

Developing a Measure of Distress-Promoting Parent Behaviours During Infant Vaccination: Assessing Reliability and Validity

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| Keywords: | Vaccination, pain, infant, caregiver, behaviour |
| Abstract: | <p>Background: Infants rely on their parent's sensitive and contingent soothing to support their regulation from pain-related distress. However, despite being of potentially equal or greater import, there has been little focus on how to measure distress-promoting parent behaviours.</p> <p>Aims: The goal of this paper was to develop and validate a measure of distress-promoting parent behaviours for acute painful procedures (e.g., vaccinations) that could be used by researchers and clinicians.</p> <p>Methods: Following initial generation of measure items, focused group discussions were held with vaccinating clinicians to understand the measure's face, content, and ecological validity. Archival video footage (n= 537 videos of infant-caregiver dyads during vaccination) was then coded using the measure of distress-promoting behaviours for three minutes post-vaccine injection. Validity and reliability were examined using correlational analyses. Construct validity was assessed by convergent relationships with infant pain-related distress and divergent relationships were assessed with parent sensitivity and soothing-promoting behaviours.</p> <p>Results: The measure demonstrated both moderate to excellent inter-rater and test-retest reliability and convergent and divergent validity (absolute magnitude of r's 0.30 to 0.46).</p> <p>Conclusions: By demonstrating strong reliability and validity this measure represents a promising new way to understand how caregivers interact with infants during painful procedures. Through focusing on distress-promotion and using a format that may be coded both from video or in vivo, it is a feasible way to operationalize the impact of the caregiver on</p> |

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| | the infant's pain experience in both research and clinical settings. |
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Developing a Measure of Distress-Promoting Parent Behaviours During Infant Vaccination:
Assessing Reliability and Validity

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ABSTRACT

Background: Infants rely on their parent's sensitive and contingent soothing to support their regulation from pain-related distress. However, despite being of potentially equal or greater import, there has been little focus on how to measure distress-promoting parent behaviours.

Aims: The goal of this paper was to develop and validate a measure of distress-promoting parent behaviours for acute painful procedures (e.g., vaccinations) that could be used by researchers and clinicians.

Methods: Following initial generation of measure items, focused group discussions were held with vaccinating clinicians to understand the measure's face, content, and ecological validity. Archival video footage (n= 537 videos of infant-caregiver dyads during vaccination) was then coded using the measure of distress-promoting behaviours for three minutes post-vaccine injection. Validity and reliability were examined using correlational analyses. Construct validity was assessed by convergent relationships with infant pain-related distress and divergent relationships were assessed with parent sensitivity and soothing-promoting behaviours.

Results: The measure demonstrated both moderate to excellent inter-rater and test-retest reliability and convergent and divergent validity (absolute magnitude of r's 0.30 to 0.46).

Conclusions: By demonstrating strong reliability and validity this measure represents a promising new way to understand how caregivers interact with infants during painful procedures. Through focusing on distress-promotion and using a format that may be coded both from video or in vivo, it is a feasible way to operationalize the impact of the caregiver on the infant's pain experience in both research and clinical settings.

Key words: Vaccination, Pain, Infant, Caregiver, Behaviour

INTRODUCTION

How a newborn infant learns to self-regulate from distress is highly dependent on caregiver behaviours during periods of distress. Although infants are born with some homeostatic self-regulatory capabilities, their caregivers' contingent sensitive soothing can facilitate this process.¹⁻³ Thus, measuring caregiver responsiveness and soothing behaviours has been an important component of infant acute pain studies for decades.⁴⁻⁸ One theory that helps us understand the infant-caregiver interaction during a painful event is Attachment Theory. Attachment Theory purports that after the first year of life, reliable infant regulation patterns can be discerned based on watching how an infant responds to distress in the presence of their caregiver. These infant regulation patterns are strongly predicated on how the parent has behaviourally responded to the infant's distress over the first year of life. A central premise of Attachment Theory is that parent behaviours that help a distressed infant are those that achieve closeness (proximity) and are contingent on the infant's signalling⁹. The behaviours that parents enact that exacerbate infant pain-related distress through limiting proximity or non-contingent responses is the subject of the current study.

Much of the literature on parenting in the pediatric pain context has focused on the effects of discrete soothing behaviours on young child pain responses.⁴⁻⁸ For example, research has shown that parental use of verbal reassurance (e.g., saying "it's ok") increases infant pain⁵⁻⁶, whereas behaviours such as pacifying, rocking, and distraction have been shown to reduce pain-related distress^{4,6-7}. Of note, not all studies have found parent soothing behaviours to be effective in reducing infant distress. For example, one study found that maternal use of soothing behaviours such as holding, rocking, and stroking, did not reduce behavioural and physiological distress following a painful procedure^{e.g., 8}.

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3 Thus, when understanding parent behaviours in a painful context, it is not just about the
4 quantity (i.e., the number of times a parent soothing behaviour is enacted) but also the quality or
5 sensitivity of parent behaviour. Measures of the sensitivity of parent behaviours on the infant's
6 distress have been shown to be consistently related to infant pain-related distress.¹⁰⁻¹⁴ However,
7 parent sensitivity has only accounted for a moderate amount of the variance in infant pain-related
8 distress and parent sensitivity measures require extensive training, significant time commitments
9 to code, and require post-graduate knowledge in clinical and/or developmental psychology to
10 achieve reliability. Moving in a new direction, the current study focuses on easily observable
11 parent *distress-promoting* behaviours that could be coded during acute painful procedures, such
12 as a vaccination appointment. Recent multivariate models suggest that when both coping-
13 promoting and distress-promoting parental behaviours are concurrently examined in the same
14 model, distress-promoting behaviours were more powerful determinants of pain-related distress
15 in early childhood.¹⁵

