EFFECTS OF ICE MASSAGE ON PRE-KINDERGARTNERS’ INJECTION PAIN

By

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Fall 1996
We, the undersigned members of the committee, have read and approved this clinical research project

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Dedication

To my children, Jonathan and Matthew
Abstract

Before entering kindergarten, children are required to update their immunization status. Research indicates preschool children are particularly vulnerable to the fear of injections. Few studies have examined interventions to reduce this fear, especially in a cost and time efficient manner. The purpose of this study was to evaluate if ice massage of the skin, before injection of the diphtheria-tetanus-pertussis (DTP) immunization, decreased pain intensity in children. Various variables were also evaluated for their association with the children’s self-reported pain intensity. The convenience sample of 44 children, ages 4 to 6 years old, was randomized into treatment and control groups. Twenty-two children (treatment group) had ice massage of the injection site, for 2 minutes, before the DTP injection. The remaining 22 children (control group) received no extra intervention. Self-reported pain intensity was measured with the Oucher pain assessment tool following the DTP injection. No statistical significant difference was found in the amount of pain intensity experienced between the groups. The amount of children’s anxiety positively correlated with their pain intensity ($r = 0.26$). There were no statistically significant correlations of the other variables and the children’s pain intensity. Limitations are discussed with suggestions for further study.
# Table of Contents

Signature Page......................................................... 2
Acknowledgments..................................................... 3
Dedication.............................................................. 4
Abstract............................................................... 5
Table of Contents.................................................... 6
List of Tables.......................................................... 8
List of Figures.......................................................... 9
List of Appendices.................................................... 10
Chapter 1: Introduction and Background......................... 11
  Purpose of the Study.............................................. 13
  Literature Review................................................ 13
    The DTP Immunization....................................... 13
    Pain............................................................ 13
    Ice Massage.................................................. 15
    Cold Urticaria............................................... 16
Variables Affecting Pain Assessment of the Pre-kindergartner 16
  Developmental Age.............................................. 16
  Past Painful Experiences..................................... 17
  Parental Presence............................................... 17
  Anxiety.......................................................... 18
  Family Cultural Values....................................... 19
  Medications...................................................... 19
Clinical Literature Review......................................... 20
  Cold Therapy and Immunizations............................. 20
List of Tables

Table 1. Cultural Heritage of Children......................... 34
Table 2. Children’s Word for Pain............................... 35
Table 3. Children’s Pain Intensity Related
       to Specific Nurses........................................... 36
Table 4. Independent Samples T-Test on Pain Intensity
       by Group.................................................. 37
Table 5. Children’s Anxiety Ratings as Identified
       by Their Parents/Guardians and Immunization
       Nurses...................................................... 38
Table 6. Variables Related to Children’s
       Pain Intensity............................................. 39
List of Figures

Figure 1. The Oucher (Caucasian version) ................. 26
Appendices

A. Medication Costs ................................................. 52
B. Immunization Schedule for Healthy Infants
   and Children .................................................... 54
C. Copyright Approval ............................................. 56
D. Informed Consent Form ......................................... 58
E. Verbal Assent Script ............................................. 63
F. Interview/Data Collection Form ................................. 65
G. Interview and Oucher Script ..................................... 67
H. Washington State University Institutional
   Review Board Approval ......................................... 69
I. Spokane County Health District Approval ...................... 72
Chapter 1
Introduction and Background

Every year before kindergarten, children in Washington state must update their immunization status. One of these immunizations is the diphtheria/tetanus/pertussis (DTP) vaccine (RCW 28A.210.080, 1992; WAC 246-100-166, 1995). While injections may be mildly painful in adults, for children they may be emotionally frightening and very painful. Eland and Anderson (1977) asked 242 hospitalized children, ages 4 to 10, "Of all the things that have hurt you, what was the worst?" 49 percent answered shot or needle. This response was magnified in that 6 of these children, who answered shot or needle, had collectively undergone a minimum of 25 surgeries. Eland (1981) also found many children use the word "shot" or "needle" synonymously for pain. Researchers have confirmed that needle sticks, whether from venipuncture or injection, increase stress reactions in children (Fassler, 1985; Menke, 1981).

Research results of interventions to decrease or prevent pain from injection in children is beginning to accrue yet is limited. Pharmacologic interventions such as topical sprays (Frigiderm® and ethyl chloride) and EMLA (Eutectic Mixture of Local Anesthetics) cream have been evaluated for reducing injection pain with significant results (Eland, 1981; Maikler, 1991; Maunuksela & Korpela, 1981).
1986). However, these medications are expensive (Appendix A—medication costs). In addition, EMLA cream requires 60 minutes after application to become effective (Farrington, 1993). Thus these medications may not be cost effective or time efficient for decreasing immunization injection pain.

Nonpharmacologic interventions including music, preparatory sensory information, pre-procedural preparation, directed play, parental presence, and use of transcutaneous electrical nerve stimulation (TENS) have been researched in children undergoing venipuncture and/or immunization with varying results (Alyea, 1978; Broome & Endsley, 1987; Ellerton, Caty, & Ritchie, 1985; Froese-Fretz, 1986; Gedaly-Duff, 1987; Ryan, 1989; Schreiber, 1982; Sturner, Rothbaum, Visintaier & Wolfer, 1980). Another nonpharmacologic intervention which is inexpensive and familiar to children is ice. Use of ice to numb the skin before injection makes sense. Yet this researcher found only one study that studied the effect of using ice on children’s injection pain. Gedaly-Duff and Burns (1992) examined the effect of 30 seconds of ice massage on 37 pre-kindergartners’ injection pain and found no significant difference. Their findings may be due to their small sample size, number of assessment tools used and short time ice massage was performed.
Purpose of the Study

The purpose of this study was to evaluate the effects of ice massage on children's acute pain from a routine DTP injection. Variables such as anxiety, medications taken within 6 hours of immunization, culture, and venipunctures or injections within the last year were also studied for their correlation with children's pain intensity.

Literature Review

The DTP Immunization

The DTP immunization, a combination of diphtheria and tetanus toxoids and pertussis vaccine, has been used widely in the United States since the 1940s. The immunization is given at 2, 4, 6, 12-18 months of age and just before entering kindergarten. Every 10 years it is recommended that people receive a Td (tetanus/diphtheria) booster (Appendix B-Immunization Schedule). The DTP is administered in a standard dose of 0.5 ml intramuscularly (Simoes, 1995). A common side effect of the DTP is localized pain. This pain occurs within 48 hours and in up to half of all DTP injections given. The pain is thought to be due to the irritating effects of the pertussis vaccine contained in the immunization (Cody, Baraff, Cherry, Marcy, & Manclark, 1981).

