The effects of therapeutic touch on pain responses in infants receiving immunizations

Mindy Lawree Manahan
Medical College of Ohio

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FINAL APPROVAL OF THESIS
Master of Science in Nursing

The Effects of Therapeutic Touch on Pain Responses in Infants Receiving Immunizations

Submitted by

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In partial fulfillment of the requirements for the degree of Master of Science in Nursing

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The Effects of Therapeutic Touch on Pain Responses in Infants Receiving Immunizations

Mindy Lawree Manahan

Medical College of Ohio

2005
DEDICATION

This work is dedicated to my husband, Patrick, for his constant encouragement, endless love, and faith in me, and to my children, Kaitlyn Noel, Shaylee Rose, and Riley Quinn Patrick, for keeping me grounded, never letting me forget I have an imagination, and for making me laugh when I felt like crying.
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CHAPTER I

Introduction

Therapeutic touch has become a treatment modality practiced by nurses worldwide in a multitude of health care environments (Krieger). The premise of therapeutic touch is based on the belief that human beings consist of energy fields and that a number of existing factors or events, such as an injury, illness, or altered state of being (e.g., pain, sickness, or anxiety), can disturb the balance of such energy fields. The proponents of therapeutic touch maintain that the subtle yet profound interplay of energy fields and the healing realignment which occurs within the client are the core objectives of therapeutic touch. It is the balance of these energy forces that creates the healing state that transpires with the treatment (Krieger). Within the field of nursing, the concept of energy fields was initially introduced by the theorist, Martha Rogers (1970). Roger's theory pertaining to energy fields provides rationale for the healing nature of therapeutic touch and recognizes the treatment as a therapeutic intervention. This study investigated the effects of therapeutic touch, within Roger’s conceptual framework, as a preventive measure in decreasing pain responses in term infants receiving multiple immunization injections. The infant's responses to therapeutic touch were observed. One group received therapeutic touch and one group served as the control which meant that the infants in this group did not receive therapeutic touch. After the injections were given the pain responses were recorded, then compared and discussed.

Statement of the Problem

At this time, there are limited non-pharmacological methods available to alleviate pain experienced by infants and even fewer methods have been identified that prevent
pain. Studies conducted on pediatric clients indicate that intravenous cannulation and parenteral injections are rated as the highest pain producing stimuli in this population (Van Cleve, Johnson, & Pothier, 1996). Considering that the goal of Healthy People 2010 is to have 100% of U.S. children immunized (London, Ladewig, Ball, & Bindler, 2003), techniques to preventing pain during injections should be a top priority, especially since some of the health care facilities are administering up to five injections at one immunization visit. The application of therapeutic touch could have positive significant effects on decreasing pain levels in term infants receiving immunizations as early as the first 12 months of life.

Identification of Nursing Conceptual/Theoretical Framework

Rogers’ Science of Unitary Beings (1970) provided the theoretical framework for this study (Figure 1). This theory has successfully been utilized in past research studies as a basis for explaining the effectiveness of therapeutic touch (Biley, 1996; Meehan, 1993). Rogers’ nursing theory views the universe as an open system in which humans operate independently and continually evolve to the next highest level.

In defining the relationship between the energy fields, it is proposed that the healer (i.e., nurse) contributes restorative energy to the environmental field shared with the client. During this process, a re-patterning occurs within the client’s energy field facilitating a transfer of power that enables the client to achieve the needed balance of energy to promote a healing state.

Statement of Purpose

The purpose of this study was to explore the effects of therapeutic touch on pain responses in term infants receiving multiple immunization injections. The anticipation
was that the relaxation response and balancing of the energy field produced by therapeutic touch would decrease the perception of pain and subsequent stress to the infant.

*Figure 1.* Therapeutic touch within a Rogerian framework.
Research Question

Was there a difference in PAIN scores between the infants who received therapeutic touch and the infants who did not?

Definition of Terms

**Conceptual definitions.** Therapeutic touch is "a healing meditation" that does not take on a religious aspect (Quinn, 1988). The process involves centering of the practitioner away from distraction in the external surroundings to the internal being and is "based on the conscious use of the hands to direct/re-direct or modulate, for therapeutic purposes..." (Krieger, 1993, p. 3-4).

Pain is "an unpleasant sensation caused by noxious stimulation of the sensory nerve endings. It is a subjective feeling and an individual response to the causal agent or stimulus (Mosby, 2002)."

**Operational definitions.** Therapeutic touch - non-contact touch intervention utilizing the five phases identified by Krieger (1993): 1) centering with intention, 2) assessment, 3) unruffling, 4) directing/modulating energy, and 5) evaluating. This study used the Krieger/Kunz method as established by the organization of Nurse Healers Professional Associates International (1999).

Quantitative measurement of pain is obtained utilizing the PAIN scale that assigns one’s intensity of pain from 0 (no pain) to 10 (maximal pain). This score utilizes a number of behavioral responses such as facial expression, cry, breathing, extremity movements, state of arousal, as well as physiological indicators such as oxygenation saturation and heart rate.
The seven indicators of pain in the infant:

Physiological indicators:

1) heart rate – increased
2) oxygen saturation - decreased

Behavioral indicators:

3) facial expression - wrinkled foreheads, grimacing
4) cry - from whimper to vigorous
5) breathing pattern - increased depth and rate of respirations
6) extremity movement - jerking (flexing and extending) of arms or legs
7) state of arousal - fussy

Significance

Effective nursing entails the proper weaving of forces, from the art of caring and science aspects of the profession, to adequately understanding and meeting the many needs of the client. Additionally, nursing seeks to promote a complementary interaction between man and the environment to further optimize one’s health potential. Rogers' nursing theory stresses the need for the nurse to look at the entire human being holistically and continually, meaning beyond the physical characteristics of the being. Energy balancing is one practice that can assist in maintaining both physiological and psychological health (Bearden, 1995).

Nursing is a humanistic and humanitarian science directed toward describing and explaining the human being in synergistic wholeness and developing the hypothetical generalizations and predictive principles basic to knowledgeable practice (Biley, 1996). Many nurses have recognized the existence of the unexplainable, yet ever present effect
of therapeutic energy fields of their clients. There has been an increase in research being conducted in this area of study due to the potential benefits of balancing the energy field, and can no longer be ethically ignored.

Ethical implications surround the care provided to infants. A major nursing responsibility is to provide protection from undue pain and to carry out the role of client advocate (Kachoyeanos & Zollo, 1995). Butler (1987) discussed the implication of pain control within the context of the American Nurse's Association (ANA), *Code of Ethics* (1985). Several keys points were brought to light. The first statement reminds nurses to be an advocate for the client when there is no other person present to do so. This takes into account the fact that infants are in the preverbal state, and therefore, changes in behavioral and physiological symptoms, due to pain, need to be assessed by the nurse because the lay caregiver may not recognize these changes nor can the infants verbalize the pain.

Historically, failure to advocate for the client has led to the "under-treatment" of pain in infants (Anand, Phil & Carr, 1989). Butler refers to section 5.1 of the ANA *Code of Ethics*, which explains the responsibility of nurses in staying abreast of scientific advances relevant to practice so that the nurse may continue to provide optimal care based on current findings. Research conducted by Anand, Phil and Carr demonstrates behavioral and physiological cues displayed by both pre-term and term infants during procedures. Another study conducted by Franck (2002) also indicated that responses to painful stimuli have been detected in full-term, as well as pre-term babies. Therapeutic touch may have the potential to decrease pain intensity experienced by these neonates and infants.
Therapeutic touch has been extensively researched and has become an important healing modality utilized by nursing when providing care to clients. Some of the significant responses experienced by the client include decreased states of anxiety (Engle & Graney, 2000; Heidt, 1981; Quinn, 1983), decreased pain (Buguslawski, 1980), and increased relaxation (Olson & Sneed, 1995; Randolph, 1984). These effects of therapeutic touch could play an important role in the health of the infant undergoing painful procedures since it has been documented that adequate treatment of pain has been associated with decreased clinical complications and decreased mortality (Franck, 2002). Another research study stated that repeated painful stimuli during infancy has shown to decrease oxygenation levels and increase heart rate and these physiological changes may have long-term detrimental effects on the neurological and cardiovascular systems, but the true ramifications of the exposure of pain have yet to be determined (Cohen, 2002).

Krieger (1993) identified the ability of therapeutic touch to restore energy where needed and intended. This use of therapeutic touch was done prior to a stressful stimulus, yet very few studies exist in which therapeutic touch was utilized as a preventive measure to preserve health or well-being. The literature available deals with pain already being experienced by the patient as opposed to addressing the health of the patient’s pre-pain state.

The purpose of this study was to initiate the modality pre-procedurally in hopes of achieving a prophylactic pain relief measure for infants receiving multiple immunization injections. If the effect of therapeutic touch produced a non-invasive, safe, prophylactic pain relief measure then significant changes may occur in how nursing care was provided to infants to control or better yet, to prevent painful experiences.
Assumptions

1. Immunizations by injections produce pain.

2. The human being consists of energy fields and is not limited to the sum of its parts, but rather extends beyond the physical being.

3. The manifestations of pain include behavioral and physiological responses, which can be assessed and altered within the human energy field.

4. Infants' pain responses are identifiable.

5. Therapeutic touch decreases pain responses and increases states of relaxation.

6. Children and caregivers want to avoid pain if possible.

Limitations

1. Convenience sampling was utilized.

2. There is no technology available to measure the mechanisms of therapeutic touch.

3. The human energy fields cannot be measured.

Summary

Therapeutic touch is a complementary modality based on the belief that energy fields exist and that when a disruption to the energy field occurs pain is experienced. The intervention is easily implemented and has shown to be a safe, non-invasive procedure.

This study investigated the effectiveness of therapeutic touch as a prophylactic pain relief measure when administered prior to multiple immunization injections as evidenced by behavioral and physiological pain indicators.

Thus far the rationale for choosing therapeutic touch as a prophylactic pain relief measurement was explored. A brief explanation regarding Rogers' (1970) theoretical
framework and how therapeutic touch intertwines with the theory was examined. The statement of the problem and statement of the purpose revealed a great need to identify pain relief measures in infants receiving injections. The research question was asked and definitions of the terms were described. The study's significance, along with possible assumptions and limitations were listed.
CHAPTER II

Literature

This chapter introduces the concept of therapeutic touch within a conceptual framework. The framework selected was Rogers' Science of Unitary Human Being, which offers guidance and organization to the dynamics of therapeutic touch (Rogers, 1970). Terms pertaining to the conceptual framework and the current study are discussed. The therapeutic touch process and phases involved are explained. The review of literature provides a historical overview and identifies effects of therapeutic touch. Last, pain responses particularly in infants are identified, along with appropriate pain assessment tools and reasoning for selecting the PAIN scale.

Conceptual Framework

Theoretical interpretation. The overall assumption of Rogers’ theory consists of a dynamic energetic process that is constantly occurring within human beings and their respective environments. These environments entail many open systems, extending universally and infinitely. There are five postulations within Rogers' theory of human beings. The first postulation states that Man can be identified by patterns and organizations and the composition of these two features create wholeness. It is the whole being that should be cared for with the understanding that there is more present than the sum of the parts (i.e. the human being extends beyond the physical being) (Rogers, 1970). The second postulation states, that since the universe is a collection of open systems, encompassing both the human being and the environment, openness exists allowing continual exchange of energy between them. The third postulation analyzes the evolutionary process that takes form when energy is exchanged between human being
and environment. The exchange occurs in a unidirectional and irreversible manner that facilitates a continual progression to a next level of existence. The fourth postulation focuses on personal patterns of energy unique to each individual. These patterns are not visually observable, but the manifestations of the pattern are observable. Each human being’s energy field has its own unique identity and intensity of interaction with the environment. This interaction is dynamic, unpredictable, creative and continuous. An analogy of this in action would be the observer’s view of the changing colors and patterns when looking through a rotating kaleidoscope. Environmental energy causes a rotation that occurs unidirectional in time (i.e., never allowing a return to a previous state). The multicolor view through the glass portal is continually transformed into an infinite flowing mosaic of magnificent and unpredictable, images, patterns and shapes. This is similar to how the human being perceives and interacts with the environment based on the degree of energy present. The fifth postulation introduces the ability to think abstractly, be imaginative and experience emotion, all of which distinguish human beings from other life forms (Rogers, 1992).

