



## Development of a scale for estimating procedural distress in the newborn intensive care unit: The Procedural Load Index

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### ABSTRACT

**Background:** Infants in the newborn intensive care unit (NICU) are exposed to routine procedures that often cause distress and carry a negative burden or load on the infant's neurodevelopment.

**Aim:** A ratio level index is introduced to estimate procedural load so as to begin to develop a system to monitor the intensity of distress associated with common NICU procedures.

**Study design:** Two psychophysical methods, magnitude estimation (ME) and the general labeled magnitude scale (gLMS) were used to survey 86 clinicians via the internet to estimate the distress associated with 55 common NICU procedures.

**Results:** gLMS and ME estimations correlated highly across all procedures ( $r = 0.97$ ). gLMS values were used to derive the procedural load index (PLI) as a ratio level estimation of procedural distress.

**Conclusion:** The PLI ranks and differentiates distress among common NICU procedures more precisely than current tools. This methodology, if correlated with infant physiological indices and health outcomes, may be operationalized at the bedside to measure procedural distress, and help to guide the ideal timing to perform procedures and minimize their negative consequence.

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### 1. Introduction

Infants in the NICU require special care and invasive procedures to keep them alive. The distress associated with these procedures may cause neural damage leading to abnormal development [1]. Specifically, due to the vulnerability of the developing brain in the premature infant, stimuli that may provoke deleterious responses are not limited to painful or invasive procedures, but may include normal handling and routine care [2,3]. Epidemiological work estimates that 16 distressful procedures are done for these patients daily for each of the first 14 days after admission to the NICU [4]. Although there are various tools to measure the general pain state of an infant in the NICU (e.g. [5]) and at least one to categorize “stress experiences,” [6] there is no metric to finely quantify the distress associated with each of the distressful procedures. To improve assessment and provision of care to the infant, a better understanding of procedural distress is needed. Important and complex aspects to consider include the intensity or “load” of the experience, the timing in relation to

other care (e.g. previous exposure), and the influence of possible mediating variables such as gestational age, sex and analgesia.

An increase in the *intensity* of distressful events (higher rates of skin-breaking procedures) is associated with higher basal cortisol levels [7] and lessened motor and mental performance at 8 and 18 months of age [1]. Intensity may also be defined by the number or cumulative effect of procedures performed. Grunau and colleagues found that the number of invasive procedures performed since birth to be the most significant factor associated with altered pain response [8]. Similarly, the *timing* of distressful events influences infant response. For example, NICU infants who have recently experienced a distressful event have shown altered pain reactions consisting of subdued [9] or hyperactive [3] responses to subsequent painful stimuli. The *Synactive Theory* and the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) [10] advocate (among other interventions) the provision of clustered care. However, clustering, or the scheduling of routine care in a bundled manner to allow for more uninterrupted periods of sleep, has been associated with lower oxygen saturations, higher behavioral stress responses, and negative stress responses in infants of earlier gestational age [2,11]. Results from this approach, including a meta-analysis [12], remain inconclusive and controversial [13]. Others advocate for more “cue-based” care in the NICU dependent on feedback about the infant's distress state and readiness to receive care [2].

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The goal of this study was to develop a scale, the Procedure Load Index (PLI), as an objective estimate of distress associated with common NICU procedures. Existing attempts at quantifying and classifying procedural distress intensity in the NICU are at best categorical [1,6]. In the present study, two psychophysical techniques were used via an online survey to ask clinicians to estimate the distress associated with common NICU procedures to derive a ratio level scale (the PLI). They were magnitude estimation (ME) and the generalized labeled magnitude scale (gLMS). Our hypothesis is that a correlation between techniques would establish the construct validity of the scale.

## 2. Methods and procedures

### 2.1. Indirect psychophysics

ME is based on Steven's power law, which states that equal stimulus ratios tend to produce equal sensation ratios [14]. ME has an established history in pain or distress estimation, such as pain catastrophizing [15], thermal pain [16], and chronic pain [17]. In ME, a reference stimulus is first given a value against which all other stimuli are compared; ME has ratio level scaling properties and has been demonstrated to be a better methodology than Likert scales, particularly with variations at higher stimulus levels [14].

The generalized labeled magnitude scale (gLMS) is a semantic scale combined with a visual analog scale based on a quasi-logarithmic axis; it has been demonstrated to yield psychophysical results equivalent to ME [18–20]. It uses standardized wording, such as 'Low', and 'Strongest Imaginable' to represent sensations. Newer than ME, the gLMS is thought to be a more "user friendly" approach requiring less abstraction; e.g. no considering of proportions/fractions. Also, it is particularly well suited for an online environment.

