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Temperament as a Predictor of Infant Immunization Distress and Response to Treatment

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TEMPERAMENT AS A PREDICTOR OF INFANT IMMUNIZATION DISTRESS AND RESPONSE TO TREATMENT

by

NAOMI JOFFE

Under the Direction of Lindsey L. Cohen

ABSTRACT

There is a growing body of research on interventions to decrease infant distress during painful procedures, and distraction is a particularly practical option. However, the effectiveness data for distraction for infant pain relief are mixed. Inconsistencies in response to distraction might be explained by unique characteristics of the infant patient. Some researchers argue that temperament is the best predictor of differences observed between individuals and also the most sensitive to novel environmental factors such as exposure to pain. This study examined whether infants' temperament is predictive of response to immunization injection pain and whether temperament moderates the relation between a distraction intervention and infant distress. Data for this study came from two prior studies of healthy infants receiving immunizations (Cohen, 2002; Cohen et al., 2006). Participants included 252 healthy infants and toddlers who ranged from 1 to 22 months of age. Infants were randomly assigned to "typical care" condition or "distraction" condition. The period of time before, during, and after the injection was videotaped and observational coding was used to assess infant distress. Prior to the immunization, parents completed six pre-injection visual analogue scales about their child's temperament. An oblique rotation factor analysis was conducted with the temperament data and provided two temperament factors that map onto the 'easy/difficult' and 'time-to-warm-up' dimensions documented in the literature; these two factors were used for analyses. After controlling for site and gender, regression analyses revealed that neither easy/difficult temperament (p = .098, β = .109) nor time-to-warm-up temperament (p = .572, β = -.037) was predictive of distress. There was a significant treatment condition and time-to-warm-up temperament interaction, b = .0011, SE = .0005, p = .0254, such that distraction decreased distress in infants that were slower to warm up, or warmed up neither slowly nor quickly. No other significant distraction x temperament interactions were found. Temperament was not found to impact infant distress during immunizations in this study but results speaking to whether temperament serves as a moderator of the relation between distraction and distress were mixed. Results suggest that temperament is a factor that warrants closer attention when examining how infants respond to interventions around pain.

INDEX WORDS: Infants, Temperament, Procedural pain, Distraction, Immunizations

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by

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1 INTRODUCTION

1.1 Infant Medical Pain

Soon after birth, healthy infants experience a host of painful medical procedures, including heel sticks and immunizations. Vaccination schedules vary by country, but it is generally recommended that infants receive up to 24 immunizations in their first 2 years of life (World Health Organization, 2011), with the vast majority being conducted via intramuscular injection. Some developing countries, such as those in northern Africa, require 15 immunizations within the first 24 months of life; Europe requires 19 within that period; and the United States requires 25 (World Health Organization, 2011). Infants who are born prematurely, who have been diagnosed with a disease, or who experience accidents or injuries will endure additional painful procedures. Stevens, Yamada, and Ohlsson (2004) estimate that neonates born between 27 and 31 weeks of age undergo an average of 134 painful procedures within the first two weeks of their lives. For the 10% of newborns at the lowest birth weights, Stevens et al. found that they receive an average of more than 300 painful procedures within the same period of time.

1.2 Effects of Untreated Infant Medical Pain

These immunizations and other medical procedures provide protection from debilitating and fatal conditions; however, they cause acute pain and distress in the infant patients. Research suggests that infants feel pain similarly to, if not more intensely than, adults (Felt et al., 2000; Porter, Grunau, & Anand, 1999; Porter, Wolf, Gold, Lotsoff, & Miller, 1997). This argument is supported by studies of infants' adrenocortical reactivity (Lewis & Ramsey, 1995). For example, Lewis and Ramsey found that infants have higher cortisol levels – a physiological marker of distress (Levin & Weiner, 1989) – during vaccinations than older children and adults.

Research indicates that if medical-procedure pain is not prevented and treated, the pain may have long-term negative effects on infants (for a review, see Young, 2005; Garg, Narsinghani, Bhutta, Rovnaghi, & Anand, 2003; Taddio, 1999). Coskun and Anand (2000) explain that during the perinatal period, the pain system may be changed permanently as a result of exposure to severe or repetitive painful procedures and that the effects are long lasting. It is not fully understood why early exposure to medical pain can have these long-term negative effects, but it is hypothesized that these effects are mediated by the damage

of developing neurons (Anand & Scalzo, 2000; Whitfield & Grunau, 2000). Anand and Scalzo provide an overview of the literature showing that repeated exposure to painful procedures during the neonatal period might lead to altered pain sensitivity, increased anxiety, stress disorders, attentional problems, impaired social skills, and even possibly increased self-destructive behavior such as suicide and drug use.

Some research with neonates has examined the more immediate effect of repeated early exposure to medical pain by examining the development of neonates into childhood. For example, Grunau, Oberlander, Whitfield, Fitzgerald, and Lee (2001) found that early exposure to repeated heel lances for blood collection in infancy predicted a dampened behavioral pain response during a later heel lance and an increased cardiac response at 32 weeks of age, suggesting that early pain led to a perpetual state of stress. Other research with neonates found that infants born prematurely were less sensitive to pain at 18 months of age than infants who were not premature; the more painful procedures the infants had experienced as neonates, the less responsive they were to pain (Grunau, Whitfield, & Petrie, 1994). In a randomized controlled trial of a local anesthetic cream for routine 4- and 6-month immunizations, Taddio, Goldbach, Ipp, Stevens, and Koren (1995) found that boys who had been circumcised had higher behavioral pain scores during their immunizations than boys who had not been circumcised. Although findings have been somewhat varied, these studies along with others show that early pain exposure has definite impact on future pain response.

Although some of the studies do focus on relatively short-term (e.g., months) effects (e.g., Grunau et al., 2001), others suggest that negative consequences of untreated infant pain might persist into adulthood. In a retrospective study comparing adolescents who had been NICU patients to adolescents who had been full-term infants, the adolescents who were previously NICU patients were found to be more sensitive to pain (Buskila, et al., 2003). The authors suggested that this information would be particularly helpful for physicians caring for neonates, given than neonates might be at greater risk for developing pain syndromes in the future (Buskila et al.).

Long-term negative effects of pain have also been examined in full-term infants. Taddio, Katz, Ilersich, and Koren (1997) examined the behavioral distress response of 87 healthy infants being immunized months after birth, comparing male infants who were not circumcised, infants circumcised with topical anesthetic, and those circumcised with placebo. Results indicated that there was a significant group effect with infants who had been circumcised with a placebo having a stronger pain response during a subsequent immunization than infants whose pain had been treated with topical anesthetic for their circumcision. This stronger pain response was reflected in infant facial action, cry duration, and visual analog scale pain scores. In summary, untreated pain in both premature and full-term infants appears to have a host of negative repercussions.

1.3 Behavioral Interventions for Infant Medical Pain

Given that infants experience frequent and intense medical pain that may lead to detrimental long-term effects, behavioral interventions are warranted. Fortunately, there are a number of low-cost and easy to implement behavioral approaches for pediatric pain relief (Powers, 1999; for reviews, see Blount et al., 2009; Cohen, 2008; Pillai Riddell et al, 2011). Some of these interventions, such as relaxation, imagery, and training in coping skills, have been shown to be effective in preschool and school-age children but are not appropriate for infants given infants' limited cognitive capacity. Fortunately, a number of behavioral interventions have been developed for infant medical pain relief (Joffe, Cohen, Bearden, & Welkom, 2009).

Physical contact ("kangaroo care"). One area of intervention that can be effective in reducing infant pain and distress is providing physical comfort (for a review see Pillai Riddell et al, 2011). Parents typically prefer to be in the room for their child's medical procedures, such as immunizations, and can help by holding the infants during the actual procedure (Piira, Sugiura, Champion, Donnelly, & Cole, 2005). Not only might this help the medical staff logistically, but it might provide some reduction in distress to the infant. Given that maternal holding has been shown to have an analgesic effect (Phillips, Chantry, & Gallagher, 2005), it should be considered either alone or as part of a treatment package for infant medical pain.

Much of the research on physical comfort has examined skin-to-skin contact, or "Kangaroo Care" (KC), with infants. The term KC comes from its similarity to how marsupials are cared for in early life (Johnston et al., 2003). According to Johnston et al., this practice of using skin-to-skin contact to soothe infants is becoming more and more widely used around the world and has been shown to effectively reduce pain and distress in newborns.

Studies examining the effectiveness of KC often compare the distress behaviors of infants who are being held in whole body, skin-to-skin contact with their parent to infants being swaddled in a crib during a painful procedure (Gray, Watt, & Blass, 2000; Johnston et al., 2003). In a study done by Gray et al., 30 newborn infants were randomly assigned to either KC or treatment as usual. Infants in the KC condition spent 10 to 15 minutes alone with their mothers lying chest to chest, with mothers applying light pressure to the infants' back before a heel lance procedure. The KC group demonstrated less crying, grimacing, and lower heart rate than the control group.

A pilot study done by Kostandy et al. (2008) examined the impact of KC on crying response to pain in 10 two- to nine-day-old preterm neonates. Infants were assigned to a sequence of heel stick with KC (skin-to-skin contact for 30 minutes against the mother's breast prior to heel stick) followed by heel stick in incubator a day later or a sequence of heel stick in incubator followed by heel stick with KC. Crying time was significantly less for the heel stick done with KC, and KC reduced crying during both the heel stick and recovery phases.

Another study examining the impact of KC on preterm neonates randomly assigned 50 newborns between 0 and 28 days to either a KC group or a control group. In this study, KC started 30 minutes before and continued for 10 minutes after an invasive procedure (Akcan, Yigit, & Atici, 2009). Infants in the KC group had significantly lower pain scores on an observational scale than those in the control group.

KC has also been shown to be effective for full term infants undergoing intramuscular injections. In a study by Kashaninia, Sajedi, Rahgozar, and Noghabi (2008), 100 term infants were randomly assigned to a KC or a standard care control group. In the KC condition, infants were held in KC for 10 minutes prior to and during the procedure. Significant differences in pain expression were noted between the two groups. This research describes KC as “contact induced analgesia” (Kashaninia, et al.). Kashaninia and her colleagues continue on to explain that this type of analgesia has a more gradual onset that others, supporting the need for at least 10 minutes of private KC time prior to any procedures for it to be effective.

Non-nutritive sucking. An additional intervention that has been shown to be effective in decreasing pain in neonates and infants less than six months of age is non-nutritive sucking (NNS; Barr et al, 1995). NNS involves an infant sucking on a pacifier or bottle nipple before, during, or after a painful procedure. Mathai, Natrajan, and Rajalakshmi (2006) conducted a randomized study of 104 stable neonates and examined a variety of different interventions. Results suggested that at two and four minutes following the heel stick procedure, pain scores were lowest in both the NNS and rocking groups as compared to distilled water, sucrose, expressed breast milk, and massage groups. The NNS and rocking groups also had the lowest total duration of crying.

A study by Boyle and colleagues (2006) examined the affect of NNS on pain in a group of 40 premature infants being screened for retinopathy. The infants were randomized to one of four interventions administered two minutes prior to their first examination. The first group received 1 ml of sterile water via syringe, the second 1 ml of sucrose solution via syringe, the third 1 ml sterile water with pacifier, and the fourth 1 ml of sucrose solution with pacifier. Results showed significantly lower observational pain scores in the two groups given pacifiers as compared to those without pacifiers but showed no difference between infants given sucrose as compared to those given water. In this study, NNS reduced distress response in premature infants undergoing a painful screening procedure.

South, Strauss, South, Boggess, & Thorp (2005) conducted a study examining the impact of NNS during circumcision. In this study, 44 infants were given Tylenol and a dorsal penile nerve block (DPNB) before the circumcision. Twenty-two of these infants were randomized to the intervention group and were offered NNS, in the form of a gloved finger, before the DPNB and throughout the procedure. Although there was no significant difference on infant heart rate between groups, results showed NNS to be effective in reducing crying time for infants during circumcision.

Liaw and colleagues (2010) examined the effect of NNS on pain response in 104 preterm undergoing a heel stick procedure. Infants were randomly assigned to NNS or standard care. Pain response, as measured through observational coding, was found to be significantly lower in the NNS group across all phases of the procedure.

Sucrose. Sucrose water (12-50%; typically 1 packet of sugar in 10mL of water) can be given to infants with or without a pacifier just before an acute painful procedure to decrease pain (Cohen, 2008). The sucrose can be administered via dipping a pacifier in a solution or instilled directly into the infant’s mouth via a syringe. Some research suggests that sucrose may be effective because it serves as a mechanism for attention redirection; thus, infants may be particularly attentive to sweet tastes and turn their attention away from the painful procedure (Blount et al., 2009). Other research proposes that sucrose is effective because it serves as an opioid antagonist and has actual analgesic effects (Blass & Hoffmeyer, 1991; Haouari, Wood, Friffiths, & Levene, 1995), but subsequent investigations have not supported this position (Taddio, Shaw, Shaw, & Katz, 2003).

Many studies have examined the impact of a sucrose solution administered via syringe just prior to a painful procedure. Harrison, Johnston, and Loughnan (2003) examined the effectiveness of one mL of a 33% sucrose solution administered orally compared to one mL of unsweetened water in a blinded randomized-controlled trial that did not involve non-nutritive sucking. The sample in this study included 128 0- to 2-month-old infants undergoing a heel lance procedure. Infants in the sucrose group showed lower facial scores at time of heel lance and at one and two minutes following the procedure than infants in the unsweetened water placebo group. When looking at the three-minute recovery period following the heel lance procedure, the sucrose group displayed a significantly lower incidence and duration of crying. Another study that did not involve non-nutritive sucking compared the impact of two mL of a 25% sucrose solution to two mL of unsweetened water, both administered via syringe, on cry duration in 39 preterm neonates undergoing venipuncture (Acharya, Annamali, Taub, & Field, 2004). The mean duration of crying was significantly lower in infants who received the sucrose solution as compared to those to received water.

Liu, Lin, Chou, and Lee (2010) examined the impact of non-nutritive sucking versus a 25% oral glucose solution to relieve pain in 105 neonates 32 weeks and older. The infants were randomly assigned to non-nutritive sucking, the glucose solution, or a control group. Observational coding found that infants in both the NNS and glucose solution groups showed a significantly lower pain response during venipuncture than the control group and that NNS appeared to be more effective than the glucose solution.