Rogers' theory centers on the concept of homeodynamics which offers a way of perceiving the unitary human being is defined by three principles: intergrality, resonancy, and helicy. Integrality describes a continuous, mutual interactive developmental process between human and environmental fields. Resonancy deals with the identification of wave patterns in which the direction of change travels from a lower to a higher frequency wave pattern in human and environmental fields. The last principle is helicy and describes the nature and direction of change experienced by the human and
environmental fields. This direction is described as continuous and innovative and full of unpredictable outcomes of increasing diversity and complexity (Rogers, 1992).

Application of the theory of therapeutic touch to the current study. Therapeutic touch focuses on holism with the intent to balance the human energy field. From the perspective of Rogers’ Science of Unitary Human Beings, energy fields are the fundamental units of humans and their environment, and explains how the dynamic process of focusing and shifting of energy during therapeutic touch can alter a clients energy field. Therefore, a strong coexistence is present between the theory and the intervention. This coexistence has been shown to be true in several studies conceptualized within the framework of Rogers' theory (Meehan, 1993; Biley, 1996). When nursing care during therapeutic touch is examined within the concept of Rogers’ system, the nurse becomes concerned with re-patterning the environmental and energy fields in order to promote healing and comfort (Quinn, 1992). Figure 1 provides a visualization of application of the theory pertaining to therapeutic touch as it relates to this study.

In Figure 1, integrality represents the broadest principal of homeodynamics encompassing in this study, the unitary human beings (i.e., nurse and infant), and the two principles resonancy (i.e., therapeutic touch) and helicy (i.e., infant’s pain response). Integrality is the outer circle, resembling the earth and beyond, and has isotonic properties, giving equality of energy exchange within and between the entities (Rogers, 1970). Meehan (1993) utilizes the principle of integrality to explain how the nurse can tap into the energy field of the infant since both exist as open systems.
The unitary human beings, depicted in the rectangle (Figure 1), represent the nurse and the infant. Rogers' (1970) theory affirms that the human being is a unified whole possessing individual integrity with many characteristics that go beyond and differentiate from the whole. The unitary human being is an irreducible, pandimensional energy field classified by patterns and characteristics that are specific and unique to the individual, and cannot be predicted by the knowledge of other people (Rogers).

Resonancy, illustrated within the oval (Figure 1), is the principle that explains the process which occurs during therapeutic touch. Resonancy provides identification of wave patterns in which the direction of change travels from a lower to a higher frequency, and in this study was accomplished by the nurse focusing with intent on utilizing her own energy field to repattern that of the infant's facilitating balance within the infant's energy field.

In this study, therapeutic touch was implemented before the injections were administered to balance the infant's energy field and provide essential energy to deal with the insult of the injections. Daley (1997) suggested that the insult to the tissue from the penetration of the needle alters the energy field and manifests as pain. Daley later explained that this physical injury, which represents a disruption in the infant's energy field, must be re-balanced before healing can occur. This view supports the belief that illness is due to or caused by energy imbalances and coincides with the theory that human beings possess the ability to change patterning directions to bring energy back into balance (Krieger, 1993).

Rogers' concept of helicy is displayed in the triangle (Figure 1), and explains the innovative and unpredictable diversity of outcomes that occur when energy fields
enmesh, and represents the infants’ pain responses observed following administration of the injections.

The goal was to balance the infant's energy field (unitary human being), by the practitioner (unitary human being) utilizing therapeutic touch (resonancy), to achieve a decreased pain response or healing state (helicy). The entire process takes place within an infinite and continual exchange of energy between human and environmental fields (integrality). The nurse performed therapeutic touch on the infant prior to immunization injections to decrease the pain responses.

**Therapeutic Touch**

*The phases of therapeutic touch.* The therapeutic touch intervention consists of five phases. The phases must be conducted in a systematic manner and pertain to 1) centering, 2) assessing, 3) unruffling, 4) directing and modulating, and 5) evaluating the energy fields (NH-PAI, 1999). Discussion of each of the five phases follows.

In the first phase, the healer (nurse) centers in order to clear the mind. This entails freeing one’s mind of other thoughts and consists of a conscious effort to commit to being with the client in order to sense changes in the energy field and allow healing to take place. This process is referred to as centering with intention. Documentation has shown the significance of maintaining the centering process during the entire treatment (Heidt, 1981, Quinn, 1983). Several studies compared a true therapeutic touch intervention to a mimic therapeutic touch intervention or a casual touch intervention. In one study conducted by Heidt, casual touch without centering was compared to therapeutic touch with centering and in a second study by Quinn, a mimic therapeutic touch intervention was compared to a true therapeutic touch intervention. In the latter
study, the practitioner used distraction by conducting mental exercises to prevent focusing and centering. In both studies the findings indicated that true therapeutic touch with centering and intention led to increased relaxation responses in clients when compared to therapeutic touch without centering or mimic therapeutic touch.

The second phase encompasses the assessment portion of performing therapeutic touch (Krieger, 1979). The phase is achieved through the use of the nurse's hands moving through the infant’s energy field to detect imbalances. This is accomplished by holding the hands 2-4 inches away from the infant’s body and slowly advancing downward in a head to toe fashion. During this process the nurse assesses the condition of the energy field by becoming aware of differences in sensory cues in the palmar surfaces of the hands as well as other intuitive cues based on the infant’s responses to the treatment. Subtle sensory cues must be recognized in order to locate imbalances, such as changes in heat, cold, pressure, tingling, and pulsations (Krieger, 1993). There are additional indicators to assess for and require observing the infant’s behavioral and physiological responses, such as calmness versus restlessness, quietness versus crying, facial expressions relaxed versus tensed, and slower respirations versus rapid breathing. The ability to perform a thorough assessment is of great importance in identifying energy patterning.

The third phase is unruffling and consists of repatterning and mobilizing the energy field in order to facilitate symmetry and fluidity in the flow of energy. Unruffling is performed over the entire body with increased concentration on the congested areas identified during the assessment phase. The phase is performed with calm and rhythmic
sweeping movements of the nurse's hands, to release blocked energy, increase the flow, and re-establish balance of energy patterning in the infant’s energy field (Krieger, 1993).

The fourth phase consists of directing and modulating, with the goal to achieve steady symmetrical harmony in the infant's energy field (Krieger, 1979). The concept of abstract thinking is a key factor and involves the ability of the nurse to internally visualize this occurrence taking place. Krieger explains this process as the redistribution or regulation of energy flow and consists of intention aimed or concentrated at balancing the infant’s energy field.

The fifth phase consists of evaluating or reassessing the infant’s energy field for balance. The nurse becomes aware of this achievement by sensing a smooth flow of energy that is uniform over the body, constant temperature sensation, and the impression of a peaceful state in the infant. If balance was not achieved by the fifth phase then the nurse may repeat any of the previous phases as they are interdynamic.

*Therapeutic Touch - Literature Review*

*Background information.* A nurse, Delores Krieger, developed therapeutic touch in the 1970s (Krieger, 1979). Through her nursing practice and passion to extend the philosophy that every individual has the potential to facilitate the healing process, thousands worldwide have benefited from receiving therapeutic touch (Krieger, 1997). Although, therapeutic touch is a newer healing modality, the concept has been around since biblical times in which touch was utilized to promote healing (Quinn, 1983).

Quinn's (1983) foundational study assimilated the act of "laying on of hands” with the earlier version of therapeutic touch. The same reference to laying on of hands was again made in the Peter's (1999) study. Practitioners who utilize therapeutic touch...
believe in the "concepts that people are open systems of energy and that during therapeutic touch, energy is transferred or channeled from the practitioner to the client (Quinn, p. 43)." Numerous research studies have been conducted analyzing positive benefits. Discussion of these studies will follow.

**Identified Effects of Therapeutic Touch**

Therapeutic touch has been utilized to decrease pain responses (Wright, 1987), decrease states of anxiety (Heidt, 1981; Hughes, Meize-Grochowski, & Harris, 1996; Kramer, 1990; Olson & Sneed 1995), and produce generalized relaxation responses (Quinn, 1983, Randolph, 1984). This modality has been studied within various populations, including infants (Hughes, et. al., 1996; Ireland, 1998; Kramer), adults (Engle & Graney, 2000; Olson & Sneed, Quinn, Randolph), geriatrics (Peck, 1998), and psychiatry (Hughes, et. al.). With the effects of therapeutic touch several objective (i.e., physiological) and subjective (i.e., bio-behavioral) findings have been identified.

Some of the objective findings were contradictory regarding the physiological effects of therapeutic touch and ranged from decreased blood pressure, pulse, and temperature, in most of the cases, to a decreased pulse amplitude and vasoconstriction that was identified in one study (Engle & Graney, 2000). A decreased pulse amplitude and vasoconstriction may produce potential adverse effects depending on the condition of the client being treated (Engle & Graney). Rationale for why contradictory physiological effects occurred may have been related to the technique photoplethysmography, which was used to measure the physical responses. "Vasodilation may have occurred in subjects' mesenteric plexus, the area directly under the TT therapist's hands, with a corresponding reflex vasoconstriction in subjects' peripheral circulation (Engle & Graney
The mesenteric plexus consists of a network of intersecting vessels or nerves connected to the autonomic system. The body’s initial response to the therapeutic touch intervention may have stimulated the parasympathetic nervous system, a branch of autonomic nervous system. This stimulation would produce vasodilatation in and around organs and tissues, thereby causing a decrease in blood pressure, pulse and temperature. In response to these physiological changes, the sympathetic nervous system, which is the other branch of the autonomic nervous system, would elicit a reflex response counteracting the vasodilatation and resulting in vasoconstriction of the periphery. Although, this study identified this potential conflicting physiological finding, further investigation regarding this effect should be carried out as this was the first study to identify a possible negative response to therapeutic touch. Previous to that study there has been no documentation of harm occurring to clients (Krieger, 1993; Jurgens, Meehan, & Wilson, 1987).

Krieger (1979) urged caution to be used not to overwhelm a client with excessive amounts of energy, particular the elderly, very sick, or very young. Skill in recognizing subtle energy changes is vital, and consists of identifying objective, as well as subjective symptoms.

A subjective finding included a change in time perception. In this study the clients described this change as feeling as if time passed by “faster” (Engle & Graney, 2000). This would be difficult to assess in the population utilized for this study since infants are developmentally unaware of the concept of clock time, but the thought of the painful injection experience being shorter-lived may be a factor to consider.
With such encouraging objective and subjective responses as discussed above, the use of therapeutic touch as a nursing intervention must be further researched in order to provide evidence at a significant level surrounding the modality's efficacy and practicality to the nursing profession. Peters (1999) conducted a meta-analysis of existing research studies that pertained to the effectiveness and practicality of therapeutic touch. In order for the research study to be included into the meta-analysis, several criteria needed to be met, and included: a) empirically based research, b) a human intervention, c) the intervention had to follow Krieger/Kunz method, d) the study design had to be experimental, e) outcomes had to be measurable, and f) the study had to be published between 1986 and 1996. Peters concluded that the intervention may elicit positive physiological and psychological effects, but due to several methodological issues, future therapeutic touch researchers needed to address four neglected areas. These areas included, sampling procedures, intervention practices, practitioner skills, and underreporting of data.

