Abstract

Anticipatory distress prior to a painful medical procedure can lead to negative sequelae including heightened pain experiences, avoidance of future medical procedures, and potential non-compliance with preventative healthcare such as vaccinations. Few studies have examined the longitudinal and concurrent predictors of pain-related anticipatory distress. This paper consists of two companion studies to examine both the longitudinal factors from infancy, as well as concurrent factors from preschool that predict pain-related anticipatory distress at the preschool age. Study 1 examined how well preschool pain-related anticipatory distress was predicted by infant pain responding at 2, 4, 6 and 12 months of age. In Study 2, using a developmental psychopathology framework, longitudinal analyses examined the predisposing, precipitating, perpetuating, and present factors that led to the development of anticipatory distress during routine preschool vaccinations. A sample of 202 caregiver-child dyads was observed during their infant and preschool vaccinations (OUCH Cohort) and was used for both studies. In Study 1, pain responding during infancy was not found to significantly predict pain-related anticipatory distress at preschool. In Study 2, a strong explanatory model was created whereby 40% of the variance in preschool anticipatory distress was explained. Parental behaviours from infancy and preschool were the strongest predictors of child anticipatory distress at preschool. Child age positively predicted child anticipatory distress. This strongly suggests that the involvement of parents in pain management interventions during immunization is one of the most critical factors in predicting anticipatory distress to the preschool vaccination.

Predicting preschool pain-related anticipatory distress: the relative contribution of longitudinal and concurrent factors

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Abstract

Anticipatory distress prior to a painful medical procedure can lead to negative sequelae including heightened pain experiences, avoidance of future medical procedures, and potential non-compliance with preventative healthcare such as vaccinations. Few studies have examined the longitudinal and concurrent predictors of pain-related anticipatory distress. This paper consists of two companion studies to examine both the longitudinal factors from infancy, as well as concurrent factors from preschool that predict pain-related anticipatory distress at the preschool age. Study 1 examined how well preschool pain-related anticipatory distress was predicted by infant pain responding at 2, 4, 6 and 12 months of age. In Study 2, using a developmental psychopathology framework, longitudinal analyses examined the predisposing, precipitating, perpetuating, and present factors that led to the development of anticipatory distress during routine preschool vaccinations. A sample of 202 caregiver-child dyads was observed during their infant and preschool vaccinations (OUCH Cohort) and was used for both studies. In Study 1, pain responding during infancy was not found to significantly predict pain-related anticipatory distress at preschool. In Study 2, a strong explanatory model was created whereby 40% of the variance in preschool anticipatory distress was explained. Parental behaviours from infancy and preschool were the strongest predictors of child anticipatory distress at preschool. Child age positively predicted child anticipatory distress. This strongly suggests that the involvement of parents in pain management interventions during immunization is one of the most critical factors in predicting anticipatory distress to the preschool vaccination.

1. Introduction

Healthy children commonly experience procedural pain from vaccinations and routine blood draws throughout childhood [37]. In addition to experiencing pain, many children also experience fear and pain-related anticipatory distress before the procedure even begins [24]. Pain-related anticipatory distress encompasses negative affect that may result in behavioural responses (e.g., crying, screaming, flailing) and physiological changes (e.g. increased heart rate, cortisol levels) displayed by a child prior to a painful medical procedure [32]. Higher fear and distress before a painful procedure have been associated with a number of negative sequalae including heightened pain experiences, avoidance of future painful medical procedures, and potential non-compliance with preventative healthcare such as vaccinations [5,35,36,47,49,53]. Despite the negative impact of pain-related anticipatory distress, there is a lack of research using longitudinal methodology examining the factors that contribute to its development.

Prior to undertaking the two studies presented in the current paper, an in-depth systematic review synthesized the factors that predict the development of pain-related anticipatory distress in children [44]. In particular, a developmental psychopathology framework [14] was used to examine predisposing, precipitating, perpetuating, and present factors to understand the development of pain-related anticipatory distress in children and adolescents. While some degree of pain-related anticipatory distress would be considered normative, this framework still provided a strong theoretical framework for organizing possible variable relationships for the review and the current analysis. The overarching goal of the current paper is to systematically test the factors that contribute to the development of pain-related anticipatory distress to vaccination in early childhood using data from an established longitudinal cohort (the OUCH [Opportunities to Understand Childhood Hurt] cohort). The current paper includes two companion studies: the first examines the relative contribution of pain from the first year of life on preschool pain-related anticipatory distress to vaccination, while the second examines broader predisposing, precipitating, perpetuating, and present factors in one large model.

1.1. The Current Study.

Starting directly with pain experiences, the goal of Study 1 was to examine how infant pain-related distress variables from vaccinations during the first year of life predict pain-related anticipatory distress at the preschool vaccination. The goal of Study 2 was to examine longitudinal predisposing, precipitating, perpetuating, and present factors that may predict pain-related anticipatory distress at the preschool immunization. For the first study, we hypothesized that pre-needle distress and initial reactivity in infancy would positively predict pain-related anticipatory distress at the preschool age. We further hypothesized that less pain regulation during vaccination appointments over the first year would predict increased pain-related anticipatory distress at the preschool vaccinations. In Study 2, based on our earlier review [44] and the findings from Study 1, we hypothesized that cumulative pain experiences at 2 and 12 months of age and previous pain events would positively predict pain-related anticipatory distress at preschool. Based on previous work [38], we also hypothesized that caregiver emotional availability at 2 and 12 months of child age would negatively predict pain-related anticipatory distress. Age was hypothesized to negatively predict pain-related anticipatory distress. Perpetuating factors such as parent worry [4], parent report of child worry, and parent distress-promoting behaviours [7, 29] were hypothesized to positively predict pain-related anticipatory distress. Finally, healthcare professional distress-promoting behaviour was a hypothesized to positively predict pain-related anticipatory distress at preschool.

2. Methods

2.1. Study sample

Participants from this study were recruited from the OUCH cohort, which has been observing caregiver-infant dyads from infancy to preschool [42]. At the time of the current study, the infancy waves were completed with a total sample size of 760 caregiver-infant dyads. Caregiver-child dyads were initially recruited from three pediatric clinics in the Greater Toronto Area, Canada. Infants and their caregivers were recruited at their 2, 4, 6, or 12 month vaccinations. At the time of the current analysis, 202 parent-child dyads were observed at the preschool time point (age 4 to 6 years) with data collection ongoing. Of the 202 parent-child dyads that were observed at preschool, 133 had 2-month data, 170 had 4-month data, 175 had 6-month data, and 177 had 12-month data. The vast majority had 3 or 4 time points (n=170), with 32 participants having data from one or two time points. Full-information maximum likelihood estimation [2] was used so that all cases could be included, which resulted in 202 cases contributing to model estimations.

Inclusion criteria for the study were that caregivers could read and speak English, that the infants had no suspected developmental delays or impairments or chronic illnesses, and had never been admitted to a neonatal intensive care unit. All children were considered healthy, from middle class families, low-risk, and developmentally typical. At the preschool appointment, parents were predominantly mothers (85.1%) with some fathers (13.9%) and other caregivers (1.0%), and an average age of 38.91 years (SD = 5.29). The preschool sample was 46.5% female (94) and 53.5% male (108) and was an average of 4.61 years (SD = 0.55). The caregivers were asked an open-ended question about the heritage culture that had most influenced them or an earlier generation of their family. A broad classification of their responses is 13.9% Canadian, 42.1% European (e.g. British, Italian, Polish), 11.4% Jewish, and 18.3% Asian (e.g. Chinese, Indian, Vietnamese). At the preschool time point, 4.5% of children were given Tylenol or EMLA before the needle procedure.

2.2. Procedure

Ethics approval was received from York University. Details of the procedure from the infant wave of the study have been published elsewhere [38] and here we describe the procedure for the preschool vaccinations. Parents who were observed during their child's vaccinations were given a flyer by a medical receptionist and asked whether they would like to learn more about a new study. If interested, informed consent was obtained and the parent completed a demographic information form. Ninety percent of approached parents allowed us to videotape their child's preschool vaccination. Once in the examination room, two video cameras were set up to capture a close-up face shot of the preschooler as well as a wide shot to obtain a full view of the parent and the child, both 5 minutes prior and 5 minutes post-needle. This footage was used to code preschool anticipatory distress behaviours and child verbalizations. Parents received a $5.00 coffee shop gift certificate for participation. At the 2, 4, 6, and 12 month vaccination appointments, infants received between 1 and 3 needles, with a means of 2.01 needles (SD=0.25).

