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COMPARISON OF HIGH AND LOW DISTRACTION FOR PEDIATRIC PROCEDURAL

PAIN

by

CRYSTAL MARIE STACK LIM

Under the Direction of Lindsey L. Cohen

ABSTRACT

Distraction is an effective pain management intervention and children's coping styles are important to consider when designing interventions. The purpose of this study was to examine two movie distractions in children 3 to 11 years old receiving venipunctures and to evaluate the relations between the effectiveness of the interventions and coping styles. Results revealed no interaction and no main effects of condition or coping style. However, coping on caregiverreport of child pain approached significance. T-tests revealed significant differences between approach and avoidance coping styles, with children with an approach coping style experiencing significantly less pain compared to children with an avoidance coping style. Descriptive statistics revealed the presence of a mixed coping style, suggesting that children's coping styles may be continuous. This study highlights the importance of examining coping styles in the context of pediatric painful medical procedures and the need to further examine the effectiveness of distraction interventions.

INDEX WORDS: pediatric pain, distraction, pain management intervention, children, venipuncture

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A Thesis Submitted in Partial Fulfillment of the Requirements for the Degree of

Master of Arts

in the College of Arts and Sciences

Georgia State University

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INTRODUCTION

The International Association for the Study of Pain (IASP) defines pain as an unpleasant sensory and affective event that is related to potential or actual tissue damage (Merskey, 1979). Unfortunately, children experience repeated pain as part of their regular health care. In fact, children's most common pain experiences are medical pain (Committee on Psychosocial Aspects of Child and Family, 2001); primarily needle pain (e.g., venipunctures, immunizations) (Blount, Piira, & Cohen, 2003). Children experience needle pain soon after birth, beginning with heel sticks and immunizations, and continuing throughout childhood with additional immunizations and blood tests. Children will undergo approximately 28 intra-muscular immunization injections and possibly a number of venipunctures by the time they reach their sixth birthday (Center for Disease Control and Prevention [CDC], 2004).

Although there are clear benefits from these routine acute painful medical procedures (e.g., immunity from fatal diseases), there is a growing body of literature documenting the negative short- and long-term repercussions of medical pain. Research examining needle procedures indicates that most children have high fear and high anxiety prior to the procedure (Blount et al., 2003), experience intense distress during the procedure (Jacobson, Swan, Adegbenro, Ludington, Wollan, & Poland, 2001), and often children have to be physically restrained by parents and health care providers in order for the procedure to be completed (Fanurik, Koh, Schmitz, & Brown, 1997). A cycle of increased anxiety, fear, and pain can result from negative experiences with injections, which in turn can exacerbate future injection experiences (Fowler-Kerry & Lander, 1987). These aversive experiences have the potential of leading to pessimistic memories about medical procedures (Cohen, Blount, Cohen, Ball, McClellan, & Bernard, 2001). In the long-term, negative medical experiences in childhood have been shown to predict avoidance of medical situations, as well as fear, anxiety, pain, and ineffective coping strategies in adulthood (Pate, Blount, Cohen, & Smith, 1996). In short, it is not only humane to reduce children's medical-related pain, but it may also lead to healthier medical behavior later in life.

Pediatric Procedural Pain Management

Pain-management interventions for children undergoing acute painful procedures include pharmacological and non-pharmacological methods, each of which has advantages and disadvantages (Fanurick et al., 1997). Common pharmacological interventions include medications used for the numbing of pain with and without consciousness. In general, pharmacological treatments are considered relatively safe and effective for many non-routine intensive procedures (e.g., surgery, bone marrow aspirates) (Fanurik et al., 1997; Kuppenheimer & Brown, 2002). However, the majority of pain medications do little to address pre-procedural anxiety children may experience; and in cases where loss of consciousness occurs, children do not learn coping skills that could be utilized during future procedures. In addition, side effects and other complications must be considered when using pharmacological treatments. Medications are also limited by practical considerations. For instance, personnel with advanced training are required to be present during certain procedures due to the possibility of medical complications. Related, additional costs and time are invariably incurred with the use of painmanagement medications. Thus, medications are not commonly used for routine outpatient painful procedures, such as immunizations or venipunctures.

Common non-pharmacological pediatric pain interventions include relaxation training, distraction, imagery, hypnosis, physical therapies, and modeling (Blount et al., 2003; Fanurick et al., 1997; Piira, Hayes, & Goodenough, 2002). Advantages of non-pharmacological interventions include their ability to help children develop a sense of mastery over stressful situations, parents can be involved in various interventions, and children suffer little to no side effects. However, often additional "coaches" or experts must be employed to teach the patients or staff coping skills and additional costs are sometimes necessary for equipment (e.g., distraction stimuli). Despite these downsides, non-pharmacological interventions currently appear to be the most promising anxiety and pain reducing techniques for children's brief outpatient procedures (e.g., immunizations, venipunctures) (Blount et al., 2003).

Multicomponent Cognitive-Behavioral Treatment Packages

Multicomponent cognitive-behavioral therapy (CBT) interventions have become the predominant non-pharmacological approach for the treatment of pediatric procedural pain (Powers, 1999). Typical components of CBT packages include breathing exercises, relaxation, distraction, imagery, coping skills, modeling, rehearsal, and reinforcement (Blount et al., 2003; Powers, 1999). Researchers have shown CBT packages to be successful at reducing children's pain associated with bone marrow aspirations (BMAs) and lumbar punctures (LPs) (Jay, Elliott, Katz, & Siegel, 1987; Jay, Elliott, Ozolins, Olson, & Pruitt, 1985), venipunctures (Manne, Redd, Jacobsen, Gorfinkle, Schorr, & Rapkin, 1990), burn debridement (Elliott & Olsen, 1983), and immunizations (Blount et al., 1992; Cohen, Blount, & Panopoulos, 1997; Gonzalez, Routh, & Armstrong, 1993). Using slightly modified criteria developed by Chambless et al. (1996), Powers (1999) deemed CBT for pediatric procedural pain management an "empirically-supported" treatment. However, the cost-effectiveness and feasibility of the implementation of these interventions in clinical settings have long been questioned (see Blount et al., 2003).

Related, Powers (1999) encouraged researchers to conduct dismantling studies to identify the critical components of these multicomponent packages.

In an effort to develop an effective non-pharmacological treatment, which was also practical, Cohen et al. (1997) compared a nurse-directed cartoon movie distraction intervention to a nurse-directed cartoon movie distraction combined with training parents and children in coping with immunization pain. Results revealed no differences in child anxiety or pain between the two treatment groups but both were superior to a control group. A cost analysis indicated that the nurse-directed condition was far more economical and time-efficient. This study also provided a partial dismantling of CBT interventions, and indicated that nurse-coached distraction might be a critical component of these packages and parent and child individual training may be unnecessary. Later studies examining components of CBT packages have suggested that distraction appears to be the critical element of effective interventions, especially for young children (Blount et al., 2003; Cohen, 2002). In fact, distraction has been recognized as the single best intervention to select when other factors, such as a child's coping preferences, are unknown (Fanurik et al., 1997).

Distraction

Various explanations for the mechanism of distraction have been presented. Melzack and Wall's (1965) gate control theory provides an explanation for the role of distraction in pain reduction. The gate control theory proposes that pain is modulated in the central nervous system and cognitions, beliefs, and emotions can diminish or heighten pain perception. Thus, distraction, which is recognized as diverting attention away from the painful procedure, is an example of a technique that can partially "shut the gate" and decrease the pain experience. Neurophysiology studies provide support for this explanation. For example, areas of the brain shown to process

pain information have been found to be minimized during distraction tasks (e.g., Bantick, Wise, Ploghaus, Clare, Smith, & Tracey, 2002; Frankenstein, Richter, McIntyre, & Remy, 2001; Petrovic, Petersson, Ghatan, Stone-Elander, & Ingvar, 2000). Thus, there appears to be an inverse and linear relation between distraction and pain; more distraction leads to lower pain. Behaviorists argue that distraction might evoke behaviors (e.g., laughing) that are incompatible with pain behavior (e.g., crying) (Cohen, 2002). Further, the repeated use of distraction may disrupt the conditioning that typically occurs between the unconditioned stimuli (e.g., tissue damage) and the neutral stimuli (e.g., nurse, bandages, clinic), resulting in less anxious behavior associated with medical stimuli (Cohen, 2002).

A number of studies have shown distraction to be an effective pain reduction technique. For example, research supports the use of movies, cartoons, guided imagery, books, bubbles, and party blowers for the reduction of pediatric pain (for reviews, see Kleiber & Harper, 1999; Piira et al., 2002; Varni, Blount, Waldron, & Smith, 1995). Although researchers have found a number of different distraction stimuli to be effective, only two studies have systematically compared the effectiveness of different distraction interventions in children.

In an effort to evaluate whether an interactive stimulus would be more distracting and yield greater pain-reduction than a non-interactive stimulus, Mason, Johnson, and Woolley (1999) compared the effectiveness of a short story requiring button pushing and a cartoon film for seven children with cancer receiving port-a-cath and Hickman line accesses. Results suggested that children displayed less distress in the interactive short-story condition than in the passive cartoon condition. However, given that there were no differences between the control and cartoon groups, the passive cartoon condition might not have been a sufficient distraction

comparison. In addition, the small number of participants raises concern about the generalizability and power of the study.

Similar to Mason et al. (1999), MacLaren and Cohen (2005) sought to compare interactive and passive distraction stimuli. In this study, the two distracters utilized were cartoon movies presented on a portable DVD player and an interactive electronic toy for young children undergoing venipuncture. The cartoon movie, the passive stimuli, was shown to be superior in reducing pain. However, the authors note that other differences besides the level of interaction between interventions preclude clear conclusions about the role of an interactive component in pain reduction. Apart from answering the question about interactive versus passive distraction stimuli, results also suggested that regardless of the distraction stimuli, there was an inverse correlation between engagement in distraction and pain. In addition, Cassidy, Reid, and McGrath (2002) found a similar inverse association between distraction with cartoon movies and pain. These studies lend support to the notion that the more distraction children experience the less pain and anxiety they will experience during a painful medical procedure.

