

TRAJECTORIES OF DISTRESS REGULATION DURING PRESCHOOL VACCINATIONS:
CHILD AND CAREGIVER PREDICTORS

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Abstract

Recent research has highlighted the need for a deeper understanding of the heterogeneity in trajectories of children's distress following acute pain exposure, moving beyond group means of behavioural pain scores at a single timepoint. During preschool vaccinations, three distinct patterns of post-vaccination pain regulation have been elucidated, with approximately 75% of children down-regulating to no distress by two minutes post-needle and 25% concerningly failing to down-regulate to no distress by two-minutes (Waxman et al., 2017). The objective of the present study was to examine child and caregiver predictors of preschool children's post-vaccination regulatory patterns. Our results indicated that child baseline distress, caregiver coping-promoting verbalizations in the first minute following the needle, and caregiver distress- and coping- promoting verbalizations in the second minute following the needle predicted the likelihood of a child displaying a trajectory pattern. Further, children's pain-related distress at various timepoints throughout the appointment was predicted by different factors depending on the trajectory that they exhibited. This research highlights the importance of considering the heterogeneity of trajectories of preschool pain responding when examining the factors that are associated with children's pain-related distress.

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Chapter 1: Introduction to the Study of Pediatric Acute Pain-Related Distress

Vaccinations are the most common type of painful medical procedure that healthy children experience (World Health Organization, 2009). Before age six, children in Canada receive at least 14 vaccinations (Public Health Agency of Canada, 2020) and they are an ongoing consistent part of care throughout the lifespan (Birnie et al., 2018; McMurtry et al., 2015). While vaccinations are recognized as being an important part of routine preventative health care, they can be highly distressing for families, causing pain and fear in children (Mahoney et al., 2010; Taddio et al., 2009, 2012) and significant stress for caregivers and healthcare providers (Birnie et al., 2018; Kennedy et al., 2008). In addition to deterring families from adhering to the recommended immunization schedule for children (Taddio et al., 2009), unmanaged pain, distress, and fear during routine medical care can have a host of deleterious effects on a child's wellbeing and development.

Young children are at risk of high procedural distress, the umbrella term for a child's negative reactions to painful medical procedures (Bearden et al., 2012), due to their limited cognitive ability to rationally conceptualize a procedure as necessary and temporary (Brown et al., 2019). Unmanaged vaccination pain and distress can reciprocally magnify each other, resulting in a sequelae of problematic responses (Brown et al., 2018; McMurtry et al., 2015). Also, significant pain and distress during vaccinations are associated with the development of fear in the context of immunizations, which can in turn increase the pain of future medical procedures (Taddio et al., 2012; Wright et al., 2009). Finally, childhood needle fear, if unmitigated, has been shown to persist into adulthood and is associated with stronger vasovagal responses, reports of increased pain, and avoidance of medical care (Mahoney et al., 2010; Nir et al., 2003; Wright et al., 2009).

In some cases, unmanaged distress and fear of needles can develop into needle phobia, an anxiety disorder characterized by persistent, severe anxiety that results in strong physiological reactions to a needle and ultimately complete avoidance (Orenius et al., 2018). Needle phobia has an incidence rate of approximately 10% in the general population (Sokolowski et al., 2010). Importantly, the median age of onset of needle phobia is 5.5 years (Bienvenu & Eaton, 1998), underscoring how critical it is to manage vaccination pain and distress in the preschool years.

Pediatric Acute Pain-Related Distress: Beyond Averages and Single Timepoint

Assessments

There is a significant body of literature focused on understanding pediatric acute pain responding and distress. This research has delineated two phases in a young child's response to acute pain exposure. First, a child experiences an initial biological response to the nociceptive input, or pain-related reactivity, often defined by researchers for some period from the instigation of the painful stimulus to 30-seconds post-stimulus onset. The pain-related reactivity is followed by pain-related regulation, during which the child recovers from peak distress and progressively returns to baseline. These two phases, while interconnected, represent distinct processes and have been shown to be influenced by different factors (Pillai Riddell, 2018 as cited in Goubert et al., 2019). To properly characterize a child's response to a painful stimulus, the distress experienced at both the reactivity and regulation phases need to be examined as each stage of this trajectory of pain response carries meaningful information. However, research on pediatric pain-related distress, particularly randomized controlled trials of interventions to mitigate pain, has typically focused on the immediate responses to the painful stimulus without incorporating the subsequent period of regulation. Further complicating this research is the consideration that

examination of trajectories of pain response is only possible with large datasets and repeated measures.

In addition to a lack of focus in the literature on the regulation phase and on trajectories of pain regulation (pain response from peak distress to baseline), researchers typically utilize overall group means in analyzing pain outcomes, ignoring potential variability in responses. Advances in statistical modeling have enhanced the ability to understand heterogeneity in longitudinal responses through the identification of homogeneous subgroups of trajectories of responses (Chassin et al., 2004). Pillai Riddell and colleagues utilized one such method, growth mixture modelling, to examine a large longitudinal cohort during vaccinations through the first year of life (Pillai Riddell et al., 2013). They identified distinct groups of pain-responses, and illustrated that averaging pediatric pain responses across an entire sample can obscure important individual differences between infants (Pillai Riddell et al., 2013). It was found that especially for infants between the ages of 6-12 months, mean pain responses misrepresent the distress of the majority of infants in the post-needle regulatory period in a clinically meaningful way (Pillai Riddell et al., 2013). This research provided important insights into the heterogeneity of trajectories in infant pain responses and highlighted the limitations of research utilizing average scores across participants. In the broader field of psychology, too, increasing attention is being paid to the use of person-oriented analyses (e.g., cluster analyses), which focus on inter-individual differences, in contrast to variable-centered approaches (e.g., regression analyses), which focus on relationships between variables (Von Eye et al., 2006).

Recent research has extended the pediatric pain literature by examining whether distinct patterns of preschool pain-related distress regulation following vaccination can be elucidated (Waxman et al., 2017). Using growth mixture modeling analyses to examine clusters of

trajectories of behavioural responses from the initial exposure to the needle through two minutes post-needle (n=302), Waxman and colleagues illustrated that variability in preschool pain responses is best represented by three prototypical trajectories (See Figure 1). The majority of the sample (75%) had a high probability (>0.8) of membership in the group that displayed a trajectory characterized by moderate initial pain response followed by regulation to almost no-distress by two minutes post-needle. This finding illustrates that down-regulation to a no-distress state by two-minutes post-vaccination is normative for the preschool period. The remaining 25% of preschool children, on the other hand, had high probabilities of membership in one of two groups of trajectories in which initial distress is moderate to high and remains so at two-minutes post-needle. It is important to note that while the three groups best represent the variability in regulatory patterns across participants, individual variability exists within each group.

Moreover, the two groups that failed to down-regulate to no-distress at two-minutes post needle displayed clinically meaningful differences in levels of pain (i.e., mild, moderate, severe; Merkel et al., 1997) at the three timepoints post-needle from the mean across all participants at each of the timepoints. In other words, a mean score collapsing over the sample would have meaningfully obscured the responses of the participants whose pain-related distress responses is most concerning. This research extends prior findings to the preschool period, reiterating how critical it is to uncover and consider the heterogeneity in children's regulatory patterns. Further, the researchers identified the "normative" response pattern in the preschool period – displaying moderate pain that regulates completely by two minutes. These findings illustrate the importance of developmental (i.e., age-related) considerations in pediatric pain-related distress research, as preschool children showed different behavioural pain response patterns than in those of infants.

Influences on Early Childhood Acute Pain-Related Distress

Now that the variability in preschool acute-pain response trajectories has been identified, the critical next step is to identify the antecedents of different trajectories in order to best support those that display non-normative, highly distressed, and relatively more concerning responses.

The Proximal-Distal Model of Children's Coping and Distress During Acute Painful Medical Procedures

The 'Proximal-Distal Model of Children's Coping and Distress During Acute Painful Medical Procedures' (referred to henceforth as the Proximal Distal Model) is a pediatric pain framework which postulates a strong connection between external proximal influences on a child during a pain-inducing medical procedure and the child's pain response (Blount et al., 2000; Varni et al., 1995). Based on assessment and treatment studies, the framework posits that a complex array of caregiver cognitive-affective and behavioural variables at various stages of the medical appointment influence a child's coping and distress in response to the pain. Importantly, it distinguishes between two types of variables – factors that are temporally and functionally proximal to the situation (e.g., in-session behaviours and verbalizations) from those that are more distal (e.g., child and caregiver psychosocial characteristics, such as negative affectivity and coping style). The model posits that while distal factors do impact a child's distress response, caregiver behaviour during the pain-inducing procedure is the more influential factor on the child's pain response (Manimala et al., 2000; Varni et al., 1995). As these proximal factors are malleable through intervention and education, the authors suggest that this finding is key for developing interventions aimed at optimizing positive outcomes for children.

