

## Critique of the Use of Neonatal Infant Pain Scale (NIPS)

Hala Obiedat<sup>1\*</sup> and Effat Ibrahim Al-Maaitah<sup>2</sup>

<sup>1</sup>Department of Maternal Child Health Nursing, Mutah University, Jordan

<sup>2</sup>Princess Muna Collage for Nursing, Mutah University, Jordan

\*Corresponding author: Hala Obiedat, Department of Maternal Child Health Nursing, Mutah University, Jordan, Tel: +970598401095; E-mail: [obeidathala@yahoo.com](mailto:obeidathala@yahoo.com)

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### Abstract

**Background:** Pain is a subjective phenomenon, difficult to quantify and qualify, especially on neonates who are unable to self-report their pain which are gold standard of pain measurement in other age groups. The need for a pain measure is a clinically important for guiding pain management practices and evaluating the effectiveness of a particular intervention. Pain assessment tools have been developed and validated, but they are rarely used because they are too complicated.

**Purpose:** The aim of this integrative literature review was to critique the studies related of the use of Neonatal Infant Pain Scale (NIPS) to measure the pain as the fifth vital sign.

**Method:** Electronic searches were conducted using the following database: CINAHL, Science Direct, Pub Med and EBSCO. The search generated 40 articles; 30articles fit to the criteria of the integrative literature review.

**Result:** Neonatal Infant Pain Scale is multidimensional tool with sufficient psychometric prosperities because it had excellent inter rater reliability, concurrent validity, construct validity and predictive validity which should be essential for accurate assessment and appropriate interventions.

**Conclusion:** This review suggests implementing the NIPS scale as valid reliable tool to monitor pain routinely in the clinical practice, because it's easily applied in comparison with other pain assessment tools.

**Keywords:** Neonatal infant pain scale; Inter-rater reliability; Pain assessment scale; Neonatal pain; Infant behavioral cues

### Introduction

More than 15 million premature infants are born worldwide each year [1]. Most of the preterm infants, along with term infants who are born ill, with compromised health status either by congenital abnormalities or by peripartum or intrauterine adverse events, which necessitates to spend their first weeks of life hospitalized in the neonatal intensive care unit (NICU) where they are exposed to multiple invasive procedures that are frequently painful [2]. It has been reported that infants born at 25 to 42 weeks of gestation experienced an average of 14 painful procedures a day during the first 2 weeks of life [3]. In addition, many neonates, both premature and term, underwent several surgical procedures associated with postoperative pain.

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage." (International Association for the Study of Pain [IASP], 2004). It is important for health care professionals to understand that preterm infants are unable to communicate their pain verbally. So they should be aware about the cues that preterm infants exhibit while they are experiencing pain. As the IASP states, "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". Indeed, this circumstance requires that health

care professionals to be knowledgeable in assessing and managing pain by using the most valid and reliable pain assessment tools to optimize pain management in this vulnerable population.

Regarding the physiology of pain in neonates is basically the same as it is in adults. Noxious stimuli excite primary afferent fibers that transmit signals from the periphery to the dorsal horn of the spinal cord via primarily the A-delta and C fibers [4]. Pain is a normal physiologic response. However, prolonged or frequent exposure to pain during invasive procedures, can results in physiologic and behavioral changes (Harrison, Evans, Johnston et al, 2002). Behavioral changes include crying, facial grimacing, and body movement. While the physiological changes include an increase in heart rate, respiratory rate, blood pressure, and decrease of oxygen saturation. In addition to, neonates experience various biochemical, hormonal, and metabolic changes in response to painful stimuli [5].

The short term consequences of pain may lead to sleep disturbances, feeding difficulties and body temperature instability [4]. In other hand the most immediate danger related to pain in newborns is an increased risk of intraventricular hemorrhage that contributes to neonatal morbidity and mortality.

Although there is still little empiric data specifically related to long-term effects of early pain exposure, studies have shown that newborns, especially preterm infants, are vulnerable to long-term negative effects that lead to permanent changes in brain processing and impaired brain development [6], which will results in poorer cognitive and motor scores, impairments of growth [7]. Moreover pain exposure result in

altered corticospinal tract structure which result in pain sensitivity and maladaptive behavior later in life [8]. A wide spectrum of developmental, learning, and behavioral problems are prevalent among preterm infants, especially in extremely low birth weight (ELBW <1000 g).

Studies indicate that pain management for infants is still inadequate [5,9-10]. The accumulative literature in pain assessment and management mentioned that the consequences of untreated procedural pain in neonates are having deleterious effect, therefore, Pain intensity and pain relief should be should be routinely assessed, reassessed, and documented at regular intervals to facilitate treatment and pain relieve [11,12].