Although research provides strong support for distraction, it continues to remain unclear whether some distraction stimuli might be preferable to others. In addition, no research to date has clearly established whether there is in fact a linear *causal* relation between the quantity of distraction and pain reduction. Whereas MacLaren and Cohen (2005) and Cassidy et al. (2002) found inverse correlations between distraction and pain reduction, the direction of the relation is not evident. Although it is logical that more distraction causes less pain, it might be that the diminished pain allows children more resources to devote to the distraction stimulus. Thus, experimental investigations are necessary to determine the nature of the inverse relation between distraction and pain.

Variables Influencing the Effectiveness of Distraction Interventions

When assessing and implementing interventions to reduce procedural pain, researchers should consider factors that might mediate or moderate the effectiveness of the intervention. For example, researchers have begun to recognize that child age, adult behaviors, and parental anxiety can influence the effectiveness of pediatric pain interventions. In addition, these variables can also influence children's perceptions of the painful procedure and the level of anxiety and pain they exhibit (for a review, see Blount et al., 2003).

Studies that have examined the relations between age and pain have consistently found an inverse association between age of the patient and the amount of anxiety and pain behavior (e.g., Rudolph, Dennig, & Weisz, 1995). Interestingly, findings from one study suggest that age differences might relate to the effectiveness of distraction stimuli (MacLaren & Cohen, 2005). Specifically, that interactive distraction interventions may be appropriate for older children and passive distractions, such as cartoon movies, may be appropriate for children of all ages. However, in the study conducted by MacLaren and Cohen (2005), the ages of participants ranged from 1 to 7 years of age. It would be interesting to see whether these results would be present in older children.

In regards to adult behaviors during painful medical procedures, correlational research has revealed that behaviors of medical personnel are associated with child coping behaviors, whereas parent behaviors are associated with child distress (Cohen, Bernard, Greco, & McClellan, 2002; Frank, Blount, Smith, Manimala, & Martin, 1995; Sweet & McGrath, 1998). Taking these correlational findings one step further, sequential analyses have revealed that specific adult behaviors, such as reassurance, giving the child control, criticism, and apologizing have been found to precede child distress behavior; and adult commands to cope, nonprocedural talk, and humor directed towards the child precede child coping behaviors (Blount, Corbin, Sturges, Wolfe, Prater, & James, 1989; Manne, Jacobson, & Redd, 1992). Again using sequential analyses, research has shown that if children were engaging in coping behaviors during cancer treatments adults were less likely to offer explanations, give control to the child, praise, and criticize/threaten/bargain (Manne et al., 1992). However, if children were exhibiting distress behaviors, such as crying, adults were less likely to distract and give control and more likely to offer explanations and criticize/threaten/bargain (Manne et al., 1992).

Not surprisingly, research has demonstrated that parents' anxiety about child medical care (e.g., hospitalizations, chemotherapy, injections) is related to children's anxiety (Cohen et al., 1997; LaMontagne, Hepworth, Byington, & Chang, 1997; Wright, Alpern, & Leake, 1973). Parent anxiety has also been found to be associated with child procedural anxiety and pain behavior (Bernard, Cohen, McClellan, & MacLaren, 2004). Whereas some researchers have targeted parent anxiety directly (e.g., Jay & Elliott, 1990), others have found reductions in parental anxiety when parents are given an active role in helping their child cope (e.g., Cohen et al., 1997). Children's natural coping styles have also been recognized as an important variable to consider when examining the effectiveness of distraction interventions for painful pediatric medical procedures.

Child Coping Style

When assessing and treating pediatric pain, it is essential to consider a child's natural style of coping (Blount et al., 2003; Stanish, Tripp, Coady, & Biddulph, 2001). Coping is a complex construct and has been defined in a number of ways (for a review, see La Greca, Siegel, Wallander, & Walker, 1992). One dimension of coping, which is commonly identified in the pediatric procedural distress literature, is categorized along the dimensions of approach and

avoidance. Approach coping refers to a child's tendency to focus on the stressor (e.g., the painful medical procedure) by asking for information and monitoring or looking at the stressor, whereas avoidance coping refers to a child's tendency to ignore or divert attention away from the stressor (Bernard et al., 2004).

The relation between approach-avoidance coping and pain in children undergoing acute medical procedures has been examined, however, findings are mixed about which coping style is more beneficial. In a review by Rudolph et al. (1995), approach coping behaviors were associated with less distress in three samples of children undergoing bone marrow aspirations and surgery. In contrast, Smith, Ackerson, and Blotcky (1989) found no significant relations between coping styles and levels of distress in children undergoing bone marrow aspirations and lumbar punctures. Some studies have reported that approach behaviors, such as information seeking, is associated with higher levels of distress in children and avoidance behaviors, such as non-procedural talk, correlates with lower levels of distress (Blount et al., 1989).

Treatment outcome studies have examined the relation between approach-avoidance coping style and the effectiveness of specific interventions designed to reduce distress in children undergoing invasive medical procedures. The congruency hypothesis suggests that when an intervention matches a child's coping style (e.g., distraction and avoidance or information and approach) it will be the most effective at decreasing distress (Christiano & Russ, 1998; Smith et al., 1989). However, consistent findings in this area of the coping pediatric pain literature are lacking. For example, Smith et al. (1989) found results opposite of the congruency hypothesis; children receiving interventions inconsistent with their coping style (e.g., distraction for "approachers") reported less pain than children receiving interventions consistent with their coping style (e.g., information for "approachers"). However, in a study using a cold pressor task,

ratings of pain were found to decrease when the intervention matched children's approach or avoidant coping style (Fanurick, Zeltzer, Roberts, & Blount, 1993), thus the congruency hypothesis was supported. However, in a study investigating children's distress during dental restoration, mixed findings for the congruency hypothesis were found for approach-avoidance coping styles (Christiano & Russ, 1998). Specifically, the congruency hypothesis was supported by child-reported distress immediately following the procedure but was not supported when behavioral distress was examined. Clearly, further research in this area is needed to examine the complex relation between children's approach-avoidance coping styles and the effectiveness of interventions aimed at reducing distress during painful medical procedures.

Assessment of Pediatric Procedural Pain and Coping

Child Pain

Given that pain is a multidimensional experience (Merskey, 1979), multiple methods of assessing pain are recommended (McGrath, 1987). Common ways of assessing procedural pain in children include self-report, observers' (e.g., parents, medical staff) reports, observational measures, and physiological measures.

Child self-report. Given that pain is a personal or subjective experience, self-report has been recognized as a critical component of a comprehensive pediatric pain assessment (Finley & McGrath, 1998). Research has indicated that children as young as three years of age can adequately report pain (Champion, Goodenough, von Baeyer, & Thomas, 1998). The most widely used self-report scales for children's procedural pain are pictorial, with photographed or cartoon faces exhibiting ranges in facial expressions (Blount et al., 2003). For example, the Faces Pain Scale-Revised (FPS-R; Hicks, von Baeyer, Spafford, van Korlaar, & Goodenough, 2001) presents six drawn faces, which range in pain intensity from no pain to very much pain. Another measure, the Children's Anxiety and Pain Scale (CAPS; Kuttner & LePage, 1983, 1989), uses two sets of faces to measure separate constructs of pain and anxiety in children undergoing painful medical procedures.

In addition to pictorial scales, visual analogue scales (VAS) have been used with pediatric patients (Johnston, 1989). VAS have been designed in which circles differing in color and width are used to represent varying degrees of pain intensity (e.g., Colored Analogue Scale; McGrath, Seifert, Speechley, Booth, Stitt, & Gibson, 1996). 100 mm VAS lines with labeled endpoints (e.g., no pain, extreme pain) are more commonly used because they do not result in the clustering of scores, which is common with likert-type ratings (McGrath, 1990; Varni, Walco, & Wilcox, 1990). Although VAS have been shown to be reliable and valid measures in adults and children over 4 years of age, their reliability and validity in younger pediatric patients has been questioned (Champion et al., 1998; McGrath, 1987).

Parent- and health care provider-report. Since parents and medical staff members are often responsible for making decisions related to the treatment and diagnosis of children's pain (Manne et al., 1992), measures that assess parents' and health care providers' perception of children's pain are particularly important. In addition, research has shown that the ratings made by children and those made by adults (e.g., parents and health care providers) represent unique perspectives, which is critical when designing and evaluating pediatric pain- and anxiety-management interventions (Manne et al., 1992). Linear VAS are commonly used to assess how parents and health care providers perceive children's pain and anxiety during medical procedures (Blount et al., 1997). In addition, other variables, such as parents' and health care providers' own anxiety and their perceived ability to comfort the child might be examined in this same manner (Cohen et al., 1997).

Observational measures. Measures of observed behaviors in procedural pain research are also commonly employed. Various reasons for measuring pain and distress via observed behaviors have been discussed in the literature (McGrath, 1998). Specifically, behaviors serve as the first indicator of pain; behavior related to pain may influence a child's perception of the painful event; behavior may influence the pattern of the child's evaluation of pain; they may influence the child's social environment; and behaviors might be less susceptible to bias than subjective reports. Numerous observation measures have been designed for use with children undergoing painful medical procedures, such as the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS; McGrath, 1998) and the Child-Adult Medical Procedure Interaction Scale (CAMPIS; Blount et al., 1989). Scales such as these typically quantify discrete behaviors believed to be indicative of child pain (e.g., cry, scream, flail). However, utilizing observational measures in clinical situations are often impractical due to their time intensive nature. In addition, there might be little incremental validity of including observational measures in a study that is already utilizing multiple modes of assessment.

