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Exploring Holistic Comfort in Children who Experience a Clinical Venipuncture Procedure

April Athena Bice
University of Tennessee - Knoxville, abice@vols.utk.edu

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I am submitting herewith a dissertation written by April Athena Bice entitled "Exploring Holistic Comfort in Children who Experience a Clinical Venipuncture Procedure." I have examined the final electronic copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, with a major in Nursing.

Tami H. Wyatt, Major Professor

We have read this dissertation and recommend its acceptance:

Joanne Hall, Lisa C. Lindley, Matthew J. Devereaux, Nan Gaylord

Accepted for the Council: Dixie L. Thompson

Vice Provost and Dean of the Graduate School

(Original signatures are on file with official student records.)

Exploring Holistic Comfort in Children who Experience a Clinical Venipuncture Procedure

A Dissertation Presented for the Doctor of Philosophy
Degree
The University of Tennessee, Knoxville

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Dedication

This dissertation and its findings are dedicated to the many children that are in need of holistic comfort everywhere.

Acknowledgments

I would first like to recognize my entire dissertation committee for their support and encouragement through my dissertation study and my doctoral education. Each one of them played a special part in my success and I will be forever grateful. Dr. Tami Wyatt, especially, played the role of a devoted advisor, a faithful mentor, a committed dissertation chair, and her effort was an extraordinary contribution to my success. Most importantly, I would like to extend the warmest appreciation and love for my family who supported my academic dreams through many years of dedication to this degree. It was because of their care encouragement that I was able to complete this journey.

Abstract

Children often experience the uncomfortable effects of invasive procedures as a part of primary health supervision and during times of illness. Inadequate procedural comfort management can lead to numerous lasting harmful effects including distrust of healthcare providers, future intensified pain responses, negative cognitive and emotional experiences, and psychosocial health problems (Czarnecki et al. 2011). Holistic comfort has been well documented in adult literature but little research exists on the understanding of holistic procedural comfort from the child's perspective. The purpose of this study was to explore perspectives of children age 4 to 7 years and their caregivers regarding procedural holistic comfort. A qualitative descriptive design described by Sandelowski (2000; 2010) was used with the philosophical underpinnings of naturalistic inquiry (Guba & Lincoln, 1982). Purposive and convenience sampling was completed with a flyer handout to recruit participants from an outpatient hospital laboratory. The sample included 13 child participants and 15 caregiver participants who were interviewed using a semi-structured format. Traditional thematic content analysis described by Hsieh and Shannon (2005) was implemented to interpret four overarching themes of holistic comfort related to venipuncture procedures in children: Body Comfort, Cognitive and Emotional Comfort, Comfort in the Procedure Surroundings, and Comfort Play. Numerous recommendations for future research are reviewed. Implications for nursing and related health sciences, organizational and administrative policy, invasive procedures, theory, and methods are discussed.

Table of Contents

Chapter One: Introduction.	1
Background	3
Statement of the Problem	4
Purpose of the Study	5
Research Question	5
Developmental Considerations	5
Philosophical Perspective	7
Researcher Assumptions	8
Conceptual Definitions	9
Delimitations.	12
Nursing Significance	13
Chapter Two: Literature Review	16
Review of the Literature	16
Analyzing the Literature	17
Invasive Procedure Context	20
Historical Perspectives of Comfort	23
Literature Review	29
Comfort Development in Children	29
Comfort Intervention Studies	38
Summary and Gaps in the Literature	68
Chapter Three: Methods.	71
Overview	71

Study Design	72
Procedures	76
Philosophical Assumptions	93
Maintaining Rigor	93
Chapter Four: Findings	95
Demographic Characteristics	95
Holistic Comfort Descriptions	98
Supplementary Findings	140
Findings Summary	160
Chapter Five: Discussion.	161
Findings Related to Preceding Literature	161
Significance and Contribution to Science.	170
Study Implications	173
References	189
Appendices	209
Appendix A: Original Preliminary and Revised Interview Questions	210
Appendix B: Dissertation Committee Confidentiality Pledge	211
Appendix C: Recruitment Flyer	212
Appendix D: Informed Consent	213
Appendix E: Demographic Data Sheet	215
Appendix F: Child Assent Form.	216
Appendix G: Child Participant Script with Interview Ouestions	217

	Appendix H: Caregiver Participant Script with Interview Questions	221
	Appendix I: Child Drawings.	223
	Appendix J: Transcriber's Confidentiality Pledge	246
	Appendix K: Reflexivity Statement	247
Vita		249

List of Tables

Table 1: Participant Pseudonyms, Demographic Data, and Child/Caregiver Dyads	96
Table 2: Overall Themes and their Corresponding Child and Caregiver Categories	99
Table 3: Perspectives of Venipuncture Procedure: Children.	143
Table 4: Perspectives of Venipuncture Procedure: Caregivers	147
Table 5: What the Child Brings to the Venipuncture: Situational Categories	153
Table 6: Detailed Background Summary: What the Child Brings to the Venipuncture	154

Chapter One: Introduction

Nurses are often responsible for performing medically necessary invasive procedures that produce pain, fear, sadness, discomfort, and anxiety. These negative experiences may be more traumatic in the pediatric population due to a child's developmental level and sometimes his or her limited ability to communicate needs. Invasive procedures frequently performed in children include, but are not limited to, venipuncture, injections, finger and heel lancing, urinary catheterization, nasogastric tube insertion, wound and other dressing changes, port access, and intravenous (IV) cannulation. These procedures may take place in a primary care setting as a part of sick or well care, while hospitalized, at an outpatient laboratory when blood sampling is needed, when having ancillary testing done such as an x-ray, MRI, or CT scan, and more. Appropriately managing these uncomfortable invasive procedures is essential in all age groups. Children, however, may not receive adequate procedural comfort interventions despite modern knowledge, availability of treatments or interventions, and the ability to significantly reduce or avoid these discomforts (American Academy of Pediatrics, 2001). The American Society for Pain Management Nursing refers to comfort management as incorporating the use of pharmacological and nonpharmacological procedural interventions, which can enhance patient comfort and overall procedural management (Czarnecki, Turner, Collins, Doellman, Wrona, & Reynolds, 2011). However, what is a child's perspective on procedural comfort? There is minimal data demonstrating how a child perceives holistic comfort related to nursing procedures, indicating the need for this dissertation study.

Based on the pediatric procedural pain literature and documented benefits of nonpharmacological interventions, it is suggested that assessing and providing pediatric holistic procedural comfort measures are superior to strictly managing pain. Nurse theorist Kolcaba

(1994) contends that comfort is holistic and should not be confused with pain because it involves more than physical ailment or suffering. Holistic comfort is more clearly defined in the adult population but poorly defined in children. Limited research exists on the perceptions of comfort as described by a young child. The majority of research published on pediatric comfort or comfort measurement is described by the absence of pain, fear, anxiety, and distress. Whereas comfort during invasive procedures certainly includes lower levels of these feelings, it may not represent the concept of procedural holistic comfort completely. In order to measure procedural holistic comfort in children, it was necessary to gain an understanding of the concept from the child's perspective. Otherwise a child's comfort needs are strictly interpreted by adults rather than provided according to a child's insights.

Evidence from this dissertation study demonstrates an improved understanding of at least one area (venipuncture blood sampling) of pediatric procedural holistic comfort. As a result, instruments to measure the construct of procedural holistic comfort in children who have received a venipuncture can be created and tested. Additionally, once procedural comfort can be properly measured in children then researchers can progress toward demonstrating comfort interventions and assessing procedural comfort outcomes. Minimal evidence exists on the outcomes of nurse-provided pediatric procedural holistic comfort interventions. This is partly related to the limited understanding of pediatric procedural comfort related to a child's cognitive/developmental capabilities. Further, limited understanding is due to the limited available qualitative research in children. More evidence was needed on procedural holistic comfort interventions that can promote a more comfortable procedure for the child.

Background

There is extant literature that separately measures outcomes of pediatric pain interventions. Inadequate procedural pain management is related to several barriers including: improper pediatric pain assessment, time management, a child's inability or decreased ability to communicate pain, a lack of nursing pain knowledge, nurses' opinions and attitudes toward pain, and nurse/provider collaboration (Ellis, Sharp, Newhook, & Cohen, 2004; Ely, 2001; Latimer, Johnston, Ritchie, Clarke, & Gilin, 2009; Manworren, 2000; Rieman & Gordon, 2007; Robins, 2007; Ware, Bruckenthal, Davis, & O-Conner-Von, 2011). Extensive literature also exists on measuring components of comfort in children during invasive procedures by providing interventions such as music, caregiver facilitation, the use of toys, screen time, or play, and pharmacological intervention. A detailed review of these studies will be discussed in chapter two. Although evidence has been presented in numerous studies regarding procedural pain, the holistic comfort management of children undergoing invasive procedures is not well understood.

Comfort is not communicated the same by all researchers. Most studies that emerged on child comfort scales, comfort assessment, and comfort interventions focused on indicators and assessment of pain, not holistic comfort management. These studies will also be discussed in the literature review. The holistic nature of the nursing profession necessitates procedural practices to include more than just a measurement and treatment of pain. It requires nurses to assess the comfort needs of children and provide comfort interventions that will make the child feel better as a whole person. Part of appropriately assessing pediatric comfort must include an understanding of child development.

There are a variety of possible components of comfort for children before, during, and after invasive nursing procedures. For example: preparedness, anxiety level, the temperature in

the environment, the child's hunger or thirst, body positioning, the child's pain level, the presence of a caregiver or loved one, the presence of a security object, sleeplessness or level of exhaustion, induced nausea, the need or desire for prayer, feelings of abandonment, voiding or stooling needs, and the fear of experiencing an invasive procedure again. As a result, there are many possible elements of procedural comfort that need nursing recognition, assessment, and intervention. This study provides clarification of the comfort elements related to an outpatient pediatric venipuncture procedure in young children.

Statement of the Problem

Invasive procedures can often not be avoided in pediatric healthcare. These procedures are frequently a part of primary, acute, chronic, surgical, palliative, and intensive care. Nurses and other clinicians regularly perform invasive procedures and the success of the procedure can depend on the state of the child. Owing to the medical necessity of these interventions, an improved management of holistic procedural comfort is needed. If the procedure cannot be avoided altogether then the affiliated pain, fear, distress, and anxiety must be holistically managed. This procedural comfort management starts with an improved understanding of the phenomenon from a child and primary caregiver perspective. Additionally, as evidenced above, procedural holistic comfort during invasive procedures has not been well understood in children. In order to realize the perceptions of procedural comfort to a young child, more knowledge and specifically descriptions from children who experience these procedures was needed. In this study, the beliefs, values, feeling, and thinking of the child within the context of holistic comfort related to a venipuncture procedure was explored. Descriptive data was also gathered from primary caregivers. Children were able to explain and freely express comfort needs related to an invasive clinical venipuncture procedure. This was followed by the explicit procedural holistic

comfort descriptions by caregivers who are closely connected to the child. Interpreting these child and caregiver descriptions of procedural holistic comfort led to valuable evidence pertaining to child procedural comfort discussed in chapter four of this dissertation.

Purpose of the Study

The purpose of this study was to explore perspectives of children age 4 to 7 years and their caregivers regarding procedural holistic comfort.

Research Question

What are the perspectives of procedural holistic comfort as described by children age 4 to 7 years (preoperational stage of development) and their caregivers who experience it with them immediately following an invasive nursing procedure?