Pain

Pain is a complex subjective sensation experienced by all people. There are several definitions of pain. The
International Association for the Study of Pain (American Pain Society, 1992) adopted the following definition of pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (p. 2). McCaffery has defined pain as "whatever the experiencing person says it is, existing whenever the experiencing person says it does" (McCaffery & Beebe, 1989, p. 7). Research supports the idea that children use different words than adults such as "hurt", "ache" and "sore" to describe pain (Tesler, Savedra, Ward, Holzemer & Wilkie, 1989). For this study pain was defined as whatever the children said it was, in their own words, associated with an immunization injection.

The Gate Control theory proposed by Melzack and Wall (1965) is generally accepted as the most complete framework to explain how pain is experienced. This theory integrates sensory, affective, and cognitive dimensions of pain. Melzack and Wall propose there are gating mechanisms all along the central nervous system which modulate pain impulses. Small diameter peripheral nerve fibers such as A-delta and C fibers send pain messages to the spinal cord where they enter through an open gate and travel to the brain where pain is perceived. In the brain the pain message is modulated by affective and cognitive variables such as past painful experiences, emotion, developmental age, and cultural values. There are also large diameter A
fibers located in the peripheral nervous system. When these fibers are stimulated, an inhibitory message is sent to the spinal cord closing the gate. The pain message is thus prevented from ascending to the brain. One hypothesis of how ice massage decreases pain is by stimulation of these large diameter A fibers (Puntillo & Tesler, 1993).

**Ice Massage**

Ice massage alters the conduction velocity and synaptic activity of the small diameter A-delta and C fibers. When the temperatures of these nerves are decreased, sensory and motor-conduction velocities also decrease and may become blocked. The most sensitive fibers to cold are the fast conducting, myelinated A-delta fibers, the same fibers which transmit the sharp prick of injection pain. These fibers are affected first by decreases in temperature. The quantity of change in velocity depends upon the duration and degrees of temperature alteration (Michlovitz, 1990). Bugaj (1975) observed the cooling, analgesic, and rewarming effects of ten-minutes of ice massage to the skin overlying the right gastrocnemius muscle. His sample consisted of sixteen healthy young adults. Analgesia began when the localized skin temperature was lowered to approximately 13.6 degrees Celsius which occurred after one minute and forty-five seconds of ice massage. Based on this information, two minutes of ice massage were performed in this study.
Cold Urticaria

Cold urticaria is a rare syndrome in which exposure to cold air, cold water or other cold objects induce localized hives, itching or angioedema (Pearlman & Comer, 1995). Usually it takes at least 5 minutes of exposure to cold for susceptible children to develop hives. In this study, exposure to cold was only 2 minutes. For highly sensitive children with this rare condition, hives could possibly develop. Parents/guardians were interviewed for their children’s past reactions to cold and informed of this possible event. In the unlikely case that children developed hives post ice massage, parents/guardians were directed for further diagnosis and treatment from their health care provider.

Variables affecting pain assessment of the pre-kindergartner

Pain assessment in children can be challenging due to numerous variables affecting the pain response. Some of these variables are developmental age, past painful experiences, parental presence, anxiety, culture and medications (Hester, Foster, & Beyer, 1992).

Developmental age.

Piaget theorized pre-kindergartners are in the preoperational stage of intellectual development. During this period egocentrism, concreteness, centeredness, irreversibility of thinking and magical thinking are present (Gedaly-Duff, 1991). These children commonly exhibit fear
of unfamiliar environments such as health clinics and fear of abandonment. Having parents stay with their children during immunization may help them with this fear. The protocol at the Spokane County Health District, which was followed during this study, was for parents to remain with their children during immunization.

Past painful experiences.

Past painful experiences are remembered by children. These experiences will affect how children respond to future painful experiences. Children interpret each new pain according to a frame of reference as defined by the number and variety of pains that they have already experienced. As children grow they experience a variety of pains that differ in intensity, location, quality, duration and offensiveness. They also learn new methods to cope with different types of pain (McGrath, 1993). As mentioned in the introduction, injections and venipunctures are painful for children. To help assess this variable, parents were asked if their children had a painful venipuncture or injection within the past year.

Parental presence.

The question of whether or not parents should be present during painful procedures has been studied with conflicting results (Gonzalez, Routh, Saab, Armstrong, Shefman, Guerra, & Fawcett, 1989; Gross, Stern, Levin, Dale & Wojnilower, 1983; Ross & Ross, 1984; Shaw & Routh, 1982).
Some health professionals believe parents should not be present because the child may blame the parents for allowing pain to be inflicted. Parents may also make inadvertent comments that do not facilitate adaptive coping, especially about the procedure or pain expectations. Other health care professionals believe parents can be a source of comfort and security to the child and thus should be present. Interestingly, research indicates when children and parents are asked for their preference, children usually want their parents with them and parents want to be present (Ross & Ross, 1984). The standard of practice at the Spokane County Health District, which was followed for this study, was to have parents/guardians accompany their children and hold them during the immunization injection.

Anxiety.

Anxiety is often provoked by painful procedures such as immunization injections. As mentioned above, children remember past painful experiences, thus anxiety is common when faced with similar experiences. When anxiety increases, children’s pain may become stronger and their behavioral, physiological and verbal responses increase (Jay, Ozolins, Elliott and Caldwell, 1983; Kuttner, Bowman & Teasdale, 1988; McGrath, 1993). For this study, children’s anxiety to injections was assessed by asking parents/guardians and nurses to rate the children’s anxiety on an arbitrary 3 point scale.
Family cultural values.

Families model appropriate forms of communication and coping skills in response to pain based upon learned cultural values (Bernstein & Pachter, 1993). While there are several studies exploring culture and pain in adults, including the classic Zborowski, (Lipton & Marbach, 1984; Reizian & Meleis, 1986; Zborowski, 1952) there is limited empirical research about children in this area. One cultural study including children (Fritz, Schechter & Bernstein, 1991) explored Vietnamese families parenting beliefs, discipline techniques and parental expectations of children’s reactions to pain. Crying and complaints were acceptable for young children but older children (age eight and above) were expected to respond stoically to pain and not be comforted with physical affection. Abu-Saad (1984a, 1984b, 1984c) has researched Arab-American, Asian-American and Latin-American children and found children of these three cultures respond to painful experiences differently and in accordance to their cultural differences. Parents/guardians were asked for their children’s cultural heritage to build upon existing research data.

Medications.

