

**A COMPARISON OF THE EFFECTS OF  
CUTANEOUS STIMULATION AND DISTRACTION  
ON CHILDREN'S PERCEPTIONS OF INJECTION PAIN**

Laurie G. Sparks, B.S.N., M.S.(R)

**A Dissertation Presented to the Faculty of the Graduate  
School of Saint Louis University in Partial  
Fulfillment of the Requirements for the  
Degree of Doctor of Philosophy**

**1998**

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## DIGEST

Research has shown that children fear injections and perceive them as painful. Virtually all children experience injections through immunizations, and, therefore, methods to decrease injection pain could have widespread results. This study examined the effects of two nursing interventions on injection pain in preschool children: distraction and cutaneous stimulation.

A quasi-experimental design was employed to test the interventions. The study was guided by Roy's adaptation theory of nursing and the gate-control theory of pain. The sample included 105 preschool children who were attending several immunization clinics in a metropolitan area. The children were randomly assigned to 1 of 3 groups prior to their Diphtheria-Tetanus-Pertussis injection. Children in group 1 received the intervention of distraction through bubble-blowing, children in group 2 received the intervention of cutaneous stimulation by touch, and children in group 3 received standard care. Demographic data and a measure of each child's fear, using the Child Medical Fear Scale, were obtained prior to injection. All children self-reported their pain using the Oucher Scale. Analyses found the lowest mean pain scores in the touch group, followed closely by the distraction group, and highest in the standard care group. Analysis of variance found no significant difference between the interventions ( $F = .08, p = .79$ ), but a significant difference between the intervention groups and the standard care group ( $F = 6.48, p = .013$ ). Factorial ANOVA demonstrated a significant treatment main

effect, but no significant interaction effect of age or gender. Therefore, both distraction and touch reduced significantly the injection pain in this sample of preschool children.

The study results have nursing research and practice implications. Further research is needed to determine if these interventions are effective with multiple injections and with other age groups, to compare distraction with topical anesthetics, and to examine the use of distraction and touch for other forms of pediatric pain. The study results demonstrate the effectiveness of distraction and touch in reducing injection pain, and all nurses are encouraged to use these methods when administering injections to help children cope with this common, painful experience.

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## CHAPTER I

### Background

#### Introduction

Experiences of pain are an inevitable part of childhood. Most childhood pain comes from the minor bumps and scrapes associated with playing and exploring the environment. Some pain, however, is associated with health care. Injections are the most common childhood health-related painful experiences (Taddio, Nulman, Goldbach, Ipp, & Koren, 1994). Childhood injections are usually in the form of immunizations. Children today receive 14 injected immunizations between birth and 6 years of age, and injections have been identified by children as one of their most feared and painful health-care events (Broome & Hellier, 1986; Fassler, 1985; Hart & Bossert, 1994; Menke, 1981; Savedra, Tesler, Ward, Wegner, & Gibbons, 1981; Scherer & Nakamura, 1968).

Adults may not always appreciate the significance of the injection event to the child. Investigators have found a significant difference in the amount of injection pain rated by children compared to ratings by adults observing the children receiving the injections (Fradet, McGrath, Kay, Adams, & Luke, 1990; Schneider & Lo-Biondo-Wood, 1992). The event from an adult perspective may appear minor, but to the child, injections are a significant event.

Fear of injections, beginning in childhood, may also be a factor in adults who avoid physicians due to fear of medical events and procedures (Agras, Sylvester,

& Oliveau, 1969). Additionally, fear of injections has been implicated in the low immunization rates of U.S. children (Abbotts & Osborn, 1993; Keane et al., 1993; Newacheck & Halfon, 1986).

Six studies were found that examined measures to decrease injection pain in children (Abbott & Fowler-Kerry, 1995; Eland, 1981; Fassler, 1985; Fowler-Kerry & Lander, 1987; Maikler, 1991; Taddio et al., 1994). Most of the reports indicated that the measures decreased needle insertion pain, but not solution injection pain (Eland; Maikler; Taddio et al.). The treatment in one study (Fassler), while apparently successful, was too lengthy to be practical in most settings. The study by Abbott and Fowler-Kerry demonstrated the power of cognitive processes in affecting pain perception. The study by Fowler-Kerry and Lander supported the use of distraction for decreasing pain perception, but used a passive approach that was less successful in younger children.

It is clear that children fear injections and perceive pain with them. The most commonly experienced childhood injections are immunizations. Immunization pain may be a factor in the unacceptably low rate of properly immunized children in this country. Few studies of measures to decrease injection pain in children have been done, and only one presented an easy, inexpensive, and effective method. The study reported here contributed to knowledge development by examining two simple methods to decrease injection pain in children. Such information is essential for nurses who specialize in the care of children.

### Purpose

The purpose of this study was to compare the effects of distraction and cutaneous stimulation on the perception of pain caused by injected Diphtheria-Tetanus-Pertussis (DTP) immunizations in preschool-age children. Pain was measured using the Oucher scale (Beyer & Aradine, 1986) which allowed children to self-report their pain perception. Fear and anxiety are known to increase pain perception (Broome, Bates, Lillis, & McGahee, 1990; Bronzo & Powers, 1967; Von Graffenreid, Adler, Abt, Nuesch, & Spiegel, 1978; Weisenberg, Aviram, Wolf, & Raphaeli, 1984), therefore, children's fear of medical care, including injections, was measured using the Child Medical Fear Scale (CMFS) developed by Broome and Hellier (1986).

### Research Questions

The research questions addressed in this study were:

1. What is the difference in perceived injection pain between children receiving distraction or cutaneous stimulation with DTP/DTaP injections?
2. What is the difference in perceived injection pain between children receiving the two interventions (distraction and cutaneous stimulation) and those receiving standard care with DTP/DTaP injections?
3. What is the relationship between fear of injections and perceived DTP/DTaP immunization pain in preschool children?
4. What is the relationship between age and gender in perceived pain of DTP/DTaP immunizations in preschool children?

5. Does age or gender influence the effect of distraction or cutaneous stimulation on perceived DTP/DTaP immunization pain?

#### Theoretical Foundation

Roy's (1987) nursing theory of adaptation and the gate-control theory of pain (Melzack & Wall, 1965) provided the theoretical foundation for this study.

#### Adaptation Theory

Sister Callista Roy's (1987) nursing theory supported the entire study. Roy's theory evolved from her work as a graduate student with Dorothy Johnson in the 1960s. Her theory was first derived from the adaptation theory of Helson (1964) which claims adaptation is the pooled effect of response to three classes of stimuli: **Focal** stimuli are those stimuli immediately confronting a person; **contextual** stimuli are all other stimuli present; and **residual** factors are stimuli from past experiences which are relevant to the present situation. Roy was further influenced by Dorothy Johnson and Ralph Turner, and her theory is a synthesis of adaptation, systems, and interactional concepts (Meleis, 1995).

Roy (1971) stated that human beings are biopsychosocial beings with innate and acquired biologic, psychological, and social mechanisms that allow them to cope with a changing environment. These coping mechanisms are in two subsystems of the adaptive system: the cognator and regulator subsystems (Fawcett, 1989). Manifestations of the cognator and regulator activity are observable through coping behavior in four adaptive modes: physiological, self-concept, role-function, and interdependence (Blue et al., 1995). The physiological

mode refers to the need for physiological integrity and encompasses the need for oxygenation, nutrition, elimination, activity and rest, and protection. The self-concept mode involves the need for psychic integrity and includes perceptions of body sensation and body image. The role-function mode encompasses the need for social integrity, or the expectations one has for oneself in relation to others. The interdependence mode also involves social integrity, but is the affectional functioning and the ability to love and nurture others as well as be loved and nurtured (Roy, 1987).

Nursing focuses on the environmental stimuli and the patient's response, and the goal "is to bring about an adaptive state in the patient which frees him to respond to other stimuli" (Roy, 1970, p. 43). Nursing interventions are aimed at altering the stimuli to the point where a positive response is possible. The stimuli to be changed can be the provoking/focal stimuli, the contextual stimuli, or the residual stimuli. "When the provoking stimulus is an unavoidably painful treatment, the nurse may raise the patient's adaptation level by changing the context of the situation..." (Roy, 1970, p. 44). This may be done through methods such as encouraging participation in the treatment.

Roy's (1971) theory has been used to guide nursing care of children. Roy (1983) applied her theory in a case study of a family with a diabetic child. Galligan (1979) used Roy's concepts to describe children's reactions to hospitalization and to help nurses plan appropriate care. She delineated common environmental stimuli in each of the four adaptive modes for various stages of

hospitalization and treatment. In the self-concept mode, young children are particularly vulnerable to poor adaptation when intrusive, painful procedures are necessary. It is important for nurses to understand this in order to provide care to alter the stimuli when possible, and/or provide methods to promote coping and to relieve stress. Galligan further recommended gathering information on how a child has responded to past stressful situations to anticipate reaction to current stressors because “any experience will, in turn, influence how the child will react in future experiences” (p. 26).

Munn and Tichy (1987) used Roy’s theory to identify stressors for school-aged children in a pediatric intensive care (PICU) setting. From interviews with PICU nurses, they found stressors to be in four categories: environmental, physical, psychological, and social. These categories were found to correspond with Roy’s stimuli as follows: environmental/contextual; physical/focal; psychological/focal; and social/residual. The physical category included procedures that children perceive as threatening. Invasive procedures, including injections, dominated the responses in this area. Munn and Tichy found that many of the identified stressors were ones that could be controlled or modified by nursing actions and encouraged nurses to assess all environmental stimuli and make alterations when possible.

In the study reported here the investigator attempted to promote positive adaptation to injections through altering environmental stimuli. The focal stimuli included the syringe and needle, alcohol wipes, and physical restraint as needed.



The contextual stimuli included the setting for the injection (room, temperature, persons in room). The residual stimuli included the child's fears, parental attitudes and beliefs, and the child's past experiences with health care.

Management of the stimuli is achieved through altering the focal and/or contextual stimuli. If possible, the focal stimulus is altered because it is the primary concern of the moment. If it is not possible to alter the focal stimulus, the contextual stimuli are manipulated to increase adaptation (Fawcett, 1989). All children in this study received the same injection and, therefore, it was not possible to alter the focal stimulus. However the contextual stimuli were manipulated through the use of distraction and touch. These interventions altered the context in which the focal stimulus was experienced. The alteration was designed to enhance the child's ability to adapt.

#### Gate-Control Theory of Pain

In addition to using Roy's (1971) theory as a framework, the gate-control theory of pain provided the theoretical rationale for the chosen interventions. The gate-control theory (Melzack & Wall, 1965) is the most commonly accepted theory of pain (Stevens, Hunsberger, & Browne, 1987). The theory proposes that peripheral nerve impulses are transmitted to the central nervous system through three spinal cord systems: the substantia gelatinosa (SG) in the dorsal horn, the dorsal column fibers, and the central transmission cells (T cells) in the dorsal horn. Pain phenomena are experienced by interactions of the three systems, and the SG acts as a control system, or gate, that increases or decreases the

transmission of nerve impulses (Melzack, 1973). “The substantia gelatinosa, working between the input to the spinal cord and onward transmitting neurons, functions ‘as a gate-control system,’ determining the input to the T-cells from the periphery” (Nathan, 1976, p. 131). The substantia gelatinosa is a functional unit of highly specialized cells that extends the length of the spinal cord, receives afferent input from large and small diameter nerve fibers, and is able to influence the activity of cells that project to the brain (Melzack & Wall, 1965).

The spinal cord continuously carries nerve impulses, predominantly by small myelinated and unmyelinated fibers, which tend to keep the gate open. If a stimulus is applied to the skin, it produces an increase in the number of active receptor-fiber units. Previously inactive larger fibers become active with peripheral stimulation and produce a disproportionate relative increase in larger-fiber over smaller-fiber activity. This activity “closes the gate” and fewer nerve impulses are transmitted (Melzack & Wall, 1965).