Developmental Considerations

According to preeminent researchers, the younger a child is, the more procedural distress, pain, anxiety, and or fear they will experience (Blount et al. 2009; Caprilli, Anastasi, Grotto, Abeti, & Messeri, 2007; Caprilli, Vagnoli, Bastiani, & Messeri, 2012; Carlson, Broome, & Vessey, 2000; James, Ghai, Rao, & Sharma, 2012; Noguchi, 2006; Press et al, 2003; Schiff, Holtz, Peterson, & Rakusan, 2001; Tak & Van Bon, 2006). This is important because children age 4 to 7 years may have different procedural comfort needs than children older than 7 years. Many developmental theories exist in the field of psychology and child development. For the purpose of this study, Piaget's cognitive stages of development were used as inspiration for the selection of the 4 to 7 year age group. This age group was chosen specifically because these children experience higher levels of procedural discomforts (higher pain, anxiety, distress, and fear) then children in more advanced developmental stages (Caprilli et al. 2007; Caprilli et al. 2012; Carlson et al. 2000; James et al., 2012; Noguchi, 2006; Press et al. 2003; Schiff et al. 2001;

Tak & Van Bon, 2006). It was also chosen because between the ages of 4 and 7 years, a child is at a developmental stage (Piaget, 1964) where he/she can cognitively communicate with intelligible speech, respond to questions, draw simple pictures, and participate in an interview.

Piaget's Theory

Piaget's theory of cognitive development is based on operations. An operation is described as making logical structure (making sense) by organizing or putting things in order on the basis of individual knowledge and reality (Piaget, 1964). This theory of cognitive development includes four chronological stages: the *sensorimotor stage* (approximately 0-2 years), the *preoperational stage* (approximately 3-7 years), the *concrete operational stage* (approximately 8-11 years), and the *formal operational stage*, which typically includes children 12 years and older (Merriam, Caffarella, & Baumgartner, 2007; Piaget, 1964; 1972). Although approximate ages are suggested for each stage, Piaget himself stated the "chronological age for these stages can vary" (Piaget, 1964, p. 178).

Piaget's stages "represent qualitatively different ways of making sense, understanding, and constructing a knowledge of the world" (Tennant, 1988, p.68). Piaget (1964) explained the stages in detail: The first stage is the sensorimotor stage. This is a preverbal stage for children, in which a foundation for later knowledge is being built. Children in the second stage, the preoperational stage, have the ability to use "beginning language, symbols, and intuitive thought" (p. 177). The third stage is the concrete operational stage, where children have basic reasoning skills and can construct simple ideas. The final stage is the formal operational stage, in which an adolescent is nearing adulthood and can construct operational logic and the ability to develop hypotheses or higher reasoning (Piaget, 1964). In this study the focus was on the second stage: preoperational development. Children in this stage have a beginning sense of perception.

This perception, intuitive thought, and increasing knowledge as Piaget describes it, allows children in the preoperational stage to communicate their feelings. This ability is noteworthy to this study because children in the preoperational stage of development were able to communicate their comfort needs related to an invasive venipuncture procedure. Also, children in the preoperational stage may have communicated their comfort differently than children at higher developmental levels who were not investigated in this study.

Philosophical Perspective

The philosophical perspective that underpins this study is naturalistic inquiry. Although qualitative descriptive research has conceivably one of the least theoretical commitments, its tenets are most closely associated with a naturalistic paradigm (Sandelowski, 2000). For the purpose of this study, no claims were made as to exactly what procedural holistic comfort means to children. Perceptions were captured by having children and caregivers describe their experiences. Interestingly, naturalistic inquiry includes qualitative research in humans and behaviors among animals and other elements in their own regular environment (Sandelowski, 2000).

Blumer (1969) stated that investigators who are looking at a problem found in its natural form use naturalist inquiry as philosophy guiding their research. This philosophy embraces an "exploration of human life" (Blumer, 1980, p. 413). Naturalistic inquiry was developed in the early works of Blumer as a new and unconventional approach to sociological research, which could serve as a substitute to positivism (Athens, 2010). Naturalistic inquiry is a paradigm that functions to support (traditionally) qualitative research focusing on the natural setting (Guba & Lincoln, 1982). In order for this to occur, no prearranged variables or order should be set in naturalistic research. In a naturalistic approach, "the researcher is driven by theory grounded in

the data; the naturalist does not search for data that fit his or her theory but develops a theory to explain the data" (Guba & Lincoln, 1982, p. 235). Paradigms are important in research because they each contain specific axioms (or postulations) and assumptions about phenomena. The axioms for naturalistic inquiry discussed by Guba and Lincoln (1982, p. 237) include:

- *Reality*: Multiple realities, holistic, prediction and control are unlikely.
- Researcher/Participant Relationship: Interrelated, Both researcher and respondent interact to influence one another.
- Nature of Truth Statements: Context bound working hypothesis, focuses on differences, generalizations are impossible.
- Attribution/Explanation of Action: Action explainable in many terms, factors, or events non-manipulable and plausible.
- Relation of Values to Inquiry: Value-Bound

Researcher Assumptions

The assumptions in this study are based upon the principal investigators' (PI) thoughts, deductions, and experiences with child traditional and advanced nursing care and are specific to comfort and pediatric invasive nursing procedures.

- Invasive pediatric nursing procedures are unpleasant and can increase distress, pain,
 fear, anxiety, and decrease overall comfort.
- Children do not experience or desire procedural comfort in the same way as the adult or elderly population.
- Children's primary caregivers have a level of understanding their child and can provide important information on what comfort needs their children require.

- Children want to be comforted before, during, and after invasive nursing procedures.
- Children's caregivers want their children to be comforted before, during, and after invasive nursing procedures.

Conceptual Definitions

Invasive Pediatric Nursing Procedure

Many invasive nursing procedures exist, however, in this study a venipuncture procedure was used. For the purpose of this study, an invasive nursing procedure was: any routine nurse or clinician-provided intervention that crosses the physical, emotional, cultural, and psychological boundary of a child. Registered nurses and other clinicians, without special certification, regularly perform these procedural interventions as a part of his or her daily responsibilities and individualized training. In this study invasive nursing procedures did not include the following:

1) those that are most consistently performed by an advanced practice or medical provider (example: lumbar puncture), 2) special procedures completed by a registered nurse who is individually certified to perform them (example: peripherally inserted central catheters or PICC lines), or 3) special non-nurse provided interventions in a particular department of a health care institution (example: voiding cysto-urethrogram or VCUG). Examples of invasive pediatric procedures include, but are not limited to, those mentioned in the introduction: wound and other dressing changes, port access, urinary catheterization, venipuncture, injections, finger and heel lancing, IV cannulation, venipuncture, and nasogastric tube insertion.

Primary Caregiver

A primary caregiver was considered to be any individual who has custody (shared, partial, or primary), guardianship or chief responsibility of the child experiencing the invasive

procedure. This may include but is not limited to: biological parents, foster parents, adoptive parents, stepparents, or family members/others that have been granted custody or guardianship.

Holism/Holistic

In this study comfort was examined from a holistic perspective. The Oxford dictionary describes holism as an understanding that all parts of a whole are constantly connected; that treating a person holistically means to consider not only physical elements but also social and mental factors. The American Holistic Nurses Association recognizes that holism involves biological, psychological, social, and spiritual parts of a person within their own environment (Frisch, 2001). Similarly, in an Ambulatory Pediatric Association presidential address, holistic care has been defined as "good medicine...caring for the whole child in the context of that child's values, their family's beliefs, their family system, and their culture in the larger community (Kemper, 2000, p. 214). Another author calls attention to the understanding that "a single holistic approach to care is oxymoronic" because holism involves numerous remedies (Freeman, 2005). A concept analysis of holistic nursing in the pediatric setting was also recently conducted. Tjale and Bruce, (2007) indicated that holistic nursing incorporates two dimensions: the whole person and the mind-body-spirit. The phrase complementary and alternative medicine (also known as CAM) was related to holistic care in this concept analysis but the two are not equivalent. CAM was recognized as a surrogate of holism, representing types of holistic interventions directed at the mind-body-spirit (Tjale & Bruce, 2007). Holism has also been considered essential to best spiritual nursing care practice: "holistic nursing asserts the balance between mind, body, and spirit, and is necessary for optimal health" (Dell'Orfano, 2002, p. 380). In an article published in the official journal of the AAP, the author claims that "return to a more holistic approach" to child health care is needed, involving not only the treatment of diseases, but also special attention to well child care- child development, and health promotion (Schor, 2004, p. 210). Additionally, holism has been recognized as the overarching theme of the well-known concept of *family-centered care*, which has been defined as "a way of caring for children and their families within health services which ensures care is planned around the whole family" (Shields, 2007, p. 893). For the purpose of this study, the definition of holistic was inspired by the literature and is understood as: an approach to caring that includes acknowledging and treating the whole child, with careful consideration of physical, psychological, social, cultural, spiritual, and environmental needs.

Comfort

No predetermined understanding of comfort for children was brought to this study. However, it is important to examine the description of comfort in research to date. The Oxford Dictionary defines comfort as physical ease and a lack of pain; a pleasant feeling, the state of well-being, or richness, and a relief of sorrow or distress. Rankin-Box (1986) adds that comfort is a "state of both mind a body" (p. 340) encompassing social, environmental, and cultural care and bound by influencing variables such as noise, sleep, warmth, communication, sight, lighting, and smell. Jones (1986) has similar views, defining comfort as a "harmonious relationship between physical, psychological, social, and environmental factors" (p. 344). Another researcher has discussed comfort through the means of self-care with compensatory physical and psychological states (Richeson (1988). An even earlier explanation of comfort was described by a nurse as providing appropriate health information in order to alleviate fear and pain: "an explanation in language the patient can understand is the one which will help to dispel fear and enable the patient to withstand pain or discomfort with equanimity" (Markham, 1962, p. 896). Morse, Bottorff, and Hutchinson, (1994) offer an understanding of comfort that is "pre-reflective

and complex" (p. 190): a state of embodiment that is outside of the human consciousness; more than just the relief of pain. Morse et al. argued it might not be possible to assume that patients are comfortable just because pain is reduced. Hence, it is as earlier described: more than relieving pain. Hamilton (1989) claimed comfort is distinctive and its definition should be clarified with each individual. Nurse theorist Katharine Kolcaba has rigorously analyzed and described comfort as: "the immediate experience of being strengthened by having needs for relief, ease, and transcendence met in the four contexts of comfort (physical, psychospiritual, sociocultural, and environmental); much more than the absence of pain or other physical discomforts" (2013, p. 193). It appears based on the earlier explained definitions of holism, that many definitions of comfort in the literature are in fact holistic. For the purpose of this study, Kolcaba's definition will be used since it synchronously fits with a holistic approach to providing comfort.

Modern

Comfort interventions for children have evolved and increased since the clarification and analysis of the concept of comfort in nursing. The word "modern" is used in this dissertation to describe interventions or treatments that occurred around or after 1990, when newer treatments for pain, anxiety, distress, and fear were investigated and explored among children experiencing nursing procedures.

Delimitations

A sample of 4 to 7 year old children in a preoperational stage of development was purposefully and conveniently selected from a population of outpatient children undergoing an invasive nursing procedure at a Southeastern children's hospital laboratory. Data saturation determined the sample size of this study and results may only be transferable to those children who have experienced an invasive nursing procedure in this region of the United States.

Transferability of results may not be applicable to populations with different characteristics and demographics. These differences may include participant populations where: (a) acute pain is not a factor, (b) a greater amount of pain is expected, (c) age group differs, (d) developmental level or social interaction of the child is delayed or affected, (e) patients are hospitalized, or (f) patients are under hospice care.