One other potential confounding variable is the administration of medication(s) which may block or decrease pain transmission. Many parents, when their children received their first series of DTP immunization, were
encouraged by health care providers to administer acetaminophen to their child before immunization. Acetaminophen is believed to decrease some of the irritability, possible fever and discomfort of infants following DTP immunization. It is possible parents may premedicate their child before the pre-kindergarten DTP. Acetaminophen could alter the child’s pain intensity if administered within 4 hours of the injection. Nonsteroidal anti-inflammatories, such as ibuprofen, are also commonly given to children for discomfort. Their duration of action is up to 6 hours (Physicians Desk Reference, 1996). To assess the potential effect of this variable the parents/guardians were asked if the children had received any medications in the past 6 hours.

Clinical Literature Review

Cold Therapy and Immunizations

There are three previous studies which examine the effects of cold on injection site pain from immunization. Two of these studies used a topical coolant spray and only one study used ice. Maikler (1991) studied 60 infants, ages 2 through 6 months old, during a routine DTP immunization. She applied Frigiderm® spray to the treatment group and an air spray to the control group. Both groups demonstrated distress behavior but the treatment group of infants displayed less behavioral distress than the control group. Distress behavior was measured by the Maximally
Discriminative Facial Movement Coding System and coded videotape of the infants’ body movements. The treated infants also startled less when the needle was inserted and took longer to begin to cry. This latent crying might be explained by C fiber pain transmission from muscle stretching by the injectant.

Eland (1981) used a 2 X 2 factorial design to study the use of Frigiderm® spray and cognitive information in decreasing the pain of DTP injection in pre-kindergarten children. The sample consisted of 20 boys and 20 girls between the ages of 4 years 9 months and 5 years 9 months. The mean amount of pain expressed by the children receiving Frigiderm® was 1.85 (SD 1.14). The mean amount of pain expressed by the control group (air spray) was 2.55 (SD 0.76). The children’s pain were measured by the Eland Color tool. When cognitive information was given, the mean amount of pain expressed was 2.1 (SD 0.46) compared to the control group mean of 2.30 (SD 0.67). Using ANOVA, the Frigiderm® group reached a statistical significance of $p = .029$. The cognitive information group ($p = .521$) and the combination Frigiderm® and cognitive information group ($p = .337$) were not statistically significant at the $p \leq .05$ level. Her sample size was small but these results indicated that there was a difference between the Frigiderm® spray group and the control group. Frigiderm® may be able to decrease a child’s DTP injection pain.
Gedaly-Duff and Burns (1992) studied the effect of ice massage on pain distress of pre-kindergartners. The sample of 15 boys and 22 girls were randomly placed in treatment and control groups. One half of the sample received 30 seconds of ice massage and the other half received the injection without an extra intervention. Assessment tools included: the Global Mood Scale, pulse rate, Oucher scale and Faces scale. There were no significant differences between the two groups. One of the limitations of this study was the short time of ice application. The researchers also believed the children were confused in answering several similar questions on different instruments about their hurt.

**Research Questions**

This clinical research project was designed to answer the following research questions:

1. Will pre-kindergarten children who have ice massaged for 2 minutes to the injection site immediately before receiving an intramuscular DTP injection express less pain than children in a control group who receive the standard DTP injection only?

2. How do anxiety level, premedication, culture or venipunctures/injections within 1 year prior correlate with children’s pain intensity rating?
Significance to Nurse Practitioners

Research results which identify effective, time-efficient, and inexpensive nonpharmacologic interventions are needed to help prevent or relieve pain in children. Nurse practitioners are in a strategic position to implement and evaluate these interventions. Health clinics in the United States are required to have access to refrigeration for storage of medicine, therefore ice is accessible. Ice massage is inexpensive, safe and easy to perform. If found effective, parents or children themselves could be taught to perform ice massage to the preinjection site to help reduce or prevent children's injection pain.
Chapter 2
Method of Study

Design

A two group, post-test, quasi-experimental design was used for this study (Burns & Grove, 1993). The convenience sample was randomly assigned to a treatment group or a control group based on individual ticket numbers. These numbers were distributed at the check-in desk of the immunization clinic.

Setting

The setting was a private immunization room at the Spokane County Health District Main Immunization clinic. As per Spokane County Health District’s policy, children’s parents or guardians stayed with them and held them on their laps during the procedure.

Sample

A convenience sample of 44 children between the ages of 4 and 6 years old who came to the Spokane County Health District for a routine DTP immunization were recruited. To be eligible to participate in the study the children: (a) needed a DTP immunization; (b) received that immunization before receiving any other immunizations; (c) gave verbal assent to participate in the study; (d) understood how to use the Oucher pain assessment tool; and (e) did not have a history of hives from exposure to cold. The children’s parents/guardians were required to speak and
understand English and gave their written consent for their children to participate.

**Instrumentation**

Two instruments were used in this study, the Oucher pain assessment tool (Figure 1) and a 3 point anxiety scale. The Oucher, developed by Beyer in 1984, was chosen for its ease of use and because its psychometric properties have been well researched (Beyer, Villarruel, & Denyes, 1995). The instrument is a 17 X 6 inch laminated poster-like tool designed to help children provide self-reports of their pain intensity. The Oucher is the only pain scale using color photographs of an actual child and consists of two scales.

The scale on the left contains a vertical numerical scale with numbers from 0 (no hurt) to 100 (the biggest hurt you could ever have). If children can count to 100 they choose the number that best describes their pain. The scale on the right is also a vertical scale consisting of six photographs of a light-skinned, androgenous appearing preschool child representing "no hurt" to "the biggest hurt you could ever have." Children choose the face that most nearly describes their pain. The photographic scale is recommended for children who are unable to count to 100 by ones or tens or are unable to identify which of any two numbers is larger. Due to the ages of the children in this study the photographic scale was used. (Beyer, Villarruel, & Denyes, 1995).
Figure 1. The Oucher (Caucasian version, Beyer, 1984). Copyright 1984 by Judith Beyer, RN, Phd. Reprinted with permission.
For statistical purposes the children's photographic selections were converted to scores from 0-5 as indicated below: the bottom picture = 0, the second picture = 1, the third picture = 2, the fourth picture = 3, the fifth picture = 4 and the sixth picture = 5. The photographic scores were treated as ordinal data (Beyer, Villarruel, & Denyes, 1995).

