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A Behavioral Intervention Targeting A Reduction In Child Distress During A Routine Immunization

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A BEHAVIORAL INTERVENTION TARGETING A REDUCTION IN CHILD DISTRESS DURING A ROUTINE IMMUNIZATION

by

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Bachelor of Science, University of Arizona, 2002
Master of Arts, University of North Dakota, 2005

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This dissertation, submitted by Matthew P. Myrvik in partial fulfillment of the requirements for the Degree of Doctor of Philosophy from the University of North Dakota, has been read by the Faculty Advisory Committee under whom the work has been done and is hereby approved.

[Signatures]

This dissertation meets the standards for appearance, conforms to the style and format requirements of the Graduate School of the University of North Dakota, and is hereby approved.

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Dean of the Graduate School

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ABSTRACT

As time advances and technology improves, children are benefiting from the newest interventions within the medical field. However, as a result, children are experiencing numerous invasive interventions potentiating an increase in pain and behavioral distress relating to these procedures. Furthermore, standard clinical practice continues to inadequately address prevention and treatment of procedural pain in children. Thus, the present study intended to evaluate the relationship between adult behaviors and child behaviors, the effectiveness of distraction as coached by adults in reducing pain and distress during routine immunizations, and two cost-effective means of teaching distraction techniques to parents (i.e., informational handout and video modeling). Ninety-seven children between the ages of 18 months and 72 months and their parents were recruited for this project and were randomly assigned to one of three groups while waiting for their immunizations: (1) Routine group which involves instructing the parents to aid their children as they typically would during the immunization and thus receiving no education on distraction techniques (n=32); (2) Distraction taught by instructional handout group which involves educating parents via an instructional handout as to various distraction techniques that can be utilized with their child (n=33); and (3) Distraction taught by video modeling group which involves educating parents via an 8-minute video demonstrating different distraction techniques that they can use with their child during the procedure (n=32). Based on previous findings, it was hypothesized that adult behavior (i.e., parent and nurse) would be
significantly related to child behavior. Furthermore, it was hypothesized that distraction as coached by adults would be significant in reducing child distress. Finally, it was hypothesized that differing formats of educating parents regarding distraction techniques would be significantly better in reducing child distress, increasing parent coping-promoting behaviors, and decreasing parent distress-promoting behaviors than the group receiving no distraction education. Observational measures and subjective ratings were used to assess the following dependent variables: children’s coping and distress behavior, parent and nurse distress-promoting behavior, and parent and nurse coping-promoting behavior (i.e., distraction). Results indicate that parent behavior is significantly related to child behavior, while nurse behavior has limited impact on child behavior. Distraction as coached by parents significantly reduced child distress, however, distraction as coached by nurses had limited impact on reducing child distress. Finally, distraction as taught by an informational handout or video modeling was no more successful in reducing child distress, increasing parent’s use of distraction techniques, and decreasing parent’s use of behaviors that induce distress in their children, than the group receiving no distraction education. Overall, the findings from this study lend support to the idea that parents need to be the target of interventions aimed at reducing child distress during painful procedures as their behavior directly impacts their child’s behavior. Furthermore, differing cost-effective means of teaching distraction to parents need to be incorporated in future research endeavors.
This dissertation is dedicated to my wife and family without whose continued love and support I could not have completed this work. This is also dedicated to my advisors, Drs. Margo Adams Larsen and Thomas Petros, who both provided excellent guidance and advice throughout this process.
CHAPTER I
INTRODUCTION

As time advances and technology improves, children are benefiting from the newest interventions within the medical field. However, as medical practice advances in the pediatric population, children are experiencing numerous invasive interventions potentiating an increase in pain and behavioral distress relating to these procedures (Jay & Elliot, 1984; Miser et al., 1987; Varni & Katz, 1987). Children are exposed to various medical procedures beginning with birth (e.g., heel sticks and circumcisions) and as the child journeys through childhood and into adolescence, they may be exposed to even more, potentially painful, medical procedures (e.g., routine immunizations, dental procedures, catheter insertion, chest tube placement and removal, lumbar punctures, bone marrow aspirations, venipuncture, burn/wound treatments). It is thus understandable why children report any procedure involving needles as the most common painful event (McGrath, Beyer, Cleeland, Eland, McGrath, & Portenoy, 1990; Taddio, Nulman, Goldbach, & Ipp, 1994) and the most difficult part of a hospital experience (Menke, 1981). The pain associated with needle-related procedures has been found to be more distressing and painful than an actual illness itself (Ljungman, Gordh, Sorensen, & Kreuger, 1999; Miser, Dothage, Wesley, & Miser, 1987). Children’s report of pain associated with medical procedures (i.e., needle procedures) is even more alarming considering that healthy children typically receive at least 14 injected immunizations between birth and 6 years of age (Blount et al., 1992; Cohen, 2002). Children with
chronic illnesses such as diabetes, immune (idiopathic) thrombocytopenic purpura, and cancer may experience even more procedure related pain. Despite the frequency with which children require painful medical procedures, standard clinical practice continues to inadequately address prevention and treatment of procedural pain in children (American Academy of Pediatrics Task Force on Pain in Infants, Children, and Adolescents, 2001; Hostetler, Auinger, & Szilagyi, 2002; Petrack, Christopher, & Kriwinsky, 1997; Walco, Cassidy, & Schechter, 1994).

Definition of Pain

Pain is an ambiguous term due to the subjective nature of the perception. This subjectivity includes factors related to the pain event as well as factors relating to the individual. Empirically speaking, pain has been operationally defined as an unpleasant sensory and emotional experience associated with actual and potential tissue damage adjacent to specific nerve fibers (International Association for the Study of Pain, 1979). The standard definition of pain requires a physical stimulus. However, one needs to consider the pain episode in the context of the individual’s characteristics and experiences as well. Thus, there are a number of factors that have been identified that impact pain reports through either amplification or diminishment in the level of pain reported (Franck, Greenberg, Stevens, 2000; McGrath & McAlpine, 1993; Ross & Ross, 1988; Schechter, 1985; Varni, Walco, & Katz, 1989; Zeltzer, 1994).

Pain Perception and Determinants of Pain Perception

Pain perception has been found to differ between individuals experiencing the same painful event (Franck, Greenberg, Stevens, 2000; McGrath & McAlpine, 1993; Ross & Ross, 1988; Schechter, 1985; Varni, Walco, & Katz, 1989; Zeltzer, 1994). This
variance can best be attributed to variables specific to each individual such as age, gender, or ethnicity. In the following sections, these variables will be described in more detail along with information regarding how each factor contributes to individual pain perception.

Age

Research has demonstrated that age is a factor that moderates individual's pain perception. Specifically within the pediatric population, researchers have noted that advancing age seems to be associated with less behavioral distress (e.g., wincing, crying, screaming) and self-reported pain in reaction to medical procedures (Bachanas & Roberts, 1995; Hubert et al., 1988; Jacobsen et al., 1990; Katz et al., 1980). Such findings may not reflect accurate age differences in pain, as these measures over-represent behaviors typical of younger children (e.g., crying, screaming, flailing) (Lander & Fowler-Kerry, 1991). For example, LeBaron and Zeltzer (1984) found that children experiencing bone marrow aspirations had a higher frequency of distress behaviors than did adolescents. When additional behaviors seen in adolescents (e.g., flinching and groaning) were additionally coded, age differences disappeared. When utilizing self-report measures, age differences have been found as well. For example, in a sample of children receiving venipunctures, Manne et al. (1992) found that younger children (aged 3-6 years) self-reported pain than did older children (7-19 years). This difference may be supported by the fact that as children develop, they are able to differentiate pain from variables similar to pain such as fear, nervousness, and anxiety (Carr, Lemanek, & Armstrong, 1998; Goodenough, Thomas, Champion, et al., 1999). Overall, these aforementioned ideas support the hypothesis that thresholds to noxious stimuli (i.e., pain)
increase with age and thus younger children report higher levels of pain when measured both through overt behavioral distress and self-report compared to older children when exposed to the same noxious stimuli (Chapman & Jones, 1944; Haslam, 1969; Schludermann & Zubek, 1962; Sherman & Robillard, 1960; Wolff & Jarvik, 1965).

Gender

Empirical support for gender as a factor moderating pain perception is inconsistent. Using self-report measures, several investigators have found that females endorse more pain and anxiety (Hilgard & LeBaron, 1982; Melamed & Siegel, 1975; Weisz et al., 1994). However, when overt behavioral distress (e.g., flailing, crying) is considered, some studies have found greater observational distress expressed in females (Hilgard & LeBaron, 1982; Katz et al., 1980) and others have reported no gender differences in observational distress (Hubert et al., 1988; Jacobsen et al., 1990). It has been hypothesized that these inconsistencies may in part result from the qualitative expression of distress differing by gender, with girls more likely to cry, cling, and seek emotional support and boys more likely to engage in uncooperative behavior, such as stalling (Katz et al., 1980). In addition, gender differences may be linked to socialization experiences where boys are encouraged to adopt more stoic attitudes about pain and girls are reinforced for passive, affective expression (McGrath, 1993). Furthermore, these results should be cautiously interpreted when applied to the pediatric population, as empirical studies evaluating this relationship in children vary by the means by which pain and distress are measured.
Ethnicity

Another moderating variable that has been demonstrated to relate to pain perception is ethnicity. Adult studies have found that pain perception differs between various ethnicities (Lipton & Marbach, 1984; Thomas & Rose, 1991; Zatzick & Dimsdale, 1990). In particular, research has found pain ratings to be generally higher in African Americans and Hispanic Americans than in Caucasian adults. Several studies using controlled laboratory stimuli provide evidence for ethnic differences in pain perception (Zatzick and Dimsdale, 1990). For example, Chapman and Jones (1944) reported lower heat pain thresholds and tolerances among African–American subjects compared to non-Hispanic Caucasian subjects. Woodrow et al. (1972) assessed pressure pain tolerance and found that African–Americans showed significantly lower tolerances than Caucasians. In more recent years, additional data demonstrating ethnic differences in pain perception have been reported using clinical samples. For example, African American chronic pain patients demonstrated lower tolerance for ischemic arm pain compared to non-Hispanic Caucasian patients (Edwards et al., 2001). Faucett et al. (1994) reported greater postoperative pain among Latino and African American patients compared to Caucasian patients. Also, following spinal fusion for scoliosis, African Americans reported greater pain than Caucasians (White et al., 1999). While these findings provide evidence of ethnic differences in acute clinical pain responses, it is important to note that several studies have reported no ethnic differences in acute clinical pain measures (Todd et al., 1994).

Empirical support for ethnic differences in pain perception within the pediatric population is limited due to the paucity of studies examining this phenomenon. Of the
studies examining ethnic differences in pain perception with child populations, significant cultural differences have been noted (Lewis et al., 1993; Rosmus, Johnston, Chan-Yip, Yang, 2000; Williams, 1996). Lewis et al. (1993) conducted a study on Japanese American and non-Japanese American infants receiving routine immunizations. The results revealed that the Japanese American infants exhibited less observed behavioral expression of pain than non-Japanese Americans. Similarly, in a study of Chinese Canadian versus non-Chinese Canadian 2-month-old infants receiving routine immunizations, Rosmus et al. (2000) found that the Chinese Canadian infants displayed greater overt behavioral distress independent observers using the Neonatal Facial Coding System. Although information regarding ethnic differences in pain perception is abundant in the adult literature (Lipton & Marbach, 1984; Thomas & Rose, 1991; Zatzick & Dimsdale, 1990), support for such findings in the pediatric literature is limited but promising (Lewis et al., 1993; Rosmus, Johnston, Chan-Yip, Yang, 2000; Williams, 1996).

Temperament

Pain perception has also been found to vary based on temperamental characteristics in children. In particular, research has found that children described by their parents as “difficult” reported a higher level of pain and somatization complaints than children described by their parents as “adaptable” (Grunau et al., 1994; Lee & White-Traut, 1996; Rocha, Prkachin, Beaumont, Hardy, & Zumbo, 2003; Schechter, Berstein, Beck et al., 1991). Schechter, Berstein, Beck, Hart, and Scherzer (1991) and Young and Fu (1988) reported that temperament dimensions of approach, nonadaptability, and rhythmicity correlated positively with pain behavior during
injections. Grunau, Whitfield, and Petrie (1994) reported that toddlers showing high emotional reactivity were also rated by their parents as highly sensitive to pain. Temperament dimensions reflecting the ease with which a child adjusts to new circumstances (adaptability) and the tendency to approach new situations (approachability) were related to distress during a voiding cystourethrogram (a notably painful procedure) (Merrit, Ornstein, & Spicker, 1994). Finally, Rocha et al. (2003) determined that preschool-aged children displaying “low adjustment” (e.g., negative mood, inadaptable, and withdrawn as rated by mothers) exhibited enhanced pain reactivity when receiving an injection as measured by the observational coding of each child’s facial expression. These findings provide support that a child’s specific temperament may result in differing pain perceptions in children exposed to similar noxious stimuli.

Procedural Pain

Procedural pain can take many forms within the pediatric population. Starting from birth, many infants are exposed to a variety of painful procedures such as heel sticks (for early screening of significant health concerns such as PKU, hypothyroidism, galactosemia), immunizations (Hepatitis B; Diphtheria, Tetanus, Pertussis; Haemophilus Influenza Type B; Polio), and circumcisions (generally elective procedure). In particular complications that are experienced surrounding pregnancy and birth (e.g., prematurity and low birth weight) may result in an infant experiencing additional invasive procedures. In a study examining premature infants, it was reported that 2 to 10 invasive procedures were conducted per day on the average newborn under 32 weeks gestational age and weighing less than 1,500 grams at birth (Johnston, Collinge, Henderson, &
Anand, 1997). These procedures are often life-saving measures that the need has been determined to outweigh the costs/risk, such as intubation, central venous access, lumbar puncture, feeding tube placements, and catheterization.

As children develop, they are generally exposed to painful procedures due to routine health management or health maintenance in relation to acute and/or chronic illnesses. For example, most children in the United States experience numerous injected immunizations between 2 to 15 months of age and again prior to entering school (Hepatitis B; Diphtheria, Tetanus, Pertussis; Haemophilus Influenza Type B; Polio; Pneumococcal; Measles, Mumps, Rubella; Varicella; Hepatitis A; Meningococcal; Influenza) (Blount et al., 1992; Cohen, 2002). When participating in these procedures, approximately 20 percent of children are reported to experience serious distress (as evidenced by overt behavior such as rigid posture, tense, white knuckles, sniffing, tearing) or more severe overt behaviors (e.g., irregular rapid movements, striking, screaming, flailing) (Jacobson, et al., 2001) prior to the procedure and approximately 45 to 90 percent report serious distress or more severe behaviors (as stated above) during the actual procedure (Jacobson, et al., 2001). Children with chronic illnesses such as insulin-dependent diabetes mellitus, renal failure, growth hormone deficiency, and idiopathic short stature may be exposed to additional procedures (e.g., multiple daily injections, finger pricks, repeated blood draws) and thus additional procedural pain. Some children with cancer undergo as many as 300 venipunctures during the course of their treatment (Jacobsen et al., 1990). These children and their parents have reported via structured interviews that pain due to medical procedures as a greater problem than pain due to the
illness itself (Ljungman, Gordh, Sorensen, & Kreuger, 1999; Miser, Dothage, Wesley, & Miser, 1987).

Implications of Procedural Pain

Inadequately managed pediatric procedural pain can potentially have immediate and long-term implications. Research has found that children as young as three years have accurate memory for details of procedures and pain events (Merritt, Ornstein, & Spicker, 1994; Zonneveld, McGrath, Reid, et al., 1997). Research has also found that distressed children, like distressed adults, can show attentional biases towards the negative components of the procedure to the exclusion of its positive or neutral aspects (Chen, Zeltzer, Craske, & Katz, 2000). This distortion of medical procedures may result in undue anxiety in children thus increasing distress when the child must undergo the same procedure on subsequent occasions (Blount, Piira, & Cohen, 2003; Blount, Sturges, & Powers, 1990; Dahlquist, 1999; Lander, Hodgins, & Fowler-Kerry, 1992; McGrath, 1990). Examples of this cycle have been found throughout the literature. One specific example involved a study analyzing the use of anesthesia for circumcisions in infants. Within this study, the infants that received a topical anesthetic demonstrated decreased behavioral response to immunization injections at 4 to 6 months of age than infants receiving no anesthesia (Taddio, Katz, Lane Ilersich, & Koren, 1997). Another study examining hospitalized children showed that increased quantity of invasive procedures was positively associated with more medical fears 6 months post discharge (Rennick, Johnston, Dougherty, et al., 2002). Finally, Princeton Survey Research Associates (1996) found that 23 percent of parents with children 13 years of age or younger report they have actually delayed or avoided medical procedures. The survey data indicated the reason for
this avoidance or delay was to avoid additional immunization procedures at the same time as another procedures perceived to be painful by the parent or child.

Even beyond the consequences of procedural pain present during childhood, research has also found that these consequences extend into adulthood. In a survey study by Pate, Blount, Cohen, and Smith (1996), recalled negative childhood medical experiences were predictive of elevated medical fear and avoidance of medical care as an adult. Furthermore, up to 25% of adults experience significant fear of needles, hospital and dental care, and have an avoidant attitude of health care (Costello, 1982; Hamilton, 1995; Ost, 1992; Oswalt & Hoff, 1975). Thus, without adequate pain management, highly aversive procedures are likely to result in a negative cycle of pain, distress, conditioned anticipatory anxiety, and more anticipation of pain for future procedures, which then results in avoidance of future medical procedures (Choiniere, 2001; Young, 2005). Avoidance of medical care could contribute to decreased health, resulting in the need for more invasive treatment procedures upon diagnosis. In addition, these negative childhood experiences could have a relationship with a parent’s adherence to standard of practice cares for their child.

Pediatric Pain Assessment

Past research has utilized various subjective and objective methods to assess pediatric pain (McGrath, 1990). The three typical methods used to assess pain consist of: pain intensity as reported by self or as reported by adults (i.e., parents or medical staff), physiological reactions (e.g., heart rate, arterial blood pressure, cortisol levels), and behavioral observations (e.g., facial expression, motoric movement, verbal utterances) (Blount, Seri, Benoit, & Simons, 2003; McGrath, 1990). Researchers typically
recommend using a combination of assessment instruments (i.e., self-report, adult report, physiological measures, behavioral observations) to provide the most valid picture of a child’s pain or distress response (Franck, Greenberg, & Stevens, 2000; McGrath, 1990).

**Child and Adult Ratings of Pain**

Child reports of pain and distress have been incorporated into many studies (e.g., Arts et al., 1994; Cohen et al., 1997; Gonzalez et al., 1993; Manne et al., 1990) assessing pediatric pain. Parent and medical staff reports of child distress/pain have also been utilized as a means of assessing pain (e.g., Cohen et al., 1997; Gonzalez et al., 1993; Manne et al., 1990). These assessment methods (i.e., parents and medical staff) provide a valuable source of information, as they provide a subjective rating from both the child, and an individual involved in the child’s pain episode. Two common types of assessment tools used for self-report and adult reports of pain are the visual analog scales (VAS) as well as faces scales (McGrath, 1990). Visual analog scales (VAS) usually involve a 10 cm line, presented vertically or horizontally, measuring a continuum of pain with endpoints labeled as “no pain” and “worst pain possible.” While viewing the scale, children are asked to mark somewhere along this 10 cm line as an indication of the amount of pain they are presently experiencing. The VAS has been used by children as young as 7 years (McGrath, 1990), however, it is recommended for older children due to the requirement of understanding concepts and abstract thinking thought to be required to complete this type of task. Research has shown that the minimum clinically significant threshold of pain in VAS scores is 10 to 13 mm thus indicating that 10 to 13 mm (e.g., rating of 80 to rating of 90) on the scale corresponds with actual changes in pain. (Gallagher, Liebman, & Bijur, 2001; Powell, Kelly, & Williams, 2001).
Faces scales (e.g., Faces Pain Scale-Revised; Hicks, von Baeyer, Spafford, van Korlaar, & Goodenough, 2001) have been typically used with preschool-age children. Faces scales generally consist of 5 to 9 faces, ranging from no pain (happy face or neutral face) to extreme pain (sad or distressed face), aligned in horizontal or vertical orientations. Cognitive requirements of this task would suggest that the child is developmentally able to complete ordering tasks such as ordering blocks. By performing such skills, it can be asserted that these children can rank pain and faces accordingly (i.e., least to worst pain). There has been considerable variability in the format of face scales. Face scales can vary in the number of faces, whether the no-pain anchor is smiling or neutral, and whether the faces are cartoon-like, realistic drawings, or actual photos as well as the orientation (horizontal or vertical) in which the scale is presented (Chambers, Giesbrecht, Craig, et al., 1999). The minimum clinically significant difference in pain report has been established to be one face (Bulloch & Tenebein, 2002). Researchers have suggested that it is optimal to have six faces depicted on the scale as it can easily be compared to other self-rating scales as well as observational scales which use a common metric of 0 to 5 Likert scales or 0 to 10 Likert scales (Hicks, von Baeyer, Spafford, van Korlaar, & Goodenough, 2001) and that neutral anchors are more valid for rating pain intensity (Chambers & Craig, 1998).