Nursing Significance

Nurses perform invasive procedures on a regular basis as part of their professional responsibilities. Providers order these procedures for medically necessary care and nurses or other clinicians must carry them out in the best interest of the patient's health. Pediatric nurses often perform these procedures on distressed or anxious children, crying flailing infants, and even fearful and nervous adolescents. But "only older children can differentiate pain from unpleasantness and fear" (Young, 2005, p. 161). In many instances more than one nurse is needed to complete these invasive procedures on children who are 7 years old and younger. This is because the child cannot (understandably) remain still due to sensitive emotional, psychological, and somatic responses. Certain children even become combative and aggressive out of extreme fear and distress before the procedure even begins. How a child reacts to procedures depends on a culmination of developmental considerations, coping behaviors, genetics, temperament, and memory of past events (Zempsky, 2008). Additionally, some procedures may require extreme precision such as accessing a vein for blood sampling, starting an intravenous line, or accessing a central line port. The physiological and psychological procedural reactions of children can affect the nurse's precision and success of the procedure. Occasionally the necessity for 2nd or even 3rd procedural attempts is inevitable leading to even more fear, pain, anxiety, and distress for the child. Furthermore, after invasive nursing

procedures are complete, children remember and can anticipate their experiences (Blount et al. 2009). They will often react in a similar or heightened way for future procedures. Since nurses are not the only health care providers who perform invasive pediatric procedures this is, indeed, an interprofessional issue. The results of this study will add to the science of nursing, lab technicians, medical assistants, emergency room technicians, physicians, physician assistants, nursing assistants, and more. With a better understanding of holistic procedural comfort, healthcare workers can minimize negative procedural experiences for children and clinicians gain the opportunity to perform optimally successful invasive interventions.

The American Society for Pain Management Nursing (ASPMN) discusses the harmful and long-term effects of inadequate comfort management as: (a) distrust of healthcare providers, (b) refusal to consent/assent to future treatment, (c) negative emotional and cognitive experiences such as fear, anger, aggression, anxiety, lack of concentration, and embarrassment, and lastly (d) psychosocial and health problems including depression, insomnia, fatigue, appetite changes, and future heightened pain response (Czarnecki et al. 2011). The long-term effects of inadequate comfort management are also substantial to society and have financial implications and costs.

The American Pain Society published evidence showing average cost of pain and discomfort in the United States at approximately \$560 to \$635 billion dollars annually (Gaskin & Richard, 2012). This included direct and indirect healthcare expenditures and loss of productivity. The ASPMN states that inadequate procedure preparation and comfort management coupled with overall lack of patient and family support may contribute to future emotional, cognitive, developmental, and or growth problems (Czarnecki et al. 2011). Comfort is a positive outcome linked to better institutional outcomes, higher patient and family satisfaction rates, and

cost savings (Kolcaba & DiMarco, 2005). An enriched understanding of procedural holistic comfort in children will more clearly define the assessment of pediatric procedural holistic comfort needs. It will also promote a more appropriate and child-focused implementation of procedural comfort interventions. For all of the reasons, the lack of science on pediatric holistic procedural comfort, and the incongruent understandings of comfort in children, this dissertation study was necessary.

Chapter Two: Literature Review

Research focused on pain related to invasive pediatric nursing procedures is replete. This study has moved away from investigating just procedural pain and instead focuses on procedural comfort. The literature includes multiple studies incorporating various interventions that are aimed at alleviating pain, anxiety, distress, and fear. There are procedural comfort interventions shown to work, interventions that do not work, and interventions that need more research. Interventional studies as well as literature focused on the evolution of comfort are reviewed in this chapter. The differences between comfort and pain are not adequately addressed in the state of the science. In fact, some researchers discuss and operationalize the concept of comfort while actually using an instrument that measures pain. The problem here is that comfort level is more than simply a measurement of pain. Many of the tools that have been designed to measure pain in children are not holistic, and therefore, cannot be used to measure comfort. Additionally, children, depending on their age and developmental level, will have different comfort needs. Developmental considerations are discussed frequently throughout the literature. Children of younger ages experience increased levels of pain and distress than older children. Until this study was completed, no research existed where young children were asked about holistic comfort with procedures. The current literature on self-reported holistic comfort has been focused only on the adult and elderly population. Qualitative research in the pediatric population was needed to capture the understanding of holistic procedural comfort from the child's perspective.

Review of the Literature

The methods that directed the literature review including databases used, research article inclusion and exclusion criteria, keywords, and publication dates will be discussed. A thorough examination of the research will be completed, along with comparing and contrasting the

evidence and knowledge in two major areas: (a) the historical perspective, development, and study of the concept of comfort in children, and (b) nonpharmacological (in some cases including pharmacological) procedural comfort interventions among preschool and school-age children. Pharmacological interventions are equally important. These studies, however, generally provide only evidence on pain outcomes, not holistic comfort. For this reason, studies including only pharmacological interventions were not included. Nonpharmacological procedural interventions are those that include no medication administration. They are not focused on a medicinal means to provide comfort but often include emotional, environmental, and psychological elements. These types of interventions for children may include distraction with toys or other entertaining objects, guided imagery, parental presence, music, and more. A brief overview of child and caregiver perspectives of procedures will also be discussed. This is to help clarify and provide context on the existing understanding of what the experience of a pediatric clinical procedure is like. Comfort studies in the adult population will also be reviewed as background information. Current gaps in the literature will be addressed as well as future nursing implications.

Analyzing the Literature

Nursing and other pertinent health-related science literature was reviewed. Electronic databases used for this review include: CINAHL, PubMed, PsycINFO, HAPI, and Google Scholar. These databases were reviewed because the goal was to obtain a pertinent comprehensive review of pediatric procedural holistic comfort. This would include literature from the disciplines of nursing, medicine, psychology, sociology, and more. The HAPI database was reviewed for two reasons: (a) to review pediatric measurement instruments used by researchers, and (b) to assess the validity and reliability of those tools. Key words were used

alone or in combination to make phrases and included: comfort, interventions, holistic, children, procedures, procedural, pediatric, nonpharmacological, nursing touch, healing touch, distraction, and comfort theory. These key words were chosen because they relate to invasive clinical procedures in children, holistic nursing care, and caring for the whole procedural experience of the child. For comfort intervention studies, peer reviewed research articles published between 2000 and 2015 that met inclusion criteria, as discussed below, were used. Seminal works and international studies were also included. No date limitation was used when reviewing the literature on the development or perspectives of comfort in children.

Analyzing Comfort Interventions Literature

A total of 1,680 studies were identified on comfort interventions. One-hundred seventyone of these were selected for further review based upon the title and abstract. Among these
remaining articles were eight systematic/comprehensive reviews, which were also scanned for
additional pertinent research studies. Inclusion criteria for the research studies reviewed were as
follows: (a) the study evaluated some form of comfort in children related to an invasive nursing
procedure, (b) the procedural comfort interventions provided included evaluation of
nonpharmacological treatment, (c) the sample used within the study included (at least in part)
preschool or school-age children aged four to seven years, and (d) the intervention could be
administered or facilitated by a registered nurse (ex: patient coaching, psychological and
behavioral distraction, and relaxation techniques). Both qualitative and quantitative research was
reviewed.

Only studies focused on comfort interventions with children aged 4 to 7 years were assessed. Studies in which a portion of the sample were outside of the selected age range was included, as long as four to seven year-olds were represented, since so many of the study samples

represented, in part, the selected age range for this review. A study was excluded if: (a) it was not available in English, (b) the invasive procedure investigated was not one that a nurse would perform or facilitate, and (c) the sample was completely outside of the target age range.

There are important rationales for study exclusion. The focus in this review is commonly occurring nursing and clinician procedures, which children frequently experience as a part of their regular health supervision. Procedures performed by other health care providers such as physicians, physician assistants, or advanced practice nurses would not be applicable to this study. Similarly, since the focus of this review is patient-focused comfort and nursing comfort interventions, reviewing comfort measures that nurses cannot realistically provide would not be pertinent to the proposed study.

Again, the concept of procedural holistic comfort is not clearly defined in the pediatric population. Researchers often define comfort as a binary opposite such as pain, anxiety, nervousness, fear, and distress. All of these words were found in the literature when conducting this review, as they are each conceivably related to discomfort. After applying criteria, 44 articles were included in the comfort intervention literature review. Relevant seminal or essential articles were included. Upon final selection and review, four themes emerged of widely studied procedural interventions. These themes are: music therapy, amusement and entertainment, caregiver facilitation, and a multifaceted approach. These comfort intervention studies offer knowledge on what may reduce pain, distress, anxiety, and fear during nursing procedures in children. These themes cannot, however, allude to the history of the concept of comfort. For this reason a historical perspective of comfort is discussed and presented.

Invasive Procedure Context

Children do not describe or perceive procedures related to medical care as enjoyable.

Receiving these invasive procedures is an unpleasant experience and has been documented as such. In order to appreciate the experience of invasive procedures it is necessary to have a basic understanding of what child and caregiver procedural perspectives involve. There is some literature that provides awareness of these experiences, the context of procedures, and the perceptions of procedural interventions.

Child and Caregiver Perspectives

Fear. One of the elements described by children who receive invasive procedures is fear. Forsner, Jansson, and Sodderberg, (2009) examined the meanings of "being afraid" when in contact with medical care as narrated by children. They found that children felt an overarching theme of being "threatened by the monster" of medical care (p. 522). One child described their experience of fear as being treated unfairly with a medical procedure: "I start to cry. And then I pull away and don't want to go there then. But then they hold on to me. And then they do it anyway. They force me still." (p. 523). In another study, researchers investigated the lived experience of parents understanding and living with their child's fear of cancer treatment (Anderzen-Carlsson, Kihlgren, Svantesson, & Sorlie, 2007). Parents describe feared procedures as a part of their child's course of treatment such as being "pricked by needles and wound dressing changes." Results of these two studies suggest that clinical invasive procedures are something that children are fearful of and that they see procedures as a personal threat.

Coping and Support. Children have also reported their perceptions of what needle procedure experiences are like and useful coping strategies. Hodgins and Lander (1997) examined child coping with fear and pain before and after venipuncture procedures. These

researchers found that children associated negative emotions such as feeling "scared, nervous, not good, terrible, sad, and angry" with their procedures (p. 277). One child looked at a picture of a child getting blood sampling and described the child feeling: "nervous if he hasn't had it done before. Cause they're needles. They're not nice. They're pointy and sharp" (p. 277). In order to cope with the negative emotions mentioned above, children reported doing things such as looking away from the procedure, thinking of something else, wanting medications, tolerating the pain, seeking moral support (mom staying with the child), seeking an inanimate comfort source (teddy bear), trusting in the health care professional or seeking physical comfort (Hodgins & Lander, 1997).

In a study conducted on parents in the emergency department, researchers aimed to determine whether parents prefer to be present during invasive procedures preformed on their child (Isoardi, Slabbert, & Treston, 2005). Perspectives were collected through surveys of 553 parental responses. Invasive procedures mentioned in the survey included blood sampling or IV insertion, nasogastric tube insertion, lumbar puncture (spinal tap), urinary catheter insertion, suprapubic bladder aspiration (via needle), and life threatening cardio-pulmonary resuscitation. Among responses, 93.9% of parents reported they would prefer to be present for their child's invasive procedure, including resuscitation with a chance of their child's death. The most common reason for parents wanting to be present for procedures was to "provide comfort to their child" (p. 244).

Another recent study used a qualitative approach to investigate Swedish parent perspectives on supporting their children during needle-related procedures (Karlsson, Englund, Enskar, & Rydstrom, 2014). The most abstract theme found among the parents descriptions was "keeping the child under the protection of one's wings" with six categories/subthemes of this

protection: "seeking additional support, rewarding the child, paying attention to the child's way of expressing itself, facilitating the child's understanding, striving to maintain control, and focusing the child's attention" (p. 4). In these findings it is communicated that parents feel their presence to accomplish this protection is a means of support. This is similar to the findings of Isoardi et al. (2005) who showed that caregivers prefer to be present for invasive pediatric procedures to provide comfort. Results of Hodgins and Lander (1997), Isoardi et al. (2005), and Karlsson, et al. (2014) suggest the use of specific procedural coping and support strategies by children and suggest that caregivers: (a) appreciate being present for invasive procedures to provide comfort and support, and (b) support their children during invasive procedures through a means of various protection interventions.