Pain travels along A-delta and C-polymodal fibers to the spinal cord. These fibers have small diameters and are lightly myelinated. Touch travels along A-beta, larger diameter, heavily myelinated fibers which carry impulses at a faster rate than the smaller fibers. Both touch and pain go through the SG which modulates the transmission of impulses to the brain. If large diameter (touch) and small diameter (pain) fibers are stimulated simultaneously, the impulse on the larger diameter fibers reaches the spinal cord first and “closes” the gate. Therefore, a decreased amount of pain impulse will be sent to the brain.

According to this theory, cutaneous stimulation, or touch, applied together with a painful stimulus will decrease the perceived pain (Melzack & Wall, 1965; Nathan, 1976; Wall, 1978).

The gate-control theory also includes the concept of central control through modulation of nerve impulses in descending efferent fibers from the brain (Melzack & Wall, 1965; Pederson, 1994). Cognitive processes alter pain perception through descending fibers to the gating system. Therefore, cognitive activities, such as distraction, also tend to close the gate and prevent transmission of pain (Donovan, 1989).

Thus, the gate-control theory of pain supports the use of both touch and distraction as methods to decrease pain perception. Theoretically, both touch and distraction will decrease the transmission of pain nerve impulses through the spinal cord to the brain; therefore, the individual should experience less pain than if the transmission were uninhibited.

## CHAPTER II

### Review of the Literature

This review of the literature included published material on children's perceptions of injections and studies of methods to alter injection pain in children. A computerized literature search of the Cumulative Index of Nursing and Allied Health Literature (CINAHL) and MEDLINE was conducted. Key words selected included: children, pain, injections, and immunization. No time restrictions were imposed on the literature searched, and an ancestry approach was used to retrieve relevant research. Additionally, when published information was unavailable, researchers were contacted through personal communication. Further, literature on touch and distraction for pain relief was reviewed also using CINAHL and MEDLINE.

#### Children's Perceptions of Injections

Anyone who has observed children receiving injections would not be surprised to learn that children fear injections and perceive them as painful. While individual differences are seen, most young children demonstrate aversive behaviors towards injections, ranging from quiet crying and clinging to screaming, combative behavior. In the past 30 years, studies of children's medical fears have confirmed the observable conclusion that children fear injections and find them painful.

Scherer and Nakamura (1968) developed an instrument to measure children's fears, the Fear Survey Schedule for Children (FSS-FC). The 80-item instrument examines normal fears in children aged 9 through 12. In the subscale on medical fears, "getting a shot from the nurse or doctor," was one item, and it ranked second in greatest fear on the subscale ("having to go to the hospital" was first), and 30<sup>th</sup> in the overall scale.

Savedra, Tesler, Ward, Wegner, and Gibbons (1981) surveyed children 9- to 12-years of age ( $N = 214$ ) to find how children describe pain and to identify the causes of children's pain. The children were asked to identify three things that had caused them pain. "Shots" was the item most frequently identified related to medical events.

Menke (1981) studied school-aged children's perception of stress in the hospital using interviews and projective techniques ( $N = 50$ ). Hospitalized children were shown cards with drawings of familiar stimuli, including items associated with hospitalization: nurse, doctor, thermometer, syringe, hospital room, hospital bed, medications, and stethoscope. Children used the cards to prompt discussion of their feelings concerning the items, and they were asked to discuss what bothered them most about being in the hospital, which generated an additional 23 stressful stimuli. The syringe was selected by 86% of the sample as stressful; it was the item identified as stressful more often than any other item.

An instrument to measure children's medical fears, the Child Medical Fear Scale (CMFS) was developed by Broome and Hellier (1986). Items for the CMFS

were generated from interviews of children in grades K through 5 ( $N = 146$ ) and included one item on injections. Using the newly created 29-item CMFS, school-aged children ( $N = 84$ ) rated “getting a shot” third of the five most feared events.

Hart and Bossert (1994) investigated school-aged children’s hospital fears by examining the influences of age, gender, cultural background, and trait anxiety on medical fears. The researchers used the CMFS with hospitalized children ages 8 to 11 ( $N = 82$ ) and found that “getting a shot” ranked second in causing most fear. These researchers also found no significant effect of age or gender, but significant differences between acute and chronic health problems (more fear in children with chronic problems), and a significant proportional relationship between scores on the CMFS and trait anxiety scores.

Hester (1979) used injected immunizations as the painful stimulus in her development of an instrument to measure children’s pain, the Hester Poker Chip Tool. Her stated reasons for choosing immunizations included that the pain they cause is sharp and brief, the pain is reproducible, and a child’s fear of hospitalization is in part due to the fear of needles.

Kuenzer (1985) investigated 11- to 12-year old children’s impressions of nurses through the children’s drawings ( $N = 60$ ) and found 32% of the pictures included the nurse holding a syringe. Kuenzer concluded, “obviously, having an injection is a memorable, if not negative, experience” (p. 63). Fassler (1982) presented several depictions of feelings by hospitalized school-aged children about needles. All descriptions conveyed fear, anger, confusion, and pain. Fassler

stated that children often concentrate on pain. As one young girl told him, “The scariest thing about the hospital is needles. They hurt! He said it was going to be a little pinch, but the little pinch hurted” (p. 59).

While adults may understand that injections are painful, they may not realize how painful they are to the child. Schneider and Lo-Biondo-Wood (1992) compared children’s ratings of their immunization pain to parents’ and nurses’ ratings of the children’s pain ( $N = 42$ ). Children reported greater pain than did either their parents or the nurse. The difference was greatest between the child and the nurse ( $F = 7.32, p < .01$ ). A similar finding occurred in a study of children aged 3-17 years receiving venipunctures (Fradet, McGrath, Kay, Adams, & Luke, 1990). Significant differences were found in the child’s rating of venipuncture pain and the nurses’ rating of the children’s pain.

Agras, Sylvester, and Oliveau (1969) found injections a common fear in children which, for most people, declines rapidly during adolescence. However, an estimated 57/1000 individuals have been treated by a physician for severe fear or phobia of medical procedures, including injections. For these individuals, failure to help them overcome the fear “leads to an adult who will not use medical help properly since they [sic] avoid physicians” (p. 155).

Childhood immunizations are widely recognized as being one of the most cost-effective means of preventing childhood diseases (Abbotts & Osborn, 1993). The Advisory Committee on Immunization Practices of the American Academy of Pediatrics recommends a series of childhood immunizations that includes 14

injected immunizations between birth and 6 years of age (Peters, 1997). Diseases prevented by these immunizations include Diphtheria, Tetanus, Pertussis, Measles, Mumps, Rubella, Hepatitis B, Polio, Varicella, and infections caused by Hemophilus Influenzae type B (see Appendix A for the recommended schedule of childhood immunizations). The primary series of immunizations includes four or more doses of DTP, three or more doses of polio vaccine, and one or more doses of measles-containing vaccine.

Completion of the primary series of immunizations, among at least 90% of the nation's 2-year-old children is an objective of the Healthy People 2000 program (U.S. Department of Health and Human Services, 1990). A recent National Immunization Survey (NIS) cited an estimated primary vaccination coverage of 78% among children aged 19 to 35 months (U.S. Public Health Service, 1998). Additional NIS findings reflected low coverage rates with the fourth DTP dose, and that approximately "1 million children still need one or more of the recommended doses of vaccine to be fully protected" (p. 111). Other studies also reported immunization rates much lower than the 90% goal (Bates, Fitzgerald, Dittus, & Wolinsky, 1994; Mustin, Holt, & Connell, 1994; Orenstein & Bernier, 1994; Salsberry, Nickel, & Mitch, 1994).

Keane et al. (1993) discussed perceptions of disease severity and vaccine efficacy with parents in focus groups ( $N = 40$ ). The researchers used word associations to explore parental feelings. The word "shot" evoked considerable discussion, focused on immediate sequelae, and the outcomes included "pain,"



“fear,” “crying,” and “screaming.” Abbotts and Osborn (1993) investigated reasons for delayed immunizations for children attending a health department clinic ( $N = 388$ ). Parental reasons for avoiding immunizations reported by 4% of the sample included “didn’t want to see him [child] cry” (p. 967). In studies using national health data, researchers found maternal behaviors, especially those reflecting beliefs and values, greatly influence ambulatory care use among children (Becker, Nathanson, Drachman, & Kirscht, 1977; Newacheck & Halfon, 1986). While immunization inadequacy is a complex, multifactorial problem, the associated pain, including the parental discomfort with injections, may be an additional barrier to proper immunization.

#### Research on Methods to Decrease Children’s Injection Pain

The research has shown that children do feel pain with injections and fear them. There are two components of injection pain: the pain of the needle insertion through the skin, and the pain of solution injection into the tissue (Travell, 1955). To be truly effective, measures to decrease injection pain need to decrease both types of pain.

The first published study of a method to decrease injection pain in children was by Eland (1981). She examined two methods to alter injection pain using the gate-control theory of pain as the theoretical basis. Children between the ages of 4 and 6-years receiving DTP immunizations were randomly assigned to one of two treatments: skin coolant sprayed on the skin immediately prior to injection, or the use of positive suggestion. A 2 x 2 factorial design was used with one-half of the

sample receiving the coolant spray (Frigiderm) and the other half receiving sprayed aerosol air, and half of the sample being told they would receive a spray that would feel cool and “make the shot hurt less,” while the other half were simply told they would receive a spray.

Pain was reported by the children using the Eland Color Assessment Tool (Eland, 1981). This instrument allows children to create their own pain scale choosing the colors that represent different levels of “hurt” to them. Children in the immunization study chose four colors to represent most pain, moderate pain, mild pain, and no pain prior to injection. After receiving the immunization and the assigned study treatment, children rated the injection pain using the color scale. Eland found the use of the coolant spray to decrease significantly injection pain regardless of the information given to the child about the spray. Limitations of this study included the small sample size ( $N = 40$ ) and the awareness by the nurses administering the injections of which spray was being used. This study demonstrated that interventions to decrease injection pain in children were possible and led the way to further investigation.

Building upon the apparent success of Eland, Maikler (1991) used the same skin coolant spray (Frigiderm) in a study of infants, ages 6 to 30 weeks, receiving DTP immunizations. Sixty healthy infants were randomly assigned to receive either the skin coolant spray or a compressed air spray immediately prior to the immunization. Pain was measured using the Maximally Discriminative Facial

Movement Coding System (MAX) (Izard, 1983), interpretation of crying, and body movement.

Study infants were videotaped during the procedure and the tapes were evaluated by research assistants, unaware of treatment groups, for pain ratings using the three measurements. The MAX has published content, criterion, and construct validity, and interrater reliability of .81 (Izard, 1983). Pain ratings using the MAX were determined from observations of facial movements in brows, eyes, nose, cheeks, and mouth. Interrater reliability for the MAX in the study was .98. Cry behavior was measured in four dimensions: the time from the needle touching the skin to first sound; the duration of crying; the duration of intense crying; and the duration of protest crying. Interrater reliability was reported as .87. Body movement was coded as movement of the extremities and torso for extension, flexion, waving, and kicking. Interrater reliability was .95.

Infants in the Frigiderm group startled less when the needle was inserted, took longer to begin crying, and had less symmetrical movements. Although all infants demonstrated distress behaviors, the Frigiderm group displayed less distress than the compressed air group; however, the difference was not significant. Therefore, although the skin coolant spray had some effect, it did not appear to reduce injection pain significantly in these infants. Maikler stated the possible explanation that the skin coolant is not effective in reducing deep muscle pain of solution injection. Further, Maikler found the skin coolant spray difficult to apply,

and if used incorrectly, appeared to cause additional discomfort (personal communication, October 10, 1995).