32 Present Study

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34 Using an Attachment perspective, specific behaviours were generated that worked against
35 proximity-seeking and contingent responding (i.e., behaviours that suggest ignoring,
36 misunderstanding, or enhancing infant pain-related distress) to an infant's distress. The purpose
37 of this study was to develop and validate a feasible measure of distress-promoting behaviours
38 that could be used for lab-based coding by researchers as well as in-vivo coding by clinicians. A
39 measure used within health settings should be appropriate to the *context* (e.g., vaccinating
40 setting), must have *content* that is based on the current evidence-based practices and that is
41 appropriate for all possible users (e.g., distress-promoting behaviours observed by researchers
42 and clinicians), must demonstrate *usability* (i.e., cost effective, not overly time consuming), as
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well as have an appropriate structure (i.e., logical and functional appearance).¹⁶ Using these priorities as our framework, we set out to answer two research questions:

1) What behaviours should be included in this measure based on both infant pain researchers and vaccinating clinicians' experience and expertise?

2) What is the reliability and validity of this measure in the vaccination context?

We hypothesized that using an Attachment lens to generate easily observable behaviours that worked against proximity and contingency would generate a list of distress-promoting behaviours that would have strong reliability and validity in an acute pain context (i.e., vaccination).

METHODS

Procedure

Ethics approval was obtained from the affiliated university and tertiary pediatric hospital for the original OUCH cohort study. The method for obtaining the footage for coding are described extensively elsewhere.¹¹⁻¹³ For the current study, there were two phases: item generation and preliminary psychometric evaluation.

Item generation. An initial set of parent behaviours (items) were anecdotally tracked during vaccination video coding from the OUCH Cohort (>2300 vaccination episodes). Initial item generation discussions involved 7 lab members who were reliable in the use of validated measures of caregiver emotional availability, discrete caregiver soothing behaviours, and/or infant pain-related distress. Once a subset of behaviours had been selected, the two lead authors (RPR and HG) presented the items to vaccinating clinicians over three iterative discussion groups. In line with published recommendations on how to run these discussion groups¹⁷, our discussion group size was manageable (less than 12 people), and open debate and discussion was

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3 encouraged. These three groups were held between July and September 2014, and each was
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5 between 60 and 75 minutes in duration. Table 2 outlines all changes that were made to the
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7 measure through these discussion group meetings, which included removal and merging of some
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9 original behaviours, enhancing behavioural descriptions, including a new behaviour, as well as
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11 change to the structure of the measure for feasible use. As saturation (i.e., no new ideas were
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13 being generated) had been achieved following the third meeting, no further meetings occurred,
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15 and the final eight behaviours were used for the second phase of the study.
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19 **Psychometric evaluation.** A total of 537 videos of 12-month vaccine injections were
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21 used to code the eight distress-promoting behaviours generated in Phase 1. This study used data
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23 from the 12-month wave ($n = 548$) of the OUCH Cohort.¹² The 12-month wave was selected as
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25 the pattern of infant distress regulation based on parent behaviours is most reliable at this time.⁹
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27 ¹⁸ Due to video footage limitations in 11 dyads, a total of 537 dyads were included in the coding
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29 effort.
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33 For reliability, 30% of the entire 12-month sample was coded by three separate raters ($n =$
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35 161). In order to examine the stability of the presence of distress-promoting parental behaviours
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37 over time, a subsample of the parents from the 12-month vaccine injection were also coded for
38
39 distress-promoting parent behaviours during their child's 6-month vaccination appointment ($n =$
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41 136). For validity, these videos had previously been coded for infant distress behaviours,^{19, 20}
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43 caregiver emotional availability,²¹ and proximal soothing.⁵
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47 Measures

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49 Parent demographic information. During the 12-month vaccination visit, caregivers
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51 completed a short demographic questionnaire inquiring about their relationship with the infant,
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53 education level, and self-reported heritage culture.
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Parent distress-promoting behaviours. The measure developed from this study included eight distress-promoting behaviours. To help create a coding mnemonic for the behaviours, all eight behaviours in the final set began with the same letter. The behaviours included: Fathom Wrong [i.e., making comments toward the highly distressed infant that does not address or discredits the infant's distress, such as 'It's not so bad'], Face Cover [i.e., covering a screaming infant's face with any object such as a hand or blanket], Fashion First [i.e., dressing a highly distressed infant with no attempt made to soothe infant], Forceful [i.e., handling the infant roughly such as pulling a supine infant across the examining table with their wrist], Frustration [i.e., any facial expressions that reflect irritation with the infant's distress, such as rolling eyes, sighing], Fearful [i.e., any parental facial expression that suggests they are scared or frightened], Flit Away [i.e., any behaviour or parental positioning that does not bring the infant close into the parent when the infant is in moderate to high distress], and Flat Face [i.e., complete lack of emotional expression in response to infant's moderate to high distress]; a rare, but established distressing behaviour for infants²².

With the exception of 'Forceful', which is coded if seen at any time during the vaccination appointment, all these parent behaviours were only coded if the parent engages in these behaviours while the child is in moderate to high distress. Moderate to high distress was determined based on the presence of a full-lunged cry¹⁹. The exception to this rule is 'forceful' because the strong use of force by a parent, whether the infant is in distress or not, would promote distress. Scores ranged from 0 to 8, with higher scores indicating a greater number of distress-promoting behaviours. Behaviours were coded for three minutes after the last needle. To facilitate in vivo coding, the presence or absence of each behaviour was used, not frequency

counts of how many times each behaviour was coded. Reliability and validity on the set of behaviours are presented in the Results section.