2.3 Apparatus

At the preschool appointment, two Sony HDRXR260V High-Definition Handycam Camcorders (2012 Model) were used to record parent and child behaviour. One camera was hand-held by a research assistant to record the close-up image of the child's face, body movements, and verbalizations. The second camera was mounted on a tripod and fitted with a wide-angle lens to record parent-child interactions from a distance.

2.4 Measures

2.4.1. Parent and child demographic information

Caregivers were asked to complete a short demographic form prior to their child's vaccination. Questions pertained to their age, their child's age, their child's sex (male coded as 1, female coded as 2)~~gender~~, the child's previous medical history, their relationship to the child, their education level, and their self-reported heritage culture.

2.4.2. Pain-Related Anticipatory Distress (Latent dependent variable; Study 1 and 2)

As will be described in greater detail in the results section, child behaviour (FLACC), proportion of child distress verbalizations (CAMPIS-R), and child cry duration were used as observed indicators of a latent variable representing pain-related anticipatory distress in Study 1 and Study 2. Using this latent variable accounts for measurement error with respect to the relations of the observed indicators to the hypothetical construct of pain-related anticipatory distress [9]. This variable is the dependent variable in all the models presented in the current paper. The three indicator variables (FLACC, child distress verbalizations, and cry) all demonstrated appropriate range and variance.

2.4.2.1. Face, Legs, Activity, Cry, and Consolability Scale

This measure was used as a component of our latent variable. The FLACC is also known as the Face, Legs, Activity, Cry, and Consolability scale [33]. The FLACC is a behavioural rating scale that is a valid and reliable measure of procedural pain in infants and young children [51] and has also demonstrated reliability, construct validity, and concurrent validity for baseline measurements of pain-related distress [46]. The FLACC consists of five behavioural indices: face, legs, arms, cry, and consolability, which are each rated using a scale from 0 to 2. These ratings are added together for an overall score between 0 and 10 for each 15-second epoch (in the current analyses it was scored for four epochs). Higher scores indicate higher distress intensity. For the current analyses, FLACC scores are presented as proportions ranging from 0 to 1. The FLACC scale was coded by trained coders and interrater reliability coefficients for the current study all exceeded .85 for the five total behaviour indices.

2.4.2.2. Preschool distress verbalizations and cry

The CAMPIS-R also provided two components to our latent variable for pain-related preschool anticipatory distress. Child distress verbalizations and cry from the CAMPIS-R [7] were also included as indicators of the latent pain-related anticipatory distress variable. Videos were transcribed by research assistants and each transcript was reviewed by one research assistant trained in coding the CAMPIS to ensure it accurately reflected the content and to ensure vocalizations were spliced into codeable CAMPIS units. One child-caregiver dyad was excluded because no English was spoken during the entire interaction and the language could not be translated. The cChild distress verbalizations variable is a proportion ranging from 0 to 1 of the total number of child verbalizations that were distress verbalizations. Cry isand cry are presented as a proportion of the total time coded with scores ranging between 0 and 1. Videos were first coded on paper using the spliced transcript. The Observer XT (Noldus Inc.) was subsequently used to facilitate coding the video data. Timed-event data coding was used to capture data on frequency, duration, and timing of codes [3]. There were two coders for the study. For verbal behaviours, percent agreements were calculated from the transcripts that were coded with a percent agreement of 85% with a range of 71% to 98% agreement. For non-verbal behaviours, reliability statistics were calculated using Noldus Observer XT version 11. A tolerance window of 2 seconds was used including gaps with an overall average percent agreement of 86% with a range of 74% to 97%.

2.4.3. Infant predictor variables

2.4.3.1. Infant pain-related distress (Study 1 and Study 2)

The Modified Behaviour Pain Scale (MBPS) [48] was used to assess infant pain-related distress for a 15-second epoch immediately prior to the first vaccination needle, immediately after the vaccination, 1 minute, 2 minutes, and 3 minutes after the vaccination. This was completed for the 2, 4, 6 and 12 month vaccinations. There are three subsections of the scale (facial expression, cry, and body movement), each requiring the coder to decide on what the maximal score based on the infant's overt behaviour during the 15-second epoch. All sections of the measure are summed to get an infant pain score out of ten. Moderate to high concurrent validity as well as item-total and inter-rater reliability have all been demonstrated in the vaccination context [48]. Inter-rater reliability was high with intraclass correlations ranging from .93 to .96.

In Study 1, the MBPS scores were used as indicators of the latent slope factor (operationalizing pain regulation) and intercept (operationalizing pain reactivity) factors in the four latent growth models (LGMs) using structural equation modeling [10]. Using a separate model within each age (2, 4, 6, and 12 months; see Figure 1), a latent slope factor represents the change in MBPS pain scores (i.e., pain regulation) from the needle observation across the 1-minute, 2-minute, and 3-minutes post-needle observations, whereas the latent intercept represents the needle pain score (i.e., reactivity or the first pain score immediately after the last needle). Pain-related anticipatory distress prior to the needle was used as a separate covariate in each model.

In Study 2, greater parsimony was needed to represent pain experience due to the number of relationships to be tested in the broader model. Thus, a cumulative pain score from the two most painful vaccinations (the 2- and 12-month cumulative pain scores) were used, as it was felt these two time points would have the highest chance of predictive power for preschool outcomes. In addition, both initial reactivity (intercept) or change in pain scores (slope) were not found to have significant predictive value in Study 1. Rather, than insert variables we knew not to have a relationship with the final dependent variable into our model, a cumulative sum score of the three pain scores were used such that the pain scores were reflective of the total distress expressed during the 2-month or 12-month appointment.

2.4.3.2. Caregiver Emotional Availability in infancy (Study 2 only)

The emotional availability scale (EAS) [6] provides a global clinical judgment of caregiving behaviour. The EAS consists of four main caregiver subscales (sensitivity, structuring, non-intrusiveness, and non-hostility), which are summed to form an overall score [6]. Inter-rater reliability for the total score was calculated between each main coder and each of the reliability coders and intraclass correlations ranged from .80 to .93. Only the 2 and 12 month EAS scores were used in this study to logically parallel the infant pain scores used for Study 2 [38].

2.4.4. Preschool Predictors (Study 2 only)

2.4.4.1. Parent distress promoting verbalizations and healthcare provider verbalizations at preschool

Parent and healthcare professional verbalizations for three minutes prior to the needle were videotaped, transcribed, and later coded using the Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R) [7]. For this study, the categories used from the CAMPIS-R were parent distress-promoting behaviours and healthcare professional distress-promoting behaviours. Scores for both categories were calculated as the proportion of total behaviour for each individual. These variables were created by summing the criticism, reassuring comment, giving control to the child, apology, and empathy verbalization codes that occurred three minutes prior to the vaccination. As above, Observer XT software (Noldus Inc, The Netherlands) was used to facilitate the video coding. Timed-event data coding was used to capture data on frequency, duration, and timing of codes [3]. Reliability for these variables an average of 85% agreement with a range of 71% to 98% agreement.

2.4.4.2. Parent report of child and self-worry pre-needle (Study 2 only)

Parents were asked to rate their own child's worry and their own worry using a scale from 0 to 10, where 0 was no worry and 10 was the most worry possible.

2.4.4.3. Number of significant painful procedures between 12 months and preschool (Study 2 only)

Parents were asked to report their child's medical history since 12 months of age by checking off which illnesses or conditions their child had experienced [45]. From this list, four significant events that are hypothesized to be painful were used to create a cumulative score of significant painful events. These four painful events were circumcision, broken bones, hospitalization, and operations. The cumulative painful event score ranged from 0 to 4, with a higher score indicating more previously experienced painful events.

2.5 Data analysis plan

2.5.1. Study 1: Impact of pain regulation over the first year of life on pain-related anticipatory distress at preschool age.

We fitted four separate models (2, 4, 6 and 12 months) to examine whether infant pain-related distress reactivity (represented using a latent *intercept* factor described above) and regulation (represented using latent *slope* factors described above) at each of these age predicted child pain-related anticipatory distress at preschool. Each model was estimated using full-information maximum likelihood with Mplus version 7 software [34]. The comparative fit index (CFI), the root mean square error of approximation (RMSEA), and the Standardized Root Mean Square Residual (SRMR) evaluated goodness of fit for the models. CFI values of 0.95 or higher and RMSEA and SRMR values of 0.05 or less indicate that a model fit the data well [11].