Ors (1999) compared the effectiveness of two mL of a 25% sucrose solution to two mL of human milk and 2 mL of sterile water syringed to anterior part of tongue for one minute two minutes prior to a heel lance. Ors found that in this sample of 102 healthy term infants, there was a significant decrease in crying time in the three minutes following the procedure for the infants who received the sucrose. When examined in isolation, without the use of pacifiers or other behavioral interventions, sucrose alone has been shown to be effective at reducing distress in infants during painful procedures.

Some research has suggested that combining non-nutritive sucking with a sucrose solution is most effective in reducing infant pain and distress. A study by Blass and Watt (1999) compared two mL of 12% sucrose administered over two minutes with a syringe, two mL of water via syringe over two minutes, a pacifier dipped in 12% sucrose solution every 30 seconds for two minutes, and a pacifier dipped in water every 30 seconds for two minutes prior to a heel lance procedure. The data from this sample of 40 newborn infants 34 – 55 hours old suggested that the sucrose solutions, despite administration method, was more effective in reducing infant pain and distress overall than water administered via syringe or via pacifier. Blass and Watt also found that although the two sucrose administration methods were equal in terms of reduction in grimacing, sucrose combined with non-nutritive sucking was significantly better in reducing cry duration than sucrose alone.

A similar study which included 36 preterm infants randomized the participants into six groups: water with and without pacifier, sucrose with and without pacifier, pacifier alone, and a control group (Elserafy, Alsaedi, Louwrens, Sadiq, & Mersal, 2009). The water and 24% sucrose solution were delivered in 0.5 mL doses. Elserafy et al. found that infants in the group given the 24% sucrose solution in combined with the pacifier had the lowest mean pain scores overall.

Research examining the effectiveness of sucrose combined with non-nutritive sucking has also been done with older infants. Hatfield (2008) evaluated the impact of a 24% oral sucrose solution combined with pacifier use to water with pacifier use in 40 infants receiving vaccines at 2- and 4-months of age. Infants were given either the sucrose solution or sterile water two minutes prior to the procedure and a pacifier was then held in their mouths until 3 minutes after the completion of the procedure. The infants who received the sucrose solution had a lower behavioral pain response than those who were given sterile water showing sucrose in combination with a pacifier to be an effective intervention in the reduction of infant pain and distress during vaccines (Hatfield).

Möreliusa, Theodorsson, and Nelson (2009) randomly assigned 98 infants receiving their 3-month immunizations to either a water or 30% sucrose solution group. Infants were further divided into pacifier or no-pacifier groups depending on whether they typically used pacifiers or not. Saliva was collected from the infant before the immunization and again thirty minutes later to assess cortisol levels as an indicator of stress. Möreliusa et al. that cortisol levels were lower in infants receiving the glucose solution in combination with a pacifier suggesting that for older infants, like research has also shown with newborns (Blass & Watt, 1999; Elserafy et al., 2009), these interventions may be more helpful in combination than independently during painful medical procedures.

Another study comparing a 44% sucrose solution to sterile water with and without pacifiers studied 0- to 6-month-old infants receiving venipuncture in the pediatric emergency department (Curtis, Jou, Ali, Vandermeer, & Klassen, 2007). Eight-four patients were randomly assigned to sucrose, sucrose with pacifier, sterile water, or sterile water with pacifier. Analyses revealed that both pacifier and sucrose significantly reduced infant cry time in the older infants but not in the younger infants. This study postulated that more research looking at the impact of infant age on response to intervention is needed. A Cochrane review of the literature evaluated the impact of sucrose on infant pain during painful medical procedures (Stevens, et al., 2004). The Cochrane review has shown sucrose to be effective in providing pain relief to infants under six months of age during heel stick and venipuncture.

Breastfeeding/expressed breast milk. Breastfeeding during single infant painful procedures has been shown to reduce pain in infants and although research has been focused primarily on neonates, it is suggested that breastfeeding may be helpful for a wider range of infants than sucrose administration (Gray, Miller, Philipp, & Blass, 2002; Shah, Aliwalas, & Shah, 2006). The effectiveness of breastfeeding and expressed breast milk as interventions to reduce infant pain and distress have been shown to be more effective than swaddling or a pacifier alone but overall may be comparable to sucrose administration (for review, see Shaw et al.). More research is needed to determine the effectiveness of breastfeeding and expressed milk for pain and distress reduction in repeated painful procedures (Shah et al.).

Although there is research on the administration of breast milk to aid in infant pain reduction, it can be difficult to obtain clear results because of the numerous variables involved. Specifically, it is difficult to tease apart which elements of breastfeeding are responsible for its analgesic effects (Phillips, Chantry, & Gallagher, 2005). For example, the literature shows that both the act of holding itself and the manner in which a baby is held during a painful procedure impacts their level of distress (e.g., Kostandy et al., 2008; Johnston, et al., 2003). Given that babies are held when being breastfed, the positive effects of breastfeeding may be due, in part, to holding. Despite some methodological differences between studies, it appears that overall breastfeeding has been shown to be helpful. Whereas, some research supports the administration of expressed breast milk as an analgesic of its own, data are mixed as it has been shown to be less effective than sucrose administration in some studies (Blass & Miller, 2001; Skogsdal, Eriksson, & Schollin, 1997).

One study aimed to determine whether breastfeeding was helpful above and beyond non-nutritive sucking while being held and whether a non-maternal holder was as effective as the mother herself (Phillips et al, 2005). This research team conducted a randomized controlled trial with 96 stable full term newborn infants undergoing a heel lance as part of a routine newborn screening. The infants were randomly assigned to one of the three following groups: breastfeeding, held by mother with use of pacifier, or held by research assistant with use of pacifier. Data collected included percentage of infants that cried, proportion of cry time, and physiological change information (i.e., heart rate, blood pressure, and oxygen saturation). The study found that breastfeeding produced the greatest analgesic effect but that there was also a significant difference in proportion of cry time between maternal and non-maternal holding in infants given a pacifier with maternal holding resulting in less distressed infants.

As noted, two potential mechanisms of sucking as an intervention to decrease infant distress have been described. It has been conceptualized by some researchers as having an analgesic effect on infants (Möreliusa, et al., 2009) and by others as a mechanism for attention redirection (Blount et al., 2009). Given that the intervention is helpful but the mechanism continues to be unclear, it is important to evaluate other behavioral interventions that function via the same channels such as distraction.

Distraction. In the preschool and school-age literature, distraction has been thoroughly evaluated for pain and has emerged as a key pain relief intervention (for reviews, see DeMore & Cohen, 2005; Kleiber & Harper, 1999; Piira, Hayes, & Goodenough, 2002). However, the effect sizes are small to moderate (Uman, Chambers, McGrath, & Kisely, 2006; Uman et al., 2008). It has been theorized that distraction is effective because it requires attentional capacity (McCaul & Malott, 1984), which leaves fewer attention resources available to process pain messages. In short, focusing on something else during painful procedures might diminish the pain experience. Viewed from a behavioral perspective, distraction may actually weaken the unconditioned and conditioned distress response by keeping the child from attending to the unconditioned unpleasant stimuli (e.g., injection) and the conditioned stimuli that was paired with pain in the past (e.g., gauze, bandages) (Cohen, 2002). In addition, distraction may work to produce a counterconditioning effect by pairing the painful procedure with an opposite incompatible behavior (e.g., laughing at a cartoon) (Cohen, 2002).

Distraction for infants' medical pain has only been examined in a few studies. The first study in this area examined immunization pain in 90 2-month to 3-year-old infants (Cohen, 2002). Infants were randomly assigned to either a typical care condition or a distraction condition. The distraction involved nurses, trained in distraction techniques, directing infants to watch a Teletubbies® movie using animated speech and gestures and also using age-appropriate toys to distract the infants throughout the procedure. Parents were also prompted, by the nurses, to engage in distraction techniques during the procedure. Cohen found that infants receiving immunizations exhibited less evidence of pain during both the anticipatory and recovery phases when participating in nurse-led movie distraction. In 2006a, Cohen et al. replicated this study with 136 1- to 21-month-olds and found consistent results. Infants in the distraction group exhibited lower behavioral distress than infants in the typical care group prior to, and during recovery from, the injection. Felt et al. also examined the effectiveness of distraction in reducing infant distress during immunization (Felt et al., 2000). In this study, 102 2- to 24-month-olds were randomly assigned to an intervention group or typical care group. The parents in the intervention group were provided with techniques, including distraction, to help their infants during the injection. Infants in the intervention group were rated as more comfortable immediately after the immunization by their parents and also had lower salivary cortisol levels for a full 60 minutes following the immunization. A commonality among these three studies is that although distraction was found to be effective prior to the injection and during the recovery phase, it was not more effective than typical care in reducing distress during the brief but distressing immunization injection phase.

In contrast to the supportive results regarding distraction, Cramer-Berness and Friedman (2005) found parent-selected distraction did not result in pain reduction in 123 2- to 24-month-olds undergoing immunizations. Infants were randomly assigned to one of three conditions: distraction which consisted of parents working to engage their child with a distracting stimuli, supportive care, or typical care. Although Cramer-Berness and Friedman found that parents in the distraction group did use more behavioral interventions during the immunization than parents in other groups, the infants in this group did not show lower behavioral distress. In 2007, Cramer-Berness explains that because of the mixed results in the literature, additional research is needed to look more closely at distraction in the infant population and to learn why its effectiveness is limited and whether distraction might be helpful to subgroups of infants. Cramer-Berness (2007) discusses the importance of selecting an age-appropriate and engaging distraction, which is challenging with infants who have limited verbal skills. A subsequent study by Cohen et al. (2006b) randomized 84 1-year-old infants to typical care, a group where they received a local anesthetic applied topically (i.e., EMLA), and distraction. Distraction was found to be helpful only in the recovery phase following the intervention with those children showing lower behavioral distress. Examination of the data showed that nurses, when given the role of distraction administrators, were not as consistent or constant with their distraction behavior as seen in other studies (Cohen and colleagues, 2002, 2006b), which may have tempered the effectiveness of distraction as an intervention. Researchers from this study suggest that the medical staff may not have been fully invested in adhering to this study protocol.

In sum, physical contact, sucking, sucrose, breastfeeding, and distraction are all viable interventions to minimize infant procedural distress (for a review, see Pillai Riddell et al, 2011). In contrast to the other approaches, distraction has garnered ample empirical support in alleviating preschool-age and older children's injection distress (for a review, see Blount et al., 2000). Thus, it deserves particular consideration for infants. However, the data regarding the effectiveness of distraction for infant procedural pain is mixed. This discrepancy is most likely explained by variability in response to treatment. Arguably the most important factor to consider regarding effect of treatment is individual differences. In other words, there might be unique personal characteristics of infants that might explain why distraction is effective for some but not all infants. Data of this sort would help clinicians personalize distraction interventions for their infant patients.

1.4 Temperament as a Predictor of Infant Medical Pain Response

Given the variability in infant response to pain relief interventions, it is important to identify those infants most in need of intervention as well as strive to match infants to intervention for optimal outcomes. The National Institute of Health developed the Personalized Healthcare Initiative to improve the quality, safety, and effectiveness of healthcare for patients (Department of Health and Human Services, 2009), which suggests that individual differences might impact treatment response. A personalized healthcare system will require the understanding of how individuals respond to specific treatments by examining predictors of treatment. Although there are many individual factors that influence how one responds to treatment, including past experience, age, gender, ethnicity, and culture (Kim et al., 2004; Lamberg, 1998; Miller & Newton, 2006), some researchers argue that individual temperament is the best predictor of differences observed between individuals and also the most sensitive to environmental factors such as exposure to pain (Chen et al., 2000; Chess & Thomas, 1986; Goldsmith et al., 1987). The body of research on temperament is vast and not easily summarized. For the purpose of this study, the lens will focus on pediatric-oriented temperament research.

Definition of temperament. Although temperament has been characterized in various ways and researchers do not consistently agree, there are some central dimensions that emerge in the literature and are generally accepted (Ranger & Campbell-Yeo, 2008). Temperament has been defined as a way to understand and describe consistent differences in behavior that appear early in life (Wachs, 1999). Thus, many studies measure temperament in infants. Temperament is also described as the way or manner in which individuals behave (Thomas & Chess, 1977). Thomas and Chess laid the groundwork for viewing temperament as the "how" of behavior instead of the "why" (e.g. individual's motivation) or "what" (e.g., individual's ability) of behavior (Thomas et al., 1977). They also focused on the idea that an individual's temperament is a product of the interaction between a child's early tendencies and outside influences; both genetics and environment play a role in temperament (Wachs & Bates, 2001). The argument that temperament is stable yet influenced and even changed by the environment is contradictory; it is posited that the environment impacts temperament simultaneously with temperament influencing one's environment (Buss & Plomin, 1984). In other words, temperament is viewed as generally stable but may change and develop over time (Thomas et al., 1977).

Despite agreement on the broader definition of temperament, some ambiguity remains. For instance, the term "early appearing" is interpreted in different ways (Wachs, 2001). Some researchers argue that not all observable aspects of temperament are present early in life whereas others question whether these early appearing traits might not be reflective of a construct other than temperament (Wachs, 2001). There might be certain traits that fit clearly into the category of temperament and others that are less clear and may fit into the category of temperament as well as overlap with another area, such as cognition (Wachs, 1999).

Dimensions of temperament. The larger construct of temperament is seen as including a number of different dimensions or domains. As opinions differ in how to define the larger construct of temperament (see Table 1), issues also exist in defining the specific dimensions. The following section will review some of the central theories.

Thomas and Chess (1977) examined temperament through a 6-year longitudinal study. Their work with children is widely accepted as influencing many other child-oriented researchers in the area of temperament (Strelau, 1998). After observing differences in children's behavior as early as the first weeks of life, they examined differences in parenting as potential influencing factors. They found that different parenting practices and attitudes led to different behavioral outcomes in children, depending on how the parenting practices interacted with children's own individual differences (Strelau, 1998). This discovery led them to their interactional theory of temperament, suggesting that a child's behavioral outcomes are dependent, in part, on how they interact and respond to their environment (Strelau, 1998). At the beginning of their work, Thomas and Chess (1977) established 9 specific dimensions that, combined, reflected a person's temperament. These categories were developed by analyzing parents' reports of their children during infancy and have remained largely unchanged since initially developed (Strelau, 1998). The 9 categories were *activity level*, *rhythmicity* (regularity), *approach* or *withdrawal*, *adaptability*, *intensity of reaction*, *quality of mood*, *attention span* and *persistence*, *distractibility*, and *threshold of responsiveness*. Each category was also defined along 3 levels of activity: high, medium, low. They rated children on each category and using factor analyses demonstrated that most children fell into 1 of 3 broad groups: the "easy child", the "difficult child", and the "slow-to-warm-up child" (Strelau, 1998; Thomas & Chess, 1977; Wachs, 1999). The "easy child" readily adapted to new experiences, showed more positive moods and emotions, and exhibited normal eating and sleeping; the "difficult child" was more emotional, slow to adapt to new experiences, irritable, fussy, cried more, and had irregular eating and sleeping; the "slow-to-warm-up child" had a low activity level, withdrew from new people and situations, and was slow to adapt to new situations (Thomas & Chess, 1977). Based on Thomas and Chess' findings, it might be expected that the "slow-to-warm-up child" would respond with more distress to a novel situation, such as an immunization, than the "easy child". It also might be expected that the "difficult" child would also show more distress given their already heightened emotionality and irritability.