Physiological measures. Numerous physiological measures have been used to measure pain and distress in pediatric procedural pain. Examples of measures used include blood pressure, heart rate, and palmar sweat index (Blount et al., 2003; McGrath, 1987). Despite their use in pediatric pain research, no single physiological measure stands out as ideal, mainly because physiological measures not only vary with pain but have also been found to vary with other extraneous factors such as emotional states, movement, and room temperature (Blount et al., 2003; Sweet & McGrath, 1998). Physiological measures may also influence anxiety and pain in children if they are invasive and produce discomfort. Some physiological measures are considered impractical to use because they can be difficult and time consuming to interpret, as well as costly (Blount et al., 2003; Sweet & McGrath, 1998). Similar to observational measures, the incremental validity of including physiological measures in a multi-modal assessment may not be sufficient enough to warrant their use.

Child Coping

Child self-report. School-age children can complete questionnaires that tap coping. For example, the Pain Coping Questionnaire (PCQ; Reid, Gilbert, & McGrath, 1998) was designed for children 7 to 17 years of age. The questionnaire consists of eight subscales: information seeking, problem solving, seeking social support, positive self-statements, behavioral distraction, cognitive distraction, externalizing, and internalizing/catastrophizing. The Kidcope is also a popular measure, which was developed for pediatric patients 7 to 18 years of age (Spirito, Stark, & Williams, 1988). The Kidcope produces scores on 10 coping strategies: distraction, social withdrawal, cognitive restructuring, self-criticism, blaming others, problem solving, emotional regulation, wishful thinking, social support, and resignation. The PCQ and the Kidcope have been found to have adequate validity and reliability (Reid et al., 1998; Spirito et al., 1988). In addition, these measures could easily be modified to obtain in depth parental reports about children's coping style. Other coping measures have been developed for children that control for differences in reading level, by reading the questions aloud to the child. The Child Behavioral Style Scale (CBSS; Miller, Roussi, Caputo, & Kruus, 1995) assesses the likelihood that children, 7 to 12 years of age, will monitor or blunt (similar to approach-avoidance) in common stressful situations.

There is only one self-report coping measure for young children. Bernard et al. (2004) developed a pictorial scale, the Child Approach-Avoidance Rating Scale (CAARS) for children four to six years of age. The CAARS presents two graphics of a child receiving an injection administered by a nurse. The graphics are identical except in one the child is watching the nurse and in the other the child is looking away. The interviewer states, "one child likes to ask questions about the shot and watch the nurse during the shot and the other child does not like to talk about the shot and likes to look away during the shot. Which one were you?" Significant correlations between children's pre- and post-injection self-report of coping using the CAARS were found and there is evidence of concurrent validity with parent- and nurse-report of child approach-avoidance coping style. However, the question posed to children on the CAARS may be problematic in that it is double-barreled (e.g., children might ask questions about the injection but they may also look away).

Parent- and health care provider-report. Assessing parent- and health care providerreports of child coping behaviors have been recognized as important in order to provide another estimate of this complex construct (Bernard et al., 2004). In the study by Bernard and colleagues (2004), parents and nurses completed VAS assessing their perceptions of children's approachavoidance coping behaviors. In addition to VAS, parent-report questionnaires assessing coping strategies have been developed for use with older children. Example measures of parent perception of child coping include the Coping Health Inventory for Children (CHIC; Austin, Patterson, & Huberty, 1991) and the Coping Strategies Inventory (CSI; Tobin, Holroyd, Reynolds, & Wigal, 1989).

Observational. The Behavioral Approach-Avoidance and Distress Scale (BAADS; Hubert, Jay, Saltoun, & Hayes, 1988) is one of the only observational measures of children's approach-avoidance coping style. The BAADS consists of two subscales, one that assesses approach-avoidance behaviors and the other that assesses distress behaviors. Each subscale is rated on a 5-point scale. Although the distress subscale has been found to have adequate concurrent validity, the approach-avoidance subscale has not, which has been attributed to the overlap of distress and avoidance coping behavioral descriptors (Bachanas & Blount, 1996; Bernard et al., 2004). In response, Bernard et al. (2004) developed the Approach-Avoidance Behavior Scale (AABS) to measure children's approach-avoidance coping behavior. The AABS allows for the independent assessment of approach-avoidance coping behaviors by measuring the quantity of each approach and avoidance behavior in 5-second intervals. As previously stated, using observational measures are often too time intensive to be practical.

Summary and Purpose

In conclusion, children experience short- and long-term negative effects as a result of painful medical procedures. Treatment packages have been found to be effective for pediatric procedural pain and anxiety management (see Powers, 1999), and distraction in particular appears to be an important component (Blount et al., 2003). However, no studies have clearly established whether the quantity of distraction is causally related to pain reduction, as would be expected. Further, research examining children's approach-avoidance coping related to procedural distress and distraction is a promising avenue for tailoring treatments; however, additional research is needed in this area. This study provides an evaluation of a distraction stimulus presented in low and high distraction conditions for children undergoing venipunctures. Further, approach-avoidance coping styles were examined to determine if coping influences the effectiveness of the interventions.

Aims

Aim 1. Compare the effectiveness of high and low distraction interventions for decreasing children's venipuncture pain.

Aim 2. Compare children's approach and avoidance coping in relation to venipuncture pain.

Aim 3. Examine whether high or low distraction is more effective with approach or avoidance coping style for venipuncture pain.

Aim 4. Investigate the impact of high and low distraction interventions on caregiver procedure-related anxiety.

Aim 5. Evaluate caregiver and health care provider treatment satisfaction of high and low distraction interventions.

Hypotheses

It is hypothesized that there will be significant main effects of treatment conditions on all pain and anxiety measures (Aim 1), where children in the High distraction group will report less and adults will rate them has having less pain and anxiety than the children in the Low distraction and Control conditions. In addition, children in the Low distraction group will report less and be rated as having less pain and anxiety compared to children in the Control condition. It is expected that there will be a main effect of approach-avoidance coping (i.e., CAARS-R). Differences in pain and anxiety are expected between children who report an approach coping style compared to children who report an avoidance coping style (Aim 2). Specifically it is expected that children with an approach coping style will report and be rated as exhibiting significantly less pain and anxiety than those with an approach coping style. It is hypothesized that an interaction between coping and condition will be present (Aim 3), with children identified as having an avoidant coping style in the High distraction condition reporting less pain and be rated by parents and health care providers as exhibiting less pain and anxiety than children with an approach coping style in the High distraction condition. Additionally, it is expected that children with an avoidance coping style in the Low distraction group will report less pain and be rated by parents and health care providers as demonstrating less pain and anxiety than children with an approach coping style in the Low distraction group, however, the difference will not be as great as that in the High distraction condition. In other words, a synergistic interaction will be found between coping and condition. Differences in the amount of procedure-related parental anxiety reported by parents and health care providers are expected (Aim 4), with parents of children in the High distraction and Low distraction conditions reporting and being rated as less anxious compared to parents of children in the Control condition. Additionally, parents of children in the High distraction condition are expected to report less and be rated as less anxious than parents of children in the Low distraction condition. It is expected that parents and health care providers will report being more satisfied with the High distraction and Low distraction interventions than the Control condition (Aim 5). In addition, it is expected that parents and health care providers will report more satisfaction with the High distraction condition than with the Low distraction condition.

METHOD

Participants

Participants included 118 children, ranging in age from 3 to 11 years of age (M = 6.99, SD = 2.57) undergoing venipuncture procedures from May 2005 to November 2005 as part of their care at a children's medical facility in the southeastern United States (See Table 1). All children were referred by a physician to the medical facility to receive the venipuncture procedure. Sixty-two children were female (52.5%) and 99 were Caucasian (83.9%). Eight children were African American (6.8%), six were Hispanic (5.1%), three were Asian (2.5%), and two children were reported as "Other" by their caregiver (1.7%). According to caregiver report, 68 children (57.6%) did not have a currently diagnosed chronic illness or medical condition and 87 (73.7%) had previously received a venipuncture procedure. Three caregivers (2.5%) failed to report how many venipunctures their child had previously received. Reasons for children receiving the venipuncture procedure were variable. Some common reasons included annual check-up, allergy testing, pre-surgery, medication management, and medical and genetic illness diagnosis.

Most children were accompanied by a female caregiver (104 children, 88.1%). Three of the female caregivers were grandmothers and the rest were mothers. The remaining 14 children (11.9%) were accompanied by their fathers. In order to simplify language, all mothers, fathers, and grandmothers will be referred to as "caregivers" for the remainder of this paper. Caregivers ranged in age from 23 to 60 years (M = 37.97, SD = 6.24) and 103 (87.3%) were Caucasian. Two caregivers failed to report their age. Seven were African American (5.9%), six were Hispanic (5.1%), and two were Asian (1.7%). Eighty-eight caregivers (74.6%) reported their annual

family income. Mean family income was \$114,614.20 (SD =\$89,859.47). Caregivers average years of education were 15.42 (SD =2.16). Six caregivers (5.1%) failed to report their highest level of education. One-hundred and three caregivers (87.3%) were married, five (4.2%) were single, four (3.4%) were divorced, one (0.9%) was separated, one (0.9%) was engaged, and three (2.5%) failed to report their marital status.

Measures

Background Information (Appendix A)

Caregivers who accompanied participants to the venipuncture procedure completed a background history form. Questions included the child's date of birth, caregiver age, caregiver and child races, genders, family income, caregiver years of education, child's current medical status, and how many previous venipunctures the child had received.

Child Pain

Child self-report. The Faces Pain Scale-Revised (FPS-R; Hicks et al., 2001; Appendix B) was utilized to assess children's self-reported pain associated with the medical procedure. The FPS-R consists of six cartoon faces exhibiting increasing levels of pain intensity. Some advantages for utilizing the FSP-R compared to other facial pain scales is that the cartoons are race and gender neutral; tears and smiling faces are not included, which has been shown to bias reports (Chambers & Craig, 1998); scores can easily be compared to other measures; and it has demonstrated adequate reliability and validity (Bieri, Reeve, Champion, Addicoat, & Ziegler, 1990; Hicks et al., 2001).

