to the substitution of words or expressions by equivalents that were easier to understand, or to changes in the order of sentences. Examples were added to some items (Fig. 2). The term NICU was replaced by intensive care unit (ICU), as this is the term most often used in Brazil.

After the changes were carried out in the questionnaire, this version was submitted to a second Comprehension Test with five mothers. At this step, before the questionnaire was handed to them, the difference regarding the function between the professionals was clarified and the explanation of the Likert scale was reinforced. This test showed complete understanding of items and more varied responses in the Likert scale.

At the Content Validation step, of the 65 professionals, ten were excluded because they were residents, and 55 questionnaires were handed out, of which 40 (72.7%) were returned, consisting of 20 neonatologist physicians, 11 nurses, one psychologist, one speech therapist, and seven physical therapists. In the group of experts, 95% had a postgraduate degree in the area and a mean of 10.6 years of experience in neonatology. Only one professional filled out the space intended for qualitative observations.

The mean and standard deviation of responses were calculated, as shown in Fig. 3. Items 32 “Even during invasive procedures, we could always stay close to our child” and 40 “It was easy to talk to the ICU by telephone” were excluded, as they obtained a mean lower than 3.5. The reliability of the data collection instrument was assessed using the internal consistency of items by calculating Cronbach’s alpha coefficient. All domains obtained values >0.7 (Fig. 4). After excluding items 32 and 40, Cronbach’s alpha was recalculated, remaining >0.7 in all of them.

After these steps, the adapted, translated, and validated parent satisfaction assessment tool for the NICU in Brazil was obtained, consisting of 53 items plus four open questions, keeping the layout and the division by sub-items of the original questionnaire, but with characters representing the Likert scale.

However, at the review step, it was decided to reintroduce the items that had been excluded during the process of cultural adaptation, with a total of 57 items in the final questionnaire, in addition to the four open questions for overall assessment of satisfaction, a section for demographic information, and a space for parents to freely express their experiences.

Discussion

The study carried out the translation into Brazilian Portuguese, cross-cultural adaptation, and validation of the content of the EMPATHIC-N questionnaire.

The Comprehension Test was performed with mothers to make it accessible to the assessed population, as the EMPATHIC-N is self-applied and was developed in the Netherlands, which has a different socioeconomic and cultural profile, with low social inequality and easy access to health services.15

When assessing the profile of pregnant Brazilian women, as shown in the “Nascendo no Brasil” study carried out from 2011 to 2012, it identified women with a mean age of 25.7 years, of whom 18.2% were adolescents and 10.5% were 35 years or older. Of the respondents, 73.5% had at least eight years of schooling and only 8.9% of them had a college/university degree.16 The 2014 IMIP epidemiological data show a similar profile, with 22.6% adolescent mothers and 90.5% with more than eight years of schooling.8
In the Netherlands, the presence of immigrant populations, with cultural diversity and language barriers in the NICU environment, can lead to increased maternal stress if the situations are not well managed. In spite of the proven importance of this issue, the pilot test demonstrated that the question "Our cultural background was taken into account" was not understood by the interviewees, and thus was excluded. This was likely due to the fact that there are no major internal cultural differences in the Northeast of Brazil, but it may possibly occur in other Brazilian regions, such as the North, where there are indigenous populations of different ethnic groups, or in the Southeast, where there are more immigrants.

The reliability of the data collection tool used for content validation by the expert panel was measured by analyzing the internal consistency of items through Cronbach’s alpha coefficient. Values >0.7 for all domains demonstrate its reliability in assessing the relevance of the items maintained in the tool final version. The statistical analysis of this phase resulted in the exclusion of two items.

One of the items addresses the permanence of parents during invasive procedures. Although the presence of parents is supported by the literature, the experts did not consider the presence of this item to be relevant in the assessment of parental satisfaction, which may reflect a habitual custom of some neonatal units. The American Heart Association, however, recommends that it should be a family decision regarding whether or not to be present at the time of cardiac resuscitation.