Pain assessment is the key step in the recognition of pain and the use of routinely planned pain -relieving interventions [13,14]. However, since neonates are unable to communicate verbally their pain; the health care professionals must rely on alternative methods to assess pain in this vulnerable population. In an attempt to increase the accuracy and reliability of pain assessment in the newborn patient, a number of pain assessment tools have been developed by health care professionals based on the behavioral and physiological cues that indicate pain [15]. These tools assist the health care professional's specifically neonatal nurses in objectively identifying, quantifying and alleviating pain. Among the most frequently used multidimensional pain scales are the NIPS and the Premature Infant Pain Profile (PIPP) [16].

Pain as the fifth vital sign, needs to be monitored routinely in the clinical setting; so it must be assessed every time vital signs are taken and after painful procedures, such as, heel lances, intubations, suctioning, venipuncture, lumbar puncture and circumcision (JCAHO, 2001). Routine assessment of pain increases the nurses' knowledge about the neonate's condition and enhances the identification and relief of pain by utilizing non pharmacologic and pharmacological interventions.

In other hand inadequate assessment and management of pain for newborns compromises the quality, cost, and quality outcomes of their care and contributes to the needless suffering of newborns [17]. For accurate and objective pain assessment nurses should use valid and reliable multidimensional instruments, that focus on measuring for both physiologic, behavioral indicators therefore, The Neonatal Infant Pain Scale (NIPS) is a suitable scale which includes all component of behavioral responses of neonatal pain. So the aim of this review is to explore the studies about the NIPS scale and it is utilization in the clinical practice.

## Methodology

Electronic searches were conducted using the following database: CINAHL, Science Direct, Pub Med and EBSCO, the search generated 40 articles; 30articles fit to the criteria of the integrative literature review are used with the following search terms: NIPS (Neonatal Infant Pain Scale), Inter-rater Reliability, Pain assessment scale, Neonatal Pain, validity, randomized clinical trials (RCT) and Infant behavioral cues. The literature search covered the period from 1993 to 2015 contains one published theses, 15 prospective randomized clinical trials and 15 Review articles.

By reviewing the literature the following themes are emerged: Developing of Neonatal Infant Pain Scale (NIPS), Validation of modified pain scales with NIPS, critiques of NIPS negatively and

positively, also the validity of NIPS as pain assessment tool and the widely use for acute, procedural, post-operative pain and evaluating the effectiveness of non-pharmacological pain management due to easy application.

## Literature Review

### Developing the neonatal infant pain scale (NIPS)

Neonatal Infant Pain Scale was developed at Children's Hospital of Eastern Ontario (CHEG) [18] is based on 6 items: cry, facial expression, breathing patterns, positioning of arms and legs, and state of arousal. Initially a survey of fourty- three experienced neonatal nurses was conducted to identify behaviors associated with pain. The pilot study used a scale with eight criteria for rating. These included facial expression, facial color, arm and leg position, torso movement, breathing patterns, cry, and state of arousal. This scale was used to document newborns behavioral changes on twenty videotaped needle-intrusive procedures. The results of the pilot study showed that changes in facial color could be caused by illness and often changed frequently. There were also difficulties observing torso movement. The final version of the NIPS used in the CHEG study deleted these two indicators. The resulting scale provides a tool that is clinically easy to use and reliable. The NIPS lists five behavioral components and one physiologic indicator (breathing patterns), the description of the scale scores and operational definitions of the behavioral cues are printed on the tool for easy reference (Appendix A). Each behavior except cry has a possible score of 0 or 1. Cry has a possible maximum score of 2 (0=no cry, 1=whimper, 2=vigorous cry). Across the top of the scale are columns for eleven recording observations at one minute intervals, before, during and after a procedure. The scale could also be used at a specified time to determine presence of pain. Scores are totaled at the bottom with scores ranging from 0 to 7. If the total pain scores from 0 to 2 indicates mild to no pain and from 3 to 4 indicates mild to moderate pain in these scores using non-pharmacologic comfort measures are benefit to infant, and greater than 4 indicates sever pain which almost require pharmacologic intervention in conjunction with comfort measures [18].