Studies have provided evidence of face and content validity for the Oucher. The photographic and numerical scales are highly associated ($r = 0.823$, $p < 0.001$; Beyer, 1984). Beyer and Aradine (1986) described significant agreement among children in sequencing the photographs of the Oucher (coefficient of concordance, $0.726$, $p < .01$), supporting the content validity of the photographic scale. Gamma coefficients indicated high correlations between the Oucher photographic scale and the Poker Chip Tool (Hester, 1979, gamma = 0.920); and moderate associations with the visual analog scale (gamma = 0.751), showing convergent validity for these pain scales (Beyer & Aradine, 1987). Construct validity was supported by a study of hospitalized children in which mean and median scores at preanalgesic times were higher than those at postanalgesic times (Aradine, Beyer & Tompkins, 1988).

Reliability testing of the Oucher is difficult because the scale is not a traditional psychometric test. It is a single-item scale so measures of internal consistency cannot be done. Also the Oucher measures pain which is a
continuously varying phenomenon. Thus test-retest procedures cannot be used to test reliability of the Oucher.

The main concern with the Oucher is its culture specificity. The Oucher uses photographs of a light-skinned child. Villarruel and Denyes (1991) have developed two additional Oucher scales using an African-American young boy and a Hispanic young boy. Psychometric testing has begun with these two new versions. However the children pictured in these versions are obviously boys and slightly older children. Some informal reports have shown girls cannot relate to these pictures as well. Further versions of the Oucher which are gender specific as well as cultural specific are needed (Beyer, Denyes, & Villarruel, 1992). Based on the need for further psychometric testing and the gender specificity of the African-American and Hispanic versions, the Caucasian Oucher was used for this study.

The three point anxiety scale used for this study was chosen as a simple instrument to help assess the amount of anxiety of the children about receiving injections. Parents/guardians and nurses independently chose a number to rate the children’s anxiety. The scale consisted of three numbers with increasing amount of anxiety, 1 = not anxious, 2 = somewhat anxious and 3 = very anxious. Several limitations are apparent with this scale. Each person’s definition of anxiety may be different. Some people will consistently rate their responses at the extremes of a scale
while others always choose the midrange of a scale, this is termed "extreme response set bias" (Polit & Hungler, 1993). This scale was used by Eland (1981) in assessing children's anxiety reactions to injections. She had parents/guardians and nurses rate the children’s anxiety. The parents'/guardians' and nurses' scores were not statistically different. Eland compared the means and standard deviations of the anxiety scores between the experimental and control groups but no statistical analysis was reported as to the relationship of anxiety to pain. This anxiety scale was chosen for this study to assess children's anxiety about injections. It was easy and quick to use to help keep the time of the study to a minimum.

Procedure

Before implementing this study, the research proposal (with emphasis on procedure) was reviewed with the immunization nurses. The researcher taught the immunization nurses how to rate children's anxiety using the 3 point anxiety scale. Standard injection technique was reviewed with each nurse. The immunization nurses were asked not to comment on the efficacy of the method of this study to the children or parents/guardians until completion of the procedure.

The immunization nurses escorted the children and their parents/guardians into a private immunization room. They assessed which immunizations the children required. If
children needed DTP immunization, the nurses introduced the researcher to the children and parents/guardians. The researcher then explained the study and sought written consent from the children’s parent/guardian (Appendix D-informed consent). Verbal assent was sought from the children using a prewritten script (Appendix E-verbal assent). Once written consent and children’s verbal assent were obtained, the children and parents/guardians were interviewed (Appendix F-interview/data). The children were placed in a control group or treatment group depending on their individual ticket number (even = treatment group, odd = control group). The children were then instructed in the use of the Oucher pain intensity rating tool by the researcher, using a prewritten script (Appendix G-interview/oucher).

Parents/Guardians stayed with their children during the study and were asked not to comment on the efficacy of the treatment, the level of their child’s discomfort or their child’s behavior until after the procedure was completed. The children sat sideways on their parent’s/guardian’s lap with their legs held between their parent’s knees or legs. The arm closest to the parent was wrapped around the parent’s waist to give the parent a hug. The other arm was then easily accessible for the ice massage and injection. This position protected the nurse from the children during
the injection and provided children the comfort of being held by their parents/guardians.

The control group had the standard DTP immunization injection and the children were asked to rate their pain intensity using the Oucher pain assessment tool following the injection. The children in the treatment group had ice massaged to the injection site for 2 minutes before the DTP injection. The treatment was performed by the researcher and the immunization by the immunization nurse.

An 8 ounce styrofoam cup of frozen water was held by the researcher to perform the ice massage. The bottom of the cup was peeled away to expose the ice to the children’s skin. Massage was performed over the deltoid muscle in small overlapping circles. During ice massage four possible sensations may occur: intense cold, burning, aching, then analgesia. If burning and aching occur, these sensations pass quickly (within 1 to 2 minutes of ice massage). Children were informed of these possible sensations. A towel to wipe the skin from melting ice and water was also used (Michlovitz, 1990).

The DTP immunization (0.5 ml) was administered using standard technique by the immunization nurse. The nurse used a 25 gauge, 5/8 inch needle attached to a 3 cc syringe for the injection. The nurse was asked to insert the needle quickly at a 90 degree angle and inject the immunization slowly into the deltoid muscle. A slow rate of injection
allows time for distention of the space within the muscles thus decreasing the amount of C fiber stimuli leading to secondary pain (Zelman, 1961). According to Spokane County Health District protocol, a bandaid was applied, unless the children refused, to the injection site. Approximately thirty seconds following the injection the children were asked to point to a photograph on the Oucher scale which corresponded to the amount of their injection pain. The children’s own word for "pain" was used when asking them to rate their pain.

**Data Analysis**

The data collected from the Oucher pain assessment tool was ordinal level data; therefore the T-test for differences was used to examine differences in pain intensity between the control and treatment groups. Pearson’s product-moment correlation coefficient examined the relationship between pain intensity and anxiety. The data obtained from medications, venipunctures/injections and culture were nominal level. Thus chi-square analysis was used to evaluate these variables’ relationship to children’s pain intensity. Chi-square evaluated the differences between children’s pain ratings and the individual immunization nurses’ technique. Descriptive statistics described the characteristics of the sample (Burns & Grove, 1993). The data was analyzed using Mystat (version 2.1). A probability of 5% was set as the criterion for statistical significance.
Human Subjects Protection

Approval was granted to perform this clinical research project by the following:
1. Clinical research project committee, Intercollegiate Center for Nursing Education.
2. The Spokane County Health District.