Most studies regarding the effects of therapeutic touch have been conducted on physically healthy adult clients, which limits the freedom to generalize the results to infants, although, the Krieger/Kunz method remains the same for every client (Engle & Graney, 2000; Olson & Sneed, 1995). Similar to the studies on adult populations, this study was conducted on physically healthy infants. This was made known by the researcher viewing a questionnaire form utilized by the health department immunization clinic and screened by the nurse to be certain the infant was in a state of wellness and eligible to receive the injections.
Fedoruk (1984) initiated true therapeutic touch, which consisted of centering with intention, on infants experiencing stress and compared the outcomes to a mimic therapeutic touch intervention which consisted of no centering or intention. Part of the hypothesis was supported when the infants who received the true therapeutic touch intervention displayed increased relaxation responses, but the transcutaneous oxygen saturation levels did not increase as expected.

Another study conducted by Kramer (1979) contrasted true therapeutic touch to casual touch. The sample consisted of infants and children ranging from 2 weeks to 2 years, who were exposed to stressful events. The stressful events included medical procedures, being awakened from sleep or being forcibly held. Results showed that the infants who received the true therapeutic touch intervention required less time to return a calm state as opposed to those infants who received the casual touch intervention.

Limitations of studies conducted with therapeutic touch. The inability to visualize energy transference and the absence of technological equipment that has the ability to assess or measure a therapeutic touch intervention leads to many questions remaining unanswered. Therefore, due to these limitations the focus needs to continue to be on the clients' responses. Similarly, we administer medications even though we cannot see the pharmacokinetics of the drug in the body; nevertheless, they are utilized for their desired effect upon the client. The administration of therapeutic touch should be assessed in the same manner.

Internal threats to validity include the actual therapeutic touch process, meaning the method or technique utilized by the practitioner and the time given to perform the treatment which ranges anywhere from 5 to 20 minutes. Most studies claim to have
utilized the Krieger/Kunz method or technique, yet the number of phases implemented varied from three (Ireland, 1998; Wright, 1987) to six (Heidt, 1981; Quinn, 1983). Quinn employed observers to scrutinize both the practitioners who were performing therapeutic touch and those who were merely mimicking the intervention to minimize threats to internal validity of the design and found that a difference could not be detected.

Threats to external validity include practitioner expertise and the variances of stressors and painful stimuli being experienced by the client. At this point in time, all articles exploring the effects of therapeutic touch possess an external threat to validity based on the belief of the modality, which is that the existence of energy fields has to be axiomatic due to the inability to empirically measure such transference.

**Pain and Therapeutic Touch**

Numerous studies have analyzed the use of non-pharmacological methods of pain reduction in infants such as rocking and non-nutritive sucking (Campos, 1994), tucking (Corff, Siederman, Venkataraman, Lutes, & Yates, 1995), and administration of oral sucrose (Blass & Hoffmeyer, 1991; Stevens, et.al., 1999). Studies for the purpose of prophylactic use of therapeutic touch to decrease infant pain responses are limited. Repeatedly, studies show that infants and children experience discomfort during pain provoking procedures. Yet, many children go under-treated during these times of hospitalization or care. Schechter (1989) offered rationale for the reasons for "under-treatment" of pain, including myths or incorrect assumptions, attitudes, complexity of pain assessments in children, along with inadequate research and training seminars. Infants and young children lack the gold standard of self-reporting when assessing pain subjectively. Therefore, the responsibility relies on the nurse to effectively assess and
identify when the pediatric client is experiencing pain. The (JACHO) standards now demand a thorough assessment of pain followed by treatment if indicated. Some agencies are referring to pain as the "fifth vital sign." A description of pain and documentation comparing and contrasting the use of various pain assessment tools will be discussed, with a focus on the infant population.

Pain -Literature Review. Historically, pain has been identified as a subjective phenomenon (International Association for the Study of Pain, 1979). Health care providers have been encouraged to reconsider behavioral indicators of pain in infants (Anand & Craig, 1996). The study conducted by Anand, Phil, and Carr (1989) found contraindications to the belief that infants possess immature neurological systems and do not experience painful stimuli. This finding was reiterated by Van Cleve, Johnson, and Pothier (1996), who explained that although the biological differences between children and adults’ perception of pain are unknown. There is plenty of literature documenting the fact that infants and children are experiencing the unpleasant effects of pain. Recognizing infant pain responses and choosing the appropriate pain assessment tool are further reviewed.

Choosing the appropriate tool requires identifying specific physiological and behavioral indicators of pain during the assessment. Assessment of pain in infants must be performed accurately to be effective. One study by Van Cleve, Johnson, and Pothier (1996), analyzed infants' and children's experience of pain during venipuncture and intravenous cannulation in order to identify indicators of pain. Dale (1986) analyzed the behaviors associated with diphtheria-pertussis-tetanus (DPT) injections in infants receiving the first or second injections. In both articles, Van Cleve et al. (1996), and
Dale and Fuller (1998) mentioned the types of pain responses observed in the infants such as changes in cortisol responses, crying, behavioral states, heart rates, respiratory rates, body movements, and tcPO2 levels. Furthermore, Fuller's qualitative study enabled the development of a pain assessment model to aid in identifying infants experiencing pain. A later study conducted by the same author tested the validity and reliability of that same model (Fuller, 2000).

Fuller’s scale determines three levels of pain, 1) no pain, 2) mild pain, and 3) severe pain and is difficult to utilize. Thus, the goal remains to be able to adopt one pain assessment scale that does not require extensive training and could be readily used by nurses caring for infants and children.

A study completed by Hudson-Barr, Capper-Michel, Lambert, Palmero, and Lombardo (2002) provided an excellent overview of the pain assessment tools available, with an emphasis on the fact that these scales have mainly been used for research purposes and/or assessed in a single clinical study. A pain assessment scale that focuses on infants' facial expressions is the Neonatal Facial Coding System (Grunau, Johnson, & Craig, 1990). This particular tool was utilized during the administration of Vitamin K intramuscularly, a painful stimuli, as compared to swabbing the umbilical cord with alcohol, a non-pain provoking stimuli. This tool was not an option for the current study due to the complexity in scoring, and the lack of attention to physiological indicators.

Another commonly utilized pain assessment tool is the Premature Infant Pain Profile (PIPP) developed by Stevens, Petryshen, & Taddio (1996). Seven indicators are assessed: 1) gestational age, 2) behavioral state, 3) heart rate, 4) oxygen saturation, 5) brow bulge, 6) eye squeeze, and 7) nasolabial furrow. This tool demonstrated construct
validity and inter-intra-rater reliability for premature neonates, but is limited by the age of the infant, by assigning 3 points for infants less than 28 weeks gestation, and 0 points for 36 weeks and over. Since the PIPP has not been tested for validity and reliability beyond the neonatal period and assigns points for age, it was determined not to be an appropriate pain assessment tool for this study focusing on term infants' pain responses.

Other pain assessment tools include the Crying, oxygen Requirement, Increased vital signs, facial Expression, Sleep (CRIES), the Children’s Hospital of Eastern Ontario Pain Scale (CHOEPS) (McGrath et. al., 1985), and the Neonatal Infant Pain Scale (NIPS) (Lawrence et. al., 1993) have established validity and reliability in all aspects, but their uses were intended to be for assessing post-operative pain and would not be appropriate for this study.

The Pain Assessment in Neonates (PAIN) is a newly developed scale, which combined CRIES with NIPS, and has shown to be valid tool in measuring infant pain responses (Hudson, Barr, et al., 2002). This particular tool has seven categories. The total score could range from 0-10 with 10 indicating the most pain. The seven categories encompass: 1) facial expression, 2) cry, 3) breathing pattern, 4) extremity movements, 5) state of arousal, 6) 0₂ required for saturation levels greater than 95%, and 7) increased heart rate. Since this pain assessment scale measures both behavioral and physiological responses and was tested on both sexes of pre-term and term neonates and on infants of various ethnic races, this tool was determined to be the most appropriate for the current study even though its use also was intended to be for post-operative pain assessment.

Several limitations of the studies conducted on pain and the effectiveness of the various pain assessment scales were identified. A majority of the studies utilized
convenience sampling and failed to mention refusals to participate, along with attrition rates (Dale, 1986; Hudson-Barr et. al., 2002; Van Cleve et. al., 1996; Fuller, 1998, 200). The sample sizes range from 10 to 196. The sample size in the Dale study consisted of 5 infants receiving their first DPT injection and 5 infants receiving their second DPT injection. Due to the small number of the sample, the study was at risk for the results being by chance. Ages of the infants ranged from 2 months to 4 1/2 months. Maturation, which considers growth plus development, could be a possible threat to validity. A power analysis was not calculated. This sample would not be representative of a majority of the population. Biases existed based on the high acuity of the neonate client and the intensive care setting.

In the qualitative study, Fuller (1998) used a population of 40 currently practicing pediatric nurses. There was a wide range of years of expertise, from 1 to 20 years, among the participants. This discrepancy is enough to pose a direct threat to internal validity. Since wisdom comes with years of experience, the novice may not yet be aware of possible pain responses in the infant, and therefore, might leave cues unidentified. This very same threat existed in the following subsequent quantitative study conduct by Fuller (2000) in which 24 pediatric nursing students were used to establish validity and reliability of an infant pain assessment instrument. In the study that examined validity and reliability of the PAIN assessment tool, several limitations were identified. The first deals with intra-rater reliability. Clinicians were instructed on the use of the scale at the time of implementation. Therefore, return demonstration was not observed. Secondly, the pain continuum of no-pain to worst-pain remains unidentified with this type of scale, and thirdly, a short time frame for the assessment of pain was assigned.
Summary

The modality of therapeutic touch can be conceptualized within the framework of Rogers' (1970) Science of Unitary Human Beings. The principles of integrality, resonancy, and helicy were utilized to describe the constant energy exchange occurring between the human being and environmental fields, and represented the nurse and infant in this study. The principles also explained the process of energy exchange during therapeutic touch and the potential impact on the infant's pain responses. The process of therapeutic touch was explained according to the Krieger/Kunz method, which consists of five phases (Krieger, 1993). The proposed study investigated the modality as a prophylactic intervention used to decrease the pain response in term infants receiving multiple immunization injections.

Historical information regarding the rationale why children go "under-treated" during times of painful stimuli was discussed. Pain in infants was explored identifying both the physiological and behavioral indicators. Various pain assessment tools were analyzed, with the acceptance of newest valid PAIN scale to be utilized in the current study.
CHAPTER III

Method

This chapter describes the research study design, which was quasi-experimental, and the process utilized to assign participants to either the treatment or the control group. The subjects in the study, type of immunizations administered, and the number of injections received are discussed. The materials utilized to collect the data, which consisted of several different forms created specifically for this study, are explained. Threats to internal and external validity are considered. A discussion of the method utilized for analyzing the data is provided, followed by the chapter summary.

Design

The design selected was quasi-experimental. Participants were randomly assigned. Data were collected from the PAIN scale (Appendix A), which scored the infant’s behavioral and physiological responses to pain. These post-test measurements were utilized to statistically compare PAIN scores between the treatment and control groups.

Subjects

The population of interest was infants who attended the health department immunization clinic and whose legally authorized representative, referred to as caregiver throughout the study, was willing to allow participation. Subjects for this study were recruited using convenience sampling from the population cared for in a small community health department from the fall of 2003 to the fall 2004. The sample included
infants of 38 weeks gestation age or older, who met criteria for immunization injections of the (DTaP), used to prevent diptheria-tetanus-pertussis, Comvax, a combination of the Hib (hemophilus) and Hepatitis B vaccines, and IPV, which is an inactivated virus used to prevent poliomyelitis, and were between 1 ¾ months to 4 months of age. Eligibility was determined by the caregiver filling out two forms, one for the purposes of this study and one for the health department, asking about the infant’s current health status (Appendices B and C). Both forms also screened for any previous immunization complications or contraindications to receiving the injections and if none were found than the infant became a candidate for the study (Appendices B and C).