Specific Child and Caregiver Factors Impacting Early Childhood Pain-Related Distress

In line with the Proximal-Distal Model, there is a large body of empirical studies that has investigated the relationship between specific child and caregiver variables and children's acute pain-related distress.

Child Factors. A child's individual pain responses and demographic characteristics have been recognized as strong predictors of pain response during medical procedures. Firstly, a child's prior pain-related distress has been shown to be one of the strongest predictors of subsequent pain-related distress, both between (Pillai Riddell et al., 2011) and within appointments (Waxman et al., 2020). This finding has been replicated in various age groups throughout early childhood where there are multiple acute pain exposures in one appointment. At vaccination appointments throughout the first year of life, earlier infant pain behaviour was a stronger predictor of subsequent pain responses than parental soothing (Campbell et al., 2013). Toddlers' acute pain responses were also shown to have high stability, with earlier pain response being a significant predictor of subsequent pain responses within an appointment (Waxman et al., 2020). Similarly, preschoolers' earlier pain response was the strongest predictor of subsequent within-appointment pain response when compared to the predictive power of prior and concurrent caregiver variables (Campbell et al., 2018).

Even before the acute pain exposure has occurred (e.g., the insertion of the needle), many children exhibit significant distress, referred to as anticipatory distress. It has been found that anticipatory distress during the early stage of the appointment is a significant predictor of ongoing distress throughout the appointment, making this anticipatory reaction an important focus of research and intervention (Blount, 2019; Blount et al., 1990). In addition to being an important predictor of distress following the pain exposure (Racine et al., 2016), anticipatory

distress may also be a marker for broader socioemotional issues such as more externalizing problems and behavioural symptoms (Racine et al., 2018).

Child age and sex have both been examined as predictors of child distress, and are important factors to consider when examining child distress outcomes. Compared to older children and adolescents, younger children generally report higher pain levels and display greater degrees and longer duration of distress (Taddio et al., 2012; Young, 2005). Age-specific patterns in pain and distress have also been elucidated. For example, in a sample of preschoolers, Racine et al. (2016) found a positive relationship between a child's age and anticipatory distress, with older children exhibiting more distress prior to the needle. Further, younger children appear to exhibit greater variability in distress patterns than older children (Blount et al., 1989a; Pillai Riddell et al., 2013). Female sex has been identified as a predictor of increased pain and distress, though this finding is less consistent in children, especially in early childhood (Goodenough et al., 1999; Racine, Pillai Riddell, et al., 2016; Young, 2005).

Caregiver Factors. The role of the caregiver in a child's pain response has been the subject of a large body of literature. Due to children's immature but developing cognitive and emotional regulatory abilities, they rely heavily on their caregivers to aid them in regulating distress (Thrane et al., 2016). Further, the specific role of the caregiver changes across the steep developmental trajectory of childhood. Early in life (i.e., infancy), children depend entirely on their caregivers to help regulate from distress while later they develop increasingly autonomous regulatory patterns (Campbell et al., 2017). It therefore follows that a child's pain response is more strongly influenced by caregiver cognition, affect, and behaviour in the younger years.

Research in this area has found that caregiver cognitive-affective variables – such as psychological distress, fear, and anxiety – are associated with a child's pain response (Brown et

al., 2018). Caregiver pain catastrophizing, or maladaptive negative cognitions about the pain experience, has been associated with increased child distress during acute painful procedures (Caes, Goubert, et al., 2014; Caes, Vervoort, et al., 2014). While these variables are important to consider, research into the potential mechanisms by which these cognitive variables impact child pain behaviour has shown that their impact on child outcomes may be indirect and mediated by caregiver behaviour. For example, high caregiver pain catastrophizing likely increases caregiver distress-promoting behaviour, thereby increasing child distress (Caes, Goubert, et al., 2014; Caes, Vervoort, et al., 2014). Further, caregiver cognitive variables, such as worry, have been shown to impact caregiver ratings of child pain (Mamedova et al., 2019), potentially serving to alter child-directed behaviour.

In line with The Proximal Distal Model outlined above, a systematic review of preschool coping responses during acute pain events suggests that what the caregiver *does* or *says* is much more impactful on child acute pain outcomes than what the caregiver *thinks* or *feels* (Campbell et al., 2017). Caregiver behaviour and verbalizations have consistently been found to strongly impact child distress and coping patterns in the acute pain context (Sobol-Kwapińska et al., 2020), accounting for up to 53% of the variance in child distress during vaccinations (Frank et al., 1995). One posited mechanism for this strong relationship is the impact of caregiver modelling (Goodman & McGrath, 2003). Correlational research studies have identified certain caregiver behaviours/verbalizations (henceforth referred to as behaviours) that appear to increase the child's focus on the frightening and painful aspects of the experience and thereby promote child distress, known as distress-promoting behaviours. Examples of such behaviours are apologizing, criticism, and giving control to the child. One seemingly counter-intuitive caregiver factor that has been consistently found to be distress-promoting in both correlational (Blount et

al., 1989b) and experimental (Manimala et al., 2000) studies is reassurance-giving, which is the most common distress-promoting behaviour. Examples of reassuring statements include, “don’t worry, I’ll hold your hand”, “you’re okay”, and “you can do this.” While caregiver reassurance can be beneficial when children are coping with prolonged stressors, reassurance in the acute pain context may serve to indicate that the caregiver is anxious or that the child is not capable of coping with the upcoming stressor. Further, caregiver reassurance may focus the child’s attention on the distressing aspects of the situation (Manimala et al., 2000; McMurtry et al., 2006). The other category of caregiver behaviours is those that were shown to be associated with increased child coping, or coping promoting-behaviours, which likely serve to prompt the child to engage in their own coping behaviours and thereby decrease distress (Blount et al., 1989). Examples of coping-promoting behaviours are caregiver distraction, nonprocedural talk, and commands to engage in coping skills.

As investigators continue to examine the relationship between caregiver behaviours and a child’s pain-related distress outcomes, some nuances in the relationships have been discovered. First, the literature has consistently illustrated the higher relative contribution of distress-promoting behaviour compared to coping-promoting behaviour on a child’s pain responses, starting from infancy (Badovinac et al., 2018) through to preschool (Campbell et al., 2018) and older childhood (Mahoney et al., 2010). Second, the relationship between caregiver behaviour and child outcomes can vary depending on the phase of the appointment (e.g., pre-needle versus two-minutes post-needle). For example, caregiver behaviour during the baseline period, prior to any exposure to a noxious stimulus, has emerged as particularly impactful. Across the first year of life and especially by 12 months, caregiver behaviour at baseline accounted for more variance in infant pain response when compared to caregiver behaviour following the noxious stimulus

(Lisi et al., 2013). Further, during the preschool period, caregiver distress-promoting behaviour was substantially more predictive of child anticipatory distress than both child variables and more distal caregiver factors (Racine et al., 2016).

Campbell et al. (2018) sought to uncover the dynamic interplay between caregiver cognitive and behavioural factors during infancy and preschool and preschool-aged children's distress throughout the vaccination appointment (distinguishing between coping responses and distress responses). The authors used cross-lagged path analyses to examine whether caregiver within-preschool appointment variables predict subsequent child outcomes in the same appointment (looking at outcomes immediately post-needle, one-minute post-needle, and two-minutes post-needle). Overall, findings from the study illustrate that preschoolers' prior pain responses were the strongest predictors of within-appointment subsequent pain and that caregiver coping-promoting behaviour at one-minute predicts subsequent child distress. Correlation analyses showed that both caregiver distress-promoting and coping-promoting behaviour were associated with concurrent child baseline distress but later in the appointment only distress-promoting behaviour (and not coping-promoting behaviour) was associated with concurrent distress. This research highlighted the importance of both child responses and caregiver behaviour in shaping preschooler pain-related distress, while illustrating the complex interplay of child and caregiver behaviour during acute pain procedures. Further, it showed that caregiver verbalizations are differentially associated with child distress depending on the phase of the appointment.