Parents/guardians of the children read and signed the written informed consent form. They had the opportunity to ask questions of the researcher. Verbal assent was obtained from the children. Due to the age of the children and reason for coming to the clinic, written assent was not obtained from the children. The children and parents/guardians were assured children's participation or nonparticipation would not affect their care. They were informed of the potential risks and benefits of this study. They were assured the children could withdraw from the study at any time without jeopardizing the quality of their care. They were informed data collected would be used only for purposes of research and the results may appear in scientific journals. The children's names were not collected and confidentiality was maintained. They were also informed that a summary of the results of the study would be posted for them to read at the Spokane County Health District when available.
Chapter 3

Results

Sample Characteristics

The convenience sample consisted of 44 children evenly distributed between two groups. There were 25 boys (57%) and 19 girls (43%). Ages ranged from 48 months to 79 months with a mean of 62 months. Parents were asked about their children's cultural heritage. There were 28 Americans (64%) and a variety of other cultural combinations as displayed in Table 1.

Table 1.
Cultural Heritage of Children

<table>
<thead>
<tr>
<th>Culture</th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>*American</td>
<td>28</td>
<td>64</td>
</tr>
<tr>
<td>Irish-German American</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Cuban American</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Hispanic American</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Irish American</td>
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<td>5</td>
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<tr>
<td>Greek American</td>
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<td>2</td>
</tr>
<tr>
<td>African American</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Norwegian-German American</td>
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<td>2</td>
</tr>
<tr>
<td>Hispanic-Guam American</td>
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<td>2</td>
</tr>
<tr>
<td>Hispanic-German-Native American</td>
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<td>2</td>
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<td>2</td>
</tr>
<tr>
<td>Italian-Hungarian-German American</td>
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<td>2</td>
</tr>
<tr>
<td>Irish-German-Hispanic-Native American</td>
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</tr>
</tbody>
</table>

*Note. "American" was the culture chosen by parents/guardians as their cultural heritage or by those who claimed no other specific cultural heritage.
Four children (9%) took acetaminophen within 6 hours of their immunization. There were also 4 children (9%) who had a venipuncture or injection within the past year. Five children (11%) had a past immunization reaction such as a sore arm (n=2) or fever (n=3). The children used a variety of words for the word "pain" as presented in Table 2. The most common word expressed was "hurt" (43%).

Table 2.

<table>
<thead>
<tr>
<th>Word</th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hurt</td>
<td>19</td>
<td>43</td>
</tr>
<tr>
<td>Owie</td>
<td>14</td>
<td>32</td>
</tr>
<tr>
<td>Ouch</td>
<td>8</td>
<td>18</td>
</tr>
<tr>
<td>Ouchie</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Ow</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>No word identified</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

All the children received the standard 0.5 ml of DTP immunization. The site for all the DTP injections was the deltoid muscle using a 25 gauge, 5/8 inch needle attached to a 3 cc syringe.

None of the 44 children participating withdrew from the study. Six additional children were invited to enter the study but refused. Of these, one parent did not want their child to participate due to their child’s inability to behave. The rest of the parents agreed to let their
children participate in the study but the children refused. Interestingly, these five children had not been told by their parents, before entering the immunization room, that they would be receiving their immunizations that day.

Due to staffing changes at the Spokane County Health District, a total of four immunization nurses took part in this study. Table 3 displays the children's injection pain intensity compared with the nurse giving the injection. A chi-square test for independence found no significant relationship between the nurses giving the injections and the amount of pain stated by the children.

Table 3.

Children’s Pain Intensity related to Specific Nurses

<table>
<thead>
<tr>
<th>Oucher Pain Intensity Score</th>
<th>Nurse 1</th>
<th>Nurse 2</th>
<th>Nurse 3</th>
<th>Nurse 4</th>
<th>Total Children</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>26</td>
</tr>
</tbody>
</table>

Chi-square = 12.378, DF = 15, p = 0.650.

Note. More than one-fifth of fitted cells are sparse (frequency < 5). Significance tests are suspect.
Research Questions

1. Will pre-kindergarten children who have ice massaged for 2 minutes to the injection site immediately before receiving an intramuscular DTP injection express less pain than children in a control group who receive the standard DTP injection only?

A one tailed T-test did not show statistical significant mean differences (p= 0.08) between the control and ice massage groups. As shown in Table 4, the mean for the control group was 2.0 with a standard deviation of 1.9. The mean for the ice massage group was 1.3 with a standard deviation of 1.4.

Table 4.
Independent Samples T-Test on Pain Intensity by Group

<table>
<thead>
<tr>
<th>Group</th>
<th>M</th>
<th>SD</th>
<th>T</th>
<th>DF</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>2.0</td>
<td>1.9</td>
<td>1.44</td>
<td>38.9</td>
<td>0.08*</td>
</tr>
<tr>
<td>Ice Massage</td>
<td>1.3</td>
<td>1.4</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note. One-tailed T test.
2. How do anxiety level, premedication, culture or venipunctures/injections within 1 year prior correlate with children's pain intensity rating?

Eighteen parents/guardians (41%) rated their children's anxiety as "not anxious" about injections. Twenty-one children (48%) were identified as being "somewhat anxious" and five children (11%) "very anxious" by their parents/guardians. The nurses' rating of the children's anxiety identified 27 not anxious (61%), 13 somewhat anxious (30%) and 4 very anxious (9%). Table 5 provides a summary of the means and standard deviations of the parents'/guardians' and nurses' ratings.

Table 5.

Children's Anxiety Ratings as Identified by Their Parents/Guardians and Immunization Nurses

<table>
<thead>
<tr>
<th>Group</th>
<th>Rating</th>
<th>M</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>Parent</td>
<td>1.73</td>
<td>0.63</td>
</tr>
<tr>
<td></td>
<td>Nurse</td>
<td>1.50</td>
<td>0.60</td>
</tr>
<tr>
<td>Ice Massage</td>
<td>Parent</td>
<td>1.68</td>
<td>0.72</td>
</tr>
<tr>
<td></td>
<td>Nurse</td>
<td>1.41</td>
<td>0.67</td>
</tr>
<tr>
<td>Total</td>
<td>Parent</td>
<td>1.71</td>
<td>0.67</td>
</tr>
<tr>
<td></td>
<td>Nurse</td>
<td>1.48</td>
<td>0.67</td>
</tr>
</tbody>
</table>

DF = 42, Significance level of 0.05, r = 0.378

Critical value for Pearson product moment correlation (r) = 0.257 for significance of a sample of 44.
As seen above, the parent’s/guardian’s rating of their children’s anxiety showed a significant positive correlation with the nurse’s rating of the children’s anxiety ($r = 0.378$).

As parent’s/guardian’s rating of children’s anxiety positively correlated with the nurse’s rating, the means of these scores were added together and divided by two to develop an overall anxiety rating (Robert Short, personal communication, August 5, 1996). Pearson’s correlation assessed the effect of overall children’s anxiety on their pain intensity. Children’s amount of anxiety positively correlated with significance of their pain intensity ($r = 0.259$).

