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THE EFFECTS OF NEEDLE PLAY ON PRE-SCHOOL CHILDREN'S
ANXIETY CONCERNING INJECTIONS

A thesis submitted in partial fulfillment of the
requirements for the degree of Master of Science
at Virginia Commonwealth University

By

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ABSTRACT

THE EFFECTS OF NEEDLE PLAY ON PRE-SCHOOL CHILDREN'S ANXIETY CONCERNING INJECTIONS

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The purpose of this study was to determine the effects of needle play in reducing pre-school children's anxiety concerning injections. The Pre-school Observational Scale of Anxiety was used to measure the degree of anxiety experienced by the children. The hypothesis stated that there would be a significant decrease in anxiety of pre-school children who participated in needle play as compared with the anxiety scores of pre-school children who did not participate in needle play.

The sample consisted of 20 pre-school children who were receiving routine health care and injections for immunizations or PPDs (purified protein derivative) at a county health department in the southeast. After obtaining informed consent, children were randomly assigned to either a control group (n = 10) or experimental group (n = 10). The control group was involved in putting together a puzzle with the investigator prior to their injection. The experimental group participated in needle play with the investigator prior to their injection. The Pre-school Observational

Scale of Anxiety (POSA) which specifies behavioral indicators of anxiety in children was used on all subjects immediately prior to the actual needle penetration and a score was given to each subject.

The scores on the Pre-school Observational Scale of Anxiety showed no statistically significant difference between the control group and the experimental group when analyzed using the Mann-Whitney U Test. On the basis of these findings, the hypothesis that pre-school children who participate in needle play immediately prior to receiving an injection would show a significant decrease in anxiety when compared to pre-school children who did not participate in needle play prior to an injection was not accepted.

CHAPTER ONE

Introduction

Administering injections to children is a common and unavoidable part of health care which is the responsibility of the nurse. Needles are fearsome in appearance and cause physical discomfort. It has been documented that "among all the possible medical procedures encountered, injections remain prominent as a separate, critical event for most children" (Lewis, 1978:18). Children interpret any sharp object placed into their body as a brutal attack by a more powerful person. Children have described needles as cold, mean, and terrible (Lewis, 1978). In reviewing the literature on preparing children for elective surgery, Crocker (1980) found the fear most commonly expressed by children was the preoperative needle. Injections are painful and intrusive to children and cause an anxiety-producing situation.

Anxiety associated with injections is a major source of distress to pediatric patients. Spielberger (1972:482) described anxiety as an "unpleasant emotional state or condition which is characterized by subjective feelings of tension, apprehension, and worry." An anxiety state is produced whenever an individual "perceives a particular stimulus or situation as potentially harmful or threatening"

(Spielberger, 1972:482). A child who is anticipating an injection is placed in a threatening situation. The child is about to experience actual physical pain over which he/she has no control. The child's parent, who ordinarily protects him/her, seemingly will not do anything to prevent the injections. In fact, the parent is usually the person who brings the child to the health facility to receive the injection.

Pre-school children have limited cognitive understanding of medical rationales for treatment regimens along with limited tolerance for painful and invasive procedures. Play is a way for expressing feelings, understanding procedures, describing experiences, and exploring relationships and environment. Therapeutic play, such as needle play, can be a means whereby children can master their anxiety over the invasive procedure of injections that are common to children who have routine health care. Through playing with injection instruments, pre-school children can attempt to make sense of a traumatic or anxiety-producing experience. "Playing out" these traumatic experiences gives children the opportunity to confront sources of anxiety. Children control play and can in the play situation become the aggressor, doing to others what will be done to them. Through this play, children can master their fears and experience a sense of emotional relaxation (Erikson, 1963).

Although the literature strongly supports the use of

therapeutic play for the hospitalized children there is a scarcity of documentation of the value of therapeutic play in the ambulatory setting. A great deal of research has been done about more complicated procedures affecting children, with injections being only one part of the procedures.

All pre-school children entering public schools are required to receive immunizations unless medically contraindicated. Because pre-school children react so strongly, both physically and emotionally, to receiving injections, more research is needed to test methods which may assist pre-school children in their coping with injections. The present study was designed to investigate the effectiveness of needle play as a helpful nursing intervention in reducing pre-school children's anxiety concerning injections.

Purpose

The purpose of this study was to determine whether needle play would reduce pre-school children's anxiety concerning injections.

Hypothesis

Pre-school children who participate in needle play immediately prior to receiving an injection will show a significant decrease in anxiety, as measured by specific behavioral indicators of anxiety, when compared to pre-school children who do not participate in needle play prior to an injection.

Definition of Terms

The following terms were defined for this study:

Anxiety: uneasy thoughts or fears about what may happen; troubled, worried, or uneasy feeling (Spielberger, 1972). In this study, anxiety was measured by the Pre-school Observational Scale of Anxiety (POSA). This tool was developed by Glennon and Weisz (1978) to measure anxiety in pre-school children through a set of specific, observable behaviors. This tool was based on Spielberger's theory of anxiety.

Injection: an intradermal or intramuscular penetration with a needle in the arm or leg.

Pre-school child: a child between the ages of three years, zero months old and five years, 11 months, who had not had: 1) more than three injections in the past year; and 2) prior hospitalizations, other than at birth or before one year of age.

Needle play: an activity in which a child has had an opportunity to observe a doll receiving an injection, to manipulate a needle and syringe, to draw up water in a syringe, to wipe the doll's skin with alcohol, to administer an injection to the doll, and to apply a band-aid to the doll. The children who participated in needle play also were able to express their thoughts and feelings regarding injections. (Time limit: 10-15 minutes).

Parent: biological mother or father or legal guardian.

Assumptions

1. Anxiety exists in all individuals.
2. Injections are anxiety producing.
3. Anxiety can be measured through specific observable behaviors.
4. Anxiety levels vary in individuals according to the situation.

Limitations

1. Children's prior experience with injections could alter their anxiety measured by observed behaviors in the study situation.
2. Contact with the investigator could alter the children's observed behaviors.
3. The reliability and validity of the Pre-school Observational Scale of Anxiety may be questioned.
4. Individual factors influencing the subjects could not be isolated and controlled.
5. The use of a convenience sample limited the generalizability of the findings of this study.

Delimitations

1. The sample size was limited to 20 pre-school children receiving health care maintenance and immunizations at a county health department in a metropolitan city in the southeast.

2. Trait anxiety was not determined in the subjects for the study.

3. The data collected for the study were obtained between July 23 and August 30, 1984.

Theoretical Framework

Nursing Conceptual Framework

The Roy Adaptation Model (Riehl and Roy, 1974) provides a framework for meeting children's physical needs along with their psychosocial needs on a health-illness continuum. Viewed as a biopsychosocial being, Roy believed that each individual is in constant interaction with a changing environment. Roy has identified four major areas in which an individual must adapt: physiological needs, self-concept, role function, and interdependence (Riehl and Roy, 1974). An individual relies on innate and acquired biopsychosocial mechanisms to cope with this changing world. One's adaptation level is comprised of a zone which indicates the range of stimulation that will lead to a positive response. If the stimuli is within the zone, the individual will respond by adapting positively. Stimuli falling outside the zone lead to a maladaptive response (Riehl and Roy, 1974).

A child's adaptation level is affected by three classes of stimuli: focal, contextual, and residual. Focal stimuli refers to stimuli immediately confronting the child which in

this study was the anticipated injection. The children had fears of pain, mutilation, and invasion of their body due to the injection. The contextual stimuli included all other stimuli present, for example, other children crying and room temperature. The third type of stimuli, residual stimuli, included the child's prior experiences with injections; the health care system; and the parent's experiences, beliefs, and fears of injections.