All four models (i.e., using data from each of the 2, 4, 6, and 12 month vaccination appointments) were specified such that pain-related anticipatory distress at preschool was conditioned on the pre-needle pain-related distress score, the intercept factor (needle pain reactivity), and the change in infant pain-related distress across the appointment (i.e. infant pain regulation or slope factor from immediately after the needle to 3-minutes post needle). To account for the non-linear pattern in the MBPS scores across the vaccination appointment, the slope factor loadings were set to 0 at needle, freely estimated for 1 and 2 minutes post-needle, and set to 1 for 3 minutes post-needle (i.e., a "freed-loading" model to produce a series of linear splines)[10]. Because the slope factor loading was set to zero for the needle pain score, the intercept factor represents the pain-related distress mean at needle in all models. Given multiple comparisons made in the LGM analyses, a Bonferroni correction was applied. Using a family-wise error rate of $\alpha = .05$ and four analyses, the criteria of $p < .0125$ was used for the LGM analyses. See Figure 1 for details.

2.5.2. Study 2: Impact of predisposing, precipitating, perpetuating, and present factors on pain-related anticipatory distress at preschool age.

First, correlations among the independent variables (MBPS baseline at 2 and 12 months, MBPS post-needle at 2 and 12 months, MBPS 1 minute at 2 and 12 months, healthcare professional distress-promoting behaviour, caregiver distress-promoting behaviour, sexgender, age, child worry, parent worry, painful events, caregiver sensitivity at 2 months, and caregiver sensitivity at 12 months) were examined to determine which relationships to include in the final model. The prediction of pain-related anticipatory distress from longitudinal and concurrent factors was then modeled using SEM so that certain constructs (child pain-related anticipatory distress at preschool, 2 month cumulative distress, and 12 month cumulative distress) could be represented by latent variables with multiple observed indicators [11]. The models were estimated using full-information maximum likelihood with Mplus version 7.31 [34]. Model fit was evaluated using the comparative fit index (CFI), the root mean square error of approximation (RMSEA), and standardized root mean square residual (SRMR). CFI values of 0.95 or higher and RMSEA and SRMR values of 0.05 or less indicate that a model has a good fit to the data [11].

The final model was specified such that the preschool pain-related anticipatory distress latent variable was conditioned on infant cumulative distress at 2 and 12-months, caregiver emotional availability at 2 months, caregiver emotional availability at 12 months, age, sex~~gender~~, pain events, parent worry, child worry, parent distress promoting behaviours, and healthcare professional distress promoting behaviours. See Figure 2.

3. Results

3.1 Study 1: Predicting pain-related anticipatory distress from infant pain responses

The means, standard deviations, and correlations among variables at 2, 4, 6, and 12 months of age are presented in Tables 1 to 4. Four models (one for each age of infant vaccination) were estimated with slope (pain regulation) and intercept (pain reactivity) latent growth factors. These four models were expanded to include the latent preschool pain-related anticipatory distress variable as the outcome. Figure 1 shows a visual of the Latent Growth Models estimated at each age (2, 4, 6, and 12 months of age).

3.1.1. Impact of pre-needle pain-related distress, pain reactivity, and pain regulation at 2 months on preschool pain-related anticipatory distress to vaccination.

The mean MBPS scores for infant pain-related distress at 2 months of age decreased from 8.79 at needle to 5.47 at 3 minutes post-needle. Pre-needle pain-related distress at 2 months was also included as a predictor of preschool pain-related anticipatory distress. Because there was minimal variability in infant needle pain at the two-month time point (the majority of infants had high pain-related distress), the residual variance for MBPS at needle was constrained to zero to avoid obtaining an improper negative residual variance estimate. The combination of fit indices suggested that this model fit the data well (CFI= 1.0, RMSEA = .01, SRMR=.05). Both standardized and unstandardized estimates are represented in Table 5.

The mean of the linear slope factor was negative and significant ($p < .001$), indicating that the change in pain-related distress scores decreased on average following the needle. There was no significant relationship between the pain reactivity and pain regulation. Pain reactivity and pain regulation did not predict pain-related anticipatory distress ($p = .06$ and $p = .25$). The pre-needle pain-related distress score at two months did not predict pain-related anticipatory distress at preschool ($p = .82$). This model accounted for only 3% of the variance in pain-related anticipatory distress at preschool.

3.1.2. Impact of pre-needle pain-related distress, pain reactivity, and pain regulation at 4 months on preschool pain-related anticipatory distress to vaccination.

The mean values for infant pain-related distress at 4 months of age decreased from 8.47 at needle to 4.30 at 3 minutes post-needle. Pre-needle pain-related distress at 4 months was also entered as a predictor of preschool pain-related anticipatory distress. Since there was minimal variability in infant needle pain-related distress at the 4-month time point (the majority of infants displayed high pain-related distress), the residual variance for pain-related distress at needle was constrained to zero to avoid obtaining an improper negative residual variance estimate. The combination of fit indices suggested that this model fit the data well (CFI= 1.0, RMSEA = .002, SRMR=.04). Both standardized and unstandardized estimates are represented in Table 6.

The mean of the linear slope factor was negative and significant (*p* < .001), indicating that the change in pain-related distress scores decreased on average following the needle. The pain reactivity and pain regulation were not significantly related at 4 months of age (*p* = .04). Using the Bonferroni-corrected α of .0125, pain reactivity did not predict preschool pain-related anticipatory distress (*p* =.03) and neither did pain regulation (*p* = .01). It should be noted that although the p-value for pain regulation was below .125 for the standardized estimate, it was not for the unstandardized estimate (*p* = .014). As such a conservative approach was taken to not deem this value significant. The pre-needle pain-related distress score at 4 months did not predict pain-related anticipatory distress at preschool (*B* = .06, *p* = .54). This model accounted for 10% of the variance in pain-related anticipatory distress at preschool.

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3.1.3. Impact of pre-needle pain-related distress, pain reactivity, and pain regulation at 6 months on preschool pain-related anticipatory distress to vaccination.

The mean values for infant pain-related distress at 6 months of age decreased from 8.50 at needle 3.97 at 3 minutes post-needle. Pre-needle pain-related distress at 6 months was also included as a predictor of preschool pain-related anticipatory distress. Since there was minimal variability in infant needle pain at the six-month time point (the majority of infants had high pain-related distress), the residual variance for pain-related distress at needle was constrained to 0 to avoid obtaining an improper negative residual variance estimate. The combination of fit indices suggested that the model fit was good

(CFI = .98, RMSEA = .05, SRMR = .05). Both standardized and unstandardized estimates are represented in Table 7.

The mean of the linear slope factor was negative and significant (p < .001), indicating that the change in pain-related distress scores decreased on average following the needle. There was no significant relationship between pain reactivity and pain regulation at 6 months. The intercept (p = .29), slope (p = .22) and pre-needle pain-related distress score (p = .60) at 6 months did not significantly predict pain-related anticipatory distress. This model accounted for only 3% of the variance in pain-related anticipatory distress at preschool.

3.1.4. Impact of pre-needle pain-related distress, pain reactivity, and pain regulation at 12 months on preschool pain-related anticipatory distress to vaccination.

The mean values for infant pain-related distress at 12 months decreased from 8.23 at needle to 4.38 at 3 minutes post needle. Pre-needle pain-related distress at 12 months was also entered as an independent predictor of preschool pain-related anticipatory distress. The combination of fit indices suggested that this model fit the data relatively well (CFI = .96, RMSEA = .07, SRMR = .06). Both standardized and unstandardized estimates are represented in Table 8.

The mean of the linear slope factor was negative and significant (p < .001), indicating that the change in pain-related distress scores was decreasing over time. There was no significant relationship between the pain reactivity and pain regulation at 12 months. Pain reactivity (p = .06) and the pain regulation did not predict preschool pain-related anticipatory distress (p = .75). The pre-needle pain-related distress score at 12 months did not predict pain-related anticipatory distress at preschool (p = .98). This model accounted for 3% of the variance in pain-related anticipatory distress at preschool.

3.2 Study 2: Predicting pain-related anticipatory distress from predisposing, precipitating, perpetuating, and present factors.