Prior to the venipuncture, children were asked two questions about their current and anticipated pain. An explanation about the measure was presented first, "These faces show how much something can hurt. This face shows no pain. The faces show more and more pain up to this one, it shows very much pain." Then children were instructed to "Point to the face that shows how much you hurt right now" and "Point to the face that shows how much you will hurt during the procedure." After the venipuncture, children were presented with the explanation of the measure then were asked the following questions about their pain, "Point to the face that shows how much you hurt during the procedure" and "Point to the face that shows how much you hurt right now." Scores on the FPS-R range from 1 to 6, with 1 representing no pain and 6 representing very much pain. The post-procedure FPS-R was the primary child report of pain utilized during analyses of study data.

Caregiver- and health care provider-report. Prior to and following the procedure, caregivers answered questions about their anxiety, as well as their child's pain and anxiety using 100mm horizontal line visual analog scales (VAS; Appendix C). Pre-procedure questions included: "How anxious were you during your child's past venipunctures?", "How anxious are you now?", "How anxious will your child be during the procedure?", and "How much will the procedure hurt your child?" In addition, after the procedure, caregivers were asked the following questions: "How anxious were you during your child's procedure?", "How anxious are you now?", "How anxious were you during the procedure?", "How anxious are you now?", "How anxious were you during the procedure?", "How anxious is your child now?", "How anxious was your child during the procedure?", "How anxious is your child now?", "How much pain did your child experience during the procedure?", "How much did your behavior help your child during the procedure?", and "How much did the medical staff's behavior help your child during the procedure?". All ratings were scored with a ruler yielding a score ranging from 0 to 100 with higher scores indicating higher pain, anxiety, and less perceived help to children. The post-procedure caregiver report of child pain and anxiety were used in analyses. Other caregiver-report measures were examined outside this study.

Health care providers administering the venipuncture were asked to complete VAS (Appendix D) immediately preceding and immediately following the procedure in order to assess their perception of the child's pain and anxiety, as well as caregivers' anxiety and their own anxiety. Pre-procedure questions answered by health care providers included the following: "How anxious is this parent?", "How anxious is this child?", and "How anxious are you now?" After the procedure, health care providers were asked "How anxious was this parent during this child's procedure?", "How anxious was the child during the procedure?", "How anxious were you during the procedure?", "How much pain did this child experience during the procedure?" Similar to caregiver VAS, health care provider VAS scales ranged from 0 to 100 with higher scores indicating higher perceived pain or anxiety. The post-procedure health care provider-report data used in analyses.

Child Coping

Child self-report. Children completed the Child Approach-Avoidance Rating Scale – Revised (CAARS-R; See Appendix E) prior to and after the completion of the venipuncture procedure. The CAARS-R evaluates children's approach-avoidance coping, which was adapted from the Child Approach-Avoidance Rating Scale (CAARS). The CAARS (Bernard et al., 2004) is the only self-report pediatric procedural pain approach-avoidance scale for young children. The scale has good construct validity as evidenced by convergent and discriminant validity and decent reliability (Bernard et al., 2004).

The CAARS was revised for this study by asking separate questions about whether children prefer to look at the procedure and whether they prefer to talk about and ask questions about the medical procedure, thus separating the double-barreled question presented in the original CAARS. The CAARS-R consisted of four cartoon images of a child receiving an injection administered by a health care provider. The four images were identical, except the child's head is rotated so that the child is facing the injection or looking away from the injection in two images. In addition, in one set of pictures cartoon bubbles were added to represent the child asking questions and the health care provider talking to the child. While pointing to the first two pictures, the researcher explained the following about the pictures: "Child #1 likes to look at the injection" and "Child #2 likes to look away from the injection". Prior to the procedure, children were asked, "Which child will you be more like today?" Following the procedure children were asked, "Which child were you like today?" While pointing to the last two pictures, the researcher explained the following: "Child #3 likes to talk about and ask questions about the injection" and "Child #4 does not like to talk about and ask questions about the injection". Prior to the procedure, children were asked, "Which child will you be more like today?" and after the procedure, "Which child were you like today?" Children's combined score pre- and postprocedure were either 2 (approach), 3 (mixed), or 4 (avoid). The post-procedure CAARS-R was the primary approach-avoidance measure utilized in this study.

Caregiver- and health care provider-report. To assess for child approach-avoidance coping, caregivers responded to the following questions in VAS format before the procedure (See Appendix C): "Compared to same-age children, does your child prefer to watch medical procedures or look away?" and "Compared to same-age children, does your child prefer to ask questions or not ask questions about medical procedures?" After the procedure, caregivers answered the following questions: "Compared to same-age children, did your child prefer to watch the medical procedure or look away?" and "Compared to same-age children, did your child prefer to watch the medical procedure or look away?" and "Compared to same-age children, did your child prefer to

child prefer to ask questions or not ask questions about the medical procedure?" Scores range from 0 to 100, with higher scores reflecting an avoidance style of coping.

Caregivers were also asked to complete an additional measure, the Child Approach-Avoidance Rating Scale – Parent Report (CAARS-PR; Appendix F). The CAARS-PR was adapted from the CAARS-R to obtain caregiver's report about children's coping styles. Similar to the CAARS-R, the CAARS-PR consisted of four images of a child receiving a medical procedure administered by a health care provider. While pointing to the first two pictures, the researcher explained the following to the caregiver: "Child #1 likes to look at the injection" and "Child #2 likes to look away from the injection". Prior to the procedure, caregivers were asked, "Which one will your child be more like today?" Following the procedure caregivers were asked, "Which one was your child like today?" While pointing to the last two pictures, the researcher explained the following: "Child #3 likes to talk about and ask questions about the injection" and "Child #4 does not like to talk about and ask questions about the injection" and "Child #4 does not like to talk about and ask questions about the injection" and "Child #4 does not like to talk about and ask questions about the injection". Prior to the procedure, caregivers were asked, "Which one will your child be more like today?" and after the procedure, "Which one was your child like today?" Caregiver-report of child approachavoidance coping (e.g., from the VAS and the CAARS-PR) were examined outside this study.

To assess for child approach-avoidance coping, the health care provider administering the procedure responded to the following questions in VAS format before the procedure (See Appendix D): "Compared to same-age children, do you think this child will prefer to watch the medical procedure or look away?" and "Compared to same-age children, do you think this child will prefer to ask questions or not ask questions about the medical procedure?" After the procedure the health care provider answered the following questions: "Compared to same-age children, did this child prefer to watch the medical procedure or look away?" and "Compared to same-age children, did this child prefer to watch the medical procedure or look away?" and "Compared to same-age

same-age children, did this child prefer to ask questions or not ask questions about the medical procedure?" The scale yields scores ranging from 0 to 100 with higher scores indicating observing the child looking away from the shot and not asking questions (i.e., avoidant coping style). The health care provider-report of child approach-avoidance coping (e.g., VAS) were examined outside the study.

Treatment Satisfaction

The Treatment Satisfaction Inventory (TSI; See Appendix G) was developed to evaluate caregiver and health care provider reaction to the two distraction conditions. The TSI was based on the Treatment Evaluation Inventory – Short Form (TEI-SF; Kelley, Heffer, Gresham, & Elliott, 1989), a validated measure of caregiver and staff satisfaction of interventions for children. Given the high reading level of the TEI-SF and that it is not specific to needle treatments the TSI was developed. Caregivers of children participating in the study completed the measure following the procedure. At the conclusion of data collection, the health care providers participating in the study also completed the TSI to evaluate their satisfaction with the treatment conditions. Cronbach's alpha for the caregivers completing this measure was 0.92, suggesting good internal consistency in this sample.

Procedure

Children scheduled to receive venipuncture procedures and their caregivers were informed about the study by clinic personnel at the receptionist desk and directed to receive additional information from a researcher waiting near by. The research assistant further explained the study and obtained caregiver consent. One-hundred and thirty-six caregivers were approached to participate and the caregivers of 16 children receiving venipunctures declined participation. Three were too busy and two did not want their child to be videotaped during the procedure. Eight cited child factors (e.g., too nervous, received shots already) as their reason for not participating and five additional caregivers did not provide a reason for declining participation. One additional caregiver cited both child factors and not wanting to be videotaped as reasons for not wishing to participate. In addition, two children whose caregivers agreed for them to participate were found to be outside the specified age range (i.e., 3 to 11), thus they were not included in the final sample.

Caregivers and children completed their pre-procedure measures (i.e., FPS-R, CAARS-R, Parent Pre-Procedure VAS, and CAARS-PR) and then waited until they were called into the treatment room. At that time, participants were randomly assigned, in accord with a generated random number table utilizing the RanSL computer program (Bakeman, 1999), to one of the following three conditions: Standard Care Control, Low Distraction, and High Distraction. Thirty-eight children were randomized into the Standard Care Control condition, 43 into the Low Distraction condition, and 37 to the High Distraction condition. When the health care provider called the family for the venipuncture, the researcher accompanied them and informed the health care provider about the child's treatment assignment. The researcher reminded the health care provider to complete the pre-procedure measures (i.e., Health Care Provider Pre-Procedure VAS) and then left the room prior to the start of the venipuncture procedure. After the completion of the venipuncture and once the family returned to the waiting area, the researcher assisted them in completing the post-procedure measures (i.e., FPS-R, CAARS-R, Parent Post-Procedure VAS, CAARS-PR, and TSI). Children were given a certificate and stickers for their participation. After the family completed the measures, the researcher assisted the health care provider with completing the post-procedure measures (i.e., Health Care Provider Post-Procedure VAS).

Health care provider-reports of treatment satisfaction were obtained after the collection of study data was complete. Two health care providers who administered the majority of the venipuncture procedures to the children in this study completed the TSI for each of the study conditions. Both health care providers were licensed phlebotomists and were employed at the children's hospital for roughly the same amount of time.

Standard Care Control (Control)

In this condition, the health care providers were instructed to follow the normal routine for the venipuncture procedure. Although this may have included some distraction, no movie intervention was introduced. This condition provided a baseline of child procedural pain and anxiety.