Pain, Anxiety, and Distress. It is not surprising that procedures have been documented as painful, anxiety provoking, and distressing. Two studies examined these perspectives of children and caregivers diagnosed with cancer while another study investigated perspectives of caregivers with chronic kidney disease. In one qualitative study, researchers examined the viewpoints of caregivers and children on various aspects of pain in children with cancer (Ljungman, Kreuger, Gordh, & Sorensen, 2006). Because the perspectives of children and caregivers were so comparable, the researchers combined their perspectives for the report of findings. Children and caregivers reported cancer treatment such as radiation, medications, and chemotherapy as the largest problem causing the greatest pain. Procedures, however, were reported as the second most prevalent problem. This was also described by children as causing pain related to the management of their disease. Children and caregivers also reported causes of failing pain treatments. These were anxiety in the parent, anxiety in the child, lack of information or preparation, and loneliness, with child anxiety ranking highest among all causes.

Similar results were found by another group of researchers who explored the numerous causes of distress among children diagnosed with cancer. In this descriptive study, researchers found that the most frequently occurring cause of physical distress reported by children was "diagnostic procedures, treatments, nausea, and fatigue" (Hedstrom, Haglund, Skolin, & von Essen, 2003, p. 124). Children from 0 to 19 years were included in the study and interviewed with their caregivers. For children less than 8 years old, caregivers provided the answers for their child. In every age group, the most frequently reported cause of distress (by caregivers or children) was diagnostic procedures and treatments. Procedures such as venipuncture, nasogastric tube insertion, injections, adhesive/plaster removal, and central line care were all reported as "statements of pain and discomfort" (Hedstrom et al. 2003, p. 126).

In a qualitative study focused on parental perspectives only, researchers aimed to explore the experiences of parents with children who have chronic kidney disease (Tong, Lowe, Sainsbury, & Craig, 2010). One of the themes that emerged was "absorbing the clinical environment" (p. 551) and within this theme was parental concern for invasive procedures related to their child's illness. Parents spoke about needles and tubes in the child's body and one parent reported her perspective on these procedures: "we watch as she's constantly tortured by the medical process. It hurts to watch" (p. 551). As evidenced by the above studies discussed, invasive clinical pediatric procedures are perceived by children and caregivers as negative experiences. These experiences are ones in which comfort is frequently sought.

Historical Perspectives of Comfort

After nearly 50 years, the understanding of holistic comfort as it relates to children has changed and transformed. Despite modern knowledge and advancements, however, the meaning remains unclear. For this reason literature on the development of comfort as a concept is

discussed chronologically, as an evolving topic. The pioneer on comfort in nursing-Katharine Kolcaba- developed a holistic theory of comfort in nursing and has completed much of her work in the adult population, as have many nurse authors after her. Kolcaba & DiMarco (2005) recommend integrating comfort theory into pediatric nursing practice. Nonetheless, this theory has only been used as a guiding framework in one unpublished pediatric dissertation study and it was not focused on invasive nursing procedures (Moriber, 2009). This inductive (theory-building) dissertation study on procedural holistic comfort in children bridges a gap in the literature with regard to a persistent lack of pediatric comfort understanding.

Holistic comfort is a relatively new concept in nursing. Kolcaba (1994) defines comfort as the immediate experience of being strengthened through *relief* (having a comfort need met), ease (calm or contentment), and transcendence (rising above a problem). The rigorous clarification and development of comfort theory in the nursing discipline began in the early 1990s (Kolcaba & Kolcaba, 1991; Kolcaba, 1991; 1992; 1994). However, the ideas of comfort and comfort interventions in nursing date back as far as Florence Nightingale's environmental theory. Something as simple as ventilation and temperature control are comfort interventions: "Keep the air he breathes as pure as the external air without chilling him" (Nightingale, 1860). In this passage Nightingale spoke about keeping the air a patient breathes similar to fresh air outside, free from foul smells, toxins, or contaminants, and at the same time keeping the surrounding environment at a temperature that is not too cold. Earlier writings on comfort included various acts of wellness such as a warm back rub, the lifting of heels off of a bed, soft pillows, and offering a liquid refreshment (Clark, 1946). But it was not until the last 30 years that researchers began to discover comfort as a concept that needed interpretation, analysis, and further investigation.

Around the same time that Kolcaba began her work on conceptualizing comfort, other authors were also exploring the concept in various areas. Morse, (1983) examined comfort in an ethnoscientific analysis, explaining the human acts of comforting and its relation to nursing. Another author explained the comfort needs of the elderly and the special role of health care providers in promoting comfort (Jones, 1986). Adding to Jones' work was a study investigating patient perceptions of comfort in aging chronically ill individuals (Hamilton, 1989). Childbirth was additionally a focus for two researchers who examined the effects of recumbent verses upright positioning on the comfort levels of laboring women (Andrews & Chrzanowski, 1990). In one paper that focused on the phenomenology and themes of comfort, authors argue that while "the central role of nursing is to provide comfort, the attainment of total comfort in nursing is not possible" (Morse, et al., 1994, p. 189). Another researcher turns the focus to the nurses' comfort and moral decision-making. This researcher found that nurses often act as mediators and communicators, using self-comfort and patient comfort as criteria for moral choices in good nursing practice (Wurzbach, 1996). As research focusing on comfort in the adult population progressed, so did the analysis of comfort- a soon to be important operationalizable concept.

Comfort Studies in Adults

Cognitive Strategies. In one of the earlier studies investigating holistic comfort, Kolcaba and her colleague's investigated the effects of guided imagery on women with early stage breast cancer who were receiving radiation treatment (Kolcaba & Fox, 1999). Participants self-reported comfort level at three different stages of radiation treatment. Kolcaba and Fox found that comfort levels increased significantly over time (F= 4.33, p < .05) for women who received the guided imagery comfort intervention. In another study using a like intervention and yielding similar results, one group of investigators showed how audiotaped cognitive strategies had significant

effects on comfort levels (F= 4.55, p= .02) among older adults diagnosed with compromised urinary bladder syndrome (Dowd, Kolcaba, & Steiner, 2000). Elimination patterns in children are extremely important because this is an important part of their development and beginning independence. These findings are meaningful to the phenomenon in this dissertation study because cognitive strategies are holistic interventions that are effective at increasing comfort levels in the adult population. There is however, limited research related to guided imagery and its effects on pediatric procedural holistic comfort. This is, of course, partly related to the ambiguous understanding of holistic comfort during pediatric procedures and the lack of theory designated to the meaning of holistic procedural comfort among children.

Kolcaba and Steiner, (2000) tested the propositions of Kolcaba's holistic comfort theory and established information on the validity of the Radiation Therapy Comfort Questionnaire RTCQ). Propositions are required in any theory and are defined as relationships that connect primary concepts together in a theory. Testing the propositions in a theory offers more evidence to the strength and understanding of a theory. Kolcaba & Steiner found positive results for all theory propositions, which is essential to the development and operationalization of comfort in adults. This dissertation study provides the beginning evidence for theory related to comfort needs among children who experience invasive procedures that has been long overdue.

End-of-Life Comfort. In a position statement focused on end-of-life care, the American Nurses Association (2010) illustrates that nurses are obliged to provide comfort, relief from suffering, and when possible a death that is congruent with the values of the dying person" (p.31). Novak, Kolcaba, Steiner, and Dowd (2001) examined the psychometric properties of different formats of comfort instruments using a sample of patients and their caregivers during the end-of-life experience. This study is pertinent because young children at the end-of-life, with

chronic illness, or who are critically ill require hands on procedural holistic comfort interventions performed by nurses; further adding to the reasons why this dissertation study is important.

These hands-on comfort interventions in nursing care are an increasing interest in pediatrics.

Hands on Comfort. Investigators later examined the effects of a comparatively new comfort measure: hand massage. These researchers explored comfort levels after hand massage among patients in hospice care (Kolcaba, Dowd, Steiner, & Mitzel, 2004) and nursing home residents (Kolcaba, Schirm, and Steiner, 2006). Although findings from both of these studies were not significant (F= .837, p= .434 and F= 2.13, p= .15, respectively), the patients who received hand massage reported higher comfort levels over time (Kolcaba et al., 2004) or higher comfort levels at specific times (Kolcaba et al., 2006). In a related but different study, a distinctive form of nursing touch was studied. Researchers conducted a comparison of coaching sessions, healing touch or both on comfort levels of younger college students (Dowd, Kolcaba, Steiner, & Fashinpaur, 2007). Healing touch was defined as a light touch on or near the body aimed at balancing energy fields. Findings indicated "healing touch had better immediate results on stress and comfort and that coaching had better carryover results on both outcomes" (p. 201). Variations of touch such as holding, rocking, stroking, or coddling are often used as calming interventions for children. But, outcomes of physical touch among children who experience invasive nursing procedures has really only been studied with regard to parental or caregiver touch. Whether or not nurse-delivered healing touch, hand massage, or other forms of tactile stimulation offer holistic procedural comfort for children is currently unknown. As previously reviewed in the background section, however, nurses provide feasible interventions more because time management is a barrier to good pediatric procedural management.

Nursing Feasible Comfort Interventions. In one study, researchers found that patient-controlled warming blankets enhanced thermal comfort and decreased preoperative patient anxiety levels prior to surgery (Wagner & Kolcaba, 2006). This was a simple intervention that increased total comfort reported by patients in a pre-procedural (perioperative) location. This study highlights the role of environmental factors in a child's comfort level. The procedural comfort effects of simple environmental modifications such as warmth or coolness, light or darkness, or even the presence of pleasant smells has not been demonstrated. This dissertation study provides some evidence on how environmental factors are related to procedural comfort in children receiving a venipuncture.

Comfort Innovation

Comfort interventions and Comfort Theory have been proposed as valuable innovations in other areas of nursing, but they lack specific evidence from research to support them.

Recommendations for nursing comfort interventions and the integration of comfort theory into practice have occurred in the following areas: geriatric orthopedic nursing (Panno, Kolcaba, & Holder, 2000), labor and delivery (Koehn, 2000), perianesthesia nursing (Kolcaba & Wilson, 2002; Wilson & Kolcaba, 2004), healthcare administration (March & McCormack, 2009), nursing curriculum/education (Goodwin, Sener, & Steiner, 2007), and pediatric nursing (Kolcaba & DiMarco, 2005). Interventions to prevent or alleviate pain in children are commonly performed. The outcomes of pharmacological and nonpharmacological pediatric pain interventions are well documented. But, the outcomes of procedural holistic comfort interventions during invasive pediatric nursing procedures have not been widely studied. This is because an understanding of pediatric procedural holistic comfort is unclear. Findings of this dissertation research study add to the clarification of procedural holistic comfort for children.

These findings will additionally lead to further research investigating efficacious procedural comfort interventions in the pediatric population.

Literature Review

Comfort Development in Children

Katharine Kolcaba pioneered the concept of nursing comfort in the late 1980s and early 1990s. But, the term comfort was used in many child health-related manuscripts before this. Although "comfort" is interchangeably used with the term pain, it is vitally important to gain a better understanding of what is already known about comfort. This will help identify the existing appreciation of comfort and determine if it strays from a holistic point of view- treating the whole person and all of their comfort needs. All of the studies reviewed in this section explicitly address the word "comfort" as an outcome or as being investigated in children. This will in turn add clarity to how child comfort began and how it is interpreted in the pediatric population. As mentioned previously, no age criteria were established in the review of child comfort development.