Abbott and Fowler-Kerry (1995) also studied the effect of a skin refrigerant anesthetic spray (Fluro-ethyl) on DTP immunization pain in children ages 4 to 5.5 years ( $N = 90$ ). Children were randomly assigned to one of three groups: refrigerant topical spray; placebo topical spray; or no-treatment control. The child's self-report of pain was used as the dependent measure; however, the authors did not provide any information on the instrument used to measure pain.

Children in both the refrigerant spray group and placebo spray group had significantly lower pain scores compared to the control group. The placebo spray was apparently equally effective in reducing injection pain as the refrigerant spray. Therefore this study demonstrated the influence of cognitive processes on pain and the response to pain. Children in both the refrigerant and placebo group were told they would receive a spray that would make the needle hurt less. The placebo effect may have been heightened through the expectation of reduced pain which in turn reduced anxiety and resulted in less perceived pain. The authors further speculated that the pre-operational cognitive developmental stage of the children allowed them to be more open to suggestion. "This finding also demonstrated the power of cognitive pain strategies in reducing injection pain" (Abbott & Fowler-Kerry, 1995, p. 589).

Fassler (1985) examined the effect of a pre-treatment program with 6- to 9-year-old children ( $N = 30$ ) to decrease injection pain by decreasing fear.

Hospitalized children receiving injected pre-operative medication served as study subjects. Children were randomly assigned to a treatment or control group.

Children in the treatment group received a pre-injection intervention of storytelling, drawing, and medical play designed to reduce injection fear. Children in the control group received routine care. Pain was measured using pulse rate, behavioral assessment, and self-report.

Pulse rates were measured pre and post-injection. Behavioral observations were made by research assistants unaware of group assignment. Children were rated on fear, cooperation, anxiety, verbal protest, physical protest, verbal expression of pain, and physical expression of pain. No information was provided on reliability or validity of the instrument used. The children rated injection pain using hand pressure: the children squeezed a rubber bulb attached to a sphygmomanometer to indicate the degree of pain. No reliability or validity data were presented for this instrument either. Further, it would seem difficult for a young child to quantify pain using this method which required considerable hand coordination and control.

Children in the experimental group were found to demonstrate significantly less fear, anxiety, verbal protest, physical protest, and physical expression of pain. They also had a significant reduction in pulse and pain rating. While the method appeared successful, the treatment was lengthy (45 minutes per child) and therefore impractical in most settings. Also, the sample size was small and the instruments used had no reported reliability or validity.

Eutectic mixture of local anesthetics (EMLA) cream has been found to reduce pain significantly in children for venipunctures (Clark & Radford, 1986) and intravenous injections (Hopkins, Buckley, & Bush, 1988), as well as in skin laser surgery (Arendt-Nielson & Bjerring, 1988), skin grafts (Ohlsen, Engleson, & Evers, 1985), and lumbar punctures (Halperin, Koren, & Attias, 1989). Three studies concerning EMLA and adult injection pain have been conducted with conflicting results. One study found EMLA decreased insertion pain but not injection pain (Taddio, Robieux, & Koren, 1992) while the other two studies found EMLA to decrease both types of pain (Himmelstein et al., 1996; Taddio, Nulman, Reid, Shaw, & Koren, 1992).

EMLA was used to determine if it would decrease the pain of DTP injections in infants 4 to 6-months of age (Taddio et al., 1994) in a study comparing EMLA to a placebo ( $N = 96$ ). Infants were randomly assigned to receive either EMLA or a placebo cream, applied by their parents, prior to immunization. Neither parents nor research assistants were aware of group assignment. Pain was measured by observers, using a 100-point visual analog scale at the time of immunization, and later from a videotape of the procedure using the Modified Behavioral Pain Scale (MBPS). The MBPS rates pain according to facial expression, cry, and body movements. No reliability or validity data for the instrument were provided.

Infants in the EMLA group took longer to cry with the injection and had significantly lower pain scores than did the placebo group. The sample size in this study was larger than previous studies, and the design was double-blinded;

however, data concerning instrument reliability and validity were not published. Also, there are no published studies on the use of EMLA with older children who could self-report pain, and therefore the efficacy of EMLA is still questionable. EMLA is reported to be absorbed to a depth of 5mm only; therefore, it is unlikely that EMLA would affect the muscular pain of injection. Additionally, EMLA is relatively expensive, and since many children receive 2-3 injections per healthcare visit, it may be prohibitively expensive. It also requires precise application 1-2 hours prior to injection which necessitates parental participation that may not be possible always (Taddio et al., 1994). Therefore, while EMLA may be effective in decreasing injection pain, it also may be impractical.

Fowler-Kerry and Lander (1987) examined the effect of music as a distractor on DTP immunization injection pain. Children ages 4.5 to 6.5-years ( $N = 200$ ) receiving DTP immunizations were randomly assigned to one of four groups: distraction (music through headphones); suggestion (headphones with no music, but the children were told an assistant would help them with the injection); suggestion-distraction (received both music and suggestion); or a control group. Children reported their pain using a 4-point visual analog scale.

A significant main effect was found for distraction, but neither the main effect of suggestion nor suggestion by distraction interaction were significant. Music decreased pain ratings by children with DTP injections ( $F = 4.20; p = .007$ ). However, age was negatively associated with injection pain ( $r = -.21, p = .001$ ). Music was a more effective distractor for older children, and the researchers

stated, “perhaps cognitive strategies which assure more active participation of children would reduce the age effect...” (Fowler-Kerry & Lander, 1987, p. 173). This study supports the validity of distraction to reduce injection pain in children as well as suggesting more active interventions for young children.

### Touch

Touch is a form of nonverbal, physical communication in which receptors in the skin are stimulated, transmitting messages to the brain. It is considered the earliest and most elemental mode of human communication (Barnett, 1972). Touch constitutes the first act of communication between mother and infant and is one aspect of the nurse-patient relationship (Hinze, 1988). Cutaneous stimulation, including touch, has been identified and advocated as a nonpharmacological pain intervention by many (Doehring, 1989; Ferrel-Torry & Glick, 1992; Groer et al., 1994; Hinze, 1988; McCaffery, 1977; McCaffery & Wolff, 1992; Mobily, Herr, & Nicholson, 1994; Patterson & Ware, 1988). “Rubbing a painful area is a universal phenomenon” (McCaffery, 1977, p. 15), and the gate-control theory provides a physiological explanation for its effect.

The effects of cutaneous stimulation through massage have been documented. In an exploratory study with cancer patients ( $N = 9$ ), massage was found to decrease pain perception and anxiety, and to increase relaxation (Ferrel-Torry & Glick, 1992). An experimental study on massage ( $N = 32$ ) found a significant increase in serum-IgA concentration following a back massage compared to a control group (Groer et al., 1994). Serum IgA concentration has been found to



increase in relaxation states and decrease during stress. Therefore, touch, applied as massage, appears to aid relaxation states.

Validation of cutaneous stimulation interventions for pain relief was studied by Mobily, Herr, and Nicholson (1994). A two-round Delphi survey of nurses with expertise in pain management identified critical activities for specific cutaneous stimulation interventions. The definition for massage in this study included stimulation of the skin to decrease pain.

Touch has been studied with women in labor. In a postpartum interview with women concerning their perceptions of touch during labor ( $N = 150$ ), touch was generally perceived as positive and helped the mothers cope with childbirth (Penny, 1979). In another study of postpartum women, Birch (1986) found 77% of the subjects ( $N = 30$ ) said they felt less pain when they were touched during labor, and 97% stated touch helped them cope with the experience. Touch not only communicates a message of caring but may help decrease painful stimuli.

Triplett and Arenson (1979) studied the effects of verbal and tactile measures on young hospitalized children. Crying hospitalized infants and young children ( $N = 63$ ) with no family present were approached by a research assistant who applied one of two interventions on a random basis. One group received verbal comfort only until the child had quieted or 5 minutes had elapsed. If the child was still upset, tactile measures were added. The other group received simultaneous verbal and tactile measures. Tactile measures were found to be far more effective than verbal measures in decreasing distress ( $F = 47.27, p < .001$ ).

Touch, as a modality to decrease needle pain in children, was found in only one study (Beaver, 1987). Hospitalized infants received the following treatments administered randomly: touching the foot with an alcohol pad and blunt end of a lancet; touching the foot with an alcohol pad and using a lancet to stick the heel; and using the lancet to stick the heel while an assistant stroked the opposite leg. In this manner, each infant acted as his own control. Heart rate, blood pressure, and oxygen saturation readings were used as measures of pain.

Touching alone resulted in minimal changes from baseline. Contrary to the expected result, when infants received stroking with the heel stick, they exhibited more pain behaviors than when the heel stick was performed without the additional touching. However, the sample was very small ( $N = 8$ ), and all infants were premature (32-34 weeks gestation). Therefore it is difficult to draw valid conclusions, especially for children whose neurological systems are vastly different from those of premature infants. Beaver (1987) concluded this study neither supported nor negated the gate-control theory of pain and that “the premature infant’s neurological system may be too immature for the gate mechanism to work” (p. 16).

### Distraction

Distraction from pain is defined as refocusing attention on stimuli other than the pain sensation (McCaffery & Beebe, 1989). Pain perception involves controlled processing and draws on attentional resources. A distracting task

requiring controlled processing occupies some degree of attention that would otherwise be devoted to pain perception (McCaul & Malott, 1984).

Distraction has been noted to be an effective method to help children cope with painful procedures (Brennan, 1994; Broome, 1990; Hockenberry & Bologna-Vaughan, 1985; McCaffery, 1990; Patterson & Ware, 1988; Pederson, 1994; Smith, Airey, & Salmond, 1990). Physiologically, distraction acts to inhibit pain sensations through efferent nerve fibers (Melzack & Wall, 1965). Additionally, distraction increases pain tolerance by putting pain at the periphery of awareness (McCaffery, 1990).

One model of pain (Melzack & Torgerson, 1971) suggests three components of pain perception: sensory, affective, and evaluative. This model subsumes cognitive processing of pain perception and interpretation. Distraction, as a method of reducing pain perception, is dependent upon cognitive processing of pain sensations (McCaul & Malott, 1984). Distraction may interrupt the process by directing attention away from the stimulus or the response.

Additionally, distraction has been found to increase levels of endorphins (Doody, Smith, & Webb, 1991). Endorphins are proteins found in synapses that have morphine-like properties that can modify and inhibit painful stimuli. Interventions that increase endorphin levels help individuals cope with pain by modifying pain levels.

The effectiveness of distraction as a method to reduce pain perception has been studied. Blitz and Dinnerstein (1971) examined the effect of attentional

control on pain threshold. Ice water was used as the painful stimulus. Adult volunteers ( $N = 36$ ) first established a baseline pain threshold by placing their hands in the ice water until they felt pain. The subjects were then randomly assigned to one of three groups. One group was told to concentrate on the cold sensation of the water, but ignore the pain. Another group was told to imagine it was a hot day and the cold water perceived as pleasant. The third group was told only to repeat the procedure as in the baseline measurement. There was a significant increase in pain threshold for both treatment groups. The researchers concluded the results demonstrated the analgesic effects of redirecting attention.

Ritchie (1990) was interested in finding coping behaviors that young children use with painful experiences. She observed hospitalized preschool children ( $N = 74$ ) as they received finger sticks and recorded the children's behaviors using the Children's Coping Strategies Checklist (CCSC) created by the author. This instrument has three subscales: information-seeking and participative behaviors; self-protective behaviors; and reaching out for support and controlling behaviors. The coefficient alpha for the 15-item scale was .55 and the interrater reliability using the CCSC in this study was .95. Seventy-five percent of the children used coping behaviors of visual examination, tense compliance, and tension-reducing activities (e.g. twisting a strand of hair). In this manner, children provided their own distraction from the painful stimulus.