Some self and adult report scales assessing pain combine faces scales and VAS. One example is the Oucher Scale (Beyer, Denyes, & Villarruel, 1992). This particular scale combines six photographic faces spanning from neutral expression to one of apparent pain for use with younger children as well as a numeric rating scale ranging from 0 to 100 for older children (Beyer, Denyes, & Villarruel, 1992). This scale is a
thermometer-style scale, with no pain at the bottom, and most pain at the top of a vertically oriented graph.

Self-report pain scales (i.e., VASs and faces scales) are considered the ideal assessment approach due to the subjective nature of pain (Finley & McGrath, 1998). Faces scales and VASs have been found to be valid and reliable and have the ability to be used with diverse ethnicities (Beyer & Knott, 1998; McGrath, 1990). Furthermore, these measures have the advantage of providing efficient data collection for children, parents, and medical personnel. Medical staff ratings of pain can provide comparative evaluation of a child’s responses in similar procedures and settings. Parents’ ratings of pain can provide a comparative evaluation of how their particular child’s reactions during the current medical procedure compares to previous reactions to medical procedures or other experiences the child has endured (Blount et al., 1992).

Self-report assessment may be problematic in children because young children may not be as accurate in their estimates of pain, are more susceptible to response bias and situational demands, are less able to separate pain from other unpleasant emotions, and have fewer painful experiences from which to compare the current event (Blount, Piira, Cohen, & Cheng, 2006).

**Physiological Measures of Pain**

Physiological measures have also been utilized in the assessment of pediatric pain. Pediatric pain has been assessed via electroencephalogram (McGrath, 1990), functional magnetic resonance imaging (Anand, 1998b), vagal tone (Gunnar, Porter, Wolf, Rigatuso, & Larson, 1995), heart rate (Cohen, Blount, Cohen, Schaan, & Zaff, 1999), arterial blood pressure (Marchette, Main, Redick, Baggs, & Leatherland, 1991),
and intracranial pressure (Stevens & Johnson, 1994). More complex investigations of physiological responses to pain and distress have been associated with neurochemical and neurohormonal concentrations as well as palmar sweating (Franck & Gregory, 1995; Johnston, 1989).

Physiological measures have the benefit of providing protection to response bias and provide objectivity; however, these measures are not ideal for various reasons. For example, several physiological measures (e.g., heart rate, respiratory rate, blood pressure) are impacted by such factors as movement, emotional state, and temperature as well as pain factors (Berman, Duncan, & Zeltzer, 1992; Franck & Gregory, 1995). Furthermore, the invasiveness, discomfort, and expense of such procedures could hinder the application of these methods to clinical settings, especially for routine acute pain procedures such as immunizations. The nature of this type of measurement would add invasiveness to procedures and potentially confound the evaluation.

Behavioral Observation

Behavior observation measures how children respond physically to pain, rather than measuring pain directly, and are typically used to assess distress before, during, and after medical procedures (McGrath, 1990). In particular, behavioral observation coding schemes score overt pain behavior such as facial expression, crying, torso movements, kicking, verbal protest, and need for restraint (McGrath, 1990).

The Observational Scale of Behavioral Distress (OSBD; Jay, Ozolins, Elliott, & Caldwell, 1983) tracks the occurrence or non-occurrence of 11 distress behaviors during 15-second intervals. Examples of distress behaviors by category include: (a) information seeking (e.g., “When will you stop?”); (b) verbal resistance (e.g., “Stop” or “No more”);
(c) fear verbal (e.g., "I'm afraid"); (d) pain verbal (e.g., "That hurt"); (e) emotional support (e.g., "Hold me"); (f) cry (e.g., sobbing, crying sounds); (g) nervous behavior (e.g., lip chewing, nail biting); (h) screaming (e.g., audible yells); (i) muscle rigidity (e.g., visible tension in the body); (j) flailing (e.g., out of control motions in the hands or feet); and (k) physical restraint (e.g., due to physical out of control behavior, the child requires any type of restraint by staff or parent for the procedure to be completed). Individual distress behaviors are weighted on a scale of 1 to 4 on a basis of severity of distress they represent (Blount, Piira, Cohen, & Cheng, 2006). Other observational scales have been created for infants' procedural pain. The Modified Behavioral Pain Scale (Taddio, Nulman, Koren, Stevens, Koren, 1995) is a rating scale of facial expression, cry, and body movement indicators of infant pain. The Neonatal Facial Coding System (NFCS; Grunau & Craig, 1987) examines the 10 discrete facial movements indicative of infant pain expression (e.g., brow bulge, eye squeeze, nasolabial furrow, open lips, horizontal mouth stretch, taut tongue, lip purse, chin quiver, and tongue protrusion).

Behavioral observation scales are beneficial because they can be utilized for non-communicative children (Breau, McGrath, Camfield, et al., 2002; Soetenga, Frank, & Pellino, 1999). Furthermore, McGrath, Ritchie, and Unruh (1993) suggest that the best evidence for reliability and validity of behavioral observation is a short, sharp pain (e.g., needle insertion). Limitations of behavioral observations are that they may be time-consuming and often require videotaping so that behaviors might be coded or transcribed and coded at a later date (McGrath, 1990). Research suggests, however, these more time-consuming coded observational scales are probably most useful for research as opposed to fast-paced clinical settings.
Observational methods also offer a wealth of information about coping behavior and the behavior of others (McGrath, 1990). For example, behavioral observations of child coping behaviors (e.g., breathing, relaxation, distraction, imagery) and the coping-promoting behaviors (e.g., prompting the child to breathe or use other coping skills) of the parents and medical personnel are an integral portion of assessing pediatric pain.

The Child-Adult Medical Procedure Interaction Scale (CAMPIS; Blount et al., 1989) includes 35 child and adult behaviors. The 35 CAMPIS codes were later regrouped into 6 codes for CAMPIS-R (Blount et al., 1990, 1997). The measure has been widely used for monitoring child coping, caregiver coping prompting, and distress prompting behaviors (Blount, Cohen, Frank, et al., 1997). These scales have high reliability and validity (Blount et al., 2006); however, have been deemed intensive and time-consuming. Thus the CAMPIS-Short Form (CAMPIS-SF; Blount, Bunke, Cohen, & Forbes, 2001) was developed using the same behavioral categories as the previous CAMPIS measures, but requires less time. Initial reliability and validity data are promising (Blount et al., 2001).

Interventions Targeting Procedural Pain

Through the knowledge of assessing procedure-related pain, various treatment interventions have been implemented and investigated to assess their effectiveness in reducing reported pain and overt behavioral distress as a result of procedures within the pediatric population. Typically, procedural pain has been treated using medical techniques (such as pharmacological agents) that are intended to produce less pain, and psychological interventions (which most often occur as some form of distraction) that are intended to reduce fear and anxiety prior to and during the procedures, minimize distress...
and pain during the procedure, and increase children’s and parents’ sense of mastery during challenging medical procedures (Powers, 1999).

**Pharmacological Interventions**

In reviewing the corresponding literature, pharmacological interventions (i.e., topical and local anesthetics) have been implemented to decrease pain and distress from pediatric procedural pain (Eichenfield, Funk, Fallon-Friedlander, et al., 2002; Fetzer, 2002; Kim, Kini, Troshynski, et al., 1999; Kleiber, Sorenson, Whiteside, et al., 2002; Squire, Kirchhoff, & Hisson, 2000; Zappa & Nabors, 1992). In particular, a eutectic mixture of local anesthetics lidocaine and prilocain cream (EMLA) has been found to be effective in reducing the pain and distress of skin punctures (Fetzer, 2002). The drawback of this procedure however, is the 30-minutes required for the patch to be adhered and the skin to absorb the substances, and the limited body location for procedures. A new nonprescription topical anesthetic, 4% liposomal lidocaine has also been found to reduce pain associated with procedures (Eichenfield, Funk, Fallon-Friedlander, et al., 2002; Kleiber, Sorenson, Whiteside, et al., 2002). Other pharmacological interventions utilized to reduce pain associated with procedures are iontophoresis of lidocaine and vapocoolant sprays (i.e., ethyl chloride and fluoromethane). Both products have gained empirical support in their ability to reduce self-reported pain and diminish overt behavioral distress in children requiring invasive, painful procedures (Kim, Kini, Troshynski, et al., 1999; Squire, Kirchhoff, & Hisson, 2000; Zappa & Nabors, 1992).

In spite of these findings of effectiveness, many pharmacological interventions are not widely accepted because of inadequate pain reduction, the requirement of
a painful needle injection to anesthetize the skin, dermal irritation, and toxicity (Hallen, Carlsson, & Uppfeldt, 1985). Furthermore, criticisms relating to the cost of these interventions as well as the long delay to onset of effect (i.e., 40 to 60 minutes) has limited their functionality as interventions for most acute procedural pain. Thus, practical limits on the use of pharmacological agents have certainly been an impetus for the development of psychological interventions for procedural pain management in medical populations.

Non-pharmacological Interventions (Distraction)

Research as demonstrated several non-pharmacological interventions that can be used to decrease pain and distress related to procedural pain. Many of the cognitive-behavioral coping techniques described in the literature (e.g., those involving progressive muscle relaxation or combinations of breathing exercise, guided imagery, and positive self-talk) are too complex for a preschool-age child (Dahlquist, 1999). It seems pertinent to discuss an intervention specifically supported for children receiving the highest frequency of needle-related procedures (McGrath, 1990). Thus, the only non-pharmacological intervention that will be discussed will be age-appropriate distraction, which is an intervention that has been shown to be effective (Kleiber & Harper, 1999; McCaffery, 1990; Pederson, 1994; Vessey, Carlson, & McGill, 1994) in increasing coping behaviors related to procedural pain.

Physiological Mechanism of Distraction

The primary physiological rationale for distraction methods derives from the Gate Control Theory of pain (Melzack & Wall, 1965; Wall, 1978). According to this theory, when cells are damaged as a result of a noxious stimulus, peripheral nerves become
excited and emit impulses that are passed along to spinal cord systems and other neuroanatomical structures before they reach the cerebral cortex, where the pain experience is perceived (Melzack & Wall, 1965). The substantia gelatinosa functions as a gate control system that modulates (i.e., opens or closes the gate) the impulses traveling towards the brain before they ascend to the cerebral cortex (Melzack & Wall, 1965). Based on the Gate Control Theory, distraction works to exceed the pain input with non-pain input. When the non-pain input exceeds the pain input, the gate can be partially or entirely shut blocking the pain signal. Thus, a distraction intervention is thought to reduce pain via descending non-pain signals that interfere with the pain signal.

Behavioral Mechanism of Distraction

Behavioral explanations for distraction mechanisms can be offered in terms of classical conditioning principles. In terms of classical conditioning, a neutral stimulus is paired with a unconditioned stimulus (UCS) that consistently produces an unconditioned response (UCR). As a result of this pairing, the neutral stimulus becomes a conditioned stimulus (CS) that elicits the conditioned response (CR; previously the UCR). The CS typically elicits avoidant responding, which is reinforced by a reduction in fear that occurs after the response; thus avoidant responding can be maintained via negative reinforcement.

In painful pediatric procedures such as immunizations, the stimuli associated with the settings of the procedure (e.g., nurses) could become CSs. The UCS is the pain associated with the needle insertion and the pain related to the vaccine’s irritation of muscle tissue and the UCR is the pulling away from this stimulus. Functional responding
in attempt to avoid the CS and the UCS could include a wide range of child behaviors that function as CRs as well as to avoid the CS and the UCS (e.g., crying).

Cohen (2002) proposed that distraction functions to reduce the CR and the UCR associated with painful pediatric procedures by diverting attention from the unconditioned pain-eliciting stimulus and the conditioned stimuli paired with the pain. In particular, distraction prevents the development of a conditioned fear response (e.g., reduces or eliminates fear) by facilitating exposure to the CS in the absence of the UCS thus reducing the probability of a UCR (e.g., crying) from occurring.

Cognitive Mechanism of Distraction

The most applicable cognitive theory associated with distraction that has received attention in the literature is limited (attentional) capacity theory (LCT; McCaul & Malott, 1984). McCaul and Malott (1984) base LCT upon two assumptions that provide a rationale for distraction’s alleviation of pain. First, pain processing is regarded as an effortful, nonautomatic process, requiring the allocation of attention to the eliciting stimulus to be detected. Secondly, LCT assumes that attentional capacity is limited; if a task occupies all of an individual’s attentional resources then painful stimuli will not be perceived (McCaul & Malott, 1984). However, focused attention is rarely complete; therefore, there are circumstances in which distraction is more or less effective. Specifically, the greater the intensity of a noxious stimulus, or the lesser intensity of the distraction stimulus, the less effective distraction will be (McCaul & Malott, 1984).

Distraction Studies

The primary objective of distraction techniques is to modify behaviors, on the part of either the children or the adult, that may initiate, maintain, or exacerbate the child’s
perception of pain. Distraction accomplishes this task by redirecting attention (by prompts from nurse/parent or by distracting objects) from threatening and anxiety provoking aspects of medical treatments (e.g., sights, smells, and sounds of the procedure) to non-threatening objects or situations (e.g., videos, bubbles, balloons, non-procedural talking). The new behaviors created by distraction serve as a means of engaging the child in behaviors that are incompatible with anticipatory anxiety, distress, and pain, thus modifying pain perceptions (McGrath, 1991).

Distraction has been implemented in a variety of different formats such as talking and stories (Gonzalez, Routh, & Armstrong, 1993; Stark, Allen, Hurst, Nash, Rigney, & Stokes, 1989), music (Arts, Abu-Saad, Champion, Crawford, Fisher, Juniper, et al., 1994; Fowler-Kerry & Lander, 1987;), cartoons, (Cohen, Blount, & Panopoulos, 1997; Ellis & Spanos, 1994), imagery (Ellis & Spanos, 1994; Fanurik, Zeltzer, Roberts, & Blount, 1993; LeBaron, Zeltzer, & Fanurik, 1989;), kaleidoscopes (Vessey, Carlson, & McGill, 1994), breathing (Broome, Lillis, McGahe, & Bates, 1992; Ellis & Spanos, 1994; Jay, Elliott, Katz, & Siegel, 1987), blowing (Ellis & Spanos, 1994; French, Painter, & Coury, 1994; Manne, Redd, Jacobsen, Gorfinkle, Schorr, & Rapkin, 1990), and hypnosis (Jay, Elliott, Katz, & Siegel, 1987; Zeltzer, Fanurik, & LeBaron, 1989) and for a variety of different procedures such as bone marrow aspirations and lumbar punctures (Broome, Lillis, McGahee, & Bates, 1992; Ellis & Spanos, 1994; Jay, Elliott, Katz, & Siegel, 1987), dental procedures (Stark, Allen, Hurst, Nash, Rigney, & Stokes, 1989), immunizations (Blount, Bachanas, Powers, Cotter, et al., 1992; Cohen, Blount, & Panopoulos, 1997; Fowler-Kerry & Lander, 1987; French, Painter, & Coury, 1994; Gonzalez, Routh, & Armstrong, 1993), and venipuncture (Arts, Abu-Saad, Champion, Crawford, Fisher,
In regards to the effectiveness of distraction, two meta-analyses have been conducted. Initially, Broome, Lillis, and Smith (1989) published a meta-analysis of the pediatric pain management literature. The authors synthesized 27 studies over two decades and concluded that a small effect size was found between behavioral interventions, such as distraction, and respective reductions in overt behavioral pain ($r=.41$), self-report pain ($r=.34$), and physiological pain reports ($r=.30$). More recently, Kleiber and Harper (1999) conducted a second meta-analysis to review the effectiveness of distraction in treating procedural pain and found a moderate effect size. Kleiber and Harper's (1999) reviewed 19 published and unpublished well-controlled studies conducted between the years of 1966 and 1996 and concluded that an expected effect size (Cohen's d) for self-report pain was found to be 0.62 ($\pm 0.42$), and for behavioral distress the effect size was found to be 0.33 ($\pm 0.26$).

Parents

Social-learning theorists like Bandura (1977) argue that a large proportion of the behavior patterns people learn are acquired simply by observing performance of other people. Thus, as a child learns a behavior, it is the parents that provide the example of the behavior to be observed early in development. Thus, parents may play an instrumental role in aiding interventions geared at alleviating pain and overt behavioral distress during painful procedures; however, evidence is mixed as to whether parents' presence is helpful. Based on empirical findings, the effectiveness of parental assistance in pain-reducing interventions appears to depend on what the parents actually do (Piira,
Sugiura, Champion, Donnelly, et al., 2005; Piira & von Baeyer, 2001). For example, parents’ behavior in the treatment room may account for as much as 53 percent of the variance in child distress behavior (Frank et al., 1995). This is disconcerting considering parents are reported to display problematic behaviors from time to time in the treatment setting. Many parents state they do not know what to say or do to help their children cope with the pain (Bauchner, Vinci, & Waring, 1989; Merritt, Sargent, & Osborn, 1990; Schepp, 1991). General office procedures typically do not provide parent or child education related to the procedures that will occur. And further, parents may be stressed by their historical experiences of their own, their child’s or their child’s current avoidance behaviors that make advocating for more information or stating “what would you like me to do” to the nurse simply doesn’t happen. Parents are placed in a confusing situation because they are watching their children experience pain without knowing the skills to help their children cope with these painful procedures.

