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**Citation:** Schardosim, J., da Motta, G. & da Cunha, M. (2015). Neonatal Infant Pain Scale: Cross-Cultural Adaptation and Validation in Brazil. *Journal of Pain and Symptom Management*, 50(3), pp. 394-401. doi: 10.1016/j.jpainsymman.2015.03.019

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**Link to published version:** <https://doi.org/10.1016/j.jpainsymman.2015.03.019>

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# NEONATAL INFANT PAIN SCALE: CROSS-CULTURAL ADAPTATION AND VALIDATION TO BRAZIL

Cross-Cultural Adaptation of NIPS

## ABSTRACT

The Neonatal Infant Pain Scale (NIPS) was initially developed in Canada and, although it has been previously used in Brazil, the scale has not been adequately adapted and validated for use in the country. Therefore, the goal of the present study was to perform the cross-cultural adaptation and clinical validation of the NIPS for use in the Brazilian population. The instrument was adapted based on the method outlined by Beaton et al., including the production and combination of translated versions, back-translation, committee review and pilot testing. The psychometric properties of the adapted instrument, including its validity, reliability and internal consistency, were then evaluated in a clinical validation study. The sample consisted of 60 at-term newborns who were evaluated by six nurses as they experienced vaccination. The psychometric properties of the scale were evaluated using Student's t-tests, prevalence-adjusted bias-adjusted kappa (PABAK) scores, the Bland-Altman method and Cronbach's alpha coefficients. The Brazilian version of the NIPS was named the *Escala de Dor no Recém-Nascido (NIPS-Brazil)*, and demonstrated excellent inter- and intraobserver reliability. Total *NIPS-Brazil* scores yielded PABAK scores of 0.93, while the Bland-Altman method revealed inter- and intraobserver reliability values of 95% and 90%, respectively. The *NIPS-Brazil* had adequate internal consistency, as evidenced by a Cronbach's alpha of 0.762. The NIPS was successfully adapted for use in Brazil, and is now available for use in the assessment of acute pain in at-term newborns in Brazil.

**Key words:** Pain; Neonates; Pain Assessment; Translation; Validation Studies.

## INTRODUCTION

The study of pain has advanced considerably in recent years, and its evaluation and treatment have become a growing concern among health care workers. The International Association for the Study of Pain<sup>(1)</sup> has defined the construct as a subjective “unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of tissue damage,” which is modulated by life experiences. However, this definition does not entirely apply to newborns, infants and preverbal children, who are unable to verbally express pain and have no prior experience with painful sensations<sup>(2)</sup>. In order to account for this, the IASP also states that the “inability to communicate verbally does not negate the possibility that an individual is experiencing pain and is in need of appropriate pain-relieving treatment”<sup>(1)</sup>.

Neonates experience pain associated with immunizations and blood collection. Preterm or sick neonates are especially likely to undergo repeated or prolonged exposure to painful diagnostic, surgical or treatment interventions<sup>(3)</sup>. In fact, it is estimated that a neonate in a Neonatal Intensive Care Unit (NICU) experiences a mean of 12 painful procedures per day of hospitalization<sup>(4)</sup>.

Pain assessments can provide important information to guide the implementation of interventions which can alleviate or eliminate pain in newborns<sup>(2)</sup>. Such assessments should be performed at least once per shift on all neonates subjected to painful procedures<sup>(5)</sup>. The absence of verbal expressions of pain poses a major challenge for the assessment of this construct in neonates. Therefore, reliable and easy instruments for the assessment of pain in this population are essential to ensure optimal patient care.

Several scales have been developed for this purpose, and are often used before, during and after neonatal exposure to painful stimuli. The most effective and widely used scales for the assessment of pain in neonates are multidimensional, and assess both physiological and behavioral indicators of pain<sup>(6)</sup>. However, such instruments are generally produced in English-speaking countries, so that translation and cross-cultural adaptation is often required to enable their use in other locations. The cross-cultural adaptation of assessment instruments is a complex process which, in addition to the translation and adaptation per se, involves the assessment of the psychometric properties of the adapted instrument, such as its experimental and clinical validity, as well as its reliability<sup>(7)</sup>.