Child Comfort 1960s-1980s. In the late 1960s, 1970s and 1980s, literature on comfort in children that emerged appeared to focus on a specific type of comfort compared to generalized comfort measurement. Previous researchers have investigated child comfort specific to: a certain area of the body, body sensations, type of illness or disease, and or a healthcare setting. Various comfort measures are essential to understand in children because many children have specific comfort indications. It is, however, equally important to obtain a universal appreciation of pediatric holistic comfort in specific situations such as invasive nursing procedures. This appreciation and exploration of comfort should relate to the various holistic needs of the child.

Thermal Comfort. One researcher conducted two related studies in two different countries: thermal comfort levels among school-age children in both England and Australia classrooms (Auliciems, 1969; 1974). In the earlier study (1969) the researcher measured thermal comfort among children in England aged 11-16 years between the months of January and April, then the following months between October and March. In the 1974 study, thermal comfort measurements were taken on children in Queensland, age 8-12 years, between May and August. In both studies subjective information was used, indicating the already recognized importance of child self-report in this time period. The researcher used a numeric thermal sensation scale with eight different measurements of thermal comfort: much too warm, too warm, comfortably warm, comfortable (neither warm nor cool), comfortably cool, too cool, much too cool (Auliciems, 1974, p. 340). Findings revealed that children in Australia experienced more cold stress while children in England had more experience with heat stress. Here the researcher assumed that child "comfort" was defined by temperature in the environmental domain and did not address physical, psychospiritual, or sociocultural aspects of comfort. While this study incorporated the use of measurement only, other studies moving forward included the provision of comfort interventions.

Verbal and Tactile Comfort. The effects of verbal and tactile comfort on distress level were later studied among 63 infants and young children age 3 days to 44 months (Triplett & Arneson, 1979). Nurse investigators used the objective assessment when crying ceased as the indicator of decreased distress. These distress levels were documented on an investigator-developed instrument. All participants were randomly chosen to receive either: (a) both tactile and verbal comfort, or (b) verbal comfort for five minutes followed by tactile comfort if verbal comfort did not stop the child from crying. Findings suggested that both tactile and verbal

comfort combined provide significantly more comfort (F= 47.27, p < .001) than verbal comfort alone and followed by tactile comfort. In this study, the researchers also use the term comfort to essentially describe only pain and distress. Triplett and Arneson's definition of distress in this case was pertinent to the review: "manifestations of displeasures as manifested by crying, whimpering, sobbing, yelling, or verbal protestations." (p. 18). Note here the definition that includes indicators of possible pain, fear, anxiety, anger, and sadness.

Oral Comfort. In a study conducted by a group of scientists in the field of pediatric dentistry, comfort levels of children undergoing a rubber dam clamp application were evaluated (Abdulhameed, Feigal, Rudney, & Kajander, 1989). A rubber dam clamp is an instrument used by dentists to isolate a tooth during procedures; it also helps to keep the tongue and cheeks protected from injury (S. Orwick-Barnes DDS, personal communication, April 12, 2014). The researchers studied the effects of peripheral electrical stimulation on the "comfort" of 30 participants between the ages of 8 and 14 years. The instrument to measure subjective comfort was used at five different times of measurement and was reported as being a Visual Analog Scale (VAS) of smiling and frown faces. A VAS is commonly made up of a 10 cm line with tic marks, much like a ruler. On one end is indication or best possible feeling (pain, fear, anxiety, distress, sadness, etc.) and on the other end is indication of worst possible feeling. The child will typically draw a line through how they feel. An objective measurement of heart rate was also monitored throughout the entire procedure. The researchers found no significant differences (F= .58, no pvalue reported) among frequencies in comfort produced by the electrical impulses. In this study the researchers found inconsistent measurements between heart rate and VAS scores. As a result they make a very important assumption that these inconsistencies "may reflect the idea that comfort is a complex construct incorporating both pain and contextual factors" (p. 55). Although

Abdulhameed et al. (1989) were assessing pain in their study; they also recognized that comfort is more than simply the absence of pain.

The development and investigation of comfort in children thus far appears to be measurements of tactile, verbal, oral, and thermal sensations- all physiological in nature. Comfort is defined by one group of researchers as "complex," encompassing more than simply pain or distress (Abdulhameed, 1989). Another group of researchers defined comfort as a lack of distress and crying. These researchers also measured pain among children in their study while simultaneously reporting results on comfort levels. Self-report of comfort was seen in three of the aforementioned studies. The purpose of this dissertation study was to ask young children to describe their holistic procedural comfort. A self-report measurement of comfort should always be used whenever it is possible (K. Kolcaba, Personal Communication, 2013).

Modern Child Comfort Development. Beginning in the 1990s and after the turn of the century, new measurement, understanding, and exploration of comfort transpired. Some of the researchers were still confusing the terms pain and comfort while others separated the concepts but provided little analysis or description of their differences.

Comfort Talk. One mixed methods study conducted by professionals from speech therapy and nursing was different than others found. Proctor, Morse, and Khonsari (1996) examined the language that trauma center nurses use to comfort patients in distress. The sample included 21 children out of 67 participants. Comfort talk also known as "talking through" was defined as "a patterned rhythmic speech to get patients through painful procedures..." (p. 1670). In this study nurses were videotaped while talking to patients and the tapes were reviewed individually for a comfort talk register and for "talking through" utterances (p. 1670). From all videos, only 29 patient scenarios (16 of these pediatric cases) had talking through language used

for patient comforting. Findings from the quantitative portion of the study indicated that pediatric patients received 77% (adults received 23%) of all patient directed comfort talk. Qualitative findings revealed that nurses used comfort talk for four main reasons: (a) to encourage patients to hold on or tolerate the pain, (b) to obtain information that helped with patient assessment, (c) to exchange information about procedures, and (d) to verbally communicate caring.

Similar to Abdulhameed et al. (1989), the dialogue in Proctor et al. (1996) demonstrated that comfort and the absence of pain are the same thing: "at other times, verbal comfort measures may enable the patient to endure, to hold on, and to maintain control when the pain is caused by injury, and essential medical procedures are overwhelming" (p. 1669). It could be interpreted here that the researcher is saying verbal comfort measures can help to manage pain. This study is important in this review as it incorporates a new type of comfort provided by nurses-talking comfort. In this dissertation study, the PI communicated verbally to children. The interview questions were carefully considered to encourage developmentally appropriate talk.

Comfort and Pain. Pain and comfort were concurrently addressed in one study. In another mixed methods approach (with limited descriptive quantitative data only) conducted by nurse scientists, the researchers examined the patterns of pain and comfort descriptions by caregivers and 21 children with sickle cell disease (Beyer, Simmons, Woods, & Woods, 1999). Results indicated that pain and comfort are chronologically ordered in eight phases starting at baseline, upwards to the middle at a peak pain experience, and down to the end at pain resolution. These terms are not holistic- they do not address the needs of the whole person. Within these stages the researchers found child and caregiver initiated pain and comfort interventions. Some of these interventions included: oral analgesics, IV analgesics, rubbing, increasing fluids, heat application, distraction, prayer, sleep, and psychological comforting.

Although, in this study the measures for treating pain and comfort are grouped together as one, leaving questions about which interventions are for comfort and which are for pain. How in fact comfort differed from pain in these patients is unclear. Beyer et al. (1999) represent pain and comfort as being the same. But, comfort cannot be reduced strictly to a lack of pain. The patient's psychological, emotional, spiritual, cultural, environmental, and physical comfort needs are important (Kolcaba, 2013). Additionally, some physical comfort needs are not necessarily painful, such as nausea, elimination needs (urge to urinate or defecate, urinary retention, constipation, bowel/bladder dysfunction), or itching.

Sleep Comforters. Another researcher used a mixed methods design to explore differences in sleep quality among children who used varying self-comfort sleep measures (Deakin, 2004). A survey method elicited quantitative measurements and qualitative data collection in the form of open-ended responses from caregivers. Convenience sampling was used to recruit 126 survey participants. Male and female children were nearly equally represented. The types of sleep comforters reported by caregivers in this study included: bottles, soft toys, hard toys, cloths/blankets, movement by parents, movement by self, sound, a pacifier, and part of the parents body. A pacifier was the most frequently reported comforter (60%), followed by sound (34%), soft toys and movement by the parent were equivalent (33%), followed by a soft cloth (27%), and to a smaller degree the remaining comforters. The researcher concluded that easier access comforters for children at times of sleep led to improved success of sleeping through the night. Deakin's findings offered important information for the procedures of this dissertation study, which were implemented during and after interviews, including the provision of toys for the children to play with during the questioning.

Interpretive Studies. In the next three studies reviewed, the investigators used an interpretive approach to elicit meanings and descriptions of comfort to children and adolescents: phenomenology and qualitative content analysis. These three studies are unique because they offer rich meaning and description of comfort as described by children and adolescents. Only one study included comfort meaning described by children younger than 11 years and only one child was younger than eight. This review of qualitative studies helps to affirm the still missing interpretive data on holistic comfort to a child in the preoperational stage of development.

In a study focused on the child explanations of being acutely (and temporarily) ill, nurse and clinical science investigators interviewed five children and adolescents age 11 to 18 years (Forsner, Jansson, Soerlie, 2005). Qualitative content analysis was conducted and participants described feeling *lost*, *hurt*, and *in need of comfort*. The children described the feelings of discomfort as needing treatment with comfort- both by themselves and by others. Self comfort was discussed as being "peace and quiet", changes in positioning, "using imagination", and having positive thoughts of the illness "not being dangerous" and that everything was going to be okay (p. 319). Comfort by others was explained as "parents being really important to them," being acknowledged by staff and family, "nurses listening," and providing explanations (p. 319-320). Methodological rigor was discussed including the use of peer debriefing and external auditing. These findings are important because, like this dissertation study, they represent holistic descriptions reported by the child and interpreted by the researchers.

Nurse researchers also conducted a phenomenological study investigating the meaning of comfort and discomfort in 12 children (age 3-17 years). Participants were previously critically ill and hospitalized in a pediatric intensive care unit (Carnevale & Guadreault, 2013). It was reported that some children had a difficult time remembering the experience, indicating that

recall of information may be an issue in young children. Researchers conducted formal interviews with the children lasting 30-45 minutes. This interview included the child drawing a picture of him or herself while critically ill. Elements of methodological rigor including credibility, confirmability, and fittingness of findings were discussed.

Overall findings of Carnevale and Guadreault's (2013) study reveal that children described discomfort as: "boredom, missing significant others, physical symptoms, noise, problems with eating, fear/worry, and pain/hurt" (p. 23). Comforts were described as: parents, visitors, friends, and hospital staff, stuffed animals, blankets, entertainment, food, gifts, sleep, and waking up" (p. 23-26). Similar findings were also noted in Forsner et al. (2005) where children reported parents and hospital staff/nurses as being important. Another similarity was found with Beyer et al. (1999) where child participants additionally indicated that sleep was comforting.

Children diagnosed with cancer require comfort because of their disease process and because of the discomfort produced from curative, palliative, procedural, and surgical treatments. So, it is not surprising that a study exploring the meaning of comfort among children with cancer has recently been conducted (Cantrell & Matula, 2009). These researchers used a hermeneutic (human understanding) analysis to describe the meaning of comfort and being cared for by pediatric oncology nurses among a sample of adolescent cancer survivors. Four individuals were interviewed in a focus group and seven of them were interviewed via phone. Although the purpose was to describe comfort as a child with cancer, all of the study participants were adults when the interviews took place. They were each asked to describe their experiences with cancer as a child. This can affect recall of information and may diffuse comfort and caring meanings perceived as an adult with those meanings perceived as a child. There was no discussion of rigor.