It is argued that these categories reflect normal variation in behavior styles and are not meant to be indicative of pathology. Additionally, researchers acknowledge that these categories do not encompass every child's temperament. In order to better explain the interaction of temperament and the environment, "goodness of fit" was introduced (Henderson, 1913; in Thomas and Chess, 1977). Goodness of fit refers to the match between a child's individual characteristics, including temperament, their own abilities, and other qualities, with the demands, expectations, and opportunities presented by their environment (Thomas, Chess, & Birch, 1968); Chess & Thomas, 1989; Chess & Thomas, 1991). According to this theory, when this match is present, optimal development occurs. They postulated that it is when an individual is an in an environment that does not fit well with their characteristics that "poorness of fit" occurs and excessive stress from this lack of consonance can result in problems. Relevant to the aims of this study, it might be argued that optimal coping with procedural distress results when there is a fit between an infant's temperament and the distress relief intervention employed.

Buss and Plomin approached the study of temperament in a systematic and methodologically-grounded manner (Strelau, 1998). Although these researchers are child-oriented, initially conducting their research with children, they followed their participants for more than two decades, and developed their theory of temperament from a developmental perspective. They defined temperaments as "inherited personality traits present in early childhood" (Buss & Plomin, 1984). According to Buss and Plomin (1984), for a characteristic to be part of temperament, it needed to be both present before the age of 2 and have some genetic heritability. They argued that genetic heritability of these traits as responsible for observed individual differences. Their theory of temperament first began with 4 main dimensions: *emotionality, activity, sociability,* and *impulsivity* (EASI) (Buss & Plomin, 1984). Sociability and emotionality are personality traits that are widely accepted and are almost always assessed when evaluating temperament (Buss & Plomin, 1984). Activity, though it becomes less prevalent into adulthood, is reflective of temperament in youth. Impulsivity was eventually dropped by Buss and Plomin (1984) as one of their primary temperaments as they found that it was more likely a combination of traits and, also, they found little evidence of the heritability of this trait (Strelau, 1998). Given the three traits described by Buss and Plomin (1984), it might be expected that children lower in sociability and higher in emotionality would react to a novel situation, such as an immunization, with more distress than children who showed more sociability and less emotionality.

Bates (1989) initially described 4 dimensions of temperament: *negative emotionality*, which includes traits such as fear or anger; *inhibition*, which is the ability to adjust or adapt to a new situation or new people; *typical level of motor activity*; *sociability*, which is the amount of satisfaction gained through social interaction; and some additional, more complex, constructs such as how "difficult" is an individual. In later work, the study of temperament began to include biological components to account for individual differences not explained via behavioral definitions (Wachs, 1999). Following this trend, Rothbart and Bates (1998) argued that the behaviors that make up the different aspects of temperament could be understood by looking not at dimensions but at 2 primary processes. The two processes were *reactivity* and *self-regulation*. Rothbart and Bates describe reactivity as how someone characteristically responds to a stimulus. This could include both whether they typically respond with positive or negative emotion as well as the intensity of their response. Self-regulation is described as process through which individuals cope with a distressing stimulus; it may involve the use of a self-soothing behavior or attending more or less to that stimulus (Rothbart & Bates, 1998). Bates (1989) initial dimensions of temperament are similar to dimensions proposed by researchers such as Thomas, Chess, Buss, and Plomin and expectations of how a child of those different temperaments might respond to a novel stimulus would likely be congruent. In considering the two processes described (Rothbart & Bates, 1998), *reactivity* and *self-regulation*, a child that is less reactive and more able to self-regulate would be expected to be less distressed during a painful immunization.

Goldsmith and Campos (1982, 1986) view the dimensions of temperament as being the individual differences in primary emotions such as disgust, joy, anger, fear, distress, interest, sadness, anger, and surprise. They define temperament as *emotionality*, which is composed of one's individual differences on all primary emotions including those that are positive and negative. Due to the strong connections that exist between infants' emotionality and their interactions with their world, Goldsmith and Campos' theory of temperament is limited to infants. Goldsmith and Campos differ from some of the other researchers in this area in that their view of temperament is a strictly behavioral one, without reference to biology, such as genetics or neurophysiology (Strelau, 1998). They argue that the behavioral view of temperament is ideal for studying infants because emotional reactions in infants are easily identified and measured and the emotional responses we observe are a reflection of the way in which infants communicate (Goldsmith & Campos, 1982). Although *emotionality* includes both positive and negative emotions, it would be expected that an infant with higher emotionality would likely respond with more distress to a painful immunization than an infant with lower emotionality, especially considering that a major marker of distress is the observable response of the infant with stronger crying, screaming, and grimacing responses indicating more distress.

Kagan focused his study of temperament on infancy and early childhood and also followed some of these participants longitudinally (Strelau, 1998). Through this research, Kagan found that introversion and extroversion were the traits that remained most stable across the lifespan. As his work progressed, Kagan proposed that two primary temperament categories are *inhibited* and *uninhibited*. He suggested that individual differences in temperament become apparent when an infant or child faces a novel situation that leads to uncertainty or stress (Kagan, 1983). He described uninhibited children as being talkative, outgoing, sociable, and minimally fearful when faced with uncertainty as compared to the inhibited child who responds as cautious, shy, quiet, reserved, and timid (Kagan 1989, 1994; Kagan & Snidman, 1991). According to Kagan's work, it is likely that the *uninhibited* child would respond with less distress in response to a stressful novel situation such as an immunization injection. In addition to viewing temperament as comprised of these two basic categories, Kagan also believed temperament to be biologically determined (Kagan, Kearsley, & Zelazo, 1978). He formed these conclusions after conducting a study with both Chinese and Caucasian children in which he found there that there were some group differences and saw them as determined by genetics (Kagan, et al., 1978).

When reviewing the different theories of temperament and the variety of perspectives that different researchers bring to the field, there are some dimensions that are fairly well agreed upon. Most child researchers include domains that reflect how a child interacts with their environment, such as his/her sociability or activity level. The idea of emotionality is also a consistent dimension across theories. As described above, this can be defined in different ways but often has to do with how a child responds to a stressful event in terms of how easily they are upset, how fearful they are, and how easily they are soothed once upset.

Measurement of temperament. Temperament can be measured in several different ways in order to assess these different domains. Measurement options include observation of the infant's behavior either directly in unstructured natural settings or via lab-based observation in structured settings, parent or caregiver responses to questionnaires, or clinical interviews with parents (Wachs & Bates, 2001). Although important research on child temperament has been conducted using parent interviews (e.g., Chess & Thomas, 1984) and unstructured observation (e.g., Bates, 1979; Rothbart, 1986), direct observation and questionnaires are more commonly used (Wachs & Bates, 2001) and will be the focus here. There are many different procedures available, and all have strengths and limitations (Wachs & Bates, 2001).

Direct observation does allow researchers more control as they are able to determine what situation to present to the infant or toddler and parent. They can then observe different participants across this same condition. Although this is a definite benefit, it has been shown that repeated observations are needed to decrease reactivity of both the parent and the child to the observer and to increase the stability of the data (Wachs, 1987). It has been reported that it may be necessary to repeat the observation six to eight times to gain stable infant data (Seifer, Sameroff, Barrett, & Krafchuk,1994), which can be costly and take more time than is practical.

Some argue that even after multiple repetitions, temperament traits that are less frequently expressed still may not be well captured (Rothbart & Bates, 1998).

Parent report questionnaire assessments also have their benefits and drawbacks. Parent report questionnaires assessing infant/toddler temperament fall into two main categories: those developed from a clinical research perspective (e.g., Bates & Bayles, 1984; Carey & McDevitt, 1978; Fullard, McDevitt, & Carey, 1984) and those developed from a psychobiological perspective (e.g., Goldsmith, 1996; Rothbart, 1986). Questionnaires are often appreciated for the ease in which they can be used. Since they are being completed by parents who have observed their child in a variety of situations and environments, they are without some of the problems of gathering a one-time observation of temperament as discussed above (Wachs & Bates, 2001). One complaint about parent report measures is that parents' emotional reactivity may influence their responding, which can influence objectivity and then their responses may be more reflective of parent characteristics than child traits (Mebert, 1991; Seifer, et al., 1994). Some work in defense of this assessment technique has been done and shows that they are subjective components to parent report. One such study, by Slabach, Morrow and Wachs (1991), found that parent report of child temperament was predictive of child temperament response in a laboratory environment. Although temperament information could be potentially helpful in guiding practitioners in their decision-making with clients, many parent-report questionnaires are quite long and not practical for a real-world setting. The length of the commonly-used questionnaires varies and ranges from a short forms of about 36 questions to some containing over a hundred items (Goldsmith, 1996; Rothbart, 1986). Designing a shorter form would allow for temperament characteristics to be considered in different practical settings, such as in a busy medical environment.

Temperament and pain. There is significant variability in how infants respond both behaviorally and psychobiologically to stressful situations such as painful procedures (Boyce, Barr, & Zeltzer, 1992). When examining these differences in pain sensitivity, perception, and tolerance, some authors consider individual temperament to be one of the most significant factors that contributes to these differences and reliably differentiates infants (Chen et al., 2000; Chess & Thomas, 1986; Goldsmith et al., 1987, Ranger & Campbell-Yeo, 2008). Although strong theoretical connections have been built between temperament and pain response, there is somewhat limited research that has examined the connections. The following section will outline some of the studies that have examined the relations between temperament and pain in children and infants during acute painful procedures.

Though much of the literature has focused on school-aged children, there is some research with infants. Researchers have found that infants rated by their parents as having more difficult temperament seem to show more distress during painful procedures (Bustos, Jaaniste, Salmon, & Champion, 2008; Sweet, McGrath, & Symons, 1999; Piira, Champion, Bustos, Donelly, & Lui, 2007). A study by Piira et al. (2007) explored pain response in 93 4- to 6-month-olds during immunization injections using observational coding. Temperament was not the primary focus of study but was included as a distal factor. Infants who had been identified as having difficult temperament by parent report on a 30-item temperament scale cried longer than other infants but showed no differences in facial pain response. Another study with similar findings also included temperament as a distal factor (Bustos et al., 2008). In this study, 50 infant-parent dyads participated and parents completed a 30-item measure of temperament. All participants were presenting for their 6-month immunizations. Bustos et al. (2008) found that those infants who had been rated by their parents as having more difficult temperament cried for a significantly longer period of time following the immunization. A study by Grunau et al. (1994) examined parent ratings of pain sensitivity and how those ratings related to parent report of child temperament at 18 months of age. To measure temperament, parents completed a 20-item measure. The participants included two groups of extremely-low-birth-weight infants and two control groups of heavier pre-term and full-birth-weight infants; there were 197 toddlers total. Temperament was found to be strongly related to pain sensitivity in the full-birth-weight group, not related in the lowest-birth-weight group, and moderately related in the heavier preterm group. The relation between temperament and pain was such that the children that were the most emotionally reactive showed the greatest response to pain.

There are several studies focused on temperament and pain response during acute painful procedures with older children. Schechter, Bernstein, Beck, Hart, and Lawrence (1991) examined factors associated with distress behavior in 65 five-year-old children receiving immunizations. Parents provided child temperament information by completing a 100-item parent questionnaire. Procedural child distress was assessed via observation and self-report. Analyses showed that “difficult temperament” as a cluster was mildly predictive of behavioral distress during immunizations. They also found that the temperament dimension of adaptability was strongly negatively correlated with high distress behavior, suggesting that children rated high on adaptability were less distressed that those viewed as low on adaptability. In another study with a similarly aged population (Young & Fu, 1988), researchers examined the effect of play and temperament on pain response during venipuncture. In this group of children ranging in age from 4 to 7 years (*N*=80), temperament was measured with a 72-item parent questionnaire. This questionnaire assigned five categories of temperament, and those five categories were used for analyses. Results showed a relation between pain response and both the “rhythmicity” and "approach/withdrawal" temperament categories, indicating that children that were higher on the approach category as less distressed. In this study, temperament accounted for 12% of the variance in how participants responded to the venipuncture.

Lee and White-Traut (1996) also examined pain response in children receiving venipuncture. Temperament was measured by a parent-report questionnaire and pain was measured through video observation, pulse oximetry, and self-report. In their sample of 3- to 7-year-olds (*N*=137), they found that 5 of the 9 measured temperament categories (i.e., activity, mood, approach, adaptability, intensity, and threshold) were strongly related to child behavior during the painful procedure providing further support for a relation between temperament and pain response. In another group of children receiving venipuncture who ranged in age from 8 to 12 (*N*=94), the temperament categories of distractability and threshold explained a smaller, but still significant amount of the variance in how the children responded to the painful procedure (Bournaki, 1997). These studies illustrate that these are clear connections between temperament and pain in older children and that some connections have also been found between infants' temperament and medical pain. To date, no researchers have linked temperament to intervention response; data in this area would help match intervention to patient.

1.5 Purpose of Study

In summary, infants experience a high number of painful procedures early in life, which might have short- and long-term detrimental consequences. Behavioral interventions have been developed to minimize infants' procedural pain, which include physical contact, non-nutritive sucking, sucrose administration, breastfeeding, and distraction (for review see Pillai Riddell et al., 2011); the efficacy of these approaches is variable and no gold standard approach has been identified. However, distraction has been the most commonly evaluated behavioral intervention in preschoolers and older children (Blount et al., 2009; Uman et al., 2006, 2010). In addition, it is one of the few behavioral interventions that might be applied – with slight modifications in content – across patient populations from infants to adults. Thus, from a training perspective (e.g., nursing students), it is a particularly viable approach. Given the variability in procedural distress as well as response to treatment, it is important to identify infants most of in need of intervention as well as strive to match infants to intervention for optimal outcome. Although there are many individual factors that influence how one responds to treatment, temperament may be the most predictive for infants. Temperament has been shown to relate to how infants experience pain, yet there is little research examining the relation between temperament and response to intervention.