The Neonatal Infant Pain Scale (NIPS)<sup>(8)</sup>, which was published in 1993, was developed based on the Children’s Hospital of Eastern Ontario Pain Scale (CHEOPS) for the

assessment of pain in children aged between one and seven years. The NIPS assesses five behavioral – facial expression, cry, arms, legs and state of arousal – and one physiological factor – breathing patterns, each of which contains two items which are assigned scores of 0 or 1 (save for the crying factor, which is composed of three items and scored on a scale of 0 to 2). Each item also contains a brief operational definition. The scale yields a total score ranging from 0 to 7, where scores over 3 are indicative of pain<sup>(8)</sup>. The NIPS is easily understood and applied, and consists of a useful tool for health professionals who work with neonates exposed to painful stimuli.

Although the NIPS is widely used in several countries including in Brazil, no studies have described its cross-cultural adaptation and clinical validity for use in the country.

Using an adapted and validated scale ensures the reliability and effectiveness of pain assessment, which may not occur when a scale is freely translated. The utilization of a validated scale allows a reliable and systematic pain assessment, which is the first step in the process of managing newborn pain within a clinical protocol.

Therefore, the goal of the present study was to perform the cross-cultural adaptation of the NIPS for use in Brazil, and to assess the clinical validity of the adapted instrument. The process included translation and adaptation of the instrument to the Portuguese spoken in Brazil and evaluation of the psychometric properties.

## **METHOD**

The present study consisted of two stages: cross-cultural adaptation and clinical validation. The cross-cultural adaptation process followed the five main steps outlined by Beaton et al.<sup>(7)</sup>: production and alignment of multiple translations, back-translation, committee review and pre-testing. These steps were performed in order to ensure that the content and validity of the original instrument were preserved in the adaptation process. After translation and adaptation, statistical analyses were performed to evaluate the psychometric properties of the translated instrument, with a focus on its clinical validity; that is, its ability to assess what it was designed to measure<sup>(7,9)</sup>. The clinical validity of the instrument was evaluated through a cross-sectional study. All data collection was performed in a NICU in a university hospital in Southern Brazil, between September 2011 and January 2013.

The translation and validation of the NIPS for use in Brazil were authorized by the author of the original instrument, as well as by the Children's Hospital of Eastern Ontario, which currently holds the copyright for the scale. The present study was also approved by the Research Ethics Committee of the Clinical Hospital of Porto Alegre under protocol number

11-0343. All research subjects, including health care workers and the parents of the newborns, provided written consent for participation in the study.

The first stage of the present study involved the translation and cultural adaptation of the NIPS for use in Brazil. This process began with the translation of the NIPS from English to Brazilian Portuguese, which was performed by two bilingual translators with Brazilian Portuguese as their first language. Each translator worked independently, and directed all observations and comments regarding the translation process to the researchers. The two translations were then compared and combined into a draft version in Brazilian Portuguese<sup>(7)</sup>, which was then independently back-translated<sup>(10)</sup> into English by two bilingual translators with English as their first language. Back-translation is a means to ensure the content equivalence between the original and adapted versions of an instrument, and to identify semantic equivalence issues<sup>(7)</sup>. Although the method proposed by Beaton does not involve the combination of multiple back-translations, the researchers felt that this procedure would make a significant contribution to the adaptation process. The combination of the two back-translations of the NIPS was then sent to the author of the original instrument for comparison with the original scale.

A panel of expert judges was asked to assist with the cross-cultural equivalence process. The panel was composed of a university professor with expertise in the cross-cultural adaptation of assessment instruments, a nurse specialized in pain management, a language worker as well as the researchers themselves. These individuals were asked to combine all versions of the instrument, producing a final version of the Brazilian NIPS which would be equivalent to the original in four areas<sup>(7)</sup>: a) *Semantic equivalence*: similarity in word meanings between the original and translated instruments; b) *Idiomatic equivalence*: identification of idiomatic expressions in Brazilian Portuguese which could be used in the place of difficultly translated expressions in English; c) *Experimental equivalence*: adequacy of translated items to culture and daily life in Brazil; d) *Conceptual equivalence*: ability of the translated version of the instrument to adequately address the cultural dimensions of the original scale.