Children are constantly confronted with stimuli to which they must adapt. "A positive response to environmental changes decreases the responses necessary to cope with stimuli and increases sensitivity to respond to other incoming stimuli (Riehl and Roy, 1974:137). Roy postulated that nursing intervention "involves changing the patient's response potential by bringing the stimuli within a zone where a positive response is possible" (Riehl and Roy, 1974:137). One way the nurse can move the stimuli into the child's zone is to help him/her gain mastery over the situation through play. According to Erikson (1940:561), the child uses play "to make up for defeats, sufferings, and frustration." "Play provides the child with an opportunity to reorganize his life; thus it reduces anxiety and establishes a sense of perspective" (Petrillo and Sanger, 1972: 99). The investigator believed that Roy's Adaptation Model supported the hypothesis that the nursing intervention of needle play would allow children to bring the stimuli of

injections within a level of adaptability which would be demonstrated by a positive response and a significant decrease in anxiety, as measured by specific behavioral indicators of anxiety.

Theory of Anxiety

Spielberger's theory of anxiety involves the concept of anxiety as a transitory state, as a personality trait, and as a psychobiological process. Anxiety is a complex emotional response resulting from stress and perception of danger or threat. Spielberger (1972:488-489) defines stress as "the objective danger that is associated with the stimulus properties of a given situation" and threat as "an individual's perception of a situation as more or less dangerous or personally threatening to him/her." Perceiving a certain situation as threatening depends on the objective stimulus properties of a situation, the individual's past experiences with a similar situation, and memories that return. If the stimulus is perceived as threatening, it will lead to an emotional response of feelings of tension, apprehension, and worry along with activation of the autonomic nervous system.

Anxiety as a transitory state is referred to as A-State Reaction. An anxiety state (A-State) is evoked if an individual perceives a particular stimulus as threatening by cognitive appraisal. The number of times that an individual perceives a threat causes A-State to vary in intensity and

change over time. Anxiety as a personality trait varies with each individual. Some individuals are more prone to feeling anxious and vulnerable to different kinds of stress. Trait-anxiety (A-Trait) refers to "differences between people in the tendency to respond to situations perceived as threatening with elevations in A-State intensity" (Spielberger, 1972:482). These individuals who are classified as high in A-Trait have a tendency to perceive more situations as threatening than low A-Trait individuals.

In this investigation, only anxiety state (A-State) was addressed. Because elevations in state anxiety due to injections are experienced as unpleasant or painful, some change in behavior should result. The intensity and duration of the A-State will depend on the child's perception of the situation as threatening. The resulting behavior will then depend on the child's prior experience with injections and whether he/she tried to avoid, cope with, or use psychological defenses to deal with the situation. By using needle play to prepare children for injections, the nurse can help children cope with their thoughts, feelings, and fears. Needle play can help children to develop mastery over the situation. According to Roy's Adaptation Model, needle play would allow children to bring the stimuli of an injection within a zone where a positive response is possible. If a child's fears and feelings of loss of control can be reduced, the child should perceive the situation as

less threatening. When the threat decreases, the child's state of anxiety should decrease as measured by specific behavioral indicators of anxiety and the child should be able to respond in a more positive manner.

CHAPTER TWO

Review of Literature

This chapter is organized into four sections. The first section presents studies involving children's reactions or responses to injections or needles. Also this section will include studies on preparation methods used with children receiving injections. The second section contains studies investigating the effects of play on children's anxiety levels during stressful situations. The third section reviews studies evaluating the use of therapeutic play as a method of preparation for children being hospitalized or facing medical procedures. The final section presents studies evaluating the use of play as a method of preparation for children undergoing dental treatment.

The literature reveals that there has been much investigation of the effectiveness of different preparation methods for children facing hospitalization, surgery, diagnostic testing, and invasive medical and dental procedures. Preparation methods that have been studied include instructing children with factual or sensory information, using modeling and film-modeling methods, teaching coping techniques (cue controlled relaxation, distracting imagery, and self-instruction), and using therapeutic play. In this literature review, only preparation studies involving the use of therapeutic play have been included.

Reactions, Responses, and Preparation Methods
Used with Children Receiving Injections

Although needle punctures for blood samples or injections are safe, routine pediatric medical procedures, injections seem to be among those procedures most feared by children. Very few studies involve reactions and responses of children to needles or methods of preparation for children receiving injections. Many of the studies are concerned with more complicated or involved medical or dental procedures and hospitalization.

Kassowitz's (1958) study investigated the different attitudes and responses of children to the use of hypodermic needles regardless of whether used for intradermal, subcutaneous, or intramuscular injection. The investigator drew up a questionnaire in order to assess the varying attitudes and responses of the children receiving needles. The person performing the injection observed and recorded the children's reaction to the injection immediately after the child was administered the injection. Reactions were tabulated for three phases of the injection which were termed "the prelude" (apprehension), "the act" (the actual puncture), and "the postlude" (resentment). Observations and recordings were made of 133 children from birth to 12 years of age inclusive. Percentiles of reaction intensity were computed from 328 individual needle punctures. The degree or absence of emotional reactions were recorded and the percentiles were computed for each age group. The

results showed the children's changing pattern of reactions from year to year. During the first six months the apprehensive reactions were absent, but the reactions during the actual puncture and immediately after were moderately intense. From seven months up to and including the fourth year all three phases of reactions were very intense with a few exceptions. From the fourth year and older, with a slight setback between six and seven years, all children showed observable signs of self-control, compliance, and pride. Less than 20 percent of the children between the ages of nine and 10 years of age showed earlier behavior reactions ranging from slight reluctance to being very scared. This study suggested that the ability to cope with painful but necessary experiences is an emotional maturity indicator of the developing child.

A study done by Hester (1979) investigated the preoperational child's behavioral response to a painful stimulus (immunization via injection) and his/her subjective rating of the experience. Forty-four children, between the ages of four and seven who attended two midwestern metropolitan immunization clinics were studied. The children were screened with two Piaget tests for the preoperational stage of development and the Denver Developmental Screening Test for age appropriate development. The children were then observed for verbal, vocal, facial, and motor behavior during the immunization. The children were asked to rate the painful

experience by use of two assessment tools which were the Eland's Projective Tool and the Hester's Poker Chip Tool. For the Eland's Projective Tool the child placed the picture of an animal receiving an injection in the ranked set of pictures of other animals receiving other painful events familiar to children. The Hester's Poker Chip Tool used four white poker chips. These poker chips were associated with degrees of feeling hurt. One chip was feeling a little hurt and four chips was feeling the most hurt. Each behavior category was correlated with the subjective pain rating. Results showed that vocal responses correlated positively and significantly ($p < 0.02$) with the responses to Eland's tool. Vocal responses were also positively and more significantly ($p < 0.0001$) correlated with the poker chip tool. However, whereas verbal responses and subject's responses to Eland's tool were positively correlated but not statistically significant, the children's verbal responses and ratings to the poker chip tool were positively and significantly correlated ($p < 0.002$). These results illustrated that with this population of children, verbal and vocal responses were indicative of the amount of hurt as measured by the poker chip tool. Both tools were negatively correlated with facial expressions. There was no correlation between the children's motor responses and their responses to Eland's tool. There was significant negative correlation between the children's motor responses and their

responses to the poker chip tool ($p < 0.001$). These results suggest that children's facial and motor responses may not be good indicators of the amount of hurt perceived by children in the preoperational stage.

The next group of studies involve preparation methods used with children receiving needles for immunizations or blood sampling. Hedberg and Schlong (1973) conducted a study to determine the influence of preinoculation instructions designed to reduce the number of childhood fainting episodes during a county-wide mass inoculation program. The subjects consisted of 4,316 students from a county in the midwest who participated in an immunization program over a three year period. The ages of the participants ranged from six to 18 years. The experimental group of children were instructed to remain standing at all times and were not to faint or fuss. The control group of children received neutral pre-immunization instructions and did receive a statement from the nurse of expected behaviors or that fainting was not to occur. Results showed that 10 (2 percent) of the children who received neutral instructions fainted but none of the 2,338 children who received immunizations under experimental instructions fainted. A chi-square test indicated that the difference between these two results was significant ($p < 0.01$). Also, whereas eight children in the control group exhibited disruptive behavior, there was no disruptive behavior among the children who were in the

experimental group.