All of the outlined studies focused on averaged pain scores in analyses, and children who responded above or below the average could be misrepresented in the findings. The current project sets out to add to the literature in a critical way. Building on a program of research in the

preschooler vaccination context, this thesis will, for the first time, examine the child and caregiver factors from within the preschool context that are associated with the different regulation trajectories. First, we will examine the child and caregiver factors that are associated with a child's likelihood of displaying a trajectory pattern. Second, given previous findings on phase-dependent associations between caregiver factors and child outcomes, we will examine the predictors of individual pain scores across the appointment for the children in the trajectory groups separately in an effort to understand whether the previously identified patterns of associations are relevant for all children. Chapter Two contains the study itself, in manuscript form. The manuscript is currently under review in the journal *Pain*. The findings of the current study have the potential to inform both research and clinical practice, by further highlighting the importance of researchers utilizing analytic techniques that can account for variability in children's patterns of pain responses and informing clinicians on ways to optimally support children who exhibit different distress patterns.

Chapter 2: Predicting Preschooler Pain-Related Distress Regulation Patterns ¹

Decades of research on pediatric acute pain have built the foundation for understanding the developmental trajectory of a child's acute pain response and the various factors that affect it. Use of advanced statistical modelling on large longitudinal samples has illustrated the importance of moving the field forward by uncovering heterogeneity in the trajectories of pain-related distress that children display across the post-vaccination period (Pillai Riddell et al., 2013).

Waxman et al. (2017) sought to understand how variability in preschooler pain responses is best represented, and elucidated three distinct trajectories of responses (See Figure 1). This research highlights the considerable heterogeneity in preschooler patterns of responses to acute pain, but we still lack an understanding of the factors associated with these differences. Understanding predictors of trajectories is critical for identifying targets for change to optimally support young children in their distress.

The present study extends previous research by examining predictors of trajectories of preschooler pain-related distress responses during the vaccination appointment. We considered two categories of predictor variables based on theoretical models (e.g., Varni et al., 1995) and empirical studies on early childhood pain-related distress. First, we focused on the individual child's characteristics that have been shown to shape child distress. Specifically, preceding child distress responses, especially during the pre-needle phase, have emerged as one of the strongest predictors of subsequent pain responses within the same appointment (Blount et al., 1990; Campbell et al., 2013, 2018; Waxman et al., 2020). We also included child sex and age given their potential to contribute to child distress outcomes. Next, we examined caregiver proximal

¹ This manuscript is currently under review in the journal *Pain*.

variables that are well-established as strongly associated with early childhood pain outcomes. Adult distress-promoting verbalizations, particularly during the baseline period, have been consistently linked to increased child distress (Lisi et al., 2013; Racine et al., 2016). We also included coping-promoting verbalizations, which have been shown to shape child outcomes albeit less strongly than distress-promoting verbalizations (Badovinac et al., 2018; Campbell et al., 2018). While some cognitive-affective caregiver factors have emerged as associated with child distress, such as caregiver pain catastrophizing, the effect is likely indirect and mediated by caregiver behaviour (Brown et al., 2018; Caes, Goubert, et al., 2014; Caes, Vervoort, et al., 2014). We therefore did not include caregiver cognitive variables in the analyses.

Present Study

The first goal of this study was to examine whether specific child variables and caregiver verbalizations are associated with a child's likelihood of displaying the Regulated Trajectory (i.e., down-regulating to no-distress by two-minutes; group 3) versus the Less Regulated Trajectories (i.e., failing to down-regulate by two-minutes; group 1 or 2). We hypothesized that a child's regulatory pattern post-vaccination would be most predicted by child factors, specifically Baseline distress, and secondarily predicted by caregiver verbalizations. Specifically, higher child Baseline distress and higher caregiver distress-promoting verbalizations at Baseline would both be associated with lower likelihood of the Regulated Trajectory.

Subsequent to predicting the likelihood of a child displaying a particular trajectory pattern, we investigated predictors of distress at individual timepoints for each trajectory separately with the goal of examining whether previously identified phase-specific associations between caregiver responses and child behaviour are relevant for both trajectory types. While exploratory, we hypothesized that for both groups, prior pain would most strongly predict

subsequent pain and that caregiver verbalizations would predict pain above and beyond the child variables.

Methods

Approval to collect data was obtained through both the York University Ethics Review Board as well as the Hospital for Sick Children Institutional Review Board. Approval for the present analyses was obtained from the York University Ethics Review Board.

Study Sample

Participants are part of a larger longitudinal study in which 760 caregiver-infant dyads were recruited from three pediatric clinics in the greater Toronto area and were observed during vaccinations over the first 12 months of a child's life (e.g., Pillai Riddell et al., 2011). Inclusion criteria were that caregivers reported that their infants had no suspected developmental delays or impairments, had no chronic illnesses, had never been admitted to a neonatal intensive care unit and were born no more than two weeks preterm (i.e., 36 weeks gestation or more). A subset (n=302) was observed at the child's preschool vaccination (i.e., 4-6 years of age), and are the focus of the current analyses. Previous analyses showed that caregivers who chose to participate versus not participate in the preschool phase of the study differed marginally on some demographic variables such as age (slightly older) and education (held marginally more graduate degrees). Refer to Table 1 for the demographic information on the subsample of participants for the current analysis.

Table 1

Demographic Variables

Variable	Value
Mean caregiver age at preschool (SD), years	38.2 (5.3)
<i>Primary caregiver education, %</i>	
Graduate school or professional training	29.5
University graduate	35.1
Partial university	4.6

Trade school or community college	13.9
High school graduate	2.0
Some high school	0.3
Junior high school graduate	0.3
<i>Caregiver Heritage Culture</i>	
European	40.8
Asian	20.7
Canadian/American	17.7
Jewish	9.2
African/Middle Eastern	4.8
South/Latin American	4.4
Other	2.4
<i>Child Sex, %</i>	
Male	52.3
Female	47.7
<i>Number of siblings at preschool, %</i>	
0	9.3
1	31.8
2	9.9
3	0.3
4	1.3
<i>Basic pregnancy risk factors, %^a</i>	
0	63.9
1-3	36.1

^a Maternal prenatal medication use, cigarette exposure, and alcohol and drug use.

Measures

Outcome

Child Pain-Related Distress. The Face, Legs, Activity, Cry, Consolability coding system (FLACC) was used to measure pain-related distress (Merkel et al., 1997). The severity of distress is reflected in 5 types of pain behaviors (face, legs, activity, cry, consolability) during 15-second epochs (15 seconds immediately after the needle [FLACC0], 1 minute after the needle [FLACC1], and 2 minutes after the needle [FLACC2]). Each category is scored on a 0 to 2 scale, which results in a total score between 0 and 10 for each 15-second epoch. FLACC0 reflects the peak pain response that occurs immediately after the needle. A lowering of scores from FLACC0 to FLACC1 to FLACC2 would represent regulation from the peak distress (i.e., returning to low or no levels of pain-related distress). Moderate to high concurrent and construct validity as well as item total and inter-rater reliability have all been shown in the acute pain context (Merkel et

al., 2002). The coders were blind to the study hypotheses and inter-rater reliability between the coders was high (intraclass correlations between .91 and .95). Severe pain is considered in the 7 to 10 range, moderate pain in the 4 to 6 range, mild pain in the 1 to 3 range, and scores of 0 represent no distress behaviors. See Appendix A for the FLACC coding sheet.

Predictors

Child Baseline Distress. Child baseline distress was measured using FLACC scores in the one minute prior to the needle.

Caregiver Within-Appointment Verbalizations. Caregiver distress-promoting and coping-promoting verbalizations throughout the vaccination appointment were coded using the Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R) (Blount et al., 1997). Verbalizations were coded according to three 60-second phases – the one-minute period prior to the first needle, the one-minute period following the last needle, the two-minute period following the last needle. 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. Interrater reliability for the CAMPIS-R raw data was calculated using Cohen's kappa. Kappa scores ranged from 0.73 to 1.00. The average kappa was 0.88. Slightly over 30% (n=99) of the 302 children seen at the preschool vaccination did not have data coded for caregiver verbalizations due to time and resource constraints on coding capacity.

Caregiver distress-promoting verbalizations were operationalized by summing the criticism, reassuring comment, giving control to the child, apology, and empathy verbalization codes that occurred during each phase. These verbalizations were divided by the total verbalizations for each individual to compute the proportion of distress-promoting verbalizations for that phase. Three composites were created: (1) caregiver distress-promoting verbalizations 1-

minute pre-needle; (2) caregiver distress-promoting verbalizations in the first minute post-needle; and (3) caregiver distress-promoting verbalizations in the second minute post-needle.