Item clarity<sup>(7)</sup> in the preliminary version of the instrument was then evaluated by 32 health care workers of the NICU, including doctors, nurses, nurse technicians and physical therapists. These individuals were asked to rate the clarity of each item of the translated NIPS on a Likert scale, where one corresponded to "not at all clear," two to "slightly unclear," three to "clear", four to "very clear" and five to "totally clear". The sample was randomly selected using a number table and the list of NICU employees. Each subject was provided with a

manila envelope containing the preliminary version of the translated NIPS and the Likert scales.

In the second stage of the study, the validity, reliability and clinical use of the instrument were assessed. Data was collected with the help of six NICU nurses, who were asked to administer the scale to a sample of newborns in blinded pairs. The reliability of an assessment instrument is defined as its ability to produce consistent results upon repeated testing, and is associated with the instrument's coherence, precision, stability, and homogeneity. That is, reliable instruments are expected to produce similar results when used to evaluate temporally stable behaviors on more than one occasion or by more than one rater<sup>(11)</sup>.

Data were collected in the NICU of the Clinical Hospital of Porto Alegre, a university hospital of the Federal University of Rio Grande do Sul, Brazil. The sample consisted of neonates who received hepatitis B vaccines in the admissions room. According to Brazilian health legislation, the first dose of this vaccine is to be administered by intramuscular injection immediately after birth, preferably in the first 12 hours of life<sup>(12)</sup>. In the unit where the study was performed, healthy newborns are vaccinated in the first two hours of life. Selection criteria for the inclusion of newborns in the study were: 37 0/7 weeks of gestation through 41 6/7 weeks of gestation, being considered healthy as per their first clinical exam, and first and fifth-minute Apgar scores  $\geq 7$ , since lower scores may be associated with alterations in the central nervous system pain processing mechanisms<sup>(13)</sup>. Additionally, the following exclusion criteria were applied: maternal use of opiates or general anesthesia during labor, since these substances may cross the placental barrier and cause changes to neonatal nociceptive pathways<sup>(13)</sup>; maternal use of alcohol or illicit drugs; absence of prenatal care; caesarian births; mother younger than 18 years without the presence of a legal guardian; mother with vertically transmissible infectious diseases such as syphilis, toxoplasmosis, cytomegalovirus infections, mumps, herpes, hepatitis B and HIV/AIDS; newborns with visible congenital malformations or difficulties in the perinatal adaptation to neonatal life.

Sample size was calculated based on recommendations for validation studies, which suggests the need for ten observations for each variable analyzed<sup>(14)</sup>. Since the scale had six main variables, a total sample of 60 neonates was recruited.

The mothers or fathers of eligible newborns were invited to take part in the study and sign the consent form in the post-partum recovery room or in the neonatal admission room. Upon arriving in the admissions room, the neonate is generally placed in a heated crib, where vital signs and anthropometric measures are obtained. The hepatitis B vaccine is administered

once the newborn is thermally stable. All vaccines were administered by a nurse in a standard fashion, in the medial third of the vast lateral muscle of the right thigh. All vaccinations were video recorded using a 10.2 megapixel Samsung S1070 camera set to film. The entire body of the neonate was filmed during vaccination.

The videos were later evaluated by six NICU nurses who were invited to take part in the study. Each nurse received a CD-R with the videos of 10 neonates, whose pain levels they were asked to evaluate using the translated and adapted version of the NIPS. The videos were reevaluated by the same researchers after 15 days. The nurses also received an additional 10 videos which had been previously evaluated by other nurses. Care was taken to ensure that each individual received videos which had been evaluated by all other nurses, so as to avoid one-to-one correspondences between raters. This procedure allowed for the evaluation of the interobserver (test) reliability of the instrument, while the 15-day reassessment would provide data on its intraobserver (retest) reliability. Raters were blind to the scores assigned by other nurses and received minimal instructions for the use of the instrument, consisting of general information on each item of the scale upon first receiving the videos and assessment instruments. All participant questions were addressed at this time. The nurses were allowed to evaluate the videos in a location of their preference.