3.2.1. Relationships among key variables

Correlations among key variables are presented in Table 9 for completeness. There were positive relationships among the baseline, needle, and one-minute pain scores at 2 months of age and at 12 months of age (see Table 9). Significant correlations were used to determine the relationships included in the final SEM model.

3.2.2. Measurement model of latent variables

Baseline MBPS, needle MBPS scores, and one-minute post-needle MBPS scores at 2-months were used as observed indicators of a 2-month cumulative distress latent variable whereas baseline MBPS, needle MBPS scores, and one-minute post-needle MBPS scores at 12-months were used as indicators of a 12-month cumulative distress latent variable. For the preschool pain-related anticipatory distress latent variable, FLACC scores, child distress behaviours, and cry were used. The combination of fit indices suggested that this model fit the data~~y~~ well (RMSEA = <.001, SRMR=.04, CFI=1.0). Parameter estimates are presented in Table 10.

3.2.3. Final model predicting pain-related anticipatory distress

The final model was specified such that the preschool pain-related anticipatory distress latent variable was regressed on the 2- and 12-month cumulative distress latent variables as well as pain events, caregiver EA at 2 months, caregiver EA at 12 months, child age, child sex~~gender~~, caregiver distress-promoting behaviour, healthcare provider distress-promoting behaviour, child worry, and parent worry. The final model depicted in Figure 2 fit the data well (CFI = 1.0; RMSEA = <.001, SRMR = .06). Completely standardized parameter estimates and correlations are presented in the text and Figure 1, while both standardized and unstandardized estimates are represented in Table 11.

3.2.4. Relationships among predictor variables

Based on a systematic review [44], the model was specified to include certain directional relationships among predictors. As was seen in the simple bivariate correlations, there were several significant relationships among predisposing, precipitating, perpetuating, and present factors (see Table 9). Both theoretical and statistical (i.e. significant bivariate correlations) were the criteria used for including a variable in the final model and for examining directional relationships among predictors. Cumulative distress at 12-months of age positively predicted parent report of child worry at preschool (B = .23, p = .01), whereby children who expressed more distress at 12-months had parents who rated them as more worried at preschool. In addition, parent self-report of worry was positively related to parent report of child worry (B = .23, p = .002). Parent worry at preschool negatively predicted healthcare provider distress-promoting behaviour (B = -.13, p = .01). Caregiver emotional availability at 2 months was negatively related to cumulative distress at 2 months (B = -.36, p = .001). Caregiver EA at 12 months was negatively related to cumulative distress at 12 months (B = -.41, p < .001). Caregiver EA and 2 and 12 months were positively related (B = .42, p < .001).

3.2.5. Factors predicting pain-related anticipatory distress at preschool

The R^2 for child pain-related anticipatory distress at preschool was .404 (p < .001), thus 40.4% of the variance in child pain-related anticipatory distress at preschool was explained by the set of latent and observed predictors. As seen in Table 11, caregiver distress-promoting behaviour positively predicted child pain-related anticipatory distress at preschool (B = .49, p < .001), whereby caregivers who used more distress-promoting behaviour had children who displayed more pain-related anticipatory distress. Caregiver distress-promoting behaviour at the preschool vaccination appointment uniquely accounted for 19.3% of the variance in child pain-related anticipatory distress at preschool. Child age positively predicted preschool pain-related anticipatory distress (B = .15, p = .01), uniquely accounting for 2.0% of pain-related anticipatory distress variance. Caregiver EA from the 2 month vaccination appointment positively predicted preschool pain-related anticipatory distress (B = .35, p = .02) and 12 month vaccination appointment negatively predicted child pain-related anticipatory distress (B = -.33, p = .01), explaining 6.4% and 6.1% of the variance in preschool pain-related anticipatory distress, respectively.

4. Discussion

The objective of the current paper using two companion analyses was to examine the relative contribution of vaccination pain and distress responses from the first year of life (Study 1) as well as broader longitudinal factors (predisposing, precipitating, perpetuating, and present) on pain-related anticipatory distress to vaccination at the preschool age (Study 2). In Study 1, using a sequential cohort design and a substantial sample of over 200 participants, our results demonstrated that vaccination pain and distress responses over the first year of life did not predict preschool pain-related anticipatory distress. In Study 2, which tested a model that encompassed broader child and contextual factors, 40% of the variance in preschool pain-related anticipatory distress was accounted for. Ultimately, concurrent parent behaviours during the preschool pre-needle epoch predicted the majority of the variance, followed by parent emotional availability during 2 and 12 months, and finally child age at preschool (ranging between 4 and 6 years of age).

4.1. Study 1: Impact of infant pain responses on preschool pain-related pain-related.

The four models from Study 1 showed that pre-needle pain-related distress, pain reactivity, and pain regulation at 2, 4, 6, and 12 months of age did not predict pain-related anticipatory distress at preschool. These findings were not in line with hypotheses, which predicted that higher pre-needle pain-related distress, higher pain reactivity, and poor pain regulation during infancy would be associated with increased pain-related anticipatory distress at the preschool age. These findings suggest that pain-related anticipatory distress does not demonstrate continuity in its development (i.e. infant pre-needle distress was not related to preschool pre-needle distress). With regards to pain reactivity, infants during the first year of life may not have yet developed the ability to build lasting cognitive schemas to make the association from relatively rare events in infancy to preschool events. Although pain regulation across infancy was not found to predict pain-related anticipatory distress at preschool, it should be noted that the relationship just missed significance at 4 months using our stringent alpha level (explaining roughly 10% of the variance in pain-related anticipatory distress at preschool) suggesting that experiencing high levels of distress immediately following routine vaccination and not demonstrating a capacity towards regulation at 4months may have some relationship with pain-related anticipatory distress at preschool. Four months of age is a critical time in infant development when the inhibitory mechanisms of the central nervous system are beginning to develop, yet the infant does still not seem to yet have the cognitive capacity to directly encode a complex emotional reaction such as experiencing distress from anticipating future pain based on past pain [28]. This reinforces the need to start scaffolding the regulation of infant distress (i.e. pain management strategies) from the very beginning of life.

4.2 Study 2: Longitudinal and concurrent factors predicting pain-related anticipatory distress

Ultimately the results from Study 1 demonstrate the importance of taking a broader approach to examining the predictors of pain-related anticipatory distress at the preschool age [44]. In line with the developmental psychopathology framework, Study 2 examined which predisposing, precipitating, perpetuating, and present factors predicted child pain-related anticipatory distress at preschool.

4.2.1. Predisposing factors

Similar to findings in Study 1, cumulative distress from infancy did not predict pain-related anticipatory distress at preschool. It may be that these pain experiences occurred when the infant was too young to form declarative memories (or too infrequent and brief to trigger a lasting non-declarative memory) to have an impact on the child’s cognitive appraisal of the vaccination as threatening at preschool. Additionally, previous research on needle phobia has demonstrated onset at the preschool age, indicating that direct conditioning from events at that age, rather than earlier, may be a significant contributor [32, 17]. The lack of a sex~~gender~~ effect is in line with findings from a previous review [44]. Our findings regarding age may be related to older children having more ability to retrieve and experience a complex emotional reaction such as expressing distress in anticipation of pain based on previous experience with pain.

The only variable from the infant vaccinations that predicted pain-related anticipatory distress was caregiver emotional availability (EA) both at 2 and 12 months of age. The finding for 12 month EA is consistent with developmental literature suggesting that caregiver sensitivity to distress is related to fewer behavioural problems, higher social competence, and better affect regulation [27]. Contrary to hypotheses, higher emotional availability at 2-months predicted higher pain-related anticipatory distress at preschool. We know from previous work there is minimal variability in pain scores at the 2 month vaccination [40] and that caregiver sensitivity is strongly related over the first year of life [38]. Perhaps being highly sensitive at 2 months reflects a predisposition to amplify distress signalling in later childhood. It is clear that over time by meeting their child's needs through subsequent vaccinations, dyads often develop secure attachment relationships and lead to EAS at 12 months of age predicting lower anticipatory distress. This discrepancy in findings between 2 and 12 months may also be a random association due to type I error.

4.2.2. Precipitating factors

Having more painful events during childhood (i.e. surgery, circumcision, hospitalization, and broken bones) did not significantly predict pain-related anticipatory distress. Previous research has shown that general and specific negative pain events can generalize to the development of fear and anxiety to painful medical procedures [5,24, 36], although this is not uniformly the case [21, 23,29, 31]. Perhaps rare painful medical events over early childhood are not predictive of pain-related anticipatory distress to vaccination.