Caregiver coping- promoting verbalizations were operationalized by summing humour directed to the child, non procedure-related talk to the child, and command to use the coping strategy that occurred. These verbalizations were divided by the total verbalizations for each individual to compute the proportion of coping-promoting verbalizations for that phase. Three composites were created: (1) caregiver coping-promoting verbalizations 1-minute pre-needle; (2) caregiver coping-promoting verbalizations in the first minute post-needle; and (3) caregiver coping-promoting verbalizations in the second minute post-needle. See Appendix B for a description of the codes.

Procedure

Appendix C shows the phases of the vaccination and the timepoints at which measures were obtained. Caregivers filled out a short demographic questionnaire before and after the vaccination. Once in the examination room, two video cameras were set up to capture a close-up face shot of the child as well as a wide shot to obtain a full view of the caregiver and the child, from 5 minutes prior to 5 minutes post-needle. This was a naturalistic observational study, so families were observed with minimal interference on the part of the research team, aside from videotaping the procedures. See Racine et al., 2016 for more information about study procedures.

Data Analysis Plan

Trajectory groups were originally discerned using Growth Mixture Modelling (GMM) in MPlus (See Waxman et al., 2017 for original analyses). Group membership was exported from MPlus into SPSS (Version 24) and the two groups representing the approximately 25% of the sample that failed to down-regulate by two minutes post-needle were combined into one group,

resulting in a dichotomous categorical variable (Regulated Trajectory, $n = 227$ versus Less Regulated Trajectory, $n = 75$). SPSS was used for all analyses pertaining to the present study.

We included all those with child pain-related distress data ($n=302$). Because the caregiver verbalization variables were missing completely at random, missing values were imputed using multiple imputation with 10 iterations (Rubin, 1987).

Sex and age analyses were completed to determine whether they should be entered as covariates in the models. The relationship between child sex and all outcome variables was nonsignificant (p 's > 0.05), so it was not included. Age was significantly correlated with some outcomes so it was included in all analyses. Correlations between all study variables were examined to ensure there was no multi-collinearity between the predictors.

Four t-tests were conducted to examine the differences between the two trajectories on mean distress scores at various timepoints (Baseline, Immediately post-needle, One-minute post-needle, Two minutes post-needle).

One hierarchical binary logistic regression model was conducted in which regulation trajectory status (coded as 1 for the Regulated Trajectory and 0 for the Less Regulated Trajectory) was regressed on two blocks of variables, entered in ascending order of the factors that were hypothesized to most strongly shape child distress. In the first block, child variables (Baseline distress and age) were entered to examine whether the impact of caregiver factors is robust to child characteristics. In the second block, caregiver verbalization variables (distress-promoting verbalizations at three timepoints, coping-promoting verbalizations at three timepoints) were entered. The statistical assumption of linearity of each predictor and the log of the outcome variable was examined by assessing whether the interaction term between each predictor and its log transformation was significant (Hosner & Lemeshow, 1989). To assess the

predictive power of each step and the overall model, chi square likelihood ratio tests and associated statistical significance were evaluated. The overall model was also evaluated using correct classification percentages. Regression coefficients, associated significance tests, and odds ratios (with 95% confidence intervals) for individual predictors were interpreted.

Eight hierarchical multiple linear regression models were estimated to assess how child and caregiver factors predict average pain scores for the Regulated and Less Regulated Trajectories at four timepoints – Baseline, Immediately post-needle, One-minute post-needle, and Two minutes post-needle. Given that children’s pain responses are strong predictors of subsequent pain responding in the short-term, all models included child distress from the previous timepoints. Statistical assumptions of normality, homoscedasticity, and linearity were inspected by examining scatterplots of the standardized residuals with standardized predicted values of the outcome. To examine the overall variance accounted for by each step and overall model, adjusted coefficients of determination (adjusted R^2) were evaluated. Standardized regression coefficients of individual predictors were interpreted based on their significance values as well as the additive benefit of the block of predictors to the overall model.

Results

Preliminary Analyses

Means and standard deviations for all study variables are provided in Table 2. Correlations between all study variables are provided in Table 3. None of the correlations between predictors was greater than 0.65, which is well below the acceptable cutoff criterion of 0.9 (Tabachnick & Fidell, 2013). All assumptions examined for the multivariate analyses were met. Further, analyses were replicated using bootstrapping methods, which generate bias-corrected confidence intervals and significance tests of the model parameters, and no differences

in patterns of relationships between child and caregiver variables were observed. Differences in mean pain scores at the four timepoints between the two trajectories are presented in Table 4, illustrating significantly higher distress in the Less Regulated Trajectory at each timepoint compared to the Regulated Trajectory.

Table 2

Study Variable Descriptive Statistics

Variable	M / %	SD	Range
1. Child Age	4.65	0.55	4 – 7
2. Female Sex	47.70%	—	—
3. Regulated Trajectory Status	75.20%	—	—
4. FLACC Baseline	7.42	9.84	0 – 40
5. FLACC Immediate	4.47	2.99	0 – 10
6. FLACC 1 Minute	2.53	2.45	0 – 10
7. FLACC 2 Minutes	1.57	2.18	0 – 10
8. Distress CAMPIS - B	0.10	0.14	0 – 1
9. Coping CAMPIS - B	0.29	0.28	0 – 1
10. Distress CAMPIS - 1	0.16	0.16	0 – 1
11. Coping CAMPIS - 1	0.10	0.14	0 – 1
12. Distress CAMPIS - 2	0.12	0.16	0 – 1
13. Coping CAMPIS - 2	0.23	0.23	0 – 1

Note. FLACC Baseline = Child distress prior to the needle; FLACC Immediate = Child distress immediately following the needle; FLACC 1 Minute = Child distress one-minute following the needle; FLACC 2 Minutes = Child distress two-minutes following the needle; Distress CAMPIS – B = Caregiver distress-promoting verbalizations at baseline; Coping CAMPIS – B = Caregiver coping-promoting verbalizations at baseline; Distress CAMPIS – 1 = Caregiver distress-promoting verbalizations in the first minute post-needle; Coping CAMPIS – 1 = Caregiver coping-promoting verbalizations in the first minute post-needle; Distress CAMPIS – 2 = Caregiver distress-promoting verbalizations in the second minute post-needle; Coping CAMPIS – 2 = Caregiver coping-promoting verbalizations in the second minute post-needle.

Table 3

Bivariate Correlations among all Study Variables

	1	2	3	4	5	6	7	8	9	10	11	12	13
1. Child Age	1	.025	.004	.199**	.137*	-.014	-.018	.048	-.116	.050	.052	-.088	-.102
2. Child Sex		1	-.096	.107	.087	.047	.030	.107	-.046	.049	-.049	.083	-.032
3. Regulatory Grouping			1	-.306**	-.496**	-.582**	-.875**	-.112	.035	-.183**	-.132	-.416**	.195**
4. FLACC Baseline				1	.561**	.355**	.327**	.421**	-.152**	.259**	-.071	.278**	.001
5. FLACC Immediate					1	.611**	.511**	.238**	-.088	.457**	-.039	.331**	-.081

6.	FLACC 1 Minute	1	.654**	.240**	-.094	.374**	.074	.448**	-.118
7.	FLACC 2 Minutes		1	.102	-.061	.197**	.180*	.362**	-.145*
8.	Distress CAMPIS - B			1	-.243**	.171*	-.004	.233**	.012
9.	Coping CAMPIS - B				1	-.026	.113	-.010	.026
10.	Distress CAMPIS - 1					1	-.149*	.389**	-.025
11.	Coping CAMPIS - 1						1	-.068	.277**
12.	Distress CAMPIS - 2							1	-.206**
13.	Coping CAMPIS - 2								1

Note. Child Sex = 0 for male, 1 for female; Regulatory Grouping = Trajectory status coded as 0 for the Less Regulated Trajectory and 1 for the Regulated Trajectory.

* $p < .05$. ** $p < .01$ (two tailed).