Primary aims. The primary aim of the study was to examine whether infants' temperament is predictive of their responses to immunization injection pain. It was expected that infants with more difficult temperaments (i.e., more easily upset, more difficult to soothe, and louder) and infants who are slower to warm up (i.e., more fearful, shy, quiet, and calm) would exhibit more distress related to the procedure than infants that were less difficult and faster to warm up (Bates, 1989; Buss & Plomin, 1984; Bustos, Jaaniste, Salmon, & Champion, 2008; Goldsmith & Campos, 1982; Kagan, 1989; Pirra, Champion, Bustos, Donelly, & Lui, 2007; Sweet, McGrath, & Symons, 1998; Thomas & Chess, 1977).

The second primary aim was to explore whether infants of different temperaments respond differently to distraction. Although this is a new area of study and there are no data examining temperament and response to pain relief treatment, based on findings that infants with easier temperaments are better at self-soothing (Keener, Zeanah, & Anders, 1988) and generally less distressed by procedural pain (Bustos, Jaaniste, Salmon, & Champion, 2008; Sweet, McGrath, & Symons, 1999; Piira, Champion, Bustos, Donelly, & Lui, 2007), it was expected that these infants' with easier temperaments would be more responsive to distraction, whereas those with more difficult temperaments would show less response to the distraction intervention. Given the literature showing that infants who are slower to warm up are typically more distressed by novel stimuli such as immunizations, it was expected that the distraction intervention would be less helpful for them and more helpful for those who are faster to warm up.

Table 1

Temperament Dimensions by Researcher

Thomas & Chess (1977)	Buss & Plomin (1984)	Bates (1989)	Rothbart & Bates (1998)	Goldsmith & Campos (1982, 1986)	Kagan (1983)
Rhythmicity, Approach or Withdrawal, Adaptability, Intensity of Reaction, Quality of Mood, Attention Span, Persistence, Distractibility, Threshold of Responsiveness	Emotionality, Activity, Sociability, Impulsivity	Negative Emotionality, Inhibition, Typical level of Motor Activity; sociability, difficultness	Reactivity, Self-regulation	Emotionality	Inhibited, Uninhibited

2 METHOD

2.1 Participants

Data for this study came from two prior studies of healthy infants receiving immunizations (Cohen, 2002; Cohen et al., 2006). Participants included 252 infants and toddlers (115 males, 137 female) who ranged from 1 to 22 months of age (M = 8.6 months, SD = 5.7 months) (see Tables 2 and 3). Five health care facilities participated: three rural health departments in the Southeastern United States, a university-affiliated medical center in the Southeastern United States, and a rural health department in the Northwestern United States. Inclusion criteria included any English-speaking families presenting for routine checkups and vaccinations. Healthy infants between 1 and 24 months of age were included. Mothers accompanied approximately 86% of the infants, fathers 12%, and other caregivers approximately 2%. The sample predominantly consisted of middle-class, Caucasian families (84.5% Caucasian, 2.5% Native American, 1.6% Asian, 1.6% Latino, 1% African American. Average annual income was reported by category and the majority of families reported income in the $20,000-40,000 range (annual income ranged from less than $10,000 to greater than $100,000; 8% $0-9,999, 8.4% $10,000-14,999, 14.7% $15,000-24,999, 5.9% $25,000-39,999, 7.2% $40,000-59,999, 8.8% $60,000-99,999, 2% $100,000 or greater). Parents had completed an average of 1.37 years of college education (mean education = 13.37 years, SD = 2.26 years).

2.2 Measures (Appendix A)

Background information. Demographic information about the parent (i.e., relation to child, age, gender, race, ethnicity, level of education, total family income, marital status) and the child (i.e., age, gender, race, and ethnicity) was collected from all families through either a structured interview or questionnaire.

Injection distress. The primary measure of infant injection distress was a behavioral measure, the Measure of Adult and Infant Soothing and Distress (MAISD; Cohen et al., 2005). The MAISD is a valid and reliable behavioral observation rating scale that was developed to evaluate the behaviors of infants, their parents, and nurses during painful pediatric medical procedures. Behaviors of interest for the infants included engagement in distraction, crying, and screaming. Engagement in distraction describes any behavior that was indicative of the child being oriented toward a distraction stimulus. Parents' and nurses' distraction behaviors were also coded. Distraction behaviors are those behaviors intended to orient the infant toward a specific distracting stimulus.

Data from all of the sites were coded by trained undergraduates from the videotaped immunizations. The coders were blind to study hypotheses. All behaviors were coded in five-second intervals, spanning from three minutes before the nurse began cleaning the skin for the injection until two minutes after the last immunization needle was removed or the child left the room, whichever came first. The index used for analysis was the proportion of five-second intervals exhibiting the coded behavior, which was calculated by dividing the number of five-second intervals in which the behavior was present by the total number of five-second intervals.

The undergraduate coders were trained on the MAISD using videotapes from other datasets until 98% agreement was obtained. Weekly meetings were held with the coders to review videotapes and to ensure that interrater agreement could be sustained. Each research assistant coded approximately 35 participants (SD = 6.45). Interrater reliability was examined on approximately 15% of the total sample (22 procedures), all of which were selected at random across all four coders. Percent agreement was coded for the infant, parent, and nurse behavioral codes. Percent agreement was selected because it is the recommended approach for evaluation of agreement for low base rate behavior (e.g., Cicchetti & Feinstein, 1990; Spitzer and Fleiss, 1974; Spitznagel and Helzer, 1985). The mean percent agreement coefficients for each of the coded behaviors were above 93.0. Given that infants are unable to report their own levels of pain, and parents' and nurses' ratings are subject to some biases, the MAISD scores were seen as the primary measure of infant distress, with parents' and nurses' ratings as secondary indices.

In addition to the MAISD, parents and nurses completed two post-injection visual analog scales (VASs) as secondary measures of infant distress. Parents and nurses used the VASs to respond to the questions "How distressed was this child during the shot?" and "How distressed was this child in the 3 minutes following the shot?" The VASs consisted of 100-mm horizontal lines with the anchor phrases *Not Upset* and *Very Upset* at the end points. VASs are commonly used in pediatric psychology research, have been shown to be valid and reliable, and result in less clustering of scores than is found with likert-type measures (Cohen et al., 2008).

Temperament. Given the limited time available to complete lengthy measures in this busy medical setting, a short temperament measure was created for this study. Parents completed six pre-injection visual analogue scales (VASs) about their child's temperament. The anchor phrases for the temperament VASs were *Quiet* and *Loud*, *Shy* and *Outgoing/Social*, *Calm* and *Active*, *Not Easily Upset* and *Easily Upset*, *Easy to Soothe When Upset* and *Not Easy to Soothe When Upset*, and *Fearful* and *Not Fearful*. These six markers of temperament were chosen because they represent the domains that are consistently agreed upon in the temperament literature (Bates, 1989; Buss & Plomin, 1984; Goldsmith & Campos, 1982; 1986; Rothbart & Bates, 1998; Thomas & Chess, 1977) and were seen as being potentially relevant to injection distress response. As discussed previously, domains reflecting how a child interacts with their environment and how they respond to stressful events are often included across researchers.

VASs were chosen because they can be quickly and easily completed and might be sufficiently practical to be used as a clinical screener in busy medical settings. In addition, VASs are commonly used in pediatric pain studies (Cohen et al., 2008), and they were used for parents' report of other variables in this study (e.g., child pain).

Given that the temperament measurement for this study was new, an oblique rotation factor analysis was conducted with the temperament data in an attempt to more parsimoniously explain how the dimensions relate to one another before conducting subsequent analyses. The factor analysis resulted in two temperament factors that map onto the easy/difficult and slow-to-warm-up dimensions found in the literature (e.g., Thomas & Chess, 1977). All subsequent analyses using temperament used these 2 factors.

2.3 Procedure

Research assistants were trained to consistent data collection protocol (Appendix B). Families were approached either in the waiting room (Northwestern U.S. location) or in the exam room (Southeastern U.S. location). Informed consent was obtained, background information was collected, and families were assigned to study conditions (i.e., either Distraction or Typical Care) as facilitated by a random numbers table or by alternating condition basis, Southeastern and Northwestern U.S., respectively. Videotaping began when the nurse entered the exam room to begin preparing for the immunizations. The nurse was informed of which condition the family was assigned to upon entering the exam room. Following the immunization, the parent completed the post-injection questionnaires.

Typical care. In the typical care condition, the parent and nurse were encouraged to interact with the infants as they usually would. Although this may have included some naturally occurring distraction, no toy or movie distraction was provided to the child. It was expected that the parent and nurse would also engage in comforting, information provision, reassurance, empathy, and apologizing to the child, as these behaviors are commonly exhibited by parents and nurses during children's medical procedures (e.g., Blount, Devine, Cheng, Simons, & Hayutin, 2008; Blount, Sturges, & Powers, 1990; Cohen, Blount, & Panopoulos, 1997; Manne et al., 1992).

Distraction. In the distraction condition, nurses were trained to coach parents to engage their children in distraction during the procedure. Before data collection, the nurses all participated in an intervention-training program, which lasted approximately 15 minutes. During this training the primary investigator provided the rationale for the intervention, modeled distraction techniques, and role-played coaching behaviors with the nurses. Parents were then also briefly instruction on distraction techniques. They were then asked to choose a DVD for their child to watch, either Sesame Street® or Teletubbies®, during the procedure. This was played on a hand-held DVD player that was held approximately six inches from the infant's face. Parents were instructed that they could redirect the infant's attention to the video with animated gestures or speech (*"Look at that!" or "Elmo is saying hello!"*). Throughout the procedure the nurses prompted the parents to engage in distraction. Given the nature of the study, the nurses were not blind to the condition, but they were not informed of any study hypotheses.

Table 2

Child Demographic Information (N = 252)

	M (SD)
Age	8.6 mo (5.7)
	N (%)
Gender	
Female	137 (54.4)
Male	115 (45.6)
Race/Ethnicity	
Caucasian	213 (84.5)
Native American	5 (2.0)
Asian	1 (0.4)
Latino	4 (1.6)
African American	2 (0.8)
Missing	20 (7.9)

Table 3

Caregiver Demographic Information (N = 252)

	N (%)
Relationship to Child	
Mother	215 (85.3)
Father	30 (11.9)
Grandparent	3 (1.2)
Other	1 (0.4)
Missing	3 (1.2)
Education Level (*M (SD)* in years)	13.4 (2.3)
Family Income	
Up to $10,000	31 (12.3)
10,001- 15,000	31 (12.3)
15,001 – 25,000	38 (15.1)
25,001 – 40,000	45 (17.9)
40,001 – 60,000	19 (7.5)
50,001 – 100,000	28 (11.1)
100,001 and above	2 (0.8)
Not Reported	58 (23.0)

3 DATA ANALYSES AND RESULTS

3.1 Overview of Analyses

Preliminary analyses were conducted to describe the sample, determine whether any covariates should be taken into consideration in primary analyses, and examine associations among the study variables. Linear regression analyses were used to determine whether temperament predicted procedural distress. Moderation analyses were conducted in accord with specified procedures (Hayes & Matthes, 2009). The moderation models were conducted to examine whether temperament moderates the relation between distraction and infant distress. For all moderation analyses, continuous variables were mean-centered prior to computing the interaction term to reduce multicollinearity. Data were deleted listwise, which resulted in variable numbers of cases being included in different analyses. Treatment condition, a categorical variable, was coded as 0 and 1 for standard care and distraction intervention respectively.

3.2 Preliminary Analyses

First, descriptive statistics (e.g., means, standard deviations, frequencies) were utilized to characterize the sample (Tables 2 and 3). Second, means and standard deviations of the study data (i.e., temperament, infant engagement in distraction, coaching by parents, infant injection distress) were obtained (Table 4). Consistent with prior research (MacLaren & Cohen, 2005), the distress variables cry and scream were both considered for use as outcome measures of infant procedural distress. Given that the average scream rate for infants (.06) was very low compared to the average cry rate (.39), with crying occurring nearly seven times more often, cry was used in the analyses. Third, analyses were conducted to determine whether there were any differences in demographics or on outcome variables between the clinics where data was collected. Chi-square analyses indicated no site differences on child gender, child ethnicity, or on parent relation to child (Table 5). Analyses of Variance (ANOVAs) revealed no significant differences between sites on child age. There was a significant difference between sites on parent education level, F (4, 233) = 3.27, $p < .05$, and on annual family income, F (4, 189) = 10.46, $p < .001$. In regards to the main outcome variables, the ANOVAs revealed no site differences on the temperament factors, the rate that infants engaged in distraction, or the rate that parents distracted infants. Yet, there were site differences in the infant distress variable cry, F (4, 230) = 18.30, $p < .001$ (Table 5).

To address site differences in parent education level, annual family income, and cry, site of participation was entered as a covariate for analyses. To adjust positive skew in the infant distress variable ($z = 4.062$, $p < .001$), a square root transformation was performed. Following transformation, normality was tested and achieved (D (234) = 0.34, $p = .200$) using the Komogorov-Smirnov test (Fields, 2005).

Fourth, potential age and gender differences were examined for both temperament and distress. Analyses with *t*-tests revealed that males and females had significantly different observed total distress scores, t (233) = -.204, with females exhibiting more distress (Table 6). Due to this finding, gender was also entered as a covariate in primary analyses. No associations were found between infant age and temperament or cry.

Fifth, an exploratory factor analysis with varimax rotation was performed on the temperament responses for the six temperament items. Two factors with eigenvalues greater than 1 were found, which accounted for 62% of the total variance (Figure 1). Factor 1 was labeled as easy/difficult and Factor 2 was labeled as time-to-warm-up. The two factors were labeled as follows with eigenvalues in parentheses: Factor 1, easy/difficult, is how easy or difficult the infant is to soothe (1.99) with higher values representing more difficult temperament and lower values representing easier temperament. Factor 1 consists of Quiet/Loud, Shy/Outgoing, Calm/Active, and Fearful/Not Fearful. Factor 2, time-to-warm-up, represents how long it takes the infant to be comfortable in new situations (1.76) with higher values representing faster-to-warm-up temperament and lower values representing slower-to-warm-up temperament. Factor 2 includes Quiet/Loud, Not Easily Upset/Easily Upset, and Easy to Soothe/Difficult to Soothe. Table 7 presents the factor loadings for the items contained in each factor. Five of the items loaded onto either Factor 1 or Factor 2, and one item loaded onto both factors. An item was kept if its primary loading was greater than 0.50 (Costello & Osborne, 2005).