4.2.3.Perpetuating factors.

The perpetuating or concurrent factors that would maintain the anticipatory anxiety at preschool included parent worry prior to vaccination, parent report of child worry prior to vaccination, and parent distress-promoting behaviours during the pre-needle period, which were all hypothesized to positively predict pain-related anticipatory distress. Study 2 found that only parent behavior positively predicted pain-related anticipatory distress at preschool. This result is consistent with previous research demonstrating that caregiver distress-promoting verbalizations are strong predictors of worry and anxiety in children [13, 15].

In terms of relationships among the perpetuating variables, parental worry negatively predicted healthcare provider distress-promoting behaviour. This suggests that healthcare providers may be more attuned to avoid distress-promoting behaviors towards the child when parents communicate worry. Parents' own worry also positively predicted their report of their child's worry. This finding supports previous research with the same sample that has shown that parental factors have an impact on parental report of child pain-related distress [39].

4.2.4. Present factors

Finally, findings Study 2 did not support the hypothesis that healthcare professional distress-promoting behaviour positively predicts pain-related anticipatory distress at preschool. This may be a result of low healthcare professional interaction and the limited sample of health care professionals coded in this study. Future research should include a larger number of health professionals that can better represent the population of immunizing health professionals.

4.3. Conclusions

To our knowledge, this paper is the first to examine both longitudinal and concurrent factors that predict pain-related anticipatory distress in preschool-aged children. Results from the two companion analyses indicate that early pain responses have a limited impact on the development of pain-related anticipatory distress. During infancy, the caregiver has been described as the most important context for the infant in pain [41]. Results from Study 2 suggest that at preschool age, the caregiver continues to be one of the most important factors in predicting pain-related anticipatory distress. Concurrent parent behaviour has been shown to be associated with pain-related anticipatory distress during painful medical procedures across childhood [8,15,16,20,29]. However, this study is the first to establish using longitudinal data that caregiver behaviour during vaccination from the first year of life and at the preschool age are *both* associated with pain-related anticipatory distress at preschool- significantly more than the child's own behaviours. Concurrent parent distress promoting behaviour at preschool was by far the most significant predictor of child pain-related anticipatory distress at preschool, which substantiates the critical role of parents during vaccination appointments in early childhood. The directionality of this relationship should be the subject of future research. ~~This paper substantiates the critical role of parents during vaccination appointments throughout early childhood~~. We have established in earlier work that pain-related anticipatory distress increases pain-related distress post-needle [1], yet there is currently little evidence that parent-led interventions can be effective for reducing child distress during vaccinations [30, 43]. Interventions that target increasing caregiver sensitivity in the first year of life and increasing coping promoting behaviours at the preschool age are needed. More research is needed on interventions relating to parental coaching for their children's vaccinations.

4.4. Limitations and future directions

Caregivers from the current study self-selected to be associated with a longitudinal study and had higher education, affecting the potential generalizability of the study. Additionally, previous research has shown that temperament [22, 26] and pre-existing child psychopathology [12,18,19,25,52] may be important predisposing factors of child pain-related anticipatory distress that were not examined in the current study. Given challenges of self-report on anxiety and pain scales for preschool-aged children [50], child self-report was not used in the current study. Alternate methods of assessing child distress, including age-appropriate self-report tools and physiology (e.g., heart rate) will be important areas for future investigation.

Conflict of interest statement

The authors report no conflict of interest.

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Figure Captions

Figure 1. Child pain-related anticipatory distress at preschool conditioned on infant needle pain (intercept) and infant regulation (slope) across the vaccination appointment. Rectangles represent observed measures, whereas ovals represent latent factors. The same model was repeated at 2, 4, 6, and 12 months of age. Solid lines represent significant paths, whereas dotted lines represent non-significant paths. Note: *N*=202, *p < .0125.

Figure 2. Anticipatory distress at preschool conditioned on 2-month cumulative distress, 12-month cumulative distress, 2-month emotional availability, 12-month emotional availability, preschool age, child sex~~gender~~, pain events, parent worry, parent report of child worry, caregiver distress promoting behaviours, and health-care distress promoting behaviours. Rectangles represent observed variables, whereas ovals represent latent variables. Single-headed arrows pointing away from latent variables towards observed measures (factor loadings) represent unstandardized parameter estimates. Double-headed arrows represent correlations. Single-headed arrows represent standardized estimates. Solid lines represent significant paths, whereas dotted lines represent non-significant paths. Note: *N*=202, *p < .05, **p < 0.01, ***p <.001; HCP: Healthcare provider.

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25 word summary:

In a longitudinal cohort of parent-child dyads, parent behaviour from infancy and preschool are strongest predictors of anticipatory distress at preschool.

Figure1

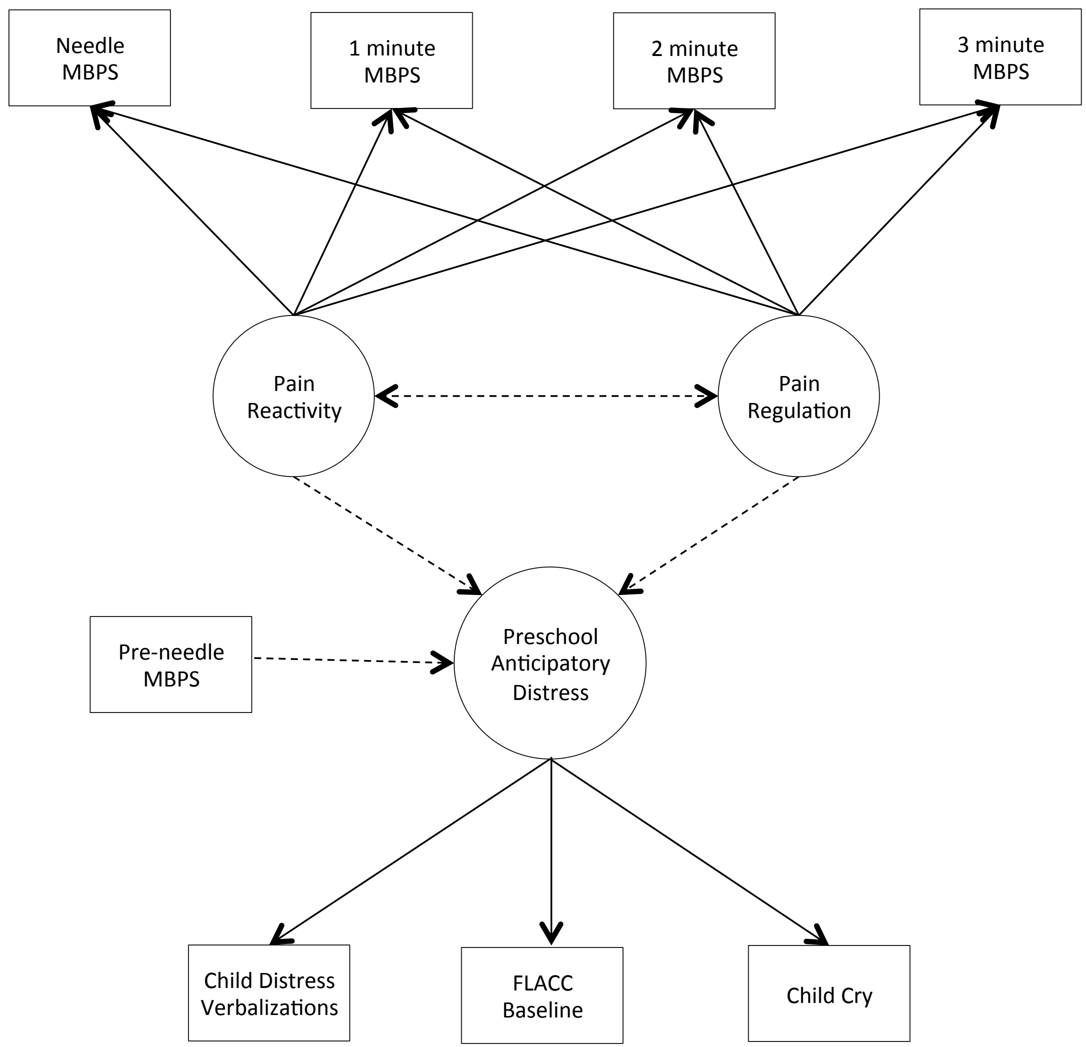
Needle
MBPS
1 minute
MBPS
2 minute
MBPS
3 minute
MBPS
Pain
Reactivity
Pain
Regulation
Pre-needle
MBPS
Preschool
Anticipatory
Distress
Child Distress
Verbalizations
FLACC
Baseline
Child Cry