Infant pain-related distress. Two different behavioural pain measures were analyzed to determine convergent validity with the distress-promoting behaviours. Higher scores on both measures reflect higher pain-related distress. Both measures provided an assessment of the infant's initial reactivity and regulation (i.e., return to homeostasis) from the needle, given the distinct differences between how an infant first responds to a stimulus (more reflexive) and how a child regulates from a painful stimulus (more deliberate).²³ In order to substantiate the distress-promoting behaviours that promote pain-related distress, there would need to be a relationship such that a greater total of distress-promoting behaviours would be related to higher pain scores. The Modified Behavior Pain Scale (MBPS)¹⁹ is a measure of broad distress behaviours and comprises the sum of three behavioural scales: facial expression (0-3), cry (0-4), and body movement (0-3) to depict the degree of infant pain-related distress on a scale of 0-10. Higher scores indicate greater pain. For study purposes, we looked at MBPS scores from four different time points: for the initial 15 seconds post-needle (MBPS Needle), for 15 seconds one minute after an initial 15 second epoch (MBPS 1min), 15 seconds two minutes after the initial 15 second epoch (MBPS 2min), and 15 seconds three minutes after the initial 15 second epoch (MBPS 3min). The MBPS has demonstrated strong concurrent and construct validity, as well as item-total and inter-rater reliability within the immunization context.^{19, 24, 25} In the present study, inter-rater reliability ranged from .93 to .96.

The Neonatal Facial Coding System (NFCS)²⁰ is a measure based on the specific facial constellation to painful stimuli, demonstrating content, construct, convergent, and face validity²⁶. It uses brow bulge, eye squeeze, nasolabial furrow, open lips, vertical stretch mouth, horizontal

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3 stretch mouth, and taut tongue to create a facial pain score. Each facial action is coded as 0 (not
4 present), or 1 (present)²⁷. Pain scores were obtained calculating the proportion of time the facial
5 actions were present for every second in a 10-second epoch following the needle (NFCS
6 Needle), 10 seconds one minute after last needle (NFCS 1min), 10 seconds two minutes after last
7 needle (NFCS 2min), and 10 seconds three minutes after last needle (NFCS 3min). Scores range
8 from 0 to 1, with higher scores indicating greater facial pain expression. In the present study,
9 inter-rater reliability ranged from .85 to .97 for each facial action.

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19 Caregiver emotional availability and proximal soothing. To examine divergent validity,
20 two well-validated measures of caregiver soothing-promoting behaviour were coded, one
21 relating to the quality of caregiving and the other related to the quantity of ‘close contact’ or
22 ‘proximal soothing’ behaviours (i.e., rocking and physical comforting) that facilitate secure
23 attachment. Thus, we set out to demonstrate that the more distress-promoting behaviours the
24 parents enacted, the lower the sensitivity and the amount of proximal soothing.

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33 The Emotional Availability Scales – 4th Edition (EAS)²¹ is a global measure of the
34 quality of caregiving behaviours, that has demonstrated construct and criterion validity²⁸. It
35 examines caregiver behaviours on four different subscales: sensitivity, structuring, non-
36 intrusiveness, and non-hostility. Through subscales that take into account the infant’s responses
37 to the parent’s behaviour, a clinical rating is made. High scores reflect greater caregiver
38 sensitivity. Caregivers received a total score by combining the four subscales (Range: 28-116).
39 In the present study, inter-rater reliability for the total EAS scores ranged from .88 to .93.

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49 The Measure of Adult and Infant Soothing and Distress (MAISD)⁵ has shown reliability
50 and concurrent validity as an observation scale developed to evaluate behaviours of children,
51 parents, and nurses during painful medical procedures. For the purposes of the present study,
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relationships with behaviours that could be considered proximal soothing were analyzed: rocking and physical comforting. Rocking and physical comfort were coded as present (1) or absent (0) in 5-second epochs for the one-minute period after the last needle (MAISD Rock 1min, MAISD Phys Comf 1min), the two-minute period after the last needle (MAISD Rock 2min, MAISD Phys Comf 2min), and the three-minute period after the last needle (MAISD Rock 3min, MAISD Phys Comf 3min). Index scores were calculated based on the proportion of time each behaviour was present out of the total number of epochs that were codeable in a time period. Index scores ranged from 0 to 1, with higher scores indicating greater frequency of that behaviour. Reliability coefficients across coders was strong to excellent, ranging from .91 to .95 for rocking and .75 to .88 for physical comfort.

Analysis Plan

To determine whether the measure was reliable, inter-rater reliability was measured using the Interclass correlation. In order to examine reliability over time, a subsample of distress-promoting parental behaviours from the 6-month and 12-month vaccination appointments were also compared.

To determine the measure's construct validity, Pearson correlation coefficients were used to assess the convergent relationships between the total number of distress-promoting parent behaviours and the MBPS and NFCS scores immediately following the vaccine injection, and at one-, two-, and three minutes post-vaccine injection. Divergent relationships were also assessed using Pearson correlation coefficients between total number of distress-promoting parent behaviours and the EAS score, and MAISD (rocking and physical comfort) scores one-, two-, and three minutes post-vaccine injection. Due to a high number of correlations run, a Bonferroni

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3 correction was used (family wise error = .10; .10/14 correlational analyses = .007). Table 3
4 reports the interrelationships between all the study variables.
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7 RESULTS

8 Demographic Data

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10 The average age of caregivers coded for this study was 34.09 years ($SD = 5.16$), and
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12 86.9% of caregivers were mothers. They self-reported a diverse array of cultural backgrounds
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14 (37.6% European, 16.1% Asian, 12.1% North American, 7.6% Jewish, 6.5% Middle
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16 Eastern/African, 3.2% Latin/South American, 8.2% Other, and 8.7% Mixed) and most reported
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18 having an undergraduate degree or more (73.8% university degree or higher).
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22 Item Development and Face, Ecological, and Content Validity

