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# The validity and reliability of the EValuation of INtervention Scale: preliminary report.

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**Title: T**he validity and reliability of the EValuation of INtervention Scale (EVIN): Preliminary report.

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**Short title.** Evaluation of intervention**.**

**Abstract: 175 words**

**Text: 2628 words**

**ABSTRACT (185 words)**

**Aim**. Pain management is a priority for infants receiving neonatal care as they undergo many painful and stressful interventions associated with negative short- or long-term consequences. This study aims to validate the content and test the reliability of the EValuation of INtervention Scale (EVIN), which is designed to evaluate the use of widely recommended non-pharmacological strategies to reduce neonatal pain and stress during procedures. .

**Methods.** The content of the EVIN was validated with multidisciplinary participation (N=80), and consistency was established via observations on preterm infants (N=12, at 31-34 weeks gestation) during interventions in a neonatal unit. A revised scale was tested for inter-rater reliability with observations of invasive (blood sampling, N= 16), and non-invasive (nappy change, N=18) interventions. The intra-class correlation coefficient (ICC) was used to determine inter-rater reliability. SPSS (PASW Statistics) version 18 was used for analysis.

**Results**. Very good intra-class correlation coefficients (>0.8) for both invasive (0.962) and non-invasive procedures (0.970) were achieved.

**Conclusion.** These results indicate that the EVIN is suitable for evaluation of non-pharmacological support during painful or stressful interventions.

**KEY NOTES** (66 words)

- The EValuation of INtervention Scale (EVIN) is a unique tool designed to evaluate the use non-pharmacological strategies to reduce pain and stress for infants receiving neonatal care.
- The EVIN records best worse and intermediate practice for 17 evidence based items that can be implemented before, during and after invasive and non-invasive interventions.

- The EVIN is potentially useful in the clinical setting, for training, audit and research.

**Key words or phrases**

Neonatal pain and stress

Non-pharmacological intervention

Developmental care

Preterm infant

NIDCAP

**Abbreviations**

ET: Endo-tracheal

EVIN: Evaluation of Intervention

ICC: Intra-class Correlation Coefficient

NICU: Neonatal Intensive Care Unit

NIDCAP: Newborn Individualised Developmental Care and Assessment Program

ROP: Retinopathy of Prematurity

SPSS: Statistical Package for the Social Sciences

**The validity and reliability of the EValuation of INtervention Scale (EVIN): Preliminary report (1930 words)**

## Introduction

Infants admitted to neonatal intensive care units (NICUs) experience many painful procedures that are often vital for their wellbeing and survival (1). Repeated exposure to pain and stress has consequences for physiological and neurodevelopmental outcome (2-4), which makes it essential to explore the best way to manage potentially stressful or painful events.

Many routine aspect of neonatal care, non-invasive as well as invasive, involve pain and stress. While the equipment used for invasive interventions can be optimised to minimise tissue damage, and the number of potentially uncomfortable "routine" procedures can often be reduced, non-pharmacological (developmental care) strategies also have an important role in the management of pain and stress. Many non-pharmacological strategies, used individually or in combination, have been found to be effective, including skin-to-skin holding, oral sucrose/glucose, swaddling and positioning, sucking, breast milk and breastfeeding (5-11).

The EVIN (EValuation of INtervention) is the first scale to systematically capture information about the quantity and quality of non-pharmacological interventions intended to reduce stress and pain in relation to routine handling or potentially painful procedures. Furthermore the EVIN is designed to be easily implemented in clinical practice.

## THE EVIN SCALE

The structure of the EVIN is derived from the NIDCAP Developmental Care Guidelines for the NICU (12) and it incorporates a range of evidence based strategies that begin with temporal planning and follow the intervention through until completion. It is used to record

details of the way the infant is approached, handled and comforted during invasive or non-invasive procedures. Invasive procedures are defined as skin-breaking procedures (e.g. heel lance, cannulation) or those requiring placement of a medical device via an orifice (e.g. suctioning, insertion of nasogastric tube). Non-invasive procedures involve handling the baby, but do not activate infant nociceptors in the skin or mucous membranes (e.g. nappy change, chest x-ray).