Figure2

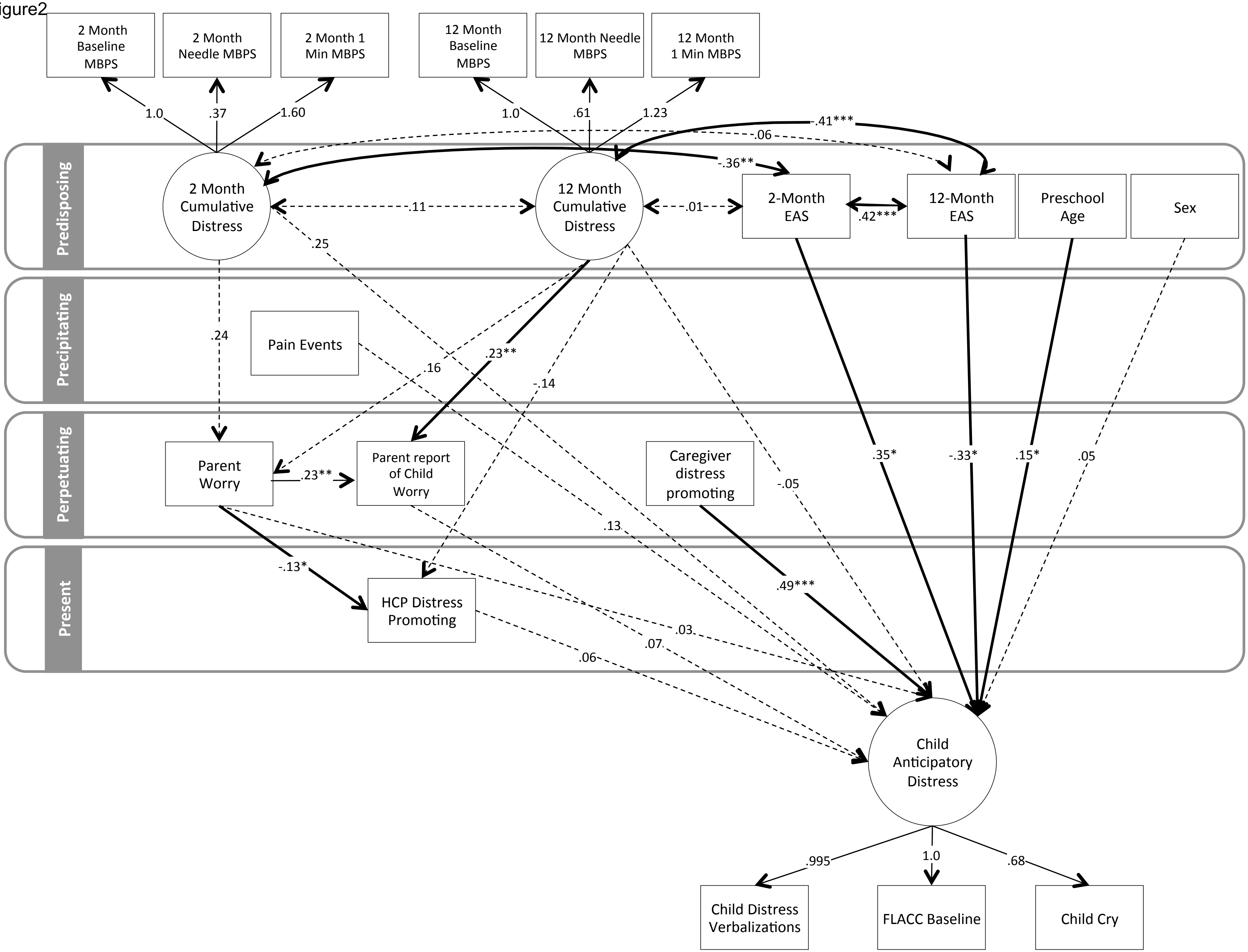
2 Month Baseline MBPS
2 Month Needle MBPS
2 Month 1 Min MBPS
12 Month Baseline MBPS
12 Month Needle MBPS
12 Month 1 Min MBPS
1.0
.37
1.60
1.0
.61
1.23
-.41***
.06
-.36**
Predisposing
2 Month Cumulative Distress
.11
12 Month Cumulative Distress
.01
2-Month EAS
.42***
12-Month EAS
Preschool Age
Sex
.25
Precipitating
.24
Pain Events
.16
.23**
-.14
Perpetuating
Parent Worry
.23**
Parent report of Child Worry
Caregiver distress promoting
-.05
.35*
-.33*
.15*
.05
.13
Present
-.13*
HCP Distress Promoting
.49***
.03
.07
.06
Child Anticipatory Distress
.995
1.0
.68
Child Distress Verbalizations
FLACC Baseline
Child Cry

Table1

Table 1. Means, standard deviations, and correlations among the pain response variables at 2 months and preschool vaccinations

	1	2	3	4	5	6	7	8
1. Pre-needle distress 2-months	-	**.19** (.03)	**.22** (.01)	**.19** (.04)	**.24** (.02)	.10 (.92)	.04 (.67)	.03 (.70)
2. Needle pain 2-months	-	-	**.27** (.002)	**.22** (.02)	.16 (.11)	.12 (.24)	.04 (.63)	.15 (.09)
3. 1 minute pain 2-months	-	-	-	**.44** (<.001)	**.41** (<.001)	.04 (.74)	.12 (.20)	.11 (.23)
4. 2 minute pain 2-months	-	-	-	-	**.65** (.00)	-.07 (.51)	-.11 (.24)	.02 (.83)
5. 3 minute pain 2-months	-	-	-	-	-	-.19 (.09)	-.10 (.34)	-.08 (.43)
6. FLACC	-	-	-	-	-	-	**.79** (<.001)	**.57** (<.001)
7. Cry	-	-	-	-	-	-	-	**.48** (<.001)
8. Child distress behaviour	-	-	-	-	-	-	-	-
Mean	2.89	8.78	5.94	5.80	5.43	.14	.06	.33
SD	1.95	.85	2.47	2.50	2.61	.21	.17	.33
Range	0-10	0-10	0-10	0-10	0-10	0-1	0-1	0-1
N	132	133	123	118	96	156	202	202

Note: p-values are in parentheses. Significant correlations are bolded.

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Table2

Table 2. Means, standard deviations, and correlations among the pain response variables at 4 months and preschool vaccinations

	1	2	3	4	5	6	7	8
1. Pre-needle distress 4-months	-	**.24** (.002)	**.26** (.001)	**.25** (.001)	**.27** (.002)	.12 (.20)	**.16** (.04)	.04 (.60)
2. Needle pain 4-months	-	-	**.31** (<.001)	**.19** (.02)	**.16** (.08)	.13 (.15)	.09 (.24)	.08 (.28)
3. 1 minute pain 4-months	-	-	-	**.49** (<.001)	**.37** (<.001)	**.18** (.05)	**.17** (.03)	.08 (.34)
4. 2 minute pain 4-months	-	-	-	-	**.59** (<.001)	.16 (.09)	.14 (.07)	.12 (.15)
5. 3 minute pain 4-months	-	-	-	-	-	**.29** (.003)	**.20** (.02)	.14 (.10)
6. FLACC	-	-	-	-	-	-	**.79** (<.001)	**.57** (<.001)
7. Cry	-	-	-	-	-	-	-	**.48** (<.001)
8. Child distress behaviour	-	-	-	-	-	-	-	-
Mean	2.75	8.48	4.75	4.65	4.22	.14	.06	.33
SD	1.79	.88	2.49	2.64	2.66	.21	.17	.33
Range	0-10	0-10	0-10	0-10	0-10	0-1	0-1	0-1
N	167	168	162	158	132	156	202	202

Note: p-values are in parentheses. Significant correlations are bolded.