The other item "It was easy to talk to the ICU by telephone" received a negative assessment, probably due to the fact that it is not customary to give information by phone in the NICU-IMIP, in order to encourage the participation of parents and prevent inadequate understanding of information. However, this practice may be present in other health services to facilitate communication, which is often
Brazilian adaptation of the EMPATHIC-N questionnaire

<table>
<thead>
<tr>
<th>Item</th>
<th>F4+5</th>
<th>Média</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Todos os dias os médicos e enfermeiros conversavam conosco sobre os cuidados tratamentos de nossa criança.</td>
<td>95</td>
<td>4,65</td>
<td>+0,69</td>
</tr>
<tr>
<td>2. Os médicos e enfermeiros respondiam claramente nossas perguntas.</td>
<td>95</td>
<td>4,78</td>
<td>+0,69</td>
</tr>
<tr>
<td>3. As informações dadas pelos médicos e enfermeiros sempre eram parecidas.</td>
<td>75</td>
<td>4,1</td>
<td>+1,12</td>
</tr>
<tr>
<td>4. Sempre que nossa criança piorava, os médicos e enfermeiros nos informavam imediatamente.</td>
<td>90</td>
<td>4,58</td>
<td>+0,74</td>
</tr>
<tr>
<td>5. Os médicos e enfermeiros sempre davam informações claras sobre a doença de nossa criança.</td>
<td>90</td>
<td>4,58</td>
<td>+0,90</td>
</tr>
<tr>
<td>6. Os médicos sempre nos informavam claramente sobre os efeitos do tratamento de nossa criança.</td>
<td>85</td>
<td>4,43</td>
<td>+0,90</td>
</tr>
<tr>
<td>7. Os médicos e enfermeiros davam informações compreensíveis ao examinar a criança.</td>
<td>87,5</td>
<td>4,53</td>
<td>+0,93</td>
</tr>
<tr>
<td>8. Os médicos e enfermeiros davam informações compreensíveis sobre os efeitos das medicações.</td>
<td>70</td>
<td>3,88</td>
<td>+1,18</td>
</tr>
<tr>
<td>9. Os médicos nos informavam sobre a evolução esperada na saúde de nossa criança.</td>
<td>85</td>
<td>4,35</td>
<td>+0,89</td>
</tr>
<tr>
<td>10. Os médicos e enfermeiros davam informações fáceis de entender.</td>
<td>90</td>
<td>4,65</td>
<td>+0,66</td>
</tr>
<tr>
<td>11. Os médicos e enfermeiros davam informações sinceras. Não escondiam a verdade.</td>
<td>87,5</td>
<td>4,5</td>
<td>+0,78</td>
</tr>
<tr>
<td>12. Os médicos e enfermeiros trabalhavam em conjunto.</td>
<td>80</td>
<td>4,45</td>
<td>+1,01</td>
</tr>
<tr>
<td>13. A equipe estava atenta à prevenção e tratamento da dor de nossa criança. (ex: crescimento, ganho de peso).</td>
<td>82,5</td>
<td>4,48</td>
<td>+0,98</td>
</tr>
<tr>
<td>14. Os médicos e enfermeiros são verdadeiros profissionais: sabem o que estão fazendo.</td>
<td>70</td>
<td>4,03</td>
<td>+1,36</td>
</tr>
<tr>
<td>15. A medicação correta sempre foi dada no horário certo.</td>
<td>77,5</td>
<td>4,25</td>
<td>+1,16</td>
</tr>
<tr>
<td>16. Os médicos e enfermeiros conheciam a história da doença denossa criança na chegada à UTI.</td>
<td>67,5</td>
<td>4,00</td>
<td>+1,21</td>
</tr>
<tr>
<td>17. Os médicos e enfermeiros prestavam atenção ao desenvolvimento de nossa criança. (ex: crescimento, ganho de peso).</td>
<td>77,5</td>
<td>4,25</td>
<td>+0,95</td>
</tr>
<tr>
<td>18. Quando havia piora das condições de saúde de nossa criança, os médicos e enfermeiros agiam imediatamente</td>
<td>97,7</td>
<td>4,93</td>
<td>+0,35</td>
</tr>
<tr>
<td>19. As necessidades (dificuldades) de nossa criança foram bem atendidas.</td>
<td>92,5</td>
<td>4,63</td>
<td>+0,80</td>
</tr>
<tr>
<td>20. A equipe tinha um objetivo em comum: dar o melhor cuidado e tratamento à nossa criança e a nós mesmos.</td>
<td>90</td>
<td>4,5</td>
<td>+1,03</td>
</tr>
<tr>
<td>21. Os médicos e enfermeiros levavam em conta o conforto de nossa criança.</td>
<td>87,5</td>
<td>4,40</td>
<td>+1,00</td>
</tr>
<tr>
<td>22. Todo dia sabíamos quem era o médico e o enfermeiro responsável pela nossa criança.</td>
<td>72,5</td>
<td>4,10</td>
<td>+1,17</td>
</tr>
<tr>
<td>23. Os médicos e enfermeiros nos davam apoio quando estávamos tristes.</td>
<td>72,5</td>
<td>4,00</td>
<td>+1,06</td>
</tr>
<tr>
<td>24. De formal geral, os médicos e enfermeiros nos atenderam bem quando tivemos alguma necessidade.</td>
<td>80</td>
<td>4,08</td>
<td>+0,97</td>
</tr>
<tr>
<td>25. A equipe era cuidadosa com nossa criança e conosco.</td>
<td>92,5</td>
<td>4,45</td>
<td>+0,95</td>
</tr>
<tr>
<td>26. Durante as situações de piora do quadro de nossacriança, sempre tivemos uma enfermeira para nos ajudar.</td>
<td>75</td>
<td>4,00</td>
<td>+0,98</td>
</tr>
<tr>
<td>27. Enquanto nossa criança estava na incubadora ou no berço sempre foi bem cuidada pelas enfermeiras.</td>
<td>85</td>
<td>4,38</td>
<td>+0,95</td>
</tr>
<tr>
<td>28. Tudo ocorreu bem quando o cuidado de nossa criança foi transferido dos profissionais da UTI para os colegas de outro setor.</td>
<td>80</td>
<td>4,25</td>
<td>+1,14</td>
</tr>
<tr>
<td>29. Nós participamos ativamente na tomada de decisão sobre os cuidados e tratamento de nossa criança.</td>
<td>50</td>
<td>3,55</td>
<td>+1,15</td>
</tr>
<tr>
<td>30. Fomos estimulados a ficar próximo de nossa criança.</td>
<td>92,5</td>
<td>4,63</td>
<td>+0,80</td>
</tr>
</tbody>
</table>