This report describes the initial validation and reliability testing for the EVIN scale, using a mixed methods (qualitative and quantitative) approach. Regulatory approval for these studies was obtained from the London-Dulwich Research Ethics Committee.

**Components of the EVIN Scale**

The EVIN includes 17 items in four sections: *Before Intervention*; *Support During Intervention; Environment;* and *After Intervention* (Table 1*)*. It includes strategies based on the best available evidence related to timing, modification of the environment, positioning, handling, use of bedding, style of approach, facilitated self-regulation, soothing and recovery. Each of the items is evaluated on a 3-point scale describing best, worst and intermediate practice. The scores are totalled and percentages worked out according to the number of items that were applicable.

*Before Intervention*: The scale begins by asking how much uninterrupted rest the infant has had since previous interventions. When episodes of handling and procedures are close together there appears to be an accumulative effect with stronger response and longer recovery time compared to episodes when handling or procedures follow a period of uninterrupted rest (13-15). Stress levels are often elevated by preparatory handling before the actual procedure begins, especially in preterm infants (16) and for this reason the style of approach to the infant is considered. Timing interventions to protect sleep is included as an important neuroprotective strategy (17); at the same time it is recognised that starting a

procedure in an infant who is already aroused and upset is likely to increase peak stress levels.

Drops of a sweet tasting oral solution, usually sucrose, are widely considered as an effective intervention (11), and although the way in which it should be used is not clear the consensus appears to be that the optimal moment for administration is before an intervention. The use of an oral solution is not usually applicable to non-invasive procedures and this item is then scored n/a and is not included in the scores. Non-nutritive sucking also reduces the pain response (9) and this is included as a separate item.

*During Intervention*. Effective strategies suggested for supporting the infant in or out of bed include being held close, or made comfortable with swaddling, nesting, or "facilitated tucking" ( 7,9,18).

Soothing sensory inputs include firm but gentle touch (19), and voice (20). Bellieni and colleagues (5) recommend a multisensory approach. Infants make efforts to self-regulate though activities such as grasping, bracing feet, clasping hands together, and bringing their hands up to their face. These efforts can be facilitated by the carer as recommended in the NIDCAP model implemented by Kleberg et al (21).

Pacing of caregiving in response to signs of stability and instability is a co-regulatory strategy based on observation of the infant's reactions and apparent stress thresholds. Interruptions are a common problem that prevent the person carrying out the care or a procedure from giving the baby, and the intervention, their full attention.

*The Environment*: The evidence for reducing environmental stressors with a quiet calm environment and without direct exposure to bright light is described by two consensus

groups (22,23). It is not practical to take measurements of light and sound during observations, and familiarity with evidence based guidelines is assumed (22,23).

*After the Intervention*. At the end of the intervention an item on settling the baby comfortably is added as basic good practice. Caregivers are asked to estimate the ease with which the procedure is carried out and their estimation of the degree of distress the infant demonstrated, which can then be compared with a parallel score from the observer.

## STUDY DESIGN

The original scale was designed specifically for assessing interventions during eye exams for retinopathy of prematurity (ROP) screening (21). It has been modified to make it more suitable for use during any intervention.

### Content validity

Content validity was established through the participation of 80 specialists in neonatal developmental care at an international multidisciplinary meeting (NIDCAP Trainers' Meeting, Combrit, France, September 2007). Participants were asked to critically review the content of the scale, the relevance of the criteria for best, worst and intermediate practice, the clarity of the wording and ease of scoring. The scale was revised subsequent to this input.

### Consistency

The consistency of the revised scale was evaluated by three observers (two English-speaking NIDCAP-trained neonatal occupational therapists, and a special needs teacher with limited experience in an acute neonatal setting and with English as a second language). All three concurrently observed interventions on 12 infants at ages equivalent to 31 - 34

weeks gestation (dated from onset of last menstrual period) in the NICU, which they scored independently. Individual scores were compared and further revisions were made in the EVIN scale to improve consistency.