A second study which was conducted by Sturner et al. (1980) was concerned with the effects of preparing hospitalized children, aged four to 12 years, for a venipuncture. Sixty-eight children were asked to draw a human figure twice: once shortly after admission; and again 90 minutes later. In the time between the two drawings only some of the subjects received stress in form of a venipuncture. Some of the subjects were prepared with information, rehearsal, and supportive care while others were not prepared but were allowed free play before the stressful situation. Results indicated that human figure drawing features (emotional indicators) increased significantly only in the group that was stressed and unprepared. Children who were prepared for venipuncture did not show an increase in the number of emotional indicators and therefore could cope better with the stressful event of a venipuncture.

Rebesco (1980) used behavior and global rating scales, self-reports, and physiologic measures to investigate the helpfulness of different techniques for children undergoing blood sampling procedures. Sixty pediatric patients, five through nine years of age, were randomly assigned to one of the following four conditions: (1) information only; (2) coping model plus information; (3) mastery model plus information; and (4) control. The children who viewed the coping and mastery films had significantly ($p < 0.05$) better scores

than the control group. All three experimental groups took significantly less time to undergo blood sampling than the control group. Only the mastery condition led to a significantly lower physiologic arousal than the control condition.

A study done by Fernald and Corry (1981) compared the reactions of a group of children that received empathic, supportive preparation for injections with a group that received directive preparation and was told to be big, brave and not to cry. The purpose of the study was to determine the effectiveness of two preparation approaches designed to reduce anxiety associated with needles. Subjects were 39 children (20 boys and 19 girls) between the ages of three years and nine years (mean = 6.1 years). All children were patients at a small community hospital in the southeast anticipating a venipuncture or fingerstick for a blood sample. Immediately following the preparatory instruction each child was observed for five categories of responses and asked six questions about his/her reactions to being stuck. Results revealed that the group prepared with empathic instructions responded significantly more positively to the needle than did the group prepared with directive instructions ($p < 0.001$). The directive group had more negative behavioral reactions, such as crying, negative statements, wincing, or refusal to cooperate than did the empathic group ($p < 0.006$). When asked, the directive group gave significantly more negative perceptions of the needle, hospitali-

zation, and hospital employees than did the empathic group ($p < 0.001$).

Use of Play in Reducing Anxiety in Children During Stressful Situations

It has often been speculated that play is important to children in their coping with distress and anxiety in the environment. Barnett and Storm (1981) studied two groups of pre-school children confronted with a stressful situation. One group of children was allowed the opportunity for free play and the other group was not allowed the opportunity for free play. Video taped recordings and physiological measures of anxiety supported expectations that play would help to alleviate the anxiety caused by a stressful situation. In 1984, Barnett attempted to replicate and expand the earlier investigation. The stressful situation used in both studies was the departure of the pre-school child's mother on the child's first day of school. Seventy-four (36 male, 38 female) children (mean age = 3.3 years) were observed as they exhibited distress at the departure of their mothers. Based on both a physiological and a behavioral measures of anxiety, children were placed in high and low anxiety groups. Results showed that children in the high anxiety group who were allowed a period of free play scored significantly ($p < 0.04$) lower in anxiety than the high anxiety group who only listened to a story. The low anxiety children who were allowed free play did not score significantly

differently from the low anxiety children in the story-telling group. Results also showed that the highly anxious children tended to involve themselves in more dramatic/fantasy and solitary forms of play as compared to the lower anxiety children who showed more functional play forms.

Milos and Reiss (1982) evaluated whether play can reduce anxiety by measuring the effects of play related to separation on separation anxiety in pre-school children. Thirty-two boys and 32 girls, two to six years of age, who were teacher rated as anxious about separation from parents participated in the study. The children were assigned to one of three separation-relevant play situations (free play, directed play, and modeling) or a fourth non-separation-relevant play situation which was the control group. All separation-relevant play situations were associated with significantly ($p < 0.03$) lower posttest anxiety scores on a speech-disturbance measure but not on teacher ratings. Results also revealed that the higher the quality of separation-relevant play performed by the child, the lower was the degree of separation anxiety evident during posttesting (significant level $p < 0.05$).

A study by Williams and Powell (1980) documented the value of supervised play in a pediatric ambulatory clinic. The investigators hypothesized that a supervised play program conducted in the clinic would increase patients' positive responses and decrease their negative responses. The

first study involved two weeks of observation in the clinic waiting area. Observations of patient's and their family's positive and negative responses in the waiting room were recorded. During the first week (control week) the clinic waiting room area, which included a few toys, was arranged as usual. For the second week (experimental week), a cart of selected toys and a play table with chairs were added to the waiting area. During the experimental week, one investigator recorded the children's responses while a second investigator assumed the role of play director. A total of 266 children and 120 adults were observed and 421 positive responses and 641 negative responses were recorded during the control week. For the experimental week, 185 children and 128 adults were observed and there were 879 positive responses and 144 negative responses recorded. Chi-square analysis of the data revealed a significant increase in positive responses during the experimental week as well as a significant decrease in the negative responses ($p < 0.001$).

To differentiate whether the toys or the play director was instrumental in causing the significant changes, a second similar study was conducted a few months later. During the control week, the same selected toys were used with no supervision. For the experimental week, a play director was involved with the children using the same toys. Chi-square analysis of the data for the two weeks revealed a significant increase in positive responses and a significant

decrease in negative responses during the experimental week ($p < 0.001$). The play director in combination with the toys had a significant effect upon the behavioral changes.

Play as a Method of Preparation for Medical Procedures and Hospitalization

There has been an increased interest in evaluating the effects of various methods of preparing children and their families for medical procedures, hospitalization, and surgery. Play has been used in many of the comprehensive preparation methods. Visintainer and Wolfer (1975) studied hospitalized children who received systematic psychological preparation and supportive care as compared to hospitalized children who did not. The hypothesis was that prepared children would show less upset behavior and more cooperation in the hospital and fewer post-hospital adjustment problems. A second hypothesis was that the parents of children who received the psychological preparation would be less anxious and more satisfied with information and care received. Eighty-four children, three to 12 years of age, hospitalized for tonsillectomies, were randomly assigned to experimental and control conditions. The experimental intervention consisted of: detailed information about sequence of events; sensory experiences; role expectations and appropriate responses; previews of procedures through play techniques; and supportive care given at critical points pre- and post-operatively. The children's hospital adjustment was measured

by ratings of behavioral upset and cooperation during: the blood sampling; medication injection; transport to surgery; induction; and by postoperative fluid intake; recovery room medications; pulse rates; and time of first voiding. Post-hospital adjustment was assessed with the Post-Hospital Behavior Inventory developed by Vernon et al. (1966). Parent outcome measures included self-rating for anxiety and satisfaction with information and care. The results strongly indicated that children who received a combination of: organized preparation; rehearsal; play techniques; and supportive care, conducted prior to each stressful procedure, demonstrated significantly less upset and more cooperation. Their parents reported significantly greater satisfaction and less anxiety than did children or parents in the control groups. Also, results showed that younger children were significantly more upset and less cooperative than older children.