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Table3

Table 3. Means, standard deviations, and correlations among the pain response variables at 6 months and preschool vaccinations

	1	2	3	4	5	6	7	8
1. Pre-needle distress 6-months	-	**.38** (<.001)	**.22** (.01)	**.36** (<.001)	**.38** (<.001)	-.07 (.43)	.06 (.41)	.11 (.17)
2. Needle pain 6-months	-	-	**.31** (<.001)	**.35** (<.001)	**.28** (.002)	.04 (.62)	.07 (.35)	.07 (.37)
3. 1 minute pain 6-months	-	-	-	**.44** (<.001)	**.34** (<.001)	.12 (.18)	.14 (.07)	**.21** (.01)
4. 2 minute pain 6-months	-	-	-	-	**.64** (<.001)	-.02 (.83)	.05 (.52)	.07 (.39)
5. 3 minute pain 6-months	-	-	-	-	-	.04 (.68)	.07 (.43)	.02 (.83)
6. FLACC	-	-	-	-	-	-	**.79** (<.001)	**.57** (<.001)
7. Cry	-	-	-	-	-	-	-	**.48** (<.001)
8. Child distress behaviour	-	-	-	-	-	-	-	-
Mean	3.12	8.50	5.09	4.50	3.85	.14	.06	.33
SD	2.16	.89	2.59	2.70	2.47	.21	.17	.33
Range	0-10	0-10	0-10	0-10	0-10	0-1	0-1	0-1
N	172	173	161	153	117	156	202	202

Note: p-values are in parentheses. Significant correlations are bolded

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Table 4. Means, standard deviations, and correlations among pain response variables at 12 months and preschool immunizations

	1	2	3	4	5	6	7	8
1. Pre-needle distress 12-months	-	**.36** (<.001)	**.28** (<.001)	**.26** (.001)	.17 (.05)	.05 (.56)	.04 (.65)	.11 (.16)
2. Needle pain 12-months	-	-	**.46** (<.001)	**.60** (<.001)	**.26** (<.001)	.13 (.14)	.09 (.24)	**.17** (.02)
3. 1 minute pain 12-months	-	-	-	**.39** (<.001)	**.26** (.002)	.11 (.22)	.10 (.21)	**.17** (.02)
4. 2 minute pain 12-months	-	-	-	-	**.52** (<.001)	.10 (.26)	.05 (.57)	.12 (.13)
5. 3 minute pain 12-months	-	-	-	-	-	.09 (.34)	.07 (.46)	.01 (.90)
6. FLACC	-	-	-	-	-	-	**.79** (<.001)	**.57** (<.001)
7. Cry	-	-	-	-	-	-	-	**.48** (<.001)
8. Child distress behaviour	-	-	-	-	-	-	-	-
Mean	3.63	8.21	5.98	4.99	4.44	.14	.06	.33
SD	2.37	1.30	2.36	2.56	2.72	.21	.17	.33
Range	0-10	0-10	0-10	0-10	0-10	0-1	0-1	0-1
N	171	176	172	158	134	156	202	202

Note: p-values are in parentheses. Significant correlations are bolded.

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Table 5. Estimates from 2-month model predicting pain-related anticipatory distress at preschool

Variable	Un-standardized estimate	*SE*	*Z*	*p*	Standardized estimate	*SE*	*Z*	*p*
Indicators of preschool pain-related anticipatory distress factor								
FLACC	1.00	.00	-	-	.98	.03	32.71	<.001
Child distress verbalizations	.97	.08	12.79	<.001	.59	.05	12.41	<.001
Cry	.68	.09	7.99	.00	.80	.04	18.26	<.001
Indicators of pain reactivity at 2 months								
2-month needle MBPS	1.00	.00	-	-	1.00	.00	-	-
2-month 1 min MBPS	1.00	.00	-	-	.32	.08	3.91	.00
2-month 2 min MBPS	1.00	.00	-	-	.34	.09	3.96	.00
2-month 3 min MBPS	1.00	.00	-	-	.33	.08	3.96	.00
Indicators of pain regulation at 2 months								
2-month needle MBPS	.00	.00	-	-	.00	.00	-	-
2-month 1 min MBPS	.79	.05	15.20	.00	.61	.05	12.32	.00
2-month 2 min MBPS	.90	.05	17.66	.00	.73	.06	13.38	.00
2-month 3 min MBPS	1.00	.00	-	-	.78	.05	15.65	.00
Prediction of anticipatory distress				.				.
Intercept (reactivity)	.03	.01	1.90	.06	.11	.05	2.43	.02
Slope (regulation)	-.01	.01	-1.15	.25	-.10	.09	-1.16	.25
Pre-needle pain score	.002	.01	.23	.82	.02	.10	.23	.82

Note: p-value for significance is p< .0125 based with the Bonferonni correction.

Table 6. Estimates from 4-month model predicting pain-related anticipatory distress at preschool

Variable	Un-standardized estimate	*SE*	*Z*	*p*	Standardized estimate	*SE*	*Z*	*p*
Indicators of preschool pain-related anticipatory distress factor								
FLACC	1.00	.00	-	-	.99	.03	30.45	<.001
Child distress verbalizations	.95	.08	12.73	<.001	.59	.05	12.08	<.001
Cry	.66	.08	8.06	<.001	.79	.05	17.50	<.001
Indicators of pain reactivity at 4 months								
4-month needle MBPS	1.00	.00	-	-	1.00	.00	-	-
4-month 1 min MBPS	1.00	.00	-	-	.34	.04	9.50	.00
4-month 2 min MBPS	1.00	.00	-	-	.35	.04	9.74	.00
4-month 3 min MBPS	1.00	.00	-	-	.33	.04	9.44	.00
Indicators of pain regulation at 4 months								
4-month needle MBPS	.00	.00	-	-	.00	.00	-	-
4-month 1 min MBPS	.87	.05	18.01	.00	.64	.04	14.44	.00
4-month 2 min MBPS	.93	.04	21.40	.00	.69	.06	12.41	.00
4-month 3 min MBPS	1.00	.00	-	-	.70	.05	13.48	.00
Prediction of anticipatory distress				.				.
Intercept (reactivity)	.04	.02	2.21	.03	.16	.07	2.28	.02
Slope (regulation)	.03	.01	2.45	.014	.27	.10	2.71	.01
Pre-needle pain score	.01	.01	.62	.54	.06	.09	.61	.54

Note: p-value for significance is p< .0125 based with the Bonferonni correction.

Table 7. Estimates from 6-month model predicting pain-related anticipatory distress at preschool

Variable	Un-standardized estimate	*SE*	*Z*	*p*	Standardized estimate	*SE*	*Z*	*p*
Indicators of preschool pain-related anticipatory distress factor								
FLACC	1.00	.00	-	-	.98	.03	28.85	<.001
Child distress verbalizations	.98	.08	13.02	<.001	.60	.05	12.36	<.001
Cry	.68	.09	7.80	<.001	.80	.05	16.90	<.001
Indicators of pain reactivity at 6 months								
6-month needle MBPS	1.00	.00	-	-	1.00	.00	-	-
6-month 1 min MBPS	1.00	.00	-	-	.33	.03	11.76	.00
6-month 2 min MBPS	1.00	.00	-	-	.35	.03	12.06	.00
6-month 3 min MBPS	1.00	.00	-	-	.35	.03	11.03	.00
Indicators of pain regulation at 6 months								
6-month needle MBPS	.00	.00	-	-	.00	.00	-	-
6-month 1 min MBPS	.75	.05	14.88	.00	.51	.04	11.66	.00
6-month 2 min MBPS	.90	.04	21.93	.00	.65	.05	12.29	.00
6-month 3 min MBPS	1.00	.00	-	-	.73	.06	12.30	.00
Prediction of anticipatory distress				.				.
Intercept (reactivity)	.02	.02	1.06	.29	.10	.09	.1.08	.28
Slope (regulation)	.02	.01	1.24	.22	.15	.12	1.22	.22
Pre-needle pain score	-.005	.01	-.53	.60	-.06	.11	-.52	.60

Note: p-value for significance is p< .0125 based with the Bonferonni correction.