Premedication, injections/venipunctures and culture were independently analyzed for their relationship to children’s pain intensity rating using chi-square. As seen below, none of these variables were significantly related to children’s pain intensity. However each sample size is small thus significance tests are suspect.

Table 6.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Chi-square</th>
<th>DF</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premedication</td>
<td>3.46</td>
<td>5</td>
<td>0.63</td>
</tr>
<tr>
<td>Injections</td>
<td>7.70</td>
<td>5</td>
<td>0.17</td>
</tr>
<tr>
<td>Culture</td>
<td>58.33</td>
<td>60</td>
<td>0.54</td>
</tr>
</tbody>
</table>
Chapter 4
Conclusions

This study attempted to evaluate the effect of 2 minutes of ice massage on children’s pain intensity from a DTP immunization injection. Ice massage did not statistically significantly decrease children’s injection pain intensity in this small study. The lack of statistical significance could be due to the size of the samples, coping strategies used by the children, family behavior patterns or other unknown variables.

Anxiety was found to positively correlate with children’s pain intensity of injections. Nurse practitioners and their nurses need to be aware of children’s anxiety levels prior to potentially painful procedures. Nurse practitioners could teach children methods to reduce their anxiety and possibly lower their pain intensity.

The variables of medication, previous injections and culture did not appear to relate to children’s pain intensity. However, these sample sizes were quite small so results of this study should not be generalized to the population.

Limitations

A threat to external validity, specifically interaction of selection and treatment is one limitation of this study. Although most children are familiar with cold, they may not
like the sensations given by the ice massage and thus refuse to participate. There were 6 children who declined to participate for unknown reasons.

A threat to internal validity may be the dropping out of subjects before completion of the study. This could be due to the possible side effects of ice massage, the nature of the clinic visit, namely, the stress of receiving an injection or other unknown reasons. No children withdrew from the research project.

A threat to construct validity is having only one instrument, the Oucher, to measure pain intensity. While the Oucher instrument has been extensively tested, some of the children may have confused fear with pain when rating their pain. One instrument was chosen due to time constraints, and a wish to avoid additional stress of testing on the children.

Interaction of different treatments or variables may also threaten construct validity. Anxiety was assessed by having the parents/guardians and clinic nurses each rate the children for anxiety. The anxiety rating scale has not received extensive reliability and validity testing. Therefore the scale may not have accurately measured anxiety.

Clinic nurses used the same injection site, type of immunization, needle, and syringe. Each nurse was instructed to avoid distraction techniques and commenting on
the efficacy of the treatment. However several times the nurses forgot and distracted the children by asking them to count to ten, blow out air and look at pictures in the room during their injections. These techniques may have altered children’s pain perception. It is also possible different injection techniques by the individual nurses may have affected the amount of children’s pain.

This study was performed at the Spokane County Health District where approximately 85% of the children served are lower income (Gwen Dutt, personal communication, August 5, 1996). Thus these study results cannot be generalized to the population.

The researcher performed the intervention and asked the children to rate their pain. While the researcher used prewritten scripts, it is possible the presence of the researcher may have affected the children’s responses.

**Recommendations**

There are few research studies which study the effects of inexpensive, time-efficient and safe methods of reducing children’s injection pain. Nurse practitioners are in a strategic position to pursue further research into this area. This research study should be repeated using a larger sample to determine statistical significance in changes of children’s pain intensity using ice massage. The sample should be drawn from a variety of income levels to better generalize to the population. A well-tested measurement
tool for fear and anxiety would be helpful to better discern the effects of these variables on children's pain. Using one nurse, or perhaps just the researcher, to control for injection technique and actions is also advised for future studies.
References


APPENDIX A

Medication Costs
### Medication Costs

<table>
<thead>
<tr>
<th>Medication</th>
<th>Amount Supplied</th>
<th>Approximate cost per Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frigiderm spray</td>
<td>$195.48/ 8 ounces</td>
<td>$4.00</td>
</tr>
<tr>
<td>Ethyl chloride spray</td>
<td>$109.08/ 4 ounces</td>
<td>$1.00</td>
</tr>
<tr>
<td>EMLA cream</td>
<td>$6.88/ 5 gm tube</td>
<td>$3.44</td>
</tr>
</tbody>
</table>

(Gebauer Company, personal communication, September 11, 1996; Physicians’ GenRx, 1995)
APPENDIX B
Immunization Schedule for Healthy Infants and Children
### Immunization Schedule for Healthy Infants and Children

<table>
<thead>
<tr>
<th>Age</th>
<th>Immunization(s)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth</td>
<td>HBV</td>
</tr>
<tr>
<td>1-2 mo.</td>
<td>HBV</td>
</tr>
<tr>
<td>2 mo.</td>
<td>DTP, Hib, OPV</td>
</tr>
<tr>
<td>4 mo.</td>
<td>DTP, Hib, OPV</td>
</tr>
<tr>
<td>6 mo.</td>
<td>DTP, (Hib)</td>
</tr>
<tr>
<td>6-18 mo.</td>
<td>HBV, OPV</td>
</tr>
<tr>
<td>12-15 mo.</td>
<td>Hib, MMR</td>
</tr>
<tr>
<td>15-18 mo.</td>
<td>DTaP or DTP</td>
</tr>
<tr>
<td><strong>4-6 y.</strong></td>
<td>DTaP or DTP, OPV</td>
</tr>
<tr>
<td>11-12 y.</td>
<td>MMR</td>
</tr>
<tr>
<td>14-16 y.</td>
<td>Td</td>
</tr>
</tbody>
</table>

* HBV = Hepatitis B virus vaccine; DTP = diphtheria and tetanus toxoids and pertussis vaccine; DTaP = diphtheria and tetanus toxoids and acellular pertussis vaccine; Hib = Haemophilus influenzae type b conjugate vaccine; OPV = oral poliovirus vaccine (containing attenuated poliovirus types 1, 2, and 3); MMR = live measles, mumps, and rubella viruses vaccine; Td = adult tetanus toxoid (full dose) and diphtheria toxoid (reduced dose), for children ≥ 7 y. and adults.

(Adapted from American Academy of Pediatrics, 1994)
APPENDIX C

Copyright Approval
June 28, 1995

Ms. Sue Dennie
8710 North Greenwood St.
Spokane, WA 99208

Dear Ms. Dennie,

It was delightful to speak with you today on the phone. I'm sorry that I had to hang up quickly because of the page I received. I'm in the middle of trying to make a decision about buying a 104 year old house, and there is alot to think about!