Wolfer and Visintainer (1979) conducted another study and developed and tested a written and illustrated form of preparation which used the principles of "stress-point preparation." Booklets were used at home by children and parents before they came to the hospital for minor surgery. The home preparatory materials duplicated the information and procedures of "stress-point preparation" by the nurse in the hospital. The materials consisted of a written and illustrated booklet and a "hospital kit" which contained: a

surgical mask; syringe without needle; rubber band; band-aid; alcohol sponge; and other items. The booklet instructed children about how to rehearse or practice procedures. One hundred and sixty-three children, three to 12 years of age, who were hospitalized for tonsillectomies were randomly assigned to one of five experimental groups or a control group. The experimental groups consisted of combinations of home preparation with different types of in-hospital preparation and supportive care. The children's hospital adjustment was measured in the same ways as in the authors' previous study. Results indicated that children who used the home preparation materials alone or in combination with inpatient preparation showed significantly ($p < 0.05$) better adjustment than children in the control group. Inpatient preparation alone was as effective as home preparation alone or home preparation in combination with hospital preparation. Parents reported more satisfaction and less anxiety when they received some inpatient preparation than when they received only home preparation.

Fassler (1980) was interested in testing the effects upon reducing preoperative anxiety of a comprehensive preparation program which incorporated both emotional support and information about hospitalization. The subjects were 45 children between the ages of six and 12 years who had been admitted to a hospital pediatric unit for a tonsillectomy with or without an adenoidectomy. Each child was randomly

assigned to one of three conditions. The experimental group received emotional support and information concerning hospitalization. The child was also given a hospital play kit with play hospital equipment and given an opportunity to play with it. The children in control group I were given emotional support without information concerning hospitalization. The children in control group II received the usual medical and nursing care given to all pediatric patients. After the interventions, two measures of anxiety (Manifest Anxiety Test and the Callahan Anxiety Pictures Test) were administered. The group that received both information, emotional support, and an opportunity to play was found to score significantly lower on both the Callahan Anxiety Pictures Test ($p < 0.01$) and the Manifest Anxiety Test ($p < 0.05$) than the group that received only emotional support. The emotional support group scored significantly lower on the Callahan Anxiety Pictures Test than the group that received no planned intervention ($p < 0.03$).

Crocker (1980) was interested in investigating a systematic preparation which included: structured and free play with puppets; dressing up in hospital clothes; using hospital equipment; playing with a doll hospital; and giving children and parents specific information about hospitalization and surgery. She wanted to see if this particular preparation would decrease children's anxiety and levels of stress both in the hospital and after hospitalization. One

hundred and thirty children between the ages of four and 10 years participated in the study. The experimental group received the specific systematic program, whereas the children in the control group did not receive any program. The experimental and control groups were compared for changes in temperature, pulse, respirations, and blood pressure, and the incidence/frequency of postoperative vomiting. The experimental group showed significantly less of a change in systolic blood pressure between the recordings at admission and in the recovery room. The prepared children vomited significantly more often than those in the control group. A comparison of responses given by the children's parents in the follow-up phone calls showed no significant differences between the experimental and control groups.

Demarest et al. (1984) conducted a study of hospitalized children to compare the effectiveness of presenting information verbally in the form of a slide show in which a model introduced hospital procedures to the children versus having the children actively utilize hospital equipment and role play the procedures. Twenty-four children, three to nine years in age, hospitalized for either tonsillectomies or adenoidectomies participated in the study. Anxiety scales, hospital fears scale, and the amount of time between the return from surgery and the first drink were variables assessed at three different times. The children in the group who used the hospital equipment and role played the procedures were significantly less anxious than the

children who viewed the slide show or who were in the control groups. These children also waited a shorter time than the children in the slide show and control groups waited between surgery and their first oral liquids.

Cassell and Paul (1968) investigated the effects of brief puppet-play therapy upon the emotional responses of 40 children between three and 11 years of age who were hospitalized for cardiac catheterization. Parental questionnaires and observations were used to measure the children's emotional responses. Results showed that children who received the therapeutic play with puppets were significantly ($0.01 > p > 0.001$) less distressed during cardiac catheterization and also expressed to their parents significantly ($0.05 > p > 0.01$) more willingness to return to the hospital for further treatment than children who did not receive puppet play. However, children who received puppet therapy did not have significantly less emotional disturbance than the control group had following the catheterization procedure while in the hospital or at home.

Schultz et al. (1981) used the Palmar Sweat Index (PSI) to investigate the effects of a preoperative puppet show and puppet play on the anxiety levels of hospitalized children. Twenty-eight children, ages two to seven years inclusive, were randomly assigned to experimental or control groups. Children in the experimental group experienced a puppet show presenting hospital routines and operational procedures and were given an opportunity to play with the puppets and

equipment whereas the control group was not. Comparisons of the PSI prints of both groups were made before and following the preparation. The results of the study indicated that the children who participated in the preoperative puppet show and play had a significant ($p < 0.045$) decrease in anxiety level as measured by the PSI whereas the control group did not.

Clatworthy (1981) conducted a study to present empirical evidence that therapeutic play is a valuable intervention with hospitalized children. One hundred and fourteen children, five to 12 years of age, hospitalized for two days or longer in two different institutions were included in different phases of the study. The children were randomly assigned and anxiety was measured on admission and on discharge using the Missouri Children's Picture Series (MCPS). The experimental group received daily, individual 30 minute therapeutic play sessions conducted by a nurse play therapist. The results of this study showed a significant difference in the anxiety levels of hospitalized children who received daily therapeutic play regardless of setting, age, sex, or diagnosis. Children who received therapeutic play presented no significant increase in their anxiety throughout hospitalization as measured by the MCPS. Children in the control group who did not receive therapeutic play demonstrated a significant increase ($p = 0.05$) in their anxiety at discharge, as measured by the MCPS.

Play as a Method of Preparation for
Dental Procedures

Play has been used to prepare children for dental procedures as well as for medical procedures and hospitalization. Schwartz (1983) studied the effects of preoperative preparation on stress reduction in children hospitalized for dental surgery under general anesthesia. Forty-five children, three and four years of age, who required dental restorations and extractions under general anesthesia were included in the study. The children had no previous hospitalizations and no history of medical or psychological conditions. Subjects were randomly assigned to one of three groups: (1) control group receiving no preparation; (2) unrelated play therapy group receiving a play session before dental surgery unrelated to hospitalization or surgical procedures; and (3) related play therapy group receiving a preoperative play session focusing on hospital and surgical procedures. The children's behavior was assessed, using behavioral observation scales, for cooperation and upset at seven identified stress points. The results showed that the related play therapy group was significantly ($p = 0.04$) more cooperative and significantly ($p = 0.05$) less upset than either the unrelated play group or the control group. No significant heart rate differences were found among the three groups. Results suggested that the use of related play therapy for hospitalization and dental surgery can

alleviate some stress and anxiety in pre-school children.

McTigue and Pinkham (1978) investigated the association between children's play behavior and their behavior during the administration of dental procedures. Twenty-five male and 25 female children, 42 to 66 months of age, who had some previous dental experience but who had no physical or mental disabilities participated in the study. The results showed that children who role played dentist-patient roles and manipulated the play dental equipment demonstrated more positive behaviors during the dental procedure when compared to children who did not participate in dental play.

Purcell et al. (1983) investigated the use of therapeutic play to prepare young dental patients for routine outpatient care. Subjects were 32 children, three to five years of age, who had no previous dental treatment and who were scheduled for an initial examination. Random assignment to either the control group who did not receive any preparation or the group receiving a preparatory play session was made at the time of the initial appointment. The preparatory play session involved role playing with a puppet character. Two observation scales were used to measure upset and cooperation. Data from the analysis of covariance indicated that the pre-school children prepared for the initial dental visits did not show significantly ($p > 0.05$) less upset or cooperation during the first dental appointment.

Summary

This literature review has presented studies concerning: (1) reactions, responses, and preparation methods used with children receiving injections; (2) use of play in reducing anxiety in children during stressful situations; (3) play as a method of preparation for medical procedures and hospitalization; and (4) play as a method of preparation for dental procedures.

Many different instruments have been used to assess children's anxiety, distress, or emotional upset. The primary methods for measuring anxiety have been physiological measurement, projective techniques, self reports, and behavioral ratings by observers. Behavioral ratings made by observers were most frequently used with pre-school children.