Interviews were 30-60 minutes. Participants were asked: "Please describe experiences you have had in being cared for by pediatric oncology nurses during your treatment for cancer" (p. 305). Researchers also used probes and encouraged expansion of perceptions and descriptions. Five themes were found in analyzing the data: (a) you just can't pretend to care, (b) try to take the hospital experience out of the hospital, (c) I'm not just another kid with cancerthere's a lot more about me that you should get to know, (d) caring for me also includes caring for my family, and (e) nurses make treatment experiences more bearable through their small acts of caring. The researchers interpreted more about child experiences with nursing caring then they did about child comfort. These are closely related concepts but they are not the same. In this dissertation study the PI listened to children's descriptions of holistic procedural comfort carefully. Interview questions were directed specifically at the child's comfort needs and procedural experiences. This helped to elicit the most purpose-driven content.

Pediatric Perioperative Comfort. One research study incorporated the specific use of Kolcaba's comfort theory and comfort interventions in children (Moriber, 2009). In this unpublished dissertation study the term "comfort" was used frequently instead of words that indicate opposites such as pain, discomfort, fear, anxiety, distress, etc., as explained previously. Moriber used Kolcaba's holistic comfort theory as her guiding framework and investigated comfort in the pediatric outpatient perioperative setting. This fills a gap in the literature thus far because the researcher is not defining comfort as the absence of pain, rather to incorporate physical, psychospiritual, environmental, and sociocultural needs.

The purpose of Moriber's study was to test the validity and reliability of the Pediatric Perioperative Comfort Instrument (PPCI). This tool was designed to measure observed comfort in this population among children aged 2 to 10 years. The author makes an essential note that

comfort outcomes have not been well evaluated in children and that instruments to measure pediatric holistic comfort are not readily available. Although having this instrument is a positive step forward in the development of knowledge related to child comfort, it is an observation instrument that does not incorporate the measurement of child self-report. This dissertation study will help to identify elements that are unique to child procedural holistic comfort so that future pediatric instruments designed to measure holistic comfort can incorporate the use of self-report.

Comfort Intervention Studies

Music Therapy. Music is an artistic expression of sounds shown to be an effective adjunctive soothing therapy. Results from a recent systematic review of intervention studies incorporating passive music, active music, and music videos, showed that music may decrease anxiety and pain related symptoms among children experiencing invasive procedures (Klassen, Liang, Tjosvold, Klassen, & Hartling, 2008). Although quantitative evidence indicates that music therapy has been helpful in reducing procedural pediatric pain and anxiety, limited qualitative research has been conducted to support this as a holistic comfort measure from the young child's perspective. Literature on studies implementing music as a procedural intervention for children will be reviewed here.

Active Music Distraction. Two of the studies in this theme used active and integrative music intervention. Press et al. (2003) and Noguchi, (2006) both investigated outcomes of active music distraction with child responses related to music content. Press et al. recruited 94 children admitted to an Israeli emergency department (ED) between the ages of 6 and 16 years. In this randomized controlled trial researchers measured pain related to a venipuncture procedure. Child pain threshold was also measured. Press et al. (2003) found that children in the experimental group reported significantly less pain but after the researchers controlled for confounding

variables the effect was not significant (F= 2.3, p= .14). Press et al. also found that girls and children with a lower pain threshold experienced less pain with the music intervention. The differences in pain among boys and girls here is important to consider. Young males and females may experience holistic comfort differently- finding increased relief with interventions that are distinctive to their gender.

Noguchi (2006) found similar insignificant outcomes. This researcher investigated the effects of an imaginative story in musical format on distress and self-reported pain. Sixty-four preschool aged children receiving routine immunizations from three different medical care clinics in a culturally diverse metropolitan area were included. Although the control group had higher levels of distress and the experimental group veered toward reporting less pain, Noguchi (2006) found that these results were not statistically significant (p > .05 for each). Like Press et al. (2003) participant gender, age, and previous number of injections received were not significantly different among the children. An important finding in this study was the increased distress levels with decreased age. This finding is particularly important to this dissertation study because minimal qualitative evidence exists on the understanding of holistic comfort in younger children. If younger children experience more pain and distress during procedures then they likely require more procedural comfort interventions. In this dissertation study, young children between the ages of 5 and 7 years described various procedural holistic comfort needs.

Both Noguchi (2006) and Press et al. (2003) had similar strengths and weaknesses. Both studies were randomized controlled trials, increasing the internal validity and strength of the results. Additionally, both studies incorporated the use of valid and reliable instruments, further increasing the validity of the study findings. Press et al. had the additional strength of using the same needle insertion site for all children, which again increases control. A weakness noted in

these two studies is the limited generalizability beyond children in the emergency department (Press et al.) and children in medical office clinics (Noguchi). The outcomes of active music distraction as in all comfort interventions may be quite different depending on the setting (emergency, inpatient, or primary care) and the situation (emergency or non-urgent). These results could however, be generalizable to the type of invasive procedure such as venipuncture needle insertions and immunization injections. Neither study addressed sample power or effect size so it is difficult to establish the appropriateness of their sample sizes. No mention of a guiding theoretical framework was found for either study. Considering the decrease in pain and or distress, but insignificant findings after controlling for covariates, more research is indicated in this area

Live Music. Three studies included the use of live music during invasive pediatric procedures. This music was performed by a music therapist or trained musician. Two of these groups of researchers showed similar results (Whitehead-Pleaux, Barzya, & Sheridan, 2006; Whitehead-Pleaux, Zebrowski, Baryza, & Sheridan, 2007) while the remaining researchers demonstrated quite different findings (Caprilli et al., 2007). Each of these studies investigated similar dependent variables and all of them used the same pain scale. Only two of the three studies integrated the use of theory and all of the researchers in these studies used valid and reliable research instruments.

Whitehead-Pleaux et al. (2006) and Whitehead-Pleaux et al. (2007) investigated the effects of live music during an invasive nursing procedure. In these studies, researchers examined effects of music performed by a music therapist on pain and anxiety. Both of these groups of researchers let patients select their own music genre. In their randomized controlled trial, Whitehead-Pleaux et al. (2006) recruited 14 pediatric burn victims age 6-16 years.

Researchers investigated anxiety and pain associated with donor burn site dressing changes. A donor burn site was defined by the researchers as being a wound in which skin is purposely removed from a healthy area to help restore burn injury in another body location. Results indicated higher levels of distress in children who received music intervention as reported by nurses. But no statistical difference was noted in self-reports of pain (p= .345) in children compared to control group. Anxiety was higher among the children in the experimental group both before and during the procedure. However, the heart rate of children in the experimental group was significantly lower (p= .003) than that of the children in the control group. No relationship between independent and dependent variables were found indicating that gender, race, parental presence, and previous music therapy did not influence results. This is different from Press et al. (2003) above who found correlations between dependent and independent variables. Whitehead-Pleaux et al. (2006) discovered variable and inconclusive results. This demonstrated a need for further evaluation of music therapy in this population group, which was completed soon thereafter.

In a similar study involving nine recruited burn victims; Whitehead-Pleaux et al. (2007) explored the effects of live music therapy on pain and anxiety. This study's design differed from Whitehead-Pleaux et al. (2006) because it was a mixed methods approach. Researchers conducted interviews with children and caregivers. There was no discussion of qualitative data analysis, only reported findings from the interviews. A non-experimental pre-test post-test measurement of dependent variables (pain, anxiety, and hear rate, oxygen saturation) was used. The invasive procedure was also different. The type of nursing procedure (burn dressing change, suture removal, and stent take down) varied from patient to patient. No differences in pain or distress were found over time (no reported p-values). However, qualitative findings suggest that

music therapy "somewhat" reduced anxiety or nervousness and that it was "a lot" helpful at reducing pain. One child reported the music therapy "took his pain away" and this child's mother agreed stating that "yes it did dull his pain a lot. Because I used to sing at home, and it brings him back to home" (Whitehead-Pleaux et al., 2007, p. 230). Talking to children and their caregivers adds to this study because it begins to describe music comfort effects through the child.

Strengths and limitations were somewhat similar in Whitehead-Pleaux et al. (2006; 2007). Strengths included the use of valid and reliable instruments. Each also integrated the use of an appropriate guiding theory: the Gate Control Theory of Pain (Melzack & Wall, 1965). Whitehead-Pleaux et al. (2006) used a randomized trial, which increases internal validity, and Whitehead-Pleaux et al. (2007) used a mixed methods approach, which adds the strength of their findings. No discussion, however, of qualitative data analysis or rigor such as maintaining credibility, confirmability, or transferability was found. Limitations were also similar in both of these studies. Neither group of researchers discussed sample power or effect size. Both studies additionally used different music interventions for each child, depending on their preference, which can affect outcomes. Similarly, Whitehead-Pleaux et al. (2007) included various invasive nursing procedures instead of only one as in Whitehead-Pleaux et al. (2006). Lastly, generalizability may be difficult considering these were all burn victims- generally known as a trauma with one of the highest rates of discomfort. Quantitative findings were similar here, showing mixed results in both studies.

The results of Whitehead-Pleaux et al. (2006; 2007) are not found in all procedural comfort intervention studies in children. Live music was found a statistically significant intervention for decreasing pain and distress in children undergoing venipuncture (Caprilli et al.

2007). In this randomized controlled study a sample of 108 Italian children (aged 4 to 13 years) undergoing blood sampling were recruited. Each child was randomly assigned to either a treatment group characterized by live music therapy during the procedure or a control group in which children received routine support and standard care. Instruments with established reliability and validity were used. Results indicated that the music intervention decreased distress and pain before, during, and after venipuncture. Further, as in Noguchi (2006), higher distress was correlated with younger age. A difference noted here from Whitehead-Pleaux et al. (2006; 2007) is the use of a trained musician, instead of a music therapist. Perhaps, the use of a professional musician is a more effective form music therapy than a music therapist. It is also possible that variations in the study procedures and recruitment affected results. But, the sample differences alone must be carefully considered. Caprilli et al. (2007) studied children in an emergency room getting blood sampling. While both Whitehead-Pleaux et al. studies included burn victims. These two patient groups have distinctively different baseline comfort needs in addition to their procedural needs. The findings of these three studies are important to this dissertation research because comfort needs appear to be greater in younger children and those with differences in baseline comfort-comfort for one child may not be the same for another child.

Amusement and Entertainment. From dolls and Lincoln logs to rubber ducks and hula-hoops, toys have long been a pleasurable part of childhood. With the turn of the century came numerous advances in technology, which have added to the development of even more digital and computerized toys containing various entertaining applications. Studies implementing the use of interactive toys for comforting children during invasive procedures were found more than any other theme.

Toys and Play. Two studies focusing on toys included the same comfort intervention. Carlson et al. (2000) and Tufekci, Celebioglu, and Kucukoglu, (2009) investigated the effects of a Kaleidoscope toy during pediatric venipuncture or IV insertion procedures. A Kaleidoscope is a cylinder-shaped visual toy that one can look through to see various scattered shapes and colors. The visual appearance changes when the body of the toy is rotated.

Carlson et al. (2000) used a two-group randomized design and conveniently recruited 384 children from 13 different hospitals across Canada and the United States. Children, 4 to 18 years were assigned to either a treatment group with Kaleidoscope play distraction and procedure explanation or a control group with simple attention and procedure explanation. Carlson et al. measured behavioral distress, self-reported pain, and self-reported fear. Findings from Carlson et al. revealed no statistical difference in pain (F= .518, p= .47), distress (F= .31, p= .58), or fear (F= .92, p= .34) among children in the experimental and control group. Younger children were significantly more distressed (p= .001), reporting higher pain (p= .03). Although it was not statistically different (p= .07), younger children were also more fearful than older children. This is now a commonly occurring outcome among the research studies discussed thus far.