DVD Movie Distraction (Low Distraction)

Children in the Low Distraction condition viewed an age appropriate movie on a hand held DVD player during the venipuncture procedure. The DVD player sat on the arm of the chair children sat in to receive their procedure. While in the waiting room, the researcher allowed children to choose whether to watch "Treasure Planet", "Finding Nemo", "Mulan", or "The Lion King". The movie was started by the researcher as soon as children entered the treatment room (i.e., approximately 5 minutes before the procedure) to allow them to become engaged in the movie. Researchers were responsible for turning on and off the DVD player before and after the procedure. No other training of the child, caregiver, or health care provider was provided. *Goggles Movie Distraction (High Distraction)*

Children in the High Distraction condition viewed an age appropriate movie via "iglasses[™]". "i-glasses[™]" are a headset consisting of goggles and headphones connected to a DVD player. The movie image was projected into goggles and the movie audio was heard through headphones. The researcher allowed children to select "Treasure Planet", "Finding Nemo", "Mulan", or "The Lion King" to watch during the procedure. When the child entered the treatment room, the researcher helped the child put on the "i-glasses[™]" and the movie was started approximately 5 minutes before the procedure to allow the child to attend to the distraction. No additional intervention was given to the child, caregiver, or health care provider.

RESULTS

Data Analyses Overview

Analyses were conducted in a series of steps. First, preliminary analyses were performed to provide a summary of demographic characteristics of the sample within each condition group (Control, Low Distraction, High Distraction) and information about the dependent variables (child post-procedure reported pain, caregivers' post-procedure report of child's pain and anxiety, and health care provider post-procedure report of child's pain and anxiety) and children's coping styles. In addition, analyses were done to ensure that the conditions were similar on demographic variables and pre-procedure measures (e.g., child report of anticipated pain, caregiver report of child's anticipated pain and anxiety, and health care provider post-procedure measures (e.g., child report of anticipated pain, caregiver, and own current anxiety). Second, associations between the dependent variables and demographic characteristics were examined. Finally, the primary analyses were conducted utilizing ANOVAs, and significant findings were followed up with *t* tests.

Some data were missing because participants did not complete all measures. In reports of children's pain and anxiety, 11 children (9.3%) did not report their own post-procedure pain; 3 caregivers (2.5%) failed to report their child's post-procedure pain and anxiety; for 6 participants (5.1%), health care providers omitted child's post-procedure pain; and for 4 participants (3.4%), health care providers omitted child's post-procedure anxiety. In addition, 3 caregivers (2.5%) omitted reporting their own anxiety during the procedure; and for 4 participants, (3.4%) health care providers failed to report parent anxiety during the procedure. For 4 participants (3.4%), health care providers also omitted their own anxiety during the procedure. In regards to children's coping styles, 13 children (11.0%) failed to answer one of both post-procedure

coping questions, thus their coping style could not be determined. Ten caregivers (8.5%) failed to answer all items on the satisfaction measure, thus total satisfaction scores could not be calculated for these caregivers. These data were left as missing data points in analyses and other actions (e.g., inserting a mean value) were not taken.

Preliminary analyses

Preliminary analyses were conducted for a variety of reasons. First, descriptive statistics were conducted to provide information about the samples demographic characteristics and to ensure that randomization resulted in equivalent groups. Analyses of variance (ANOVAs) were used to compare the three conditions (Control, Low Distraction, High Distraction) on child age, family income, and the number of prior venipunctures the child had received. The ANOVAs revealed no significant group differences (Table 1). In addition, ANOVAs were conducted on Table 1 *Continuous and Categorical Demographic Variables of Entire Sample and by Condition*

			Treatment Condit	tion	
	Entire Sample	Control	Low Distraction	High Distraction	
	(n = 118)	(n = 38)	(<i>n</i> = 43)	(n = 37)	
	M (SD)	M(SD)	M(SD)	M (SD)	$F(\mathrm{df})$
Child Age	6.99	6.78	6.93	7.27	0.36
(years)	(2.57)	(2.62)	(2.61)	(2.51)	(2, 117)
Family Income	114,614.20	89,666.67	119,564.06	137,307.69	2.09
(dollars)	(89,859.47)	(47,155.16)	(125,178.52)	(69,111.95)	(2, 87)
# of Prior	10.45	13.42	7.00	11.61	0.67
Venipunctures	(25.45)	(34.85)	(15.94)	(23.78)	(2, 114)
-	Entire Sample	Control	Low Distraction	High Distraction	X^2 (df)
Child Gender	52.5	63.2	55.8	37.8	5.11
(% Female)					(2)
Child Race	83.9	81.6	79.1	91.9	8.23
(% Caucasian)					(8)
Parent Gender	88.1	78.9	93.0	91.9	4.55
(% Female)					(2)
Parent Race	87.3	81.6	88.4	91.9	3.38
(% Caucasian)					(6)

Note: No significant group differences.

pre-procedure measures (e.g., child report of anticipated pain, caregiver report of child's anticipated pain and anxiety, and health care provider report of child, caregiver, and own current

anxiety) to ensure that there were no initial group differences. Results revealed no significant differences. Chi-square analyses indicated no differences between groups on child and caregiver race or child and caregiver gender (Table 1). Descriptive statistics were also performed on the dependent variables and children's coping styles (Tables 2 and 3).

			Treatment Cond	ition	
	Entire Sample	Control	Low Distraction	High Distraction	
	(n = 118)	(n = 38)	(n = 43)	(n = 37)	
	M (SD)	M(SD)	M(SD)	M(SD)	F(df)
Child Pain					
Self-report	3.16	2.97	3.25	3.24	0.21
-	(1.71)	(1.61)	(1.75)	(1.78)	(2, 105)
Caregiver-report	33.88	34.30	30.54	37.16	0.95
	(24.47)	(23.01)	(21.00)	(26.20)	(2, 103)
HCP-report	9.56	7.50	10.62	10.44	0.43
-	(16.10)	(12.89)	(17.23)	(17.89)	(2, 99)
Child Anxiety					
Caregiver-report	59.97	57.89	60.46	61.49	0.05
	(32.80)	(27.92)	(33.35)	(37.21)	(2, 103)
HCP-report	22.21	17.72	24.95	23.46	0.35
-	(32.62)	(25.39)	(36.33)	(34.79)	(2, 101)
Caregiver Anxiety					
Self-report	36.03	37.57	34.41	36.30	0.10
-	(31.12)	(28.95)	(31.48)	(33.49)	(2, 115)
HCP-report	6.73	5.78	7.79	6.40	0.11
-	(19.57)	(18.46)	(21.75)	(18.32)	(2, 114)
Satisfaction					
Caregiver-report	40.23	40.03	42.25	38.17	2.63
	(7.90)	(8.26)	(6.86)	(8.30)	(2, 108)

Table 2 Post-Procedure Report of Child Pain and Anxiety, Caregiver Anxiety, and Treatment Satisfaction: Entire Sample and by Condition

Note: No significant group differences. Child-report Pain: FACES-R scores ranged from 1 (no pain) to 6 (very much pain). Caregiver, HCP-report Pain and Anxiety: VAS scores, range 0 (no pain, not anxious) to 100 severe pain, very anxious)

			Coping Style		
	Entire Sample	Approach	Mixed	Avoidance	
	(n = 105)	(n = 33)	(n = 36)	(n = 36)	
	M(SD)	M(SD)	M(SD)	M(SD)	F(df)
Child Pain					
Self-report	3.16	2.90	3.19	3.42	0.94
	(1.71)	(1.59)	(1.77)	(1.76)	(2, 105)
Caregiver-report	33.88	25.75 ^a	31.97	40.80^{b}	2.93
	(24.47)	(20.48)	(22.96)	(27.95)	(2, 103)
HCP-report	9.56	9.28	5.14	11.63	0.19
-	(16.10)	(16.07)	(9.84)	(19.18)	(2, 99)
Child Anxiety					
Caregiver-report	59.97	53.25	58.03	65.11	1.07
- *	(32.80)	(36.14)	(31.61)	(31.06)	(2, 103)
HCP-report	22.21	24.16	15.77	23.24	0.47
	(32.62)	(33.31)	(25.98)	(38.06)	(2, 101)

Table 3 Post-Procedure Report of Child Pain and Anxiety: Entire Sample and by Coping Style

Note: No significant coping differences. Different subscripts in same row indicate approaching significant differences at p = 0.058. Child-report Pain: FACES-R scores ranged from 1 (no pain) to 6 (very much pain). Caregiver, HCP-report Pain and Anxiety: VAS scores, range 0 (no pain, not anxious) to 100 (severe pain, very anxious).

Second, associations were examined among demographic variables and the dependent variables in order to determine whether considerations (e.g., covariates) of these variables would be needed in subsequent analyses. Specifically, the relation between child age and number of prior venipunctures, collapsed across conditions, was correlated with child pain and anxiety (e.g., child-, caregiver-, health care provider-report). Results revealed significant negative correlations between child's age and child's report of post-procedure pain (r = -0.30, p < 0.01) and child's age and health care provider's report of child post-procedure pain (r = -0.21, p < 0.05), with younger age associated with higher pain. Thus, child age was entered as a covariate in subsequent analyses examining child report of post-procedure pain and health care provider report of child post-procedure pain and health care provider pain. No significant correlations were found between children's number of prior venipunctures and the dependent variables. Child ethnicity and gender were also examined with ANOVA procedures to determine whether child pain and anxiety differed across groups. No significant differences were found.

During the course of data collection, the health care provider venipuncture procedures changed (i.e., the institution implemented the use of vapocoolant cold spray or numbing cream as standard care). Therefore, additional ANOVAs were conducted to examine whether there were any differences on the dependent measures for 22 of the total 118 children (18.6%) who experienced the new procedures and those who did not. Results revealed a significant difference in caregiver post-procedure report of child pain, F(1, 115) = 5.03, p < 0.05, with children receiving numbing medication rated by parents as experiencing less pain. Thus, the use of numbing medication was entered as a covariate in subsequent analyses of caregiver post-procedure report of child pain. No other significant differences were found on the other dependent variables.