Caty, Ellerton and Ritchie (1997) studied young children's appraisal of a venipuncture using a projective technique. Hospitalized children ages 4 to 9-years

( $N = 45$ ) were interviewed concerning venipunctures using cards depicting three phases of the procedure: anticipatory, procedural, and post-procedure. Children were asked about feelings and thoughts associated with venipuncture and for specific suggestions for coping with the experience. The children's behavioral coping strategies were coded according to the CCSC, and their cognitive coping strategies were coded using the Cognitive Coping Interview (CCI) (Curry & Russ, 1985). The correlation coefficient for the CCI is reported as .83 and reliability coefficients for individual coping strategies ranged from .76 to .98.

Most children (86.6%) gave behavioral coping reducing suggestions, and self-protective, tension reducing strategies were identified most frequently. Almost all children (97.7%) described cognitive strategies for coping, including diversionary thinking (e.g. thinking about nice things). This study demonstrated children's natural use of cognitive strategies for coping with painful events.

Children receiving lumbar punctures (LP) have been studied for coping behaviors. Broome, Bates, Lillis and McGahee (1990) explored the relationship of fear and coping behaviors on a child's reaction to lumbar puncture. Children aged 3 to 15-years ( $N = 17$ ), receiving lumbar punctures for cancer in an out-patient setting, completed the Child Medical Fear Scale (Broome & Hellier, 1986) and were videotaped during the LP. Research assistants viewed the tape and coded coping behaviors using Rose's Coping Assessment Tool (Savedra & Tesler, 1981). The interrater reliability of the instrument in this study was .89. Children rated their degree of pain from the LP using the Wong-Baker FACES

scale (Wong & Baker, 1988). This scale has 6 faces representing increasing levels of pain, and the test-retest reliability in this study was 77.4% agreement.

The children rated the LP as painful, and a moderately positive relationship was found between fear and pain ( $r = .54, p = .01$ ). Therefore, children with more fear tended to rate the LP as more painful. Children who used active coping behaviors (e.g. asking questions, resisting, controlling) had significantly lower pain scores than children using passive coping behaviors (e.g. cooperative or ignoring). It is possible that active behaviors were used “as a gating mechanism that distracted them from attending to the pain” (Broome, Bates, Lillis & McGahee, 1990, p. 366).

Building upon their findings, Broome, Lillis, McGahee and Bates (1992) explored the effectiveness of relaxation and imagery on pain during lumbar punctures. Fourteen children aged 3 to 15-years receiving LPs for cancer treatment were studied using a multiple case study design. Baseline data were obtained during one LP using the Child Medical Fear Scale for fear assessment and the FACES scale for pain measurement. Distress during the LP was measured using the Observation of Behavioral Distress Scale (OBDS) (Jay & Elliott, 1984). The OBDS measures the frequency of 8 distress behaviors and had an interrater reliability coefficient in this study of .80.

The children were measured for pain and coping on two more occasions after being taught relaxation and imagery techniques to use during the procedure. The children’s medical fear scores did not change, but their pain ratings decreased

significantly over time ( $t = 3.21, p = .008$ ). Therefore, the cognitive strategies employed appeared to decrease pain perception. Also, in a finding similar to their earlier study, children who demonstrated more distress during the LP reported significantly less pain than children who employed more passive coping behaviors.

Music as a distractor was studied by Ryan (1989). Hospitalized children aged 9 to 12 years receiving venipunctures ( $N = 14$ ) were nonrandomly assigned to a treatment or control group. The treatment group listened to music of their choice through headphones during the venipuncture, and the control group received routine care. Children rated the pain using a 0 to 10 visual analog scale. Children in the treatment group reported lower pain scores than in the control group, although the difference was not statistically significant, possibly due to the small sample size. Although this study used nonrandom assignment and a small sample, the results correspond to the earlier study by Fowler-Kerry and Lander (1987) on music as a distractor for injection pain.

A visual distractor for venipuncture pain was studied by Vessey, Carlson, and McGill (1994). A sample of children aged 3.5-years to 12-years receiving venipunctures ( $N = 100$ ) were randomly assigned to one of two groups. Subjects in the experimental group were given a kaleidoscope to look through during the procedure, and subjects in the control group received routine care. Distress during the procedure was evaluated using the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) (McGrath et al., 1985), and pain was measured using the

FACES scale. The CHEOPS measures pain intensity on 6 observed behaviors, and interrater reliability coefficients for the items range from .90 to .99. Construct validity of the CHEOPS to a visual analog scale is reported with a correlation of .91.

Significantly lower pain scores were reported in the experimental group compared to the control group ( $F = 11.50, p = .001$ ). This study supported the use of distraction as an effective method to decrease pain perception during procedures involving needles.

#### Summary

To date in the published research literature, 522 infants and children receiving injections have been studied to determine the efficacy of several methods to reduce injection pain. Except for one study (Fassler, 1985) which used preoperative medication as the injection, all studies used DTP immunizations as the injection. Most studies assessed the efficacy of a topical anesthetic on injection pain. Three studies (Eland, 1981; Maikler, 1991; Abbott & Kerry-Fowler, 1995) examined the effect of a skin coolant spray on injection pain. Eland found the coolant spray to decrease injection pain while Maikler found the same spray to decrease needle insertion pain but not solution injection pain. Using another coolant spray, Abbott and Fowler-Kerry found no difference between the spray and a placebo spray. Therefore, using a skin coolant spray may reduce needle insertion pain but appears to have limited value in decreasing overall distress in children.



One study examined the effect of EMLA cream on injection pain in children (Taddio, Nulman, Goldbach, Ipp, & Koren, 1994). EMLA appeared to reduce injection pain, however, due to the application considerations, it may be impractical in most settings.

Fassler (1985) examined the effect of an anxiety-reducing treatment on injection pain. He found significant results, but the reliability and validity of the pain measurement instruments is questionable and the treatment, even if effective, was too lengthy to be practical.

Only one study (Fowler-Kerry & Lander, 1987) examined the effect of distraction on injection pain. Music, as a distractor, was found to reduce injection pain, although it was less effective for younger children. The researchers stated a more active distractor than music might be more effective for younger children.

In related studies, distraction has been found to reduce pain in children undergoing lumbar punctures (Broome, Lillis, McGahee, & Bates, 1992) and to reduce needle pain of venipunctures (Ryan, 1989; Vessey, Carlson, & McGill, 1994).

Few studies of touch to reduce pain in children have been done, although touch is advocated as a nonpharmacologic pain relief modality. Triplett and Arenson (1979) found touch to be more effective in reducing children's distress than verbal measures. Only one study on touch and needle pain in children was found (Beaver, 1987), and in it infants who were touched while receiving heelsticks demonstrated more distress behaviors than those not touched. While

this appears to contradict the effectiveness of touch in reducing pain, the results need to be interpreted cautiously due to the small sample size and prematurity of the subjects.

No topical anesthetic has been found to be both practical and effective in reducing children's injection pain. Distraction appears to have a positive effect, but only one study was found, therefore the effectiveness was still in question. Roy's theory of adaptation provided a framework for designing a study to compare methods of reducing injection pain. By altering the contextual stimuli, children should experience less pain and, therefore, be able to adapt positively to the event. The gate-control theory of pain provided the rationale for the specific interventions chosen: cutaneous stimulation and distraction. Both methods are easy and practical in any setting, but their effectiveness in altering injection pain has not been validated.

## CHAPTER III

### Methodology

#### Overview of the Study Design

The investigator used a quasi-experimental design to compare the effects of cutaneous stimulation and distraction on the pain of DTP injections in preschool-aged children. A convenience sample of 105 children aged 4 to 6 years who attended school-based and health department immunization clinics were randomly assigned to receive one of three treatments with their injections:

(a) distraction, (b) cutaneous stimulation, or (c) standard care. Demographic and background information and a measurement of the child's medical fears were obtained prior to immunization. Children self-reported their injection pain using the Oucher scale (Beyer & Aradine, 1986).

All injections were given by registered nurses who were staff members of the clinics used. Study treatments were administered by the investigator and 5 research assistants trained by the investigator. Data collection took place over an 18-month period at three sites in a large mid-western metropolitan area.

#### Definitions

For study purposes, the following definitions were employed:

Pain: an "unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (International Association for the Study of Pain, 1979, p. 248). Pain is a subjective experience,

and the 'gold standard' of pain measurement is self-report (McGrath & Unruh, 1987). Therefore, pain was operationalized through a self-report instrument, ranging from 0 to 5, with higher scores indicating greater pain.

Medical Fear: an unpleasant emotional response and feeling of danger regarding health care events. This was operationalized through use of an instrument to measure medical fear (Broome, Hellier, Wilson, Dale, & Glanville, 1988), with higher scores indicating greater fear.

Cutaneous Stimulation: light stroking of the skin around the injection site, administered by an assistant, just prior to and during injection. The stroking was moderate in intensity and rhythmic, as recommended by McCaffery (1977). The most effective site for touch to relieve pain is directly over or around the pain (McCaffery & Wolff, 1992).

Distraction: an activity that redirects attention away from another event. All children in the study were aware of the impending injection, and distraction was provided to children in the distraction group by having the children blow bubbles during the injection. This distractor was chosen because it met the criteria recommended by other investigators of being a familiar activity (Coty, Ellerton, & Ritchie, 1997), requiring attentional capacity (Vessey, Carlson, & McGill, 1994), and an active instead of passive activity (Fowler-Kerry & Lander, 1987). In addition, blowing bubbles can help the child breathe more deeply and exhale slowly, which promotes relaxation (Pederson, 1994).

**Injection Event:** injected Diphtheria-Tetanus-Pertussis (DTP) vaccine was the injection event. The vaccine is in two forms: DTP or DTaP (acellular DTP vaccine). The DTaP is the newer form of the vaccine and is recommended due to the lower incidence of side effects; however, a few children early in the study received DTP vaccine. There are no published comparisons of DTP and DTaP concerning perceived pain with injection. According to the manufacturer, Wyeth-Ayers Laboratories, the pH value of DTaP is 6.9 plus or minus .05, and the pH of DTP is between 5.5 and 6.5 (personal communication, May 22, 1998). The pH value of DTaP is closer to neutral than DTP, and it is possible the two vaccines do not feel comparable upon injection. Therefore, the two vaccines were analyzed separately for comparison.

The immunizations were given using recommended technique (Beyea & Nicoll, 1995; Wong, 1995). Children needing oral polio vaccine received it prior to injected vaccines since the oral immunization is not painful. The DTP and DTaP were administered intramuscularly, in either the right or left leg, in the vastus lateralis muscle, using a 1", 22-gauge needle.

**Socioeconomic Status:** the concept of stratifying people in society based on wealth and social standing. Two measures were used to operationalize the concept: education and income.

**Health Status:** the assessment of past and current health of a child as perceived by the parent(s). Items assessed by the parent(s) included: overall health,

hospitalization, numbers of health care visits, recent past experience with needles, and presence of chronic illnesses.

**Immunization Information:** knowledge of the immunization event by the child.

Parent(s) report of injection information given to their child and timing of the information were obtained.

**Past Injection Response:** behavior demonstrated by the child with prior injections, reported by the parent(s).

### **Instrumentation**

Anxiety and fear are important factors in pain perception (Broome, Bates, Lillis, & McGahee, 1990; Hinze, 1988). According to the gate-control theory of pain, anxiety and fear opens the gate and increases pain perception (Pederson, 1995). In experimental studies of pain, anxiety and fear have been found to increase reported pain (Bronzo & Powers, 1967; Von Graffenried, Adler, Abt, Nuesch, & Spiegel, 1978; Weisenberg, Aviram, Wolf, & Raphaeli, 1984). Therefore, the investigator concluded that fear may be an important covariate in pain perception.