The CHEO trial of the NIPS included thirty-eight infants videotaped during ninety procedures. Using the same infant in more than one video rating may prove a problem in the determination of validity. Sixty-seven procedures were on preterm infants and twenty-three on full term infants. Other than preterm or full term, the exact gestational age was not designated. There is a need for better correlation of the NIPS with preterm infant pain assessment. Inter-rater reliability for NIPS was high. Twenty procedures were scored by both the research assistant and an independent observer. Comparisons of the scores from the two raters at three times, once before, during and after the procedures were calculated. Pearson's correlations ranged from 0.92 to 0.97 and were statistically significant ( $p < 0.00001$ ). Results from paired t-tests indicated only small inter-rater differences ranging from 0-0.3, which did not approach statistical significance. It was concluded that the NIPS has a high inter-rater reliability at that institution.

To determine if there was a change in NIPS scores over time as an indication of a change in intensity of pain, repeated measures ANOVA was done on NIPS scores for twenty-two infants undergoing painful procedures. Results were significant ( $F=18.97$ ,  $df=2.42$ ,  $p < 0.000$ ) Mean NIPS scores before the procedure were (1.1), during the procedure were (4.8), and after the procedure were (2.0). The Friedman test was

used to confirm that there was statistical significance in the pattern of increase followed by decrease of NIPS score this indicate that construct and concurrent validity (Pearson correlations ranging from 0.53 to 0.84) were established. Internal consistency was tested using scores before, during and after a procedure. The NIPS showed a high internal consistency with Cronbach's alphas of 0.95, 0.87, and 0.88, respectively. There were no reported problems using videotapes for rating. Results showed increases in NIPS scores with painful procedures and suggest the NIPS is a reliable and valid instrument [18,19].

### Validation of modified NIPS pain scales

Neonatal Infant Pain Scale is multidimensional pain scale it measures pain with a composite score that includes a variety of physiologic, behavioral, and contextual indicators. It has psychometric properties which include reliability, validity, sensitivity, and specificity that enhance its use in a specific population and clinic setting [20].

Backus [21] conducted study on 30 premature and term infants during painful procedures, the reliability between the inter-rater were reported as the following: ( $r=0.69-0.90$ ,  $p<0.001$ ). Mean scores of NIPS, before, during and after the painful intervention were 0.44, 3.04 and 0.6 respectively. The study conclude that the NIPS validly evaluate pain in term and preterm infants and also the researcher modified the NIPS by removing the score for legs, making the total possible score a maximum of 6. The reasons for this include increased use of swaddling and other means of confining limbs. In addition, the definition for scoring legs gives a zero (0) for restrained legs. Finally, the procedure for drawing blood from the heel often obscured the view of the legs. The NIPS was further modified to include heart rate, respiratory rate and oxygen saturation. The adapted NIPS can be found in (Appendix B). Furthermore the study by Ivan, Lawrence, Donna, Laura, and Charles, (2010) concluded in their study that the NIPS has both concurrent and construct validity so it can be used in the clinical setting to assess pain during the neonatal and infancy period and it can be applied to all neonates, regardless of their age or physiological state during invasive procedures and at the period of recovering from surgery.

Hudson-Barr, et al. [22] developed the Pain Assessment in Neonates scale (PAIN) by combining categories of the NIPS and the CRIES into a new scale. In the newly developed PAIN (Appendix C), seven categories are to be assessed, with the total score ranging from 0 to 10 and with a higher score indicating increased pain. The categories and scoring of facial expression, cry, breathing pattern, and state of arousal were retained from NIPS. The arm and leg movement categories from the NIPS were combined into one category, designated as extremity movement, to accommodate assessment of infants who are swaddled. Two categories are retained from the CRIES: the requirement of supplemental oxygen to maintain saturation  $>95$  percent and an increase in vital signs (heart rate). The research was conducted using a correlational design to compare scores obtained on the PAIN with scores obtained on the established NIPS. They suggested that the PAIN scale has both criterion and construct validity as a neonatal pain measurement scale. Therefore, experienced clinicians had provided feedback used to modify two existing scales into a different version that was easy to use.

Also more of the neonates  $<28$  weeks gestational age experienced a painful Procedure than did neonates in other age groups and had the highest mean on both the PAIN and the NIPS, suggesting that the scales may detect pain in the younger gestational age neonate. Neonates who had experienced a painful event in the previous 30 to 60

minutes scored significantly higher on both the PAIN and the NIPS than did those who had not experienced a painful event. Furthermore the NIPS was successfully adapted culturally and validated for use in different countries and the studies proved that NIPS had adequate psychometric properties and excellent interobserver and intraobserver reliability and good internal consistency. So the NIPS scale can be used in preterm and term infants exposed to acute pain [23].