Most researchers indicated that injections were among the procedures most feared by children and that pre-school children's reactions to needles were very intense. Few studies have involved methods of preparation for non-hospitalized children who were administered needles to obtain blood samples or for injections. Many of the studies were concerned with more complicated or involved medical or dental procedures and hospitalization. One study concerned only with preparing children for injections showed that pre-inoculation instructions which explained expected behavior to the children reduced fainting and disruptive behavior. In

other studies when children received preparation in the form of information, rehearsal, and supportive care, they coped better and showed less disturbance. The empathic approach in preparing children for needle punctures was much more effective than the directive approach. No published studies were found which evaluated the effects of needle play on pre-school children's anxiety concerning injections.

Few studies have examined the use of just therapeutic play as a single method of preparation for medical and dental procedures and hospitalization. Studies that compared related therapeutic play to unrelated play agree that the related therapeutic play is much more effective in increasing cooperative behavior and decreasing upset behavior. Most of the studies have used play as a part of the comprehensive preparation methods. The research studies indicated strongly that systematic psychological preparation and supportive care resulted in less upset behavior, more cooperation, and fewer post-hospital adjustment problems. Very few studies evaluated which part of the comprehensive preparation was most effective. For example, was the active participation of the children with preparation methods (playing with equipment and role playing) as opposed to passive participation (watching film or slide show) more effective in reducing anxiety?

Most studies involving the use of play for reducing anxiety in children during stressful situations revealed

that play is effective in lowering anxiety levels, fostering adaptive behavior, and increasing cooperation. Play specifically related to the stressful situation decreased anxiety in children. Play seemed to be important to children in their coping with stress and anxiety in the environment.

CHAPTER THREE

Methodology

Twenty pre-school children who received injections for immunizations or PPDs (purified protein derivative) at a health department participated in this study to determine the effects of needle play on pre-school children's pre-injection anxiety. The sample was obtained from a population of male and female pre-schoolers, three through five years of age inclusive, who were receiving health care at a county health department in the southeast. The subjects were randomly assigned to two groups. The control group interacted with the investigator by putting a puzzle together for ten minutes prior to the injection, while the experimental group participated in needle play with the investigator for ten minutes prior to the injection. The Pre-school Observational Scale of Anxiety (POSA) which specifies behavioral indicators of anxiety in children was used to observe for anxiety in all children immediately prior to the actual needle penetration and a score was given to each child.

Study Design

The research design that was used for this study was experimental. There was a control group and experimental group with a post-test only. An experimental approach is characterized by the properties of control, manipulation,

and randomization (Poilit and Hungler, 1983). The criterion of control was carried out through the inclusion of an experimental and control group. The investigator assigned subjects to a control or experimental group on a random basis. The control group participated in putting a puzzle together with the investigator before the injection. The experimental group participated in needle play with the investigator before the injection. This experimental study involved the manipulation of the independent variable which was the needle play. The dependent variable was the specific behavioral indicators of anxiety. Randomization was accomplished by randomly assigning children to either the control group or the experimental group.

A pre-test was not done on the subjects. An identical post-test which was the Pre-school Observational Scale of Anxiety was used for each subject after the manipulation. A convenience sample of the most readily available pre-school children receiving routine health care at a county health department was used. This study was also a field experiment because it was done in an existing situation.

Criteria for admission to this study included:

1. The child was three to five years old, inclusive.
2. The child was able to cooperate for puzzle making or needle play.
3. The child was receiving an injection which could be

in the form of an intradermal PPD (purified protein derivative) or an intramuscular DPT (diphtheria/pertussis/tetanus).

4. The child had no more than three injections in the past year.

5. The child had no previous hospitalizations after 12 months of age.

6. The child had age appropriate development and cognitive abilities.

7. The child and parent were English-speaking.

8. The child's parent willingly signed an informed consent for the child's participation in the study.

Setting

This study was conducted in a county health department in a metropolitan city in the southeast. The manipulation was performed in a closed off room with the children and their parents. The data collection was performed in the examination room where the children and parents waited for the injection.

Sample

The sample included a total of 20 pre-school children who were receiving routine health care at a county health department in a metropolitan city in the southeast. A convenience sample of the most readily available pre-school children receiving routine health care at a county health department was used.

Instrumentation

After reviewing the literature on the methods used to measure anxiety, the investigator decided to use a behavior rating scale to measure children's anxiety. Glennon and Weisz (1978) searched the anxiety literature and assembled a detailed list of behavioral indicators of anxiety in children. This list was used to form the Pre-school Observational Scale of Anxiety (POSA). To assess the reliability of the POSA, 36 pre-schoolers were observed and scored on the scale during two test sessions. The first session was with mothers absent, and was expected to provoke high anxiety. The second session was with mothers present and was expected to cause minimal anxiety. The inter-rater reliability of the POSA was assessed by Pearson correlations between the calculated rating of two observers for each indicator separately and the sum of all indicators. The correlation coefficient for the 30 indicators together was .78 ($p < .001$).

"The validity of the scale was determined through assessment of its relation to three independent inventory measures of anxiety and through an experimental manipulation of stressors" (Glennon and Weisz, 1978:1248). The instrument was correlated with teachers' and parents' inventory ratings of children's anxiety. The results revealed that the children's POSA scores were significantly higher in the first session than in the second session ($p < .01$). The

findings in the research done by Glennon and Weisz (1978) suggested that the POSA provides a way of assessing situationally caused anxiety in children who are too young to verbally state their internal emotions.

In this study, three items were not included because these three items did not apply to the particular situation in the study. The items of: "silence to one question in the interval;" "silence to more than one question in the interval;" and "distraction: must be indicated by a verbal reminder by the examiner to the child to pay attention;" were excluded because questions were not asked and the child was not expected to pay attention. (See Appendix A for the list of items in the POSA). Each time one of the items on the POSA was observed, the subject was given one point. A behavior was scored once regardless of the number of times it was observed. The final score for each subject was the total of all the points. The higher the score, the more anxiety the child was experiencing.

Procedure

Written permission was requested and received to use the Pre-school Observational Scale of Anxiety from John R. Weisz, Associate Professor in the Department of Psychology at the University of North Carolina at Chapel Hill (see Appendix B). Before data collection, a colleague was trained in the use of the Pre-school Observational Scale of Anxiety. The colleague and the investigator practiced

using the tool to achieve an accepted inter-rater reliability. Verbal permission was received from the pediatric ambulatory clinic associated with the university medical center to observe ten pediatric patients receiving venipunctures. The investigator also obtained written permission from the patient's parents to observe their child having blood drawn. To determine inter-rater reliability it is necessary to have two or more observers "watching some event simultaneously and independently recording the relevant variables according to a predetermined plan or coding system" (Polit and Hungler, 1983:392). To determine inter-rater reliability the observations which both the investigator and the independent observer agreed upon were summed. The sum was then divided by the total number of observations. The inter-rater reliability was determined at 92 percent.

A letter was written to the Director of Health at the county health department describing the study and requesting permission to conduct the study at the health department (see Appendix C). Written permission was granted to conduct the study at the health department (see Appendix D). Data were collected between July 23, 1984 and August 30, 1984.

Before meeting with the investigator, all children were subjected to a health history by a nurse, a finger stick for laboratory studies, and a physical examination by a nurse practitioner or a physician. After identification of the subjects who met the study criteria, the study's purpose and procedure were explained to the parents of the children.