The target sample size was 20 infants with an end result of 17 participating. Participation in this study required a brief meeting with the caregiver and the researcher. After the consent form (Appendix D) was reviewed and permission was granted, the infants were randomly assigned to either the treatment group or the control group. The experimental intervention consisted of administrating therapeutic touch according to the Krieger/Kunz method prior to immunization injections. The control group did not receive the intervention.

The immunization vaccines injected varied (Table 1); 13 of the infants received three injections which included the (DTaP), Comvax (Hib and Hepatitis B combination), and (IPV). Two of the infants received four injections which encompassed the three previously mentioned plus Prevnar, which prevents against infections caused by *Streptococcus pneumoniae* that can lead to meningitis, blood, and ear infections. The remaining 2 infants received two injections which consisted of the Hib and Pediarix, which is the latest combination vaccine that combines the immunizations for DTaP,
Hepatitis B, and IPV. These are the recommended immunizations for the 2-month-old pediatric population, according to the Advisory Committee on Immunization Practices, American Academy of Pediatrics, and American Academy of Family Physicians (London, Ladewig, Ball, & Bindler, 2003). Although, the individual dose amounts of the vaccines remained constant, the total volume injected varied depending upon which combination of immunizations the infant received.

Table 1

Pain Assessment in Neonates (PAIN) Scores for Participants (n=17)

<table>
<thead>
<tr>
<th>ID #</th>
<th>Control PAIN Score</th>
<th>TT PAIN Score</th>
<th># Injections</th>
<th>Acetaminophen</th>
</tr>
</thead>
<tbody>
<tr>
<td>001</td>
<td>9</td>
<td>4</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>002</td>
<td></td>
<td>7</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>003</td>
<td>6</td>
<td>3</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>004</td>
<td></td>
<td>7</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>005</td>
<td>8</td>
<td>3</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>006</td>
<td></td>
<td>7</td>
<td>Yes</td>
<td></td>
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<tr>
<td>007</td>
<td>5</td>
<td>3</td>
<td>No</td>
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<tr>
<td>008</td>
<td></td>
<td>9</td>
<td>No</td>
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<tr>
<td>009</td>
<td>8</td>
<td>3</td>
<td>No</td>
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<tr>
<td>010</td>
<td></td>
<td>9</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>011</td>
<td>7</td>
<td>3</td>
<td>No</td>
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<tr>
<td>012</td>
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<td>1</td>
<td>No</td>
<td></td>
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<td>013</td>
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<tr>
<td>014</td>
<td></td>
<td>9</td>
<td>Yes</td>
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<tr>
<td>015</td>
<td>8</td>
<td>3</td>
<td>No</td>
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<tr>
<td>016</td>
<td></td>
<td>9</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>017</td>
<td>7</td>
<td>3</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

Mean: 7.2
SD: 1.20

Note. For sample totals, differences between PAIN scores between the control and therapeutic touch groups were not significant (p = .75).
Materials

Prior to data collection, caregivers were approached regarding participation in the study. After the study was explained, the consent forms, which were developed and approved using the guidelines provided by the Institutional Review Board at Medical College of Ohio (Appendix D), were presented and described in detail.

Demographic data was collected on a survey form, which was developed by the researcher (Appendix B). The caregiver accompanying the child to the clinic completed the form. Information included in the survey consisted of age, gender, gestational age at birth, socioeconomic status, the relationship of the caregiver to the infant, how the infant responded to any previous injections, infant’s health history, and if there were any symptoms of illness that day.

Data were collected from the data-collection sheet – observer (Appendix A), which utilized the PAIN scale to score the infant’s pain responses based on seven criteria: 1) heart rate, 2) oxygen saturation levels, 3) facial expression, 4) cry, 5) breathing pattern, 6) extremity movement, and 7) state of arousal (Hudson-Barr et. al., 1995). The rationale for monitoring heart rate and oxygen saturation was based on the premise that therapeutic touch is believed to produce a relaxation response (Krieger, 1979), which is represented by decreased heart and respiratory rates, and increased oxygen saturation levels (Benson, 2000). The PAIN scale was scored by an observer who was blind to group affiliation. Several correlation designs have been utilized comparing the PAIN scale to the CRIES (Hudson-Barr, 1995) and NIPS (Hudson-Barr et. al., 2002) and a significant association between the scores were presented, thereby validating the newer scale chosen for this study.
Data Collection

The data collection site was a health department immunization clinic in a small, mideastern rural town. Random sampling was utilized in the study. The first infant was assigned to the control group and given the number one, and then every other infant who continued to be assigned an odd number was appointed to the control group. Assignment of subjects to the treatment group consisted of those infants’ assigned even numbers. Tracking of assigned groups was accomplished through identification numbers, in order to protect patient confidentiality. The assigned identification numbers were recorded on the consent form (Appendix), demographic data form (Appendix B), and data collection sheets (Appendices). The identification number was not recorded on the PAIN assessment form (Appendix) until after the infant’s pain responses were scored in order to prevent the observer, who was one of the two registered nurses who administered the injections, from identifying which infants served in the control or the treatment group.

Procedures for protection of human rights included submission of the proposal for the study to the Institutional Review Board at the Medical College of Ohio, as well as an institutional review conducted by the health department (Appendix).

The researcher in this study was a registered nurse who had been trained in therapeutic touch and had practiced the modality for a period of 1 year. For this study, the researcher administered the treatment of therapeutic touch and could potentially pose a bias threat to the research outcomes (Peters, 1999). Although, discussion pertaining to the researcher performing the intervention and the possible attachment to the outcomes was debated in the Winstead-Fry and Kejik (1999) article, and the authors also reported that when this is the case the hypotheses are just as likely to be refuted as to be accepted.
To counteract the threat in the current study, a blind observer, who was one of the two nurses who gave the injections, and who had no prior experience with therapeutic touch, scored the PAIN scale. After the injections were given, the observer's task was to obtain an infant pain response score by utilizing the PAIN scale, which meant circling a numerical value based on heart rate and oxygen saturation, along with behavioral states (i.e., facial expression, cry, breathing pattern, extremity movement and state of arousal). The summation of the numerical values displayed the PAIN score.

In this study, there were several reasons for not using a mimic therapeutic touch intervention on the control group. Fedoruk (1984) found that the mimic intervention increased the infants' state of arousal and produced an active effect on the infant. One possible explanation for this occurrence may be that the nurses performing the mimic intervention had higher levels of anxiety from feeling uncomfortable and fearful about making a mistake during the intervention. Meehan (1993) found that the nurses providing the mimic intervention to their clients felt anxious and guilty administering the “fake” intervention to those who needed pain relief. Therefore, the choice of using a mimic intervention was discredited in this study.

When the infants and their caregivers arrived at the immunization clinic for the injections, the infants were assessed for any allergies, recent illnesses, and appropriate ages for immunization, according to the clinic protocol (Appendix). Excluding factors for the study were ages younger than 7 weeks and older than 4 months, gestational ages less 38 weeks or greater than 42 weeks at birth, if the infant was not accompanied by the caregiver, if the infant had responded adversely to previous injections, did not have a good health history, or had symptoms of illness that day.
After the caregiver registered the infant and had initial contact with a staff member at the clinic, the researcher approached the caregiver and was responsible for describing the purpose and procedure of the study, the concept of therapeutic touch, and how the infant would be assigned. Time was given to provide an opportunity to ask questions, and then if there was an acceptance to participate the consent form (Appendix) was completed. A signed copy of the consent form was given to the caregiver for the child’s records.

Next, the caregiver was asked to fill out the demographic data form (Appendix B) and group assignment was completed. As mentioned earlier, group assignment was determined based on whether the infant was given an even number or an odd number. An even number placed the child in the treatment group, which received the therapeutic touch intervention. Infants who were assigned an odd number did not receive the therapeutic touch intervention.

The caregiver remained in the room with the infant for both the therapeutic touch and the control groups. At the beginning of the session, the caregiver was instructed not to talk about whether the infant received therapeutic touch or not to the clinic nurses, in order to keep the observer blind to the group of the infant.

The infant was either held by the caregiver or remained in a car seat for both the therapeutic touch and the control interventions and a pulse oximetry machine was attached to the infant’s foot measuring the percentage of oxygenation saturation and heart rate. Pre-treatment information, such as heart rate, pulse oximter reading, and state, were recorded (Appendix).
Infants in the treatment group received therapeutic touch utilizing the Krieger/Kunz method. This included the five phases consisting of centering with intention, assessing, unruffling, and directing/modulating, and evaluating the infant’s energy field. During the entire treatment, attention was focused on the infant’s energy field in order to identify cues, which was an important component of each phase. Time limitations were not placed on the intervention, and ranged anywhere from 5 to 15 minutes, which was constant with Krieger’s (1997) beliefs that the nurse needs to recognize the infant’s cues and proceed in the correct manner. The treatment of therapeutic touch in this study was administered for a prophylactic purpose, which is similar to Krieger’s idea of utilizing the treatment as "preventive(ly) before an operation...gently vitalizing the healee's energy field" ( p. 69). At the end of the session, the caregiver was asked for a second time not to reveal to the nurses at the clinic whether the infant received therapeutic touch or not. Post-treatment information, such as heart rate, pulse oximeter reading, and state, were recorded (Appendix).

Infants in the control group did not receive therapeutic touch. As with the treatment group, at the beginning of the session, the caregiver was asked not to reveal to the clinic nurses whether or not the infant received therapeutic touch. As with the control group, the pulse oximeter machine was attached to the infant’s foot measuring the percentage of oxygenation saturation and heart rate. Information such as heart rate, pulse oximeter reading, and state, were recorded. The researcher utilized the session time to discuss any growth and developmental concerns that the caregiver may have had. It was decided to include this discussion session with the caregivers of the infants who were not receiving the treatment prior to the injections to help fill in the time and conceal to the
observer who belonged to the treatment or the control group. Again, at the end of the session the caregiver was asked to not reveal to the clinic nurses if the infant received therapeutic touch.

After administration of the therapeutic touch intervention or discussion period, the researcher notified the nurses to let them know the infant was ready for immunization injections. Next, the caregiver and the infant entered another room where the two registered nurses, with one of the nurses functioning as the observer, gave the injections. The injections were given utilizing the same technique by two registered nurses. All injections were administered intramuscularly into the quadriceps muscle utilizing a 25-gauge needle, at a 90 degree angle, with aspiration before the injection of medication.

The injections were given in a manner that the DTaP injection was solely administered in one leg and the administration of the other injections were in the opposite leg. The number of injections, and therefore amounts of medication injected, did not remain constant for all subjects, but rather 4 of the infants received a different combination of immunizations. Two out of the 4 received the Hib and Pediariix (which is the latest combination vaccine that combines the vaccines for DTaP, Hepatitis B, and IPV, requiring two injections. The other 2 out of the 4 infants received Prevnar, which is an additional vaccine that fights against a pneumococcal disease that can be life-threatening; therefore, these infants received a total of 4 injections.

The nurses administering the injections were not aware of which infants received therapeutic touch and which did not. After 30 seconds, as instructed when using the PAIN scale (Appendix), the infant’s pain responses were scored (Hudson-Barr et. al.,
The pulse oximeter that had been attached to the infant’s foot revealed oxygen saturation levels and heart rates. Heart rates also were evaluated utilizing a stethoscope by the registered nurse who was the observer. After the infant left the room the observer handed the PAIN scale form to the researcher. The researcher put the participant’s identification number on the top of the form and filed it with the rest of the infant’s information.