### Critiques of NIPS negatively

Unfortunately, there is no standardized pain scale exist to date for evaluation of fetal pain. Bellieni [24], despite the recent development of fetal surgery has raised the problem of fetal pain and analgesi, making it important to recognize pain even in fetuses.

There are many challenges to selecting appropriate scales for a given NICU setting. This includes the fact that NICU populations are divers often made up of premature and term infants; some sedated, paralyzed, and mechanically ventilated preterm infants; and some underwent surgical interventions. If a given scale like NIPS relies on an audible cry for assessment, then this scale may not be usable for a sizable portion of the given population. So one of the limitations for using NIPS scales which have demonstrated validity and reliability only for a certain gestational age and a certain type of pain, which makes selecting a single scale for the entire NICU population very difficult considerations [2,20]. So one of the limitations of using NIPS scale that it does not takes sedation into account like (Neonatal Pain Agitation and Sedation Scale (N-PASS)).

Premature infants of all gestational ages (fewer than 37 weeks) demonstrate a decreased ability to mount a physiologic response to painful stimuli. Multiple factors may influence a premature infant's vital signs, and an increase in heart rate and/or respiratory rate may not be an indicator of pain alone. In addition, very premature infants may be completely unable to demonstrate a change in vital signs because of pain, and the ability to sustain this for any prolonged period of time is markedly diminished, similarly, the lack of energy reserve present in premature infants of any gestational age may result in an absent or muted behavioral response to painful stimuli.

So there is no combination of physiologic and/or behavioral indicators that mark the presence of pain in preterm neonates as reliably and specifically as those validated in full term infants. This can make pain assessment in preterm neonates particularly challenging. Only two pain assessment tools have a metric adjustment to account for prematurity which are PIPP and N-PASS however, other scales like NIPS have demonstrated validity and reliability in the premature and full term infants but doesn't take the sedation state of the newborn into account [2,20].

Neonatal Infant Pain Scales were designed just for acute pain not for prolonged pain like the (N-PASS) and EDIN scale (Échelle Douleur Inconfort Nouveau-Né, neonatal pain and discomfort scale) However, the presence of prolonged pain in neonates is much more difficult to assess, as neonates may adapt to the presence of prolonged pain from the standpoint of both physiologic and behavioral measures [2].

Spasojevic and Bregun-doronski [25] conducted a Prospective observational study to evaluate application of different neonatal pain scales in clinical settings during two most frequently performed procedures in newborns – venepuncture and heel stick, these pain scales are (NPAS,DAN, NIPS, and PIPP). Significant value changes that have been observed for each of used pain scales demonstrated their high sensitivity. However, certain differences among them that

can influence their use in clinical practice were noticed, they found that DAN is a pain scale convenient for the use in clinical settings, especially if a fine distinction of magnitude of the present pain is not needed, whereas PIPP can be recommended for use in clinical practice.

Also they mentioned in their study that NIPS was easy and quick to use to. However, graduations of indicators by design are limited and this can cause difficulties in differentiation of intensity response. This arose as a problem especially with indicators position of arms and legs, where simple graduation (relaxed, unchanged position, extension and flexion) made it difficult for distinction between moderate and intense movements, especially in premature infants. Although this pain scale is capable of detecting the change. Analysis of NIPS's confidence parameters showed the lowest sensitivity (0.44) and negative predictive values (0.64) during low intensity pain and therefore leads to conclusion that NIPS cannot precisely register the pain level.

### Critiques of NIPS positively

Pain is a subjective experience that is difficult to quantify and qualify. The need for a pain measurement and management is a clinically important issue for substantiating a therapeutic decision and evaluating the effectiveness of a particular intervention. Many acute-procedural pain assessment tools have been validated; But we have to notice that is the NIPS as pain assessment tool is easy to use or not.

Sarhangi et al. [26] conducted methodological study. Sixty-eight hospitalized infants were selected in NICU of one of the hospitals of Tehran (Iran) using available and purposive sampling method. They indicated that using NIPS in comparison with other scales was more user friendly by the nurses because its ease used. The researchers rationalize that NIPS does not require so much time or using extra and special equipments. Therefore, NIPS can be used for pain assessment for term and preterm infants during painful procedures like (venipuncture and catheter insertion) in onward. The previous study supported Carlo [27] who carried studies that evaluated NIPS and other scales and confirmed the reliability, validity and usability of NIPS.