Table 4

Comparison of Distress at Four Timepoints Between Trajectories

	Regulated		Less Regulated		t-test
	M	SD	M	SD	
FLACC Baseline	5.70	8.32	12.69	12.13	4.49***
FLACC Immediate	3.62	2.72	7.03	2.21	10.91***
FLACC 1-Minute	1.70	1.92	4.99	2.23	12.31***
FLACC 2-Minute	0.47	0.74	4.86	1.69	21.70***

*** $p < .001$ (two tailed).

Primary Analyses

Predicting Child's Likelihood of Displaying Regulated Trajectory

Table 5 presents the details of the hierarchical binary logistic regression model. The first step was significant ($X^2(2) = 25.73, p < 0.001$), indicating that the block of predictors is significantly associated with a child's likelihood of displaying the Regulated Trajectory versus the Less Regulated Trajectory. Higher child baseline distress was significantly associated with a decreased likelihood of displaying the Regulated Trajectory ($B = -0.07, SE = 0.02, p < .01, OR = 0.93, 95\% CI [0.89, 0.97]$). The second step significantly improved the model over the first step ($X^2(6, 8) = 62.83, p < 0.001$). Higher caregiver coping-promoting verbalizations in the first minute post-needle was associated with a decreased likelihood of displaying the Regulated Trajectory ($B = -4.84, SE = 1.51, p < .01, OR = 0.01, 95\% CI [0.00, 0.16]$). Higher caregiver

distress-promoting verbalizations in the second minute post-needle was also associated with a decreased likelihood of displaying the Regulated Trajectory ($B = -5.50$, $SE = 1.45$, $p < .01$, $OR = 0.01$, 95% CI [0.00, 0.16]). Finally, higher caregiver coping-promoting verbalizations in the second minute post-needle was associated with an increased likelihood of displaying the Regulated Trajectory ($B = 3.54$, $SE = 1.12$, $p < .01$, $OR = 34.55$, 95% CI [3.77, 316.44]) The overall model was significant ($X^2(8) = 89.55$, $p < 0.001$) and yielded 82.02% correct classifications.

Table 5

Model 1: Hierarchical Binary Logistic Regression Predicting Child's Likelihood of Displaying the Regulated Trajectory

	<i>B (SE)</i>	<i>OR</i>	<i>OR 95% CI</i>	<i>Model X^2</i>	<i>Step X^2</i>
<i>Step 1</i>				25.73***	
Age	0.38 (0.34)	1.47	0.75, 2.85		
FLACC Baseline	-0.07 (0.02)**	0.93	0.89, 0.97		
<i>Step 2</i>				89.55***	62.83***
Distress CAMPIS - B	1.42 (1.57)	4.13	0.19, 91.27		
Coping CAMPIS - B	0.77 (0.76)	2.16	0.48, 9.69		
Distress CAMPIS - 1	-0.56 (1.22)	0.57	0.05, 6.27		
Coping CAMPIS - 1	-4.84 (1.51)**	0.01	0.00, 0.16		
Distress CAMPIS - 2	-5.50 (1.45)***	0.00	0.00, 0.07		
Coping CAMPIS - 2	3.54 (1.12)**	34.55	3.77, 316.44		

Note. * $p < 0.05$. ** $p < 0.01$. *** $p < 0.001$.

Secondary Analyses

Predicting Pain-Related Distress at Each Timepoint

Model 2: Regulated Trajectory – Predicting Baseline Distress. Table 6 presents the details of the first hierarchical linear regression model predicting Baseline distress for the Regulated Trajectory. The first step was significant $F(1, 225) = 15.62$, $p < 0.01$ and accounted for 6% of the variance in pain scores. Child age was a unique predictor of increased child distress ($\beta = 0.22$, $p < .001$). The second step significantly improved the model over the first step,

adjusted $R^2_{\text{change}} = 0.14$, $F_{\text{change}}(2, 223) = 14.26$, $p < 0.001$, illustrating that caregiver verbalizations account for additional variance in Baseline distress above and beyond child variables. Increased caregiver distress-promoting verbalizations at Baseline was a unique predictor of increased child distress ($\beta = 0.37$, $p < .001$). The full model predicted a significant amount of the variance in Baseline distress, $F(3, 223) = 15.15$, $p < 0.001$, adjusted $R^2 = 0.20$.

Table 6

Model 2: Hierarchical Linear Regression Predicting Baseline Distress for Regulated Trajectory

	<i>B (SE)</i>	β	Adjusted R^2	Adjusted R^2 Change
<i>Step 1</i>			0.06***	--
Age	3.36 (0.95)	0.22***		
<i>Step 2</i>			0.20***	0.14***
Distress CAMPIS - B	22.31 (4.73)	0.37***		
Coping CAMPIS - B	-1.09 (2.13)	-0.04		

Note. * $p < 0.05$. ** $p < 0.01$. *** $p < 0.001$.

Model 3: Regulated Trajectory – Predicting Distress Immediately Post-Needle.

Table 7 presents the details of the second hierarchical linear regression model predicting distress Immediately post-needle for the Regulated Trajectory. The first step was significant $F(2, 224) = 43.79$, $p < 0.001$ and accounted for 28% of the variance in distress. Child baseline distress was a unique predictor of distress Immediately post-needle ($\beta = 0.53$, $p < .001$). The second step did not significantly improve the model over the first step, adjusted $R^2_{\text{change}} = 0.00$, $F_{\text{change}}(2, 222) = 0.01$, $p = 0.99$, illustrating that caregiver verbalizations do not account for additional variance in Immediate distress above and beyond child variables. The full model predicted a significant amount of the variance in distress Immediately post-needle, $F(4, 222) = 17.57$, $p < 0.001$, adjusted $R^2 = 0.28$.

Table 7

Model 3: Hierarchical Linear Regression Predicting Distress Immediately Post-Needle for Regulated Trajectory

	<i>B (SE)</i>	β	Adjusted R ²	Adjusted R ² Change
<i>Step 1</i>			0.28***	--
Age	0.26 (0.29)	0.05		
FLACC Baseline	0.15 (0.02)	0.53***		
<i>Step 2</i>			0.28***	0.00
Distress CAMPIS - B	-0.13 (1.56)	-0.01		
Coping CAMPIS - B	-0.09 (0.77)	-0.01		

*Note** $p < 0.05$. ** $p < 0.01$. *** $p < 0.001$.

Model 4: Regulated Trajectory – Predicting Distress One-Minute Post-Needle. Table 8 presents the details of the third hierarchical linear regression model predicting distress at One-minute post-needle for the Regulated Trajectory. The first step was significant $F(3, 223) = 23.97$, $p < 0.001$ and accounted for 24% of the variance in distress scores. Child distress Immediately post-needle was a unique predictor of distress at One-minute post-needle ($\beta = 0.43$, $p < .001$). The second step significantly improved the model over the first step, adjusted $R^2_{\text{change}} = 0.05$, $F_{\text{change}}(4, 219) = 3.21$, $p < 0.05$, illustrating that caregiver verbalizations account for additional variance in distress at one minute above and beyond child variables. Caregiver distress-promoting verbalizations in the first minute after the needle was a unique predictor of child distress at one minute ($\beta = 0.22$, $p < .01$). The full model predicted a significant amount of the variance in distress at One-minute post-needle, $F(7, 219) = 11.17$, $p < 0.001$, adjusted $R^2 = 0.29$.

Table 8

Model 4: Hierarchical Linear Regression Predicting Distress One-Minute Post-Needle for Regulated Trajectory

	<i>B (SE)</i>	β	Adjusted R ²	Adjusted R ² Change
<i>Step 1</i>			0.24***	--
Age	-0.32 (0.21)	-0.09		
FLACC Baseline	-0.02 (0.02)	-0.11		
FLACC Immediate	0.28 (0.05)	0.43***		
<i>Step 2</i>			0.29***	0.05**
Distress CAMPIS - B	1.38 (1.02)	0.10		
Coping CAMPIS - B	-0.38 (0.51)	-0.05		
Distress CAMPIS - 1	2.76 (0.94)	0.22**		

Coping CAMPIS - 1 0.55 (0.98) 0.04

Note. * $p < 0.05$. ** $p < 0.01$. *** $p < 0.001$.

Model 5: Regulated Trajectory - Predicting Distress Two-Minutes Post-Needle.

Table 9 presents the details of the fourth hierarchical linear regression model predicting distress at Two-minutes post-needle for the Regulated Trajectory. The first step was significant $F(4, 222) = 6.71$, $p < 0.001$ and accounted for 9% of the variance in child distress scores. Child distress at one minute was a unique predictor of distress at Two-minutes post-needle ($\beta = 0.38$, $p < .001$). The second step did not significantly improve the model over the first step, adjusted $R^2_{\text{change}} = 0.03$, $F_{\text{change}}(6, 216) = 0.42$, $p = 0.86$, illustrating that caregiver verbalizations do not account for additional variance in distress above and beyond child variables at Two minutes post-needle. The full model predicted a significant amount of the variance in distress at Two-minutes post-needle, $F(10, 216) = 2.55$, $p < 0.01$, adjusted $R^2 = 0.12$.