**Parents Present vs. Parents Absent**

The presence versus absence of parents during medical procedures has been extensively evaluated within the pediatric literature (Boudreaux, Fancis, & Loyaccano, 2002; Frankl et al., 1962; Shaw & Routh, 1982). Despite this attention, the effect of parental presence on children’s pain and distress response has been mixed and likely depends on the parent’s own anxiety level, parent-child interactions, and the parent’s ability to help the child cope effectively (Blount, Landolf-Fritsche, Powers, et al., 1991). One early study conducted in a dental clinic examined the effects of parental presence, specifically on maternal presence and absence during a dental procedure (Frankel, Shiere, & Fogels, 1962). This study evaluated young children ages 41 to 49 months whose
mothers were present versus those whose mothers were absent. The results indicated that children whose mothers were present cried less during a dental exam. It is possible that separation anxiety in the mother-absent condition may have triggered children's negative behavior, which then continued throughout the exam. Contrary to these findings, Vernon, Foley, and Schulman (1967) found that maternal presence during anesthesia induction resulted in less child distress in 2- to 5-year-old children than maternal absence. In 1982, Shaw and Routh reported that 18-month-old children displayed more crying and fussing prior to injection in a mother absent condition as opposed to a mother present condition; however, during the injection, the children in the mother present condition displayed more negative behaviors than the mother absent group. They also reported that 5-year-old children remained upset longer during the post-injection phase when mothers were present. Gross et al. (1983) reported that prior to injection, children ages 4- to 7-years-old displayed more crying when the mother was present than when their mother was absent. However, during the injection, when mother interaction was limited, the mother-present and mother-absent groups did not differ in observed distress. Similar to Shaw and Routh (1982), Gonzalez et al. (1989) examined 3-year-old and 5½-year-old children and reported that the older children displayed greater distress when a parent was present as opposed to when they were absent. Finally, Broome and Endsley (1989) found no significant differences in the distress exhibited by children during immunization on the basis of mothers' present or absence. Overall, it appears that the presence versus absence of parents during medical procedures is variable in terms of decreased child distress, but further consideration needs to be placed on what factors are interfering with the clarity of parental presence versus parental absence results.
Parental Behaviors during Procedures

The Proximal-Distal Model of Children's Coping and Distress During Acute Painful Medical Procedures (Blount, Bunke, & Zaff, 2000; Varni, Blount, Waldron, & Smith, 1995) suggests that parent in-session behavior has a direct impact on children's in-session coping and distress behavior. Supporting this model is the finding that parent behavior accounts for 53 percent of the variance in child distress behavior during medical procedures (Frank, Blount, Smith, Manimala, & Martin, 1995). In particular, research has shown that parents display various behaviors that can be typified as those that enhance child distress skills and those that enhance child coping skills (Blount et al., 1989; Dahlquist, Power, Cox, & Fernbach, 1994; Manne et al., 1992). Parental behavior during medical procedures that have gained empirical support for increasing distress in children and thus interfere with coping include: making reassuring comments (e.g., "It'll be all right"), making empathic comments (e.g., "I know it's hard"), apologizing (e.g., "I'm sorry you have to go through this"), criticizing (e.g., "You're being a baby"), bargaining with the child (e.g., "I'll get you a play station if you let them do it"), providing explanations during the procedure, giving the child control over when to start the procedure (e.g., "Tell me when you're ready"), and castrophizing and becoming agitated (Blount et al., 1989). In contrast parental behaviors that have been found to increase child coping during medical procedures include: non-procedural talk (e.g., birthday parties, pets, favorite activities, etc), distraction methods (e.g., favorite music, toys, games, bubbles, clowns, etc.), prompted breathing techniques, and adult prompting of the child to use coping strategies.
Based on these findings, statements that promote distress during medical procedures (e.g., reassurance, empathy, apologizing) fail to distract the child’s attention away from the painful procedure. In fact they focus the child’s attention on the threatening and painful aspects of the medical procedure or on their own negative reactions, which often makes the procedure more distressing (Blount et al., 1989; Dahlquist, Power, Cox, & Fernbach, 1994; Manne et al., 1992). However, because coping promoting and distress promoting are appear to be mutually incompatible behaviors, assuring that parents engage in more coping-promoting behaviors simultaneously assures that they engage in fewer of the undesirable distress-promoting behaviors. Based on these findings, parent coping-promoting behaviors can directly and positively impact child coping while decreasing distress.

Parents as Coaches

Using the assertion that parent coping-promoting behaviors can increase child coping (e.g., Gonzalez et al., 1993; Manimala, Blount, & Cohen, 2000; O’Laughlin & Ridley-Johnson, 1995), it appears that this should be the focus of interventions designed at distracting children during invasive medical procedures. Although the current pediatric literature emphasizes the importance of families in helping children cope with medical procedures (Melamed & Ridley-Johnson, 1988), the majority of research on distraction has been done using professionals (i.e., nurses, psychologists, child life specialists) as the prompters for distraction techniques. While, this may be the preferred role from a child or parent basis, the literature would suggest teaching the parent a bit about pain-related procedural “etiquette” would be helpful. In addition, the role of
parents as “distraction coaches” has not been thoroughly explored (Kleiber, Craft-Rosenberg, & Harper, 2001).

Relatively few studies have examined the effectiveness of parents as distracting coaches in children experiencing painful medical procedures (e.g., Gonzalez et al., 1993; Manimala, Blount, & Cohen, 2000; O’Laughlin & Ridley-Johnson, 1995). Manimala, Blount, and Cohen (2000) compared the effects of parental distraction (taught through role-playing and modeling distraction with a party blower) versus parental reassurance on eighty-two children between the ages of 3.8 and 5.9 years receiving routine immunizations. The results indicated that children in the distraction group demonstrated a decrease in distress levels relative to the children in the parental reassurance group. Furthermore, children in the reassurance group were restrained during a greater proportion (three times more) of the immunization procedures. Gonzalez et al. (1993) examined the effects of maternal distraction and reassurance on children’s reactions to immunizations. The sample of forty-two 3- to 7-year-old children and their mothers, groups were taught instructions on how to reassure their child or were taught on how to distract their child via an audiocassette and role-playing. The results demonstrated that children in the distraction group exhibited less behavior distress than children in the maternal reassurance group or the control group. O’Laughlin and Ridley-Johnson (1995) assessed the effect of varying levels of maternal assistance on thirty-six children receiving routine immunizations during their 5-year well-child visit. The mother-child dyads were randomly assigned to one of four groups: mother present as usual, mother absent, mother watching the procedure but not actively participating, and mother as a coping coach. For the last group, the mothers were taught distraction procedures via
handout on distraction. The results determined that limited maternal involvement (watch condition) resulted in less behavioral distress than any of the other conditions.

These findings provide support to the assertion that parents can aid in distraction interventions geared at reducing pain and distress in children experiencing painful procedures, however, more research is needed to further evaluate the effectiveness in parents as coaches as well as how best to educate these parents.

**Benefit of Parents as Coaches**

In addition to the empirical evidence supporting the use of parents as coaches in distraction, parents are ideal for several additional reasons. First of all, parents are likely to remain present during general non-invasive procedures, such as immunizations, blood draws, suturing, or dressing wounds (Boie, Moore, Brummett, et al., 1999; Boudreaux, Francis, & Loyacano, 2002). Secondly, parents provide valuable information as to previous experiences their child may have in relation to painful procedures. Third, parents know what is likely to interest their own child and what will hold their attention during the distraction procedure. Fourth, distraction will result in a reduction of parents’ anxiety by giving them an assigned role as well as teaching parents techniques that can be used for other painful events in the future (Kleiber, Craft-Rosenberg, & Harper, 2001). Fifth, parents can be a source of comfort, reassurance, and security for their children (Peterson & Mori, 1988). Finally, once parents learn how to use distraction, it can be performed in settings outside of the hospital that induce fear or distress in their child (Kleiber, Craft-Rosenberg, & Harper, 2001).

Additional benefits include the ease of integration of such an intervention into health care setting and clinic time. Potentially significant financial costs and time
considerations are associated with interventions that require as much as 15 minutes be
added to each families visit in order to train parents and children. Such training could
maximize ease of use (for staff and parents) by minimizing the length of each family’s
visit because the training can be accomplished in relatively short time while the family is
waiting for the immunization in the waiting room (DeMore & Cohen, 2003).

The Present Study

Research demonstrates that parents can be effectively trained in the use of
strategies to assist children during immunizations, although further research is warranted
to provide clearer direction for which coping/distraction strategies are the most effective
in reducing distress as well as how best to implement such procedures. The current
clinical setting culture allows parents to choose to remain present for procedures, which
they generally do (per nursing reports). Thus, it seems advantageous to teach parents
skills that will aid in distraction as opposed to having parents display distress-promoting
behaviors that typically occur when parents are allowed to participate “as usual” during
procedures (Frank et al., 1995; Kleiber, Craft-Rosen, & Harper, 2001; Manne, Bakeman,

Since parent behavior often serves to modulate child distress during painful
medical procedures, it seems imperative that the transition and training of parents to be
change agents is necessary (Blount, Corbin, Sturges, Wolfe, Prater, James, 1989). Thus,
the present study evaluated specific features of teaching distraction to parents as a tool to
aid their children in coping with routine immunizations. Thus, the study consisted 99
child and parent dyads between the ages of 18 months and 7 years that were divided into
three groups of parents receiving varying degrees of distraction training. In the “routine”
group, parents were instructed to coach their child "as usual" during the immunization process and received no other training regarding distraction procedures. They were told to remain in the room during the entire procedure so that all individual's behaviors could be coded. In the distraction training via "handout" group, the parents were informed of various distraction procedures via a handout that they received in the waiting room prior to the immunization. Then were prompted to use the techniques described in the handout to aid their child during the immunization procedure. Finally, in the distraction via "video training" group, the parents were instructed in how to use the same distraction techniques covered in the handout, through a brief introduction and observation of role-plays in an 8-minute video. Thus, this group received the added benefit of visual modeling of the distraction techniques. The video training group was also prompted to use the techniques described on the video to aid their child during the procedure.

What New Does This Study Add?

As presented in the materials above, distraction has been found to be moderately effective in reducing pain in children experiencing painful procedures. Furthermore, an argument has been made above that parents are important individuals that can aid children in reducing pain. However, in order for an intervention to be utilized in the clinical setting, it must be cost-effective and thus utilize very few resources from a clinic. Thus, the aim of this project was to demonstrate the relationship between parent and nurse behavior and child behavior during immunizations. Additionally, the project was to evaluate the effectiveness of distraction in reducing children's behavioral distress during routine immunizations. Finally, the project was to evaluate the most effective method of teaching distraction to parents to use on their kids.
Hypotheses

Specific research questions addressed in this study include: (1) Children’s overt behavior during the immunization session would be correlated with their parent’s overt behaviors as measured by the CAMPIS-R. More specifically, children would display more distress when their parents displayed more distress promoting behaviors. Additionally, children would display more coping behaviors when their parents displayed more coping promoting behaviors. (2) Children’s overt behavior during the immunization session would be correlated with the nurse’s overt behaviors as measured by the CAMPIS-R. More specifically, children would display more distress when the nurses displayed more distress promoting behaviors. Additionally, children would display more coping behaviors when the nurses displayed more coping promoting behaviors. (3) When parents performed more distraction (i.e., coping promoting behaviors) during the immunization procedure as measured by the CAMPIS-R, their children would demonstrate significantly less distress as measured by child self-report, parent report of child behavior, nurse report of child behavior, and independent rater of child behavior (i.e., CAMPIS-R). (4) When nurses performed more distraction (i.e., coping promoting behaviors) during the immunization procedure as measured by the CAMPIS-R, the children would demonstrate significantly less distress as measured by child self-report, parent report of child behavior, nurse report of child behavior, and independent rater of child behavior (i.e., CAMPIS-R). (5) There would be a significant difference in overt behavioral distress between the child participants using distraction (via handout or video modeling) and those in the routine group, with a preference towards even lower distress levels in the distraction via video modeling versus the
distraction via handout. (6) There would be a significant difference in post-procedural self-reported pain ratings between the child participants using distraction (via handout or video modeling) and those in the routine group, with a preference towards even lower pain levels in the distraction via video modeling versus the distraction via handout. (7) There would be a significant difference in post-procedural parent-reported pain ratings between the child participants using distraction (via handout or video modeling) and those in the routine group, with a preference towards even lower pain levels in the distraction via video modeling versus the distraction via handout. (8) There would be a significant difference in post-procedural nurse-reported pain ratings between the child participants using distraction (via handout or video modeling) and those in the routine group, with a preference towards even lower pain levels in the distraction via video modeling versus the distraction via handout. (9) There would be a significant difference in observed parental coping-promoting behavior between the child participants using distraction (via handout or video modeling) and those in the routine group, with a preference towards even more coping-promoting behaviors in the distraction via video modeling versus the distraction via handout. (10) There would be a significant difference in observed parental distress-promoting behavior between the child participants using distraction (via handout or video modeling) and those in the routine group, with a preference towards even less distress-promoting behaviors in the distraction via video modeling versus the distraction via handout.
CHAPTER II

METHOD

Participants

Child Subjects

The sample size for this study was based upon an expected effect size (Cohen's d) obtained from a meta-analytic review (Kleiber & Harper, 1999) reporting various studies utilizing distraction techniques to reduce pain and behavioral distress during routine immunizations. Kleiber and Harper’s (1999) meta-analysis, reviewing 19 published and unpublished well-controlled studies conducted between the years of 1966 and 1996, concluded that an expected effect size (Cohen’s d) for self-report pain was found to be 0.62 (± 0.42), and for behavioral distress the effect size was found to be 0.33 (± 0.26). Based on these effect sizes and utilizing a power of 0.80, it was determined that a total of 90 subjects were needed with 30 subjects assigned to each of the three experimental groups. Therefore, subjects were recruited to attain this minimal number of participants. The resulting sample consisted of 97 parents and 97 children between the ages of 18 months and 7 years who were receiving routine immunizations at a pediatrics clinic in a predominantly Caucasian rural center in the upper Midwest.

Selection criteria for the parent and child participants consisted of children between the ages of 18 months and 7 years obtaining routine vaccinations who were accompanied to the visit by a parent or consenting primary caretaker. The parent or caretaker had to be able to read and speak English. The child had to display an
understanding of counting, following directions, ranking, and determining happy faces from sad faces. These skills were assessed via counting balls, following a simple direction (i.e., point to your nose), arranging different sized blocks in order from smallest to largest, and pointing to happy and sad faces on a picture card of faces. This knowledge was required to determine that children could understand the assessment measures (i.e., Oucher Scale). Furthermore, siblings were excluded from the group to remove the potential for teaching effects of distraction by parents in alternate groups. When two parents accompanied a single participant, the parent behaviors were combined to form a “parental unit” for coding purposes. Furthermore, when two or more nurses were present for the shot, all of the nurses’ behaviors were coded as a “nurse unit” for coding purposes.

Measures

Demographic Questionnaire

The demographic data form was designed to elicit information from the parents about the child’s gender, age, race, occupation of parent, age of parent, SES of parent, previous medical experiences, and how the child was prepared for their immunization on the date of the research.

Child-Adult Medical Procedure Interaction Scale-Revised

The behaviors displayed by the child, parent, and nurse during the immunization session were coded from videotape using the Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R; Blount et al., 1997). The initial version, CAMPIS, coded 35 individual behaviors, which were later combined into a six category CAMPIS-R (Blount et al., 1990) based on both conceptual and empirical bases. The CAMPIS-R contains
three child codes (coping, distress, and neutral behaviors) and three adult codes (coping promoting, distress promoting, and neutral). For this study, the “child coping” codes included the following behaviors: making coping statements, nonprocedural-related talk by the child, audible deep breathing, and humor by the child. The “child distress codes” included the following behaviors: crying, screaming, verbal resistance, requests for emotional support, verbal fear, verbal pain, verbal emotion, and information seeking. For the ease of data analysis, each individual behavior was collapsed into its respective category and an average was calculated to determine the amount of intervals that contained each category of behavior: child coping behavior or child distress behavior.

The “adult coping promoting codes” included: humor directed to the child, nonprocedural-related talk to the child, and commands to engage in a coping strategy. The “adult distress promoting codes” included behaviors of empathy to child, reassurance to child, giving control to child, apologizing to child, and criticism. The adult codes were used to code the nursing staff and parent behaviors. For the ease of data analysis, each individual behavior was collapsed into its respective category and an average was calculated to determine the amount of intervals that contained each category of behavior: adult coping promoting behavior and adult distress promoting behavior. The child and adult neutral codes from the CAMPIS-R were not of interest in this study and thus were not examined.

A CAMPIS-R code was recorded as occurring if a single behavioral incident began, occurred, and/or ended at any time during each 15-second interval. Interval coding allows for ease of coding and it has been used in previous investigations of children’s procedural distress (e.g., Elliott & Olson, 1983; Gonzalez, Routh, &
The metric used in this study was the percentage of intervals in which a particular CAMPIS-R code or restraint occurred. Percentage of intervals was chosen to report the statistics as this metric allows participants with differing amounts of segments to be compared. The percentage of intervals was determined by dividing the number of intervals in which a particular CAMPIS-R code occurred during each particular phase of the procedure (i.e., anticipatory, procedural, and post-procedural phases) by the total number of intervals required for the respective phase to be completed. For example, a child who was seated waiting for a shot for 45 seconds, would have 3 intervals of observations in the anticipatory phase. If the shot lasted 10 seconds, there would be 1 interval. Furthermore, if a child only displayed a behavior for one of the three intervals, the corresponding percentage would be 33% of the intervals contained that specific behavior. High interrater reliability and validity for the CAMPIS and CAMPIS-R has been established in several studies (Blount et al., 1989, 1990, 1991; Frank et al., 1995).

For sessions in which two parents or two nurses were present, the parents and nurses were coded as a unit. For example, if a behavior was observed for either parent or either nurse during the 15-second interval, the behavior was coded.

**Oucher Scale**

The Oucher Scale (Beyer, 1989) was intended as a visually based mechanism to obtain self-report levels of anticipated pain prior to the procedure and pain for children immediately following medical procedures. The Oucher Scale consists of two scales presented on a poster. One scale, intended for older children, depicts a numerical scale ranging from 0-100. The other scale, intended for younger children, depicts a six-picture photographic scale showing faces of a child depicting gradations of pain. Scores on the
faces side of the Oucher range from 0 (no hurt) to 5 (most hurt you could ever have). The Oucher Scale demonstrates adequate psychometric properties when used for children aged 3.1 years to 7.9 years (Beyer & Aradine, 1986). Given the age range for this study, the photographic scale was used for all subjects. The subjects were asked by the researcher to point to the picture that best showed how much they hurt and a score was recorded prior to the start of the immunization session and immediately following completion of the session.

*Myrvik Distress Scale for Children-Parents Report*

The Myrvik Distress Scale for Children-Parent Report was created for this study and resembled a visual analogue scale (VAS) consisting of an adapted Oucher scale for parents. The anchors for the scale were 1 (extremely relaxed) and 10 (extremely anxious). The parent was asked by the researcher to provide a score prior to the immunization representing how distressed they believed their child would be during the procedure and immediately after the immunization to assess how much distress they thought that their child experienced during the immunization.

*Myrvik Distress Scale for Children-Nurse Report*

The Myrvik Pain Scale for Children-Nurse Report was created for this study and resembled a visual analogue scale (VAS) consisting of an adapted Oucher scale for nurses. The anchors for the scale were 1 (extremely relaxed) and 10 (extremely anxious). The nurse was asked to provide a score immediately after the injection on how much distress they thought the child experienced during the immunization.
Procedures

Parents and their children were informed about the study upon presenting for their appointment at the clinic for a scheduled immunization well-child and/or flu shot visit by receiving an informational flyer from the front-desk staff. They were informed that the IRB-approved study was to better understand children's responses to routine immunizations. Once told about the opportunity to participate in the study, the parent-child dyads were directed toward a research assistant to obtain more information about the study as well as obtain informed consent. If eligibility criteria were met, informed consent was obtained. The doctor visit was provided as usual, and participation or non-participation in this study had no effect on the patient's or family's ability to access health care or decisions related to health care during the child's medical visit. Once the medical provider had completed their portion of the visit, the researcher again met with the participants, during the regularly expected wait for the scheduled immunization. The researcher obtained demographic data including gender, age, race, occupation of parent, age of parent, parent education, previous medical experience, degree of preparation of child for the immunization, previous immunization history, and typical response to medical procedures. Furthermore, the Oucher Scale was administered to the child to determine their anticipated distress levels. Once the demographic information was obtained, the researcher immediately informed the participants of the shot procedures for that day (i.e., routine care, distraction taught via handout, or distraction taught via video modeling) and then the child and parent began the training procedures (except in the parent as usual group). Immunizations for Hepatitis A, DTaP (Diphtheria, Tetanus, Pertussis), IPV (Inactive Poliovirus), MMR (Measles, Mumps, Rubella), Meningococcal,
and Influenza were given. Upon completion of the training, the participants were directed to the immunization room where the immunization was completed as usual. The entire immunization procedure (from entering the room to leaving the room) was video taped for further analysis via the CAMPIS-R to measure overt child, parent, and nurse behavior during the routine immunization procedure.

Upon completion of the immunization (leaving the shot room), the child and the parent were asked to complete ratings of distress via the Oucher Scale and the Myrvik Distress Scale for Children-Parent Report. Similarly, after the patients left the room, the nurse completed the Myrvik Distress Scale for Children-Nurse report to obtain ratings about what degree the child experienced pain in relation to what they would typically anticipate for a same-aged peer.

Experimental Groups

Ninety-seven parent/child dyads were randomly assigned to one of three intervention groups prior to the immunization following a format similar to O’Laughlin and Ridley-Johnson (1995).

Routine Group (Parenting as Usual)

The routine (parenting as usual) condition consisted of 32 parent/child dyads and was utilized to represent typical parenting strategies during the immunization procedures. The parent was asked to be involved as they would for typical immunization procedures, in other words to do what they normally would do. Furthermore, the parents were provided access to distraction toys (similar to the other groups), but were not specifically told to use these items for distraction or to distract their child during the immunization
session. If the nurse required assistance in holding the child during the immunization, the parent was instructed to assist in holding the child during the injection.