3.3 Primary Analyses

A primary goal of this study was to examine whether temperament predicts procedural distress (Primary Aim 1). To examine Aim 1, linear regression analyses were conducted. In the first regression, site and gender were entered into block 1 and the time-to-warm-up temperament factor was entered as the independent variable in block 2 predicting cry. Results of this regression indicated that time-to-warm-up temperament, $\beta = -.037$, $p = .572$, was not associated with distress, and accounted for 0.1% of the variance. In the second regression, the easy/difficult temperament factor was entered in as the independent variable in predicting distress. After controlling for Site and Gender, easy/difficult temperament, $\beta = .109$, $p = .098$, was not associated with crying, accounting for 1.2% of the variance in the outcome variable.

The second aim was to examine whether temperament moderates the relation between distraction and infant distress (Primary Aim 2). Distraction was measured through group assignment (i.e., Typical Care versus Distraction), infant engagement in distraction (Engagement), and how much parents distracted their infants (Parent Coaching). Given that these measures tap slightly different distraction constructs, separate analyses were conducted with each of the temperament factors (i.e., easy/difficult, time-to-warm-up) predicting the three measures of distraction for a total of 6 moderation analyses. Hayes and Matthes (2009) outline computational procedures for estimating and probing interactions in OLS regression models and these procedures were used for all moderation analyses. Specifically, regression coefficients, conditional effects, and regions of significance were generated. Summary of primary aims results can be found in Table 3.

Temperament as a moderator of the treatment condition – distress relation. Results revealed that the first model, with the time-to-warm-up temperament factor moderating the relation between treatment condition and infant distress, significantly predicted infant distress, F (5, 222) = 5.2895, $p < .001$. However, whereas there was a statistically significant main effect of treatment condition on infant distress, b = -.1529, SE = .0460, p = .001, there was not a significant main effect for the time-to-warm-up temperament factor on distress, b = -.0002, SE = .0004, p = .5943. Results did reveal a significant interaction effect, thus the main effects will not be further interpreted. The interaction between treatment condition and time-to-warm-up temperament factor was significant, b = .0011, SE = .0005, p = .0254, suggesting that the relation between distraction and distress is influenced by the time-to-warm-up temperament of the infant. Post-hoc probing revealed that the interaction effect was significant at both low (1 SD below the mean), b = -.1269, SE = .0370, $p < .001$, and moderate (mean), b = -.0673, SE = .0260, p = .0102, scores on time-to-warm-up temperament factor. The interaction was not significant at high values (1 SD above the mean), b = -.0076, SE = .0372, p = .8376. Thus, infants rated as low and moderate on the time-to-warm-up temperament factor, meaning those that are slow or moderate to warm up, are more likely to express less distress during the distraction condition than those infants rated as high on this factor, those faster to warm up (Figure 3 and Table 8).

The model also used easy/difficult temperament factor as the moderator. Results revealed that although this model also significantly predicted infant distress, F (5, 216) = 3.6981, p = .0031, there were no main effects of treatment condition, b = -.1315, or SE = .0683, p = .0555, temperament, b = -.0003, SE = .0003, p = .2833, nor was the interaction effect significant, b = .0004, SE = .0004, p = .2934 (Table 8).

Temperament as a moderator of the infant engagement in distraction – distress relation. In this model the MAISD infant engagement in distraction scores were used to reflect the construct of distraction. Results revealed that the first model, using the time-to-warm-up temperament factor as the moderator, significantly predicted infant distress, F (5, 217) = 4.3535, p < .001. However, whereas there was a statistically significant main effect of infant engagement in distraction on infant distress, b = -.2040, SE = .0585, p < .001, suggesting that as infant engagement increases infant distress decreases, there was not a significant main effect of the time-to-warm-up temperament factor on distress, b = .0000, SE = .0002, p = .8179, nor was the interaction effect significant, b = -.0001, SE = .0007, p = .9405 (Table 8).

The second model, using the easy/difficult temperament factor as the moderator, also significantly predicted infant distress, F (5, 224) = 4.9440, p < .001. There was a statistically significant main effect of infant engagement in distraction on infant distress, b = -.1916, SE = .0568, p < .001, with increases in engagement relating to decreases in distress, and there was not a significant main effect of the easy/difficult temperament factor on distress, b = .0004, SE = .0002, p = .0996, nor was the interaction effect significant, b =.0007, SE = .0010, p =.4610 (Table 8).

Temperament as a moderator of the parent distraction behavior – distress relation. In this model the MAISD parent distraction behavior variable was used to reflect distraction. Results revealed that the first model, looking at the time-to-warm-up temperament factor as a moderator, approached statistical significance in predicting infant distress, F (5, 215) = 2.2101, p = .0544. There were no significant main effects of parent distraction behavior on distress, b = -.0401, SE = .0801, p = .6173, or of temperament on distress, b = -.0001, SE = .0002, p = .7310, nor was the interaction effect significant, b = .0006, SE = .0013, p = .6586 (Table 8).

The next model, using the easy/difficult temperament factor as the moderator, also significantly predicted infant distress, F (5, 222) = 3.0704, p = .0106. There was a significant main effect of temperament on infant distress, b = .0005, SE = .0002, p = .0389, such that infants that were lower on the easy/difficult temperament factor, meaning quieter, less easily upset, and easier to soothe, showed less distress than those infants rated as higher on this factor. There was not a significant main effect of parent distraction behavior on infant distress, b = -.1220, SE = .0002, p = .3125, nor was the interaction effect significant, b = .0020, SE = .0020, p = .3125 (Table 8).

3.4 Exploratory Analyses

Another goal of this study was to explore whether moderation results were the same when using parent and nurse report of infant distress following the injection as the dependent variable instead of the MAISD distress score as done in Aim 2. For these moderation analyses, Hayes and Matthes (2009) computation procedures, as described above, were used. Six moderations were done to examine parent report as the outcome variable: two for each of the three distraction predictor variables (i.e., treatment condition, infant engagement in distraction, parent distraction behavior) for each of the two temperament factors as moderators. Another six moderations were conducted using the same three predictors with nurse report of infant distress as the dependent variable. Prior to analyses, parent report of infant distress was transformed to address negative skew. The variable was reverse scored, square rooted, and then reverse scored again resulting in normality. Nurse report of infant distress met the assumption of normality.

Temperament as a moderator of the treatment condition-parent report of infant distress relation. Results revealed that treatment condition significantly predicted parent report of infant distress 3 minutes following the injection when moderated by the time-to-warm-up temperament factor, F (5, 229) = 2.3706, p = .0402. There were no statistically significant main effects of treatment condition, b = .5325, SE = .8593, p = .5361, or the time-to-warm-up temperament factor, b = .0061, SE = .0032, p = .0603, on parent report of distress, nor was the interaction effect significant, b = -.0031, SE = .0044, p = .4882 (Table 9).

The second model used the easy/difficult temperament factor as the moderator. Results revealed that this model also significantly predicted infant distress, F (5, 235) = 4.4757, p < .001, and that there was a main effect of temperament, b = .0149, SE = .0045, p = .0010, such that infants who were lower on the easy/difficult temperament factor, meaning quieter, less easily upset, and easier to soothe, showed less distress than those infants rated as higher on this factor. There was no main effect of treatment condition, b = .5948, SE = .5643, p = .2930, nor was the interaction effect significant, b = -.0082, SE = .0058, p = .1575 (see Table 9).

Temperament as a moderator of infant engagement in distraction-parent report of infant distress relation. In this model the MAISD infant engagement in distraction variable was used to reflect the construct of distraction. Results revealed that the model, using the time-to-warm-up temperament factor as the moderator, significantly predicted parent report of infant distress, F (5, 216) = 4.0266, p = .0016, as did the second moderation using the easy/difficult temperament factor as the moderator, F (5, 223) = 5.8374, $p < .001$. The analyses showed there was a significant main effect of infant engagement on parent report of infant distress for the first moderation, b = -1.9357, SE = .7337, p = .0089, and the second moderation, b = -1.7728, SE = .7061, p =.0128, such that as infant engagement increases, parent report of infant distress decreases. There was also a significant main effect of the time-to-warm-up temperament factor on reported distress, b = .0052, SE = .0022, p = .0196, suggesting that as infants are rated as higher on this factor, meaning louder, more outgoing, more active, less fearful, their parents are seeing them as less distressed. Similarly, there was a significant main effect of the easy/difficult temperament factor on reported distress, b = .0107, SE = .0030, $p < .001$, such that infants rated as louder, more easily upset, and more difficult to soothe, there were seen as more distressed by their parents. Neither the model examining the time-to-warm-up temperament factor as a moderator, b = -.0040, SE = .0094, p = .6724, nor the model examining the easy/difficult temperament factor as a moderator, b = -.0025, SE = .0126, p = .8394 produced a significant interaction effect (Table 9).

Temperament as a moderator of the parent distraction behavior-parent report of infant distress relation. In this model the MAISD parent distraction behavior variable was used as the predictor to reflect distraction. Results revealed that the first moderation which included time-to-warm-up temperament as the moderator did not predict parent report of infant distress, F (5, 214) = 2.1049, p = .0664. There were no significant main effects of parent distraction behavior on distress, b = -.3942, SE = 1.0034, p = .6948, or temperament on distress, b =.0042, SE = .0023, p = .0694, nor was the interaction effect significant, b = -.0066, SE = .0163, p = .6856 (Table 9).

The second model, which used the easy/difficult temperament factor as the moderator, significantly predicted parent report of infant distress, F (5, 221) = 5.1654, $p < .001$. However, whereas there was a statistically significant main effect of temperament on reported infant distress, b = .0119, SE = .0030, $p < .001$, there was not a significant main effect of parent distraction behavior on distress, b = -1.8074, SE = .9978, p = .0714. Most importantly, results revealed a significant interaction effect, thus the main effect will not be further interpreted. The interaction between parent distraction behavior and the easy/difficult temperament factor was significant, b = .0535, SE = .0242, p = .0284, suggesting that the relations between parent distraction behavior and parent report of infant distress is contingent on the temperament of the infant (see Figure 3). Post-hoc probing revealing that the interaction effect was only significant at low levels (1 SD below the mean), b = -4.8368, SE = .2.1274, p = .0239, on the easy/difficult temperament factor. The interaction was not significant at medium (mean), b = -1.8074, SE = .9978, p = .0714, or high levels (1 SD above the mean), b = 1.2220, SE = 1.1111, p = .2726. Thus, parent distraction behavior decreases distress in infants rated as having easier temperaments.

Temperament as a moderator of the treatment condition-nurse report of infant distress relation. Results revealed that neither moderation significantly predicted nurse report of infant distress 3 minutes following the injection, F (5, 227) = .4186, p = .8355 (time-to-warm-up), F (5, 233) = 1.5846, p = .1652 (easy/difficult). For the first model there were no statistically significant effects of treatment condition, b = -5.3344, SE = 10.3192, p = .6057, or the time-to-warm-up temperament factor, b = -.0009, SE = .0390, p = .9811, on nurse report of distress, nor was the interaction effect significant, b = .0189, SE = .0534, p = .7231 (see Table 10). Similarly, the second model also showed no statistically significant effects of treatment condition, b = -

7.6234, *SE* = 6.8372, *p* = .2660, or the easy/difficult temperament factor, *b* = .0359, *SE* = .0545, *p* = .5104, on nurse report of distress, nor was the interaction effect significant, *b* = .0718, *SE* = .0708, *p* = .3111 (Table 10).

Temperament as a moderator of the infant engagement in distraction-nurse report of infant distress relation. In this model the MAISD infant engagement in distraction variable was used to reflect the construct of distraction. The first model, which used the time-to-warm-up temperament factor as the moderator, did not significantly predicted nurse report of infant distress, *F* (5, 214) = 1.9547, *p* = .0866. There was a significant main effect of infant engagement, *b* = -25.0780, *SE* = 8.8353, *p* = .0050, such that as infant engagement increases, nurse report of infant distress decreases. There was no significant main effect of the time-to-warm-up temperament factor on reported distress, *b* = .0132, *SE* = .0271, *p* = .6263, nor was there a significant interaction effect, *b* = -.0740, *SE* = .1131, *p* = .5136.

The second model, which used the easy/difficult temperament factor as the moderator, significantly predicted nurse report of infant distress, *F* (5, 220) = 3.0494, *p* = .0111. There were significant main effects of both infant engagement, *b* = -25.5804, *SE* = 8.6211, *p* = .0033, and temperament, *b* = .0842, *SE* = .0363, *p* = .0213, such that as infant engagement increased, nurse-reported distress decreased and that as scores on the easy/difficult factor increased, meaning as infants were rated as more difficult, nurse report of infant distress decreased. No significant interaction effects were found, *b* = -.0829, *SE* = .1536, *p* = .5897.

Temperament as a moderator of the parent distraction behavior-nurse report of infant distress relation. In this model, the MAISD parent distraction behavior variable was used as the predictor to reflect distraction. Results revealed that the first model, which included the time-to-warm-up temperament factor as the moderator, did not predict nurse report of infant distress, *F* (5, 212) = .9101, *p* = .4754. There were no main effects of parent distraction behavior, *b* = -21.8851, *SE* = 11.9964, *p* = .0694, or infant temperament, *b* = -.0014, *SE* = .0277, *p* = .9606, on nurse report of infant distress (Table 9), nor was the interaction effect significant, *b* = -.3119, *SE* = .1961, *p* = .1133.

The second model, which used the easy/difficult temperament factor as the moderator, significantly predicted nurse report of infant distress, *F* (5, 218) = 2.4664, *p* = .0337. There was a statistically significant main effect of parent distraction behavior on distress, *b* = -28.6074, *SE* = .12.2491, *p* = .0204, with nurse report of infant distress decreasing as parent distraction behavior increased. There was also a significant main effect of temperament on reported infant distress, *b* = .1088, *SE* = .0372, *p* = .0038, with infants higher on the easy/difficult, more difficult temperament, factor being rated by nurses as having more distress (see Table 10). There was no significant interaction effect, *b* = .4942, *SE* = .2978, *p* = .0984.

Table 4

Means and Standard Deviations of Study Variables

Measures	*M (SD)*
Infant Temperament Dimensions [a]	
Time-to-Warm-Up	39.8 (18.9)
Easy/Difficult	59.9 (19.1)
Observational Data (MAISD) [b]	
Rate of Infant Cry	.40 (.26)
Rate of Infant Engagement in Distraction	.19 (.23)
Rate of Parent Coaching Distraction	.12 (.21)
Proxy Report of Infant Distress	
Parent Report	69.63 (27.31)
Nurse Report	55.41 (30.61)

Note. [a] Scores on the infant temperament dimensions range from 0 to 100, with higher scores representing on time-to-warm-up representing infants who are slower to warm up and higher scores on easy/difficult representing more difficult temperament. [b] Higher scores on the MAISD represent higher observed distress, higher engagement in distraction, and greater parent coaching.