Table 9

Model 5: Hierarchical Linear Regression Predicting Distress Two-Minutes Post-Needle for Regulated Trajectory

	<i>B (SE)</i>	β	Adjusted R^2	Adjusted R^2 Change
<i>Step 1</i>			0.09***	—
Age	-0.02 (0.09)	-0.01		
FLACC Baseline	-0.01 (0.01)	-0.08		
FLACC Immediate	0.02 (0.02)	0.09		
FLACC 1 Min	0.12 (0.03)	0.38***		
<i>Step 2</i>			0.12*	0.03
Distress CAMPIS - B	0.26 (0.45)	0.05		
Coping CAMPIS - B	0.04 (0.19)	0.01		
Distress CAMPIS - 1	-0.05 (0.40)	-0.01		
Coping CAMPIS - 1	-0.62 (0.46)	-0.11		
Distress CAMPIS - 2	-0.80 (0.44)	-0.17		
Coping CAMPIS - 2	0.27 (0.29)	0.08		

Note. * $p < 0.05$. ** $p < 0.01$. *** $p < 0.001$.

Less Regulated Trajectory Analyses

Model 6: Less Regulated Trajectory – Predicting Baseline Distress. Table 10 presents the details of the fifth hierarchical linear regression model predicting Baseline distress for the Less Regulated Trajectory. The first step was not significant $F(1, 73) = 1.05, p = 0.31$ and accounted for 0% of the variance in pain scores. The second step significantly improved the model over the first step, adjusted $R^2_{\text{change}} = 0.14, F_{\text{change}}(2, 71) = 5.26, p < 0.01$. Increased caregiver distress-promoting verbalizations at Baseline was a unique predictor of increased child distress ($\beta = 0.40, p < .01$), and the full model predicted a significant amount of the variance in Baseline distress $F(3, 71) = 4.04, p < 0.05, \text{adjusted } R^2 = 0.15$.

Table 10

Model 6: Hierarchical Linear Regression Predicting Baseline Distress for Less Regulated Trajectory

	<i>B (SE)</i>	β	Adjusted R^2	Adjusted R^2 Change
<i>Step 1</i>			0.00	--
Age	1.88 (2.46)	0.09		
<i>Step 2</i>			0.15*	0.14**
Distress CAMPIS - B	34.00 (10.21)	0.40**		
Coping CAMPIS - B	-0.30 (6.02)	-0.01		

Note. * $p < 0.05$. ** $p < 0.01$. *** $p < 0.001$.

Model 7: Less Regulated Trajectory – Predicting Distress Immediately Post-Needle.

Table 11 presents the details of the sixth hierarchical linear regression model predicting distress Immediately post-needle for the Less Regulated Trajectory. The first step was significant $F(2, 72) = 7.84, p < 0.01$ and accounted for 15% of the variance in pain scores. Child baseline distress was a unique predictor of pain ($\beta = 0.38, p < .01$). The second step did not significantly improve the model over the first step, adjusted $R^2_{\text{change}} = -0.02, F_{\text{change}}(2, 70) = 0.00, p = 0.99$, illustrating that caregiver verbalizations do not account for additional variance in distress Immediately post-needle above and beyond child variables. The full model predicted a significant amount of the variance in distress Immediately post-needle, $F(4, 70) = 3.45, p < 0.05, \text{adjusted } R^2 = 0.13$.

Table 11

Model 7: Hierarchical Linear Regression Predicting Distress Immediately Post-Needle for Less Regulated Trajectory

	<i>B (SE)</i>	β	Adjusted R^2	Adjusted R^2 Change
<i>Step 1</i>			0.15**	--
Age	0.35 (0.45)	0.09		
FLACC Baseline	0.09 (0.03)	0.38**		
<i>Step 2</i>			0.13*	-0.02
Distress CAMPIS - B	0.19 (2.15)	0.01		
Coping CAMPIS - B	0.01 (0.99)	0.00		

Note. * $p < 0.05$. ** $p < 0.01$. *** $p < 0.001$.

Model 8: Less Regulated Trajectory – Predicting Distress One-Minute Post-Needle.

Table 12 presents the details of the seventh hierarchical linear regression model predicting distress at One-minute post-needle for the Less Regulated Trajectory. The first step was significant $F(3, 71) = 4.22, p < 0.01$ and accounted for 11% of the variance in pain scores. Child baseline distress was a unique predictor of distress at One-minute post-needle ($\beta = 0.33, p < .05$). The second step did not significantly improve the model over the first step, adjusted $R^2_{\text{change}} = -0.03, F_{\text{change}}(4, 67) = 0.29, p = 0.88$, illustrating that caregiver verbalizations did not account for additional variance in distress at One minute post-needle above and beyond child variables. The full model did not predict a significant amount of the variance in distress at One-minute post-needle, $F(7, 67) = 1.68, p = 0.13$, adjusted $R^2 = 0.08$.

Table 12

Model 8: Hierarchical Linear Regression Predicting Distress One-Minute Post-Needle for Less Regulated Trajectory

	<i>B (SE)</i>	β	Adjusted R^2	Adjusted R^2 Change
<i>Step 1</i>			0.11***	--
Age	-0.23 (0.47)	-0.06		
FLACC Baseline	0.02 (0.04)	0.08		
FLACC Immediate	0.24 (0.11)	0.33*		
<i>Step 2</i>			0.08	-0.03
Distress CAMPIS - B	-0.45 (2.67)	-0.03		

Coping CAMPIS - B	-0.20 (1.14)	-0.02
Distress CAMPIS - 1	0.63 (2.09)	0.04
Coping CAMPIS - 1	0.78 (2.15)	0.05

Note. * $p < 0.05$. ** $p < 0.01$. *** $p < 0.001$.

Model 9: Less Regulated Trajectory – Predicting Distress Two-Minutes Post-Needle.

Table 13 presents the details of the eighth hierarchical linear regression model predicting distress at Two-minutes post-needle for the Less Regulated Trajectory. The first step was significant $F(4, 70) = 5.08, p < 0.05$ and accounted for 22% of the variance in distress scores. Child distress at One-minute was a unique predictor of distress at Two-minutes post-needle ($\beta = 0.64, p < .001$). The second step did not significantly improve the model over the first step, adjusted $R^2_{\text{change}} = 0.10, F_{\text{change}}(6, 64) = 1.52, p = 0.19$, illustrating that caregiver verbalizations do not account for additional variance in distress above and beyond child variables at Two-minutes post-needle. The full model predicted a significant amount of the variance in distress at Two-minutes post-needle, $F(10, 64) = 2.78, p < 0.01$, adjusted $R^2 = 0.33$.

Table 13

Model 9: Hierarchical Linear Regression Predicting Distress Two-Minutes Post-Needle for Less Regulated Trajectory

	<i>B (SE)</i>	β	Adjusted R^2	Adjusted R^2 Change
<i>Step 1</i>			0.22**	—
Age	-0.10 (0.32)	-0.03		
FLACC Baseline	0.04 (0.02)	0.21		
FLACC Immediate	-0.16 (0.08)	-0.28		
FLACC 1 Min	0.44 (0.09)	0.64***		
<i>Step 2</i>			0.33**	0.10
Distress CAMPIS - B	-2.48 (1.46)	-0.20		
Coping CAMPIS - B	-0.95 (0.68)	-0.15		
Distress CAMPIS - 1	0.55 (1.64)	0.05		
Coping CAMPIS - 1	2.54 (1.62)	0.20		
Distress CAMPIS - 2	-1.75 (1.67)	-0.17		
Coping CAMPIS - 2	0.75 (0.93)	0.10		

Note. * $p < 0.05$. ** $p < 0.01$. *** $p < 0.001$.

Discussion

The aim of the current study was to gain a deeper understanding of the child and caregiver factors that are associated with preschooler pain-related distress regulation trajectories, and to determine whether the factors differentially predict pain scores in children who display the different trajectories. To the best of our knowledge, this is the first study to identify the specific concurrent child and caregiver factors that contribute to differences in patterns of preschooler regulatory behaviour in response to acute pain. Distinct predictors differentiated the group of children who completely regulated within two minutes post-vaccination versus those that did not completely regulate.