Teaching Distraction Through a Handout

The Teaching Through Handout condition was comprised of 33 parent/child dyads and involved the parent being provided with a handout (see Appendix A for a copy) and given 10 minutes to review, prior to the immunization procedure. The pamphlet provided specific instructions in the use of distraction during injections and a list of methods of distraction (i.e., counting, deep breathing, toys, pinwheels, talking about non-medical information) (Appendix A). These items were provided in a bucket made available during the procedure for the parents to utilize. Before entering the room, the parent was prompted to use these skills from upon entering the room until the needle is removed. If the nurse required assistance in holding the child during immunization, the parent was instructed to first attempt to distract the child before aiding the nurse in holding the child.

Teaching Distraction Through Video Modeling

The Teaching Distraction Through Video Modeling (DVD) condition was made up of 32 parent/child dyads and involved the parent and child independently viewing an 8-minute video (see Kleiber, Craft-Rosenberg, & Harper, 2001) which depicted specific instructions in the use of distraction techniques during injections and a visual and verbal modeling of the steps to various distraction procedures prior to the immunization procedure. The distraction items (e.g., bubbles, pinwheels, whistles, books) were provided in a bucket present during the procedure for the parents to utilize. Before entering the room, the parent was prompted to use these skills from upon entering the room until the needle is removed. If the nurse required assistance in holding the child
during immunization, the parent was instructed to first attempt to distract the child before aiding the nurse in holding the child.

Data Collection

One experimenter/researcher assisted in collecting child and parent ratings and videotaping each immunization session from when the child enters the room until the child left the room. This was generally the same researcher who described the research at the outset of consent. There were only two researcher conducting the study.

Discrete behavioral observations were collected during three phases (Dahlquist & Shroff Pendley, 2005): anticipatory phase, procedural phase, and post-procedural phase. The anticipatory phase consisted of the time prior to the nurse first touching the child. The anticipatory phases varied between 15 seconds and 90 seconds during the study (or between 1 to 6 intervals). The procedural phase consisted of the time between when the nurse first touched the child until the needle was inserted (varied between 15 seconds and 150 seconds, or from 1 to 10 intervals)). The post-procedural phase consisted of the time from the needle was extracted until the parent and child left the room (varied between 15 seconds and 90 seconds, or from 1 to 6 intervals). Each phase was further divided into 15-second intervals for discrete coding utilizing the CAMPIS-R. As noted, intervals ranged from 1 to 10 per phase and this varied per child.

Following completion of all the subject recruitment and data collection, six research assistants coded the video observation samples. The videos were coded using the CAMPIS-R to rate overt behavioral distress or coping displayed by the child during the three procedural phases. Additionally, these video samples were coded using the
CAMPIS-R to rate parental and nurse distress promoting or coping promoting behaviors during the three procedural phases.

Each rater completed a 3-week training program. Initially, they studied the CAMPIS-R and the coding procedures. The observers then practiced coding sections of training video segments, which had been coded by the lead investigator on this project. This was done independently, with discussion of their responses. Upon meeting the criterion of 80% agreement with the training segments for three consecutive days, raters were allowed to code the true data video segments.

Cohen’s kappa (Cohen, 1960) was utilized to provide a chance-corrected measure of interobserver agreement. Kappa was calculated by first formulating a contingency table demonstrating the agreements and disagreements between the observers. Next, the expected frequencies for each of the diagonal cells were calculated assuming independence. Finally, the kappa coefficient value was calculated by subtracting the summed expected frequencies from the summed observed frequencies and then dividing this value by the value of the summed expected frequencies subtracted from the total number of observations. Reliability was assessed on 15 participants/videos with 5 videos/participants coming from each group (i.e., routine care, distraction via handout, distraction via video). Based on Barlow and Hersen (1984), a kappa value ranging from .60 to .75 is considered acceptable.

Reliability

Reliability was calculated for the CAMPIS-R using the formula for Cohen’s kappa (Cohen, 1960). Reliability codes were used for 15 (5 from each experimental condition) randomly selected participants providing reliability for an estimated 15% of
the videotaped immunization sessions. Kappa was calculated separately for child, parent, and nurse behaviors and agreement was counted if both coders agreed that a behavior occurred or did not occur during a 15-second interval. Kappa reliability values for the child categories were: child coping behaviors, .86 and child distress behaviors, .92. Kappa coefficients for the CAMPIS-R parent and nurse categories were: parent coping promoting behaviors, .85; parent distress promoting behaviors, .79; nursing coping promoting behaviors, .82; and nurse distress promoting behaviors, .84. These represent excellent levels of agreement (Barlow and Hersen, 1984).
CHAPTER III

RESULTS

Descriptive Demographics

Over a period of 7 months, 111 parents and their children were approached to be in this study. Fourteen families declined participation in this study due to time constraints or lack of interest in the study. The cohort for this study was 97 child-parent dyads, all recruited from a Pediatrics Clinic located in a rural, upper Midwest center.

Overall, the child participant sample consisted of 45 girls and 52 boys. The sample was found to be predominantly white, reflecting the racial composition of the study site. After conducting a one-way analysis of variance (ANOVA) for child age and a Chi-square analysis for gender and race, there were no significant group differences for child gender, age, or race as demonstrated in Table 1.

Table 1. Demographic Information of Child

<table>
<thead>
<tr>
<th>Randomly Assigned Teaching Condition</th>
<th>Parenting as Usual (N=32)</th>
<th>Handout (N=33)</th>
<th>Video (N=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DV</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>20</td>
<td>17</td>
<td>15</td>
</tr>
<tr>
<td>Female</td>
<td>12</td>
<td>16</td>
<td>17</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>49.50 mo</td>
<td>49.55 mo</td>
<td>48.59 mo</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>27</td>
<td>31</td>
<td>25</td>
</tr>
<tr>
<td>Black</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Hispanic</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Native American</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>
The parent participant sample included 83 mothers and 14 fathers. As noted previously, there were several families where more than one parent attended the medical visit. For research purposes, the demographic data were only collected on one parent. This parent was the parent that completed the consent form and all of the additional forms. Comparison based on demographic variables obtained through the Demographic Questionnaire was conducted using a one-way analysis of variance (ANOVA) for age and a Chi-square analysis for gender, marital status, and educational status revealed no significant differences for parent age, gender, or education, as shown in Table 2.

Table 2. Demographic Information of Parent

<table>
<thead>
<tr>
<th>DV</th>
<th>Randomly Assigned Teaching Condition</th>
<th>Parenting as Usual (N=32)</th>
<th>Handout (N=33)</th>
<th>Video (N=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother</td>
<td></td>
<td>27</td>
<td>29</td>
<td>27</td>
</tr>
<tr>
<td>Father</td>
<td></td>
<td>5</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td></td>
<td>32.5 yr</td>
<td>31.2 yr</td>
<td>32.5 yr</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td></td>
<td>27</td>
<td>26</td>
<td>26</td>
</tr>
<tr>
<td>Single</td>
<td></td>
<td>5</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Educational Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9-12 years</td>
<td></td>
<td>7</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>13-15 years</td>
<td></td>
<td>15</td>
<td>16</td>
<td>11</td>
</tr>
<tr>
<td>16 years</td>
<td></td>
<td>8</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>&gt; 16 years</td>
<td></td>
<td>2</td>
<td>5</td>
<td>7</td>
</tr>
</tbody>
</table>

Hypotheses and Results

*Hypothesis 1: Child Behavior and Parent Behavior Relationship*

Hypothesis 1 stated that there would be a significant correlation between the child's overt behavior during the immunization session and the behavior of the parent as measured by the CAMPIS-R, regardless of experimental group. In particular, it was
suggested that a strong, positive correlation would be found between the overall percentage of immunization phases containing child distress behaviors (e.g., crying, screaming, verbal resistance) and the overall percentage of immunization phases containing parent distress promoting behaviors (e.g., empathy, criticism). Furthermore, it was thought that a strong, positive correlation would be found between the overall percentage of immunization phases containing child coping behaviors and the overall percentage of immunization phases containing parent coping promoting behaviors.

Analysis using bivariate correlations between CAMPIS-R ratings revealed support for this hypothesis. The overall percentage of intervals containing child distress behaviors was significantly and positively correlated with the overall percentage of intervals containing parent distress promoting behaviors, $r(91) = .387, p < .01$. As well, the overall percentage of intervals containing child coping behaviors was significantly and positively correlated with the overall percentage of intervals containing parent coping promoting behaviors, $r(91) = .242, p = .021$. These findings provide support to the hypothesis that child behavior and parent behavior during the immunization session are indeed directly related. There is support for the hypothesis that parental behaviors are related to child behaviors.

To further investigate this relationship between parent and child behaviors, data across procedural phase was analyzed. The correlations during each specific phase (i.e., anticipatory, procedural, and post-procedural) of the immunization session, as opposed to the overall average of the entire session were evaluated using a bivariate correlation between the parent and child behaviors during each respective phase. Statistically significant relationships between child overt behavioral distress ratings and parent
distress promoting behaviors were noted. Correlations based on the CAMPIS-R data from the procedural phase, $r(91)=0.357$, $p<.01$, and post-procedural phase, $r(91)=.454$, $p<.01$) were significant. However, significant findings were not found between child overt behavioral distress ratings and parent distress promoting behaviors as measured by the CAMPIS-R during the anticipatory phase, $r(91)=.191$, $p=.070$. These findings indicate that child distress and parent distress promoting behaviors are related during injection and post-procedural phases.

Similar findings were evident for the relationship between parent and child coping behaviors. In particular, a significant correlation was found between child overt coping behaviors and parent coping promoting behaviors as measured by the CAMPIS-R during the procedural phase, $r(91)=0.264$, $p=.011$, and during the post-procedural phase, $r(91)=.349$, $p<.01$). However, significant findings were not found between child overt behavioral distress ratings and parent distress coping behaviors as measured by the CAMPIS-R during the anticipatory phase, $r(91)=.190$, $p=.071$. These findings indicate that child coping and parent coping promoting behaviors are related during the injection and post-procedural phases. Overall, these findings suggest that child behavior and parent behavior are directly related, such that during the injections and following injections, parents are likely engaging in behaviors that promote the emotional state (either coping or distress) of their child.

*Hypothesis 2: Child Behavior and Nurse Behavior Relationship*

Hypothesis 2 stated that there would be a significant correlation between the child’s overt behavior during the immunization session and the behavior of the nurse as measured by the CAMPIS-R, regardless of experimental group. In particular, it was
suggested that a strong, positive correlation would be found between the overall percentage of immunization phases containing child distress behaviors and the overall percentage of immunization phases containing nurse distress promoting behaviors. Furthermore, it was suggested that a strong, positive correlation would be found between the overall percentage of immunization phases containing child coping behaviors (e.g., crying, screaming) and the overall percentage of immunization phases containing nurse coping promoting behaviors (e.g., empathy, criticism). Analysis utilizing bivariate correlations between CAMPIS-R ratings revealed findings that do not support this hypothesis. The overall percentage of intervals containing child distress behaviors was not significantly correlated with the overall percentage of intervals containing nurse distress promoting behaviors, $r(91) = .123, p = .245$. The overall percentage of intervals containing child coping behaviors was also not significantly correlated with the overall percentage of intervals containing nurse coping promoting behaviors, $r(91) = .087, p = .413$. These findings do not provide support to the hypothesis that child behavior and nurse behavior during the immunization session are related, when behaviors were averaged across all three phases of the immunization session (i.e., anticipatory, procedural, post-procedural). However, when viewing the correlations during each specific phase, significant findings are noted.

In particular, a significant correlation was found between child overt distress behaviors and nurse distress promoting behaviors as measured by the CAMPIS-R during the procedural phase, $r(91) = .283, p < .01$, and during the post-procedural phase, $r(91) = .268, p = .010)$. However, significant findings were not found between child overt behavioral distress ratings and nurse distress promoting behaviors as measured by the
CAMPIS-R during the anticipatory phase, \( r(91) = -0.073, p = 0.490 \). Differing findings were evident for the relationship between nurse and child coping behaviors. Specifically, no significant relationships between child overt coping behaviors and nurse coping promoting behaviors as measured by the CAMPIS-R were found during the anticipatory phase, \( r(91) = 0.134, p = 0.205 \), procedural phase, \( r(91) = 0.032, p = 0.763 \), and during the post-procedural phase, \( r(91) = 0.045, p = 0.674 \).

Overall these findings suggest that when behaviors are considered within each phase of the immunization session (i.e., anticipatory, procedural, post-procedural), nurse’s distress behaviors and child’s distress behaviors were significantly related during the procedural phase and post-procedural phase of the session; however, nurse’s coping and child’s coping behaviors were not significantly correlated.

**Hypothesis 3: Parental Coping Promoting Behavior and Child Distress Behavior**

Hypothesis 3 stated that there would be a significant correlation between the child’s overt distress behavior during the immunization session and parent coping promoting behavior during the immunization session. More specifically, when parents perform distraction techniques during the immunization session, children will display decreased levels of distress. To assess this hypothesis, CAMPIS-R ratings of parent coping promoting behaviors were compared to child self-report distress ratings, parent ratings of child distress, nurse ratings of child distress, and independent raters of child distress (i.e., CAMPIS-R) using bivariate correlations. Findings indicate that the overall percentage of intervals containing parent coping promoting behaviors (e.g., non-procedural talk, commands to engage in coping strategy) was not significantly correlated with child self-report of distress, \( r(85) = -0.171, p = 0.117 \), parent report of child distress,
r(90) = -0.033, p = .758, nurse report of child distress, r(84) = -0.174, p = .113, or independent
ratings of child distress using the CAMPIS-R, r(91) = -0.178, p = .092 when averaged across
the procedural phases. Based on these findings, there is limited support for the
hypothesis that parental coping promoting behavior (i.e., distraction) is related to
decreased child distress behavior.

However, when viewing the correlations during each specific phase (i.e.,
anticipatory, procedural, and post-procedural) of the immunization session, as opposed to
the overall average of the entire session, significant findings become evident. In
particular, significant, negative correlations were found between parent coping promoting
behaviors and child distress behaviors as measured by the CAMPIS-R during the
procedural phase, r(91) = -0.454, p < .01, and during the post-procedural phase, r(91) =-
.337, p < .01). These findings provide support to the hypothesis that parental coping
promoting behaviors (i.e., distraction) can significantly reduce child distress behaviors
during and immediately after the immunization.

Hypothesis 4: Nurse Coping Promoting Behavior and Child Distress Behavior

Hypothesis 4 stated that there would be a significant correlation between the
child’s overt distress behavior during the immunization session and nurse coping
promoting behavior during the immunization session. More specifically, when nurses
perform distraction techniques during the immunization session, children will display
decreased levels of distress. To assess this hypothesis, CAMPIS-R ratings of overall
average of nurse coping promoting behaviors were compared to child self-report distress
ratings, parent ratings of child distress, nurse ratings of child distress, and independent
raters of child distress (i.e., CAMPIS-R) using bivariate correlations. It was determined
that the overall percentage of intervals containing nurse coping promoting behaviors (e.g., non-procedural talk, command to engage in coping strategy) was not significantly correlated with child self-report of distress, \( r(85) = -0.032, p = .771 \), parent report of child distress, \( r(90) = 0.107, p = .316 \), nurse report of child distress, \( r(84) = -0.011, p = .921 \), and independent ratings of child distress using the CAMPIS-R, \( r(91) = -0.075, p = .481 \). Based on the above findings, there is little support for the hypothesis that nurse coping promoting behavior (i.e., distraction) is related to decreased child distress behavior.

When viewing these correlations during each specific phase (i.e., anticipatory, procedural, and post-procedural) of the immunization session, as opposed to the overall average of the entire session, similar findings are evident. In particular, nonsignificant correlations were found between nurse coping promoting behaviors and child distress behaviors as measured by the CAMPIS-R during the anticipatory phase, \( r(91) = 0.064, p = .547 \), procedural phase, \( r(91) = -0.023, p = .832 \), and during the post-procedural phase, \( r(91) = -0.122, p = .249 \). These findings fail to provide support for the hypothesis that nurse coping promoting behaviors (i.e., distraction) can significantly reduce child distress behaviors during and immediately after the immunization.

**Hypothesis 5: Overt Behavioral Distress and Distraction Education Type**

Hypothesis 5 stated that there would be a significant difference in observed behavioral distress between the child participants based on the educational condition their parents were given on using distraction (taught by handout or taught by video modeling) and child participants in the control group (i.e., parenting as usual). Furthermore, it was predicted that child participants in the distraction taught by video would display significantly less behavioral distress than the distraction taught by handout group.
A 3(condition) x 3(phase) mixed analysis of variance (ANOVA) was conducted on this data. The three phases were the phases of the immunization session: anticipatory, procedural, and post-procedural phases. The three conditions were the “methods” of educating parents regarding distraction techniques: parenting as usual (no education), distraction taught by handout, and distraction taught by video modeling. The dependent variable for this hypothesis was the child overt behavioral distress score as measured by the CAMPIS-R obtained by each participant as coded per phase. The means and standard deviations for this analysis are presented in Table 3. Overall, the results indicated a significant main effect, $F(2,176)=25.996, p<.01$, for phases. This means that independent ratings of overt child behavioral distress varies significantly between procedural phases. The main effect for condition (i.e., parenting as usual, handout, video) was not found to be significant, $F(2,176)=2.09, p=.129$. This means that it appears the educational method did not seem to have an impact on the overall behavioral distress displayed by the children in this study. Furthermore, no significant interactions between phase and condition were found. Based on these findings, the hypothesis that the distraction groups would result in significantly less child distress than the control group was not supported, however, child distress was found to vary significantly between phases of the immunization session.

Table 3. Mean Percentage for CAMPIS-R Ratings of Child Distress Behavior

<table>
<thead>
<tr>
<th>Condition</th>
<th>Anticipatory</th>
<th>Phases</th>
<th>Post-Procedural</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parenting as Usual</td>
<td>3.05% (sd=6.10)</td>
<td>8.78% (sd=9.59)</td>
<td>5.64% (sd=6.44)</td>
</tr>
<tr>
<td>Handout</td>
<td>6.24% (sd=9.57)</td>
<td>11.68% (sd=9.53)</td>
<td>10.41% (sd=9.14)</td>
</tr>
<tr>
<td>Video</td>
<td>3.62% (sd=6.44)</td>
<td>10.81% (sd=10.63)</td>
<td>8.02% (sd=9.04)</td>
</tr>
</tbody>
</table>

52
However, given that several parents in the “parenting as usual” group were observed to engage in distraction techniques with their child, the reader is referred back to Hypothesis 3 where evaluation of the use of distraction techniques (rather than educational method) does appear to have an impact on reducing child distress during immunizations.

**Hypothesis 6: Child Self-Report Distress and Distraction Education Type**

Hypothesis 6 stated that there would be a significant difference in post-procedural self-reported pain ratings between the child participants whose parents were instructed specifically in the use of distraction taught by handout or by video modeling compared to those in the parenting as usual group. Furthermore, it was predicted that child participants in the distraction taught by video modeling would report significantly less behavioral distress than the distraction via handout group.

A one-way analysis of variance (ANOVA) was conducted on the relationship between child Oucher Scale Self-Report Ratings and distraction education type data. The independent variable for this hypothesis was the group membership of the participant (i.e., parenting as usual-no education, distraction via handout, distraction via video). The dependent variable for this hypothesis was the child’s self-report of distress as measured by the Oucher Scale Self-Report Ratings obtained immediately after the immunization. The means and standard deviations for this analysis are presented in Table 4. Overall, the results indicate that child self-report of distress during immunization was not significantly different (ANOVA) between treatment groups, $F(2,89)=2.59, p=.081$. 

53
Hypothesis 7: Parent-Report of Child Distress and Distraction Education Type

Hypothesis 7 stated that there would be a significant difference in post-procedural parent report of perceived child pain ratings between the child participants of parents who were educated in using distraction (taught by handout or taught by video modeling) compared to those grouping the group providing parenting as usual (no distraction education). Furthermore, it was predicted that child participants in the distraction taught via video would display significantly less behavioral distress as reported by their parents than the child participants in the distraction via handout.