The Child Medical Fear Scale (CMFS), developed by Broome, Hellier, Wilson, Dale, and Glanville (1988), was used to measure each child's fear of medical procedures, including injections. The CMFS is a 17-item questionnaire of medical procedures/events with each item rated: "not at all afraid" (0 points); "a little afraid" (1 point); or "a lot afraid" (2 points). The points are summed to obtain a total score which may range from 0 to 34; the higher the score, the greater the

child's fear. The instrument is designed to be used with children 5 to 12 years of age; however, the first author stated she used the CMFS successfully with children as young as 4 years (Broome, personal communication, August 8, 1996).

The original CMFS (Broome & Hellier, 1986) was developed from interviews of 140 elementary school children who were asked to identify how they felt about being ill, going to the doctor, or going to the hospital. This resulted in a 29-item instrument that was then tested on 84 school-age children for reliability and validity. Some items appeared redundant, and a revised CMFS of 17-items was created (Broome et al., 1988). Internal consistency estimates of the revised CMFS, using coefficient alpha, ranged from .81 to .86 for the sample of 84 children. A 2-week test-retest reliability coefficient of .81 was obtained. Criterion validity was established through measuring concurrent validity between the CMFS and the Medical Fear Subscale of the Fear Survey Schedule for Children (FSS-FC) (Scherer & Nakamura, 1968). The FSS-FC is an 80-item Likert-type questionnaire that measures type and effectiveness of fear cues that evoke emotional stimuli. It was expected that children who scored high on the FSS-FC Medical Fear Subscale would also score high on the CMFS. The correlation coefficient between the two measures was  $r = .71(p < .001)$ , indicating a positive relationship supporting the expectation. Therefore, the CMFS has established reliability and validity.

Pain was measured using the Oucher scale (Beyer & Aradine, 1986). The Oucher is a poster with two vertical scales: a numeric scale from 0 to 100 for

older children, and a 6-picture photographic scale ranging from “no pain” to “the worst pain” for younger children. The photos are of a preschool-aged child and convey increasing levels of discomfort. Children are asked to compare their pain to either the numeric or photo scale. Caucasian, Hispanic, and African-American versions of the Oucher are available; however, the photos in each are of male children. No female version is available currently.

The Oucher is designed to be used with children from 3- to 12-years of age. Content validity of the Oucher was established by having children ( $N = 78$ ) in a variety of settings sequence the pictures from “no hurt” to “the biggest hurt possible”; the coefficient of concordance was .72 for this task (Beyer & Aradine, 1986). Convergent validity was established through strong correlations between the Oucher and two other measures of pain: Hester’s (1979) Poker Chip Tool and a visual analog scale. The coefficient correlations between the measures ranged from .69 to .97. Construct validity was demonstrated through a known-group approach. Children admitted for a surgical procedure ( $N = 102$ ) were administered the Oucher before and after surgery; it was hypothesized that the children would have no pain before the procedure and significant pain post-operatively. The results supported the hypothesis; further, it was found that children undergoing more extensive surgical procedures reported higher pain levels.

Traditional reliability testing of the Oucher is not possible because it is a single-item test measuring a dynamic phenomenon. However, indirect reliability was established by having children ( $N = 50$ ) use the Oucher to rate the presumed



pain intensity of 17 pictures depicting a variety of painful situations. Correlation coefficients ranged from .54 to .72; therefore, moderate levels of test-retest reliability were obtained (Beyer, Denyes, & Villarruel, 1992).

Demographic and background information were obtained from parents using a questionnaire. Items included child's age, gender, ethnicity, health, recent experience with needles, and past response to injections, and parent's education and income. Additionally, parents were asked if they had told their child she or he would be receiving an injection, and if so, when the information was given.

See Appendices B, C, and D for copies of the instruments used.

### Sampling Plan

#### Sampling Criteria

Inclusion criteria for subject selection were that a child (a) was between 4 and 6 years of age, (b) could understand spoken English, (c) was to receive a DTP/DTaP immunization, and (d) was accompanied by one or both parents or a guardian who could understand spoken and written English.

The inclusion criteria were chosen because research has shown that preschool-age children find injections stressful and need help to cope with the event. Further, preschool children are able developmentally to attend to distractors and able to self report pain. Parental presence during painful procedures has been shown to be a significant factor in how children perceive the events (Broome & Endsley, 1989; Pederson, 1994; Pederson, 1995). Therefore, to control for this variable, parental presence during the injection was required in the study.

### Sample Size

Sample size was determined with a power analysis based upon prior research with distraction as a method to decrease perceived pain (Vessey, Carlson, & McGill, 1994). Setting the probability of Type I error at .05 (alpha level), the power at .90, and using a standard deviation of 1.0, a sample of 60 subjects per group, or 180 subjects in total, was predicted to be required.

### Recruitment

All children in the United States, unless medically exempt, are required to receive a series of immunizations prior to entering school. The final injections in the series are given to children between the ages of 4 and 6 years and include one dose of Diphtheria-Tetanus-Pertussis vaccine.

Subjects for the study were recruited in two school-based programs and a health department in an urban metropolitan area. Two school districts in the area provide immunizations to local children, free of charge, several times each month throughout the year. Vaccine is provided by the health department, and the clinic is staffed by school nurses. These clinics provide no other health services; the children were there only to receive immunizations. In addition, a county health department, providing a "walk-in" immunization service, was used as a site to recruit subjects. The three sites provided access to a range of families from lower-middle to upper-middle class backgrounds, and an ethnic mix approximately 25% African-American and 75% Caucasian, which is similar to the ethnic mix in the

greater metropolitan area. Authorities at all sites agreed to allow the study to be conducted.

No lists of families attending the clinics were available; therefore, a convenience sample was drawn from the clinics. From the waiting area of each clinic, the investigator identified parents with preschool children and approached them for possible inclusion. The study was explained and, if parental consent were granted, the child was randomly assigned to one of three groups: distraction by blowing bubbles (group 1); cutaneous stimulation, or touch (group 2); or a control group who received standard care (group 3). Prior to data collection, slips of paper with the numbers 1, 2, and 3 were used to draw a random start. The number 2 was drawn; therefore, data collection began with the first subject in group 2. Subsequent subjects were systematically placed in groups to achieve equal group size. Participation in the study was voluntary, and there were no consequences for nonparticipation. Parents and children did not receive any remuneration for participation.

#### Data Collection Procedure

Children were screened for immunization need by clinic personnel. Families of eligible children agreeing to participate signed the consent form (Appendix E) and completed the self-administered demographic questionnaire. At the same time, while waiting for the immunization, study children completed the CMFS. Since the children were too young to read the questionnaire, the investigator read the questions to the children and recorded their answers. The investigator also

explained the Oucher instrument to the child and helped the child practice its use, as recommended by the instrument developers (Beyer & Aradine, 1986).

To control environmental variables, study participants received immunizations and treatment in a separate room from nonparticipants. All vaccines and supplies were provided by the clinics. Clinic staff administered the immunizations while the investigator and/or research assistants provided the treatments. Prior to implementation, the investigator observed clinic staff administering immunizations to validate correct technique and consistency of methods. Research assistants were nursing students trained by the investigator in treatment techniques and data collection. The investigator was present during all data collection to observe for correct protocol.

Children assigned to group 1 received distraction as an intervention. While the clinic staff administered the immunization, an assistant encouraged children to blow bubbles. The children were introduced to the activity just prior to injection and were told to “keep blowing the pretty bubbles” as the injection occurred.

Children in group 2 received cutaneous stimulation as the intervention. Cutaneous stimulation was provided by an assistant stroking the skin of the area around the injection site, just prior to and during the injection. The children were told the assistant was going to keep touching their leg and to “keep thinking about how nice that feels.”

Children in group 3 served as the control group and received immunizations in a routine manner with no additional intervention. Immediately following the DTP

immunization, all children rated their injection pain using the Oucher scale. The investigator recorded the location, type of immunization, and pain rating for each child. Children requiring additional immunizations had them administered after rating the DTP injection; additional injections were not rated for pain.

#### Protection of Human Subjects

This study was approved by the Institutional Review Board of Saint Louis University. Confidentiality was maintained through use of assigned code numbers; except for the consent forms, no other forms had the child's name or the names of the parents. No other identifying information, such as addresses or telephone numbers, was collected. The signed consent forms and data sheets were stored in a locked file to which only the investigator had access.

Parents read and signed consent forms before their children were enrolled in the study. The investigator discussed the information on the consent form with the parent(s), and each parent was given the opportunity to ask questions. Parents were told clearly that their participation was voluntary and that there were no consequences to not participating.

Risks to the subjects were minimal. All children received their immunizations as scheduled, and study participation did not alter or pose a threat to the subject's immunization status. It was believed one possible risk was an increased sensitivity to the experience through completing the CMFS, since the questions concerned fear of stressful health care events. However, the questionnaire was completed in the waiting area, away from the injection area, and therefore in a "safe" place.

Also, with few exceptions, all children were aware of the impending injection and consequently did not appear upset by the questions.

Parents also were made aware of the possible benefits of study participation. The investigator explained that the study findings might identify a way to make injections less stressful for children.

#### Data Analysis Procedure

Demographic data were analyzed using descriptive statistics. Planned comparisons within analysis of variance tested the difference in pain scores between children in the treatment groups. This method of analysis was chosen because the research questions concerned comparing two contrasts: the two treatment groups as one contrast and the treatment groups and control group as a second contrast. Using planned comparisons provided greater statistical power than using simple analysis of variance with post hoc analysis. Factorial analysis of variance was used to determine the influence of age and gender on treatment effect. The effect of medical fear on perceived pain was analyzed with correlational statistics and factorial analysis of variance.

## CHAPTER IV

### Data Analysis and Results

#### Characteristics of the Sample

Data were collected at 3 immunization clinics over a period of 18 months. Fifty-three females and 52 males ( $N = 105$ ) ages 4 through 6 years and their parent(s) participated. Demographics of the sample are shown in Table 1.

Table 1

#### Demographic Characteristics of the Children in the Sample

Gender	Age	Ethnicity
Male = 52	4 yrs. = 21	Caucasian = 76
Female = 53	5 yrs. = 77	Latino = 2
	6 yrs. = 7	African-American = 23
		Asian = 2
		Native American = 1
		Missing Data = 1

Study children were in good health as rated by their parents (52% rated health as excellent, 38% rated health as very good, and 10% rated health as good). Only 8% of the sample stated their children received health care less than once per year, and 62% stated their children received health care 2-4 times per year. Parents were asked to list any chronic health problems of their children, and 5 parents did so, with the following conditions cited: strabismus, asthma, anemia, and "ear

problems requiring surgery.” Most study children did not have recent experience with needles. In the 6 months prior to the study, 8% of the sample had received a blood test, and 6% had received an injection

Families in the study tended to be lower- to middle-class according to the variables of education and income (see Table 2).

Table 2

Socioeconomic Characteristics of the Parents in the Sample

Variable	Number	Percent
<b>Education</b>		
Some high school	10	09.5
High school graduate	40	38.1
Some college	29	27.6
Associate degree	7	06.7
Bachelor's degree	10	09.5
Master's degree	1	01.0
Professional degree	2	01.9
Missing Data	6	05.7
<b>Income</b>		
\$15,000 or less	26	24.8
\$15,001 to \$30,000	24	22.9
\$30,001 to \$45,000	27	25.7
\$45,001 to \$60,000	18	17.1
\$60,001 or more	6	05.7
Missing Data	4	03.8

Most parents (87%) informed their children about the immunization in advance, but the timing of the information varied. Fifty-five percent of parents who informed their children of the injection did so from 1 day to 7 days in



advance, and 32% informed the child the day of the event. Children's past responses to injections, according to their parents, are presented in Table 3.