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24 Clinicians and researchers came to consensus about the final items for inclusion (See
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26 Table 1). The participants agreed that the final content of the measure reflected distress-
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28 promoting behaviours (face and content validity) that are commonly seen during routine
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30 vaccination across their practices (ecological validity), and believed that the final measure was
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32 useable, with a clear structure and images that could be used both in a research and clinical
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34 setting.
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38 Descriptive Statistics

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40 The mean caregiver total of distress-promoting behaviours was 1.47 ($SD = 1.10$). The
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42 observed scores ranged from 0 to 5 (total possible was 8). Of the entire sample, 22.5% had a
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44 score of 0, 30.7% had a score of 1, 26.3% had a score of 2, 18.2% had a score of 3, 2% had a
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46 score of 4, and 0.2% had a score of 5. Of the eight behaviours, the most commonly coded
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48 behaviour was Fathom Wrong (53.8%), and the least common behaviour was Flat Face
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50 (occurring in only 1% of the sample). Table 4 shows descriptive statistics for all other study
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52 variables.
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Reliability

Interrater reliability between three independent coders for this study was excellent (Averaged $ICC = .92, p < .001$; Coder 1 with Coder 2 = $.93, p < .001$, Coder 1 with Coder 3 = $.89, p < .001$). Further, distress-promoting parent behaviours were also coded on a subsample of the same parents during the 6-month ($n = 136$) vaccine injection to examine the stability of distress-promoting behaviours over time. The relationship showed a medium effect size ($r = .36, p < .001; d = .77$).

Construct Validity (Convergent and Divergent Validity)

Infant Pain Scores: The total of distress-promoting behaviours was strongly correlated with the MBPS and NFCS immediately following and in the minutes post-vaccine injection. Moderate to strong positive relationships were seen between the total number of distress-promoting behaviours and the MBPS immediately following the needle [$r = .35, p < .001$; medium effect size ($d = 0.75$)], one minute post-vaccine injection [$r = .42, p < .001$; large effect size ($d = .93$)], two minutes post-vaccine injection [$r = .46, p < .001$; large effect size ($d = 1.04$)] and three minutes post-vaccine injection ($r = .33, p < .001$; medium effect size ($d = .70$)). Strong positive relationships were also seen between the total distress-promoting behaviours and NFCS immediately following the needle [$r = .31, p < .001$; medium effect size ($d = 0.65$)], one minute post-vaccine injection [$r = .36, p < .001$; medium effect size ($d = .77$)], and two minutes post-vaccine injection [$r = .30, p < .001$; medium effect size ($d = .63$)].

Caregiver Behaviour Scores: A strong negative relationship was seen between the total distress-promoting behaviours and EAS [$r = -.40, p < .001$; large effect size ($d = .87$)].

Significant relationships were not seen between the total distress-promoting behaviours and the

MAISD caregiver proximal soothing and rocking subscales at any time point. Table 3 displays all convergent and divergent relationships.

DISCUSSION

Infants heavily rely on their parents' sensitive responses to regulate their pain-related distress.¹⁻³ According to Attachment Theory, distressed infants signal to their parents to bring them close and elicit caregiving.⁹ To soothe their infant's distress sensitively, parents need to be attuned to their signalling and maintain close proximity, with ongoing monitoring of the infant's changing needs, alongside flexible responding to these changing needs. While parent soothing and caregiver sensitivity has been extensively examined in the pediatric pain literature and has been shown to reduce infant pain-related distress¹¹⁻¹⁴, a large amount of variance in infant pain behaviours is still left unaccounted for. Given no tools exist that operationalize parent behaviours that promote pain-related distress in infants, the goal of this study was to develop and validate such a measure.

Interpretation of Findings

This measure demonstrated moderate to strong interrater and test-retest reliability. There was high agreement on the total number of distress-promoting behaviours present between coders, and there was a moderate relationship between the total of these parent behaviours at the 6- and 12-month vaccination appointments. It is important that two of the three coders were undergraduate students who had less than one year of pain-specific research experience when learning the measure, as this suggests the ease at which these behaviours can be learned.

The final structure of this measure included eight distress-promoting behaviours. This was based on in-depth discussions between researchers with experience coding parent behaviours during vaccination, as well as vaccinating health care professionals. Through three

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3 focused discussion groups with clinicians, we were able to create an ecologically valid measure
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5 with content and face validity. Involving both researchers and vaccinating clinicians in the
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7 development phase was critical as we strove to have feasibility in both research and clinical
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9 settings.
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12 As hypothesized, our measure was shown to be a reliable and valid way to measure
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14 parent distress-promoting behaviours using archival vaccination footage. Construct validity was
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16 shown through convergent relationships with infant pain measures. Moderate to strong
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18 convergent relationships were found between the number of distress-promoting behaviours and
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20 the two separate measures of infant pain-related distress post-vaccine injection. The more
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22 distress-promoting behaviours the parents enacted, the greater the infant's pain-related distress.
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24 These relationships were strongest following the needle, one-minute following the needle, and
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26 two-minutes following the needle, and confirm the importance of coding these distress-
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28 promoting behaviours when the infant is in moderate to high distress. In addition, there was a
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30 strong divergent relationship between the total number of distress-promoting behaviours and
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32 caregiver emotional availability, suggesting that the more distress-promoting behaviours present,
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34 the less emotionally available or sensitive the caregiver was in the minutes following the needle
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36 puncture.
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43 Interestingly, no relationships were found between distress-promoting parent behaviours
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45 and discrete soothing parent behaviours. This could be due to the previously discussed issue that
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47 the higher frequency of a 'soothing behaviour' (i.e., how many times rocking and physical
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49 comforting occurred) may not always be what a particular infant wants in that moment (i.e.,
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51 contingency). Thus, high scores and low scores on the soothing measure could mean exactly the
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53 same thing for different infants within the sample. This was not the case for our set of distress-
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3 promoting behaviours. The behaviours were carefully selected because they were consistently
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5 distress-promoting in our sample when done to an infant who is in moderate to high distress.
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7 Thus, the higher the number of distress-promoting behaviours, the greater the presence of a
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9 variety of distress promotion responses (i.e., coders did not count how many times a specific
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11 distress-promoting behaviour occurred, just that it occurred). The very strong inverse
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13 relationship found with a clinical judgment of caregiver sensitivity (i.e., the EAS, the measure
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15 that takes into account the impact of those behaviours on the infant and thus higher scores always
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17 mean higher sensitivity) adds strength to this speculation.
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21 Implications and Future Directions