A one-way analysis of variance (ANOVA) was conducted. The independent variable for this hypothesis was the group membership of the participant (i.e., parenting as usual-no education, distraction via handout, distraction via video). The dependent variable for this hypothesis was the parent report of perceived child behavioral distress as measured by the Myrvik Distress Scale for Children-Parent Report immediately after completion of the immunization. The means and standard deviations for this analysis are presented in Table 5. Overall, the results that parent report of child behavioral distress during the immunization session was not significantly different between groups, $F(2, 94) = .673, p = .513$. 

Table 4. Means of Self-Reported Pain Ratings on the Oucher (1-10)

<table>
<thead>
<tr>
<th>Group</th>
<th>Parenting As Usual</th>
<th>Handout</th>
<th>Video</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child Mean Rating</td>
<td>4.81 (sd=3.59)</td>
<td>6.23(sd=3.40)</td>
<td>4.37(sd=2.91)</td>
</tr>
</tbody>
</table>
Table 5. Means of Parent Reported Child Distress (1-10)

<table>
<thead>
<tr>
<th>Group</th>
<th>Parent Mean Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parenting As Usual</td>
<td>4.90(sd=2.65)</td>
</tr>
<tr>
<td>Handout</td>
<td>5.67(sd=2.90)</td>
</tr>
<tr>
<td>Video</td>
<td>5.16(sd=2.52)</td>
</tr>
</tbody>
</table>

**Hypothesis 8: Nurse Report of Child Distress and Distraction Education Type**

Hypothesis 8 stated that there would be a significant difference in post-procedural nurse report of perceived child pain ratings between the child participants whose parented received education in using distraction (taught by handout or taught by video modeling) and those grouping the parenting as usual group (no distraction education). Furthermore, it was predicted that child participants in the distraction taught via video would display significantly less behavioral distress as reported by their parents than the child participants in the distraction via handout.

A one-way analysis of variance (ANOVA) was conducted. The independent variable for this hypothesis was the group membership of the participant (i.e., routine care, distraction taught by handout, distraction taught by video). The dependent variable for this hypothesis was the nurse report of perceived child behavioral distress as measured by the Myrvik Distress Scale for Children-Nurse Report immediately after completion of the immunization. The means and standard deviations for this analysis are presented in Table 6. Overall, the results that nurse report of child behavioral distress during the immunization session was not significantly different between groups, $F(2,87)=1.08, p=.344$. 

55
Hypothesis 9: Parental Coping-Promoting Behavior and Distraction Education Type

Hypothesis 9 stated that there would be a significant difference in observed parental coping-promoting behavior between the parent participants who received education in using distraction (taught by handout or taught by video modeling) and the parent participants who were parenting as usual (no distraction education). Furthermore, it was predicted that parent participants taught distraction by video would display significantly more coping-promoting behaviors than the distraction by handout group.

A 3(condition) x 3(phase) mixed analysis of variance (ANOVA) was conducted on this data. The three phases were the phases of the immunization session: anticipatory, procedural, and post-procedural phases. The three conditions were: parenting as usual (no distraction education), distraction taught by handout, distraction taught by video modeling. The dependent variable for this hypothesis was the parent coping promoting score as measured by the CAMPIS-R obtained by each participant and coded per phase. The means and standard deviations for this analysis are presented in Table 7. Overall, the results indicated a significant main effect, $F(2,176)=8.63$, $p<.01$, for phase. This indicates that independent ratings of parent use of coping promoting behaviors (distraction techniques) varied significantly between procedural phases. The main effect for condition (i.e., control, handout, video) was not found to be significant, $F(2,176)=.223$, $p=.801$. No significant interactions between phase and condition were
found. Based on these findings, the hypothesis that the distraction groups would result in significantly more parent coping promoting behaviors than the control group was not supported, however, parental coping promoting behaviors were found to vary significantly between phases of the immunization session. This main effect suggests that parents are not consistent across the phases of the immunization procedures in their use of distraction techniques.

Table 7. Means for CAMPIS-R Parent Coping Promoting Behaviors

<table>
<thead>
<tr>
<th>Condition</th>
<th>Anticipatory</th>
<th>Group</th>
<th>Post-Procedural</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parenting as Usual</td>
<td>19.88(sd=14.78)</td>
<td>26.31(sd=18.80)</td>
<td>25.41(sd=10.62)</td>
</tr>
<tr>
<td>Handout</td>
<td>19.73(sd=14.13)</td>
<td>27.65(sd=15.19)</td>
<td>21.95(sd=12.02)</td>
</tr>
<tr>
<td>Video</td>
<td>20.64(sd=10.20)</td>
<td>28.75(sd=17.21)</td>
<td>25.16(sd=10.72)</td>
</tr>
</tbody>
</table>

Hypothesis 10: Parental Distress Promoting Behavior and Distraction Education Type

Hypothesis 10 stated that there would be a significant difference in observed parental distress-promoting behavior between the parent participants educated in using distraction (taught by handout or taught by video modeling) and parent participants in the parenting as usual group. Furthermore, it was predicted that parent participants taught distraction via video would display significantly less distress-promoting behaviors than the distraction via handout group.

A 3(condition) x 3(phase) mixed analysis of variance (ANOVA) was conducted on this data. The three phases were the phases of the immunization session: anticipatory, procedural, and post-procedural phases. The three conditions were: parenting as usual (no distraction education, distraction taught by handout, and distraction taught by video modeling). The dependent variable for this hypothesis was the parent distress-promoting
score as measured by the CAMPIS-R obtained by each participant coded per phase. The means and standard deviations for this analysis are presented in Table 8. Overall, the results indicated a significant main effect, $F(2,176)=12.86, p<.01$, for phase. This indicates that independent ratings of parent distress promoting behaviors varied significantly between procedural phases. The main effect for condition (i.e., control, handout, video) was not found to be significant, $F(2,176)=2.303, p=.106$. No significant interactions between phase and condition were found. Based on these findings, the hypothesis that the educated in distraction groups would result in significantly less parent distress-promoting behaviors than the control group was not supported, however, parental distress promoting behaviors were found to vary significantly between phases of the immunization session.

Table 8. Means for CAMPIS-R Parent Distress Promoting Behaviors

<table>
<thead>
<tr>
<th>Condition</th>
<th>Anticipatory (sd)</th>
<th>Procedural (sd)</th>
<th>Post-Procedural (sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parenting as Usual</td>
<td>1.93(4.51)</td>
<td>6.12(7.91)</td>
<td>5.52(6.72)</td>
</tr>
<tr>
<td>Handout</td>
<td>4.10(6.56)</td>
<td>6.22(6.97)</td>
<td>9.19(7.89)</td>
</tr>
<tr>
<td>Video</td>
<td>1.88(3.31)</td>
<td>4.43(6.03)</td>
<td>6.53(7.98)</td>
</tr>
</tbody>
</table>
CHAPTER IV
DISCUSSION

The present study provided insight into three specific aspects of child distress and behavior during routine immunizations. The study assessed the relationship between adult and child behaviors during the immunization session by sampling behavioral observations and utilizing independent raters along with parent and nurse ratings of perceived child distress. Second, the study assessed the effectiveness of distraction performed by adults in reducing child behavioral distress as observed through independent ratings of behavioral observations. Finally, the study examined the effectiveness of teaching distraction to parents to assess brief and cost-effective approaches to such education for practical use in a busy pediatric primary care setting.

Supportive Findings

Relationship Between Parent and Child Behavior During Immunization

The present study provided insight into the role of parent-child interaction on children's reaction to painful medical procedures, specifically immunizations. In comparing the effects of distress-promoting and coping-promoting behaviors as evidenced by parents, a clear pattern of the effects of parent behavior on child behavior emerged. Specifically, based on independent raters, children were observed to display more distress (e.g., crying, screaming, verbal resistance) when their parents demonstrated distress-promoting behaviors (e.g., reassuring comments, empathizing, apologizing). For example, parents stating to their children that the shot will only hurt a little were observed
to have children who would cry and scream. Conversely, children demonstrated more coping behaviors (e.g., deep breathing, playing with toys, talking about a preferred activity) when their parents demonstrated coping promoting behaviors (e.g., non-procedural talk, comments to engage in coping strategy, interaction with the toys). For example, parents initiating interest in discussing a recent event (e.g., birthday) along with interacting over distracting toys with their child were observed to have children who imitated and interacted with them in these coping behaviors. Parent and child behaviors during the immunization session were consistently and significantly related. This provides evidence for the need to educate parents, medical providers, and staff on effective techniques aimed at increasing parent awareness, knowledge, and utilization of coping behaviors to effect change and reduce child distress during immunizations.

The significant relationship between parent and child behavior found in this study is similar to the existing literature. Research has found that parents’ behavior in the treatment room may account for as much as 53 percent of the variance in child distress behavior (Frank et al., 1995). Furthermore, research has shown that parents’ behaviors typified as those that promote child “distress” skills and those that promote child “coping” skills result in increasing levels of child distress or increasing levels of child coping, respectively, similar to the findings of the current study (Blount et al., 1989; Dahlquist, Power, Cox, & Fernbach, 1994; Manne et al., 1992). Additionally, the findings of this study serve to bolster support for the Proximal-Distal Model of Children’s Coping and Distress During Acute Painful Medical Procedures (Blount, Bunke, & Zaff, 2000; Varni, Blount, Waldron, & Smith, 1995), which as described
previously, asserts that parents’ behavior during painful medical procedures has a direct impact on their child’s behavior.

Effectiveness of Distraction on Child Distress as Coached by Parents

The findings of this study further the understanding of the effectiveness of distraction as a distress-reduction strategy for children. When parents displayed increased amounts of coping-promoting behaviors, as measured by independent raters, their children demonstrated significantly less distress (noted by the same raters), during the procedural and post-procedural phases of the immunization session. Parent and nurse’s perceptions were consistent with independent raters, however, these results were not found to be significant.

Similar results have been found in the literature (Gonzalez et al., 1993; Manimala, Blount, & Cohen, 2000; O’Laughlin & Ridley-Johnson, 1995). For example, Manimala, Blount, and Cohen (2000) compared the effects of parental distraction (taught through role-playing and modeling distraction with a party blower) in reducing child behavioral distress for eighty-two children between the ages of 3.8 and 5.9 years receiving routine immunizations. The results indicated that children in the distraction group demonstrated a significant decrease in distress levels relative to the children in the control group. Furthermore, Gonzalez et al. (1993) examined the effects of maternal distraction on children’s reactions to immunizations. The sample of forty-two 3-year- to 7-year-old children and their mothers involved parent/child dyads being taught instructions on how to distract vs. reassure their child via an audiocassette with role-playing. The results demonstrated that children in the distraction group exhibited less behavioral distress than children in the maternal reassurance group or the control group.
This current study further identifies the phases of immunization procedures have different impacts from this relationship. For example, in the first phase (pre-injection), parental distraction had little impact on reducing child distress as reported by independent raters. However, in the injection through post-immunization phase, parenting coping promoting behaviors or distress promoting behaviors impacted their child. These results provide evidence suggesting that when the injection began until immediately after, parents were effective in reducing their child distress when they performed distraction.

Unsupported Findings

Relationship Between Nurse and Child Behavior During Immunization

The findings addressing the role of nurse-child interaction on children's reaction to painful medical procedures were variable. More specifically, a non-significant trend between overall child distress (e.g., crying, screaming) and nurse distress promoting behaviors (e.g., reassuring comments, apologizing) was found during the immunization session. Similarly, non-significant findings for the relationship between overall child coping behaviors (e.g., deep breathing, non-procedural talk) and nurse coping promoting behaviors (e.g., non-procedural talk, comments to engage in coping strategy) were found during the immunization session. Significant findings were evident, however, between child distress behaviors and nurse distress promoting behaviors during the procedural and post-procedural phases of the immunization session. So, similarly to parent impact during these phases, when distress promoting behaviors are utilized by the nurse (or parent), child distress increases. Overall, these findings suggest that nurse behavior can impact the amount of distress a child displays during and immediately after the procedure; however, nurse behavior has limited impact on the child's ability to display
coping behaviors. This is most intriguing in light of the context and initial idea that instigated this study. The nurses in this particular facility were concerned regarding the management of difficult parents and children and how to be more effective in de-escalating shot distress. These findings appear to vary slightly from the current literature. Specifically, Cohen, Bernard, Greco, and McClellan (2002) determined that nurses behavior throughout the immunization session directly impacted child behavior in that when nurses displayed distress-promoting behaviors, the child responded with increased distress and when the nurses displayed coping-promoting behaviors, the child responded with increased child coping. Thus, the study failed to find support for the direct impact in nurse behavior on child coping skills.

**Effectiveness of Distraction on Child Distress as Coached by Nurses**

Differing results were found for the nurses’ utilization of distraction. When nurses displayed increased amounts of coping-promoting behaviors, as measured by independent raters, the children did not demonstrated significantly less behavioral distress. However, nurse coping-promoting behaviors did not increase behavioral distress either, in this study. There have been several studies demonstrating the effectiveness in nurse-directed distraction (i.e., distraction training directed specifically at the nurses) in reducing child distress (Cohen et al., 1997, Cohen, Blount, Cohen, Schaen, & Zaff, 1999). Nurse behavior was coded as a behavior of interest (with their permission), however, nurse behavior was not controlled for per se, therefore conditions of assessing when or why nurses engaged in distraction strategies (i.e., a particularly difficult patient where they supported the parents failed attempts; a patient for which the parent did not engage in supportive strategies; or a patient for which the parent was distressed and
promoting distress for their child). The best interpretation would be to consider this study based on "nursing as usual". Although these results are unexpected when compared to the literature, the nurses in this study were not the target of the distraction education and thus, differing results are expected.

Effects of Educational Format on Teaching Distraction

The overall goal of this study was to evaluate a low cost and practical intervention for reducing children's distress during a routine immunization procedure. In order for an intervention to be feasible, it must be easily and seamlessly integrated into a busy healthcare setting. These interventions must be practical as well as easy to teach, implement, use, cost-effective, and acceptable to parents and clinicians. For example, EMLA (eutectic mixture of local anesthetics lidocaine and prilocainecream is easy to instruct parents and staff in the use of, is highly acceptable to parents and children, provides relatively optimal sensation management for procedures as invasive as blood draws, however, the implementation requiring a waiting period of 30 minutes and a wish to reduce exposure to one area/arm at a time, along with the cost of such a pharmaceutical intervention, makes the use of such a procedure for immunizations (particularly multiple ones) impractical.

For this study, two low-cost interventions were selected as fairly typical and routine methods of information provision within today’s modern pediatric office setting (i.e., the use of printed handout materials and the use of DVD instruction). These were selected as most group pediatric offices tend to have some type of video display or television running in the lobby (note this was not the method of viewing in this study), and handouts are generally considered a more informative resource than verbal
instruction alone. In addition, utilizing the typical waiting time between office-visits and immunization procedures was utilized to enhance the practicality of this study. In many clinics, particularly during flu shot season, it is not uncommon for the wait to be longer than 30 minutes to 90 minutes.

While the findings overall suggest that the use of distraction is effective in increasing child coping behaviors, there were no differences between the method of instruction utilized to deliver the education regarding the distraction technique. There were no differences when evaluating the child's self-reported stress, parent report of perceived child distress, nurse report of perceived child distress, and independent observations of child distress. One could assume that although distraction was found to be significant in reducing child distress during routine immunizations, teaching distraction by handouts or by video modeling was not sufficient to result in significantly different findings than the control group. However, in hindsight, assessing the educational goals of these methods may be better conducted through a pre/post knowledge based assessment rather than considering the implementation of the distraction technique as mastery and learning from the educational method. For example, in the “parenting as usual group” there were several parents who implemented distraction techniques, yet they had not been “taught” per se. We can therefore assume that individuals in the handout and video group may also have had some base knowledge coming in, and it may not have been the “teaching” from these methods that contributed to their effective use of the techniques either. Likewise, failure to implement known techniques is not a true indicator of effective education, but rather a sign of a separate skill deficit (i.e., when to use the skill). Failure to demonstrate an effect for the video and
handout education of distraction here does not suggest that distraction is not an effective technique, and conclusion should not be drawn about the relative efficacy of the treatment as usual procedures compared to distraction. Rather, given the robust findings otherwise supporting the effectiveness of distraction (Broome, Lillis, & Smith, 1989; Kleiber & Harper, 1999), the absence of effects here may indicate a failure to effectively teach distraction in an effective manner. Furthermore, although parents in the education by handout and education by training video were instructed to use distraction, not all of the parents complied with the instructions to distract their child during the procedure. The education conditions might have been more effective had experimenters been more involved in training the parent-child dyads to ensure parent’s active participation and rehearsal prior to, as well as during, the immunization, however, the purpose of this investigation was to test the efficacy of techniques that might be realistically used in a busy doctors’ office; thus, parents were only provided with either a brief handout of a brief training video. While similarly intensive training programs could be developed, these findings do raise the question of where the parents are learning distraction, and how they have been reinforced for coaching their children with these techniques.

Conclusions and Limitations

Overall, the results of this study demonstrated that parent and child behaviors are significantly related and that parent-directed distraction is effective in reducing child behavioral distress during immunizations. Furthermore, limited findings between nurse distress-promoting behaviors and child distress behaviors support the need to target parents as a primary influencing model in treatment interventions targeting procedural pain. Practical educational interventions (i.e., handout and video) targeting parents were
not demonstrated to have significant changes on the implementation of distraction techniques by parents.

Based on the overall findings of this study several conclusions are made regarding children and painful medical procedures. First, immunization procedures produced distress for children. Second, parent behavior has a direct impact on child behavior suggesting that parents are key players in reducing pediatric procedural pain. Third, the findings indicated that parent distress-promoting behaviors result in child distress, whereas, parent coping-promoting behaviors result in child coping behaviors. Support for the education of parents in the use of adaptive coping behaviors (i.e., coping-promoting behaviors) during the immunization session is founded. Fourth, nurses' coping promoting behavior did not have a significant impact in child behavior, when the parent was present meaning that nurses did not have as significant of an impact on a child's behavior as their parent. Finally, distraction was effective, however, teaching distraction techniques by handout or by video was no more effective at reducing child distress than when the parents received no distraction education, suggesting that parents may indeed have a base-rate level of distraction skills they utilize with their children. Taken together, these findings suggest the need for further analysis and study related to how to educate parents most effectively in these techniques, how to reduce distress-promoting behaviors in parents and nurses, and how to perhaps teach nurses effective coping-promoting techniques to utilize with children and their parents.

Several limitations of the study should be discussed further. Due to the practical/applied nature of the investigation, it is not possible to determine which specific aspects of the intervention contributed to decreased child, parent, or nurse distress. For
example, children's low distress may have been due solely to the distracting objects and not related to adult coaching behaviors. However, in previous assessment research, coaching has been closely associated with child coping behaviors (e.g., Blount et al., 1989). Further investigative dismantling studies could identify the contribution of each of these factors.

Further, the coaching used in this study required no staff time, was implemented without staff-parent discussion, and appeared to be "easily taught". The lack of staff engagement and seemingly "easy" implementation, parents may not have received sufficient education or confidence in implementing these techniques. In addition, this was but one training time, and follow-up data from a return visit might have provided further evidence for sustained education, improved learning history (i.e., "the last immunization procedure went better, so I'm not so worried"), or demonstrate more parental implementation of the "new" skill set.

The children who participated were from a narrow age range; only one medical stressor, (immunizations), was targeted; all children were healthy; and only one setting; a primary care clinic was used. The generalization of these limited findings to other ages, procedures, patient histories and settings would be cautioned. This limitation is especially relevant when considering more invasive procedures such as lumbar punctures or bone marrow aspirations.

The sample size and composition is another factor that is relevant to consider. There was sufficient power in the sample of 97 to detect group differences for parent use of distraction; however, because children's responses to immunizations are extremely variable, power was very low to evaluate the children's responses to parental distraction.
Continued data collection that would enhance the sample size, and perhaps increase the sample demographics (hospital setting or urban center) would be valuable. Furthermore, subjects were primarily middle class Caucasians, reflecting the composition of the population at the study site. However, research findings have indicated cultural and gender differences in the perception of pain, and therefore, while this sample was relatively homogeneous for culture, generalization to more diverse populations would be cautioned.