Table 3

Past Responses of the Children to Injections as Reported by 98 Parents

Response	Number	Percent
"Fights" injection	10	10
Cries, controlled with help	34	35
Cries but cooperative	28	29
Quiet and cooperative	20	20
Unknown	6	6

Fear Measurement

Fear was presumed to be an important variable in pain perception. Scores from the Child Medical Fear Scale (CMFS) were used to examine pre-immunization fear in children and the results are presented in Table 4. The coefficient alpha for the CMFS was .91 for this study, and therefore, the instrument was considered to be reliable.

In this study, 5-year-old children reported greater fear than either the 4- or 6-year-old children, and females tended to report greater fear than did males. Additionally, slight differences in fear were reported among treatment groups. The analysis found that fear varied significantly by gender ( $F = 3.85, p = .05$ ), but not by age or treatment group.

Ten study children (9.5%) refused to answer the entire CMFS, however, all children responded to the item concerning fear of injections. Scores on the item can range from 0 to 2. Mean scores on this item by group were: distraction (.67); touch (1.09); and control (.80). Analysis of variance on the item by treatment group was not significant ( $F = 2.07$ ;  $p = .13$ ). Therefore, fear was not

Table 4

Fear Scores (CMFS) of the Children According to Age, Gender, and Treatment

Variable	Mean	SD	n
Age			
4 years	10.83	8.03	18
5 years	13.40	9.22	70
6 years	11.86	8.69	7
Gender			
Female	14.63	8.55	46
Male	11.08	9.04	49
Treatment Group			
Distraction	12.54	8.02	33
Touch	13.66	9.41	30
Control	12.25	9.58	32

Note. Values for the CMFS range from 0 to 34; higher scores indicate greater fear. Ten children refused to answer the Child Medical Fear Scale, and, therefore, the sample size for each variable is slightly less than the total children in the study.

significantly different among the study groups for either the entire CMFS or the item concerning injections.

Pain Measurement

The children's pain scores, as measured by the Oucher scale, were compared by age, gender, treatment group, and immunization received (DTP or DTaP). Scores on the Oucher can range from 0 to 5 with higher numbers reflecting greater reported pain. Table 5 presents the means of the study groups on reported pain.

Table 5

Comparison of Oucher Scale Mean Pain Scores of the Children by Age, Gender, Immunization Type, and Treatment Group

Variable	Mean	SD	n
<b>Age</b>			
4 years	2.81	1.67	21
5 years	2.13	1.92	77
6 years	2.00	1.15	7
<b>Gender</b>			
Female	2.38	1.78	53
Male	2.13	1.91	52
<b>Immunization</b>			
DTP	2.73	1.93	22
DTaP	2.13	1.81	83
<b>Treatment Group</b>			
Distraction	2.00	1.68	35
Touch	1.89	1.73	35
Control	2.89	1.98	35

The findings indicated that younger children and females tended to report greater pain, and children receiving DTP reported greater pain than children receiving DTaP. Pain scores in the touch treatment group were lowest (1.89), followed

closely by the distraction group (2.0), with the control group reporting the highest pain scores (2.89).

Research Questions

The first two research questions concerned differences in perceived injection pain among the treatment groups. To answer these questions, analysis of variance of pain scores by treatment group using planned comparisons was conducted. The results are presented in Table 6.

Table 6

Comparison of Treatment Groups vs. Control Group on Pain Scores

Source	<i>F</i>				
	SS	<i>df</i>	MS	F	Sig
Distraction vs. Touch	.26	1	.26	.08	.79
Treatment vs. Control	21.04	1	21.04	6.48	.013*
Within	331.08	102	3.24		

\* *p* < .05

The difference between the two treatment groups, distraction and touch, was not significant (*F* = .08, *p* = .79). However, the difference between the combined treatment groups and the control group was significant (*F* = 6.48, *p* = .013). Therefore, both distraction and touch significantly reduced reported injection pain.

The third research question concerned the relationship between fear of injections and perceived immunization pain. A modest relationship between fear scores (CMFS) and pain scores (Oucher) was found (*r* = .24, *p* = .021). The

difference in pain scores, by treatment group with fear as a covariate (ANCOVA) was highly significant and is presented in Table 7.

Table 7

Analysis of Variance of Pain Scores by Treatment Group with Fear Scores

Source	<i>F</i>				
	SS	<i>df</i>	MS	F	Sig
Covariate CMFS	29.12	1	20.12	6.87	.01*
Main Effects Treatment Group	32.33	2	16.16	5.52	.005*
Explained	49.97	3	16.66	5.68	.001
Residual	266.66	91	2.93		

\*  $p < .05$

The fourth research question concerned the relationship between age and gender on perceived immunization pain. Younger children and females tended to report greater pain (see Table 5). However, analysis of variance among pain scores was not significant for either age or gender: age ( $F = 1.2, p = .30$ ) and gender ( $F = .45, p = .50$ ). Therefore, no significant relationship was found between age or gender and perceived DTP/DTaP pain.

The fifth research question concerned the effects of age and gender on immunization pain by treatment. This was answered through factorial ANOVA and is presented in Table 8.

Table 8

Analysis of Variance of Children's Pain Scores with Medical Fear Scores by Treatment, Age, and Gender

Source	<i>F</i>				
	SS	<i>df</i>	MS	F	Sig
<b>Covariate</b>					
CMFS	23.20	1	23.20	8.14	.005*
<b>Main Effects</b>					
Treatment	33.19	2	16.60	5.50	.006*
Age	11.83	2	5.92	2.08	.18
Gender	1.19	1	1.19	.40	.53
Explained	71.34	8	8.92	3.13	.004
Residual	245.29	86	2.85		

\*  $p = <.05$

A significant main effect of treatment was found; however, neither age nor gender was found to interact significantly with the treatment to alter pain perception. Therefore, the treatment does not appear to be influenced by age or gender.

The data analysis indicated that both cutaneous stimulation and distraction significantly reduce injection pain in preschool children in comparison to children who receive standard care. Neither age nor gender altered significantly the treatment effect. The treatment was effective without considering fear. With fear scores as a covariate the significance level of the treatment effect increased.

## CHAPTER V

### Summary, Discussion, and Implications

#### Summary

The purpose of this study was to compare the effects of cutaneous stimulation (touch) and distraction (bubble-blowing) on preschool children's perceptions of injected DTP/DTaP pain. This chapter discusses the study findings, compares the findings to the literature and the theoretical framework, addresses the limitations of the study, and presents implications for nursing practice and future research.

Recruitment of subjects for this study was not difficult. Eligible parents were generally eager to assist in a study of methods to decrease injection pain. Very few parents refused to participate, and those that did stated they were concerned about the time commitment. Demographic data from the sample reflected an ethnic and socio-economic mix consistent with the greater metropolitan area, and there were a similar number of males to females. The majority of the sample were 5-year-olds which is expected since the fourth DTP/DTaP injection is a pre-kindergarten immunization.

The treatments were easy to administer. Not all children in the bubble-blowing group were able to attend to the distraction during the injection. While all were interested in blowing bubbles, many stopped to focus on the injection despite encouragement to keep blowing the bubbles. Others were able to concentrate on the bubbles and even appeared to understand it as a distraction. At one clinic a 5-

year-old girl ineligible for the study (did not speak English) appeared very apprehensive about the injection. Clinic staff tried their best to calm the child with little success. One of the nurses asked if she could use the bubbles even though the child could not be part of the study. The child smiled when she saw the bubbles and eagerly blew bubbles during the injection, which then proceeded smoothly.

Children in the touch group received the treatment with or without their attention to the stimulus. The treatment did not require their participation as did the bubble-blowing. This may account for the touch group having the lowest pain scores of the three groups: cutaneous stimulation may be effective whether the child focuses on the touch or on the injection. Additionally, stroking the area near the injection site was easily performed and did not interfere with injection technique.

### Study Findings and the Literature

#### Pain

Pain was measured using the Oucher scale (Beyer & Aradine, 1986). The Oucher scale was explained to the children, and the investigator practiced with each child prior to the injection. The children seemed interested in the pictures and attended to the explanation well. A few children had difficulty choosing pain levels during practice, but all children were able to use the instrument after receiving an injection.



Using distraction to affect needle pain in children had been studied in three previously published research articles. The effect of music as a distractor was studied with venipuncture pain (Ryan, 1988) and injection pain (Fowler-Kerry & Lander, 1987). A visual distractor was used for children who required venipuncture by Vessey, Carlson, and McGill (1994). Children in the distraction treatment groups of these studies rated the needle less painful than children in control groups. Distraction in the current study also significantly reduced the pain of DTP/DTaP injections in the sample of preschool children. Children in the bubble-blowing group had a mean pain score of 2.0, compared to 2.89 for the control group ( $p = .04$ ).

Fowler-Kerry and Lander (1987) found an overall significant main effect of music distraction on children's pain scores, but they also found age to be negatively associated with pain scores. The distractor (music) appeared to be less effective for younger children, and the investigators proposed a more active distractor might be more effective for younger children. Bubble-blowing requires active participation by the child, and the investigator believed that it would provide a pleasant, familiar activity that would be effective for younger children. In the current study, age and pain scores were also negatively associated ( $r = -.14$ ,  $p = .15$ ), although less associated than in Fowler-Kerry and Lander's study ( $r = -.21$ ,  $p = .001$ ). Younger children in the current study rated the injections as more painful than older children (4-years = 2.81; 5-years = 2.13; 6-years = 2.0), however, the difference between the scores was not significant ( $F = 1.2$ ,  $p = .30$ ).

nor was there an interaction effect between age and treatment ( $F = 2.08, p = .18$ ). Therefore, although younger children reported higher pain scores, age was not a significant variable in the treatment effect.

The literature supports the use of touch as a nonpharmacologic pain treatment, but very few studies of touch for pain relief in children were found. Only one study of touch with needle pain in infants was found (Beaver, 1987), and the results did not support the effectiveness of touch to relieve pain. This study was of a very small sample of premature infants ( $N = 8$ ). In the current study, the touch group reported the lowest pain scores of the three groups: 1.89 as compared to 2.89 for the control group and 2.0 for the distraction group. The difference between the two treatment groups, touch and distraction, was not significant ( $F = .08, p = .79$ ), however, the difference between the two treatments and the control was significant ( $F = 6.48, p = .013$ ). Both touch and bubble-blowing significantly reduced injection pain perception in the sample of preschool children.

There was no significant effect of gender on treatment. Females reported slightly more pain than males (2.38 to 2.13), however, the difference was not significant ( $F = .45, p = .50$ ), nor was the interaction between gender and treatment significant ( $F = .40, p = .53$ ).

### Fear

Fear was measured using the Child Medical Fear Scale (CMFS) by Broome and Hellier (1986). The investigator read the instrument to the children and

recorded their responses. Most children appeared to have no difficulty understanding and responding to the items. A few children were very “shy” and did not want to answer the questions; however, all children were able to respond to the item concerning receiving injections.

According to the literature, younger children and females tend to report greater fear levels than older children and males (Broome, Bates, Lillis, & McGahee, 1990; Broome & Endsley, 1989; Broome, Hellier, Wilson, Dale, & Glanville, 1988). In this study, females reported significantly greater fear than males; 14.63 compared to 11.08 ( $F = 3.85, p = .05$ ). Age was not related to fear as predicted from previous research findings. The mean fear score was lowest for 4-year-olds (10.83) and highest for 5-year-olds (13.4), although the difference was not significant ( $F = .62, p = .53$ ). The reason for this difference is unclear. The CMFS is designed to be used with children age 5 and older, although the first author stated she had successfully used the CMFS with younger children (Broome, personal communication, August 8, 1996). It is possible that the scale is less reliable with younger children, and the results may not reflect the true state of younger children’s medical fear.