Primary Analyses

Five 3 x 3 analyses of variance (ANOVAs) were used to examine the impact of treatment condition (High Distraction, Low Distraction, Control) and coping (post-procedure CAARS-R Approach, Mixed, Avoidance) on the following dependent variables: child post-procedure reported pain, caregivers' post-procedure report of child's pain and anxiety, and health care provider post-procedure report of child's pain and anxiety. Main effects for condition and coping were examined as well as the interaction between the two factors (Aims 1, 2, & 3). Results revealed no significant interaction between condition and coping style and no main effects of condition or child coping style on any of the dependent variables (Tables 2 and 3). However, results approached a significant main effect of coping style on caregiver post-procedure report of child pain, *F* (2, 103) = 2.93, *p* = 0.058 (Table 3). Although not significant, the effect of coping style on caregiver report of child pain was followed-up with exploratory *t* tests. These analyses revealed that children with an avoidance coping style were rated by caregivers as experiencing

more pain during the venipuncture than children with an approach coping style, t (65) = 2.49, p < 0.05. There were no significant differences between caregiver-report of child pain for children with a mixed coping style and children with an approach or avoidance coping style. Of note, roughly equal numbers of children reported approach (33, 28.0%), mixed (36, 30.5%), and avoidance (36, 30.5%) coping styles on the post-procedure CAARS-R (Table 3).

To examine the impact of the distraction interventions on caregiver procedure-related anxiety (Aim 4), two ANOVAs were utilized. Dependent variables of caregiver-report postprocedural anxiety and health care provider-report of caregiver post-procedural anxiety were compared across the three conditions (High distraction, Low Distraction, Control). Results revealed no significant differences in caregiver anxiety across the conditions (Table 2).

One ANOVA was used to compare the High Distraction, Low Distraction, and Control conditions on TSI treatment satisfaction for caregiver report (Aim 5). No significant differences in caregiver satisfaction were found (Table 2). Statistical analyses were not conducted on healthcare provider TSI treatment satisfaction (Aim 5) due to the small number available (i.e., 2); however, average satisfaction scores for the treatment groups were as follows: Typical Care M = 37.00, Low Distraction M = 35.00, and High Distraction M = 15.50.

DISCUSSION

This study evaluated a movie distraction stimulus presented in low and high distraction conditions for children undergoing venipunctures. Additionally, children's coping styles were examined to determine whether coping style influences the effectiveness of the distraction interventions.

Effectiveness of Distraction Interventions

Results of the current study revealed no significant differences in child pain and anxiety as reported by children, their caregivers, and health care providers across the two distraction or control conditions. These findings are inconsistent with past research demonstrating that movie distraction interventions are effective at reducing children's distress during painful medical procedures (e.g., Cohen et al., 1997; DeMore & Cohen, 2005; MacLaren & Cohen, 2005). There are several viable explanations for the discrepancy in findings.

First, caregivers and health care providers in this study were not trained to coach children to attend to the distraction stimuli. This decision was guided by a prior finding suggesting that coaching is unnecessary when there is a sufficiently engaging distraction stimulus (MacLaren & Cohen, 2005). However, there are a number of prior studies suggesting that coaching is necessary to ensure that children engage in the intervention (e.g., Cohen et al., 2002).

Refraining from training staff was also deliberate because the intervention was designed to make it readily generalizable into a busy clinical setting. In other words, it is not timeefficient, cost-effective, or user-friendly to require that all staff coach children in clear specified ways when using a distraction intervention. Although translational research is encouraged and needed in the pediatric pain area (e.g., Powers, 1999), in this instance it might have undermined the effects of the intervention.

Second, the goggles distraction stimulus selected might have been flawed. Anecdotally, a number of children in the High Distraction condition took the goggles off their heads before the venipuncture procedure was complete. Perhaps these children preferred to look away from the movie to observe the medical procedure or to see their caregiver, thus decreasing the amount of time they were exposed to the distraction stimuli. In addition, having a foreign object covering their vision and muffling their hearing may have increased their distress. This is the first evaluation of goggles as an intervention and additional pilot work might be in order to determine whether they are acceptable to children. Further, other procedures (e.g., introduction of stimuli in the waiting room) might increase engagement with the goggles.

Third, effect sizes obtained in this study were relatively small, suggesting a lack of power to identify significant group differences. Effect sizes between the Control and Low Distraction condition ranged from 0.23 on health care provider report of child anxiety to 0.08 on caregiver report of child anxiety. Between the Control and High Distraction conditions effect sizes ranged from 0.19 on health care provider report of child pain and anxiety to 0.11 on caregiver report of child pain and anxiety. Effect sizes comparing Low Distraction to High Distraction ranged from 0.26 on caregiver report of pain to 0.01 on child report of pain. Although typically low power suggests insufficient sample size, in this case it is more likely due to a lack of strong effects of the distraction interventions examined. In this line of study, clinical significance is often a more important consideration than statistical significance. However, measures of clinical significance such as satisfaction with the intervention, were not found in this study.

Fourth, the dependent measures were all subjective ratings (child-, caregiver-, and health care provider-report) of children's pain and anxiety. Previous research has demonstrated the

importance of also including an observational measure of children's distress when distraction interventions are utilized. In a review by DeMore and Cohen (2005), distraction interventions resulted in consistently reduced observational measures of pain but results were less consistent when other measures of pain were examined, such as self-report and other's reports. For example, Cohen (2002) found significant distraction treatment effects with an observational measure but not for ratings provided by caregivers and health care providers. Additionally, Manne et al. (1992) found that children's, caregiver's, and health care provider's ratings of acute pediatric pain are associated with different factors. Specifically, child report of pain was found to correlate with age, which was consistent with preliminary analyses conducted in this study, where younger children were found to report more pain. Caregiver's ratings were found to mostly reflect their own anxiety about the procedure, whereas health care provider ratings were related to children's overt behavioral distress and also providers' past experiences with other children (Manne et al., 1992). Thus, the inclusion of an observational measure, which is often considered more objective than self-report measures, may have provided more in depth analyses of children's distress during the venipuncture procedure.

In addition, child-report, caregiver-report, and health care provider-report might be limited in that they often rely on a global evaluation of a complex procedural experience. For example, when asked about pain and anxiety, children, caregivers, and health care providers may base their ratings on a small but memorable portion of the painful experience. Specifically, they are likely to report a score reflecting the pain and anxiety during the actual venipuncture procedure (i.e., tissue damage) and not on the emotions prior to and following the venipuncture. In fact, behavioral data suggest that distraction is most effective at reducing anticipatory anxiety (i.e., prior to the tissue damage) and recovery anxiety and pain, such as the few minutes after a needle has been removed (e.g., Cohen, 2002; Cohen et al., 2006). Having children, caregivers, and health care providers rate pain and anxiety during different phases of the medical procedure may have revealed different results.

Another explanation for the lack of effects with health care provider's ratings might be their competing demands. In other words, health care providers must prepare medical equipment, reassure caregivers, explain the procedure, do paperwork, and perform other duties, which may interfere with their ability to attend and accurately rate children's pain and anxiety (MacLaren & Cohen, 2005). In fact, health care provider data had poor variability in this study. Overall, health care providers rated children as exhibiting "no pain" during the venipuncture 53.6% of the time and "no anxiety" during the venipuncture 50.9% of the time. This is inconsistent with children's self-report and caregivers' ratings. Specifically, 15.9% of children rated "no pain" and 3.5% of caregivers reported children experienced "no pain" and 2.6% reported "no anxiety" was experienced by children during the venipuncture procedure.

Finally, children in this study were older than children participating in other distraction interventions. MacLaren and Cohen (2005) compared the effectiveness of two distraction interventions in children 1 to 7 years of age, whereas children in this study ranged in age from 3 to 11. Perhaps the distraction stimuli utilized in this study were not as effective at reducing pain and anxiety associated with a venipuncture procedure in older children. This is consistent with a prior study with 9- and 10-year-olds receiving injections, in which no differences were found between distraction and control on child- or nurse-report (Cohen et al., 1999). In addition, children in this study are unique in that the majority had a history of receiving venipunctures. Children who received previous venipunctures may have already developed their own ways of dealing with the painful procedure and the introduction of distraction stimuli may have interfered with their routine and possibly even heightened their distress.

Due to the lack of significant group differences on children's pain and anxiety, it is not surprising that no significant group differences in caregiver anxiety and treatment satisfaction were found. In other words, research suggests that caregiver anxiety is closely linked to child pain and anxiety (Bernard et al., 2004; Cohen et al., 1997; LaMontagne et al., 1997; Wright et al., 1973). In addition, caregiver satisfaction with the procedure is most likely tied to how much anxiety and pain their child displays. As for health care provider satisfaction, it is likely that changes to routine are not readily accepted unless a clear and clinically significant improvement is evident. In the case where health care providers may perceive that additional efforts are required for little benefit, it is likely that their satisfaction would be low.

Coping Style

Analyses of child coping style approached significance, where caregivers rated children with an approach coping style as exhibiting significantly less pain than children with an avoidance coping style. This is consistent with a review by Rudolph et al. (1995), which found that approach coping behaviors were associated with less distress during acute medical procedures but contradicts the meta-analysis conducted by Suls and Fletcher (1985), which revealed that avoidant coping strategies are more beneficial at reducing short-term distress. Given that no differences between coping styles were found on children's and health care provider's reports of pain and anxiety and caregiver's reports of anxiety, interpretations of the relation between coping and distress in this study are limited. However, these tentative results may have occurred for a variety of reasons.

As mentioned previously, health care provider reports of child pain and anxiety lacked variability, reducing the likelihood of finding significant differences. It is interesting that

caregiver report of child pain differed across coping styles and their report of child anxiety did not. Perhaps, when compared to reports of anxiety, caregiver report of pain may be influenced by children's overt behaviors. And in turn, children's overt behaviors may be influenced by their natural coping style. For example, a child with an approach coping style may look at the procedure which caregivers may perceive as them experiencing less pain than a child with an avoidant style who looks away from the procedure. In addition, anxiety is often considered an internal response, which caregivers may not associate with specific overt coping behaviors. Thus, their reports of anxiety may not differ as a result of children's coping styles. Clearly utilizing a multi-method approach to measure distress and coping is important when examining relations among these constructs in children (Bernard et al., 2004).