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24 To our knowledge, this is the first measure to focus specifically on distress-promoting
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26 behaviours. One of the primary benefits of creating and validating this measure is finding a new
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28 way to assess the impact of the parent on their infant's pain responding. While parent soothing
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30 and sensitivity have been studied in the pediatric pain literature, measuring these constructs
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32 present with their unique challenges. First, frequency counts of soothing behaviours lack a
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34 demonstration of whether particular soothing behaviours are attuned to the infants' needs (i.e.,
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36 sensitivity). Second, measures of parent sensitivity are time-consuming to learn, often need to be
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38 learned from the original developers of the scale due to the nuance of its coding (it is generally
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40 seen as a 'clinical judgment' measure), is costly to maintain reliability in a lab over time, and
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42 often requires a high level of health professional or clinical psychology graduate training to
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44 become successfully reliable. The current measure of easily observable distress-promoting
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46 behaviours combines the feasibility of coding the presence of a behaviour in vivo, with an
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48 emphasis on behaviours known not to be attuned to the infant's needs.
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3 This measure therefore can benefit a wider range of scientists, as well as clinicians. In
4 terms of research use, providing non-clinical scientists with a feasible measure of parenting
5 behaviours allows for a more thorough exploration of their research questions (e.g., the
6 confounding parent variable on treatment effects). Further, behavioural scientists would benefit
7 from a new way to measure parent behaviour, with the possibility of accounting for more
8 variance in infant pain responding. Finally, there is great potential for incorporation into primary
9 care by clinicians. By teaching vaccinating health professionals to look for these distress-
10 promoting behaviours, clinicians will be better able to coach parents in the immediate moment
11 on different strategies that may enhance pain-related distress regulation rather than inhibit it.
12 Future research should explore ideal training initiatives with researchers and vaccinating
13 clinicians, as well as explore psychometric properties to validate the measure's use when used
14 during vaccinations.
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31 Another important future direction relates to predictors of the distress-promoting
32 parenting behaviours. For example, by supporting parental mental health (e.g., depression,
33 anxiety, parenting stress, trauma) one may be able to reduce the number of distress-promoting
34 responses a parent uses with their distressed infant.
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40 Limitations

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42 Past research by our lab²⁹⁻³⁰ has shown that there are rare cases of infants who do not
43 respond with moderate to high levels of pain-related distress immediately post-vaccine injection.
44 In these cases, the presence of these eight distress-promoting behaviours become ambiguous
45 post-vaccine injection because it is unclear if the infant is not signalling pain after the needle
46 because of no pain or because they have learned that expressing distress to their parent does not
47 elicit help (one hallmark of insecure attachments). It is critical that the set of behaviours only be
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3 coded in the presence of moderate-high infant distress. In addition, there was no experimental
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5 manipulation, thus causation should not be inferred from the significant correlations in this work.
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7 Finally, as this was a low-risk sample, generalizability to higher risk samples must be
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9 established.
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11 12 CONCLUSION

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14 In conclusion, this new measure appears to be a valid way to measure distress-promoting
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16 parent behaviours in the infant vaccination context. Measuring distress promoting behaviours
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18 appears to be a novel and fruitful way to explore the relationships between caregiver behaviour
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20 and infant pain. Not only does the measure's feasibility allow for research use by a wider range
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22 of disciplines, but the potential for incorporation into primary care will allow for better parent
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24 coaching and support during painful procedures.
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DECLARATION OF INTEREST STATEMENT

No conflicts of interest are declared.

For Peer Review Only

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Distress-Promoting Parent Behaviours

Table 1. *Descriptions of Behaviours*

| Caregiver Behaviour | Description |
|---------------------|--|
| Frustration | Parent expressed any sign of frustration at the infant's high/moderate distress (e.g., sighing, eye rolling), or verbally expresses frustration (e.g., "Oh come on, just calm down") |
| Fear/Distress | Parent face looks scared or nervous around the needle/doctor or verbally expresses fear (e.g., "Oh I hate needles – they are awful", "needles are scary") when infant is in high/moderate distress |
| Flat Face | Parent shows no emotion (positive or negative) throughout the vaccination and particularly in response to infant's high/moderate distress. |
| Fathom Wrong | When the infant is in high/moderate distress, the parent makes a statement that does not reflect the infant's high distress level (e.g., saying "You're fine" over three times to a screaming infant, laughing at infant who is turning red from crying) |
| Face Cover | When the infant is in high/moderate distress, the parent tries to cover his/her face (or mouth or eyes) with her hand, a blanket, etc. |
| Fashion First | When the infant is in high/moderate distress the parent begins to dress the infant. |
| Forceful | At any time, the parent uses excessive force with the infant (e.g., lifts the infant by the arms, puts infant down in a rough manner, pulls a supine infant across the table by the wrist). |
| Flit Away | When the infant is in high/moderate distress, parent a) puts the infant down, b) holds infant away from her, c) passes the infant off to someone else, or d) is purposefully outside room while child has vaccination. |