Table 5

Examination of Site Differences

	Site					
Variables	Site 1 (n = 67)	Site 2 (n = 26)	Site 3 (n = 7)	Site 4 (n = 71)	Site 5 (n = 81)	Chi square
Child Gender (% Female)	56.7	42.3	42.9	63.4	49.4	$X^2(4) = 5.18$
Child Race/Ethnicity (% Caucasian)	91.0	92.0	100.0	90.0	93.7	$X^2(20) = 25.50$
Parent Relation to Child (% Mothers)	91.0	100.0	85.7	81.4	82.5	$X^2(12) = 13.06$
Variables	*M (SD)*	*M (SD)*	*M (SD)*	*M (SD)*	*M (SD)*	Anova
Child Age	8.40 (7.88)	9.27 (6.79)	7.37 (6.17)	7.14 (4.93)	10.11 (5.65)	$F(4, 240)=1.89$
Parent Education Level (in years)	12.86 (1.98)	12.70 (1.69)	13.57 (2.30)	12.29 (2.13)	14.07 (2.59)	$F(4, 233)=3.27^{*}$
Annual Family Income[a]	3.19 (1.69)	2.94 (1.56)	4.00 (1.22)	4.51 (1.51)	2.82 (1.35)	$F(4, 189)=10.46^{***}$
Time-to-Warm-Up	57.73 (24.52)	61.38 (17.66)	66.32 (12.16)	61.08 (17.83)	59.65 (16.05)	$F(4,236)=.50$
Easy/Difficult	36.65 (20.50)	37.74 (17.17)	36.86 (18.27)	40.49 (19.33)	42.77 (17.54)	$F(4,243)=1.09$
Infant Cry	.40 (.22)	.42 (.18)	.26 (.23)	.59 (.31)	.24 (.13)	$F(4,230)=22.37^{***}$
Infant Engagement in Distraction	.21 (.26)	.27 (.25)	.22 (.24)	.19 (.24)	.14 (.19)	$F(4,229)=1.75$
Parent Coaching Distraction	.12 (.34)	.18 (.17)	.15 (.12)	.09 (.13)	.09 (.10)	$F(4,227)=.43$
Parent Report of Distress	68.40 (29.02)	53.12 (25.96)	43.43 (32.72)	74.33 (23.39)	74.18 (26.03)	$F(4, 241)=5.33$
Nurse Report of Distress	64.42 (30.51)	24.04 (28.26)	31.29 (14.91)	65.09 (31.60)	51.15 (22.47)	$F(4,238)=13.06$

Note. [a]Family income ranged from 1 = Up to \$10,000 to 7 = \$100,001 and above. $^{*}p < 0.05$, $^{**}p < 0.01$ $^{***}p < 0.001$

Table 6

Examination of Gender Differences

	Gender		
	Males (n = 111)	Females (n = 130)	
Variables	*M (SD)*	*M (SD)*	*t*-tests
Easy/Difficult	60.74 (19.45)	59.20 (18.80)	t (239) = .625
Time-to-Warm-Up	41.38 (18.90)	38.51 (18.79)	t (246) = 1.197
Rate of Infant Cry	.37 (.25)	.42 (.26)	t (233) = -1.621
Rate of Infant Scream	.04 (.10)	.07 (.12)	t (233) = -1.858
Composite Distress Score (Cry + Scream)	.41 (.31)	.49 (.31)	t (233) = -.204*
Rate of Infant Engagement in Distraction	.18 (.22)	.20 (.24)	t (232) = -.291
Rate of Parent Coaching Distraction	.10 (.12)	.12 (.25)	t (230) = -.722
Parent Report of Distress	65.95 (29.46)	72.81 (24.97)	t *(244)* = -1.98*
Nurse Report of Distress	53.09 (30.61)	57.38 (30.59)	*t (241)= .277*

Note. * $p < 0.05$

Table 7

Factor Structure of Temperament Measure

	Factor Loadings	
Item No.	I: Time-to-Warm-Up	II: Easy/Difficult
1: quiet/loud	**.58**	**.56**
2: shy/outgoing	**.74**	-.22
3: calm/active	**.71**	.39
4: not easily upset/easily upset	-.06	**.80**
5: fearful/not fearful	**.71**	.28
6: easy to soothe/difficult to soothe	-.13	**.76**

Note: The highest factor loading for each item is provided in bold type.

Table 8

Regression Analyses: Distraction, Temperament and Distraction x Temperament as Predictors of MAISD Observed Infant Distress

	Beta	*SE*	*t*	*p ≤*
Treatment Condition as Measure of Distraction				
Factor 1 Temperament (Time-to-Warm-Up)				
Constant	.6376	.0622	10.2522	.0000
Clinic Site	-.0224	.0079	-2.8463	.0048
Infant Gender	.0491	.0263	1.8672	.0632
Treatment Condition	-.1529	.0460	-3.3255	.0010
Factor 1 Temperament	-.0002	.0004	-.5334	.5943
Condition x Temperament	.0011	.0005	2.2498	.0254
Factor 2 Temperament (Easy/Difficult)				
Constant	.6697	.0724	9.2528	.0000
Clinic Site	-.0216	.0081	-2.6478	.0087
Infant Gender	.0496	.0270	1.8342	.0680
Treatment Condition	-.1315	.0683	-1.9257	.0555
Factor 2 Temperament	-.0003	.0003	-1.0756	.2833
Condition x Temperament	.0004	.0004	1.0533	.2934
Infant Engagement in Distraction as Measure of Distraction				
Factor 1 Temperament (Time-to-Warm-Up)				
Constant	.5996	.0531	11.2851	.0000
Clinic Site	-.0242	.0083	-2.9245	.0038
Infant Gender	.0462	.0273	1.6962	.0913
Infant Engagement	-.2040	.0585	-3.4851	.0006
Factor 1 Temperament	.0000	.0002	-.2305	.8179
Condition x Temperament	-.0001	.0007	-.0747	.9405
Factor 2 Temperament (Easy/Difficult)				
Constant	.5897	.0515	11.4531	.0000
Clinic Site	-.0241	.0081	-2.9832	.0032
Infant Gender	.0508	.0266	1.9058	.0580
Infant Engagement	-.1916	.0568	-3.3761	.0009
Factor 2 Temperament	.0004	.0002	1.6535	.0996
Condition x Temperament	.0007	.0010	.7385	.4610
Parent Distraction Behavior as Measure of Distraction				
Factor 1 Temperament (Time-to-Warm-Up)				
Constant	.6060	.0537	11.2848	.0000
Clinic Site	-.230	.0084	-2.7412	.0066
Infant Gender	.0414	.0277	1.4958	.1362
Parent Distraction	-.0401	.0801	-.5004	.6173
Factor 1 Temperament	-.0001	.0002	-.3442	.7310
Condition x Temperament	.0006	.0013	.4425	.6586
Factor 2 Temperament (Easy/Difficult)				
Constant	.5957	.0518	11.5080	.0000
Clinic Site	-.0235	.0082	-2.8656	.0046
Infant Gender	.0458	.0269	1.7007	.0904
Parent Distraction	-.1220	.0809	-1.5070	.1332
Factor 2 Temperament	.0005	.0002	2.0779	.0389
Condition x Temperament	.0020	.0020	1.0123	.3125

Table 9

Regression Analyses: Distraction, Temperament and Distraction x Temperament as Predictors of Parent Reported Infant Distress

	Beta	*SE*	*t*	*p ≤*
Treatment Condition as Measure of Distraction				
Factor 1 Temperament (Time-to-Warm-Up)				
Constant	2.3801	.9011	2.6415	.0088
Clinic Site	.2272	.1029	2.2073	.0283
Infant Gender	.5653	.3373	1.6761	.0951
Treatment Condition	.5325	.8593	.6197	.5361
Factor 1 Temperament	.0061	.0032	1.8879	0603
Condition x Temperament	-.0031	.0044	-.6943	.4882
Factor 2 Temperament (Easy/Difficult)				
Constant	2.2379	.7634	2.9316	.0037
Clinic Site	.1904	.0995	1.9143	.0568
Infant Gender	.6945	.3279	2.1183	.0352
Treatment Condition	.5948	.5643	1.0540	.2930
Factor 2 Temperament	.0149	.0045	3.3399	.0010
Condition x Temperament	-.0082	.0058	-1.4181	.1575
Infant Engagement in Distraction as Measure of Distraction				
Factor 1 Temperament (Time-to-Warm-Up)				
Constant	3.4014	.6689	5.1080	.0000
Clinic Site	.1865	.1040	1.7926	.0744
Infant Gender	.6914	.3424	2.0194	.0447
Infant Engagement	-1.9357	.7337	-2.6383	.0089
Factor 1 Temperament	.0052	.0022	2.3512	.0196
Condition x Temperament	-.0040	.0094	-.4234	.6724
Factor 2 Temperament (Easy/Difficult)				
Constant	3.3192	.6406	5.1818	.0000
Clinic Site	.1644	.1006	1.6337	.1037
Infant Gender	.7902	.3320	2.3803	.0181
Infant Engagement	-1.7728	.7061	-2.5107	.0128
Factor 2 Temperament	.0107	.0030	3.6239	.0004
Condition x Temperament	-.0025	.0126	-.2029	.8394
Parent Distraction Behavior as Measure of Distraction				
Factor 1 Temperament (Time-to-Warm-Up)				
Constant	3.5393	.6731	5.2584	.0000
Clinic Site	.2120	.1053	2.0133	.0453
Infant Gender	.5544	.3479	1.5934	.1126
Parent Distraction	-.3942	1.0034	-.3929	.6948
Factor 1 Temperament	.0042	.0023	1.8247	.0694
Condition x Temperament	-.0066	.0163	-.4054	.6856
Factor 2 Temperament (Easy/Difficult)				
Constant	3.4896	.6372	5.4765	.0000
Clinic Site	.1936	.1010	1.9170	.0565
Infant Gender	.5805	.3320	1.7485	.0818
Parent Distraction	-1.8074	.9978	-1.8114	.0714
Factor 2 Temperament	.0119	.0030	3.9452	.0001
Condition x Temperament	.0535	.0242	2.2068	.0284

Table 10

Regression Analyses: Distraction, Temperament and Distraction x Temperament as Predictors of Nurse Reported Infant Distress

	Beta	*SE*	*t*	*p* ≤
Treatment Condition as Measure of Distraction				
Factor 1 Temperament (Time-to-Warm-Up)				
Constant	50.9626	10.7958	4.7206	.0000
Clinic Site	-.6417	1.2327	-.5206	.6032
Infant Gender	4.7220	4.0314	1.1713	.2427
Treatment Condition	-5.3344	10.3192	-.5169	.6057
Factor 1 Temperament	-.0009	.0390	-.0238	.9811
Condition x Temperament	.0189	.0534	.3548	.7231
Factor 2 Temperament (Easy/Difficult)				
Constant	49.3478	9.2577	5.3305	.0000
Clinic Site	-1.0395	1.2079	-.8606	.3903
Infant Gender	4.7431	3.9774	1.1925	.2343
Treatment Condition	-7.6234	6.8372	-1.1150	.2660
Factor 2 Temperament	.0359	.0545	.6592	.5104
Condition x Temperament	.0718	.0708	1.0151	.3111
Infant Engagement in Distraction as Measure of Distraction				
Factor 1 Temperament (Time-to-Warm-Up)				
Constant	50.9965	8.0329	6.3485	.0000
Clinic Site	-.7886	1.2561	-.6278	.5308
Infant Gender	4.3896	4.1326	1.0622	.2893
Infant Engagement	-25.078	8.8353	-2.8384	.0050
Factor 1 Temperament	.0132	.0271	.4877	.6263
Condition x Temperament	-.0740	.1131	-.6543	.5136
Factor 2 Temperament (Easy/Difficult)				
Constant	51.0804	7.8848	6.4783	.0000
Clinic Site	-1.1719	1.2326	-.9508	.3428
Infant Gender	5.1913	4.0791	1.2726	.2045
Infant Engagement	-25.581	8.6211	-2.9372	.0033
Factor 2 Temperament	.0842	.0363	2.3199	.0213
Condition x Temperament	-.0829	.1536	-.5400	.5897
Parent Distraction Behavior as Measure of Distraction				
Factor 1 Temperament (Time-to-Warm-Up)				
Constant	49.6195	8.0945	6.1300	.0000
Clinic Site	-.1688	1.2680	-.1331	.8942
Infant Gender	3.8537	4.1872	.9204	.3584
Parent Distraction	-21.885	11.9964	-1.8243	.0695
Factor 1 Temperament	-.0014	.0277	-.0495	.9606
Condition x Temperament	-.3119	.1961	-1.501	.1133
Factor 2 Temperament (Easy/Difficult)				
Constant	50.2125	7.8810	6.3714	.0000
Clinic Site	-.6045	1.2438	-.4860	.9275
Infant Gender	4.0203	4.0981	.9811	.3276
Parent Distraction	-28.607	.12.2491	-2.3355	.0204
Factor 2 Temperament	.1088	.0372	2.9233	.0038
Condition x Temperament	.4942	.2978	1.6595	.0984