The parents were asked to read the information sheet. If they agreed to have their child participate in the study, they were asked to sign the consent form (see Appendix E). Demographic data consisting of age, sex, and race were elicited. Each subject was randomly assigned to either the control or experimental group. The subjects in the control group were involved in putting a puzzle with different shapes and colors together with the investigator prior to receiving the injection. The subjects in the experimental group participated in needle play with the investigator immediately prior to the injection. All subjects were told that they would receive an injection after the play activity. The parents were allowed in the room during the play activity. After the play activity, which was either puzzle making or needle play, the child and parent were escorted back to the examination room. The colleague, who did not know if the subject was in the control or experimental group, observed each subject from the time the nurse entered the examination room with the syringe and needle until the needle penetrated the skin. The colleague then would immediately check the behavioral indicators of anxiety according to the Pre-school Observational Scale of Anxiety, total the number of items checked, and compute each subject's score. All the data collection using the Pre-school Observational Scale of Anxiety was done by the same colleague whose inter-rater reliability had been determined.

Data Analysis

Each subject's anxiety score was calculated based upon the Pre-school Observational Scale of Anxiety. One point was given for each observed behavior listed on the scale. A raw score was calculated for each subject in both groups.

The Mann-Whitney U Test was used to determine if the differences were significant between the scores of the control group versus the scores of the experimental group. This test was used to compare the scores of the two groups and tested at a significance level of .05. The Mann-Whitney U Test is a nonparametric procedure for testing the difference between two independent samples. The test is based upon the assignment of ranks to the two groups of measures (Siegel, 1956).

With the use of a convenience sample, caution must be used when analyzing and interpreting data. Generalization to a target population is limited by representativeness of the sample (Polit and Hungler, 1983).

Chapter four presents analysis of data, findings, and interpretation of the findings.

Summary

Twenty pre-school children who were receiving routine health care at a county health department participated in this study to determine the effects of needle play on pre-school children's anxiety concerning injections. The

subjects were aged three through five inclusively. Subjects were randomly assigned to either a control or experimental group. The control group was involved in putting together a puzzle with the investigator prior to their injection. The experimental group participated in needle play with the investigator prior to their injection. The Pre-school Observational Scale of Anxiety (POSA) which specifies behavioral indicators of anxiety in children was used on all subjects immediately prior to the actual needle penetration and a score was calculated for each subject.

CHAPTER FOUR

Data Analysis and Interpretation

Introduction

The purpose of this study was to determine the effects of needle play on reducing pre-school children's anxiety concerning injections. The Pre-school Observational Scale of Anxiety was used to measure the degree of anxiety experienced by the children. Twenty pre-school children who received injections for immunizations or PPDs (purified protein derivative) at a health department participated in this study. The children were three through five years of age inclusively and were randomly assigned to either a control or experimental group. Ten of the children (control group) were involved individually in putting together a puzzle with the investigator prior to their injection. The remaining ten children (experimental group) participated individually in the needle play with the investigator prior to their injection. The Pre-school Observational Scale of Anxiety (POSA), which specifies behavioral indicators of anxiety in children, was used to measure each child's anxiety immediately prior to the actual needle penetration. A score representing the amount of anxiety expressed was calculated for each child.

Characteristics of the Sample

The children utilized for this convenience sample ranged from three to five years of age inclusive. Months of age were not considered. One subject was three years old, 10 subjects were four years old, and nine subjects were five years old. In the experimental group, one subject was three years old, five subjects were four years old, and four subjects were five years old. In the control group, five subjects were four years old and five subjects were five years old.

Nine subjects were female and 11 subjects were male. The experimental group consisted of seven females and three males whereas the control group consisted of two females and eight males.

All subjects in the study were either white or black. There was a total of 12 white children and eight black children. Six white children and four black children were in each of the experimental and control groups. (Appendix F provides information on each subject's age, sex, race, and score).

All subjects who met the sample criteria between July 23 and August 30, 1984 were included in the study. All the children in the study were receiving routine health care and an injection in the form of a PPD (purified protein derivative) or a DPT (diphtheria/pertussis/tetanus) at the county health department. All children were subjected to a

health history by a nurse, a finger stick for laboratory studies, and a physical examination by a nurse practitioner or physician before the injection. All subjects were cooperative during the intervention and no parents refused to allow their child to participate in the study.

Hypothesis

Pre-school children who participate in needle play immediately prior to receiving an injection will show a significant decrease in anxiety, as measured by specific behavioral indicators of anxiety, when compared to pre-school children who do not participate in needle play prior to an injection.

Data Analysis

There were 10 subjects in each of the control and experimental groups. Each subject's anxiety score was calculated based upon the Pre-school Observational Scale of Anxiety (see Appendix F for the subjects' scores). The odd numbered subjects were in the experimental group and the even numbered subjects were in the control group. The experimental group's raw score was 92.5. The control group's raw score was 117.5. The Mann-Whitney U Test was used to test for a significant difference between the scores of the two groups and the level of significance was set at level 0.05. The value of 37.5 was computed using the Mann-Whitney

U Test. The critical value of U for a one-tailed test having 10 subjects in each group at a significance level of 0.05 is 27. Therefore, the difference between the scores of the experimental and control group was not significant at the 0.05 level.

The Mann-Whitney U Test was also used to determine if there were significant differences between the subjects' age (four and five year olds), sex (males and females), and race (white and black). No significant differences at the $\alpha = 0.05$ were found between age, sex, and race. Although there were no significant differences between male and female children, male children seemed to score higher and exhibit more gross motor behaviors than female children.

Interpretation of Data

The findings of this study indicated that pre-school children who participated in needle play immediately prior to receiving an injection did not show a significant decrease in anxiety, as measured by specific behavioral indicators of anxiety, when compared to pre-school children who did not participate in needle play prior to an injection. Therefore, the study's hypothesis was rejected.

One possible reason for insignificant results could have been due to sample size. Due to the small sample size and the use of a convenience sample, findings could not be generalized beyond the group studied. Use of a small sample

could have limited the variance between the experimental and control groups leading to a lack of significant differences.

The design of the study did not take into account the trait anxiety of the children. Due to time restraints and the clinical situation it was impractical to determine trait anxiety initially. Therefore, there was no way to determine if the control and experimental groups had the same anxiety level initially and that there were no significant difference between both groups. Also due to time limitations and difficulty obtaining numbers of subjects, the experimental and control groups were not matched for age, sex, and race. Matching for sex could have been important because the male children tended to score higher and exhibit more gross motor behaviors than the female children.

Other variables which were impossible to control that could have affected the results were: (1) parental anxieties; (2) parents' individual preparation of their child about injections; (3) children's past experiences with injections; and (4) noise level in the clinic at the time of the child's appointment. Individual nursing personnel administering the injections could also have affected the results of this study.

Another important variable that may have affected the results of this study was the instrument used. Of prime concern was the possibility that the instrument had

limitations in measuring the anxiety experienced by pre-school children anticipating an injection. The highest possible score a child could receive on the Pre-school Observational Scale of Anxiety was 27. The highest score that the children in the study received was seven. This seemed to be a very low score considering the children had just experienced a finger stick and a physical examination and then were anticipating an injection. The only published use of the Pre-school Observational Scale of Anxiety was done in an educational setting. Observations were made over a 10 minute time span. In this study the observations were made from the time the nurse entered the examination room with the injection to when the needle penetrated the child's skin. The observations were made during a very short period of time which may account for the very low scores. It is possible that not enough time was allowed to accurately assess the anxiety experienced by the children in this study.

Most studies involving the use of play for reducing anxiety in children for stressful situations or medical and dental procedures revealed that play was effective in lowering anxiety levels, fostering adaptive behavior, and increasing cooperation. Play specifically related to the stressful situations has been shown to decreased anxiety in children so it was surprising that this study's hypothesis was not accepted. The variables mentioned above

could have been responsible for the statistically nonsignificant difference between the experimental and control groups.