Predicting Likelihood of Displaying Regulated Trajectory versus Less Regulated Trajectory

In line with hypotheses, higher child Baseline distress was uniquely associated with a decreased likelihood of a child exhibiting the Regulated Trajectory. In other words, higher distress expression prior to the needle being administered meant the child had a lower likelihood of regulating within two minutes post-vaccination. Replicating findings with infants (Pillai Riddell et al. 2014) and toddlers (Waxman et al., 2020), these results further demonstrate the pivotal role that distress prior to the vaccination needle plays in the sequelae of preschooler behaviour following the needle and importantly extended it to a child pain outcome that accounts for different regulation patterns across the vaccination appointment. The addition of the caregiver verbalization variables significantly improved the predictive power of the model over the child variables alone, consistent with findings on the importance of caregiver verbalizations above and beyond the amount of distress the child expressed pre-needle. Contrary to hypotheses, pre-needle caregiver verbalizations were not associated with a child's likelihood of displaying

the Regulated Trajectory versus the Less Regulated Trajectory. However, post-needle caregiver verbalizations were significantly associated with trajectory outcomes.

Coping-promoting verbalizations in the first minute as well as distress- and coping-promoting verbalizations in the second minute predicted group membership. Specifically, higher coping-promoting verbalizations in the first minute post-needle as well as higher distress-promoting verbalizations in the second minute post-needle predicted membership in the Less Regulated Trajectory group, while higher coping-promoting verbalizations in the second minute post-needle predicted membership in the Regulated Trajectory group. Because the trajectories take into account the full pattern of responses that children exhibit across the vaccination, these findings are not surprising. In the first minute post-needle, children in the Less Regulated Trajectory are displaying considerable distress, likely preceded by high distress at Baseline. Their caregivers may display coping-promoting verbalizations in an attempt to sooth their highly distressed child. By the second minute post-needle, these caregivers may be more likely to exhibit distress-promoting verbalizations, perhaps due to mild frustration or fatigue. Caregivers of children in the Regulated Trajectory, on the other hand, may be more able and willing to exhibit coping-promoting verbalizations by the second minute as their child is close to down-regulating to no distress.

Predictors of Pain-Related Distress at Different Timepoints for Each Trajectory

Next, pain-related distress at each timepoint throughout the appointment was explored separately for each trajectory to further understand differences between these groups of children. Analyses explored the factors that predict individual child pain scores at different timepoints throughout the appointment (i.e., Baseline, Immediately post-needle, One-minute post-needle, Two-minutes post-needle). For both the Regulated and Less Regulated Trajectories, prior child

pain at the immediately preceding timepoint was the strongest predictor of pain at the next timepoint. A clear pattern, consistent with previous work, was shown for both the Regulated and Less Regulated Trajectories. A child that starts distressed will continue to express distress over the vaccination, such that the higher the initial distress pre-needle, the higher the post-needle distress (Immediately post-needle, One-minute post-needle, Two-minutes post-needle). Further, we show that only the most proximal pain score remained significant, illustrating a ‘domino effect’. For example, when predicting distress at Two-minutes for both Regulated and Less Regulated Trajectories, only One-minute distress remained predictive, with Immediate post-needle distress and Baseline distress dropping out (despite being significant in prior models predicting One-minute distress or Immediate post-needle distress). This finding reiterates the importance of minimizing distress prior to the needle in order to attenuate the ‘domino-effect’. Of interest, given the importance of Baseline distress in serving as the first ‘domino’ to trigger post-needle distress, for both trajectories, the strongest predictor of Baseline distress was caregiver distress-promoting verbalizations during the Baseline period.

Two variables distinguished the prediction of distress between the two groups. Firstly, child age predicted Baseline distress in the Regulated Trajectory group only, showing that the older the child at vaccination the higher the Baseline distress. This extends findings from Racine and colleagues (Racine et al., 2016), importantly showing the pattern in one sub-set of children only. Secondly, higher caregiver distress-promoting verbalizations in the first minute post-needle predicted greater child distress at one-minute in the Regulated Trajectory group only. For the children exhibiting highly distressed regulation patterns, it appears as if once the pain ‘domino effect’ was set into motion, external caregiver factors had little effect on child distress.

Finally, another interesting difference that was discerned between the analyses conducted for each trajectory related to the patterns in the amount of variance accounted for in the models. When examining the overall effect size (i.e., adjusted R^2 values) in the Regulated Trajectory analyses, the values ranged between .20 and .29 (a strong relationship for behavioural science), except for the model predicting pain-related distress at Two-minutes which dipped to an adjusted R^2 of .12. However, the opposite pattern was shown for the Less Regulated Trajectory models, where all of the adjusted R^2 values were less than .15, except for the two-minute model which was the highest of all the analyses with an adjusted R^2 value of .33. Further, the amount of variance accounted for by the individual prior pain predictors reflected a similar pattern in which the amount of variance accounted for by the prior pain variable in the two-minute model was the lowest of all models in the Regulated Trajectory group and the highest of all models in the Less Regulated Trajectory group. This suggests that in the earlier phases of the vaccination (Immediately post-needle and One-minute post-needle) the pain ‘domino-effect’ is more pronounced in the Regulated Trajectory and then tapers off. However, in the last epoch under study (i.e. Two-minutes post-needle), the predictive value of prior pain-related distress in the Less Regulated Trajectory was most powerful. This finding is interesting in light of the fact that the two-minute distress score is one of the distinguishing features of the groups (i.e., down-regulation to no distress versus the maintenance of moderate distress), further illustrating the importance of disaggregating the groups to understand predictions of distress patterns.

In conclusion, results from both the primary and secondary analyses illustrate a number of important points. Replicating findings from other developmental stages, during the preschool vaccination, Baseline distress and caregiver behaviours (both distress-promoting and coping-promoting verbalizations) were influential in predicting the likelihood of being in the Regulated

versus the Less Regulated Trajectory. When exploratory analyses were run for the two groups of children separately and individual pain scores were predicted, different patterns emerged. Across both sets of models, the ‘domino-effect’ of prior pain predicting subsequent pain was seen, and a few key distinguishing factors were found. Only in the Regulated Trajectory was older age a significant predictor of Baseline distress and caregiver distress-promoting verbalizations a predictor of One-minute distress. Moreover, the magnitude of the effects of the regression models tended to also be stronger for the Regulated Trajectory analyses, except for the final timepoint. At Two-minutes post-needle, the overall effect size of the adjusted R^2 for the Less Regulated group was almost three times that of the Regulated group. The totality of our findings lends further evidence for the need for both researchers and clinicians to take care to disaggregate subgroups of pain responders when understanding, assessing, and managing pediatric acute pain.

Research and Clinical Implications

The present findings highlight, for the first time, important factors that are associated with different regulatory trajectories across the preschool vaccination. We showed that child and caregiver factors differentially predict different regulatory trajectories.

The findings have important implications for both research and clinical work. In terms of preschooler pain research, it is critical that researchers continue to examine pain trajectories as well as heterogeneity in pain responses. Failing to do so has two repercussions. First, it misrepresents child pain, either under or over estimating the pain of most children in a clinically meaningful way (Pillai Riddell et al., 2013). Second, as illustrated here, it obscures our understanding of the ways in which child and caregiver factors shape child distress distinctly for children who display different distress trajectories.

The findings also provide insight for healthcare providers and caregivers to support children during immunization appointments. Because all children show the prior pain ‘domino-effect’, it is critical for health care providers to try to avoid vaccinating a distressed preschooler. Adopting techniques that allow the child to be approached without distressing them (e.g., allowing a child to stay close to their caregiver while viewing a video on a smartphone as a distraction) will help minimize the pain ‘domino effect’ this study elucidated. Moreover, for both groups, specifically teaching caregivers to avoid distress-promoting behaviours prior to the vaccination will be critical. Also, based on our disaggregated findings, it is recommended that for the majority of preschoolers, being vaccinated earlier rather than later within the preschool period would be beneficial.

Limitations and Future Directions

As discussed in the other published papers using the same preschooler sample (e.g., Campbell et al., 2018; O’Neill et al., 2020; Racine et al., 2016), the study sample is quite homogeneous in regard to demographics (i.e., socioeconomic status and education). Additionally, there is self-selection bias associated with the caregiver’s choice of participating in a longitudinal study for upwards of 4 years (i.e., since early infancy). Accordingly, it is difficult to determine how the study findings may generalize to a different population of caregiver–child dyads, especially those with higher risk profiles.