**Figure 3** Demonstration of frequency distribution of the relevant and very relevant answers (4 and 5), mean, standard deviation per item of the translated version of the EMPATHIC-N questionnaire applied to experts.
unsatisfactorily conducted in several situations. A study carried out in a Danish NICU in 2007 included interviews with 780 parents and identified the fact that it requires time to be able to talk with a doctor or nurse as the main communication complaint.

In the present study, the step consisting of the evaluation by the expert panel identified the importance of communication, as all the items from the group “Information” were assessed as relevant and maintained in the study.

The statement that addressed the presence of an explanatory leaflet was initially excluded, because there is no such practice in the assessed unit. This is a method used that allows a first contact of parents with the ICU, used in many countries, providing important information regarding their stay at the unit. A European study carried out in 125 neonatal units observed that 43% of parents reported not having received information about the unit and 46% did not receive clear information about the machines, monitors, and alarms used there. Therefore, this practice, although promising, does not yet show adequate coverage in most units.

Importantly, the item “We actively participated in the decision-making about the care and treatment of our child” showed only 50% “relevant” and “very relevant” answers. A systematic review assessing the needs of parents of newborns admitted to the NICU highlighted six primary needs,
Therefore, among them the adequate information and inclusion in care and decision-making related to the child.\textsuperscript{21} Therefore, it is clear that there are still flaws regarding the acknowledgment of basic concepts of patient- and family-oriented medicine by NICU professionals.

Four health team behaviors are suggested to meet the parents' needs: emotional support, parental empowerment, welcoming environment, and unit support policies and education of parents in practicing new skills through guided participation.\textsuperscript{22} All these issues are addressed in the EMPATHIC-N in the domains of information, care and treatment, parental participation, and organization.

The method proposed in this study would result in the exclusion of these four items of the questionnaire. However, the importance of these items, according to literature evidence, resulted in the re-evaluation of their exclusion. Considering the opinion of the original questionnaire's author, who was against the exclusion of items, it was decided to keep them.

The indication for the exclusion of these items by the proposed method does not seem to be related to methodological error, but to the incipience of the concepts of family and patient-oriented medicine in the assessed service. Routines such as telephone contact, presence of parents during invasive procedures, and the presence of explanatory leaflets are supported by the literature and should be encouraged. Therefore, the items were reintroduced in the final questionnaire, considering that the questionnaire can, in the future, be applied at different locations and that if these items cannot be applied, the alternative "does not apply" can be used.

After all the proposed steps, the EMPATHIC-N, of Dutch origin, is available in its Brazilian version, filling this gap in the literature. The importance of such a tool for its capacity to assess satisfaction is emphasized, which is considered one of the attributes of quality in healthcare\textsuperscript{22} and stimulate questioning about routines within the NICU, aiming at excellence in the offered service.

Further studies should evaluate the psychometric properties of the translated and adapted questionnaire. Regional characteristics that may influence the cross-cultural adaptation should be taken into consideration.

### Conflicts of interest

The authors declare no conflicts of interest.

### Acknowledgements

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164