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Table 2. *Item Generation Sequence with Clinicians*

| | Items | Key Changes Generated from Clinicians |
|---------------------------------------|--|--|
| Discussion Group 1 (Original Meeting) | <p><i>Caregiver Behaviours:</i></p> <ol style="list-style-type: none"> 1. Frustration 2. Fear/Distress 3. Flat Face 4. Fathom Wrong 5. Face Cover 6. Fashion First 7. Flit Away 8. Fork Over | <p>Add behaviour– <i>Flee the Scene</i>: Parent not present at any time during the needle</p> <p>Group caregiver behaviours into meaningful subcategories so easier to understand (i.e. Face-related [Frustrated, Fearful Face, Flat Face]; Saying/Doing to the Infant[Fathom Wrong, Face Cover]; Distancing from infant [Flit Away, Fork Over, Flee the Scene])</p> <p>Clarify Items using descriptions more understandable to vaccinating professionals</p> <p>Add pictures to make it easier to skim</p> <p>Clarify Focus that infant had to be in high distress post-needle; 3 minutes post-needle</p> |
| Discussion Group 2 | <p><i>Caregiver Behaviours:</i></p> <ol style="list-style-type: none"> 1. Frustration 2. Fear/Distress 3. Flat Face 4. Fathom Wrong 5. Face Cover 6. Fashion First 7. Flit Away 8. Fork Over 9. <i>Flee the Scene</i> | <p>Create a separate sheet from the checklist with brief descriptions as a reminder</p> <p>Add one behaviour – <i>Forceful</i> - when you note a parent is ‘too’ rough with their child post-needle.</p> <p>Condensed all <i>Distance</i> behaviours into one behaviour to make easier to score <i>Flit Away</i></p> |

Distress-Promoting Parent Behaviours

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| 1 | | |
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| 3 | Focus Group 3 | Caregiver Behaviours: |
| 4 | (Final | |
| 5 | Consensus) | |
| 6 | | 1. Frustration |
| 7 | | 2. Fear/Distress |
| 8 | | 3. Flat Face |
| 9 | | 4. Fathom Wrong |
| 10 | | 5. Face Cover |
| 11 | | 6. Fashion First |
| 12 | | 7. Forceful |
| 13 | | 8. Flit Away |
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Table 3. Correlations of Total Insensitive Behaviours with Measures of Caregiver Behaviours and Infant Distress

Distress-Promoting Parent Behaviours

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| | Total Inensitive Behaviours | MBPS Needle | MBPS 1min | MBPS 2min | MBPS 3min | NFCS Needle | NFCS 1min | NFCS 2min | NFCS 3min | EAS | MAISD Rock 1min | MAISD Rock 2min | MAISD Rock 3min | MAISD Phys Comf 1min | MAISD Phys Comf 2min | MAISD Phys Comf 3min |
|----------------------|-----------------------------|----------------|----------------|----------------|----------------|---------------|----------------|----------------|---------------|--------------|-----------------|-----------------|-----------------|----------------------|----------------------|----------------------|
| Total Behaviours | - | | | | | | | | | | | | | | | |
| MBPS Needle | .35*** | - | | | | | | | | | | | | | | |
| MBPS 1min | .42*** | .38*** | - | | | | | | | | | | | | | |
| MBPS 2min | .46*** | .33*** | .52*** | - | | | | | | | | | | | | |
| MBPS 3min | .33*** | .28*** | .37*** | .51*** | - | | | | | | | | | | | |
| NFCS Needle | .31*** | .53*** | .31*** | .24*** | .16** | - | | | | | | | | | | |
| NFCS 1min | .36*** | .24*** | .51*** | .38*** | .25*** | .33*** | - | | | | | | | | | |
| NFCS 2min | .30*** | .22*** | .28*** | .42*** | .26*** | .16** | .35*** | - | | | | | | | | |
| NFCS 3min | .20*** | .14** | .26*** | .36*** | .51*** | .15** | .29*** | .23*** | - | | | | | | | |
| EAS | -.40*** | -.20*** | -.20*** | -.22*** | -.21*** | -.12** | -.20*** | -.18*** | -.15** | - | | | | | | |
| MAISD Rock 1min | .02 | .13** | .17*** | .19*** | .14** | .12** | .09* | .11* | .08 | .09 | - | | | | | |
| MAISD Rock 2min | -.05 | .12** | .18*** | .14** | .17*** | .16*** | .09* | .09* | .13** | .01 | .55*** | - | | | | |
| MAISD Rock 3min | -.05 | .15** | .14** | .09 | .14** | .09 | .10* | .10* | .05 | -.02 | .36*** | .61*** | - | | | |
| MAISD Phys Comf 1min | .02 | .10* | .14** | .05 | .01 | .18*** | .03 | .07 | .02 | .14** | .36*** | .24*** | .09 | - | | |

Distress-Promoting Parent Behaviours

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| 4 | MAISD | .04 | .11* | .19*** | .14** | .14** | .13** | .14** | .14** | .09 | .04 | .27*** | .41*** | .27*** | .43*** | - |
| 5 | Phys Comf | | | | | | | | | | | | | | | |
| 6 | 2min | | | | | | | | | | | | | | | |
| 7 | MAISD | -.01 | .03 | .11* | .09 | .09 | .12** | .11* | .11* | .09 | .05 | .18*** | .28*** | .36*** | .29*** | .46*** |
| 8 | Phys Comf | | | | | | | | | | | | | | | |
| 9 | 3min | | | | | | | | | | | | | | | |

Note. The correlations of interest in this table are those assessing the relationships between the total insensitive behaviours and measures of caregiver soothing behaviours (MAISD), emotional availability (EAS), and infant pain-related distress (MBPS, NFCS). Further, correlations below $r = .30$ are considered weak, regardless of statistical significance due to the large sample size in this study.