The conduction of the study did not disrupt the usual routine of the health department immunization clinic. It is routine protocol that the children who receive immunization injections at the clinic do not receive prophylactic measures to decrease the pain experienced from the injections, although after the injections are given the nurses asked the caregivers if they had acetaminophen at home to give to the infant, and if not it was provided by the clinic. The caregiver also was instructed to give acetaminophen prior to coming to the clinic for the next set of immunization injections.

Discussion of Potential Threats to Validity

When the study was being constructed careful consideration to threats of internal and external validity were examined. Burns and Grove (2001) offered guidance with controlling both internal and external validity, and a discussion pertaining to these areas will be discussed.

Subjects who choose not to participate were asked the reasons why, as suggested by Burns and Grove (2001). Two caregivers decided not to have their infants entered in the study. One reason was a time factor where the caregiver did not have the time available to participate due to other commitments or responsibilities, such as caring for
their other children who came to the clinic that day. Another reason for non-participation was that the researcher was not fluent in Spanish and the caregivers spoke Spanish only.

In the beginning, control for applicable threats to internal validity was attempted by obtaining adequate and accurate collection of data pertaining to gestational age, current age, previous experience with injections, health history, and health state that day. While the researcher was performing therapeutic touch, the caregiver provided additional demographic information that listed gender, the identification of the caregiver, and the annual household income (optional), which could have an overall impact on the growth and development of the infant and affect how the infant responds to painful stimuli.

During this time of data collection a confounding threat to internal validity became apparent. The researcher discovered that some of the subjects in the sample received acetaminophen prior to coming to the clinic.

Threats of external validity, as outlined by Burns and Grove (2001), were addressed. The first threat involved a limitation of the sample to persons who would always participate in a study when the general population may otherwise decline for some reason. One approach for controlling this threat suggested limiting the time investment for participating in order to increase the variety of population participation. This posed a challenge since much criticism has surfaced regarding time limitations on the intervention of therapeutic touch (Peter, 1999; Winstead-Fry & Kejik, 1999). In fact, in many studies the practitioner was not permitted to perform the entire intervention. Time limitations on performing therapeutic touch intervention can affect the results due to the inability to perform all the phases. In order to promote the most favorable outcome from receiving the treatment, for this study, there were no time limitations placed on the
therapeutic touch intervention and was left up to the discretion of the nurse. The researcher explained to the caregiver that the time involved with participation in the study could range anywhere from 10 to 20 minutes.

The second threat to external validity involved the setting and treatment at the time of the study. Burns and Grove (2001) suggested that the bias of the institution hosting the study must be considered. This could affect access to subjects for participation, as well as subtle messages they may receive as they participate in the process of the study. Every attempt was made to evaluate the institution's biases towards research during the Institutional Review process. There was never an unreceptive impression made or feeling of imposition sensed in the health department environment, but rather encouragement and eager willingness to assist. In addition, the researcher worked closely with the staff to determine the best way to set up the mechanics of the study in order to offer the least amount of interference with the day-to-day operations of the immunization clinic. This was accomplished by the researcher observing the flow of clinic activities prior to initiating the research study. Periodically, the researcher and the nurses at the clinic reviewed the impact of the study on clinic activities and adjustments were made accordingly.

The third and final threat to validity involved historical and societal factors at the time of the study, including societal attitudes and trends regarding the use of complementary therapies. Although the researcher was unable to have control over these factors, careful collection of the details of the population demographics was performed in order to facilitate future utilization if needed.
Data Analysis

Data analysis was directed at addressing the research question: was there a difference in PAIN scores between the infants who received therapeutic touch and the infants who did not? A t-test was completed providing a comparison between the treatment and control group PAIN scores, as well as a paired t-test looking at pre- and post-treatment heart rates and oxygenation saturation levels.

In addition to the statistical information, data from the anecdotal notes were gathered and investigated giving rise to a qualitative component to the study, which will be further discussed in the following chapters.

Summary

This study utilized a quasi-experimental design. The sample was drawn from full-term infants with ages ranging from 1 ¾ months to 4 months, who attended a rural northwest Ohio community health department immunization clinic. The study included infants receiving the recommended 2-month immunization injections, and was accompanied by a caregiver with the legal authority to give consent for participation. A detailed explanation of how the study was conducted was provided. Data were gathered by collecting the PAIN scores for both the treatment and control groups. An analysis utilizing a t-test was run providing a comparison between the groups. In addition, a qualitative component was incorporated into the study identifying other infant responses to the treatment of therapeutic touch, which could not be addressed on the PAIN scale.
CHAPTER IV

Results

This chapter describes the characteristics of the sample, and provides demographic and socioeconomic information. The performance of therapeutic touch and time parameters are discussed. Types of statistical analyses along with finding are presented with respect to gender, administration of acetaminophen, PAIN scores, heart rates, oxygenation saturation levels, and the number of injections received. Findings from the anecdotal reports are covered.

Sample

The sample size for this study consisted of 17 participants (Table 1). Eight (47%) of the subjects were in the treatment group and received the therapeutic touch. Nine (53%) of the subjects were in the control group and did not receive therapeutic touch.

Demographic information collected included the current age of the infant, gender, gestational age, identification of the adult accompanying the subject, previous responses to injections, infant’s health history, and any present symptoms of illness (Appendix B). The mean age of the subjects was 2.2 months, with a minimum age of 1¾ months and a maximum age of 4 months. Six (35%) of the subjects were boys, and 11 (65%) were girls. The mean gestational age was 39 weeks, with a minimum age of 38 weeks and a maximum age of 42 weeks at birth. Most of the infants were accompanied by their mothers; one was accompanied by a father. A majority of the infants’ health histories were described as either good or healthy, with the exception of two. One infant had a history of constipation problems and the other had a previous upper respiratory infection. Neither of these histories were reasons to exclude the infants from participation. Fifteen
(89%) of the infants presented with no current symptoms of illness, while 2 (11%) exhibited a runny or stuffy nose, which are mild symptoms allowing the administration of the immunizations to still be given and did not exclude them from participation in the study.

Socioeconomic status information was optional and 13 (78%) of the caregivers choose not to answer the question. Reported socioeconomic status information regarding income included: 1 (5.5%) in $12,000-$20,000, 1 (5.5%) in $20,000-$35,000, and 2 (11%) in $35,000-$60,000 (n = 4).

In the current study, therapeutic touch was performed until infant cues indicated that treatment should stop. Some examples of the cues included a smooth flow of energy, cessation of obstructive indicators, such as heat in the infant’s field, or the infant appearing to be in a relaxed state, displaying quietness, calmness, decreased heart rate, as well as increased oxygen saturation levels, revealed from the readings displayed on the pulse oximeter. Administration times ranged from 10 minutes to 15 minutes. The amount of time spent with the control subjects mirrored the treatment group in order to conceal who actually received therapeutic touch and who did not. During this time with the control group, the researcher covered normal developmental milestones for the infant’s particular age, and answered any questions that the caregiver may have had.

Findings

Key variables were explored for the 17 cases using descriptive statistics. This included frequency distributions and the range of scores. The PAIN scores were analyzed to determine whether infants responded differently to pain following therapeutic touch.
A t-test was run comparing the differences of PAIN scores and gender with no statistical significance found (p = .75). Another t-test was calculated to determine if there was a difference in PAIN scores between the infants who received acetaminophen (n = 7) and the infants who did not (n = 10) with no statistical significance found (p = .22).

Scores on the seven individual items of the PAIN scale ranged from 0 to 2, with a composite score of 0 indicating no pain and 10 indicating the most pain, therefore, theoretically the higher the PAIN score the higher the intensity of pain. The mean value of PAIN scores for the treatment group (TT) was 7.1 (SD = 2.57, range = 1 – 9). The mean value of PAIN scores for the control group (no TT) was 7.2 (SD = 1.20, range = 5 – 9). The results of the completed t-test indicated that the differences in PAIN scores between the treatment and the control groups were not statistically significant (p = 0.91), providing the answer to the research question posed in chapter one (Table 1).

Although, there was not a statistical significance in the PAIN scores, there were statistical significances found in the pre- and post-treatment group heart rates (p = .01), oxygenation saturation levels (p = .04), and number of injections received (p = .05). Mean heart rate values were 130 beats per minute (SD = 20.17) for the pre-treatment group and 120 beats per minutes (SD = 18.20) for the post-treatment group. Mean oxygenation saturation levels were 94% (SD = 2.34) for the pre-treatment group and 96% (SD = 1.95) for the post-treatment group. The mean number of injections for the treatment group was 2.8 (SD = .46, range = 2 – 3) and for the control group was 3.2 (SD = .44, range = 3 – 4).
Anecdotal recordings that were completed before and after therapeutic touch displayed a variety of behavioral changes in many of the infants. Three of the infants, who were active with moving their extremities, seemed to enter an alert, but quiet state of relaxation. Three different infants, who were calm initially, became visually fixated, with eyes wide open, intently following the practitioner’s hands. One of the infants mentioned above began to making cooing noises within minutes of beginning the treatment. In addition to the above infants, 3 were sleeping prior to the treatment and remained as such throughout the process. Seven of the infants presented in a calm state and continued to display this behavior post-treatment. One infant, who was exceptionally alert and active before treatment, sustained that state. In addition to observing the infants’ behaviors, there were subjective reports given by the caregivers, which were experienced during therapeutic touch, such as feeling sensations of warmth coming from the hands of the practitioner and pleasure from seeing their infant respond in a calm, quiet manner.

**Summary**

This chapter described the sample by listing both similar and unique characteristics of the participants. Additional information such as socioeconomic status was discussed, but had no direct effect upon the study. The performance of therapeutic touch and the amount of time spent with the infant was examined. An explanation was provided stating that there were no time restraints posed on the administration of therapeutic touch and that the time frames varied from 10 to 15 minutes according to the infant’s responses and cues during the treatment. Findings from analysis of the data comparing gender and PAIN scores, administration of acetaminophen and PAIN scores, and PAIN scores between the treatment group and control group, resulted in no statistical
significances. Whereas, findings from the analysis of the data comparing pre- and post-
treatment group heart rates and oxygenation saturation levels resulted in statistical
significances indicating therapeutic had an impact on these physiological factors. In
addition, there was statistical significance found in the number of injections received,
indicating that overall, the control group sustained a greater number of injections than the
treatment group.
CHAPTER V

Discussion

This chapter includes pertinent information on findings regarding the effects of therapeutic touch on infant pain responses and explanations of why such findings arose in relation to Rogers’ theory of energy balancing and relative literature. Several perplexing discoveries are discussed surrounding the administration of acetaminophen and number of injections, within both the treatment and control groups, and the unexplainable impact on the PAIN scores. Limitations are identified and include: sample size, time restraints, developmental stage of infants, role of the researcher in the study, problems with the PAIN scale and equipment utilized for scoring, administration of acetaminophen prior to coming to the clinic, differences in the number of injections given, and the unknowns pertaining to therapeutic touch. Clinical significance in assessing and addressing pain experienced by infants and the implications for nursing practice in regard to the moral and ethical responsibilities, when considering the physiological and psychological effects of pain on quality of life, are discussed. In addition, recommendations and suggestions for further research are proposed, followed by a conclusion, and a chapter summary.

Findings

The purpose of the research study was to explore whether the administration of therapeutic touch decreased pain experienced by the infant, as evidenced by lower PAIN scores. This was to be achieved by administering therapeutic touch to balance the infant’s energy field allowing the infant’s body to employ the energy in a manner that would facilitate effective coping when receiving the injections. The nurse performed therapeutic touch with intent to not only balance the infant’s energy field, but also to
focus specifically on treating the vastus lateralis aspects of the thigh where the injections were given. The theory of Rogers’ Science of Unitary Human Beings offers an explanation to the dynamic process that occurs during the administration of therapeutic touch. The theory describes energy fields as the fundamental units of humans and their environment. In this study, the nurse and infant represented the unitary human beings that existed in a state where energy was continually being exchanged within and between the two, as well as their relative environment. The process of constant energy exchange with the environment is referred to as the principle of integrality. Meehan (1993) utilizes this principle to explain how the nurse can tap into the energy field of the infant since both exist as open systems.