Psychophysical measurement asks respondents to estimate the amount of a given stimulus directly experienced or imagined. For example, Strulov and associates [15] asked pre-operative women to estimate levels of pain based on various temperature stimuli administered. Respondents were asked here to estimate the intensity of distress that various stimuli are thought or believed to produce in an "average NICU infant" (i.e. *not* themselves). This approach is referred to here as "indirect psychophysics." Indirect estimation of pain is common in pain research and often referred to as "proxy rating," wherein a clinician (or a parent) estimates the pain state of a child. A recent meta-analysis evaluating this approach found weak to moderate correlations for the dyads of clinician and child, parent and child, and clinician and parent [21]. This fact highlights the challenge of making valid estimates of others' distress. However, an attempt to correlate estimates by clinicians with NICU infants is impossible because infants cannot estimate their own distress. Thus, to contrast with previous work, this study used ratio-scaling psychophysical techniques to estimate not the direct experience but rather the amount of distress associated with a stimulus or specific procedure.

### 2.2. Procedure list

Based on the reported literature, e.g. [4,22,23] a preliminary list of 46 procedures commonly performed in the NICU was created and presented to a panel of 5 experts (2 neonatologists, 1 neonatal nurse practitioner, and two staff nurses). The panel was asked to review and edit the list as appropriate to reflect "commonly performed procedures" in their practice. The list was re-circulated to the panel for agreement and a final list consisting of 55 procedures was derived.

### 2.3. Online survey and respondents

An online survey was developed and hosted by The Survey System (Version 9.5, surveysystem.com, Petaluma, CA). The respondent

population consisted of approximately 200 clinicians actively working at a level IV NICU in a research-intensive institution in the Northeastern United States and registered in the unit's email list. The respondents included in the study were physicians and nurses providing direct care to infants in the NICU.

The study was approved by the institutional Research Subjects Review Board and carried out according to published standards [24]. Respondents were reached by email with a link to the Survey System website. They were asked to provide demographic information and estimate the distress level thought by them to be associated with each of the 55 procedures on "an average NICU infant" using both ME and gLMS. Thus, each procedure was rated twice by each respondent. To avoid order bias, ME or gLMS was randomly presented to the respondent. Additionally, the order of all questions was randomized on a respondent-to-respondent basis.

### 2.4. Psychophysical procedure I: magnitude estimation (ME)

"Heel stick," a common procedure performed in the NICU, was assigned as the reference stimulus which other stimuli were to be subsequently compared. After assigning this value, all subsequent procedures were randomly presented one at a time for comparison. For example, if the distress associated with a heel stick was rated 20, and the respondent felt that the distress of an intravenous cannula insertion was twice that of the heel stick, the respondent would assign an intensity of 40 to that procedure. Likewise, if a diaper change was thought to cause half the distress of a heel stick, the respondent would assign an intensity of 10 to diaper change.

Completion of this section then led to the gLMS section of the survey (if ME was the first section being completed) or to the end of the survey (if ME was the second section being completed).

### 2.5. Psychophysical procedure II: general labeled magnitude scale (gLMS)

In gLMS, clinicians were asked to estimate the level of distress for each of the 55 procedures by sliding, with the computer mouse or touchpad, a blue pointer along a horizontal axis. This axis consisted of a linear scale from 0 to 999 (numbers were invisible to respondents), and on which words were spaced in a quasi-logarithmic fashion with the following labels: barely detectable, low, moderate, strong, very strong, and strongest imaginable [18,19]. Respondents were instructed to "rate the procedures relative to all other procedures in the NICU. 'Strongest imaginable' refers to the most intense distressful/painful procedure that you can imagine an infant experiencing in the NICU." Similar to ME, each procedure was individually presented in random order. Respondents were given an opportunity to comment or provide feedback about the survey.

### 2.6. Data analysis ME

Responses of individual respondents for both ME and gLMS procedures tend to have a log-normal distribution [20]. Therefore, raw data for each set of responses for each individual were normalized by computing the logarithm. ME values for each procedure were then standardized by dividing by the mean of the logarithm of the response values for that individual (Eq. (1)) across for all procedures.

$$X_{ij} = \frac{\log_{10}(x_{ij} + c)}{\frac{1}{n} \sum_j \log_{10}(x_{ij} + c)} \quad (1)$$

where  $x_{ij}$  is the raw response value for procedure  $i$ , from a given respondent  $j$ ,  $c$  is an additive constant, and  $n$  is the number of procedures ( $n = 55$ ). Values entered as zero or approximately zero, which occurred in the data, produced invalid results because  $\log_{10}(0)$  is

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