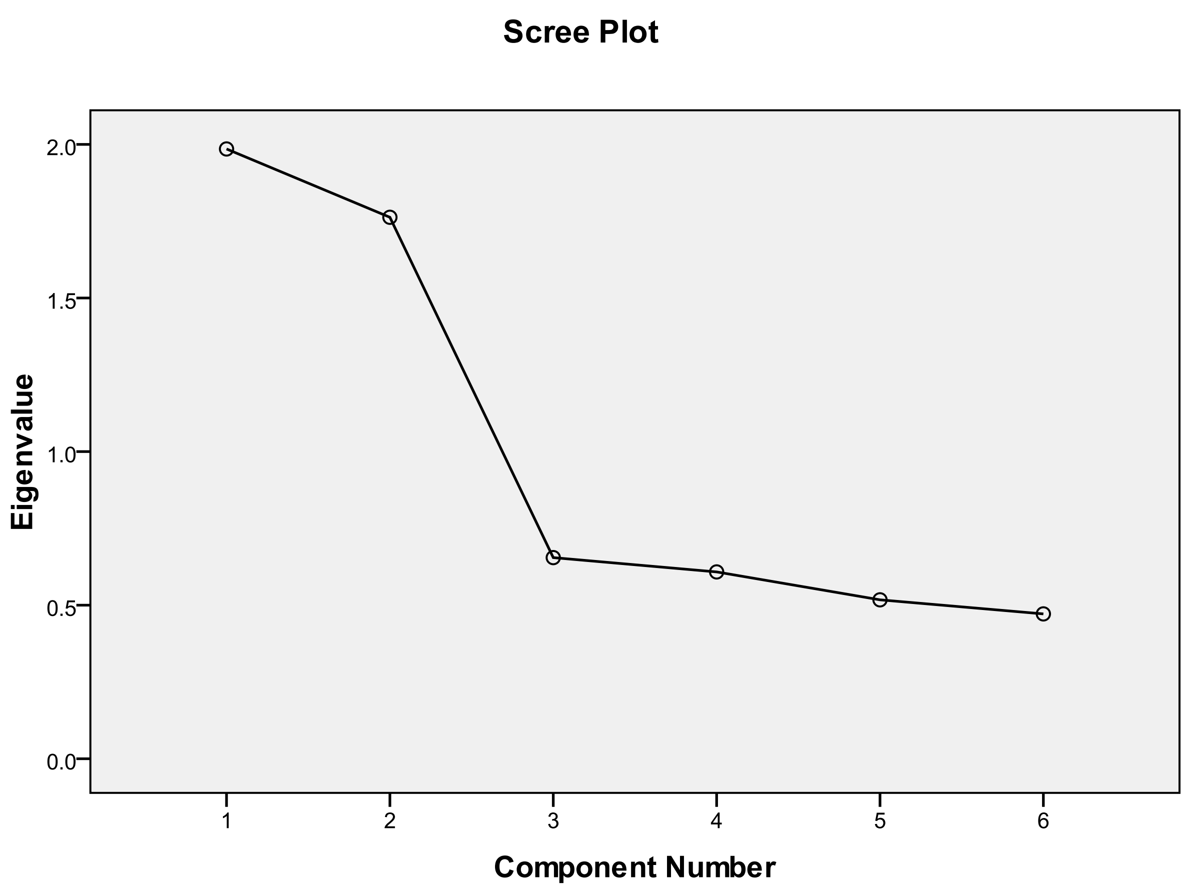

Figure 1 *Scree plot for principal component analysis with varimax rotation of temperament scale items*

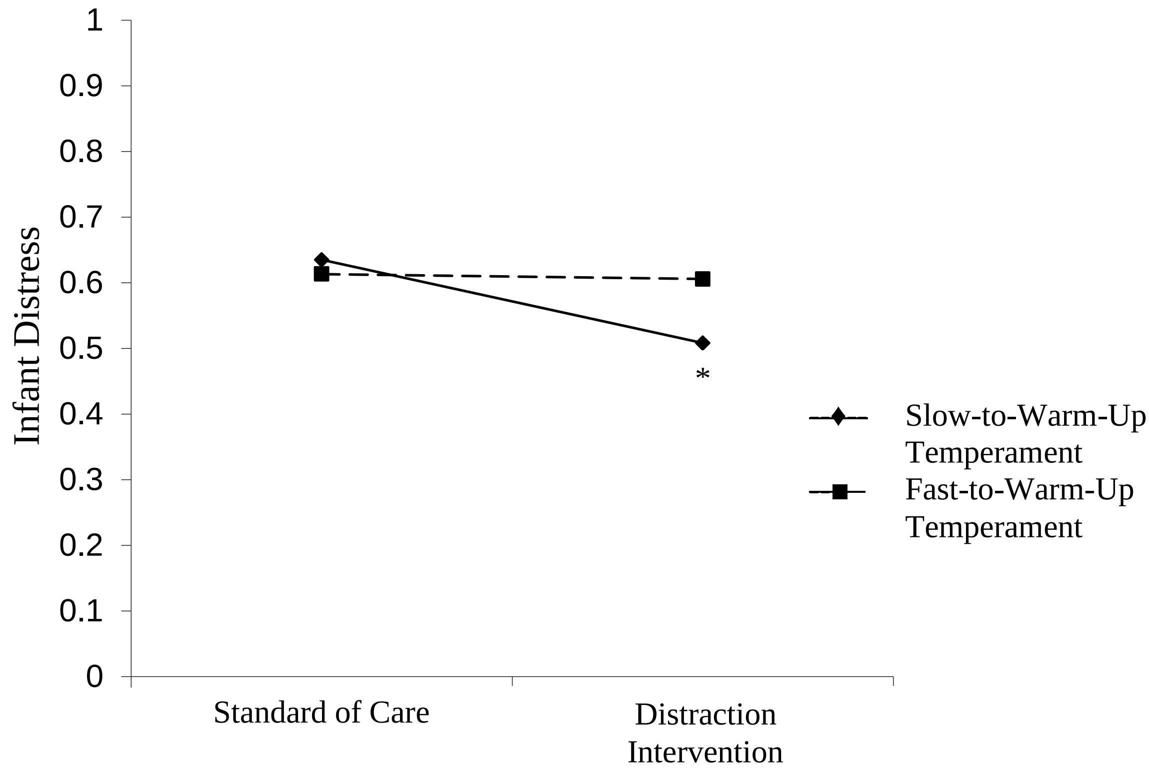

Figure 2 *MAISD infant distress as a function of time-to-warm-up temperament factor and treatment condition. Note.* $^{*}p < 0.001$

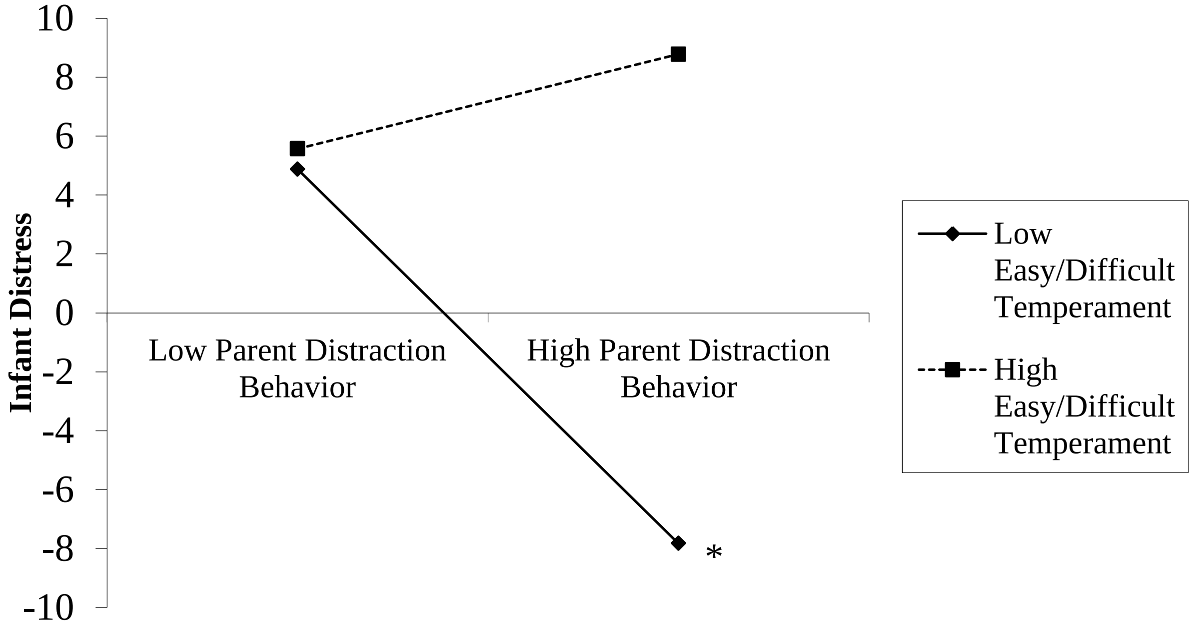

Figure 3 *Parent Report of Infant Distress as a function of Easy/Difficult Temperament Factor and Parent Distraction Behavior*

4 DISCUSSION

There are many factors that influence how an individual responds to a novel situation; some researchers argue that temperament is the best predictor of differences observed between individuals and also the most sensitive to environmental factors such as exposure to pain (Chen et al., 2000; Chess & Thomas, 1986; Goldsmith et al., 1987). This study examined the relation between temperament and pain response and also whether temperament predicts how infants respond to distraction as an intervention during immunizations.

4.1 Temperament and Pain

Theoretical connections have been made; however, there has been limited research exploring the relation between temperament and infant response to pain. The primary aim of this study was to further examine whether infants' temperament is predictive of their responses to immunization pain. It was hypothesized that temperament would be predictive, such that infants with more difficult temperaments and infants that were slower to warm up would exhibit more distress related to the procedure than infants that were less difficult and faster to warm up. These predictions were based on Thomas and Chess's work (1977), which described infants with difficult temperament and infants who were slower to warm up as more distressed by novel stimuli. Results did not support these hypotheses as neither of the two temperament factors was associated with infant distress.

Past research shows variability in its findings with some temperament dimensions relating to distress in some studies (e.g., Lee et al., 1996) but not in others (e.g., Wolff et al., 2011). The studies that have demonstrated a relation between temperament and distress during painful procedures have found that infants rated by parents as having more difficult temperaments (Piira et al., 2007; Bustos et al., 2008) and infants rated as more emotionally reactive (Grunau et al., 1994) have increased distress. Although these results were not replicated in the current study, the findings from this study are consistent with a recent study by Wolff et al. (2011), which found no relation between temperament traits such as fear and recovery from distress and procedural distress in 14-month-old infants undergoing venipuncture. Potential reasons for the inconsistency in findings across these various studies could be that different measures of temperament were used. It is possible that our brief measure – developed as a screener for a fast-paced pediatric practice – might not be sufficiently sensitive to detect important temperamental distinctions. Due to variable findings from this current study and prior research, there is a need for continued examination of the temperament and pain reaction relations in infant populations undergoing medical procedures.

4.2 Distraction, Temperament, and Distress

Given that infants' response to distraction interventions during painful procedures has been mixed (Cohen, 2002; Cohen et al., 2006b; Cramer-Berness & Friedman, 2005; Felt et al., 2000), the second primary aim was to explore whether temperament predicted infants' response to distraction during immunizations. It was predicted that temperament might explain some of the variability in how infants respond to distraction interventions through a moderating effect. Specifically, it was hypothesized that infants with easier temperaments, as well as infants who are faster to warm up, would respond to a distraction intervention with decreased distress, whereas those with more difficult temperaments, as well as those who are slower to warm up, would show diminished response to the distraction intervention. Results partially supported these expectations, as there was a moderating effect on one of the temperament variables, but the results did not support the predictions. It was revealed that time-to-warm-up temperament moderated the relation between group assignment and infant distress, but the distraction intervention decreased distress for infants who were rated as slow or moderately slow to warm up. There are several potential explanations for the unexpected finding. Chess and Thomas (1996) found that infants who are slower to warm up also have a tendency to withdraw from new situations and tend to show less intense emotional response. Perhaps the distraction intervention allowed these infants to be engaged rather than withdraw, which might have resulted in lower distress. Another possibility is that infants who are faster to warm up are typically more engaged in their environment and more likely to be attending to available stimuli during immunizations, as compared to slower-to-warm-up peers, so distraction does not provide added benefit. It could also be, given that the primary distractors used were children's movies, that the slower-to-warm-up infants were able to focus on the movie and disengage with the environmental stimuli that were distressing, resulting in less crying. This may have tapped into their natural inclination to withdraw.

Easy/difficult temperament did not moderate the relation between distraction and distress. A main effect for infant engagement was found such that increased infant engagement, as measured by video observation of parent engagement behavior, led to decreased distress. This result is consistent with some past literature findings that distraction interventions decrease infant distress during medical procedures (Cohen, 2002, 2006a). Engagement as measured by group assignment did not predict infant distress. As demonstrated by this study, there are various ways to capture "distraction". This is a behavior that parents often engage in without instruction and, according to these findings, is helpful in decreasing distress when parents are distracting and infants are attending. Given inconsistent findings linking adult distraction behavior with infant distress within this study and in the extant literature (see Cramer-Berness, 2007), continued investigation is warranted.

4.3 Distraction, Temperament, and Distress: Nurse and Parent Report

Although video observation provides a somewhat objective measure of infant distress, parent- and nurse-report are important indices given that their perspectives often dictate the use of distress-management intervention. Although this study might be underpowered to definitively test these additional relations, exploratory analyses were consistent when parent- and nurse-report of infants distress served as the outcome measures. Past research demonstrates discordance in parent-report, nurse-report, and video observation (see Cohen et al., 2008; McClellan, Cohen, & Joseph, 2003), thus it was not surprising that results of the moderations were inconsistent across these three assessment methods.

Analyses revealed that time-to-warm-up temperament does not moderate the relation between distraction and distress as measured by parent or nurse report. Results did show a significant interaction between parent distraction behavior and easy/difficult temperament, such that increases in parent distraction led to decreases in parent report of distress in infants rated as having easier temperaments. This finding is consistent with original predictions based on data that infants with easier temperaments are better at self-soothing (Keener et al., 1988) and generally less distressed by procedural pain (Bustos et al., 2008; Piira et al., 2007; Sweet et al., 1999), and thus, might be more able to engage in a distraction intervention. It may be that infants with easier temperaments were more able to benefit from the distraction intervention due to their decreased distress and that parents' reporting was more sensitive to their child's experience than the observational measurement. Considering parents' role during the immunization, it could also be that the parents who are working harder to distract their infants may be doing so because they believe it to be effective. If they believe they are doing something that is helpful in reducing distress, they may perceive their infants as less distressed. This effect seems to only hold true in infants that parents perceive as easier to soothe in general.