Rogers’ termed the transferring of energy from lower frequencies to higher frequencies as resonancy and this describes the dynamics taking place during the therapeutic touch treatment, where energy was transferred from the nurse to the infant. Within Rogers’ theory, the principle of helicy represents the innovative and unpredictable outcome that can occur as a result of energy exchange between the unitary human being and the environment, and in this study, between the nurse and the infant. This outcome in the study was measured utilizing the PAIN scale that assessed the infant’s pain responses. The individual scales were totaled and scores between the treatment group and control group were compared.

Analysis of the data pertaining to whether therapeutic touch decreased the infant’s pain responses following injections was not statistically significant. Despite the lack of statistical significance to support lower pain levels related to the administration of therapeutic touch, there were statistical significances found with pre- and post-treatment
heart rates and oxygenation saturation levels, as well as essential qualitative anecdotal findings, which are discussed under conclusions.

In addition, there were several findings that remain unexplainable. For example, 4 out of 8 infants in the treatment group scored a 9 on the PAIN scale, whereas 1 out of 9 infants in the control group scored a 9 on the PAIN scale, which indicated a greater level of pain experienced by the infants who received therapeutic touch. Ironically, 5 out of the 8 infants in the treatment group were given acetaminophen approximately 1 hour prior to coming to the clinic, yet 3 out of the 5 scored a 9, and 2 scored a 7 on the PAIN scale. These findings resulted in no statistical significance found between the administration of acetaminophen and PAIN scores, indicating the use of the medication as a prophylactic analgesic was ineffective. This finding could have an impact upon the current recommendations given to caregivers to administer the medication prior to coming to the immunization clinic and warrants further research regarding the effects of acetaminophen on pain responses to injections.

Another perplexing finding regarding the number of injections administered was discovered. An analysis of the data displayed a statistical significance between the numbers of injections given to the treatment group versus the control group. The outcome showed that the treatment group received fewer injections when compared to the control group, yet there were no differences noted in PAIN scores. In fact, two out of the four scores in the treatment group that totaled a 9 received only two injections, as well as acetaminophen. Therefore, further research regarding the effects of the number of injections on infant pain responses is recommended.
Limitations

There are numerous limitations to the study that were identified. Such limitations included sample size, time restraints, developmental stage of infants, role of the researcher in the study, problems with the PAIN scale and equipment utilized for scoring, administration of acetaminophen prior to coming to the clinic, differences in the number of injections given, and the unknowns pertaining to therapeutic touch. Discussion of each follows.

The first limitation pertained to the small size of the sample that was affected by the limited infant population served by the immunization clinic and lack of additional time on the researcher’s part. An additional factor contributing to the small size of the sample, by further narrowing the number of infants who could participate in the study, included an age limitation, which ranged from 2-4 months. The age limitation was necessary to control for extraneous variables, such as altered pain responses related to physiological development and previous injection exposure which could give a classical conditioning response. Therefore, the combination of the limited number of infants seen at the clinic, a lack of additional time of the researcher, and the age limits, led to a small sample size and ultimately may have affected the results of the statistical analysis. It is often recommended that the statistical power be evaluated prior to determining sample size, but Burns and Grove (1997) proposed that a smaller sample size may be utilized for the purposes of a pilot study, which is what the current study may serve as, considering that there are a limited number of research studies done on the use of therapeutic touch as a prophylactic pain reduction intervention.
The second limitation dealt with the developmental language level of the infant, or rather thereof. At this particular level of development infants are pre-verbal, meaning they lack the ability to verbalize their experience of pain and associated feelings. Due to this limitation, researchers, clinicians, and caregivers must rely on the infant’s behavioral and physiological indicators of pain. These cues are currently in an explorative state.

A third limitation and a key difference in this study when compared to the general model of control intervention was the performance of both the treatment and control interventions by the researcher. There were several reasons for the decision that the researcher would perform both interventions for this study. The time commitment required was too expensive to make the recruitment and reimbursement of another team member feasible. This study required over 1 year to complete in order to reach the participant number of 17 due to the limited population of infants falling into the appropriate age category served by the clinic.

A fourth limitation which may have affected the results of the data analysis, surrounded the choice of the pain scale. The scale utilized in this study was the Pain Assessment in Neonates (PAIN) which was the newest developed tool that combined the CRIES with the NIPS pain scales (Hudson et. al., 2002). This scale was developed for assessing pain in neonates, from birth up through 4 weeks of age, and who are in the post-operative phase. The infants in this study were older than the neonatal period and experienced procedural pain versus post-operative pain. However, due to the limited number of infant pain scales available, and having knowledge that the PAIN scale was the most recent tool developed based reliable and valid indicators of pain, it was determined that this scale would provide adequate information for the purposes of this
study since a comparison of pain responses between the two groups was the focus. The observer found the PAIN to be easy to utilize when assessing the infants’ responses as outlined by the criteria of the scale. Scoring of the PAIN scale was straightforward and efficient, but restrictions existed due to the limited scoring choices for the behavioral descriptors (i.e., facial expression, cry, breathing pattern, extremity movement, and state of arousal). Most of the descriptors gave only two choices for scoring. For example, the facial expression category choices were relaxed or grimace with no inbetween expressions identified, such as eye brow and lip corner positions. A second example was the extremity movement category choices which were relaxed/restrained or flexed/extended with no inbetween movements identified. Due to these limited parameters, description of the more subtle indicators was not documented.

Yet another concern pertaining to scoring with the PAIN scale was the particular physiological indicator of oxygen requirement for saturations greater than 95%. As mentioned earlier, the scale was meant to be used post-operatively, and none of the infants in the study required oxygen; therefore, each participant received an individual score of 0 for that indicator, meaning there was no need for oxygen administration.

As developed, the PAIN was not sensitive to the more specific aspects of the infant’s behavioral and physiological responses. Perhaps a more expressive scale would prove to be most accurate in determining the effects of therapeutic touch on infants.

A fifth limitation stemmed from a potential problem with the use of the medical equipment employed in the study, which was the pulse oximeter machine. Pulse oximetry is a quick, noninvasive tool used for measuring oxygen saturation levels in the blood and can be obtained by applying the probe with the sensor to a body part, like the earlobe,
finger, toe, or foot of an infant. The particular probe, due to the large size (adult), posed challenges with maintaining accurate placement on the infant’s foot, and some optical shunting may have occurred allowing light to get to the sensor. Likewise, the sensitivity of the machine to movement created yet another challenge. A snug fitting sock was applied over the foot of the infant covering the entire probe, but this was not always enough to maintain proper positioning of the probe. These types of occurrences with pulse oximetry equipment can result in false oxygenation readings (Bohnhorst, Peter, & Poets, 2002).

A sixth limitation included the administration of acetaminophen to a portion of infants by the caregivers before coming to the clinic, which the researcher was unaware of until after the treatment or control intervention was completed. In fact, 7 (40%) of the infants had the medication within 1 hour of arriving to the clinic, and of those 7 infants, 5 (39%) received the treatment (with PAIN scores = 7, 7, 9, 9, and 2), and 2 (11%) served in the control group (with PAIN scores = 6 and 7). In comparing the infants who received the medications to the treatment and control groups, neither group had significantly lower PAIN scores. Since administration of acetaminophen can be such a confounding variable, it would be beneficial to repeat this study screening for this prior to allowing participation.

A seventh limitation dealt with the number of injections received, which did not remain constant for all the infants in the study. Two (11%) of 17 infants received 2 injections, and two (11%) others received four injections, the remaining 13 (78%) received three injections.
An eighth limitation encompassed issues related to therapeutic touch and is for the most part related to the unknown. As stated by Gerber (2000), it is not known how therapeutic touch affects physiological processes or to what degree. This concept has led to a guessing which physiological parameters to assess, or which combination of parameters should be analyzed concurrently. There are no specific instruments available that measure the physiological effects of therapeutic touch. As previously stated, the effects tend to be more generalized. On the other hand, there is not enough research to know if the effects of therapeutic touch may be illness specific, since it is common practice for the practitioner to intend for the body to take the energy and use it as needed, having no intentional connection to a specific result.

*Implications*

Although analysis of the data did not support the use of therapeutic touch as a pain preventative intervention for injections, it should be noted that potential positive effects of the treatment remain unexplored, such as decreased fevers and levels of soreness, increased peripheral circulation and amount of sleep, and decreased length of time to return to a calm state. These effects are further discussed under recommendations for further research, which follows this section.

For practicing nurses who care for infants experiencing pain and increased vital signs, consideration of the statistical significance in the pre- and post-treatment group heart rates should not be over-looked. Therapeutic touch had a direct lowering effect on heart rates, and could lessen the cardiovascular stress that is exerted when pain is experienced.
Furthermore, at the time of the administration of therapeutic touch it was noted by the practitioner (i.e., nurse) that several of the infants’ oxygenation levels increased several percentages, with statistical results indicating a level of significance, as their movements decreased and they became more relaxed during the procedure. Anecdotal recordings show that some of infants seemed to enter an alert, but quiet state of relaxation with eyes wide open and intently following the hands of the practitioner. One male infant, who was extremely active before the treatment, flailing and moving his arms and legs, almost immediately became still and calm with initiation of therapeutic touch. Another male infant was so restlessness and active that the researcher was unable to obtain a pulse oximeter reading, but within minutes from when the treatment began, he calmed down to where a reading from the machine could be obtained. A female infant began to make cooing noises shortly after the intervention was started. Some of the caregivers reported feeling heat or warmth coming from the hands of the practitioner and were pleased by the calm, quiet reaction of their infant.

As discussed previously, therapeutic touch positively impacted several of the infants’ pain responses. These results may be clinically significant. The modality could be used to enhance the care of patients in the health care setting promoting physiological and psychological healing. Therapeutic touch does not require equipment or extensive amounts of time, and can be accomplished with the tools carried on our person – the hands. It can easily be incorporated into the time spent providing client care and can enhance the nurse’s therapeutic use of self by taking full advantage of the nurse-client interaction. An immeasurable benefit of therapeutic touch is the time spent with the client, which can facilitate the creation of a healing environment, provide opportunities to
build a trusting relationship, and reduce stress and anxiety (Hughes, Meize-Grochowski and Harris, 1996).

In the United States, the use of complementary modalities is increasing (Eisenberg et al., 1998). Many health institutions are recognizing the need to remain competitive and have begun to offer a variety of non-traditional interventions. In the community, therapeutic touch can be utilized by health departments such as the one employed in this study. The modality can be offered concurrently with other services provided to the individual or family, such as lead screenings, nutritional teachings, iron checks, immunizations, parenting classes, and early childhood screenings. The resources required to provide therapeutic touch include a private room and persons willing to attend a seminar to receive basic certification. Analysis of the architectural/environmental set up of the health department would indicate that there would be no problem allocating a room to provide the service due to the number of rooms available, as well as the variances of times and days when those rooms are currently being utilized.