The results of the clinical validation process were entered and analyzed using the Statistical Package for the Social Sciences (SPSS), version 18.0. Continuous variables were described as means and standard deviation or median and interquartile ranges. Categorical variables were expressed as absolute and relative frequencies. All tests were performed at a 5% significance level ( $p < 0.05$ ). Student's t-tests for paired samples were used to compare mean intra- and interrater scores, and Prevalence-Adjusted and Bias-Adjusted Kappa (PABAK) were used to evaluate intra- and interrater agreement for each item in the NIPS. Kappa values range from 0 to 1, where scores closer to 1 are indicative of higher agreement. Values below 0.20 suggest poor interobserver agreement, while scores of 0.21 to 0.40 are indicative of reasonable agreement, scores of 0.61 to 0.80 suggest good interobserver agreement, and scores between 0.81 and 1 indicate very good interrater agreement<sup>(15)</sup>. The Bland-Altman method was used to calculate the intra- and interobserver reliability of total NIPS scores (continuous variables)<sup>(16)</sup>. The internal consistency of the instrument was evaluated using Cronbach's alpha, whose values range from 0 to 1, with 0.7 generally set as the minimum acceptable level for internal consistency<sup>(14)</sup>.

## RESULTS



The steps in the translation and adaptation process are described in Table 1. Once the initial translations were combined, the resulting document was back-translated into English. The back-translations of the scale were very similar to its original English version. The term “whimper” in the Portuguese version of the scale (“choro fraco”) was translated to whimper and soft cry. The latter term was selected due to its similarity to the equivalent term in Portuguese. The Portuguese word for “indrawing” was translated as “retractions” by both translators. However, the Medical Entities Dictionary (2007) defines retraction as the backward or inward movement of an organ or part, which does not adequately express the meaning of the original item. This discrepancy was also noted by the author of the original scale, who observed that the term “retraction” is not used in the English language to refer to respiratory difficulty. Therefore, in this item, the term was replaced by the word “indrawing.” The Portuguese term for “fussy” (“agitado”) was translated to either fussy or agitated. Although “agitated” would be a more accurate translation of the Portuguese term, the word “fussy” provides a more semantically adequate representation of the restless or anxious behaviors observed in neonates during exposure to painful stimuli.

Once the back-translated NIPS was approved by the author of the original instrument, a panel of expert judges evaluated the cross-cultural equivalence between the original and adapted versions of the NIPS. The changes made to the translated scale gave rise to the preliminary version of the Brazilian Portuguese NIPS. The professor with expertise in cross-cultural adaptation, the pain management specialist and the language professional received the original scale, the combined translation and back-translation of the instrument as well as all comments made by the translators and researchers throughout the process. The panel compared all versions of the instrument and discussed their idiomatic, experimental, conceptual and semantic equivalence. The latter variable was evaluated by classifying each word in the scale as having “exactly the same meaning”, “nearly the same meaning”, or “a different meaning” from the equivalent item in the original scale. At the end of this process, a preliminary final version of the Brazilian NIPS was developed.

The clarity of items in this version of the scale was then evaluated by another sample of health care workers using a Likert scale developed specifically for this purpose. This stage of the study involved the participation of physicians, nurses, nursing technicians and a physical therapist. A total of 87.5% of items in the scale were classified as "clear," "very clear" and "totally clear". Participants also made additional suggestions which were incorporated in the final version of the scale. The assessment of item clarity completed the adaptation process, resulting in the construction of the final version of the scale, which was

named the *Escala de Dor no Recém-nascido (NIPS-Brazil)*. The clinical validity of this scale was then evaluated in a cross-sectional study, whose results are described below.