Of note, children's self-report data suggest that the approach-avoidance coping may not be a dichotomous construct. Specifically, roughly one-third of children in this study reported a mixed coping style, which includes behaviors categorized as both approach and avoidant. For example, children might have reported that they watched the procedure (approach) but did not talk about or ask questions about the procedure (avoidance). Perhaps children's approachavoidance coping style is more appropriately represented on a continuum as opposed to a dichotomy. The presence of a mixed coping style would complicate implementation of the congruency hypothesis, which suggests that interventions to reduce procedural distress should match children's natural coping style (Christiano & Russ, 1998; Smith et al., 1989). It is unclear what interventions may be most effective for children who may both approach and avoid the medical procedure.

The development of children's coping styles may help explain why some children may have a mixed coping style. Perhaps children who utilize a mixed coping style during medical procedures differ from children who are approach or avoiders in important ways. Children may utilize a mixed coping style before they incorporate a stable coping style into their repertoire when confronted with a stressful situation (i.e., painful medical procedure). In addition, perhaps children with a mixed coping style differ in regards to age, gender, or medical experience compared to children with an approach or avoidance coping style; however, this was not examined in the current study. It could also be that children's responses reflect a fluid use of both approach and avoidance. For example, a child might approach at the beginning of the procedure and then avoid during the actual injection, and then approach again after the procedure. In addition, it is unclear whether and how caregivers own coping styles and behaviors during painful medical procedures may influence children's coping styles.

Given that there are very limited data in regard to children's approach-avoidance coping, additional work is needed in this area. In exploring this, it might be important to query children, caregivers, and health care providers about approach-avoidance in a manner that allows for a continuum of responses. An observational coding system might also help illuminate how children cope during specific phases of medical procedures (Bernard et al., 2004).

Limitations and Future Directions

Limitations of this study should be noted. First, the sample consisted of mostly uppermiddle class Caucasian children and families, which resulted in better internal validity but limited generalizability to children of different races/ethnicities and lower social economic classes. In addition, this study enrolled children receiving venipunctures thus limiting the generalizability to children receiving other procedures (i.e., immunizations). Also, most of the children in this study had already received at least one venipuncture, which may have influenced the effectiveness of the distraction interventions. Future studies should examine the effectiveness of distraction interventions and coping styles in children receiving various medical procedures and who are from diverse demographic backgrounds.

Second, problems with the distraction interventions should be noted. Specifically, children in the High Distraction condition often removed the goggles from their head before the procedure was complete. Perhaps offering incentives to keep the goggles on and to watch the movie would have decreased these behaviors. In addition, caregivers and health care providers may not have known how to direct children's attention to the distraction interventions. Thus, providing caregivers and health care providers with training about how to coach children to use the distraction interventions would be important.

Third, the implementation of this study in a clinical setting (e.g., outpatient lab in a children's hospital) created some difficulties. The procedures for administering venipunctures in the setting changed more than halfway through data collection. Numbing medication was utilized more frequently at the end of data collection, which influenced the primary outcomes examined in this study. Thus, additional analyses were conducted and appropriate statistical control was utilized to control for this difference. Another limitation related to the setting was the lack of variability in health care provider reports of child, caregivers, and their own feelings and behavior. This is problematic as health care providers often make decisions about what pain reduction medication children receive during painful medical procedures.

Fourth, the lack of an observational measure limits the ability to draw conclusions about the effectiveness of the distraction interventions at reducing children's distress, especially in terms of anticipatory and recovery phase distress. In addition, an observational coping measure could provide additional information about children's coping styles, including further examining the characteristics of a mixed coping style. Fifth, children's post report of their coping style was the only coping examined in this study. This does not take into account how the distraction interventions may have influenced children's natural coping styles or whether children can accurately predict the coping style they may engage in during a painful procedure. Future research should examine whether children's coping styles are influenced by pain management interventions and whether they can accurately predict their own coping styles. In addition, the influence of caregiver coping styles and caregiver behaviors during painful medical procedures on children's coping styles should be studied.

Future studies should continue to examine which distraction stimuli and interventions may be most effective at reducing distress in children undergoing painful medical procedures, as well as the role caregiver and health care provider coaching may play. In addition, identifying developmentally appropriate distraction stimuli would be an important endeavor for future researchers to pursue, as younger and older children may require different types of distractions to effectively reduce levels of pain and anxiety during painful medical procedures.

Conclusions

No differences in child pain or anxiety were found across two movie distraction stimuli conditions and a typical care condition for children receiving venipuncture procedures. In addition, there was no indication of an interaction between children's natural coping styles and the effectiveness of the distraction interventions. Results on caregiver ratings suggested that children with an approach coping style may experience less venipuncture pain than do children with an avoidance coping style. Examinations of approach-avoidance coping revealed that children may also have a mixed coping style, which consists of a combination of both approach and avoidance coping behaviors. Further research is necessary to examine whether approachavoidance coping reflects a dichotomy or a continuum of coping. Caregivers reported children experienced moderate levels of anxiety during the venipuncture procedure, suggesting that developing interventions to reduce children's anxiety during painful medical procedures is warranted, as well as continuing to examine how children coping styles may be related to the effectiveness of these interventions. In conclusion, current finding do not answer whether distraction and procedural distress are linearly related. However, the results as well as the lack of results contain important avenues for further study of children's coping and distress associated with invasive pediatric medical procedures.

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APPENDIX A

Background Information

Background Information

Questions about the Family			
What is your relation to the child?	Your gender?	Your race	?
Your age (years & months)?	Are you single, m	arried, separated	d, divorced?_
What is the highest grade you completed (HS =	= 12, College grad = 1	6, etc.)? S	pouse's?
Approximate total family annual income?	/year		
How many other children live in your home?	What are their a	ıges?	
Questions about the Child			
Gender of the child? Child's race?	Child's dat	te of birth?	
Is this child currently on any medication (pleas	se circle)?	YES	NO
If so, what kind	and for what? _		
Does your child have a chronic illness or media	cal condition? YES	NC)
If so, what is it?			
Approximately how many times has this child	received venipuncture	es (e.g., blood di	raws)?
Why have they received them previously?			
Why is your child receiving a venipuncture to	lay?		
When and how did your child learn that he/she			

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., marking in the middle indicates that you view this child as about the same as other children).

Quiet	Loud
Shy	Outgoing/Social
Calm	Active
Not easily upset	Easily upset
Easy to soothe when upset	Difficult to soothe
Fearful	Not fearful at all
How distressed was this child during previous venipunctures?	
Not distressed	Very distressed

APPENDIX B

Faces Pain Scale – Revised

Faces Pain Scale - Revised

For Researcher Use

Show the child the laminated Faces Pain Scale-Revised (FPS-R)

Say:

These faces show how much something can hurt. This face (point to the left most face) shows

no pain. The faces show more and more pain (point to each from left to right) up to this one

(point to right most face) it shows very much pain.

For Pre-Procedure Say:

1. Point to the face that shows how much you hurt right now

Child's response: Face #_____

2. Point to the face that shows how much the needle will hurt you

Child's Response: Face # _____

Show the child the laminated FACES Pain Scale-Revised (FPS-R)

For Post-Procedure Say:

1. Point to the face that shows how much the needle hurt you

Child's response: Face #_____

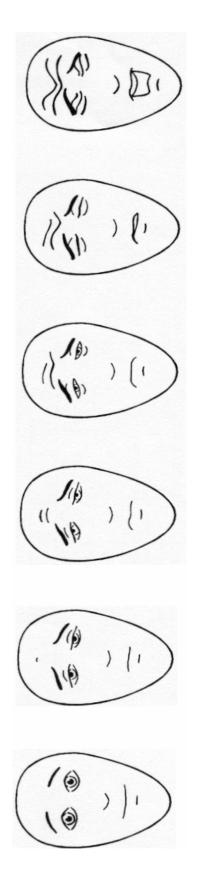
2. Point to the face that shows how much you hurt right now

Child's response: Face #_____

Note: Score the chosen face 1, 2, 3, 4, 5, or 6 counting from left to right.

Do not use words like "happy" and "sad". This scale is intended to measure how children feel

inside, not how their face looks.



APPENDIX C

Caregiver Visual Analogue Scales

Parent Pre-Procedure VAS

Please answer the following questions using the lines below. Please put a mark on the line so that it intersects. If you have any questions, feel free to ask.

1. How anxious were you during your child's past venipunctures?	
Not Anxious	Very Anxious
2. How anxious are you now?	
Not Anxious	Very Anxious
3. How anxious will your child be during the venipuncture?	
Not Anxious	Very Anxious
4. How much will the venipuncture hurt your child ?	
No Pain	Severe Pain
5. Compared to same-age children, does your child prefer to watch med away?	ical procedures or look
Watch	Look away
6. Compared to same-age children, does your child prefer to ask question about medical procedures?	ons or not ask questions
Ask questions	Not ask

Parent Post-Procedure VAS

Please answer the following questions using intersecting lines in the same way you did on the last form. If you have any questions, feel free to ask.

1. How anxious were you during your child's venipuncture?	
Not Anxious	Very Anxious
2. How anxious was your child during the venipuncture?	
Not Anxious	- Very Anxious
3. How much pain did your child experience during the venipuncture?	
No Pain	- Severe Pain
4. Did your child prefer to watch or look away from the venipuncture?	
Watch	– Look away
5. Did your child prefer to ask questions or not ask questions about the venipu	uncture?
Ask questions questions	– Not ask
6. How much did your behavior help your child during the venipuncture?	
Not at All	Very Much
7. How much did the medical staff's behavior (e.g., distraction, medication) during the venipuncture?	help your child
Not all	Very Much

APPENDIX D

Health Care Provider Visual Analogue Scales

Health Care Provider Pre-Procedure VAS

Please answer the following questions using the lines below. Remember to write a mark so that it intersects the line. If you have any questions, feel free to ask.