Anyway, I regret that I didn't find out the exact nature of your study. I hope that you will let me know about that in your letter to me. As you requested, this letter includes my permission to you regarding the Oucher. It also includes a copy of the User's Manual and Technical report. I believe that most of this report is included in one or both of the articles I referred you to, except for the summary of findings about the construct validity on the African-American and Hispanic Ouchers. I don't believe that will be an issue for you since you plan to use the Caucasian version of the Oucher.

The cost of the Oucher and User's Manual is $12.95 which includes first class postage. I decided to go ahead and trust that you would send me the check at your convenience. Anyone going for their FNP and MS has got to have integrity! Please make the check out to me.

Finally, let this letter serve as my permission to you to use the Oucher you have purchased in any research you might conduct with it. You also have my permission to reproduce a picture of the Ocher to be placed in the final draft of your clinical research project.

My best wishes to you. I hope your research process is smooth, interesting, and fun!

Sincerely,

Judith E. Beyer, RN, PhD
Associate Professor
APPENDIX D

Informed Consent Form
Effects of Ice Massage on Pre-Kindergartners' Injection Pain

INFORMED CONSENT FORM

Susan Dennie, RN, BSN
(509) 468-1451

Invitation to participate

I am a Family Nurse Practitioner student who is currently enrolled at the Intercollegiate Center for Nursing Education. I am inviting your child to participate in a study about the effects of ice massage on his or her pain intensity associated with a routine DTP (diphtheria/tetanus/pertussis) immunization injection. Your child’s participation in this study is completely voluntary. This project has been reviewed and approved by the Intercollegiate Center for Nursing Education, the Washington State University Institutional Review Board and the Spokane County Health District.

Purpose of the study

The purpose of this study is to investigate the effect of a safe, inexpensive method (ice massage) on the intensity of pain from a needle stick for a routine DTP immunization injection.

Procedure

1. After agreeing to allow your child to participate in this study, it will be necessary for you, as the child’s parent/guardian, to sign this consent form. Verbal assent from your child will also be needed. I would ask you remain with your child throughout the study. This study should only increase your visit to the immunization clinic by 10 minutes.

2. Your child will be assigned to either the treatment group (ice massage) or the control group (no extra treatment done). You can not choose which group your child is in.

3. You will be asked some questions about your child such as reactions to past painful experiences, today’s medicines taken, shots in the past year, words used for pain, birthdate and culture. The answers to these questions help me to understand how different children may respond in this study. You may answer all, part or none of these questions.

4. You will be asked to rate your child’s anxiety with a simple scale that will be thoroughly explained to you. In addition, the immunization nurse will rate your child’s anxiety using the same scale.

5. Your child will be shown and taught how to use the Oucher pain assessment tool.
6. If your child is in the ice massage group, ice massage will be done to the immunization injection site 2 minutes before the injection.

7. To avoid influencing the results of this study, you are asked not to discuss the methods to take place in either group with your child until after the study and you leave the clinic.

8. The immunization nurse will give your child the DTP injection using standard technique.

9. Thirty seconds after the injection your child will be asked to rate his or her pain by choosing a picture that most describes this pain, with the Oucher tool. You are asked not to help your child choose his/her picture of pain on the Oucher.

10. When available, a summary of the results of this study will be posted at the Spokane County Health District for you to read.

Potential risks and discomforts
Your child may feel a temporary feeling of coldness, aching, burning and/or numbness if he or she is in the ice massage group. Water may drip down your child’s arm. A towel will be available to dry the skin as needed. Your child may choose not to continue to participate in the study at any time. A choice not to continue in the study will not effect his or her relationship with the nurses or staff. You and your child are free to answer as many of the health questions as you choose.

Potential benefits
A potential benefit is a reduction in injection pain. Your child may also develop a sense of mastery over a difficult situation- receiving an injection. Your child’s participation in this study may assist health care providers in gaining knowledge of a method that is safe, easily accessible and inexpensive to decrease the pain from injections in children.

Furthermore, there is a very rare condition called "cold urticaria" that this study may help diagnose in your child. The presence of hives, after prolonged exposure to cold, is a sign of this condition. Usually it takes at least 5 minutes of exposure to cold for a susceptible child to develop hives. In this study, exposure to cold is only 2 minutes. But for a highly sensitive child with this rare condition hives could possibly develop. In the unlikely case that your child develops these hives, you would be directed for further diagnosis and treatment from your health care provider.

Assurance of confidentiality
The grouped results of this study may appear in scientific journals. However, data obtained as part of this
study will be strictly confidential and for research purposes only. Your child’s first name will be known to myself and the immunization nurse during this study but it will not be included in the data collected. Completed data collection materials will be kept in a locked file and destroyed upon completion of this study. Never will your child’s study number and personal data be available to anyone but your child, you and the research team.

Withdrawal from the study
You and your child’s participation are completely voluntary. If you and your child agree to participate, you may choose to withdraw your consent at any time. Your child may withdraw from the study at any time.

Eligibility
To participate in this study your child must:
  a. be receiving a routine DTP immunization, before receiving any other immunization.
  b. be pre-kindergarten age (4-6 years old).
  c. give his/her verbal assent to participate.
  d. be able to speak and understand the English language.
  e. be able to understand how to use the Oucher pain assessment tool.
  f. not have a history of hives from exposure to cold.
In addition, you must:
  a. be able to read, speak and understand the English language.
  b. give your written consent for your child to participate.

Costs
There will be no additional cost to you.

Emergency Care
In the remote chance your child should suffer from an injury during participation in this study, emergency medical care will be provided by the investigator, the Spokane County Health District health care providers and/or anyone else you should choose.

Informed consent
I fully understand the above procedures and risks of this study.
I understand participation is voluntary and that my child may withdraw at any time.
I authorize Susan Dennie, RN, BSN to use and dispose of the findings from this study. I understand the investigator and other professionals who work with the investigator agree to confidentiality of the data.
I have read and understand the above information. I have been given the opportunity to ask questions concerning this study and methods to be used and these questions have been answered to my satisfaction. I have received a copy of this form.

I may contact Susan Dennie, RN, BSN at (509) 468-1451, or her project chairperson, Dr. Margaret Bruya at (509) 324-7273 to obtain information or clarify questions I may have about this study.

Parent/Guardian signature

Witness Signature

Child verbal assent_________ (Parent/Guardian initials)

Investigator signature
Susan Dennie, RN, BSN

Date
APPENDIX E

Verbal Assent Script
Hello __________ (child’s first name), my name is Susan Dennie. I’m a nurse too. Your (mom, dad, etc...) told me it’s time for you to get your immunization(s) today. Sometimes immunizations hurt and sometimes not. I’m here today investigating how it feels when you get an immunization. **Experiment group:** (I’m also trying to find out if I can make the immunization not hurt as much or not.) I am inviting you to help me with my investigation.