**Inter-rater reliability**

Inter-rater reliability of the EVIN scale was tested at the cotside during observations of invasive (blood collection, N=16) and non-invasive (nappy change, N=18) procedures carried out by healthcare staff (doctors and nurses) on 34 infants at ages corresponding to between 30 and 34 weeks gestation at the time of intervention. All three observers evaluated each intervention concurrently and then scored the EVIN scale independently. Their scores for each intervention were compared using the intra-class correlation coefficient (ICC), in a two-way mixed effects model where observer effects were random and measured effects were fixed. SPSS version (PASW Statistics) version 18 was used for the analysis.

**RESULTS**

Written feedback from the content validity exercise was reviewed (N=80 professionals). Four of the original 20 items were removed, 2 items were added and the 18 remaining items were grouped into 4 sections pertaining to different stages of the intervention. Wording was adjusted for 12 items.

As a result of the observations to establish consistency (N=12 infants), 7 content revisions were made; the number of items was reduced from 18 to 17 and an instruction manual was written for the final EVIN scale, Version 2.

The intraclass correlation coefficient (ICC) was used to determine inter-rater reliability (compare the total scores for the researchers). An ICC of > 0.8 was considered to be very

good (27). Comparison of the three independent scores for each of the 34 interventions achieved very good intraclass correlations, 0.962 for blood sampling (N=16, $p<0.0001$) and 0.970 (N=18, $p<0.0001$) for nappy changes. Fig. 1 shows the distribution of scores for invasive and non-invasive interventions for comparison of the non-pharmacological interventions employed.

The current version of the scale has been further amended due to concerns raised by recent evidence suggesting that sucrose may dampen the behavioural signs of pain without eliminating the cortical or physiological response (25-27). Breast milk, which has also been shown to reduce signs of pain and stress in newborn infants (10), is perceived to be a healthier option and therefore the item recommending sucrose in the original scale has been modified to suggest the use of a breast milk or colostrum as alternative oral solutions.

**DISCUSSION**

Non-pharmacological management of stress and pain is an important component of developmental care but the lack of a tool to capture the quantity and quality of non-pharmacological interventions has made it difficult to interpret findings in studies that compare different styles of intervention. The EVIN records a range of strategies (quantity) and the quality of their implementation by indicating best, intermediate, or poor practice. This makes documentation and data collection possible for both medical and nursing procedures and could therefore help to improve developmental care and pain management research.

These preliminary results show the EVIN scale to have good content validity, and very good inter-rater reliability (24). This indicates that the EVIN is a consistent and reliable tool to assess the quality of developmental care as an approach to the non-pharmacological management of stress and pain during episodes of handling and medical procedures. It is the only tool of its kind.

This is a preliminary study with several limitations. It is based on a small sample of infants within a narrow age band, on one site, with a limited number of observers completing the scoring. Next steps to establish clinical utility and feasibility will be to score the EVIN with a larger sample, across several sites with a greater variety of infants and observers. It has not been possible to validate the EVIN against another scale as there is nothing similar with which to compare it. However it will be useful to compare EVIN scores with a validated neonatal pain/stress scale during events that involve both invasive and non-invasive interventions.

The EVIN is a versatile tool that has many potential applications in clinical practice, including research, teaching, benchmarking and audit, for personal reflection and practice improvement. The EVIN has already been used for training nurses, therapists and doctors, and to evaluate the impact of developmental care education and training. There is increasing interest to translate it into different languages, thus making it accessible to neonatal teams worldwide.

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**Conflict of Interest**

The authors declare no conflict of interest.

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Table 1: Items included in EVIN scale

| | |
|---|---|
| BEFORE INTERVENTION | |
| 1 | **REST:** Did the baby have uninterrupted rest prior to being approached for the intervention? |
| 2 | **SLEEPING/WAKING:** Was the intervention timed to fit the baby's sleeping/waking/feeding pattern? |
| 3 | **ORAL SOLUTION:** Was the baby offered expressed breast milk/colostrum/sucrose* before the intervention? N/A for this procedure. |
| DURING INTERVENTION | |
| 4 | **APPROACH**: How was the baby approached before the intervention started? |
| 5 | **POSITION**: N/A if baby in cot. |
| 6 | **BEDDING:** How much support did the bedding give the baby? N/A if baby held in arms.<br>How was the baby positioned during the intervention? Side □ Back □ Front □ |
| 7 | **SUCKING**: Was sucking (soother / breast feeding) offered to the baby? N/A baby asleep or has oral ET Tube. |
| 8 | **COMFORT 1**: Was anyone available to support the baby during the intervention? |
| 9 | **COMFORT 2**: How was the baby soothed during the intervention? |
| 10 | **FACILITATION**: How was the baby helped to use his/her hands and feet for |