Tufekci, Celebioglu, and Kucukoglu, (2009) also examined the effects of a Kaleidoscope toy on pain in children receiving a venipuncture procedure. This group of nurse scientists in Turkey recruited a sample of 206 school-age children. The children were evenly distributed with regard to gender and were nonrandomized to either a control group (no Kaleidoscope intervention) or treatment group (Kaleidoscope intervention). Findings from the study revealed that the Kaleidoscope intervention did significantly affect perceived pain as compared to the control group (p < .01), thus yielding different findings than Carlson et al. (2000) who found no statistical significance between groups with a Kaleidoscope distraction.

Both Tufekci et al. (2009) and Carlson et al. (2000) have strengths and limitations. Each of these studies has larger sample sizes than previous studies. Carlson et al. used a strong power of .80 and medium effect size to determine their sample. Use of a control and experimental group adds to the internal validity of these two studies: Carlson used an experimental design whereas Tufekci et al. used quasi-experimental- both strong designs. Both groups of researchers also used valid and reliable study instruments. There were limitations in these studies. Neither Tufekci et al. or Carlson et al. discussed the integration of theory to guide their work. Limitations unique to Carlson et al. included multiple procedure sites, which could affect how procedures were administered among locations, and two different nursing procedures performed (venipuncture and IV insertion). Similarly, Tufekci et al. was a nonrandomized study, affecting normal population distribution, and they reported no discussion of sample power or effect size. These control issues may have contributed to why one group found significance with the Kaleidoscope and the other did not. It appears that a Kaleidoscope may be one toy that offers comfort to a child related to invasive procedures. This is important because in this dissertation study, toys were provided for children to play with in the interview procedures.

Interactive toy distraction has been investigated among children diagnosed with cancer (Dahlquist, Pendley, Landthrip, Jones, & Steuber, 2002a). This is the first study that involved an electronic toy- a type of entertainment that has become exceedingly popular for children of all age groups. Twenty-nine children aged 2 to 5 years undergoing chemotherapy with routine port access (IV chemotherapy) or intramuscular injection (chemotherapy injected into the muscle) were recruited and evaluated for behavioral distress levels. Dahlquist et al. (2002a) randomized children to the distraction group or the wait-list control group. Children in the distraction group were assessed at baseline without intervention for three procedures and then with the distraction

intervention for three more procedures. Children in the control group were assessed at baseline procedures and then again for three more procedures without the distraction intervention. Results indicated significantly lower distress among children reported by parents (t=5.42, p<.01) and nurses (t=2.52, p<.02) who received distraction with the electronic interactive toy.

Dahlquist et al. (2002a) used a randomized repeated measures two-group design. No sample power, however, was discussed and an instrument with unknown validity and reliability was used which both affect validity of the study findings. Moreover, the study results lack generalizability beyond children receiving IV or intramuscular chemotherapy. Additionally, like Whitehead-Pleaux et al. (2006; 2007) who investigated children with burns, Dahlquist et al. (2002a) have investigated children with cancer. These children may have varying comfort needs and different baseline needs. The fear of receiving chemotherapy alone could affect the dependent variables measured in this study. This important detail was considered when outlining criteria for inclusion in this dissertation study, which began by exploring descriptions of children without serious or life-threatening acute illnesses. More qualitative descriptive research will be needed in the future to address the holistic procedural comfort needs of children with specific chronic illnesses or unique health problems.

Screen Time. Screen time is another form of amusement/entertainment that was found in the literature. Three studies integrated the use of TV cartoons and one very recent study investigated the use of an iPad as distraction. Researchers investigated their effects on pain, anxiety, distress, or both in children during immunizations and venipuncture procedures.

Cassidy et al. (2002) compared the analgesic effects of audiovisual cartoon television distraction with that of a blank TV screen. Sixty children, in Canada, age 5 years needing a routine preschool immunization were recruited for this study. Each participant was randomly

assigned to receive distraction with a TV musical cartoon (experimental group) or a blank TV screen (control group). The authors focused on effects of pain, however, anxiety was also measured. Results demonstrated that cartoon TV distraction did not significantly affect postneedle pain levels (p < .07) in children undergoing routine immunization. These results differ from that of two other studies involving TV distraction: MacLaren & Cohen (2005) and James, et al. (2012).

In one experimental study, investigators explored the effects of two different distraction approaches: a passive cartoon movie distraction and an interactive toy robot distraction (MacLaren & Cohen 2005). Researchers recruited 88 children receiving venipuncture during the pre-surgery admission process from a university-affiliated hospital. These children were randomly assigned to the passive distraction or interactive distraction. Observed distress and self-reported pain were measured. Self-report of pain was communicated by the child in response to a computer-generated scale of faces depicting smiles and frowns with no discussion of validity or reliability. Results from MacLaren and Cohen's study suggest that the passive distraction with a cartoon movie is superior to the interactive distraction in lowering distress levels among children during routine venipuncture. The results of MacLaren & Cohen (2005) differ from Cassidy et al. (2002) who found no statistically significant effect of cartoon TV during immunization needle injections.

Another group of researchers found significantly (t= 9.04, p= .001) less pain and behavioral distress responses among Indian children who received an animated cartoon intervention (James et al., 2012). Researchers recruited 50 children, receiving venipuncture between the ages of 3 and 6 years, and who were admitted to a pediatric surgery ward. A quasi-experimental design was used: participants were nonrandomized to a control group with routine

procedural care and a treatment group including an intervention with an animated TV cartoon.

James et al. used the Face, Legs, Activity, Cry, Consolability (FLACC) scale (Merkel, Voepel-Lewis, Shayevitz, & Malviya, 1997) to measure "pain-related behavior" and whether the child felt "relaxed and comfortable, mild discomfort, moderate pain, severe discomfort, or both" (p. 200). This study is important in this review. The FLACC scale was designed to measure pain.

Note here how the researchers use the words comfort and pain similarly, as if being comfortable denotes no pain or being severely discomforted denotes a lot of pain. This is a clear example from the pediatric literature demonstrating how comfort and pain are often used interchangeably. Additionally, James et al. found that younger children experience higher rate of pain/discomfort, further indicating that younger children in the preoperational stage have increased comfort needs.

In a study investigating a more contemporary form of screen time, physician scientists examined caregiver perceptions of pain and distress with iPad movie videos or iPad interactive games during child immunizations in Illinois (Shahid, Benedict, Mishra, Mulye, & Guo, 2015). Researchers recruited 103 caregivers of 2 to 6-year old children for this six-month quasi experiment. The first three months of research and recruitment was designated as the control group while the subsequent three months made up the distraction intervention group. Using a survey developed by the authors, parents answered five questions focused on perceptions of their child's pain, fear, and anxiety. Researchers found that when comparing survey questions individually, fear and anxiety were significantly lower (P=.006), crying time was significantly less (p=.02), and overall caregiver satisfaction with pain control was significantly higher (P=.03). Overall perception of distress was not significant when compared to the control group (P=.07). This study is significant to the review because interventions with an iPad are quick, small, and relatively easy for a nurse/clinician to administer during invasive procedures. The results of

Shahid et al. (2015) differ from Cassidy et al. (2002) who found no significant differences in pain among children watching TV during immunizations.

Cassidy et al. (2002), MacLaren and Cohen (2005), James et al. (2012), and Shahid share similar strengths. Two groups of researchers used all valid and reliable instruments (Cassidy et al. (2002); James et al. (2012). Additionally, Cassidy et al. (2002), James et al. (2012), and Shahid et al. (2015) incorporated either experimental or quasi-experimental procedures, which add to the strength of study findings. A unique strength noted is MacLaren & Cohen's inclusion of appropriate theoretical underpinnings related to distraction. Limitations were also noted. The instrument to measure "comfort" in MacLaren & Cohen's study is indicated for the measurement of pain. Generalizability to various ethnicities and backgrounds is a concern in some of these studies. Cassidy et al. and MacLaren & Cohen, recruited 93% and 92% Caucasian participants, respectively. In Shahid et al.'s study, Black and Hispanic participants were over-represented. James et al. did not collect information on ethnicity, which is a weakness because comfort experiences may differ among children of different cultural backgrounds and ethnic origins. Additionally, MacLaren & Cohen (2005) and Shahid (2015) used measurement instruments that had no discussion or documentation of validity or reliability. This may negatively affect internal validity of the study. Additionally, Shahid et al. used a survey that included the same five questions to address perceptions of pain and distress in children between 2 and 6 years old. More research is indicated testing the comfort effects of screen time among children with various ethnic backgrounds, such that generalizations can be inferred about children.

Screen time interventions, including TV and the use of an iPad have varying results. Two studies showed significant decreases in pain among children in India and the United States.

Three studies showed significantly reduced distress. Only one study showed no significant

differences in pain or distress among participants in Canada. More research is needed in this area to conclude if screen time is an efficacious comfort intervention in children during invasive clinical procedures.

Virtual Reality. A newer form of audiovisual technology to reduce pain has also been examined. Two studies examining the effects of virtual reality entertainment were found. Wolitzky, Fivush, Zimand, Hodges, and Rothbaum, (2005) and Gold, Kim, Kant, Joseph, and Rizzo (2006) used virtual reality as a distraction technique during invasive nursing procedures. Gold et al. recruited 20 children (age 8-12 years) needing IV placement for magnetic resonance imaging (MRI) or computed tomography (CT). Wolitzky et al. used a sample of 23 children (age 7-14 years) diagnosed with cancer and needing central line port access. Both studies were conducted in the United States and incorporated valid and reliable measurement instruments. Both Wolitzky et al. and Gold et al. showed significantly reduced pain (p < .05, p < .01 respectively) among children who received the virtual reality intervention, respectively. These studies are significant to this review because technology use among children is rapidly growing. Whether these technology devices can enhance procedural holistic comfort (not only pain) among children receiving invasive procedures is unknown.

Live Animal Intervention. One experimental study significantly differed from all other studies found in this theme. Vagnoli et al. (2014) examined effects on pain and distress when implementing the use of a live dog during blood sampling procedures. Fifty children aged 4 to 11 years were recruited from Florence, Italy. Children who never before received a venipuncture were randomly assigned to one of two groups: (a) a control group where standard venipuncture care was provided, or (b) the intervention group where an animal assisted intervention expert encouraged the child to interact with the dog before, during, and after the blood sampling. No

topical anesthetic medication was used. Pain was measured using the Wong & Baker FACES scale or a VAS pain scale and distress was measured using the amended Observational Scale of Behavioral Distress- all valid and reliable instruments. No significant child self-reported pain differences were found between the two groups. However, distress was significantly lower among children in the experimental group. Cortisol levels were also measured and were found to be lower among children who received the dog intervention.

Vagnoli et al. (2014) implemented several procedures that strengthen internal validity: discussion of sample size/power determination, random sampling of participants, the use of all valid and reliable instruments, and recruitment of children with the same procedure experience history. The results of this study may however only be generalizable to children in Italy receiving routine venipuncture procedures. Additionally, although children were of varying ages, the use of two different pain instruments in the study does affect the pain outcomes. The implementation of a dog intervention seems like something that may increase some form of child comfort. The results are significant to this dissertation study in which children discussed comfort from significant others during venipunctures. While this animal intervention has some beginning evidence of lowering pediatric procedural distress, it would not be a feasible (or even possible) option for all child populations receiving an invasive procedure.

Caregiver Facilitation. Not surprising, the literature on comfort, included studies involving caregivers playing a role in procedural comfort interventions. Children may seek the comfort of a loved one during times of high distress, anxiety, or pain- again all possible elements of procedural comfort. Encouragement and guidance offered by caregivers is an important element of caregiver facilitated comfort interventions.