The study design was observational in nature so causal inferences are limited and only based on temporal precedent. The directionality of the relationships should be investigated in future experimental research. Further, the sample size of the Less Regulated Trajectory was smaller than that of the Regulated Trajectory ($n = 75$ vs. 227), thus those analyses should be considered exploratory and replication is needed. Given the Less Regulated Trajectory is the

less-normative response pattern, this is to be expected despite the large sample size of over 300 preschoolers in this study.

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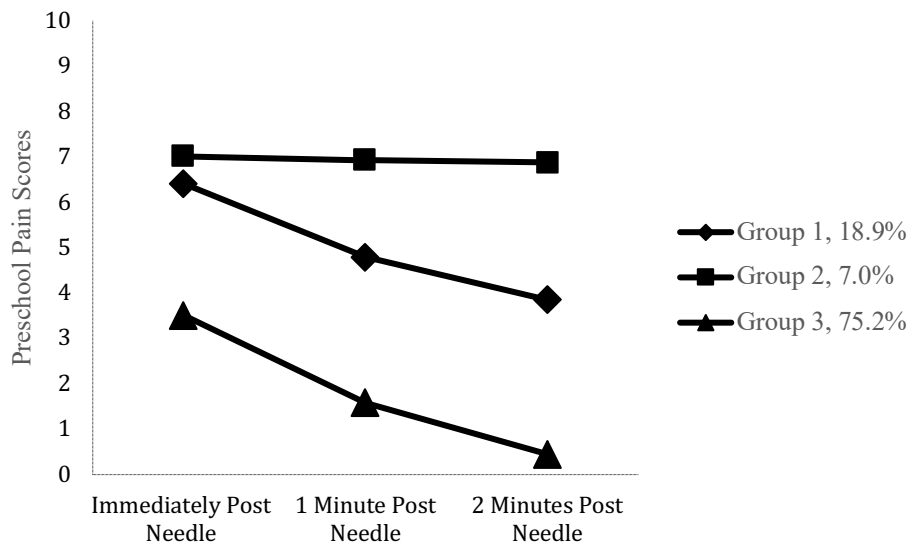
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Figures

Figure 1

Latent groups for preschool pain regulation trajectory (adapted from Waxman et al. 2017)



Appendix A

FLACC CODING SHEET

Date Coded: _____ Coder Name: _____ Participant ID: _____
 Coding Time: _____ to _____ Clip Start: _____ Clip Finish: _____

Cleaning Time: Needle #1 Time: Needle #2 Time:	BASELINE (1 min. before Needle 1) START: _____ FINISH: _____	POST NEEDLE 1 (1 min. after last needle) START: _____ FINISH: _____	POST NEEDLE 2 (2 min. after last needle) START: _____ FINISH: _____	POST NEEDLE 3 (3 min. after the last needle) START: _____ FINISH: _____
Epoch Times (15 sec):				
FACE <i>0 - no expression or smile 1 - occasional grimace, frown, withdrawn 2 - frequent to constant frown, clenched jaw, quivering chin</i>				
LEGS <i>0 - normal position or relaxed 1 - uneasy, restless, tense 2 - kicking or legs drawn up</i>				
ACTIVITY <i>0 - Lying quietly, normal position, moves easily 1 - squirming, shifting back and forth, tense 2 - arched, rigid, or jerking</i>				
CRY <i>0 - no cry 1 - moans or whimpers, occasional complaint 2 - Crying steadily, screams or sobs, frequent complaints</i>				
CONSOLIBILITY <i>0 - content, relaxed 1 - reassured by occasional touching, hugging, or being talked to, distractable 2 - difficult to console or comfort</i>				

Appendix B

Abridged Coding Manual Child-Adult Medical Procedure Interaction Scale- Revised (CAMPIS-R)

Blount, R.L., Cohen, L.L., Frank, N.C., Bachanas, P.J., Smith, A.J., Manimala, M.R., Pate, J.T.
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Relevant Codes for Parent Verbal Behaviors

CODE	DESCRIPTION	EXAMPLES
Coping-Promoting Verbalizations		
<u>Humor directed to child (HMC)</u>	Any statement that is clearly intended to be humorous and is primarily lighthearted in tone. Humor is often accompanied by laughter from the person making the statement may evoke laughter in the patient or in other staff members. Sarcasm may be coded as humor if it is accompanied by laughter on the part of the speaker or on the part of the listener. Sarcasm is not coded as humor if it is accompanied by an angry or harsh tone of voice.	<ol style="list-style-type: none"> 1. Outright jokes of the “one-liner” variety. 2. Statements that suggest purely facetious, outlandish or outrageous ideas. 3. Statements that emphasize the humorous aspects of a situation or problem. 4. Statements which present lighthearted criticism of someone else in such a manner that would be lightly received (e.g. oh you silly duck) 5. “Sure, working on Sunday is my top priority” 6. Laughter (generally coded + for affect)

<p><u>Non procedure-related talk directed toward child (NPTC)</u></p>	<p>Talk that does not pertain to the treatment procedure or about the child's illness.</p>	<ol style="list-style-type: none"> 1. Conversation about the child's pet, siblings, parents, school, toys, etc. 2. Questions, unrelated to the child's illness or treatment, about the child's plans, wants, desires 3. Conversations about activities on the ward or about other children or staff members on the ward
<p><u>Command to use coping strategy (CCS)</u></p>	<p>Any orders, suggestions, or statements of a rule, which direct the child to engage in a coping behavior. These strategies are generally issues immediately prior to a painful event, and may suggest one (but not exclusively one) of the following: relaxation, distraction, use of coping statements, or deep breathing. An example such as "Can you breath now" is coded CCS in spite of it giving the impression of control to the child (GCC)</p>	<ol style="list-style-type: none"> 1. Use your deep breathing now 2. Would you like to count backwards from 10 very slowly? 3. Imagine you are Superman and this is a test of your strength 4. Squeeze your mother's hand when you feel the bumble bee 5. Just relax, alright? 6. Count to three...

Distress-Promoting Verbalizations		
<u>Criticism (CRT)</u>	Any verbalization that finds fault or implies fault with a) activities, b)products, or c) attributes of the child. Criticism includes negatively evaluative adjectives or adverbs referring to the child, statements of disapproval, statements pointing out something wrong about the child or the child’s behavior, and statements pointing out that the child is not doing something positive. Also included as Criticism are obvious sarcastic statements, if these are unaccompanied by laughter on the part of either the speaker or listeners. Usually criticism is accompanied by a harsh voice tone.	<ol style="list-style-type: none"> 1. Timmy has not been going to school the way he should have 2. Boy, you are in a bad mood today 3. That was not a very nice thing to say 4. That was not very funny 5. You didn’t use your breathing that time like I told you to 6. Boy, you really controlled yourself that time (after a big scream) 7. You’re being a pain.
<u>Reassuring Comment (REASUR)</u>	Procedures related comments that are directed toward the child with the intent of reassuring the child about his/her condition, or the course of the procedure. These may be volunteered by staff and/or parents and may be in response to questions by the child or may reflect the child’s comments. If procedure related information is repeated in response to the child’s request for reassurance or emotional support, code these procedural notifications as REASU	<ol style="list-style-type: none"> 1. “A little bit of exercise will take care of that” 2. “You’re okay” 3. “It’s almost over” 4. “We’re hurrying” 5. “Honey, its just soap, okay?” 6. “I’m not doing anything”

		7. “Just touching honey”
<u>Giving control to child (GCC)</u>	Any statement to child denoting that child has control over some event to occur with relation to the procedure. Generally this includes staff suggestions where the child is given a choice about the procedure. “Can you breath now?” is coded CCS even though it has the impression of giving control to the child.	<ol style="list-style-type: none"> 1. “Let me know when you are ready to start.” 2. “Which side would you like to lie one?” 3. Do you want a pillow for your head? 4. Do you like it better when we tell you or don’t tell you? 5. Can you start now? 6. Are you ready?
<u>Apologizes (APOL)</u>	Any statement relating a sense of sorrow or a sense of responsibility for the pain the child is expressing. These statements may occur prior to, during, or after a painful event, and may occur in conjunction with other verbal codes.	<ol style="list-style-type: none"> 1. “Timmy, we don’t like doing this either” 2. “I’m sorry this is taking so long” 3. “I wish I didn’t have to hurt you”

<u>Empathy (EMP).</u>	Statements which show an appreciation for the frame of reference of the person being spoken to.	<ol style="list-style-type: none">1. "I know this is hard"2. "I know this is taking a long time"3. "I know it hurts"4. "This must be hard"5. "You must be getting tired"6. "You must be getting sick of this"
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Appendix C

Vaccination Timeline