**Table 1** – Original instrument, combined translations, combined back-translations and final version of the *NIPS-Brazil*.

Original Instrument	Combined translations	Combined back-translations	Final version
<b>Neonatal Infant Pain Scale (NIPS)</b>	<b>Escala de Avaliação da Dor no Recém-Nascido (NIPS-Brasil)</b>	<b>Neonatal Pain Evaluation Scale</b>	<b>Escala de Dor no Recém-Nascido (NIPS-Brasil)</b>
<b>Facial expression</b> 0 – Relaxed Muscles – Restful face, neutral expression 1 – Grimace – Tight facial muscles, furrowed brow, chin, jaw (negative facial expressions – nose, mouth, and brow)	<b>Expressão facial</b> 0 – Músculos relaxados – Face descansada, expressão neutra 1 – Careta – Músculos faciais contraídos; testa, queixo e maxilar franzidos (expressões faciais negativas – nariz, boca e testa)	<b>Facial expression</b> 0 - Relaxed muscles – Restful face, neutral expression 1 - Grimace – Contracted facial muscles; furrowed forehead, chin, and jaw (negative facial expressions – nose, mouth, and forehead)	<b>Expressão facial</b> 0 = Músculos relaxados – Face descansada, expressão neutra 1 = Careta – Músculos faciais contraídos; testa, queixo e maxilar franzidos (expressões faciais – do nariz, da boca e da testa)
<b>Cry</b> 0 – No cry – Quiet, not crying 1 – Whimper – Mild moaning, intermittent 2 – Vigorous cry – Loud scream, rising, shrill, continuous (Note: Silent cry may be scored if baby is intubated, as evidenced by obvious mouth, facial movement)	<b>Choro</b> 0 – Sem choro – Tranquilo, não chora 1 – Choro fraco – Gemido brando, intermitente 2 – Choro vigoroso – Grito alto, crescente, estridente, contínuo (Observação: O choro silencioso poderá ser considerado se o bebê estiver entubado, evidenciado por movimentos óbvios da boca e da face)	<b>Cry</b> 0 – No cry – Quiet, not crying 1 – Soft cry – Mild moan, intermittent 2 – Vigorous cry – Loud scream, rising, shrill, continuous (Observation: Silent cry may be scored if baby is intubated as evidenced by obvious mouth and facial movements)	<b>Choro</b> 0 = Sem choro – Tranquilo, não está chorando 1 = Choro fraco – Gemido fraco, intermitente 2 = Choro vigoroso – Choro alto, crescente, estridente, contínuo (Observação: Se o bebê estiver entubado, o choro silencioso é considerado quando evidenciado por movimentos óbvios da boca e da face)
<b>Breathing patterns</b> 0 – Relaxed – Usual pattern for this baby 1 – Change in breathing – Indrawing, irregular, faster than usual, gagging, breath holding	<b>Padrão Respiratório</b> 0 – Relaxado – Padrão usual para este bebê 1 – Alteração da respiração – Retrações, respiração irregular, mais rápida do que o usual, engasgo, pausa respiratória	<b>Breathing Patterns</b> 0 – Relaxed – Usual pattern for this baby 1 – Change in breathing – Indrawing, irregular breathing, faster than usual, gagging, holding breath	<b>Padrão Respiratório</b> 0 = Relaxado – Padrão usual para este bebê 1 = Alteração da respiração – Retrações, irregular, mais rápida do que o usual, engasgo, pausa respiratória
<b>Arms</b> 0 – Relaxed/Restrained – No muscular rigidity, occasional random movements of arms 1 – Flexed/Extended – Tense, straight arms, rigid and/or rapid extension, flexion	<b>Braços</b> 0 – Relaxados/controlados: Nenhuma rigidez muscular, movimentos ocasionais dos braços 1 – Flexionados/Estendidos: Braços tensos, esticados, rígidos e/ou rápida extensão e flexão	<b>Arms</b> 0 – Relaxed/Restrained – No muscular rigidity, occasional arm movements 1 – Flexed/Extended – Tense arms, straight, rigid and/or rapid extension and flexion	<b>Braços</b> 0 = Relaxados/Contidos – Sem rigidez muscular, movimentos ocasionais dos braços 1 = Flexionados/Estendidos – Braços tensos, esticados, rígidos e/ou rápida extensão e flexão