This study was done in conjunction with a colleague's study entitled "The Effects of Videotaped Puppet Show on Pre-schooler's Pre-injection Anxiety." The same experimental design and instrument but different subjects were used. Instead of the experimental group receiving needle play, the group viewed a videotaped puppet film showing a puppet receiving an injection. The colleague's control group viewed a puppet show depicting a story unrelated to injections or medical procedures. The difference between the colleague's experimental and control groups was statistically not significant so the effectiveness of preparing children with either needle play or puppet film modeling could not be justified by these studies.

Summary

Twenty pre-school children's anxiety scores based upon the Pre-school Observational Scale of Anxiety showed no statistically significant difference between the control group and the experimental group when analyzed using the Mann-Whitney U Test for independent samples. Therefore, the hypothesis that pre-school children who participate in needle play immediately prior to receiving an injection will show a significant decrease in anxiety when compared to

pre-school children who do not participate in needle play prior to an injection was rejected. Possible variables affecting the results of this study could have been small sample size, no trait anxiety pre-test done on both groups, parental anxieties, parents' individual preparation of their children about injections, children's past experiences with injections, noise level in the clinic, individual nursing personnel, and instrument limitations. These variables which were not controlled in this study may have been responsible for the statistically nonsignificant difference between the experimental and control groups.

CHAPTER FIVE

Summary, Conclusions, and Recommendations

Summary

The purpose of this study was to determine whether needle play would reduce pre-school children's anxiety concerning injections. The hypothesis was that pre-school children who participated in needle play immediately prior to receiving an injection will show a significant decrease in anxiety, as measured by specific behavioral indicators of anxiety, when compared to pre-school children who do not participate in needle play prior to an injection.

Roy's Adaptation Model for nursing and Spielberger's theory of anxiety formed the theoretical basis for the study. According to Roy's Adaptation Model, needle play should allow children to bring the stimuli of an injection, which is anxiety producing, within a zone where a positive response is possible. If children's fears and feelings of loss of control can be reduced, children should perceive the situation as less threatening. When the threat decreases, children's state of anxiety should decrease as measured by specific behavioral indicators of anxiety and children should be able to respond in a positive manner. The nursing intervention of needle play should allow children to bring the stimuli of injections within a level of adaptability

which would be expressed by a significant decrease in anxiety.

The review of literature presented studies concerning: (1) reactions, responses, and preparation methods used with children receiving injections; (2) use of play reducing anxiety in children during stressful situations; (3) play as a method of preparation for medical procedures and hospitalization; and (4) play as a method of preparation for dental procedures. Many different instruments have been used to assess children's anxiety, distress, or emotional upset concerning hospitalization and medical treatment procedures. Behavioral ratings made by observers were most frequently used with pre-school children. Most researchers indicated that injections were among the procedures most feared by children and that pre-school children's reactions to needles were very intense. Many studies were concerned with more complicated or involved medical or dental procedures and hospitalization. Few studies involved methods of preparation for non-hospitalized children who were administered needles to obtain blood samples or for injections. Studies in which children received preparation in the form of information, rehearsal, and supportive care showed that the children had less upset behavior, more cooperation, and fewer post-hospital adjustment problems. Most studies involving the use of play for reducing anxiety in children during stressful situations revealed that play is effective

in lowering anxiety levels, fostering adaptive behavior, and increasing cooperation. Play specifically related to the stressful situation decreased anxiety in children. Play seemed to be important to children in their coping with stress and anxiety in the environment. No published studies were found which evaluated the effects of needle play on pre-school children's anxiety concerning injections.

A post-test, control group-experimental group design was used for this study. Subjects were randomly assigned to either the control group or experimental group. The sample consisted of 20 pre-school children who were receiving injections for immunizations or PPDs (purified protein derivative) at a health department. The experimental group consisted of 10 children who participated in needle play with the investigator prior to their injection. Control group subjects consisted of 10 children who were involved in putting together a puzzle with the investigator prior to their injection. The Pre-school Observational Scale of Anxiety (POSA) which specifies behavioral indicators of anxiety in children was used for all subjects immediately prior to the actual needle penetration. A score representing the amount of anxiety expressed was calculated for each child.

The Mann-Whitney U Test was used to test for a significant difference in the scores of the two groups and the level of significance was set at level 0.05. There was no statistical difference between the scores of the control

group children and the scores of the experimental group children when analyzed using the Mann-Whitney U Test for independent samples. Therefore, the hypothesis could not be accepted.

Conclusions

The investigator concluded that for this group of pre-school children needle play immediately prior to receiving an injection did not cause a significant decrease in anxiety when measured by the Pre-school Observational Scale of Anxiety. Because of the small number of subjects and the use of subjects who were readily available, results cannot be generalized to other populations.

Recommendations

As a result of this study, the investigator makes the following recommendations for further study:

1. Replicate this study using a larger sample. The larger the sample, the more representative of the population the sample should be. Smaller samples tend to produce less accurate estimates than the larger samples. The larger the sample the smaller the sampling error.

2. Design the study to take into account the trait anxiety of the children so it can be determined that the control group and the experimental group had the same anxiety level initially.

3. Further research to test the reliability and

validity of the Pre-school Observational Scale of Anxiety is needed. There is only one published study that has attempted to test the instrument's reliability and validity.

4. Conduct the study using longer observation periods. Some behaviors that did not occur in the relatively short time span of the present investigation may occur if children were given a lengthier opportunity to display them.

5. Conduct a similar study using different instruments to measure situational anxiety to see if significant results would occur. Other instruments used to measure anxiety may be more suitable to the clinical situation.

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APPENDIX A

List of Items in the Pre-School
Observational Scale of Anxiety

APPENDIX A

1. Physical complaint: Child says he or she has a headache, stomachache, or has to go to the bathroom.
2. Desire to leave: Child says he or she wants to leave the testing room or makes excuses about why he or she must leave; desire to "need" to leave must be explicit.
3. Expression of fear or worry: Child complains about being afraid of or worried about something; must use the word "afraid," "scared," "worried," or a synonym.
4. Cry: Tears should be visible.
5. Scream.
6. Whine or whimper.
7. Trembling voice.
8. Stutter.
9. Whisper: Child speaks softly, without vocal cords; should not be a playful whisper.
10. Nail-biting: Child actually bites his or her nails in the testing room.
11. Lip-licking: Tongue should be visible.
12. Fingers touching mouth area: not counted if bites nails while touching mouth.
13. Sucking or chewing object: not fingernails.
14. Lip contortions.
15. Trembling lip.
16. Gratuitous hand movement at ear area.
17. Gratuitous hand movement at top of head.
18. Gratuitous hand movement at an object separate from body or at a part of clothing separate from body.
19. Gratuitous hand movement at some part of body (not ear, hair, mouth, or genitals).
20. Gratuitous hand movement.
21. Gratuitous leg movement.
22. Gratuitous foot movement: below ankles, distinguish from foot merely moving along with leg.
23. Trunk contortions (e.g., arching back).
24. Rigid posture: Part of body is held unusually stiff or motionless for the entire 30-sec interval.
25. Masturbation: touches genital area.
26. Fearful facial expression.
27. Avoidance of eye contact: Examiner should be having clear trouble making eye contact with child.

APPENDIX B

Permission to Use the Pre-school
Observational Scale of Anxiety



THE UNIVERSITY OF NORTH CAROLINA
AT
CHAPEL HILL

Department of Psychology

The University of North Carolina at Chapel Hill
Davie Hall 013 A
Chapel Hill, N.C. 27514

4/30/84

Ms. Michelle A. Belyea
8608 Queensmere Place, Apt. 5
Richmond, VA 23229

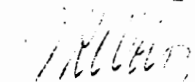
Dear Michelle:

Thank you for your letter of April 26. Certainly you have my permission to use the Preschool Observational Scale of Anxiety. I would appreciate receiving a summary of your findings with the measure.

The Scale is presented in its entirety in the JCCP article, of which I (unfortunately) have no more reprints. We have no information on reliability and validity other than that published in the article. My colleague, Blair Glennon, went to law school after we published this study, and the research died with her departure.