The literature supports an association between fear and reported pain (Bronzo & Powers, 1967; Von Graffenried, Adler, Abt, Nuesch, & Spiegel, 1978; Weisenberg, Aviram, Wolf, & Raphaeli, 1984), and fear was a significant covariate in this study. A modest relationship between fear scores and pain scores

was found ( $r = .24, p = .021$ ), however, fear as a covariate with pain scores and treatment was found to be highly significant ( $F = 5.52, p = .005$ ).

Although fear was a significant covariate, the pain scores between the treatment and control groups differed significantly even when fear was not used as a covariate. This means the reported pain in treatment groups was significantly less than the control group whether fear was considered or not considered: the treatment was effective despite differing fear levels in children.

### Theory

Roy's adaptation theory (1987) provided the theoretical framework for this study, and the gate-control theory of pain (Melzack & Wall, 1965) provided the rationale for the chosen interventions. The study findings support the value of both Roy's theory and the gate-control theory in developing nursing interventions to help children cope with injection pain.

In Roy's adaptation theory (1970) nursing interventions are aimed at altering stimuli to allow for a positive response. When the provoking/focal stimulus is painful, the nurse may raise the patient's adaptation by altering the context in which the pain occurs. The injection was an unavoidable painful experience for the children, but the context in which it was experienced was altered by the treatments (distraction and touch). Children who received these treatments tended to report less injection pain, therefore they were better able to cope with the event and adapt with a positive response.

The gate-control theory of pain (Melzack & Wall, 1965) supports the use of touch and cognitive processes as methods to decrease pain perception. Both touch and attentional cognitive activities decrease the amount of pain stimulation to the brain by closing a “gating” mechanism in the spinal cord. The theory then supports both touch and distraction to decrease pain perception. The study results validate the gate-control theory: both touch and distraction significantly altered pain perception with injections.

Additionally, the gate-control theory contends that anxiety “opens” the gate and increases pain perceptions (Pederson, 1995). The theory further supports the connection between anxiety/fear and pain. This connection was validated also in this study since fear was found to covary with pain significantly.

#### Summary of Findings

This study found distraction, in the form of bubble-blowing, and cutaneous stimulation (touch) to decrease DTP/DTaP pain significantly in preschool children. A significant main effect of treatment was found, but no significant age or gender interaction effect was found. Fear was found to covary significantly with pain, however, the treatments altered pain perception even when fear was not used as a covariate. This study is consistent with previous research on distraction and pain and provides preliminary support for touch as a method to decrease injection pain. Study results validate Roy’s adaptation theory: altering the context in which a painful stimulus is experienced effects the perception of the event. The

study also validates the gate-control theory of pain: touch and attentional activities applied during a painful event tend to decrease pain perception.

#### Limitations of the Study

There are several limitations of this study. While children were randomly assigned to treatment groups, a convenience sample of children was used for study participation. The three study sites were in suburban locations, and the sample did not include inner city or rural children. Additionally, families using these sites were bringing their children for immunizations exclusively and not as part of other health care. Therefore the investigator assumed that these families were motivated to seek and use preventive health care. This assumption appeared to be supported by the number of annual physician visits that parents reported for study children. The children also appeared to be very healthy with few children having chronic illnesses or past hospitalizations as reported by their parents. Although the study included children from ages 4 to 6, the sample was predominantly 5-year-old children resulting in inequality of groups by age. Therefore, the generalizability of this study to other samples of children is limited.

Another study limitation is the number of nurses giving the injections. While the equipment was the same (i.e., same size needles), and all nurses used the same procedure, individual differences in injection technique may have existed. Some nurses may be better at giving injections than others, and this variation was not taken into account. Ideally, one nurse would have given all the injections to limit this variable, but this was not possible. The investigator did monitor injection

technique for consistency, but some variation undoubtedly occurred and is, therefore, a limitation.

The Child Medical Fear Scale (Broome & Hellier, 1986) was used to measure children's fears of medical procedures, including injections. The instrument has established reliability and validity; however, it was designed to be used with children ages 5 years to 12 years. Eighty-three percent of the sample were at least 5 years of age and, therefore, the results of the CMFS can be presumed reliable and valid. However, the CMFS results from the 4-year-old children may not be reliable or valid and, therefore, constitute another study limitation.

#### Implications for Nursing Practice

The results of this study validate the effectiveness of distraction in decreasing needle pain in young children. Nurses caring for children frequently need to perform procedures involving needles, and making the event less painful for the children should be of great interest. Knowing that distraction can decrease pain perception is valuable information. All nurses should be encouraged to use distraction during painful events. The particular form of distraction may be less important than its use in general. Music, visual distraction, and bubble-blowing have been found to decrease injection pain. Nurses should be advised to have several distractors available to give children a choice. The distractors need not be elaborate; they should be simple, familiar activities which require no prior preparation.

This study also demonstrated the effectiveness of touch as a way to decrease pain perception. This is particularly useful knowledge since touch requires no equipment nor does it require the child's attention. Whenever possible, the skin near an injection site should be moderately, rhythmically stroked just prior to and during injection to decrease the pain. If available, parents can be taught to do this for their child. In this way, parents will be given a specific activity shown to reduce pain and, therefore, help parents cope with the injection as well as the children.

It is important to note that the child's behavior during the injection may not reflect any alteration in discomfort. The child may still cry and "fight" the injection even if experiencing less pain. Research results indicate children's pain ratings and observers' ratings of the children's pain are often uncorrelated (Broome, Lillis, & Smith, 1989; Hockenberry & Bologna-Vaughan, 1985; Ryan, 1989). Additionally, children exhibiting more active responses during the procedure often rate the procedure as less painful than children who cope passively (Broome, 1990; Broome, Bates, Lillis, Thayer, & McGahee, 1990). Perhaps the more active behavior functions as a distractor to the pain. It is easy then to misinterpret active behaviors as indicating greater pain and less effective distraction.

Simple distractors and/or touch are easy to perform and take a minimal amount of time. They can be performed even in the busiest health care settings. The



investigator recommends that touch and distraction be added to injection protocols for all young children.

#### Implications for Nursing Research

This study demonstrated the effectiveness of distraction and touch on DTP/DTaP injection pain in preschool children, but it needs to be replicated with other forms of injections, such as other injected immunizations. It has not yet been determined if distraction or touch is effective with multiple injections. Most children require 2-3 injected immunizations at a time, and no research on distraction with multiple injections was found. It is possible that the distraction loses its effectiveness over time and, as the novelty “wears off,” so too does its effectiveness. Additionally, the study needs to be replicated with children of other ages to determine the effectiveness in more age groups.

Further research should compare distraction/touch to topical anesthetics such as EMLA. EMLA continues to be studied for needle pain, but no published research was found comparing EMLA to distraction.

In particular, more studies are needed using touch to reduce pain. Only one previous study of touch and needle pain in children was found while there were several of distraction and pain. The effectiveness of touch on other types of pain should also be studied.

The current study did not examine the effect of positive suggestion on pain perception. Other studies have included this as a variable. Fowler-Kerry and Lander (1987) found no effect of positive suggestion, while Abbot and Fowler-

Kerry (1995) found a placebo cream used with positive suggestion to be as effective as a topical anesthetic for pain relief. The effect of positive suggestion combined with distraction/touch should be investigated.

### Conclusions

Children perceive pain with injections and experience this commonly through injected immunizations. Young children may have difficulty and need help to cope with this experience. Nursing interventions that decrease needle pain should help children adapt to the event and attain a positive outcome.

Distraction and touch reduced significantly the self-reported DTP/DTaP injection pain in the preschool children who participated in this study. While fear of medical events significantly covaried with pain scores, both treatments were effective even when fear was not used as a covariate. Neither age nor gender interacted significantly with treatment effect. Therefore, both distraction and touch are recommended as nursing interventions to decrease injection pain in young children regardless of age, gender, or level of fear.

Injections tend to be a traumatic event for everyone involved: children, parents, and nurses. Having a technique to reduce injection pain will help make this event, if not pleasant, then more tolerable to all.

**APPENDIX A**

**Recommended Childhood Immunization Schedule**

## Recommended Childhood Immunization Schedule United States, January - December 1998

Vaccines are listed under the routinely recommended ages. **Bars** indicate range of acceptable ages for immunization. Catch-up immunization should be done during any visit when feasible. **Shaded ovals** indicate vaccines to be assessed and given if necessary during the early adolescent visit.

Age ► Vaccine ▼	Birth	1 mo	2 mos	4 mos	6 mos	12 mos	15 mos	18 mos	4-6 yrs	11-12 yrs	14-16 yrs
<b>Hepatitis B</b>	Hep B-1	Hep B-2			Hep B-3						Hep B
<b>Diphtheria, Tetanus, Pertussis</b>			DTaP or DTP	DTaP or DTP	DTaP or DTP		DTaP or DTP		DTaP or DTP	Td	
<b>H Influenzae type b</b>			Hib	Hib	Hib	Hib					
<b>Polio</b>			Polio	Polio	Polio				Polio		
<b>Measles, Mumps, Rubella</b>						MMR			MMR	MMR	
<b>Varicella</b>						Var				Var	

Approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).

Source: American Academy of Pediatrics, Committee on Infectious Diseases

**APPENDIX B**  
**Background Questionnaire**

## BACKGROUND QUESTIONNAIRE

ID Number \_\_\_\_\_

Date \_\_\_\_\_

The following information will be helpful in determining the effectiveness of the pain relief method under study. Please complete all questions marking an "X" as appropriate, or answering the questions to the best of your ability. Thank you.

1. What is your relationship to the child?
  - MOTHER
  - FATHER
  - GUARDIAN
  
2. What is your child's age? \_\_\_\_\_
  
3. What is your child's date of birth? \_\_\_\_\_  
 Month    Day    Year
  
4. What is your child's gender?
  - FEMALE
  - MALE
  
5. What is your child's race/ethnicity? Check one only.
  - WHITE, NON-LATINO
  - WHITE, LATINO (HISPANIC)
  - BLACK, AFRICAN-AMERICAN
  - BLACK, LATINO (HISPANIC)
  - ASIAN OR PACIFIC ISLANDER
  - NATIVE AMERICAN
  - OTHER (SPECIFY) \_\_\_\_\_
  
6. How much school have you completed: check one for the highest level completed or degree received. If you are currently in school, check the level of the previous grade attended or highest degree received.
  - SOME HIGH SCHOOL OR LESS
  - HIGH SCHOOL GRADUATE OR EQUIVALENT
  - SOME COLLEGE BUT NO DEGREE
  - ASSOCIATE DEGREE
  - BACHELOR'S DEGREE
  - MASTER'S DEGREE
  - PROFESSIONAL DEGREE (Please specify) \_\_\_\_\_
  - DOCTORATE (Please specify) \_\_\_\_\_

7. What is your family's total gross income? (Before taxes)
- \$15,000 OR LESS
  - \$15,001 TO \$30,000
  - \$30,001 TO \$45,000
  - \$45,001 TO \$60,000
  - \$60,001 OR MORE
8. In general, how would you rate your child's health?
- EXCELLENT
  - VERY GOOD
  - GOOD
  - FAIR
  - POOR
9. In general, how many times a year does your child visit a physician, or other health care provider, for health care?
- LESS THAN ONCE PER YEAR
  - ONCE A YEAR
  - TWICE A YEAR
  - 3-4 TIMES PER YEAR
  - 5 OR MORE TIMES PER YEAR
10. Has your child received any injections (shots) in the past 6 months?
- YES                       NO
- If yes, approximately how many injections? (Please state the number of injections you think the child has received in the past 6 months) \_\_\_\_\_
11. Has your child had any blood tests in the past 6 months?
- YES                       NO
- If yes, approximately how many blood tests? (Please state the number of times your child has had a blood test in the past 6 months) \_\_\_\_\_
12. Does your child have any condition which requires continuing health care? (such as diabetes, asthma, kidney disease, etc.)
- YES                       NO
- If yes, what is the condition? \_\_\_\_\_

13. Please describe your child's past response to immunizations (shots) by indicating the response most like your child's response.