Let me tell you what we would do. First we would look at some pictures on my poster and talk about them. I would ask you about other times you felt hurt and you would point to the picture that looks like how you felt then. **Experiment group:** (Next I would rub this cup of ice over your arm where the nurse is going to give you the immunization.)

Then the nurse will give you your immunization. After that I would like you to point to the picture on my poster which looks like how you feel inside. Then we will be all done. It shouldn’t take more than 10 minutes. You will need to have the immunization today but you don’t have to help me if you don’t want to.

Would you like to help me?

Verbal assent: __________ (child’s initials if child able to write or parent/guardian initials)
APPENDIX F

Interview/Data Collection
**Interview/Data Collection**

Child's #: __________  
Ice Massage: 1 __________

Birthdate: __________  
Control: 2 __________

Culture: ____________  
Gender: F 1  M 2

Medications in past 6 hours: ____________________________

Venipunctures/injections within 1 year? __________________

Word(s) uses for pain: _________________________________

Past reactions to immunizations: _______________________

**Anxiety rating of child:**

Parent/Guardian: 1 = not anxious  2 = somewhat anxious  3 = very anxious

Nurse: 1 = not anxious  2 = somewhat anxious  3 = very anxious

ID. # of Nurse:  1  2  3  4

**Oucher rating:**  0  1  2  3  4  5

Withdrawal from study: __________  Why? ____________________________

Comments:
APPENDIX G

Interview and Oucher Script
Interview and Oucher Script

__________ (Child’s name), this is my poster called the Oucher. It helps children tell me about their *hurt. Do you know what I mean by "hurt?" (The child explains.) See this little (girl/boy)? In this picture (point to bottom picture) she/he has ‘no hurt,’ no hurt at all. In this picture she/he has just a little bit of hurt (point to the second picture). This picture shows a little bit more hurt (point to the third picture). This picture shows even more hurt (point to the fourth picture). This picture shows a lot of hurt (point to the fifth picture). And this picture shows the biggest hurt you could ever have (point to the top picture).

Can you remember ever getting hurt? When you . . . (whatever the child describes) how much hurt did you have? Would you point to the picture of how much hurt you had?

EXPERIMENT GROUP ONLY: See my ice cube. I’m going to rub this ice cube in this cup, over your arm for a couple of minutes. Then the nurse will give you your immunization.

After the immunization is done I want you to point to the picture on this poster which is most like how you feel right then. Okay? (Allows child permission to withdraw from study)

(Immunization nurse administers immunization, parent/guardian holding child on lap, apply bandaid, wait 30 seconds)

Okay__________ (child’s name) point to the picture of how much hurt you are having right now.

Good! Thank you! You have helped me a lot. We are all done now.

*For simplicity the word "hurt" is used here. However whatever word the child normally uses for "pain" or "hurt" was used instead.
APPENDIX H

Washington State University Institutional Review Board Approval
March 1, 1996

MEMORANDUM

TO: Susan L. Dennie, ICNE/Nursing (5291)
FROM: Paul Whitney, Chair, WSU Institutional Review Board
SUBJECT: Review of Human Subjects Protocol

Your Human Subject Review Summary Form and additional information provided for the proposal entitled "Effects of Ice Massage on Pre-Kindergartners' Injection Pain," OGRD #NF was reviewed for the protection of the subjects participating in the study. Based on the information received from you, the IRB has approved your human subjects protocol on February 28, 1996.

The IRB approval indicates the IRB's belief that the Human Subjects protocol as presented in the Human Subjects Review Summary Form by the investigator, is designed to adequately protect the subjects participating in the study. This approval does not relieve the investigator from the responsibility of providing continuing attention to ethical considerations involved in the utilization of human subjects participating in the protocol. This approval is valid for one year from approval date. If any significant changes are anticipated in the study please notify the IRB before implementation.

In accordance with federal regulations, this approval must be kept by the researcher for THREE years after completion of the research.
I. Description of the Population:

Approximate number: 50

Age range: 4 to 6 year olds

How will subjects be selected or recruited?

A convenience sample will be obtained from the Spokane County Health
strict main immunization clinic. Children coming in for their routine
phtheria/tetanus/pertussis injections before beginning kindergarten will be
cruited. Each child will receive a number, even numbered children will be
the treatment group and odd numbered children in the control group.

Will subjects be compensated (include extra credit)? If yes, how much,
end how. Must they complete the project to be paid? No

Are there any of the subjects not competent to give consent (e.g., minors,
isoners, institutionalized)? If yes, how will consent be obtained? From
om? Are there procedures for gaining assent? (Submit copy of Assent Form).

Yes. Written consent will be obtained from the child's parent/guardian.
e to the age of the child, the child will be asked for verbal assent only.
tent of the child will be acknowledged by the child's parent/guardian with
parent/guardian's initials on the consent form.
APPENDIX I

Spokane County Health District Approval
SPOKANE COUNTY HEALTH DISTRICT

January 30, 1996

Sue Dennie, RN, BSN
N. 8710 Greenwood St.
Spokane, WA., 99208

Dear Mrs Dennie,

We have read, considered and approved your Master of Nursing research study conducted through the Intercollegiate Center for Nursing Education entitled:

EFFECTS OF ICE MASSAGE ON PRE-KINDERGARTNERS' INJECTION PAIN

It is our understanding that the following will occur:

1. You will obtain consent from the parents to apply ice frozen in a Dixie cup to the immunization site prior to administration of the injection.
2. Fifty children 4 to 5 years old will be the sample population.
3. You will ask the child to rank post injection pain on a pain scale.
4. The project will be conducted on Fridays between March and August, 1996.
5. The results of the project will be shared with staff at the conclusion of the study.
6. You will obtain Institutional Review Board approval through Washington State University and share a copy of the approval with our Acting Clinical Services Supervisor.

Spokane County Health District will provide/request the following:

1. Copy the signed consent and attach to the immunization record.
2. Allow access to Spokane County Health District's main immunization clinic to obtain study participants.
3. Whenever possible, provide a consistent immunization nurse as a partner.
We expect your project to be successful; however, in the event that a problem develops that could negatively impact the client or the Health District, we reserve the right cancel the project in this agency.

Please feel free to contact me if there are any questions.

Sincerely,

Barbara Feyh, RN, MS
Director of Community and Family Services

cc: Judy Miller, RN, BSN
    Acting, Clinic Supervisor