Another limitation of this study was that children were allowed to watch the instructional videotape and read the instructional handout with their parents. The investigators did not want to separate the parent and child during the stressful situation of a clinic visit, and the practicality of doing so was questionable. Children want to stay near their parents throughout clinic visits, especially when something unpleasant is going to occur. Allowing the child to see the film or read the handout along with the parent adds a confounding factor. Viewing the film or viewing the handout may have influenced the children's behavior. Which leads to another dismantling factor for analysis, and a host of other research options in exploring the direct education of children in implementing distraction for themselves, preparing for immunizations, and the education regarding coping skills.

Many of the parents in the control group used distraction with their children as part of their natural behavior, and some of them were very effective in capturing their children's attention and keeping them calm. This "contamination" of the control group was unavoidable. Although control group parents were not instructed to use distraction, the investigators felt that it would have been ethically wrong to instruct them not to use
techniques known to help their children. Some studies have utilized a specific technique in one condition and none in another, however, this study focused on more of the practical and applied applications of what parents already bring in their “tool bag” and what staff might do to enhance children’s coping with distress.

Questions for Future Research

This study paves the way for further studies. In terms of the relationship between parent behaviors (i.e., distress promoting and coping promoting behaviors) and child behaviors (i.e., distress and coping behaviors), further research is needed to ascertain the causal nature of this relationship. Assessing the interrelationship between these factors, along with the components (i.e., toys, discussion of favorite things, proximity) is needed to determine if parent behaviors direct child behaviors or if child behaviors dictate how the parents will behave during their child’s procedures.

Another area of emphasis relates to the behaviors of nurses. Based on the findings from this study, nurses’ behavior did not directly relate to child behavior when considering behavior throughout all phases. However, nurses were helpful in reducing child distress during the procedural phase and post-procedural phase. It would be interesting to determine why these phase effects are present. One suggestion is that perhaps nurses are too involved preparing for the shot and thus attention is focused on preparation and not the child. Another suggestion is that they may begin to respond to differing levels of distress in the child or their parent during these phases.

Although findings were averaged across participants, it would be interesting to determine if length of procedural phase impacted either child distress or parent behavior. More specifically, it would be interesting to determine if a child sits in the room longer
anticipating the receipt of a shot, do they display more distress and/or would their parents demonstrate less coping-promoting behaviors over timed. A related extrapolation is the time leading up to the visit, and the methods utilized in preparing the child for the immunization procedures.

Data was presented in a group manner, and most data was based on averages. Factors relating to the number and location of shots were averaged as well. The subjects in this study received anywhere from 1 shot to 6 shots in either or both arms and either or both legs. The children also received shots either individually or two at a time. Furthermore, shots were provided either intramuscular or subcutaneously. Immunizations for Hepatitis A, DTaP (Diphtheria, Tetanus, Pertussis), IPV (Inactive Poliovirus), MMR (Measles, Mumps, Rubella), Meningococcal, and Influenza were given. Further research needs to be conducted to determine if there are differences in child distress and parental use of distraction when the number of shots, location site, type of immunization (IM or SC), or substance injected. These factors may lead us to further understand if the efficiency method (two shots at a time) is truly less distressing for the child.

In terms of the effectiveness of distraction as an intervention to reduce child procedural pain, additional information is required to determine moderating and mediating variables. More specifically, what factors of the child or parent are important in making distraction even more effective? What are the specific elements of the distraction intervention that are necessarily required for distraction to be effective? What factors in the shot room could further enhance the effectiveness of these techniques?
Another area assessed by research is differing raters of child distress. Based on the findings of this study, children, parents, nurses, and independent raters all rated the child distress differently. Further research could be conducted to determine what specific variables result in these differences. While this would be globally important, it will also be important to consider the standardized and utilized observation procedures to ensure that further studies are able to be compared.

Finally, more information is required to find what the most minimal form of intervention to educate parents on techniques to use for distraction. More specifically, after determining the specific components, what will be the most efficient way of educating parents into distraction interventions. This is certainly an area that will require a two-step assessment approach – one that evaluates the learning and knowledge based data of the training procedure, and another that evaluates the implementation of these learned skills. Such a study would not easily be conducted in an applied clinic setting; the outcome would need to consider the cost-effectiveness so that it can be implemented in busy pediatric settings.

Despite these limitations, all enrolled subjects completed their immunization procedures on the day of the appointment. While this study leads us to further questions, it has confirmed that distraction does indeed increase coping behaviors for children experiencing distress during immunizations. Capable parents can be encouraged with these findings to promote acceptance and coping when their children face time-limited pain provoking medical procedures.
APPENDICES
Is your child having an immunization today?!!

Want to learn more about reducing your child’s pain!

Would you like to participate in a study about reducing children’s pain during immunizations?

- Potential training on brief pain-reducing methods
- Learn skills that will be useful in other future medical procedures
- Possibly reduce your child’s pain during immunization
- Participation and training materials are free!!

Contact research assistant in waiting area or Matthew Myrvik for more information (777-4346)
APPENDIX B

PARENTAL CONSENT FOR CHILD PARTICIPATION FORM (1 of 2)

Study Title: Behavioral Interventions to Reduce Parent and Child Distress During Routine Immunizations

Principal Investigator: Matthew Myrvik, M.A., Department of Psychology, University of North Dakota, Box 8380, Grand Forks, ND 58202. Tel. (701) 777-4348.

Student Advisor: Margo Adams-Larsen, Ph.D., Psychological Services Center, University of North Dakota, Box 7108, Grand Forks, ND 58202. Tel. (701) 777-3691.

Permission for Your Child to Participate in a Research Study

I AM BEING ASKED TO READ THE FOLLOWING MATERIAL TO ENSURE THAT I AM INFORMED OF THE NATURE OF THIS RESEARCH STUDY AND OF HOW MY CHILD WILL PARTICIPATE IN IT, IF I GIVE MY CONSENT. SIGNING THIS FORM WILL INDICATE THAT I HAVE BEEN SO INFORMED AND THAT I CONSENT TO MY CHILD'S PARTICIPATION. FEDERAL REGULATIONS REQUIRE WRITTEN INFORMED CONSENT PRIOR TO PARTICIPATION IN THIS RESEARCH STUDY SO THAT I CAN KNOW THE NATURE AND RISKS OF MY CHILD'S PARTICIPATION AND CAN DECIDE WHETHER MY CHILD SHOULD PARTICIPATE OR NOT PARTICIPATE IN A FREE AND INFORMED MANNER.

PURPOSE

Since your child is scheduled to receive an immunization, you have been invited to participate in a study reevaluating what behaviors children and parents display during routine immunizations. Thus, you are being asked to review this document to inform you of research related to your child's participation. The purpose of this research is to evaluate what behaviors children and their parents are displaying during immunizations and what behaviors are useful in reducing parent and child distress during such procedures.

SELECTION CRITERIA

You are being asked to review this consent form because you and your child have demonstrated an interest in participating in this research project, your child is scheduled to receive an immunization today, you are able to speak and read English and your child is between the ages of 18 months and 84 months (7 years). Approximately 90 children will be enrolled in this study in the coming year.

PROCEDURE

If your child participates, you will complete a questionnaire relating to their perception of pain associated with the upcoming immunization. We will be inviting your child, along with you, to participate in any educational training that is available for implementing distraction on the day of your child's scheduled visit. Upon completion of the procedure, your child will be asked to report levels of distress during the procedure. The entire immunization procedure will be recorded for future rating of individual behaviors. The video camera will begin recording upon you and your child enter the immunization room or when the nurse enters the examination room to administer the shot and will be concluded upon you exiting the room. No portion of the preceding visit with the physician will be recorded. Upon completion of these ratings after the procedure, your child's participation in the project will no longer be required. You will be provided copies of the study pamphlets and consent forms to take home for your records and future use if you so desire.

RISKS

A potential risk associated with this study is disclosing confidential information. To minimize this risk, your child will be given the option of withdrawing from the research study at any time without repercussion to your ability to receive health services, your relationship with the University of North
Dakota, your relationship with Altru Health Systems, and your presence in the community. Furthermore, a number of steps will be taken to protect the confidentiality of your child’s participation, content of sessions, and assessment data. If your child feels discomfort at any time, you and your child are encouraged to contact the principal investigator, Matthew Myrvik, or the student’s advisor, Dr. Margo Adams Larsen, at any time and they will answer questions and provide other referrals if you wish to seek services elsewhere at your expense. Also in the unforeseen case of medical or psychological trauma, you are to notify your primary physician at your own expense.

**BENEFITS**

One direct benefit relating to this study is that your child may receive education of implementing distraction procedures during medical procedures. These procedures have been found to be moderately effective in reducing child reports of pain as well as behavioral distress (Kleiber & Harper, 1999). These procedures may be utilized during today’s procedure as well as during future procedures to aid in reducing procedure related distress.

**CONFIDENTIALITY**

Your child’s privacy is important. All data is considered protected health information, and is confidential, and managed in accordance with the HIPAA Policies and Procedures. Consent to participate will be stored in a locked file cabinet in the principle investigators office within the UND Department of Psychology. Research data will be identified by a participant number rather than by name, and your child’s data will remain confidential during the collection, analysis, or in any written or published report. In addition, all data will be reported in group format. When analyzed, the data will be entered into a computer using only participant numbers (not names) and the files will be password protected. Audio/video data will be collected on a video camera and will be transferred immediately to a portable laptop where it will be stored and password protected. This laptop, when not in use, will be locked and stored in another file cabinet away from any identifying information, but within the Department of Psychology facility, and will be utilized solely for research purposes. Finally, the data will be transferred between the clinic and the UND Department of Psychology in a locked briefcase. Your consent approves the use of these research materials beyond your participation in the study. The research materials will be maintained for a period of 3 years following the end of your participation in this study or sooner if the researcher has concluded the needed analyses for this project. At the conclusion of the study, the materials will be shredded or erased as applicable to remove all data. Only researchers, clinicians, and persons authorized to audit clinical and IRB procedures will have access to the data.

**PARTICIPATION AND SUBJECT COMPENSATION**

Your child’s participation is completely voluntary, and you and your child may stop at any time without penalty by simply asking to do so. This will not affect you or your child’s relationship with the researcher, Altru Health Systems, and the University of North Dakota in any manner. Your child will be compensated for participation in this study by receiving small token items such as bubbles, pinwheels, stickers, etc.

**CONTACTS**

If you require additional information, please call the principal investigator, Matthew Myrvik, at (701) 777-4348 or the student advisor, Margo Adams-Larsen, at (701-777-3691). If you have questions concerning your child's rights as a research subject, you should call UND’s Office of Research and Program Development at 777-4279.

**AUTHORIZATION**

BEFORE GIVING MY CONSENT BY SIGNING THIS FORM, THE METHODS, INCONVENIENCES, RISKS, AND BENEFITS HAVE BEEN EXPLAINED TO ME AND MY QUESTIONS HAVE BEEN ANSWERED. I MAY ASK QUESTIONS AT ANY TIME AND MY CHILD IS FREE TO WITHDRAW FROM THE PROJECT AT ANY TIME WITHOUT PENALTY. MY CHILD'S PARTICIPATION IN THIS PROJECT MAY BE ENDED BY THE INVESTIGATOR FOR REASONS THAT WOULD BE EXPLAINED. NEW INFORMATION DEVELOPED DURING THE COURSE OF THIS STUDY WHICH MAY AFFECT MY WILLINGNESS TO LET MY CHILD CONSENT TO THE RESEARCH PROJECT WILL BE GIVEN TO ME AS IT BECOMES AVAILABLE. THIS CONSENT FORM WILL BE FILED IN AN AREA DESIGNATED BY THE HUMAN SUBJECTS COMMITTEE WITH ACCESS
RESTRICTED TO THE PRINCIPAL INVESTIGATOR, MATTHEW MYRVIK OR AUTHORIZED REPRESENTATIVES OF THE UNIVERSITY OF NORTH DAKOTA. I DO NOT GIVE UP ANY OF MY LEGAL RIGHTS BY SIGNING THIS FORM. A COPY OF THIS SIGNED CONSENT FORM WILL BE GIVEN TO ME.

Print Child's Name

Date of Birth

Parent/Guardian Signature

Date
APPENDIX C

PARENT CONSENT FORM (2 of 2)

Study Title: Behavioral Interventions to Reduce Parent and Child Distress During Routine Immunizations

Principal Investigator: Matthew Myrvik, M.A., Department of Psychology, University of North Dakota, Box 8380, Grand Forks, ND 58202. Tel. (701) 777-4348.
Student Advisor: Margo Adams-Larsen, Ph.D., Psychological Services Center, University of North Dakota, Box 7108, Grand Forks, ND 58202. Tel. (701) 777-3691.

Permission to Participate in a Research Study
I AM BEING ASKED TO READ THE FOLLOWING MATERIAL TO ENSURE THAT I AM INFORMED OF THE NATURE OF THIS RESEARCH STUDY AND HOW I WILL PARTICIPATE, IF I GIVE MY CONSENT. SIGNING THIS FORM WILL INDICATE THAT I HAVE BEEN SO INFORMED AND THAT I CONSENT TO MY PARTICIPATION. FEDERAL REGULATIONS REQUIRE WRITTEN INFORMED CONSENT PRIOR TO PARTICIPATION IN THIS RESEARCH STUDY SO THAT I CAN KNOW THE NATURE AND RISKS OF MY PARTICIPATION AND CAN DECIDE WHETHER I SHOULD PARTICIPATE OR NOT PARTICIPATE IN A FREE AND INFORMED MANNER.

PURPOSE
Since your child is scheduled to receive an immunization, you have been invited to participate in a study evaluating what behaviors children and parents display during routine immunizations. Thus, you are being asked to review this document to inform you of research related to your participation. The purpose of this research is to evaluate what behaviors children and their parents are displaying during immunizations and what behaviors are useful in reducing parent and child distress during such procedures.

SELECTION CRITERIA
You are being asked to review this consent form because you have demonstrated an interest in participating in this research project, your child is scheduled to receive an immunization today, you are able to speak and read English, and your child is between the ages of 18 months and 84 months (7 years). Approximately 90 children will be enrolled in this study through the coming year.

PROCEDURE
If you decide to participate, you will complete a number of questionnaires pertaining to the medical history of your child. You will be asked to recall previous medical experiences of your child as well as their typical reaction to such experiences. You will also be asked to record your distress level as well as your child's distress level prior to the immunization. Upon completing these questionnaires, we may be inviting you to participate in prompting distraction techniques with your child while they are receiving their immunization. Thus, we will be asking you to participate in any educational training that is available for implementing distraction on the day of your child’s scheduled visit. The entire immunization procedure will be recorded for future rating of individual behaviors. The video camera will begin recording upon you and your child enter the immunization room or when the nurse enters the examination room to administer the shot and will be concluded upon you exiting the room. No portion of the preceding visit with the physician will be recorded. Upon completion of the procedure, you and your child will be asked to report levels of distress during the procedure. Upon completion of these ratings after the procedure, your participation in the project will be complete. You will be provided copies of the study pamphlets and consent forms to take home for your records and future use if you so desire.

RISKS
A potential risk associated with this study is disclosing confidential information. To minimize this risk, you will be given the option of withdrawing from the research study at any time with no repercussions to your ability to receive health services, your relationship with the University of North Dakota, your relationship with Altru Health Systems, and your presence in the community. Furthermore, a number of steps will be taken to protect the confidentiality of your participation, content of sessions, and assessment data. If you feel discomfort at any time, you are encouraged to contact the principal investigator, Matthew Myrvik, or the student's advisor, Dr. Margo Adams Larsen, at any time and they will answer questions and provide other referrals if you wish to seek services elsewhere at your expense. Also in the unforeseen case of medical or psychological trauma, you are to notify your primary physician at your own expense.

BENEFITS
One direct benefit relating to this study is that you may receive education of implementing coping procedures with your child during medical procedures. These procedures have been found to be moderately effective in reducing child reports of pain as well as behavioral distress (Kleiber & Harper, 1999). These procedures may be utilized during today's procedure as well as during future procedures to aid in reducing procedure related distress. In addition, upon completion of your participation today, you will be given educational materials, including a DVD, to learn more about these procedures, and your child will receive a coping kit to take home for use in the future.

CONFIDENTIALITY
Your privacy and your child's privacy is important. All data is considered protected health information, and is confidential, and managed in accordance with the HIPAA Policies and Procedures. Consent to participate will be stored in a locked file cabinet in the principle investigators office within the UND Department of Psychology. Research data will be identified by a participant number rather than by name, and your data will remain confidential during the collection, analysis, or in any written or published report. In addition, all data will be reported in group format. When analyzed, the data will be entered into a computer using only participant numbers (not names) and the files will be password protected. Audio/video data will be collected on a video camera and will be transferred immediately to a portable laptop where it will be stored and password protected. This laptop, when not in use, will be locked and stored in another file cabinet away from any identifying information, but within the Department of Psychology facility, and will be utilized solely for research purposes. Finally, the data will be transferred between the clinic and the UND Department of Psychology in a locked briefcase. Your consent approves the use of these research materials beyond your participation in the study. The research materials will be maintained for a period of 3 years following the end of your participation in this study or sooner if the researcher has concluded the needed analyses for this project. At the conclusion of the study, the materials will be shredded or erased as applicable to remove all data. Only researchers, clinicians, and persons authorized to audit clinical and IRB procedures will have access to the data.

PARTICIPATION AND SUBJECT COMPENSATION
Your participation is completely voluntary, and you may stop at any time without penalty by simply asking to do so. This will not affect your relationship with the researcher, Altru Health Systems, and the University of North Dakota in any manner. You will not be compensated for participation in this study.

CONTACTS
If you would like additional information, you may call the principal investigator, Matthew Myrvik, at (701) 777-4348 or the student advisor, Dr. Margo Adams Larsen, at (701)-777-3691. If I have questions concerning my rights as a research subject, you should call UND's Office of Research and Program Development at (701) 777-4279.

AUTHORIZATION
BEFORE GIVING MY CONSENT BY SIGNING THIS FORM, THE METHODS, INCONVIENCES, RISKS, AND BENEFITS HAVE BEEN EXPLAINED TO ME AND MY QUESTIONS HAVE BEEN ANSWERED. I MAY ASK QUESTIONS AT ANY TIME AND I AM FREE TO WITHDRAW FROM THE PROJECT AT ANY TIME WITHOUT PENALTY. MY PARTICIPATION IN THIS PROJECT MAY BE ENDED BY THE INVESTIGATOR FOR REASONS THAT WOULD BE EXPLAINED. NEW INFORMATION DEVELOPED DURING THE COURSE OF THIS STUDY WHICH MAY AFFECT
MY WILLINGNESS TO CONSENT TO THE RESEARCH PROJECT WILL BE GIVEN TO ME AS IT BECOMES AVAILABLE. THIS CONSENT FORM WILL BE FILED IN AN AREA DESIGNATED BY THE HUMAN SUBJECTS COMMITTEE WITH ACCESS RESTRICTED TO THE PRINCIPAL INVESTIGATOR, MATTHEW MYRVIK, OR AUTHORIZED REPRESENTATIVES OF THE UNIVERSITY OF NORTH DAKOTA. I DO NOT GIVE UP ANY OF MY LEGAL RIGHTS BY SIGNING THIS FORM. A COPY OF THIS SIGNED CONSENT FORM WILL BE GIVEN TO ME.

Print Name

Date

Signature
APPENDIX D

STAFF CONSENT FORM

Study Title: Behavioral Interventions to Reduce Parent and Child Distress During Routine Immunizations

Principal Investigator: Matthew Myrvik, M.A., Department of Psychology, University of North Dakota, Box 8380, Grand Forks, ND 58202. Tel. (701) 777-4348.

Student Advisor: Margo Adams-Larsen, Ph.D., Psychological Services Center, University of North Dakota, Box 7108, Grand Forks, ND 58202. Tel. (701) 777-3691.

Permission to Participate in a Research Study

I AM BEING ASKED TO READ THE FOLLOWING MATERIAL TO ENSURE THAT I AM INFORMED OF THE NATURE OF THIS RESEARCH STUDY AND HOW I WILL PARTICIPATE (AS A MEDICAL/NURSING CARE PROVIDER), IF I GIVE MY CONSENT. SIGNING THIS FORM WILL INDICATE THAT I HAVE BEEN SO INFORMED AND THAT I CONSENT TO MY PARTICIPATION. FEDERAL REGULATIONS REQUIRE WRITTEN INFORMED CONSENT PRIOR TO PARTICIPATION IN THIS RESEARCH STUDY SO THAT I CAN KNOW THE NATURE AND RISKS OF MY PARTICIPATION AND CAN DECIDE WHETHER I SHOULD PARTICIPATE OR NOT PARTICIPATE IN A FREE AND INFORMED MANNER.