4.4 Limitations

Limitations of the study should be noted. First, although the measure of temperament allowed for efficient assessment of this construct in a busy medical setting, it has not been sufficiently validated and might not adequately tap relevant domains. Given the practicality of the measure, future work might evaluate concurrent validity of this scale with commonly used and psychometrically sound measures of temperament. A second limitation is that it is difficult to disentangle some dimensions of temperament and state medical distress. In particular, fearfulness is a common temperament quality that might be difficult to distinguish from anticipatory medical distress, especially with paper-and-pencil measures. Given that the primary measure of medical distress was a behavioral observational tool and the temperament instrument was completed via parent report, there is some confidence in the current study that the constructs were distinct. In addition, the correlations between the individual temperament items and observational distress ranged from .003 to .16 and the correlations between the temperament dimensions and observational distress ranged from .06 to .09, suggesting that although they are related, there is only minimal overlap. A third potential limitation of the study is that temperament data was only gathered through parents' report and gaining information on an infants' temperament from their parents can result in a potentially biased response. Although some literature suggests that biases are typically present in this data collection method (Kagan, 1998), there are significant benefits to parent report as well. Parents arguably know their child better than, and have had more interactions with their child than anyone else, making parents the obvious candidates for providing temperament information (Carey & Jablow, 1997). That said, complementing parent report with other measures (e.g., observations in a lab) would provide richer and potentially more accurate information. Fourth, there are other contextual factors, such as birth order of child, which could have influenced parents reporting of infant temperament that were not addressed. It could be that parents of first children report their child's temperament as different as compared to parents who have a baseline of older children to which they can compare their infant. The context of the medical setting may have also biased responding both due to parental anxiety of immunization and parental concerns related to how infant would likely respond. Lastly, given than some of the infants were very young, temperament data might have been limited.

4.5 Future Directions

Several potential future directions are highlighted by the current results. To address potential confounding factors related to context, it might be helpful to send temperament measures home to families prior to immunization as well as collect information on birth order of infants. Researchers might also examine how natural parenting styles (e.g., physical contact, reassuring comments) and other parenting factors (e.g. belief in distraction intervention, parent anxiety, quality of distraction administration) might interact with temperament to influence infants' medical distress. Given the potential influence of these factors, studying variability in parent-infant interaction in the time prior to the immunization might provide additional information about which dyads are most helped by this intervention. It is likely that the match of parenting style with temperament best predicts success during a stressful medical event. Comparing the effects of the intervention when consistently administered by a non-parent figure (e.g., nurse) would be interesting as it might help isolate the intervention-temperament interaction. Other similar lines of inquiry might evaluate additional brief screeners to identify infants most in need of intervention or those most responsive to available treatments. For example, parent report of their own anxiety has been shown to relate to infants' medical distress (Bernard & Cohen, 2006) and might be important to explore in depth.

4.6 Clinical Applications

Given that immunizations are recommended for all infants, the majority of caregivers are very familiar with the infant distress that occurs around painful procedures during medical visits. Some general recommendations that may help lower infant distress during immunizations can be gleaned from this study's results. Engagement in distraction seems to be helpful for some infants. Specifically, infants who are seen by parents as having slower-to-warm-up or moderate-to-warm-up temperaments seem to receive the most benefit. Parents of these infants may want to implement increased distraction for their children during painful procedures. For the infants not helped by distraction, no negative effects seem to be incurred as a result of this intervention.

4.6 Conclusions

Temperament was not found to directly predict infant distress during immunizations in this study, but temperament did moderate the distraction-distress relation in some analyses. Infants who were rated as faster to warm up had lower distress when receiving distraction than those who were slower to warm up and receiving distraction. Further, infants describes as having easier temperaments had lower parent-reported immunization distress when their parents provided distraction than infants described as having more difficult temperaments. Although the role of temperament on response to distraction for injection pain was not consistent across indices, results suggest that it is a variable deserving of closer inspection. As there is increasing recognition of the value in individualizing healthcare treatment (Department of Health and Human Services, 2009), it is important to continue to examine personal characteristics that might impact the effectiveness of intervention. More closely examining the role of temperament could be instrumental in understanding the mechanisms involved in distraction interventions for infants undergoing painful medical procedures.

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APPENDICES

Appendix A *Demographic Questionnaire*

Appendix B *Measure of Adult and Infant Soothing and Distress (MAISD)*

Appendix C *Parent Pre-Shot Questionnaire*

Appendix D *Nurse Pre-Shot Questionnaire*

Appendix E *Parent Post-Shot Questionnaire*

Appendix F *Nurse Post-Shot Questionnaire*

Appendix G *Recruitment and Data Collection Protocol*

Appendix A ***Demographic Questionnaire***

Date_____ Code #_____ Condition_____

Questions about the Family

What is your relation to the child?__________ Your gender?_____ Your race?_____ Your date of birth?_____
What is the highest grade that you completed (HS = 12, College grad = 16, etc.)?____ Spouse's education?____
Approximate total family annual income? _____/year
What is the gender of this child?____ Child's race?_____ Child's date of birth?_____
How many other children live in the home?_____ What are their ages?_________________________________

Questions about the Child

Has this child received injections other than the regularly schedule immunizations?
If so,
Why?____

How would you describe this child compared to other same-age children? Please indicate by making a vertical mark on the horizontal line below (e.g., a mark in the middle area indicates that you view this child as about the same as other children/typical children on this scale).

Quiet ____ Loud

Shy ____ Outgoing/Social

Calm ____ Active

Not easily upset ____ Easily upset

Easy to sooth when upset ____ Difficult to soothe

Fearful ____ Not fearful at all

How distressed was this child during previous injections?

Not distressed ____ Very distressed

Is this child his/her usual self today (please circle)? Y N If not, please explain____________________________

Identifying characteristics (e.g., shirt color, hair color):

Appendix B *MAISD Infant Coding Sheet*

Subj#:_____ Date:_____ Coder:_____
Number of shots:_____ Title of child's Video:_____ Nurse name:_____

Time	Infant Distraction	Infant Comfort	Infant Cry	Infant No Cry Distress	Parent Distraction	Parent Comfort	Nurse Distraction	Nurse Comfort	Movie Start and Stop	Phase
:00										
:05										
:10										
:15										
:20										
:25										
:30										
:35										
:40										
:45										
:50										
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:10										
:15										
:20										
:25										
:30										
:35										
:40										
:45										
:50										
:55										
:00										
:05										
:10										

Appendix C ***Parent Pre-Injection Questionnaire***

Code #_____ Condition_____ Date_____

How distressed are you during your own injections?

Not Distressed ____ Very Distressed

How distressed are you during your child's injections?

Not Distressed ____ Very Distressed

How distressed are you now?

Not Distressed ____ Very Distressed

How aware is your child that he/she will receive injections today?

Not Aware ____ Very Aware

How distressed is your child now?

Not Distressed ____ Very Distressed

How distressed will your child be during the injections?

Not Distressed ____ Very Distressed

* * * * * * * ***Treatment conditions only*** * * * * * * *

How much will the Comforting/Distraction help *you* with the injections?

Very Helpful ____ Not Helpful

How much will the Comforting/Distraction help your child with the injections?

Very Helpful ____ Not Helpful

Child Baseline Pulse rate. _____ beats in 60 seconds. Taken when the child entered the clinic.

Parent Baseline Pulse rate. _____ beats in 60 seconds. Taken when the parent enters the clinic.

Appendix D *Nurse Pre-Injection Questionnaire*

Nurse's Initials_____ Code #_____ Condition_____ Date_____

How distressed are you?

Not Distressed ____ Very Distressed

How distressed is this parent?

Not Distressed ____ Very Distressed

How distressed is this child?

Not Distressed ____ Very Distressed

How aware is this child that he/she will receive injections today?

Not Aware ____ Very Aware

* * * * * * * ***Treatment conditions only*** * * * * * * *

How much will the Comforting/Distraction help *you* with the injections?

Very Helpful ____ Not Helpful

How much will the Comforting/Distraction help this child with the injections?

Very Helpful ____ Not Helpful

Child Pre-Injection Pulse rate. _______beats in 60 seconds. Taken immediately prior to the injection.

Parent Pre-Injection Pulse rate. _______beats in 60 seconds. Taken immediately prior to the injection.

Appendix E *Parent Post-Injection Questionnaire*

Code #_____ Condition_____ Date_____

How distressed were you *during* your child's injections?

Not Distressed ________________________________ Very Distressed

How distressed was your child *during* the injections?

Not Distressed ________________________________ Very Distressed

* * * * * * * ***Treatment conditions only*** * * * * * * *

How much did the Comforting/Distraction help *you* with the injection?

Very Helpful ________________________________ Not Helpful

How much did the Comforting/Distraction help your child with the injection?

Very Helpful ________________________________ Not Helpful

Child Delayed Pulse rate. _____ beats in 60 seconds. Taken 2-5 minutes after the injection.

Parent Delayed Pulse rate. _____ beats in 60 seconds. Taken 2-5 minutes after the injection.

Appendix F *Nurse Post-Injection Questionnaire*

Code #_____ Condition_____ Date_____

How distressed were you *during* this child's injections?

Not Distressed ______________________________ Very Distressed

How distressed was this parent *during* this child's injections?

Not Distressed ______________________________ Very Distressed

How distressed was this child *during* the injections?

Not Distressed ______________________________ Very Distressed

* * * * * * * ***Treatment conditions only*** * * * * *

How much did the Comforting/Distraction help you with the injection?

Very Helpful ______________________________ Not Helpful

How much did the Comforting/Distraction help the parent with the injection?

Very Helpful ______________________________ Not Helpful

How much did the Sucrose/Distraction help this child with the injection?

Very Helpful ______________________________ Not Helpful

Child Post-Injection Pulse rate. _______beats in 60 seconds. Taken immediately following the injection.

Parent Post-Injection Pulse rate. _______beats in 60 seconds. Taken immediately following the injection.

Appendix G ***Recruitment and Data Collection Protocol***

1. *Gather Black Bag of Study Materials.*
   - The bag should include the following:
     - *i.* Fairmont Binder**.** Check to make sure the following are in the binder**:** Participant Tracking Form, Participant Decline Form, big font condition pages, 20 full questionnaire packets, directions to pediatric clinic, and stamped return envelopes.
     - *ii.* Clipboard
     - *iii.* Video camera
     - *iv.* Blank tapes DVD player and movies (in a wallet)

2. *Go to waiting room and greet receptionist.*
   - Wait for potential participants. The receptionist will likely mention the study to potential participants. If an infant appears to be in our age range, and the receptionist doesn't direct them to you, ask the receptionist if the infant is scheduled to have an immunization. If so, approach the potential participants.

3. *Recruitment.*
   - Example: "Hi, my name is ________, and I am working with the _________ on a study to lower infants' and their parents' distress during shots."
   - Inform them that this study should add almost *no additional time* to their appointment.

4. *Briefly review the consent form and **HIPAA authorization form***
   - REVIEW BOARD: All studies through _______ must be approved by a review board. The board stamped this form indicating that this study is beneficial to you and poses no threats. Before being in the study, you must initial and sign this form. There is a copy for you to keep.
   - CONTACT INFORMATION: The form has contact information for, tells you about the study, and tells you that you will fill out some brief questionnaires.
   - VIDEOTAPE: Also, we will videotape the procedure so that we can compare infants' distress behavior. The tapes are kept locked up and will be destroyed later.
   - CONFIDENTIAL: You are given a code number so that everything is kept confidential.
   - CONDITIONS: You will be randomly assigned to either Standard Care, what the nurse normally does to help, or Distraction, the nurse will try to distract your baby during the shot.
   - VOLUNTARY PARTICIPATION: Your participation is voluntary and you are free to withdraw at any point.

5. *Sign consent form and **HIPAA authorization form***
   - Keep the signed copy and give them an extra copy. If they decline, note the reason on the Decline Participation Form.

6. *Complete questionnaire*
   - Briefly show parents how to complete the Demographic Questionnaire and Parent Pre-Immunization Form. If they have trouble reading, read it to them. Review the forms after parents complete them in order to check for any skipped questions.

7. *Complete the Participant Tracking Form*
   - While the parent is completing questionnaires, fill in the appropriate information on the Participant Tracking Form found in the binder. Please assign participants on an alternating basis to the Distraction (D) condition or the Typical Care Control (C) condition. Also, write anything that you think is important in the 'Comments' column (e.g., "There was a sibling in the room").

8. *Condition Training*
   - Inform participant of their assigned condition
     i. Distraction Condition. If the family is in the Distraction condition, inform the parent that he/she will be encouraging his/her infant to watch a DVD movie throughout the procedure. Tell the parent to try to prompt watching during the entire time in the treatment room, including prior to, during, and after the immunization. Tell the parent that the more the infant watches the movie, the more it will help decrease distress. Use the large print reminder card as a guide to train the parent.
     ii. Typical Care Condition. If the family is in the Typical Care condition, the parent does not need any special guidance or training. Inform the parent the medical staff will carry out their typical procedure.

9. *Enter Treatment Room, Setup and Turn on Camera*
   - When the nurse is ready to give the immunization, accompany the family into the treatment room. Immediately turn on the video camera, wait a few seconds, and state into the camera the subject number.

10. *Nurse Prompt*
   - Place the correct big font condition card on the desk. Remind the nurse to OVERDO and EXAGGERATE her coaching behavior and repeat the specific behaviors (e.g., "This infant is in the distraction condition. Try to do lots of Distraction and no comforting or other behavior." OR "This infant is in the standard treatment condition. Do whatever you normally do.")

11. *Set up Other Equipment*
   - If the infant is in the Distraction Condition: Place the DVD player on the side of the table, put in the appropriate movie, and start the movie playing. If the infant is in the Standard Treatment Condition: Make sure the DVD player is hidden.

12. *Nurse Pre-Procedure Questionnaire*
   - Remind Sandi to complete the Nurse Pre-Injection Questionnaire

13. *Injection*
   - If the infant is in the **Distraction Condition**: Hold the DVD player to the side of the infant. DO NOT say anything (including coaching the nurse or parent or distracting the infant) during the procedure. If the infant is the **Standard Treatment Condition**: Stand near the camera so you can make sure the infant is in the frame.

14. *Nurse Post-Procedure Questionnaire*
   - Remind Sandi to complete the Nurse Post-Injection Questionnaire

15. *Post-Injection*
   - When the family leaves the treatment room, turn off the camera, collect the DVD player and nurse questionnaires, and follow them into the hallway. Remove the tape and label it with the subject #. Check the tape to ensure there is still space left. If so, place the tape back in the camera, if not, replace the tape with a new one.

16. *Parent Post-Questionnaires*
   - Help the family complete the post-injection questionnaires, including the Parent Post-Injection Questionnaire and the Health Care Attitudes Questionnaire.

17. Label Questionnaires

- Please label every page of the questionnaire packet and the consents with the subject number and condition.

18. Other Participants

- When family is finished, return to the waiting room, gather materials, cross fingers, and hope that another participant shows up. If so, go to step 5.

End of Day

- Organize the completed forms. Double check to make sure that every page is labeled with the participant # and condition and that the tape is labeled with all participant numbers from that day
- Label the videotape (label the tape itself, not just the box)
- Make sure the Participant Tracking Form is updated.
- Collect the camera, tripod, tapes, binder, forms, DVD player, and movies.
- Say goodbye to everyone