<b>Legs</b> 0 – Relaxed/Restrained – No muscular rigidity, occasional random leg movements 1 – Flexed/Extended – Tense, straight legs, rigid and/or rapid extension, flexion	<b>Pernas</b> 0 – Relaxadas/controladas: Nenhuma rigidez muscular, movimentos ocasionais das pernas 1 – Flexionadas/Estendidas: Pernas tensas, esticadas, rígidas e/ou rápida extensão e flexão	<b>Legs</b> 0 – Relaxed/Restrained – No muscular rigidity, occasional leg movements 1 – Flexed/Extended – Tense legs, straight, rigid and/or rapid extension and flexion	<b>Pernas</b> 0 = Relaxadas/Contidas – Sem rigidez muscular, movimentos ocasionais das pernas 1 = Flexionadas/Estendidas – Pernas tensas, esticadas, rígidas e/ou rápida extensão e flexão
<b>State of arousal</b> 0 – Sleeping/Awake – Quiet, peaceful, sleeping or alert and settled 1 – Fussy – Alert, restless, and thrashing	<b>Estado de consciência</b> 0 – Dormindo/Acordado: Tranquilo, calmo, dormindo ou alerta e quieto 1 – Agitado: Alerta, inquieto e se debatendo	<b>State of consciousness</b> 0 – Sleeping/Awake – Quiet, peaceful, sleeping or alert and still 1 – Fussy – Alert, restless and thrashing	<b>Estado de consciência</b> 0 = Dormindo/Acordado – Tranquilo, quieto, dormindo ou alerta e calmo 1 = Agitado – Alerta, inquieto e se debatendo
The total score ranges from 0 to 7. A score greater than 3 indicates pain (pain: $\geq 4$ )	A pontuação total varia de 0 a 7. Uma pontuação superior a 3 indica dor (dor: $\geq 4$ pontos)	The total score ranges from 0 to 7. A score greater than 3 indicates pain (pain: $\geq 4$ points)	A pontuação total varia de 0 a 7. Uma pontuação superior a 3 indica dor (dor: $\geq 4$ pontos)

Copyright 1989 Children's Hospital of Eastern Ontario, Ottawa, Ontario, Canadá. Lawrence, J., Alcock, D., McGrath, P., Kay, J., MacMurray, B., & Dulberg, C. (1993). The development of a tool to assess neonatal pain. Neonatal Network, 12(6), 59-66.

The clinical validation study involved the assessment of sixty neonates, all of whom successfully took part in the study. The sample was predominantly male (51.7%) and Caucasian (74.6%), weighed a mean of 3265g ( $\pm 386$ g), and had adequate weight for gestational age at birth (83.3%).

Student's t-test comparisons of mean observer scores revealed no significant intra- or inter-observer differences. The means  $\pm$  standard deviations of interobserver scores were 6.00 $\pm$ 1.62 and 5.97 $\pm$ 1.63 for observers 1 and 2, respectively, with  $p=0.840$ . The mean  $\pm$  standard deviation for intraobserver scores at times 1 and 2 were 6.00 $\pm$ 1.62 and 5.93 $\pm$ 1.57, respectively, with  $p=0.583$ .

Inter- and intraobserver agreement on the presence or absence of pain, as indicated by total NIPS scores  $\geq 4$  or  $< 4$ , respectively, yielded PABAK values of 0.93. These findings suggest very good inter- and intraobserver reliability in the detection of pain in neonates (Table 2).