PURPOSE

The purpose of this research is to evaluate what behaviors children and their parents are displaying during immunizations as well as what behaviors are useful in reducing parent and child distress during such procedures. Thus, you are being asked to review this document to review your participation in this project as a medical/nursing care provider.

SELECTION CRITERIA

You are being asked to review this consent form because the study will require videotaping the child’s immunization procedure through its entirety. Since you are a member of the medical team administering immunizations to children, you will need to provide authorization and consent for your visual image as well as your interactions with each child participating in the study to be stored and utilized for data collection purposes. In addition, you will be asked to provide some information regarding your interaction with the child and their family members during this routine office procedure. This study will be collecting data on about 90 children, thus, repetitive participation is anticipated.

PROCEDURE

If you consent to allowing your work sample and visual image to be recorded, you will administer the immunization as you typically would. You will also complete a brief questionnaire after the procedure to record various information regarding the procedure itself as well as distress levels of the parent and the child. You will only be asked to complete this for children whose parents have agreed to participate in this research project. Furthermore, the immunization procedure will be recorded to rate the behaviors of all individuals at a later date. Upon completion of these ratings after the procedure, your participation in the project will be complete. It is very likely that you will be participating frequently in this study as a medical team member routinely administering immunizations at your work site. The study will be collecting data on about 90 children.

RISKS

The primary risks associated with this study relates to the primary participants (the children and their parents). As a medical team member, you are being asked to provide immunizations in the manner you have always done, and then complete a brief questionnaire about the procedure. A potential risk for you is that your work procedures and practical interactions with patients will be videotaped. To minimize this risk, specific procedures for managing protected health information and confidential information have been established in our protocol, and all records will be maintained securely. You can withdraw your participation as a provider in this study at any time, at which point you need to inform the Principle...
Investigator (Matthew Myrvik, MA, at 701.777.4494) so that other arrangement may be made to provide immunization procedures for children participating in this study. Your participation or withdrawal from participation will have no impact on your work, relationship with your employer, or patient care needs. If you feel discomfort at any time, you are encouraged to contact the principal investigator, Matthew Myrvik, M.A., or the student’s advisor, Dr. Margo Adams Larsen (701.777.4494), at any time and they will answer questions and discuss solutions. Also in the unforeseen case of medical or psychological trauma, you are to notify your primary physician at your own expense.

**BENEFITS**

One direct benefit relating to this study is that the child you are working with may receive education of implementing coping procedures and how to manage immunization and other medical procedures more effectively, making your job easier, and more pleasant. The techniques being taught have been found to be moderately effective in reducing child reports of pain as well as behavioral distress (Kleiber & Harper, 1999). At the end of data collection for this study, you will receive the educational materials provided to the parents, and your clinic will receive the coping tools that were utilized in the study for our future use with patients.

**CONFIDENTIALITY**

Your privacy is important. All patient data is considered protected health information, and is confidential, and managed in accordance with the HIPAA Policies and Procedures. Likewise, your visual image and digital recording of immunization procedures with your patient is also managed in the same manner. Consent to participate will be stored in a locked file cabinet in the principle investigators office within the UND Department of Psychology. Research data will be identified by a participant number rather than by the patient’s name, and your name will remain confidential during the collection, analysis, or in any written or published report. In addition, all data will be reported in group format. When analyzed, the data will be entered into a computer using only participant numbers (not names) and the files will be password protected. There will not be data analysis based on individual provider groups, thus, the only data that will be pertinent is what you provide in questionnaire form about the study participants. Audio/video data will be collected on a video camera and will be transferred immediately to a portable laptop/jump drive/DVD where it will be stored in encrypted and password protected form. This laptop/jump drive/DVD, when not in use, will be locked and stored in another file cabinet away from any identifying information, but within the Department of Psychology facility, and will be utilized solely for research purposes. Finally, the data will be transferred between the clinic and the UND Department of Psychology in a locked briefcase. Your consent approves the use of these research materials beyond your participation in the study. The research materials will be maintained for a period of 3 years following the end of your participation in this study or sooner if the researcher has concluded the needed analyses for this project. Only researchers, clinicians, and persons authorized to audit clinical and IRB procedures will have access to the data.

**PARTICIPATION AND SUBJECT COMPENSATION**

Your participation is completely voluntary, and you may stop at any time without penalty by simply asking to do so. This will not affect your relationship with the researcher, Altru Health Systems, and the University of North Dakota in any manner. You will not be compensated for participation in this study.

**CONTACTS**

If you would like additional information, you may call the principal investigator, Matthew Myrvik, at (701) 777-4348 or the student advisor, Dr. Margo Adams Larsen, at (701) 777-3691. If you have questions concerning your rights as a research subject, you can call UND’s Office of Research and Program Development at (701) 777-4279.

**AUTHORIZATION**

BEFORE GIVING MY CONSENT BY SIGNING THIS FORM, THE METHODS, INCONVENIENCES, RISKS, AND BENEFITS HAVE BEEN EXPLAINED TO ME AND MY QUESTIONS HAVE BEEN ANSWERED. I MAY ASK QUESTIONS AT ANY TIME AND I AM FREE TO WITHDRAW FROM THE PROJECT AT ANY TIME WITHOUT PENALTY. MY PARTICIPATION IN THIS PROJECT MAY BE ENDED BY THE INVESTIGATOR FOR REASONS THAT WOULD BE EXPLAINED. NEW INFORMATION DEVELOPED DURING THE COURSE OF THIS STUDY WHICH MAY AFFECT
MY WILLINGNESS TO CONSENT TO THE RESEARCH PROJECT WILL BE GIVEN TO ME AS IT BECOMES AVAILABLE. THIS CONSENT FORM WILL BE FILED IN AN AREA DESIGNATED BY THE HUMAN SUBJECTS COMMITTEE WITH ACCESS RESTRICTED TO THE PRINCIPAL INVESTIGATOR, MATTHEW MYRVIK, OR AUTHORIZED REPRESENTATIVES OF THE UNIVERSITY OF NORTH DAKOTA. I DO NOT GIVE UP ANY OF MY LEGAL RIGHTS BY SIGNING THIS FORM. A COPY OF THIS SIGNED CONSENT FORM WILL BE GIVEN TO ME.

Print Name

Signature

Date
APPENDIX E

DEMOGRAPHIC QUESTIONNAIRE

Participant #: __________________
Date: __________________

Parent Information

Your Relationship to Child (please check):

____ Mother  ____ Father  ____ Stepmother  ____ Stepfather
____ Other

Your age: ____________ years  Your Occupation: __________________

Your Ethnicity (please check):

____ Caucasian  ____ African American  ____ Asian American  ____ Native American
____ Hispanic American  ____ Other

Your Current Marital Status (please check):

____ Married  ____ Divorced/separated  ____ Remarried
____ Widowed  ____ Never married  ____ Other

Your Education (please check one):

____ Graduate School/Professional training  ____ High School Graduate
____ University Graduate (4 year college)  ____ Some high school (min 10th gr.)
____ Partial university (at least 1 year)  ____ Junior high school graduate
____ Trade School/Community College  ____ Less than 7th grade

Your Spouse’s/Partner’s Ethnicity (please check):

____ Caucasian  ____ African American  ____ Asian American  ____ Native American
____ Hispanic American  ____ Other

Your Spouse’s/Partner’s Education (please check one):

____ Graduate School/Professional training  ____ High School Graduate
____ University Graduate (4 year college)  ____ Some high school (10th grade)
____ Partial university (at least 1 year)  ____ Junior high school graduate
____ Trade School/Community College  ____ Less than 7th grade

Your Spouse’s/Partner’s Occupation: __________________

Number of Family Members Total:
____ Adults (21+ years)  ____ Young adults (18-21 years)  ____ Children (Birth – 17 years)

Child Information

Child’s birthdate: ____________ (month/date/year)
Child’s gender: ____ Male  ____ Female
Child's Ethnicity *(circle one)*

- [ ] Caucasian  
- [ ] African American  
- [ ] Asian American  
- [ ] Native American  
- [ ] Hispanic American  
- [ ] Other  

Child's Current Grade in School/Preschool: ___________________

**CHILD'S MEDICAL HISTORY**

Do you ever avoid doctor's visits due to painful procedures?:  
- [ ] No  
- [ ] Yes

Does your child have a chronic illness (check one):  
- [ ] No  
- [ ] Yes  
Describe: _______________________________________________________

Is your child currently on any medications (check one):  
- [ ] No  
- [ ] Yes  
Describe: _______________________________________________________

How many times has your child experienced and what is their *typical reaction*:

<table>
<thead>
<tr>
<th>Reaction</th>
<th>N/A</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experience</td>
<td>No</td>
<td>Absolutely Positive</td>
<td>Somewhat Positive</td>
<td>OK</td>
<td>Somewhat Negative</td>
<td>Absolutely Negative</td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number of times(estimate)</th>
<th>Typical Reaction(see above)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Throat Cultures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Appointments</td>
<td></td>
<td></td>
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<tr>
<td>Dental Appointments</td>
<td></td>
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<tr>
<td>Dental Procedures</td>
<td></td>
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<tr>
<td>Swallowing Pills</td>
<td></td>
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<tr>
<td>Swallowing Liquid Meds</td>
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<tr>
<td>Applying Topical Meds</td>
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<tr>
<td>Blood Work</td>
<td></td>
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<tr>
<td>X-Rays</td>
<td></td>
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<tr>
<td>Hospitalizations</td>
<td></td>
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</tr>
</tbody>
</table>
Castings

Same Day Surgery

Overnight Stay Surgery

How does YOUR CHILD typically react to having a shot/immunization? (Please circle one):

<table>
<thead>
<tr>
<th>Experience</th>
<th>N/A</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
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<tr>
<td>Difficulty</td>
<td>No</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
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<tr>
<td>Minimal</td>
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<td>Moderate</td>
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</tr>
</tbody>
</table>

How anxious do YOU typically feel during your child's shot procedures (circle one):

<table>
<thead>
<tr>
<th>Experience</th>
<th>N/A</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Experience</td>
<td>Extremely</td>
<td>Relaxed</td>
<td>OK</td>
<td>Anxious</td>
<td>Extremely</td>
<td>Anxious</td>
<td></td>
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</tbody>
</table>

My child typically begins to get anxious for shots/immunizations: (check all that apply)

- Any time we discuss shot(s)
- When we talk about doctor visits
- When we talk about the appointment
- When the nurse tells us about the shot(s)
- When the doctor tells us about the shot(s) during the visit
- When we are waiting for the shot(s)
- When we are in the immunization room
- When my child sees a needle
- My child does not seem to get anxious about these procedures

PARENT'S MEDICAL HISTORY

Are your immunizations up to date? (please check): ___No ___Yes

Do you ever avoid doctor's visits? (please check): ___No ___Yes

Did you have a chronic illness as a child (please check): ___No ___Yes

Describe: ____________________________

Approximately how many times you experienced and what is your typical reaction to:

<table>
<thead>
<tr>
<th>Reaction</th>
<th>N/A</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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86
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number of times</th>
<th>Typical Reaction</th>
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<tr>
<td>Dental Procedures</td>
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<td>Swallowing Pills</td>
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<td>Swallowing Liquid Meds</td>
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<td>Applying Topical Meds</td>
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<td>Castings</td>
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<td>Same Day Surgery</td>
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<td>Overnight Stay Surgery</td>
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**TODAY'S PROCEDURE**

Was this shot provided in conjunction with a well-child check:  ____No  ____Yes

Was this appointment scheduled specifically for the immunization? ____No  ____Yes

How distressed will YOUR CHILD be during the shot, today? (circle one):

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<tr>
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</tbody>
</table>

Extremely Relaxed  Relaxed  OK  Anxious  Extremely Anxious

How do you anticipate YOUR CHILD will react to having a shot today? (circle one):

<table>
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<tr>
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<td>10</td>
</tr>
</tbody>
</table>

No Difficulty  Minimal Difficulty  Moderate Difficulty  Much Difficulty  Extreme Difficulty
How anxious are **YOU** about today's shot for your child? *(circle one):*

1 2 3 4 5 6 7 8 9 10

Extremely Relaxed  OK  Anxious  Extremely Anxious

Did your child take any pain-relieving medication before the procedure? **_No_** **_Yes_**

*If yes, what medication(s) and dose did you give?* ____________________________

What is your typical strategy to prepare your child for shots? *(Check all that apply)*

- No preparation.
- Have my spouse/significant other bring child to immunizations.
- Told child about doctor visit, but not about shot.
- Discussed the shot with my child.
- Discussed the shot and practiced it with my child.
- Practiced deep breathing.
- Practiced distraction techniques.
- Read age-appropriate books about going to doctors, but *not* about shots.
- Read age-appropriate books about going to the doctors that *included* shots.
- Allowed them to play with doctor toys prior to coming today.
- Allowed them to play with doctor toys that included giving shots.
- Other: ____________________________

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APPENDIX F

OUCHER DIRECTIONS
(Beyer, 1989)

Participant #: __________________________
Date: __________________________

Pre Post (Circle the appropriate time)

This picture shows not hurt (point to the bottom picture), this picture shows just a little bit of hurt (point to the 2nd picture), this picture shows a little more hurt (point to the 3rd picture), this picture shows even more hurt (point to the 4th picture), this picture shows a lot of hurt (point to the 5th picture), and this picture shows the biggest hurt you could ever have (point to the 6th picture). Can you point to the picture that shows how much hurt you are having right now?

CHILD’S RATING (please circle the child’s response):

Pre Post (Circle the appropriate time)

This picture shows not hurt (point to the bottom picture), this picture shows just a little bit of hurt (point to the 2nd picture), this picture shows a little more hurt (point to the 3rd picture), this picture shows even more hurt (point to the 4th picture), this picture shows a lot of hurt (point to the 5th picture), and this picture shows the biggest hurt you could ever have (point to the 6th picture). Can you point to the picture that shows how much hurt you are having right now?

CHILD’S RATING (please circle the child’s response):
APPENDIX G

RATING FOR CHILDREN-PARENT REPORT (POST)

Participant #: __________________________
Date: __________________________

Please compare his or her behavior with their past behaviors during shots (circle one number):

How did YOUR CHILD react to having a shot, today? (Please circle one):

1  2  3  4  5  6  7  8  9  10
No Difficulty Minimal Difficulty Moderate Difficulty Much Difficulty Extreme Difficulty

How anxious were YOU during today's shot? (circle one number):

1  2  3  4  5  6  7  8  9  10
Extremely Relaxed Relaxed OK Anxious Extremely Anxious

What techniques did you use during today’s procedures: (please circle all that apply)

1  Deep breathing
2  Blew bubbles
3  Told stories
4  Progressive Muscle Relaxation
5  Non-procedural talk (talking about everything but the shot)
6  Holding the child
7  Gently touching the child.
8  Watch TV or a video during the procedure
9  Play with toys with your child
10  Listened to music
11  Empathize with your child (I know that this is hard)
12  Reassure your child (It will be alright)
13  Apologize to your child (I am sorry you have to go through this)
14  Criticize your child (You’re being a baby)
15  Offer a prize for your child (I will get you a game if you do this)
16  Allowed your child to control the procedure (Please decide when you are ready)
17  Other: (please list) ____________________________________________

How effective do you think that you were in reducing your child’s distress? (Please circle one)

1  2  3  4  5  6  7  8  9  10
Extremely Successful Successful OK Worse Extremely Worse
APPENDIX H

RATING FOR CHILDREN-NURSE REPORT

Participant #: ____________
Date: ____________

Please rate how distressed the child was during their immunization procedure just now. In making your judgment, please compare his or her behavior with the behaviors of all other children you have observed, and not with this child’s past behaviors (circle one number only):

What immunizations were provided today? __________________________________

Where on the body were the shots administered? ______________________________

How many immunizations were given to this child today? 1 2 3 4 5 6

How did the CHILD react to having a shot, today?

1 2 3 4 5 6 7 8 9 10
No Difficulty Minimal Difficulty Moderate Difficulty Much Difficulty Extreme Difficulty

How anxious did the CAREGIVER appear to be during today’s shot?

1 2 3 4 5 6 7 8 9 10
Extremely Relaxed Relaxed OK Anxious Extremely Anxious

What techniques did the care-giver use during today’s procedures: (Please circle all that apply):

1 Deep breathing
2 Blew bubbles
3 Told stories
4 Progressive Muscle Relaxation
5 Non-procedural talk (talking about everything but the shot)
6 Holding the child
7 Gently touching the child.
8 Watch TV or a video during the procedure
9 Play with toys with your child
10 Listened to music
11 Empathize with your child (I know that this is hard)
12 Reassure your child (It will be alright)
13 Apologize to your child (I am sorry you have to go through this)
14 Criticize your child (You’re being a baby)
15 Offer a prize for your child (I will get you a game if you do this)
16 Allowed your child to control the procedure (Please decide when you are ready)
17 Other: (please list) ______________________________________________________
Did the care-giver help during the procedure? 

No  Yes

Was the care-giver respectful to staff during the procedure? 

No  Yes

How effective do you think that the care-giver was in reducing their child’s distress?

1  2  3  4  5  6  7  8  9  10
Extremely Successful  OK  Worse
Successful            Extreme  Worse
APPENDIX I

CAMPIS-R
(Blount, Sturges, & Powers, 199)

ADULT CODES

ADULT TO ADULT

HDA = Humor Directed to Adults
NPA = Nonprocedure-Related Talk To Adults
PTA = Procedure-Related Talk To Adults
CMC = Commands For Managing Child’s Behavior

ADULT TO CHILD

HDC = Humor Directed To Child
NPC = Nonprocedure-Related Talk To Child
CCS = Command To Use Coping Strategy
CPA = Command To Engage In Procedural Activity
PRA = Praise
CRIT = Criticism
NPC = Notice Of Procedure To Come
REA = Reassuring Comment
GCC = Giving Control To The Child
APO = Apology
BCC = Behavioral Commands To The Child
CST = Checking Child’s Status
EMP = Empathy

ADULT TO EITHER ADULT OR CHILD

CCT = Child’s General Condition Related Talk
CSC = Current General Status Comments
**Adult Code Definitions**

**HUMOR DIRECTED TO ADULTS (HDA)**

*Any statement that is clearly intended to be humorous* and is primarily lighthearted in tone. Humor is often accompanied by laughter from the person making the statement and may evoke laughter in the patient or in other staff members. Sarcasm may be coded as humor if it is accompanied by laughter on the part of the speaker or on the part of the listener. Sarcasm is not coded as humor if it is accompanied by an anger or harsh tone of voice.

Examples:
1. Outright jokes of the “one-liner” variety.
2. Statements that suggest purely facetious, outlandish, or outrageous ideas.
3. Statements that emphasize the humorous aspects of a situation or problem.
4. Statements which present lighthearted criticism of someone else in such a manner that would be lightly received (e.g., “Oh you silly goose!”).
5. “Sure, working on Sunday is my top priority.”
6. Laughter (generally coded + for affect).

**HUMOR DIRECTED TO CHILD (HDC)**

*Any statement that is clearly intended to be humorous* and is primarily lighthearted in tone. Humor is often accompanied by laughter from the person making the statement and may evoke laughter in the patient or in other staff members. Sarcasm may be coded as humor if it is accompanied by laughter on the part of the speaker or on the part of the listener. Sarcasm is not coded as humor if it is accompanied by an anger or harsh tone of voice.

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3. Statements that emphasize the humorous aspects of a situation or problem.
4. Statements which present lighthearted criticism of someone else in such a manner that would be lightly received (e.g., “Oh you silly goose!”).
5. “Sure, working on Sunday is my top priority.”
6. Laughter (generally coded + for affect).