1. How anxious is this parent ?	
Not Anxious	Very Anxious
2. How anxious is this child ?	
Not Anxious	Very Anxious
3. How anxious are you now ?	
Not Anxious	Very Anxious
4. Compared to same-age children, do you think this child will prefer to watch or from the venipuncture?	look away
Watch	Look away
5. Compared to same-age children, do you think this child will prefer to ask ques questions about the venipuncture?	tions or not ask
Ask questionsquestions	Not ask

Health Care Provider Post-Procedure VAS

Please answer the following questions using the lines below. Remember to write a mark so that it intersects the line. If you have any questions, feel free to ask.

1. How anxious was this parent during this child's venipuncture?	
Not Anxious	Very Anxious
2. How anxious was this child during the venipuncture?	
Not Anxious	Very Anxious
3. How anxious were you during the venipuncture?	
Not Anxious	Very Anxious
4. How much pain did this child experience during the venipuncture?	
No Pain	Severe Pain
5. Did this child prefer to watch or look away from the venipuncture?	
Watch	Look away
6. Did this child prefer to ask questions or not ask questions about the venipunctu	ire?
Ask questions questions	Not ask

APPENDIX E

Child Approach-Avoidance Rating Scale – Revised

Child Approach-Avoidance Rating Scale – Revised

For Researcher Use

Show the child the laminated Pre-Procedure CAARS-R.

For Pre-Procedure Say:

Child #1 likes to look at the needle (point to child #1). Child #2 likes to look away from the needle (point to child #2). Which child will you be more like today?

Circle Child's response: Child #1 Child #2

Child #3 likes to talk about and ask questions about the needle (point to child #3). Child #4 does not like to talk about or ask questions about the needle (point to child #4). Which child will you be more like today?

Circle Child's response: Child #3 Child #4

Show the child the laminated Post-Procedure CAARS-R.

For Post-Procedure Say:

Child #1 likes to look at the needle (point to child #1). Child #2 likes to look away from the needle (point to child #2). Which child were you more like today?

Circle Child's response: Child #1 Child #2

Child #3 likes to talk about and ask questions about the needle (point to child #3). **Child #4 does not like to talk about or ask questions about the needle** (point to child #4). **Which child were you more like today?**

Circle Child's response: Child #3 Child #4

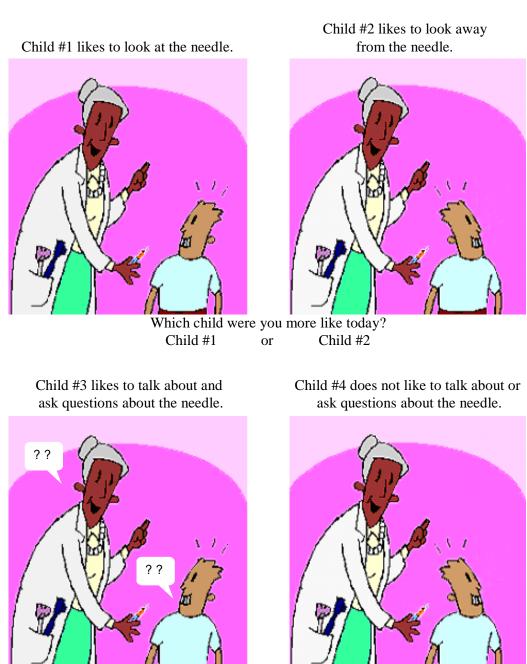
Child #2 likes to look away Child #1 likes to look at the needle. from the needle. Which child will you be more like today? Child #1 Child #2 or Child #3 likes to talk about and Child #4 does not like to talk about or ask questions about the needle. ask questions about the needle. ?? Which child will you be more like today?

or

Child #4

Child #3

Pre-Procedure CAARS-R



Post-Procedure CAARS-R

Which child were you more like today? Child #3 or Child #4

APPENDIX F

Child Approach-Avoidance Rating Scale – Parent Report

Child Approach-Avoidance Rating Scale – Parent Report

For Researcher Use

Show the parent the laminated Pre-Procedure CAARS-PR.

For Pre-Procedure Say:

Child #1 likes to look at the needle (point to child #1). **Child #2 likes to look away from the needle** (point to child #2). **Which one will your child be more like today?**

Circle Parent's response: Child #1 Child #2

Child #3 likes to talk about and ask questions about the venipuncture (point to child #3). **Child #4 does not like to talk about or ask questions about the venipuncture** (point to child #4). **Which one will your child be more like today?**

Circle Parent's response: Child #3 Child #4

Show the parent the laminated Post-Procedure CAARS-PR.

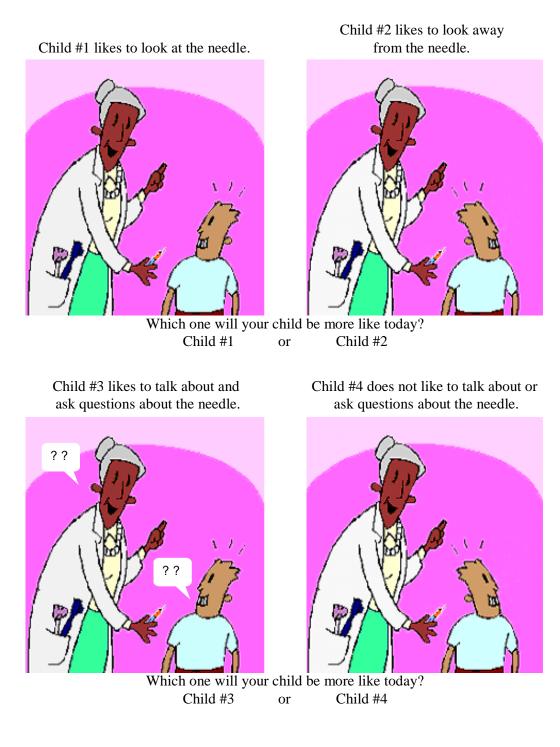
For Post-Procedure Say:

Child #1 likes to look at the needle (point to child #1). Child #2 likes to look away from the needle (point to child #2). Which one was your child more like today?

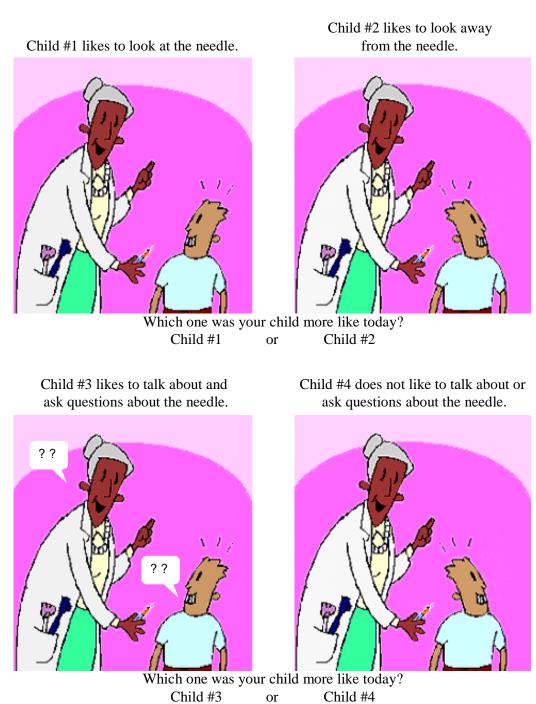
Circle Parent's response: Child #1 Child #2

Child #3 likes to talk about and ask questions about the needle (point to child #3). Child #4 does not like to talk about or ask questions about the needle (point to child #4). Which one was your child more like today?

Circle Parent's response: Child #3 Child #4



Pre-Procedure CAARS-PR



Post-Procedure CAARS-PR

APPENDIX G

Treatment Satisfaction Inventory

Treatment Satisfaction Inventory – Parent Report

Please use the scale below to circle the answer that indicates how you feel about each statement. There are no right or wrong answers. "Treatment" refers to the methods used to help your child during the procedure.

SD = Strongly Disagree		D = Disagree	N = Neutral	$\mathbf{A} = \mathbf{A}\mathbf{g}$	ree	\$	$\mathbf{S}\mathbf{A} = \mathbf{A}$	Stror gree	ngly
1.	This treatmen procedural dis		ealing with a child's		SD	D	N	А	SA
2.	-	nis treatment again it	f I wanted to lower a	child's	SD	D	N	A	SA
3.	 I believe that it would be ok to use this treatment with all 					D	N	A	SA
4.	-	s of this treatment.			SD SD	D	N	A	SA
5.	I believe this	treatment works.			SD	D	Ν	А	SA
6.	I believe that	children will not like	e this treatment.		SD	D	Ν	А	SA
7.	I believe this child.	treatment will have	good long-term effec	ts on a	SD	D	N	А	SA
8.	I would recon	nmend this treatmen	t to others.		SD	D	N	А	SA
9.	This treatmen	t is not helpful at all			SD	D	N	А	SA
10.	Overall, I am	very satisfied with t	his treatment.		SD	D	N	А	SA

Treatment Satisfaction Inventory – Health Care Provider Report

Please use the scale below to circle the answer that indicates how you feel about each statement. There are no right or wrong answers. "Treatment" refers to the methods used to help the children during the procedure.

SD = Strongly Disagree		D = Disagree	N = Neutral	A = Agree		SA = Strongly Agree			
1.	This treatmer procedural di		lealing with a child'	S	SD	D	N	А	SA
2.		his treatment again i	if I wanted to lower	a child's	SD	D	N	А	SA
3.		it would be ok to us ng this procedure.	se this treatment with	n all	SD	D	N	А	SA
4.	I like all parts	s of this treatment.			SD	D	N	А	SA
5.	I believe this	treatment works.			SD	D	N	А	SA
6.	I believe that	children will not lik	te this treatment.		SD	D	N	А	SA
7.	I believe this child.	treatment will have	good long-term effe	ects on a	SD	D	N	А	SA
8.	I would recor	nmend this treatmen	nt to others.		SD	D	N	А	SA
9.	This treatmer	nt is not helpful at al	11.		SD	D	N	А	SA
10.	Overall, I am	very satisfied with	this treatment.		SD	D	N	А	SA