Starn (1998) stated that hospitals in several states have begun to offer energy healing along with traditional western medical practices. Data show that there are increasing numbers of insurance companies and managed care organizations willing to cover alternative modality treatments. Not only is the financial gain through reimbursements attractive for the providing facilities, but also are the numerous health restorative benefits for the patient, such as pain relief, lowered blood pressure, relaxation, and increased healing time, to name a few. These are important factors to assess when considering the use of therapeutic touch as a nursing intervention. Perhaps the most appropriate place and time to teach the modality is during nursing school as it could
easily be incorporated into the curriculum when discussing alternative therapies. There are several implications for introducing therapeutic touch to schools of nursing and include the teaching and understanding of three basic concepts. They are as follows: 1) man is an energy field, 2) energy is continually being exchanged between man and the environment, and 3) there is some type of universal order that drives the force of energy (Boguslawski). Therapeutic touch should be taught utilizing the Krieger/Kunz method which is comprised of the five phases: 1) centering with intention, 2) assessment, 3) unruffling, 4) directing/modulating energy, and 5) evaluating. Lastly, as charting the effects of therapeutic touch can be challenging a universal terminology needs to be established and applied. Some suggestions would include having both the nurse and the client chart and use that data to establish continuity of communication (Boguslawski, 1979).

Recommendations for Further Research

Although the research data surrounding therapeutic touch are numerous, so are the questions regarding the potential benefits of utilizing the modality with infant populations. In this study, after several injections were given the infant’s immediate pain responses were observed, but there is additional longer term physiological and behavioral factors that need to be considered when analyzing the effects of therapeutic touch on immunization responses, therefore requiring further investigation and research.

Physiological factors that could be assessed include skin temperature and body core temperature. In the study by Kramer (1990) therapeutic touch was found to increase peripheral body temperature, which could increase circulation in that area. In regards to receiving immunizations, therapeutic touch could potentially assist the immune system
by enhancing the normal inflammatory response that occurs when there is an insult or break in the integumentary system, and facilitate a quicker healing process. Therefore, a research study on therapeutic touch and healing times after immunization injections could be explored. By measuring core body temperatures, Heidt (1981) found that hospitalized infants who received therapeutic touch experienced a reduction in fevers. Again, when applying this concept to infants receiving immunization injections, a pyrexic response is almost guaranteed, and most clinics recommend administering acetaminophen for this reaction. Perhaps if the infant received therapeutic touch, a non-pharmacological intervention, there would not be a need for the anti-pyretic medication.

Behavioral factors to consider are sleep and relaxed state. In a study by Heidt (1981) infants who received therapeutic touch had increased periods of restful sleep, and both Fedoruk (1984) and Kramer (1990) discovered that infants who were treated with therapeutic touch took less time to return to a calm state after a stressful experience. Research, pertaining to the subjects in this study, assessing the amount of sleep on the night following the injections and length of time required to return to a calm state after the receiving the injections may be significant.

The article by Snyder (1985) states the two most commonly observed benefits of therapeutic touch are general relaxation and pain relief. The use of therapeutic touch as either a pain relief intervention, in attempting to lessen the soreness often experienced after an injection, or a prophylactic measure, in trying to prevent discomfort, could be replicated with a population able to self-report their experience of pain, which may offer a clearer understanding of the effects of the intervention when used with the intention of preventing or lessening such the experiences.
In addition to furthering research regarding potential benefits of therapeutic touch in preventing or reducing pain in infants, consideration needs to be given toward the tools used to effectively measure such outcomes, which can be a challenge. A survey of the available literature on pain assessment tools, addressed in detail under the literature review in chapter two, for young infants, revealed that there is an adequate selection of pain assessment tools for the premature and neonatal populations, as well as those who are beginning to use verbal expressions of pain. However, the lack of valid and reliable assessment tools, measuring pain in infants no longer in the neonatal period, but still unable to self-report, represents another area of need, as demonstrated in this study.

According to Macrae (1979), infants and children are more sensitive to therapeutic touch treatments. Additional studies analyzing the effects of therapeutic touch on various ages of children would be helpful, by enhancing our understanding of the impact the treatment has on children. Another point to take into consideration, as suggested by Bugaslawski (1980), is that some subjects may not be open to or ready to accept the intervention at the level of the energy field. With this in mind, determining which client profile lends itself to therapeutic touch could be valuable information for future practitioners and researcher alike.

Conclusions

With regard to the research question, which explored the effect of therapeutic touch as a preventive pain measure, prior to immunization injections, the results were insignificant. Although, statistical significance was demonstrated in decreased heart rates and increased oxygenation saturation levels in the pre- and post-treatment group. These results are encouraging to the continued study of therapeutic touch, especially with
infants hospitalized for injuries, illnesses, or surgeries, where stress reduction and relaxation provoking measures could have a profound impact on healing or survival rates.

Profound factors that may have impacted the results included a small sample size, the pain assessment scale utilized, and the instrumentation available for measuring physiological indicators. The PAIN scale used to measure pain responses was not found to be sensitive enough to the subtle intricacies in the behavioral states which were demonstrated by the subjects. Additional observations made, but not included in the PAIN scale, were eyebrows bulging and furrowed, eyes squeezed shut, lips pursed together and a quivering chin. Also, intensity and pitch of the cry, along with length of time to return to a calm state, were not taken into consideration. Therefore, the use of a more sensitive pain assessment tool may have led to different results. Analysis of the data surrounding the use of the pulse oximetry instrument proposed problems with the external monitoring device, which can easily be affected by positioning, optical shunting, and movement of the foot.

A qualitative questionnaire or component assessing the effects of therapeutic touch prior to immunization injections on infant pain responses would have been useful for the purposes of further evaluating the impact of the treatment. Qualitative data may have been able to capture clinical changes and phenomena which could not be measured by the tools or instruments used. Several of these qualitative phenomena, previously discussed under implications, were reported by the staff and caregivers, observed by the researcher and demonstrated by the infant’s behavioral responses to therapeutic touch.

*Summary*
In summary, the investigation into the use of therapeutic touch as a preventive measure for infants receiving immunization injections yielded insignificant statistical results. However, there was a significant decrease of the infant’s heart rate and increase in oxygenation saturation levels. These findings were related to Rogers’ theory and relative literature. A number of perplexing discoveries were discussed pertaining to the administration of acetaminophen and number of injections, within both the treatment and control groups, and the unexplainable impact on the PAIN scores.

Limitations were outlined and consisted of: sample size, time restraints, developmental stage of infants, role of the researcher in the study, problems with the PAIN scale and equipment utilized for scoring, administration of acetaminophen prior to coming to the clinic, differences in the number of injections given, and the unknowns pertaining to therapeutic touch. Implication for nursing practicing in assessing and addressing pain experienced by infants and the implications for nursing practice in regard to the moral and ethical responsibilities, when considering the physiological and psychological effects of pain on quality of life, were discussed.

In addition, numerous recommendations for further research were proposed. The conclusion mentioned the encouraging qualitative effects of therapeutic touch, as evidenced by the observation of certain physical and behavioral indicators which were noticeable to the staff, caregiver, and researcher. The therapeutic touch intervention, in this particular study, did not interfere with the normal flow of client care and would potentially hold true for many other facilities, making it easy to implement as part of client care. Based on the additional findings identified by this study, regarding the effects of therapeutic touch on infants, a multitude of opportunities to promote
physiological and psychological health have yet to be discovered. As written by Heidt
(1981) “before the scientific era of health care, helping persons relied on their own
presence as a source of helping and/or healing” (p. 36). Health care has lost sight of the
value and importance of human contact, with an unquenchable thirst to discover new
drugs and advance in technology, when the act of giving therapeutic touch offers
restorative healing, simply through the power of human interaction.
REFERENCES


Butler, N. C. (1987). The ethical issues involved in the practice of surgery on


### Appendix A

**Data Collection Sheet – Observer**

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<th>Identification Number</th>
<th>Date</th>
<th>Time</th>
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<table>
<thead>
<tr>
<th>Leg:</th>
<th>R</th>
<th>L</th>
<th>Treatment or Control</th>
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<tbody>
<tr>
<td></td>
<td></td>
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(PAIN) Pain Assessment in Neonates Scale:

(Baseline Heart Rate: _________)

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<tr>
<td>Fussy</td>
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<table>
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<th>O2 required for sat &gt; 95%</th>
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<td></td>
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<tr>
<td>&lt; 30%</td>
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<tr>
<td>&gt; 30%</td>
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<td>HR within 11-20% of baseline</td>
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**PAIN Total Score (0-10)**
Appendix B

Demographic Data

Identification Number ________

Please answer the following questions about your infant to the best of your ability:

1. How old is your infant (months)? ________

2. Is your infant Male ______ Female ______

3. What was your infant's gestational age at birth? ________ weeks

4. Please check one to indicate your family's yearly income:
   ______ under $12,000              ______ $35,000-$60,000
   ______ $12,000-$20,000           ______ $60,000 & above
   ______ $20,000-$35,000

5. What is your relationship to this infant?
   Mother ______ Father ______ Guardian ______

6. Has your infant received a DTaP immunization before? Yes _____ No _____
   If yes, how did he/she respond? ______________________________

7. How does your infant usually respond to injections? ______________
   __________________________________________________________________

8. Please describe your infant's health history. _____________________
   __________________________________________________________________
   __________________________________________________________________
   __________________________________________________________________

9. Does your infant have any symptoms of illness today? Yes _____ No _____
   If yes, please describe. __________________________________________________________________
   __________________________________________________________________
Appendix C

Screening Form from Health Department

PLEASE COMPLETE THE FOLLOWING TO HELP US DETERMINE IF THERE IS ANY REASON YOU/YOUR CHILD SHOULD NOT BE IMMUNIZED TODAY? FAMILY DOCTOR

______________________________________________________________

IS THE PERSON RECEIVING THIS VACCINE : YES NO DON'T KNOW
1. ALLERGIC TO ANY MEDICINE, EGGS, GELATIN OR LATEX?
2. SICK WITH FEVER, VOMITING OR DIARRHEA?
3. TAKING ANY MEDICINES OTHER THAN VITAMINS OR IRON?
4. PREGNANT?
5. IN CLOSE CONTACT WITH A PREGNANT FEMALE WHO HAS NEVER HAD CHICKENPOX?
6. IN CLOSE CONTACT WITH AN INFANT WHOSE MOTHER HAS NEVER HAD CHICKENPOX?

DOES THE PERSON RECEIVING THIS VACCINE:
1. HAVE A CHRONIC ILLNESS OR BLOOD DISEASE?
2. HAVE A POOR RESISTANCE TO INFECTION DUE TO DISEASE OR MEDICATION?
   (I.E. ANTI-CANCER DRUGS: STEROIDS, CORTISONE OR X-RAY TREATMENT)

HAS THE PERSON RECEIVING THIS VACCINE:
1. EVER HAD A SERIOUS REACTION TO ANY VACCINE?
2. EVER HAD A CONVULSION, PARALYSIS, OR OTHER DISEASE OF THE NERVOUS SYSTEM?
3. RECEIVED ANY SHOTS IN THE PAST 3 MONTHS?
4. RECEIVED A TRANSFUSION OF BLOOD OR BLOOD PRODUCTS IN THE PAST 6 MONTHS?
5. RECEIVED A TB SKIN TEST IN THE PAST 3 MONTHS OR HAVE ACTIVE TB?
6. SEEN A PHYSICIAN WITHIN THE LAST YEAR?
   WHO AND FOR WHAT REASON? ___________________________ WHEN ______________________

I ACKNOWLEDGE THAT I RECEIVED A COPY OF THE NOTICE OF PRIVACY PRACTICE.

SIGNATURE ______________________________________ DATE ________________________

THIS RECORD CAN BE RELEASED UNTIL THE AGE OF 21 YEARS.
School of Nursing
Medical College of Ohio Collier Building
3015 Arlington Avenue Toledo, Ohio 43614-5803

Medical College of Ohio

Healing Begins with Knowledge

Principal Investigator: Jane C. Evans, Ph.D., R.N.

RESEARCH CONSENT FORM FOR PARENTAL INFORMED CONSENT

The effects of therapeutic touch on pain response in infants receiving vaccinations

What you should know about this research study:

• We give you this consent form so that you may read about the purpose, risks, and benefits of this research study. All information in this form will be communicated to you verbally by the research staff as well.