*** $p < .001$

** $p < .01$

* $p < .05$

Distress-Promoting Parent Behaviours

Table 4. Means and Standard Deviations for Infant Pain-Related Distress, Caregiver Sensitivity, and Sensitive Soothing Behaviours

| | Mean (SD) | Possible Scale Range |
|--|---------------|----------------------|
| NFCS Needle | 0.73 (0.22) | 0-1 |
| NFCS 1-min Post-Needle | 0.33 (0.24) | 0-1 |
| NFCS 2-min Post-Needle | 0.26 (0.27) | 0-1 |
| NFCS 3-min Post-Needle | 0.21 (0.18) | 0-1 |
| MBPS Needle | 8.26 (1.15) | 0-10 |
| MBPS 1-min Post-Needle | 5.59 (2.49) | 0-10 |
| MBPS 2-min Post-Needle | 4.79 (2.57) | 0-10 |
| MBPS 3-min Post-Needle | 4.17 (2.50) | 0-10 |
| EAS | 92.83 (10.29) | 28-116 |
| MAISD Rocking 1-min Post-Needle | 0.37 (0.32) | 0-1 |
| MAISD Rocking 2-min Post-Needle | 0.20 (0.29) | 0-1 |
| MAISD Rocking 3-min Post-Needle | 0.12 (0.24) | 0-1 |
| MAISD Physical Comfort 1-min Post-Needle | 0.31 (0.26) | 0-1 |
| MAISD Physical Comfort 2-min Post-Needle | 0.16 (0.21) | 0-1 |
| MAISD Physical Comfort 3-min Post-Needle | 0.11 (0.20) | 0-1 |

Distress-Promoting Parent BehavioursTable 1. *Descriptions of Behaviours*

| Caregiver Behaviour | Description |
|---------------------|--|
| Frustration | Parent expressed any sign of frustration at the infant's high/moderate distress (e.g., sighing, eye rolling), or verbally expresses frustration (e.g., "Oh come on, just calm down") |
| Fear/Distress | Parent face looks scared or nervous around the needle/doctor or verbally expresses fear (e.g., "Oh I hate needles – they are awful", "needles are scary") when infant is in high/moderate distress |
| Flat Face | Parent shows no emotion (positive or negative) throughout the vaccination and particularly in response to infant's high/moderate distress. |
| Fathom Wrong | When the infant is in high/moderate distress, the parent makes a statement that does not reflect the infant's high distress level (e.g., saying "You're fine" over three times to a screaming infant, laughing at infant who is turning red from crying) |
| Face Cover | When the infant is in high/moderate distress, the parent tries to cover his/her face (or mouth or eyes) with her hand, a blanket, etc. |
| Fashion First | When the infant is in high/moderate distress the parent begins to dress the infant. |
| Forceful | At any time, the parent uses excessive force with the infant (e.g., lifts the infant by the arms, puts infant down in a rough manner, pulls a supine infant across the table by the wrist). |
| Flit Away | When the infant is in high/moderate distress, parent a) puts the infant down, b) holds infant away from her, c) passes the infant off to someone else, or d) is purposefully outside room while child has vaccination. |

Table 2. *Item Generation Sequence with Clinicians*

| | <u>Items</u> | <u>Key Changes Generated from Clinicians</u> |
|--|--|--|
| <u>Discussion Group 1 (Original Meeting)</u> | <u>Caregiver Behaviours:</u> 1. Frustration 2. Fear/Distress 3. Flat Face 4. Fathom Wrong 5. Face Cover 6. Fashion First 7. Flit Away 8. Fork Over | <u>Add behaviour– <i>Flee the Scene</i>: Parent not present at any time during the needle</u> <u>Group caregiver behaviours into meaningful subcategories so easier to understand (i.e. Face-related [Frustrated, Fearful Face, Flat Face]; Saying/Doing to the Infant[Fathom Wrong, Face Cover]; Distancing from infant [Flit Away, Fork Over, Flee the Scene])</u> <u>Clarify Items using descriptions more understandable to vaccinating professionals</u> <u>Add pictures to make it easier to skim</u> <u>Clarify Focus that infant had to be in high distress post-needle; 3 minutes post-needle</u> |
| <u>Discussion Group 2</u> | <u>Caregiver Behaviours:</u> 1. Frustration 2. Fear/Distress 3. Flat Face 4. Fathom Wrong 5. Face Cover 6. Fashion First 7. Flit Away 8. Fork Over 9. <i>Flee the Scene</i> | <u>Create a separate sheet from the checklist with brief descriptions as a reminder</u> <u>Add one behaviour – <i>Forceful</i> - when you note a parent is ‘too’ rough with their child post-needle.</u> <u>Condensed all <i>Distance</i> behaviours into one behaviour to make easier to score <i>Flit Away</i></u> |

| <u>Focus Group 3 (Final Consensus)</u> | <u>Caregiver Behaviours:</u> | <u>Consensus achieved on finalized format (checklist, 'cheat sheet) and content (behavioural definitions resonate with vaccinating clinicians)</u> |
|--|------------------------------|--|
| | <u>1. Frustration</u> | |
| | <u>2. Fear/Distress</u> | |
| | <u>3. Flat Face</u> | |
| | <u>4. Fathom Wrong</u> | |
| | <u>5. Face Cover</u> | |
| | <u>6. Fashion First</u> | |
| | <u>7. Forceful</u> | |
| | <u>8. Flit Away</u> | |