**Table 2** – Inter- and intraobserver agreement.

Variables	Rater 1	Rater 2	2nd	Kappa $\S$	Agreemen	Kappa $\S$	Agreemen
	1st	1st	assessment	Rater1 x	t	1st x 2nd	t
	assessment	assessment	t	Rater2		assessment.	
	t	t		(PABAK		(PABAK	
	n (%)*	n (%)*	n (%)*	)		)	
Facial expression				0.97	Very good	1.00	Very good

Relaxed muscles	2 (3.3)	1 (1.7)	2 (3.3)				
Grimace	58 (96.7)	59 (98.3)	58 (96.7)				
Cry				0.68	Good	0.85	Very good
No cry	4 (6.7)	2 (3.3)	3 (5.0)				
Whimper	7 (11.7)	16 (26.7)	7 (11.7)				
Vigorous cry	49 (81.7)	42 (70.0)	50 (83.3)				
Breathing patterns				0.47	Moderate	0.67	Good
Relaxed	12 (20.0)	10 (16.7)	8 (13.3)				
Change in breathing	48 (80.0)	50 (83.3)	52 (86.7)				
Arms				0.57	Moderate	0.63	Good
Relaxed/restrained	8 (13.3)	11 (18.3)	13 (21.7)				
Flexed/extended	52 (86.7)	49 (81.7)	47 (78.3)				
Legs				0.53	Moderate	0.80	Good
Relaxed/restrained	13 (21.7)	13 (21.7)	15 (25.0)				
Flexed/extended	47 (78.3)	47 (78.3)	45 (75.0)				
State of arousal				0.70	Good	0.57	Moderate
Sleeping/awake	10 (16.7)	7 (11.7)	13 (21.7)				
Fussy	50 (83.3)	53 (88.3)	47 (78.3)				
Classification				0.93	Very good	0.93	Very good
Total score $\geq 4$ (pain)	56 (93.3)	54 (90.0)	56 (93.3)				
Total score $< 4$ (no pain)	4 (6.7)	6 (10.0)	4 (6.7)				

\*Results expressed as frequency (percentage).

§Agreement analyzed by prevalence-adjusted and bias-adjusted kappa (PABAK) coefficients.

The Bland-Altman<sup>(16)</sup> method was used to analyze the inter and intraobserver reliability of total scores on the *NIPS-Brazil*. According to these analyses, interobserver agreement was 95%, while intraobserver reliability was 90%.

The Cronbach's alpha for the scale was 0.762, suggesting satisfactory internal consistency. Item removal did not substantially affect this value, suggesting that NIPS items are highly correlated and complementary.

## DISCUSSION

The cross-cultural adaptation process was successful, and produced a version of the NIPS (the *NIPS-Brazil*) which was semantically, idiomatically, experimentally and conceptually equivalent to the original instrument. Although slight cultural adaptations had to be made during translation and back-translation to ensure the semantic and conceptual equivalence of the two versions of the instrument, all issues were discussed and effectively

addressed by the expert committee. Similar difficulties were also reported in other cross-cultural adaptation studies<sup>(17,18)</sup>.

The use of systematic methods for the cross-cultural adaptation of assessment instruments has increased greatly over recent years<sup>(9)</sup>. Additionally, nearly all studies involving the validation of pain assessment scales for use in pediatric and neonatal populations have evaluated the reliability of the instruments used based on inter and intraobserver agreement as well as internal consistency<sup>(17-19)</sup>. In the last few years, two newborn pain assessment scales were translated and adapted for Brazilian culture, but they are not yet validated<sup>(20,21)</sup>. Both studies adopted the same process outlined by Beaton et al.<sup>(7)</sup> and undertaken in the present study.

The results of the pilot test of the preliminary translation of the NIPS suggested that the cross-cultural adaptation process had been adequately performed, since item clarity according to the health care workers sampled was greater than 87.5%. These results were similar to those obtained by another study in the literature<sup>(19)</sup>.

The Brazilian version of the NIPS, which was named the *Escala de Dor no Recém-nascido (NIPS-Brazil)*, was clinically validated in a study involving the assessment of 60 neonates by six neonatal nurses. The *NIPS-Brazil* showed excellent inter and intraobserver reliability, yielding similar coefficients to those obtained by the original version of the scale<sup>(8)</sup>, whose scores before, during and after painful procedures displayed correlations of 0.92 to 0.97. The internal consistency of the *NIPS-Brazil* was also satisfactory, albeit lower than that of the original scale (alpha values of 0.95, 0.87 and 0.88 for scores obtained before, during and after painful procedures)<sup>(8)</sup>.