• Routine care is based upon the best known treatment and is provided within the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.

• We cannot promise that this research will benefit your child. Just like regular care, this research can have side effects that can be serious or minor.

• You have the right to refuse to allow your child to take part, or agree for your child to take part now and change your mind later.

• Whatever you decide, it will not affect your child’s regular care.

• Please review this consent form carefully. Ask any questions before you make a decision.

• Your choice to allow your child to participate is voluntary.

APPROVED BY MCO IRB
11/03/03 11/02/04
FROM ___ TO ___

Consent Form D Version Date 10/23/03
PURPOSE

You are being asked to allow your infant to take part in a research study of the effect of therapeutic touch on the pain your infant experiences when he/she gets an injection (shot). Therapeutic touch is based on the belief that human beings consist of energy fields and that a disruption of the energy fields can disturb the balance. For example, the immunization (shot) that your infant will receive can cause a disruption in your infant's energy fields. In this study, therapeutic touch will be used to maintain the subtle energy fields and create the healing that takes place, and in the case with your infant a decrease in your infant's pain responses. Therefore, the purpose of the study is to see if an infant who gets a therapeutic touch treatment feels less pain when given an injection and to gather information on the effects. This means looking at your infant's heart rate, oxygen in the blood (this is accomplished with a small device that attaches to your infant's foot with tape) and state (facial expressions, cry, breathing patterns and body movements). Your infant is being asked to join in this study because he/she is attending the Williams County Health Department at Montpelier, Ohio for immunization against DTaP (diphtheria-tetanus-pertussis). This study will include approximately 20 infants. The experimental treatment being studied is the use of therapeutic touch. The DTaP injection will be given to your infant attending this clinic whether or not you agree to allow him/her in this study.

PROCEDURES AND DURATION

If you decide to allow your infant to be part of this study, you and your infant will meet with the researcher for a therapeutic touch treatment. The researcher will meet with you and your infant for 10-20 minutes before the injection is given. At the beginning you will be asked to fill out a short form that asks you about your infant. Your infant will then be placed in either the experimental (therapeutic touch) or control (no therapeutic touch) group based upon your numerical status when you arrived at the health department. Your infant will also be hooked up to a monitor, which measures his/her heart rate and the amount of oxygen in his/her blood. Connection to this monitor should not cause your infant any discomfort. The heart rate and oxygen level in your infant's blood will be noted from the readings on the monitor several times during the study, both before and after therapeutic touch, and once after the injection.

Therapeutic touch is a healing method generally done by nurses. The steps of the procedure include assessment, unruffling, and directing/modulating of energy. During assessment, the researcher will move her hands 3 to 6 inches above your infant's body in a head to foot direction. The purpose of assessment is to read your infant's energy field to see if there any differences. This will tell the researcher what to do next. Unruffling looks like assessment but is done more quickly. It is useful for helping the infant to relax and smoothing out minor areas of extra energy found in the infant's field. Direction or modulation of energy happens when the researcher places her hands in specific spots 3 to 6 inches away from your infant's body to allow energy to transfer to the infant's field.

For this study, this step will be performed based on what is found during assessment and in the area where the injection will be given. After direction and modulation of energy there will be another assessment, and more unruffling motions until therapeutic touch is finished. After therapeutic touch is finished, your infant will be given his/her injection. The nurse who usually gives the DTaP injections will be giving your infant his/her injection. There will be one other nurse in the room with you. She will be watching your infant's reaction to the injection.

Therapeutic touch will be done on your infant one time during the study. If your infant does not receive therapeutic touch, a meeting between the researcher and you and your infant will be carried out in which discussion and questions regarding normal growth and development can take place. The effect on your infant is

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expected to be as if nothing was done, as in a usual injection. The purpose of the two types of groups is so that the observer and the nurse doing the injection will not know which infant gets the therapeutic touch treatment.

Please do not discuss the therapeutic touch treatment or non-treatment with the nurse giving the injection or the nurse watching your infant's reaction. You will be encouraged to hold your infant during the therapeutic touch session, but not during the injection.

RISKS AND DISCOMFORTS
There are no known risks of using therapeutic touch with children. It is usually found to be pleasant and relaxing. There may, however, be risks that are currently unforeseeable. There is always a slight risk of loss of confidentiality.

BENEFITS AND/OR COMPENSATION
Therapeutic touch usually makes people feel relaxed and calm. Your infant may show less of a pain response and may seem calmer after the injection has been given. We do not guarantee or promise that your infant will receive any benefits from this study. What is learned may possibly benefit other children in the future.

ALTERNATIVE PROCEDURES OR TREATMENTS
Therapeutic touch will not be substituted for any of the normal care given to your infant. There are no other treatments for children getting injections. Your infant will be treated the same by the clinic nurses whether or not he/she joins this research study.

CONFIDENTIALITY
By agreeing to take part in this research study, you give to the Medical College of Ohio, the Principal Investigator and all personnel associated with this research study your permission to use or disclose health information that can be identified with you that we obtain in connection with this study. We will use this information to determine if an infant who receives a therapeutic touch treatment prior to painful procedures feels less pain.

The information that we will use or disclose includes statistical data on infant heart rate, oxygen saturation levels and state which has been obtained by observing the response of infants 1 to 3 months of age receiving therapeutic touch treatments prior to immunization compared to data obtained on a control group of infants not receiving therapeutic touch treatments prior to immunization in an attempt to determine if an infant who receives a therapeutic touch treatment prior to painful procedures feels less pain.

We may use this information ourselves, or we may disclose or provide access to the information to the Williams County Health Department, Food and Drug Administration or other applicable governmental agencies for the purpose of safety, efficacy and compliance reports, the Medical College of Ohio as study sponsor and its designees for study oversight and monitoring, the Medical College of Ohio School of Nursing for data collection and study monitoring, statistician for analysis of data, etc. as part of the research study. Under some circumstances, the Institutional Review Board and Research and Grants Administration of the Medical College of Ohio may review your information for compliance audits.

APPROVED BY MCO IRB
FROM 11/03/03 TO 11/02/04

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The Medical College of Ohio is required by law to protect the privacy of your health information, and to use or disclose the information we obtain about you in connection with this research study only as authorized by you in this form. There is a possibility that the information we disclose may be re-disclosed by the persons we give it to, and no longer protected. However, we will encourage any person who receives your information from us to continue to protect and not re-disclose the information.

Your permission for us to use or disclose your personal health information as described in this section is voluntary. However, you will NOT be allowed to participate in the research study unless you give us your permission to use or disclose your personal health information by signing this document.

A more complete statement of Medical College of Ohio's Privacy Practices are set forth in its Joint Notice of Privacy Practice. If you have not already received this Notice, a member of the research team will provide this to you. If you have any further questions concerning privacy, you may contact the person identified in the Notice.

ADDITIONAL COSTS
There are no costs to you with joining this study.

PAYMENTS TO SUBJECTS
You will not be paid for allowing your infant to participate in this study.

FINANCIAL INCENTIVES FOR INVESTIGATORS
The investigator will not be paid for conducting this study.

IN THE EVENT OF A RESEARCH RELATED INJURY
In the event of injury resulting from your child's participation in this study, treatment can be obtained at Medical College Hospitals or Williams County Health Department. You should understand that the costs of such treatment would be your responsibility. Financial compensation is not available. By signing this form you are not giving up any of your legal rights as a research subject.

In the event of injury, contact Jane C. Evans, Ph.D., R.N., Principal Investigator, at (419) 383-5826.

VOLUNTARY PARTICIPATION
Participation in this study is voluntary. If you decide not to allow your infant to participate in this study, your decision will not affect you and your infant's future relations with the Medical College of Ohio, its personnel, and associated hospitals, and the Williams County Health Department or their personnel or affiliates. If you decide to allow your infant to participate, you and your infant are free to withdraw your consent and discontinue participation at any time without penalty. You may have a copy of this form if you wish.

APPROVED BY MCO IRB
Consent Form Version Date 10/23/03 FROM 11/03/03 TO 11/02/04
OFFER TO ANSWER QUESTIONS
Before you sign this form, please ask any questions on any aspect of this study that is unclear to you.

AUTHORIZATION
YOU ARE MAKING A DECISION WHETHER OR NOT TO ALLOW YOU AND YOUR INFANT TO PARTICIPATE IN THIS STUDY. YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTOOD THE INFORMATION PROVIDED ABOVE, HAVE HAD ALL YOUR QUESTIONS ANSWERED, AND HAVE DECIDED TO ALLOW YOUR INFANT TO PARTICIPATE.

The date you sign this consent form to enroll your infant in this study, that is, today's date, MUST fall between the dates indicated on the approval stamp affixed to each page. These dates indicate that this form is valid when you enroll your infant in the study but do not reflect how long your child may participate in the study. Each page of this Informed Consent Form is stamped to indicate the form's validity as approved by the MCO Institutional Review Board (IRB).

Name of Subject (please print) ___________________________________________

Name of parent or Subject’s Legally Authorized Representative (please print) Date
________________________________________________________________________

Signature of Parent or Subject's Legally Authorized Representative Time
________________________________________________________________________

Relationship to the Subject _____________________________________________

Mindy Manahan, R.N., B.S.N.
Name of Person Obtaining Informed Consent (please print)

____________________________________
Signature of Person Obtaining Informed Consent (as required by ICH guidelines)

____________________________________
Signature of Witness to Consent Process (as required by ICH guidelines)

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research subject or research-related injuries please feel free to contact R. Douglas Wilkerson, Ph.D.; Associate Vice President for Research; Medical College of Ohio at (419) 383-4251.

APPROVED BY MCO IRB

Consent Form Version Date 10/23/03

FROM 11/03/03 TO 11/02/04
Appendix E

Approval from Health Department

WILLIAMS COUNTY COMBINED HEALTH DEPARTMENT
310 LINCOLN AVE., P.O. BOX 146
MONTPELIER, OHIO 43543
PHONE: (419)485-3141
FAX: (419)485-5420
E-Mail: Williamsbd@bright.net

September 11, 2003

Mindy Manahan, BSN, RN
22-600 State Rte 34
Archbold, OH 43502

Dear Mindy,

On behalf of the Williams County Health Department, I am pleased to inform you that your research on "The Effects of Therapeutic Touch Prior to Vaccinations on Term Infant Pain Responses" was approved.

We ask that you send an update annually on the status of your project and on completion share the results. If the Health Department can be of any assistance, please do not hesitate to contact me.

The Williams County Health Department appreciates the time and effort you put into meeting and submitting information on your research. Thank you for your cooperation and good luck.

Sincerely,

Jean Wise RN MSN
Health Commissioner
Appendix F

Data Collection Sheet – Experimenter

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Infant Held:  Y  N  By whom:  ____________  Treatment  or  Control

Baseline Data:

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Notes: __________________________________________________________

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ABSTRACT

This study explored the use of therapeutic touch as a prophylactic intervention to minimize the pain experienced by infants receiving multiple immunization injections. The history, philosophy, and practice of the modality and its physiological effects on the body’s energy field were discussed in a review of the literature. Seventeen infants, from a small rural immunization clinic, participated in the study. Each of the infants received multiple immunization injections, ranging from two to four injections, with the goal of preventing communicable diseases. One group of infants received therapeutic touch and one group, who served as the control, did not receive therapeutic touch. The treatment of therapeutic touch was provided by the researcher and observed by clinic nurses who were unaware of which group, either treatment or control, that the infants were assigned to. The infant’s pain response was recorded utilizing the PAIN (Pain Assessment in Neonates) scale. Scores were compared using t-tests. The results of the analysis were not significant, potentially due to numerous factors discussed under limitations of the study, although there was a statistical significance within the treatment group, when the pre- and post-treatment heart rates and oxygenation saturation levels were analyzed.