Best wishes in your work.

Sincerely


John R. Weisz
Associate Professor

APPENDIX C

Information Letter
and
Request for Permission
to Conduct the Study

8608 Queensmere Place Apt. 5
Richmond, Virginia 23229
July 27, 1984

Dear Dr.

This letter is to explain the nature of our research study to you. Karla Jones R.N. and myself would like to use the Henrico Health Department to conduct our study with preschool children. We will be studying the effects of preparing children for immunizations via injections and the resulting level of anxiety. Ms. Jones will be looking at the effects of puppet film modeling on children's anxiety level concerning injections. I will be investigating the effects of needle play on children's anxiety level concerning injections. The time frame for collecting data will be between July 30 and August 31, 1984. Preschool children between the ages of three and six years of age will be included if they are scheduled for an immunization via injection. Parents of children who meet the criteria of the study will be handed the information sheet and consent form. The parents will be asked if they will give their written permission for their child to participate in the study. The children will be randomly placed in either a control group or experimental group. Ms. Jones' control group will be watching a five minute video taped puppet show entitled "Mr. Rabbit and the Lovely Present." The experimental group will see a five minute video taped puppet show entitled "Hugo Gets and Injection." This video tape shows a puppet receiving an injection with explanation of procedure and verbalization of feelings.

In my study, children in the experimental group will participate in needle play for ten minutes before the injection. I will interact with each child in the experimental group by first letting the child observe a doll receiving an injection. The child will be able to manipulate a needle and syringe, draw up water, wipe the doll's skin with alcohol, administer an injection, and place a band-aid on the site to the doll under the supervision of the researcher. The child participating in needle play will also be able to express thoughts and feelings regarding injections. The child that is placed in the control will interact with the researcher by putting a puzzle together for ten minutes. After the play activity or the puppet video tape show, each child will be observed while receiving the injection and observed behavior will be recorded. The tool that will be used is called the Pre-School Observation Scale of Anxiety

July 27, 1984

Page 2

developed by Glennon and Weisz from the University of North Carolina at Chapel Hill. The tool is a detailed list of behavior indicators of anxiety in children. The purpose of these two studies is to see if children's level of anxiety concerning injections can be reduced by either puppet film modeling or needle play and to look at which method is more effective.

We have all the equipment that is necessary for our studies. We will need a small, closed off area to do the play activities or show the puppet shows. We do need a written letter from you giving your consent to do these studies in the Henrico Health Department. We thank you for your participation. If you have any further questions, I can be reached at the following number: 747-6136.

Sincerely,

Michelle A. Belyea R.N.

APPENDIX D

Approval from the Director of Health
of the County Health Department

Dear Dr.

In order to conduct my study in the Henrico Health Department, I need your written consent. I will be conducting the study I explained to you in the information letter between July 30 through August 31, 1984. I will be studying the effects of preparing pre-school children for immunizations via injections and the resulting level of anxiety. I will have two groups of children selected randomly. The experimental group will participate in needle play which will take approximately ten minutes. The children participating in needle play will have an opportunity to observe a doll receiving an injection. They will be able to manipulate a needle and syringe and administer an injection to a doll under my supervision. The control group will be involved in putting a puzzle together for ten minutes. After the play activities, a colleague will be in the examination room to record observed behavior during the injection. All names will be kept confidential. Thank you for your participation.

Sincerely,

Michelle A. Belyea

I give my permission for Michelle Belyea R.N. to conduct the study about the effects of needle play before immunization injections on the anxiety level in pre-school children in the Henrico Health Department. I understand the nature and purpose of the study and that all names will be kept confidential.

Name: _____

Date: _____

HENRICO COUNTY HEALTH DEPARTMENT
PARHAM AT HUNTER HOLLOW ROAD
P. O. BOX 27002
RICHMOND, VIRGINIA 23273

August 23, 1984

In cooperation with the
State Department of Health

Michelle A. Belyea, R.N.
8608 Queensmere Place, Apt. 5
Richmond, Virginia 23229

Dear Ms. Belyea:

Thank you for your letter of July 27, 1984 describing the research protocol that you and Karla Jones, R.N. would like to involve the staff and pre-school children of Henrico Health Department. As we discussed in a recent phone conversation, I share enthusiasm with my staff for studying methods of preparing children for immunization via injections and evaluating resulting levels of anxiety.

The staff has assured me that every effort will be made to provide a small closed off area to do the play activities or show the puppets. It is my understanding that this study will be conducted at no cost to Henrico Health Department or our patients.

Enclosed is written authorization to proceed with the study as agreed to in our telephone conversation and your letter of July 27, 1984.

Very truly yours,

Forrest W. Pitts, M.D.
Director of Health

FWP/mr

APPENDIX E

Parent Information Sheet
and
Consent Form

Parent Information Sheet and Consent Form

Dear Parent:

My name is Michelle Belyea, and I am a graduate student in nursing at the Medical College of Virginia/Virginia Commonwealth University. I will be conducting a study today about preparing children for injections. The information gained will be used for my graduate studies, and I hope to find an effective way to help children cope with injections. This information may also be used for a professional journal article and shared with other nurses and doctors if requested.

Your child can only be included if an immunization via injection has been ordered for him/her. If your child participates, he/she will spend about ten minutes with me either making a puzzle or giving a doll an injection. You can observe the play activity. After the play activity, a colleague will be in the examination room to observe your child receiving the immunization injection. All names will be kept confidential, and your child's participation will in no way influence his/her care now or in the future. You may withdraw your child from the study or ask me questions at any time. I would like to ask your permission to include your child in my study. If you agree, please sign below. Thank you for your help.

Sincerely,

Michelle A. Belyea, R.N.

I give my permission for Michelle Belyea R.N. to include my child in a study about injections and anxiety. I have read and understand the above letter and the nature of the study. I understand that all names will be kept confidential.

Name: _____ Relationship: _____

Date: _____

Child's age: 4 5 6 (please circle)

Child's sex: Male Female (please circle)

Child's race: _____

APPENDIX F

Characteristics and Scores of the Subjects

Characteristics and Scores of the Subjects

<u>Subject</u>	<u>Age</u>	<u>Sex</u>	<u>Race</u>	<u>Score</u>
1	4	F	White	5
2	5	M	Black	6
3	5	F	White	0
4	5	F	White	3
5	4	M	Black	1
6	4	F	White	4
7	5	M	White	7
8	5	M	Black	5
9	4	F	Black	2
10	4	M	White	5
11	5	F	White	1
12	4	M	Black	7
13	3	F	White	7
14	5	M	White	5
15	4	F	Black	3
16	4	M	White	3
17	4	M	Black	5
18	5	M	Black	3
19	5	F	White	3
20	4	M	White	2

experimental group = odd numbered subjects

control group = even numbered subjects

VITA

Michelle Anne Belyea was born in Bangor, Maine on June 12, 1957. She obtained her early education in Old Town, Maine and graduated from Old Town High School in June, 1975.

Ms. Belyea entered the University of Maine at Orono in September 1975 and attended this university for two years. In September 1977 she transferred to the University of Southern Maine to complete her Bachelor of Science degree in Nursing. She graduated summa cum laude from the University of Southern Maine in May 1979.

Following graduation, Ms. Belyea worked as a staff nurse on a surgical unit at Eastern Maine Medical Center in Bangor, Maine for one and one-half years. She transferred to the pediatric unit at the same medical center, where she worked for two and one-half years. During this time, she held positions of staff nurse and charge nurse on the general pediatric unit and the pediatric special care unit.

In August 1983, Ms. Belyea began graduate study in the pediatric nurse practitioner program at the Medical College of Virginia, Virginia Commonwealth University in Richmond, Virginia. Ms. Belyea will receive her Master of Science degree in Nursing with a major in Nursing of Children and finish the pediatric nurse practitioner program in May 1985.