Suraseranivongse et al. [28] designed a prospective study to cross-validate three pain scales, concluded that, CRIES, CHIPPS and NIPS had excellent inter rater reliability, demonstrable concurrent validity, construct validity and good predictive validity. However, NIPS was the most practical scale because the items were easy to score and there was no need to calculate the change of vital signs, which was an obstacle in a busy clinical practice with limitations of manpower. Furthermore, pulse oximeter is not commonly available in their hospital with limited resource. Therefore, they recommended using NIPS to assess pain in newborn infants in the postoperative period.

Joint Commission of Accreditation of Healthcare Organizations (JCAHO) recommends the selection of a valid and reliable and age appropriate pain assessment tool. Therefore, Malarvizhi, et al. [29] conducted three observers prospective observation study to establish reliability and validity of NIPS among 27 neonates who underwent venipuncture, Hepatitis vaccination (intramuscular) and heel prick at a tertiary care level III NICU but babies with critical illness and cardiac defects and who are on ventilator with major congenital anomalies were excluded. The baseline data and behavioral responses to procedural pain were rated by three observers trained in NIPS scale. At the end of 100 observation across the various time intervals and three phases, inter-rater reliability of NIPS scale among the three observers were 0.82, 0.81, 0.75 respectively. Acceptable psychometric properties

are reported for the tool which includes cronbach's alpha levels of 0.9, 0.85, 0.9 between the observers. The researchers found that NIPS was highly reliable and valid multidimensional scale and practical tool with high significance to clinical utility, because it's easy, feasible and does not require additional monitor, to record saturation and heart rate.

### Utilization of NIPS for evaluating the effectiveness of non-pharmacological pain management

Yilmaz and Arikan [30] conducted a prospective, randomized, controlled study involved 120 newborns in Turkey to compare the effects of mother's milk, sucrose and pacifier use to overcome pain during painful interventions to the newborns on the crying time and pain. The newborns who had blood sampling by heel stick were divided into four groups: mother's milk, sucrose, pacifier and control groups with 30 newborns in each, using Pulse oximeter for oxygen saturation and heart rate and neonatal infant pain scale(NIPS) for the measurement of the behavioral responses of newborns, Comparing the NIPS means of the control and experimental groups according to the procedure times, the result of the study should that there is statistically significant differences found between the groups for values obtained before and after the procedure The result of the study indicate that all three practices reduce the behavioral responses to pain at a higher rate than in the control group.

Axelin et al. [31] conducted a randomized crossover design study to examine the effectiveness of facilitated tucking by parents in pain management during endotracheal/pharyngeal suctioning of preterm infants, the outcome measure was the NIPS score, HR, and oxygen saturation were recorded, The highest NIPS score was median equals 3 using 'facilitated tucking by parents' and median equals 5 without tucking during suctioning procedure. They concluded that Facilitated tucking by parents is an effective and safe pain management method during suctioning of preterm infants. Even though there is no standardized approach to the measurement of pain in preterm and term infants and most of pain studies used different scales for pain assessment, the NIPS scale can be used to direct health care professionals to use the proper non-pharmacological pain management measures to alleviate pain among preterm and term infants [28].

### Nursing implications

As it is well established in the scientific health literature that neonates perceive, respond to and remember pain. And to improve the health outcomes of this vulnerable population, health care professionals specifically neonatal nurses should use pain assessment tools to recognize and treat pain promptly so they can alleviate suffering of preterm and full term infants.

This review suggests implementing the NIPS for assessing pain as the fifth vital sign to monitor pain routinely in the clinical practices for premature, full term infants and as well as the healthy babies who may receive painful interventions, such as circumcision and blood sampling for metabolic screening purposes in the first few days of life, because of its easy in utility compared with other pain assessments tools, although some studies critique NIPS negatively, however, it has widely used for procedural, post-operative and acute pain and to assist in evaluating the effect of pharmacological and non-pharmacological measures to alleviate pain thus improving the quality of care for this vulnerable population.



On other hand, it is recommend orienting the health care professionals about the proper ways of demonstrating the use of this tool in the clinical encounters regarding pain assessment, management and to initialize the tool in the health care settings. Furthermore implementing an educational program for neonatal nurses about the proper way of using NIPS scale for pain assessment and proper pain management to avoid suffering of newborns.

## Conclusions

NIPS is multidimensional tool with a psychometric prosperities, it had excellent inter rater reliability, concurrent validity, construct validity and predictive validity which should be essential for accurate assessment and appropriate interventions. Although many assessment tools have been developed but most have limited application in clinical practice. The Neonatal Infant Pain Scale was introduced to provide comprehensive newborn care in the clinical setting. Many studies illustrate for successful implementation of using NIPS and its ease of application in clinical practice. Thus improving physiologic, behavioral, and hormonal outcomes of preterm and full term infants.

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