- SCREAMS, KICKS, "FIGHTS" THE INJECTION
- CRIES AND SQUIRMS, BUT IS CONTROLLED WITH HELP
- CRIES BUT IS CONTROLLED WITH NO ASSISTANCE
- QUIET AND COOPERATIVE
- OTHER (PLEASE SPECIFY) \_\_\_\_\_
- UNKNOWN

14. Did you tell your child he/she would get an injection today?

- YES  NO

If yes, when did you first tell him/her?

- 1 WEEK AGO OR MORE
- 2-6 DAYS AGO
- YESTERDAY
- TODAY, 2 OR MORE HOURS BEFORE
- TODAY, LESS THAN 2 HOURS AGO

If yes, what was your child's reaction to the information? (Please describe)

Thank you for your cooperation in completing this questionnaire. Is there anything else you would like to add that you think would be helpful for me to know? If so, please add it here.



**APPENDIX C**

**Child Medical Fear Scale**

Child Medical Fear Scale: 5-12 Year Old

**Directions to child:** I am going to ask you some questions about things that you may think about when you are sick, see a doctor, or go to the hospital. I want you to tell me how afraid you are of each of the sentences I read to you. For instance, if I say "I am afraid of throwing up if I'm sick," I want you to tell me if you are not at all afraid, a little afraid, or a lot afraid of throwing up when you are sick. OK? Do you have any questions before we begin?

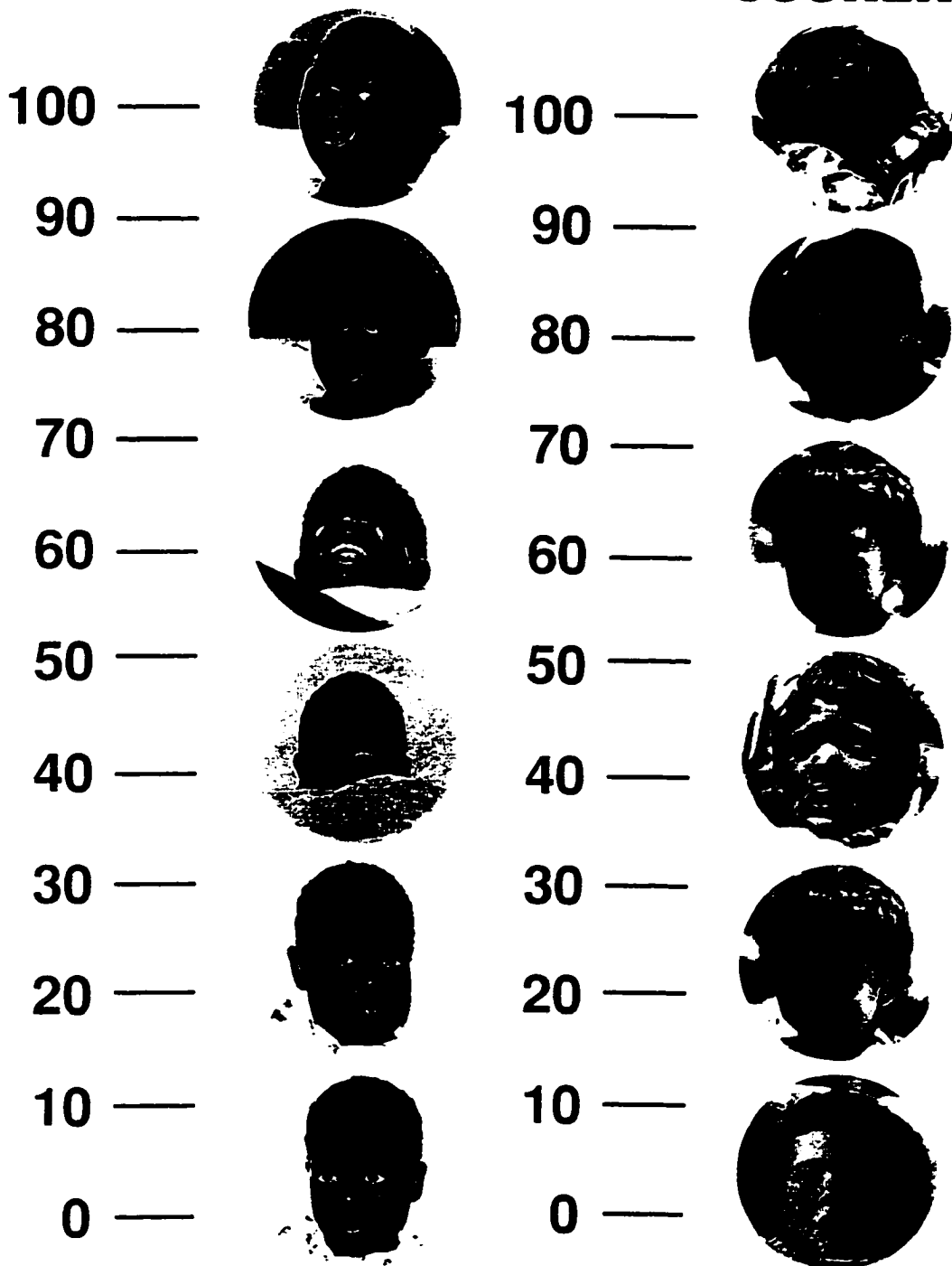
		not at all	a little	a lot
1.	I am afraid of hurting myself.	—	—	—
2.	I am afraid of going to the doctor's office.	—	—	—
3.	I am afraid of getting a shot.	—	—	—
4.	I am afraid of seeing blood come out of me.	—	—	—
5.	I am afraid of going to the hospital	—	—	—
6.	I am afraid of having my finger stuck.	—	—	—
7.	I am afraid the doctor and nurse will not tell me what they are going to do to me.	—	—	—
8.	I am afraid to throw up	—	—	—
9.	I am afraid of missing school if I'm sick.	—	—	—
10.	I am afraid I will cry when I get hurt.	—	—	—
11.	I am afraid if I went to the hospital I'd have to stay a long time.	—	—	—
12.	I am afraid my friends/family will catch something I have if I'm sick and play with them.	—	—	—
13.	I am afraid I might die if I go to the hospital.	—	—	—
14.	I am afraid of having the doctor or nurse look down my throat.	—	—	—
15.	I am afraid the nurse or doctor will tell me something is wrong with me.	—	—	—
16.	I am afraid of being away from my family if I go to the hospital.	—	—	—
17.	I am afraid of the doctor putting a tongue blade in my mouth.	—	—	—

**APPENDIX D**

**Oucher Scale**

# OUCHER<sub>®</sub>

# OUCHER<sub>®</sub>



African-American Version

Caucasian Version

**APPENDIX E**

**Consent Form**

## SAINT LOUIS UNIVERSITY

Consent For Participation in Research Activities

Laurie Sparks, RN, MS  
Graduate Student, School of Nursing

1. Laurie Sparks has requested my participation and my child's participation in a research study at this institution. The title of this study is, "A Comparison of the Effects of Cutaneous Stimulation and Distraction on Children's Perceptions of Injection Pain."
2. I understand that the purpose of this research is to see if either distraction or gentle touch has an effect on the pain perceived by children from injected immunizations. Children fear and experience pain with immunizations, and no easy, effective method of decreasing injection pain has been previously found.
3. My participation will involve:
  - a. Completing a short questionnaire (5-10 minutes to complete).
  - b. Staying with my child during the immunization.

My child's participation will involve:

- a. Answering questions about being afraid on the Child Medical Fear Scale (a questionnaire to determine fear of common medical experiences) administered to my child by a research assistant (10-15 minutes to complete).
  - b. Receiving required immunizations from a nurse using the same vaccines and technique as children receive who are not participating in the study.
  - c. Receiving distraction (bubble-blowing), cutaneous stimulation (touch applied to the skin of the area around the immunization by a research assistant), or neither.
  - d. Rating the amount of pain experienced using a standardized scale, the Oucher scale (2-3 minutes to complete).
4. The only risk to participation is possible increased awareness and sensitivity to the immunization event by completion of the Child Medical Fear Scale. Study participation involves no added risk from the immunization itself as my child will receive the same immunization as he/she would if not participating in the study.

5. I understand that the results of the research study may be published but that my name or identify, and the name of my child will not be revealed and that our record will remain confidential. In order to maintain confidentiality, Laurie Sparks will use code numbers on all information forms, and all information will be kept in a locked cabinet. I understand that the Saint Louis University Institutional Review Board may have access to study records.
6. I understand that the possible benefits of my participation in this research study are to help determine a method to decrease injection pain and that my child may experience less pain with the immunization by participating in this project.
7. I understand that the alternative to this procedure is nonparticipation.
8. I understand that my participation is voluntary and that refusal to participate will involve no penalty to me or my child or loss of any benefits to which we are otherwise entitled. I understand that we may withdraw from the research study at any time without penalty or prejudice.
9. Any questions that I may have concerning my participation in the research study will be answered by Laurie Sparks, who can be reached at [REDACTED].
10. I understand the University will provide immediate treatment in the event that an injury results because of my participation in this project. I understand the University does not provide compensation to human subjects in the event the research results in physical injury; however, this does not mean I have waived my legal rights by signing this form.
11. If I have any questions about my rights as a research subject or in the event I believe I have suffered an injury as a result of participation in the research project, I may contact the Chairperson of the Saint Louis University Institutional Review Board ([REDACTED]), who will discuss my questions with me or will be able to refer me to the individual who will review the matter with me, identify other resources that may be available to me, and provide further information as to how to proceed.
12. I have read the above statement and have been able to ask questions and express concerns, which have been satisfactorily responded to by the investigator. I believe I understand the purpose of the study as well as the potential benefits and risks that are involved. I hereby give my informed and free consent to be a participant in this study and to have my child participate.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Consent Signature of Subject

\_\_\_\_\_  
Print Name of Subject

13. I certify that I have explained to the above individual the nature and purpose and the potential benefits and possible risks associated with participation in this research study, have answered any questions that have been raised, and have witnessed the above signature.
14. These elements of informed consent confers to the assurance given by Saint Louis University to the DHHS to protect the rights of human subjects.
15. I have provided the subject with a copy of this signed consent document.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Research Assistant



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### **Biography of the Author**

**Laurie Sparks was born in Detroit, Michigan. She earned a Bachelor of Science in Nursing and a Master of Science (Research) in Nursing from the University of Maryland and is a certified Pediatric Nurse Practitioner. She is currently employed as an Associate Professor of Nursing at Jewish Hospital College of Nursing and Allied Health in St. Louis, Missouri. She is enrolled in the Doctor of Philosophy in Nursing program at Saint Louis University and is currently a degree candidate. A poster presentation of her dissertation research earned an award at the 1998 conference of the Midwest Nursing Research Society.**

**Mrs. Sparks is a member of Sigma Theta Tau International Honor Society for Nursing; the Midwest Nursing Research Society; the National League for Nursing; the National Association for Pediatric Nurse Associates and Practitioners, and the St. Louis Association for Pediatric Nurse Associates and Practitioners. Mrs. Sparks resides in St. Louis county with her husband and two daughters.**