Table 3. Correlations of Total Insensitive Behaviours with Measures of Caregiver Behaviours and Infant Distress

Distress-Promoting Parent Behaviours

| | Total Insensitive Behaviours | MBPS Needle | MBPS 1min | MBPS 2min | MBPS 3min | NFCS Needle | NFCS 1min | NFCS 2min | NFCS 3min | EAS | MAISD Rock 1min | MAISD Rock 2min | MAISD Rock 3min | MAISD Phys Comf 1min | MAISD Phys Comf 2min | MAISD Phys Comf 3min |
|----------------------------|------------------------------------|----------------|----------------|----------------|----------------|----------------|---------------|---------------|---------------|--------------|-----------------------|-----------------------|-----------------------|-------------------------------|-------------------------------|-------------------------------|
| Total Behaviours | - | | | | | | | | | | | | | | | |
| MBPS Needle | .35*** | - | | | | | | | | | | | | | | |
| MBPS 1min | .42*** | .38*** | - | | | | | | | | | | | | | |
| MBPS 2min | .46*** | .33*** | .52*** | - | | | | | | | | | | | | |
| MBPS 3min | .33*** | .28*** | .37*** | .51*** | - | | | | | | | | | | | |
| NFCS Needle | .31*** | .53*** | .31*** | .24*** | .16** | - | | | | | | | | | | |
| NFCS 1min | .36*** | .24*** | .51*** | .38*** | .25*** | .33*** | - | | | | | | | | | |
| NFCS 2min | .30*** | .22*** | .28*** | .42*** | .26*** | .16** | .35*** | - | | | | | | | | |
| NFCS 3min | .20*** | .14** | .26*** | .36*** | .51*** | .15** | .29*** | .23*** | - | | | | | | | |
| EAS | -.40*** | -.20*** | -.20*** | -.22*** | -.21*** | -.12** | - | - | -.15** | - | | | | | | |
| | | | | | | | .20*** | .18*** | | | | | | | | |
| MAISD Rock 1min | .02 | .13** | .17*** | .19*** | .14** | .12** | .09* | .11* | .08 | .09 | - | | | | | |
| MAISD Rock 2min | -.05 | .12** | .18*** | .14** | .17*** | .16*** | .09* | .09* | .13** | .01 | .55*** | - | | | | |
| MAISD Rock 3min | -.05 | .15** | .14** | .09 | .14** | .09 | .10* | .10* | .05 | -.02 | .36*** | .61*** | - | | | |
| MAISD Phys Comf 1min | .02 | .10* | .14** | .05 | .01 | .18*** | .03 | .07 | .02 | .14** | .36*** | .24*** | .09 | - | | |

Distress-Promoting Parent Behaviours

| | | | | | | | | | | | | | | | | |
|---|-----------|-------------|------|--------|-------|-------|-------|-------|-------|-----|-----|--------|--------|--------|--------|--------|
| 1 | | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | | | | |
| 4 | MAISD | .04 | .11* | .19*** | .14** | .14** | .13** | .14** | .14** | .09 | .04 | .27*** | .41*** | .27*** | .43*** | - |
| 5 | Phys Comf | | | | | | | | | | | | | | | |
| 6 | 2min | | | | | | | | | | | | | | | |
| 7 | MAISD | -.01 | .03 | .11* | .09 | .09 | .12** | .11* | .11* | .09 | .05 | .18*** | .28*** | .36*** | .29*** | .46*** |
| 8 | Phys Comf | | | | | | | | | | | | | | | |
| 9 | 3min | | | | | | | | | | | | | | | |

Note. The correlations of interest in this table are those assessing the relationships between the total insensitive behaviours and measures of caregiver soothing behaviours (MAISD), emotional availability (EAS), and infant pain-related distress (MBPS, NFCS). Further, correlations below $r = .30$ are considered weak, regardless of statistical significance due to the large sample size in this study.

*** $p < .001$

** $p < .01$

* $p < .05$

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Table 4. Means and Standard Deviations for Infant Pain-Related Distress, Caregiver Sensitivity, and Sensitive Soothing Behaviours

| | Mean (SD) | Possible Scale Range |
|--|---------------|----------------------|
| NFCS Needle | 0.73 (0.22) | 0-1 |
| NFCS 1-min Post-Needle | 0.33 (0.24) | 0-1 |
| NFCS 2-min Post-Needle | 0.26 (0.27) | 0-1 |
| NFCS 3-min Post-Needle | 0.21 (0.18) | 0-1 |
| MBPS Needle | 8.26 (1.15) | 0-10 |
| MBPS 1-min Post-Needle | 5.59 (2.49) | 0-10 |
| MBPS 2-min Post-Needle | 4.79 (2.57) | 0-10 |
| MBPS 3-min Post-Needle | 4.17 (2.50) | 0-10 |
| EAS | 92.83 (10.29) | 28-116 |
| MAISD Rocking 1-min Post-Needle | 0.37 (0.32) | 0-1 |
| MAISD Rocking 2-min Post-Needle | 0.20 (0.29) | 0-1 |
| MAISD Rocking 3-min Post-Needle | 0.12 (0.24) | 0-1 |
| MAISD Physical Comfort 1-min Post-Needle | 0.31 (0.26) | 0-1 |
| MAISD Physical Comfort 2-min Post-Needle | 0.16 (0.21) | 0-1 |
| MAISD Physical Comfort 3-min Post-Needle | 0.11 (0.20) | 0-1 |