Several pain assessment scales are available in the literature for use in different neonatal populations. Although some scales are known to provide more comprehensive assessments of neonatal pain, none of the existing instruments allow for the assessment of pain levels in the general neonatal population. Therefore, to ensure a wider applicability of the *NIPS-Brazil*, the instrument was validated in the present study based on the results obtained from a sample of neonates delivered at term.

Instruments used for the assessment of pain in neonates are distinct from those developed for adult or child populations, both of whom can verbally report pain. In the absence of such reports, health care workers play an especially critical role in the identification, evaluation and management of pain<sup>(2,22,23)</sup>. Given the differences between the scales used in each of these populations, concurrent criterion validity could not be established in the present study, since no gold-standards exist for the assessment of neonatal pain.

Although many scales are available for the assessment of acute pain in newborns, the NIPS was selected for cross-cultural adaptation due to its reliance on behavioral variables for the assessment of pain. Instruments focusing on physiological parameters alone have been found to be insufficiently sensitive in the detection of pain<sup>(24)</sup>.

This was the first study to adapt and validate the NIPS for use in a language other than English. However, the author of the original scale played an important role in the cross-cultural adaptation process. According to the literature, such procedures are an important means of ensuring the semantic and conceptual equivalence of the original and adapted versions of assessment instruments<sup>(7,25)</sup>.

The use of *NIPS-Brazil*, like that of any other instrument, requires knowledge and expertise with regard to the location and population in which the instrument is used. In the case of the *NIPS-Brazil*, the examiner must be able to distinguish signs of stress, hunger and discomfort from actual symptoms of pain. The development and validation of assessment instruments are known to be susceptible to observer bias, which may result in the voluntary or involuntary distortion of observer perceptions or assessments. To reduce bias and increase the accuracy of assessment instruments, it is important that all observers be adequately trained, as was done in the present study. In clinical practice, health care workers should always receive the training required to recognize neonatal pain and to use pain assessment instruments, to ensure the adequate detection and management of neonatal pain<sup>(22)</sup>.

The present study had some limitations, such as the exclusive involvement of at-term newborns rather than the inclusion of preterm neonates, and the assessment of a single type of painful procedure.

However, in spite of these limitations, the *NIPS-Brazil* may still be considered for future validations of similar scales in Brazil, in the same way as the original NIPS has been used in the validation of other scales in English-speaking countries<sup>(26,27)</sup>.

## CONCLUSIONS

The objectives of the present study were achieved, and the NIPS was successfully adapted and validated for use in Brazil. The version of the scale produced in the present study, the *Escala de Dor no Recém-nascido (NIPS-Brazil)* had adequate psychometric properties, and excellent inter- and intraobserver reliability as well as good internal consistency. As a result of the present study, the scale is now valid for use in newborns submitted to acute pain in Brazil.

The availability of a pain assessment tool for newborns adapted to Brazilian Portuguese is essential for qualified and humanized care in the neonatal period. However, despite the importance of pain assessment, it does not guarantee that newborns receive appropriate treatment and experience lower pain scores. It is necessary a pain management protocol to guide health professionals to deal with neonatal pain in a systematic and standardized way in order to reduce pain inside neonatal units.

## **DISCLOSURES AND ACKNOWLEDGMENTS**

This research was funded by the Clinical Hospital of Porto Alegre Research Incentive Fund. This source of funding had no direct role in the data collection, analysis, interpretation or presentation of the results presented in this manuscript. The authors declare no conflicts of interest.

The authors would like to thank all the professionals from different areas of knowledge who supported this study. The authors also specially thank Dr. Patrick McGrath and the Children's Hospital of Eastern Ontario, Canada, for their permission and valuable collaboration to the development of this study.

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