**NONPROCEDURE-RELATED TALK DIRECTED TOWARD CHILD (NPC)**

*Talk that does not pertain to the treatment procedure or about the child’s illness.*

Examples:
1. Conversations about the child’s pet, siblings, parents, school, motorcycles, toys, etc.
2. Questions, unrelated to the child’s illness or treatment, about the child’s wants, desires, etc.
3. Conversations about activities on the ward or about other children or staff members on the ward.

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NON-PROCEDURE RELATED TALK DIRECTED TOWARD OTHER ADULTS (NPA)
Talk that does not pertain to the treatment procedure or the child’s illness.
1. “Did you drive in this morning?”
2. “How is the new baby doing?”
3. Questions about parents, other child, spouse, home, garden, the nurse on 3-south, etc.
4. “Susie embarrassed me last night with her comments about the lady across the hall.”

PROCEDURE-RELATED TALK-ADULT TO ADULT (PTA)
Any talk that directly pertains to the current treatment procedures. Comments about past treatment procedures are included in this category only if they relate to what is going on now. Commands included in this category may relate to actual physical manipulation of the child (e.g., “Help him curl up in a ball.”), as this relates to the ongoing procedures and is not issued as a result of child distress behavior. Not included in this category are commands or suggestions related to managing the child’s distress behaviors during the procedures (“Hold his legs.”). The implication is that he is moving about and should be restrained (Code this as Commands or Suggestions for Managing the Child’s Behavior.)
Examples:
1. “Hand me the betadine, please.”
2. “Give me a swave.”
3. “I can’t find the marrow.”
4. “How much spinal fluid do you need?”
5. “Is it dripping?”
6. “Are you using lidocane today?”
7. It’s not dripping yet.”
8. I’m Dr. Smith. I will be doing the procedure today.
9. “You need to stand over here.”
10. “Would you hand me some #7 gloves?”
11. “How many of these tubes do we use?”
12. “This isn’t the usual bone marrow procedure!”

CHILD’S GENERAL PHYSICAL CONDITION RELATED TALK (CCT)
Questions or comments about the child’s history or future health care. For example, comments could refer to the BMA if that procedure is done and resident is currently conducting the LP. These comments must relate to the child’s illness or treatment.
Examples:
1. Questions about the child’s history.
2. Parent’s request for information.
   A. “How long does it take to get results back?”
   B. “Will she have to come back tomorrow?”
   C. “She thought she was going to have to have this every week.”
   D. “How many visits do we have to make?”
   E. “When does Dr. Grush believe her medication will be changed?”
   F. “Does Janie have to have chemo next time we visit?”
G. “Is she having any problems with vomiting?”
H. “How does she like her wig?”
I. “Last time he got too much valium, he didn’t do too well during the procedures.”

3. Child comments such as:
   A “That time it took a long time.” (Referring to something about the procedure.)
   B. “The other doctor washed too hard last time.”

CURRENT GENERAL STATUS COMMENTS (CSC)
Comments by adults regarding the child’s current physical, emotional and/or behavioral status. Merely an observation rather than a comment directed toward changing that which is observed would qualify for this category.
   1. “She seems to have labored breathing today.”
   2. “He has stiff muscles.”
   3. “Johnny, your muscles are tight.”
   4. “He is upset today.”
   5. “Boy is she out of it.”

COMMAND TO USE COPING STRATEGY (CCS)
Any orders, suggestions, or statements of a rule, which direct the child to engage in a coping behavior. These strategies are generally issued immediately prior to a painful event, and may suggest one (but not exclusively one) of the following: relaxation, distraction, use of coping statements, or deep breathing. An example such as “Can you breath now” is coded CCS in spite of it giving the impression of control to the child (GCC).
   1. “Use you deep breathing now.”
   2. “Would you like to count backwards from 10 very slowly?”
   3. “Imagine you are Superman and this is a test of your strength.”
   4. “Squeeze your mother’s hand when you feel the bumble bee.”
   5. “Just relax, alright?”

COMMAND TO ENGAGE IN PROCEDURE-RELATED ACTIVITY (CPA)
Any orders, suggestions, or statements of a rule, which directs the child to engage in some procedure-related activity. Common commands might include asking the child to prepare his/her pajamas for the wash, telling the child to curl up for the LP, asking a child to move a part of his/her body, or asking the child to tell them when something hurts.
   1. “It’s time to roll up in a ball for the LP.”
   2. “Could you move your hand so that I can fix the IV?”
   3. “You need to turn over for the wash.”
   4. “Tell me when this hurts, OK?”

PRAISING (PRA)
Any statement referring to the child or the child’s prior, ongoing, or future behavior that is positive in evaluation, shows approval or is rewarding.
   1. The positive behavior is specified: e.g., “You used your deep breathing very well.”
2. The positive behavior is not specified: e.g., “Great.” “There you go!”
3. Descriptions of child’s behavior denoting better-than-average performance: e.g., “Tommy is doing so well!” or “You are really being braver than ever!”

CRITICISM (CRIT)
Any verbalization that finds fault or implies fault with the (a) activities, (b) products, or (c) attributes of the child. Criticisms include negatively evaluative adjectives or adverbs referring to the child, statements of disapproval, statements pointing out something wrong about the child or the child’s behavior, and statements pointing out that the child is not doing something positive. Also included as Criticism are obvious sarcastic statements, if these are unaccompanied by laughter on the part of either the speaker or listeners. Usually, criticism is accompanied by a harsh voice tone.
   1. “Timmy has not been going to school the way he should have.”
   2. “Boy, you are in a bad mood today.”
   3. “That was not a very nice thing to say.”
   4. “That was not very funny.”
   5. “You didn’t use you breathing that time like I told you to.”
   7. “You’re being a pain.”

NOTIFICATION OF PROCEDURE TO COME (NPC)
Any statement denoting that a procedure is about to occur, including the wash, the “bee sting,” the “stick,” etc. If the same information is repeated by the parents or staff, either without the child’s request for reassurance or emotional support, or with the child asking for mere repetition of the information, code the subsequent notification as NPC.
   1. “Okay, here comes the wash.”
   2. “Now, it’s gonna be just a little bee sting.”
   3. “One more stick.”
   4. “This is going to feel cold.”
   5. “Dr. Powell is going to put on her gloves now, O.K.”
   6. “It’s that soap.”
   7. “I’m going to give you a little break” (to let the anesthetic work).

REASSURING COMMENT (REA)
Procedures related comments that are directed toward the child with the intent of reassuring the child about his/her condition, or the course of the procedure. These may be volunteered by staff and/or parents and may be in response to questions by the child or may reflect the child’s comments. If procedure related information is repeated in response to the child’s request for reassurance or emotional support, code these procedural notifications as REA.
   1. “A little bit of exercise will take care of that.” (In response to the child’s comment re. some soreness)
   2. “You’re O.K.”
   3. “It’s almost over.”
4. “We’re hurrying.”
5. “Honey, it’s just soap. O.K.”
6. “I’m not doing anything.”
7. “Just touching honey.”

**GIVING CONTROL TO CHILD (GCC)**

Any statement to child denoting that child has control over some event to occur with relation to the procedure. Generally this includes staff suggestions where the child is given a choice about the procedure. “Can you breathe now?” is coded CCS even though it has the impression of giving control to the child.

1. “Let me know when you are ready to start.”
2. “Which side would you like to lie one?”
3. “Do you want a pillow for your head?”
4. “Do you like it better when we tell you or don’t tell you?”
5. “Can you start now?”
6. “Are you ready?”

**APOLOGIZES (APO)**

Any statement relating a sense of sorrow or a sense of responsibility for the pain the child is expressing. These statements may occur prior to, during, or after a painful event, and may occur in conjunction with other verbal codes.

1. “Timmy, we don’t like doing this either.”
2. “I’m sorry this is taking so long.”
3. “I wish I didn’t have to hurt you.”

**COMMANDS/SUGGESTIONS FOR MANAGING CHILD’S DISTRESS BEHAVIOR (CMC)**

Statements suggesting methods for controlling the child’s behavior while in the treatment room. Suggestions may include direct demands to treat the child in a particular way, or stating alternatives for managing the child, such as referring to methods that have or have not worked well in the past or “wondering aloud” whether different methods might result in less stress.

1. “I think she does better when she knows what is going to happen.”
2. “When he gets too upset, if you’ll just stop a few seconds he’ll calm down.”
3. “He does best with Dr. Horne.”
4. “Hold his legs.”

**BEHAVIORAL COMMANDS TO THE CHILD (BCC)**

Commands by adults toward the child, which direct the child to change some aspect of his or her behavior. This category is designed to include the limits that parents typically set on their child’s behavior and behavioral request/commands of the child. This category is distinguished from CRIT in that the focus of BBC is toward managing the child’s behavior, whereas the focus of CRIT is to find fault with the child and/or has an evaluative nature to the verbalizations. BBC is distinguished from CPA in that CPA is directed toward some specific procedural activities.

1. “No, don’t hurt your mom.”
2. "Don’t slap me, you’re not allowed to hit me."
3. "Shhh..."
4. "Wipe the tears."
5. "Ralph, you need to talk to us."
6. "Ralph, talk to your dad."
7. "Ralph, you have to behave."
8. "Sit down and be quiet."

CHECKING CHILD’S STATUS (CST)
*Any question directed toward child, which asks for his or her opinion about his or her status.* Inquiries may refer to how the child is feeling, whether the child is afraid, whether the pain is too bad, etc. Also included are reflections of the child’s answers to adult’s questions regarding his or her status. Examples such as “Can you breathe now?” even though they do in a sense inquire about the child’s condition, are coded as CCS because they are suggesting to the child the use of a coping strategy.

1. “Did you feel that?”
2. “Do you think you sleepy medicine is wearing off?”
3. “Are you comfortable?”
4. “That didn’t hurt, did it?”
5. Reflecting to the child, “Sore all back there,” in response to the child’s comment about being sore.

EMPATHY (EMP)
*Statements that show an appreciation for the frame of reference of the person being spoken to.*

1. “I know this is hard.”
2. “I know this is taking a long time.”
3. “I know it hurts.”
4. “This must be hard.”
5. “You must be getting tired.”
6. “You must be getting sick of this.”
CAMPIS-R CHILD CODES

Cry (CRY)
Scream (SCR)
Verbal Resistance (VRE)
Emotional Support (EMS)
Verbal Fear (VF)
Verbal Pain (VP)
Verbal Emotion (VE)
Information Seeking (IS)
Child Informs About Status (CIS)
Request Relief From Nonprocedural Discomfort (RRD)
Making Coping Statement (MCS)
Nonprocedure-Related Talk by Child (NPT)
Assertive Procedural Verbalizations (APV)
Child’s General Condition Related Talk (CCT)
Audible Deep Breathing (ADB)
Humor by Child (HC)
Restraint (R)
Flailing (F)
CHILD CODE DEFINITIONS

Cry (CRY)
Crying sounds-usually unintelligible but can be double coded with verbal categories.
1. “Sobbing”
2. “Booohooohooo”
3. Crying sounds

Scream (SCR)
Vocal expression of pain at high pitch/intensity, usually non-intelligible but can be coded with other verbal categories. Not included in this category is loud yelling at a low pitch.
1. Sharp, shrill, harsh, high tones
2. Shrieks
3. “Owwwh”

Verbal resistance (VRE)
Any verbal expression of delay, termination, or resistance. It must be intelligible.
1. “Stop”
2. “No more”
3. “Don’t”
4. “Let me rest”
5. “Take the needle out”
6. “I don’t want it”
7. “Take me home”
8. “I have to go to the bathroom”

Emotional support (EMS)
Verbal solicitation of hugs, hand holding, physical or verbal comfort by the child. Do not code EMS for “Mommy” if part of statement requires another code. For example, “Mommy, get me out of here” is coded as Verbal Resistance.
1. “Hold me”
2. “Mommy and Daddy”
3. “Momma please”
4. “Help me”
5. “I want my pacifier”

Verbal fear (VF)
Statement of being apprehensive or in fear. The statement must be intelligible.
1. “I’m afraid”
2. “I’m scared”

Verbal pain (VP)
Statement of pain, damage or being hurt. May be in any tense. Can be anticipatory as well as actual. Has to be a statement, not a question.
1. “That hurts”
2. “It stings”
3. “Owwwh” or “Owwhee”
4. “You’re killing me”
5. “You are pinching me”
6. “Don’t hurt me”

Verbal emotion (VE)
Statements other than VF or VR, which express the child’s emotional state. Anger, self-pity, or resentment would be emotions conveyed here. This category is reserved for negative emotions only.
1. “Why does this have to happen to me.”
2. “I hate you.”
3. “I don’t like doing this.”

Information seeking (IS)
The child asks questions about the medical procedures.
1. “When will you stick me.”
2. “When will you be finished.”
3. “Will you let me know when you’re ready to start?”
4. “Will you tell me when you are going to do something?”
5. “Is the needle in?”
6. “Is the drip coming?”

Child informs about status (CIS)
The child either volunteers or answers questions about his or her current status.
1. “I’m sore back there.”
2. “I’m sleepy,” or “Yes, a little,” in response to the question, “Are you sleepy?”
3. “Yes,” or “No,” to the question, “Are you numb yet?” or “Can you still feel it?”

Request relief from nonprocedural discomfort (RRD)
The child requests relief from something that is clearly not procedurally related.
1. “Prop up my pillow.”
2. “My elbow hurts.”
4. “You’re squeezing my hand too hard.”
5. “I can’t move my foot.”

Making coping statements (MCS)
The child makes some statements, which indicates courage or attempts to soothe himself or herself verbally.
1. “I’ll be O.K.”
2. “I’m Superman/woman.”
3. “I can take it.”
4. “It won’t hurt.”
5. “It won’t last long.”
6. “Superman would not cry.”
7. "I can get an ice cream afterward."
8. "I get a band-aid."
9. "I did good."

**Nonprocedure related talk by child (NPT)**

The child engages in talk that is in no way related to his or her current physical condition or the procedure.

1. "That cat was a girl."
2. "I was watching He-man the other day."
3. "School is going OK."
4. "We exercise some at home."

**Assertive procedural verbalizations (APV)**

Commands, statements, or requests by the child which seek to direct the course of the procedure, or some aspect of the adult's behavior as it relates to the procedure, without attempting to terminate the procedure or some aspect of the procedure. The essence of what is being targeted here is the child exercising some aspect of control over the course of the procedure without trying to terminate the procedure.

1. "Don’t mash too hard."
2. "Count to three, then stick it in there, okay?"
3. "Push it in fast."
4. "Please tell me when you are ready."
5. "Can you hurry?"
6. "Go slow."

**Child's general condition related talk (CCT)**

Comments by child regarding his or her current physical, emotional and/or behavioral status. Merely an observation rather than a comment directed toward changing that which is observed would qualify for this category.

1. "I seem to have labored breathing today."
2. "I have stiff muscles."
3. "I am upset today."
4. "Boy am I out of it."

**Audible deep breathing (ADB)**

Deep breathing that is used to cope with the procedures. Breathing that is part of the child's distress does not count as B.

**Humor by Child (HC)**

Any statement that is clearly intended to be humorous and is primarily lighthearted in tone. Humor is often accompanied by laughter from the person making the statement and may evoke laughter in the patient or in other staff members. Sarcasm may be coded as humor if it is accompanied by laughter on the part of the speaker or on the part of the listener. Sarcasm is not coded as humor if it is accompanied by an anger or harsh tone of voice.

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3. Statements that emphasize the humorous aspects of a situation or problem.
4. Statements which present lighthearted criticism of someone else in such a manner that would be lightly received (e.g., “Oh you silly goose!”).
5. “Sure, working on Sunday is my top priority.”
6. Laughter (generally coded + for affect).

**Restraint (R)**

*Child must be physically held down by staff member with noticeable pressure and/or child must be exerting force, resistance in response to restraint.* 
Sometimes it is not clear if the child is exercising pressure against staff restraint if for example, the child is completely immobilized by several staff members. In such cases where restraint is obvious, but the child’s resistance is not clear, code R. Code R if only certain limbs are restrained, while other limbs are restrained, while other limbs are allowed to move freely.

**Flailing (F)**

*Random gross movements or arms or legs or whole body.* Flail often occurs along with restraint. Must not be movement of a limb in response to a request by staff; must be random.

Examples:
1. Pounding fists
2. Throwing out arms
### APPENDIX J

#### CAMPIS-R CODING SHEET (CHILD)

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CRY=Crying  
SCR=Scream  
VRE=Verbal Resistance  
EMS=Emotional Support  
VF=Verbal Fear  
VP=Verbal Pain  
VE=Verbal Emotion  
IS=Information Seeking  
CIS=Child Informs of Status  
RRD=Requests Relief from Non-Proced. Discom.  
MCS=Making Coping Statements  
NPT=Non-procedure Related Talk (Child)  
APV=Assertive Procedural Verbalizations  
CCT=Child’s General Condition Related Talk  
ADB=Audible Deep Breathing  
HC=Humor by Child  
R=Restraint  
F=Flailing
## CAMPIS-R CODING SHEET (PARENT)

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HDA = Humor Directed to Adults
NPA = Non-procedure Talk to Adults
PTA = Procedure Talk to Adults
CPA = Command to Engage in Procedure Activity
NPC = Notice of Procedure to Come
BCC = Behavioral Commands to Child
CST = Checking Child's Status
CCT = Child's General Condition Related Talk
CSC = Child's General Status Comments
CMB = Commands for Managing Child's Behavior
PRA = Praise
HDC = Humor Directed to Child
NPT = Non-procedure Related Talk to Child
CCS = Command to Engage in Coping
CRIT = Criticism
REA = Reassuring Comment
GCC = Giving Control to the Child
APO = Apology
EMP = Empathy
# CAMPIS-R CODING SHEET (NURSE)

**Observer:** ___________________________  **Participant #:** ___________________________

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**Key:**
- **HDA** = Humor Directed to Adults
- **NPA** = Non-procedure Talk to Adults
- **PTA** = Procedure Talk to Adults
- **CPA** = Command to Engage in Procedure Activity
- **NPC** = Notice of Procedure to Come
- **BCC** = Behavioral Commands to Child
- **CST** = Checking Child's Status
- **CCT** = Child's General Condition Related Talk
- **CSC** = Child's General Status Comments
- **CMB** = Commands for Managing Child's Behavior
- **PRA** = Praise
- **HDC** = Humor Directed to Child
- **NPT** = Non-procedure Related Talk to Child
- **CCS** = Command to Engage in Coping
- **CRIT** = Criticism
- **REA** = Reassuring Comment
- **GCC** = Giving Control to the Child
- **APO** = Apology
- **EMP** = Empathy
Appendix K
Distraction Handout

Distraction: How do you do it?

Help make immunization less stressful by distraction!

Did you know that distraction is a way for many parents to help make shots as easy as possible? Through distraction, fear of immunizations can be greatly reduced, and sometimes eliminated.

What is Distraction?
Distraction is a way to move attention away from the fearful aspects of medical treatments (needles) towards more friendly objects (bubbles, books, music).

How do I use Distraction?
Find something that will really grab your child’s attention such as blowing bubbles, telling or reading stories, looking through kaleidoscopes, breathing deeply, using interactive sound books, or playing with a new toy, etc. It is helpful to talk with your child about what activities will help them during the procedure ahead of time.

How do I know If It Is right?
You know the best way to hold your child’s attention because you know your child better than anyone. Don’t hesitate to ask the staff members to find items for you to use.

7 things to remember about distraction:

1. Your child might cry. Kids need to let out their feelings as it is healthy.
2. Be calm during the procedure. When parents are anxious, children are likely to be anxious. Try to talk calmly and say friendly, positive words.
3. Help your child focus their attention away from the medical procedure.
4. Come up with some distraction ideas before entering the room.
5. Choose activities that hold your child’s attention such as:
   a. Blowing bubbles.
   b. Playing with new toys.
   c. Reciting favorite stories.
   d. Counting.
   e. Singing favorite song.
6. If you lose your child’s attention, keep trying to get it back by using the element of surprise – Oh, look at the fish!!
7. Use fun, new toys!

Things to remember:

- Pick a fun toy/book to grab their attention
- Focus on this object instead of the procedure
- Realize that your child may fuss a little
- Be calm
- Keep your child’s attention as much as possible
- Praise them for being brave at the end!
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study to evaluate the efficacy of ELA-Max (4% liposomal lidocaine) as compared
with eutectic mixture of local anesthetics cream for pain reduction of