Table8

Table 8. Estimates from 12-month model predicting pain-related anticipatory distress at preschool

Variable	Un-standardized estimate	*SE*	*Z*	*p*	Standardized estimate	*SE*	*Z*	*p*
Indicators of preschool pain-related anticipatory distress factor								
FLACC	1.00	.00	-	-	.97	.03	34.01	<.001
Child distress verbalizations	.99	.08	13.29	<.001	.60	.05	12.67	<.001
Cry	.69	.09	8.01	<.001	.81	.05	17.98	<.001
Indicators of pain reactivity at 12 months								
12-month needle MBPS	1.00	.00	-	-	.87	.16	5.42	.00
12-month 1 min MBPS	1.00	.00	-	-	.49	.10	4.94	.00
12-month 2 min MBPS	1.00	.00	-	-	.46	.10	4.84	.00
12-month 3 min MBPS	1.00	.00	-	-	.38	.08	4.47	.00
Indicators of pain regulation at 12 months								
12-month needle MBPS	.00	.00	-	-	.00	.00	-	-
12-month 1 min MBPS	.61	.06	10.53	.00	.47	.07	6.87	.00
12-month 2 min MBPS	.88	.06	15.07	.00	.64	.09	6.97	.00
12-month 3 min MBPS	1.00	.00	-	-	.59	.09	6.78	.00
Prediction of anticipatory distress				.				.
Intercept (reactivity)	.03	.01	1.89	.06	.15	.07	2.21	.03
Slope (regulation)	.01	.01	.32	.75	.04	.13	.32	.75
Pre-needle pain score	.00	.01	.02	.98	.002	.10	.02	.98

Note: p-value for significance is p< .0125 based with the Bonferonni correction.

Table 9. Means and Correlations Among Variables.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1. Baseline pain 2-months	1	**.19** (0.03)	**.22** (.01)	.127 (.19)	-.059 (.53)	.075 (.44)	.14 (.10)	-.07 (.43)	-.01 (.89)	.05 (.58)	.01 (.89)	.08 (.35)	-.02 (.85)	.07 (.44)	**-.19** (.03)
2. Needle pain 2-months	-	1	**.27** (<.001)	.103 (.28)	-.01 (.96)	-.06 (.51)	.07 (.40)	.11 (.22)	-.102 (.24)	-.12 (.16)	.08 (.39)	-.04 (.68)	**-.21** (.02)	.01 (.96)	-.12 (.17)
3. One minute pain 2-months	-	-	1	.09 (.38)	.09 (.37)	.06 (.54)	.02 (.87)	.09 (.31)	.15 (.11)	-.03 (.77)	.04 (.65)	**.21** (.02)	-.00 (.97)	-.01 (.93)	**-.22** (.02)
4. Baseline pain 12-months	-	-	-	1	**.29** (<.001)	**.35** (<.001)	-.10 (.21)	.05 (.56)	.05 (.53)	-.06 (.45)	.15 (.05)	.11 (.14)	**-.17** (.03)	**-.34** (<.001)	-.02 (.87)
5. Needle pain 12-months	-	-	-	-	1	**.45** (<.001)	**-.16** (.04)	.07 (.36)	.06 (.40)	-.06 (.45)	**.20** (.01)	**.17** (.02)	.01 (.90)	**-.21** (<.001)	.03 (.78)
6. One minute pain 12-months	-	-	-	-	-	1	-.10 (.20)	.09 (.24)	.03 (.66)	-.02 (.78)	**.19** (.01)	.11 (.15)	.00 (.97)	**-.28** (<.001)	-.02 (.82)
7. HCP Distress Promoting	-	-	-	-	-	-	1	.02 (.84)	.11 (.12)	.10 (.17)	-.11 (.11)	**-.16** (.03)	-.10 (.23)	.02 (.90)	-.04 (.65)
8. Caregiver Distress Promoting	-	-	-	-	-	-	-	1	.11 (.13)	.01 (.93)	.07 (.33)	-.02 (.77)	-.04 (.54)	-.06 (.45)	.08 (.36)
9. ~~Gender~~Sex	-	-	-	-	-	-	-	-	1	-.01 (.91)	.05 (.46)	-.02 (.80)	-.08 (.27)	-.05 (.51)	-.03 (.75)
10. Age	-	-	-	-	-	-	-	-	-	1	.06 (.44)	-.06 (.37)	.05 (.46)	-.10 (.18)	-.05 (.57)
11. Child Worry	-	-	-	-	-	-	-	-	-	-	1	**.27** (<.001)	.03 (.65)	.01 (.95)	.09 (.33)
12. Parent Worry	-	-	-	-	-	-	-	-	-	-	-	1	.04 (0.54)	.05 (.51)	-.04 (.65)
13. Events	-	-	-	-	-	-	-	-	-	-	-	-	1	.14 (.07)	.07 (.45)
14. Caregiver EAS 12months	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**.46** (<.001)
15. Caregiver EAS 2 months	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1
Means	2.89	8.78	5.94	3.63	8.21	5.97	.04	.07	94-female 108-male	4.61	3.96	2.37	.17	93.58	91.90
SD	1.95	.85	2.47	2.36	1.30	2.36	.07	.09	-	.55	3.30	2.89	.50	11.23	12.19
Range	0-10	0-10	0-10	0-10	0-10	0-10	0-1	0-1	1-male 2-female	3.92-6.58	0-10	0-10	0-4	28-116	28-116
N	132	133	123	171	176	172	202	202	202	202	201	201	202	176	132

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Note: P-values are in parentheses. Significant correlations are bolded.

Table 10. Completely standardized results of measurement model

Variable	Standardized estimate	SE	*Z*	*p*
2-month cumulative distress				
Baseline pain 2-months	.40	.10	4.07	<.001
Needle pain 2-months	.47	.14	3.32	.001
One-minute pain 2-months	.59	.18	3.26	.001
12-month cumulative distress				
Baseline pain 12-months	.48	.06	8.27	<.001
Needle pain 12-months	.61	.07	8.88	<.001
One-minute pain 12-months	.74	.08	9.87	<.001
Preschool anticipatory distress				
FLACC	.96	.03	33.05	<.001
Child distress verbalizations	.60	.05	12.67	<.001
Cry	.81	.05	17.91	<.001

Table11

Table 11. Estimates from final model predicting pain-related anticipatory distress at preschool

Variable	Un-standardized estimate	*SE*	*Z*	*p*	Standardized estimate	*SE*	*Z*	*p*
2-month cumulative distress								
Baseline pain 2-months	1.00	.00	-	-	.46	.10	4.42	<.001
Needle pain 2-months	.37	.18	2.00	.05	.38	.10	3.84	.002
One minute pain 2-months	1.60	.73	2.20	.03	.58	.14	4.22	<.001
12-month cumulative distress								
Baseline pain 12-months	1.00	.00	-	-	.55	.07	7.96	<.001
Needle pain 12-months	.61	.18	3.38	.001	.62	.08	8.14	<.001
One minute pain 12-months	1.23	.26	4.69	<.001	.68	.08	8.66	<.001
Preschool anticipatory distress								
FLACC proportion	1.00	.00	-	-	.97	.04	27.90	<.001
Child distress behaviour	.995	.09	11.15	<.001	.60	.05	12.14	<.001
Cry proportion	.68	.10	6.86	<.001	.79	.06	13.42	<.001
Predicting preschool anticipatory distress								
2 month cumulative distress	.06	.03	1.76	.08	.25	.14	1.77	.08
12 month cumulative distress	-.008	.02	-.41	.68	-.05	.13	-.41	.68
Healthcare provider distress promoting	.19	.18	1.05	.29	.06	.06	1.05	.29
Caregiver distress promoting	1.03	.23	4.44	<.001	.49	.10	4.84	<.001
~~Gender~~Sex	.02	.03	.83	.40	.05	.06	.83	.40
Age	.05	.02	2.47	.01	.15	.06	2.49	.01
Child worry	.004	.005	.89	.38	.07	.08	.87	.39
Parent worry	.002	.005	.38	.70	.03	.07	.39	.70
Events	.05	.03	1.83	.07	.13	.07	1.91	.06
Emotional Availability	.006	.002	2.46	.01	.35	.14	2.42	.02

2 months								
Emotional Availability 12 months	-.006	.002	-2.52	.01	-.33	.13	-2.49	.01
Healthcare Provider Distress Promoting								
12-month cumulative distress	-.007	.006	-1.91	.23	-.14	.11	-1.31	.19
Parent worry	-.003	.001	-2.38	.02	-.13	.05	-2.53	.01
Child Worry								
12-month cumulative distress	.57	.24	2.40	.02	.23	.09	2.64	.008
Parent worry	.27	.09	2.97	.003	.23	.07	3.09	.002
Parent Worry								
2-month cumulative distress	.74	.43	1.71	.09	.23	.12	1.91	.06
12-month cumulative distress	.34	.21	1.66	.10	.16	.09	1.85	.07