| | |
|---|---|
| | self-regulation? |
| 11 | **PACING 1**: Was the pace adjusted to maintain the baby's autonomic stability? |
| 12 | **PACING 2**: Were there any delays or interruptions during the intervention? |
| ENVIRONMENT | |
| 13 | **LIGHT**: Was lighting adjusted for the baby's comfort? |
| 14 | **ACTIVITY:** How busy was the area around the baby during the intervention? |
| 15 | **NOISE:** Were sound levels in the nursery appropriate for the baby? |
| AFTER INTERVENTION | |
| 16 | **COMFORT:** How was the baby made comfortable after the intervention? |
| 17 | **SUCKING**: Was sucking facilitated after the intervention? N/A baby settled or asleep |
| | |
| | |

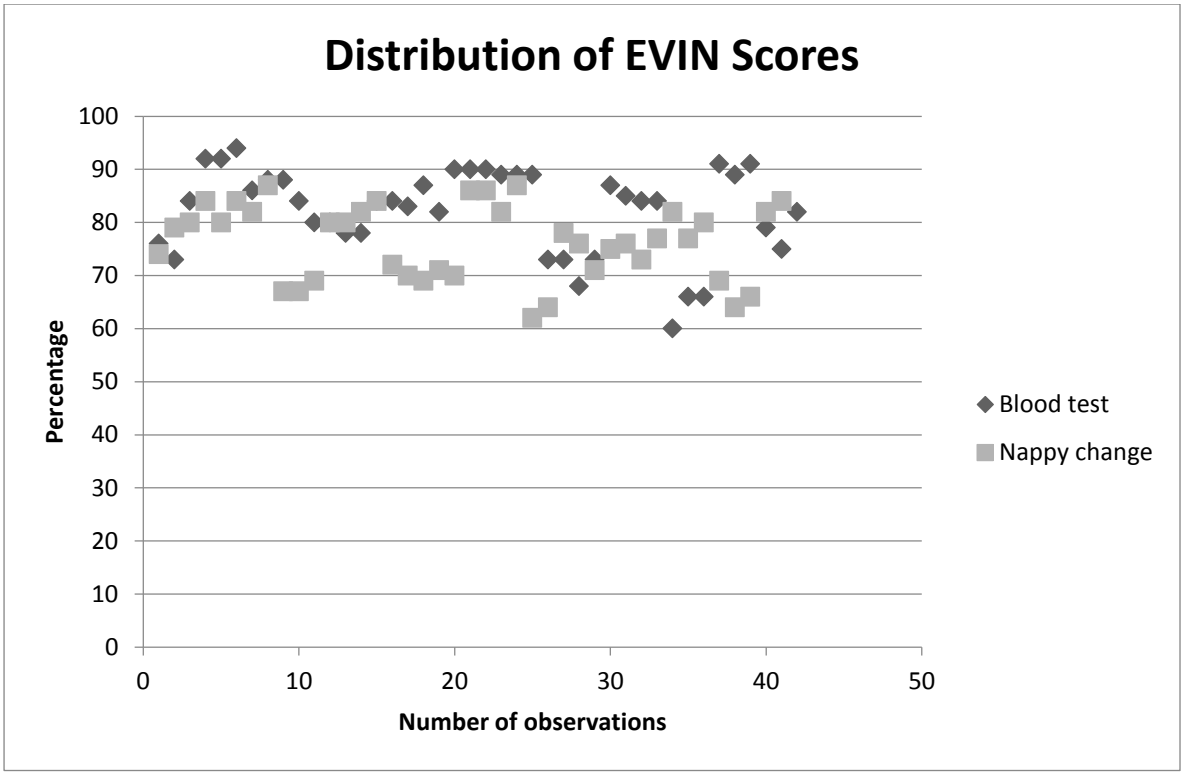


**Figure 1: Distribution of EVIN Scores**