Parental Coaching. Three different studies used parental coaching and distraction. One of the studies showed no differences in pain or anxiety while two studies showed decreased behavioral distress. One nurse scientist and her colleagues investigated the efficacy of parents as distraction coaches for children needing intravenous (IV) cannulation (Kleiber, Craft-Rosenberg, & Harper, 2001). A sample of 44 preschool and school-age participants- diagnosed with a nonfatal chronic illness- and their parents were recruited for this single-blind experimental study. Adequate sample power and effect size was used. Children were assigned to an experimental or control group. The researchers evaluated children who had histories of repeated procedural interventions and controlled for this by using block randomization. The study took place in a large Midwestern United States hospital with a predominantly Caucasian population. This is becoming a recurrent finding, showing that more research on procedural holistic comfort is indicated in children with African American, Hispanic, Asian, American Indian, and other descents.

Pain, distress, and parent use of distraction were measured. The researchers developed a 7-minute video to show caregivers in the experimental group focused on child distraction with IV insertion. Results indicated that parents in the experimental group used significantly more distraction. But no statistical significance was found among pain (p= .44) or distress (p= .49) scores between groups. Distress did, however, decrease more over time in the experimental group showing progressive positive reaction to the distraction. Kleiber et al.'s research design, use of valid and reliable instruments, and content validity of the video are all strengths noted here. However, as is the case with most small-scale intervention studies, generalizability to a larger and more diverse population may be not be possible. This particular study shows that one

parenting distraction intervention may not enhance procedural holistic comfort. It does not show parents are not comforting to children in other ways during procedures.

In the same year, another group of researchers used an across subjects design to similarly investigate the use of parent coaching and distraction techniques during repeated episodes of port-a-cath access, intramuscular injection, and IV insertion (Pringle et al. 2001). Eight children diagnosed with leukemia, sickle cell disease, or chronic anemia participated in the study. The participants were between the ages of 3 to 7 years. Long term and immediate effects of a distress management program were examined over a period of 3 to 16 weeks. Interventions included parent training for coaching their child through an invasive nursing procedure and distraction with a computerized toy robot over three consecutive phases: baseline, treatment, and follow up. The researchers found that the distress management program including both parent coaching and the interactive robot toy can effectively reduce child distress. These results differ from Klieber et al. (2001) who found no significant difference in pain or distress with caregiver distraction. The longitudinal aspect and the repeated measures in this study as well as the use of a valid and reliable tool are noted strengths. The various nursing procedures investigated as well as the lack of sample power discussion are weaknesses. These issues may lead to increased risk for problems with internal validity and question of causality. Research about caregiver involvement is pertinent to this dissertation study because caregiver perspectives and descriptions of procedural holistic comfort were also explored.

Behavioral distress and pain were also examined in a replication study that assessed the effectiveness of a parent provided distraction intervention for pain management on various nursing procedures (Dahlquist et al., 2002b). Parents were instructed on how to coach and provide comfort to their child during the invasive procedure. The researchers also aimed to

evaluate whether the use of various age-centered interactive toy distractors were more, less, or as effective as one distractor such as the toy robot used in Pringle et al. (2001). Six children age 2 to 8 years were recruited for this across subjects longitudinal and repeated measures design. Similar to Pringle et al. (2001), participants in this study were recruited from a hematology, oncology, and immunology setting, and age appropriate electronic toys were used as distractors. Each child also received topical anesthetic prior to the nursing procedure. This extra intervention of topical anesthetic for standard procedure care in Dahlquist et al. (2002b) is noteworthy. Topical anesthetic pain prophylaxis was not completed for all participants prior to their venipuncture in this dissertation study. This raises an important question: what should standard of care for routine pediatric invasive needle procedures include?

Investigators found that mean behavioral distress scores decreased in five out of six children, indicating lower behavioral distress (Dahlquist et al., 2002b). These results support the findings of Pringle et al. (2001). The longitudinal design, use of a valid and reliable distress scale, and repeated measures are strengths here. The lack of discussion on sample power and small sample is a main weakness.

Positioning and Distraction. Another caregiver facilitation comfort intervention was positioning and distraction. Two similar studies examined the effectiveness of caregiver assisted positioning with venipuncture (Cavender, Goff, Hollon, & Guzzetta, 2004) and IV insertions (Sparks, Setlik, and Luhman, 2007). Both of these studies recruited participants from an emergency department setting. Each group of investigators used a randomized experimental design and their instruments utilized were valid and reliable.

Cavender et al. (2004) recruited 43 preschool school-age children receiving venipuncture or IV insertion to participate. Researchers examined the effects of positioning and distraction on

pain, distress, and fear. Children in the experimental group received standard care plus a parent guided positioning and distraction intervention. The parents were instructed on how to facilitate one of two comforting positions as well distractor toys. No statistically significant difference between groups was found in self-reported fear (p= .58), pain (p= .68), or observed distress (p= .13). All levels, however, were lower in the comparison group.

In a similar study, Sparks, et al. (2007) examined the effects of laying flat on an exam table versus being held upright by a parent on child distress during an IV procedure. One hundred eighteen Children aged 9 months to 4 years were recruited and randomly assigned to either a treatment group (upright position for IV insertion) or a control group (supine position for IV insertion). Topical anesthetic application was applied at the nurse's discretion. As a result 76 of the 118 participants received no topical anesthetic. Results indicated a significant decrease in distress (p=.02) in the experimental group as compared to the control group (Sparks et al. 2007). These findings support the conclusion of the previous study by Cavender et al. (2004) that positioning during venipuncture in children can at least in part lower distress levels. Limitations of these two studies were noted. Neither Cavender et al. (2004) or Sparks, et al. (2007) addressed sample power analysis. These researchers also each did not discuss a guiding theoretical framework. One limitation unique to Sparks et al. was the variance of topical anesthetic use, with some children receiving additional needle insertion pain relief while others did not. These two studies are important in this review because they indicate the presence of a caregiver holding or facilitating positioning may increase holistic procedural comfort. The findings of this dissertation study provide needed qualitative evidence from the child's (and caregiver's) perspective regarding caregiver holding/touch and holistic procedural comfort.

The integration of toys and television combined with the supplementary use of caregiver presence and facilitation of a comfort intervention was used in two studies: Bellieni et al., (2006) and Matziou, Chrysostomou, & Perdikaris, (2013). Both of these studies used a randomized controlled design, increasing strength of the evidence presented. Similar to MacLaren and Cohen, (2005) and Cassidy et al. (2002) previously discussed, the use of TV for passive distraction was implemented among outpatient pediatric patients in Italy. Bellieni et al. (2006) recruited 69 children aged 7 to 12 years receiving a routine venipuncture at an outpatient laboratory. Each child's mother was also recruited to participate. Researchers aimed to investigate the analgesic effect of passive television cartoons compared with that of active distraction with caregivers. Children were randomly assigned to one of three groups: no distraction, interactive distraction facilitated by mothers, or passive distraction with a television cartoon. No topical anesthetics were used. Bellieni et al. (2006) had similar findings to MacLaren and Cohen. Passive distraction with television cartoons had significantly (p < .05) more of an analysesic effect than interactive distraction by mothers. These results can be compared to Cavender et al. (2004), who found that parent-positioning distraction lowered pain and fear.

Similar to earlier reviewed studies by Carlson et al. (2000) and Tufekci et al. (2009), the next group of researchers also used a Kaleidoscope for distraction during venipuncture to reduce pain and anxiety among school age children (Matziou, Chrysostomou, & Perdikaris, 2013). But, this study also incorporated caregiver facilitation with distraction. One hundred thirty Greek children admitted to a pediatric hospital unit were recruited for this randomized controlled design. The study included two treatments groups (caregiver presence intervention and Kaleidoscope intervention) and a control group (neither intervention).

No discussion of validity or reliability was found on the measurement instruments. The tool for anxiety, however the State-Trait Anxiety Inventory for Children; Spielberger et al., (1973), has documentation of validity and reliability. Vital signs were also measured and used as an adjuvant objective rating of distress. Matziou et al. (2013) found that children who were touching their parent during venipuncture had: (a) reduced respirations, mean blood pressure, and pulse, (b) decreased pain response, and (c) less anxiety/distress. One limitation noted in this study is the unknown psychometrics of the pain scale. Additionally, for the control group: "the parent was not present nor was a toy provided" (p. 472). There was no discussion on what standard care for the control group included.

Seminal Study. In one earlier but classic study, researchers investigated the effects of "blowing away shot pain" and caregiver presence during childhood immunizations (French, Painter, & Coury, 1994). This study introduced increasing the use of a new distraction technique for children during invasive procedures. One-hundred forty-nine children age 4 to 7 years old were recruited and randomized to a control group defined by standard supportive care or a treatment group in which participants were taught "a trick" to blowing away the pain (French et al., 1994, p. 385). Results revealed significantly lower pain behaviors (p< .04) among children in the treatment group and a trend (although not significant) toward lower self-reported pain (p= .06). French et al. concluded that this blowing distraction is an effective way to alleviate a child's discomfort during immunization procedures.

Multifaceted approach. Invasive procedural management in children can be multimodal, including various interventions to ameliorate outcomes. Pharmacological and nonpharmacological interventions are at times combined during invasive procedures to enhance comfort and well-being. This combination of therapies is recommended for all procedures by the

American Society for Pain Management Nursing across the life span (Czarnecki et al., 2011). A number of studies were found in the literature that integrated more than one type of nonpharmacological comfort intervention or adjuvant therapy with pharmacological measures. This is a very important outcome indicating a more holistic approach to comforting children during procedures, treating the physical domain of the whole person and psychospiritual and sociocultural domain.

Routine Procedures. Five studies in the multifaceted approach were found in which researchers recruited children from an outpatient laboratory, on a routine basis, or in primary care. Outpatient procedures and primary care are important because the holistic comfort needs of a child in acute care or emergency care are different from those preparing for an outpatient or routine procedure. Three of these studies used child blowing distraction exercises in the multimodal approach while the other two studies integrated the provision of procedural information as a preparation intervention for children.

Kolk, Van Hoof, and Fiedeldij, (2000) and Tak & Van Bon, (2006) both used a multifaceted approach to comfort interventions. But their studies differed because they used a preparation technique that involved giving the child information about the procedure prior to child receiving it. Kolk et al. investigated the effects of topical anesthetic cream and parental involvement in procedure preparation on child distress during routine venipuncture. In this experimental study 31 children age 3 to 8 years living in Amsterdam were randomly assigned to a treatment or control group. The control group was brought into the exam room with their parent and "injected right away" without provision of any interventions (p. 256). The authors found that prepared children in the treatment group exhibited significantly less degree of distress (p= .01) than children without preparation and prepared children showed lower distress levels

overall (Kolk et al. 2000). These findings are pertinent because children and caregivers in this dissertation study offered related qualitative descriptions on preparation and explanation for children receiving needle procedures.

Tak & Van Bon, (2006) showed somewhat different results in their study. Researchers also investigated the effects of topical anesthetic cream, verbal procedural preparation, and distraction on distress levels of children age 3 to 12 years. One hundred thirty-six Dutch children were randomly assigned to one of six groups: (a) control group with no intervention, (b) treatment group with information preparation only, (c) treatment group with EMLA topical anesthetic cream and information preparation, (d) treatment group with a placebo topical cream and information preparation, (e) treatment group with EMLA cream, preparation information, and distraction, or (f) treatment group with placebo cream, distraction, and information preparation.

Results indicated that EMLA cream decreased distress at the time of injection only, placebo decreased reported pain slightly, and procedural preparation with information and distraction show no effects. Although the word comfort was not used in this study, researchers implemented a more holistic intervention plan because they addressed nonpharmacological and pharmacological interventions. Another finding included older children experiencing less distress and pain than younger children (Tak & Van Bon, 2006). Again, this is a frequently occurring finding across the literature review, further verifying that younger children may have increased comfort needs.

Both Kolk et al. (2000) and Tak & Van Bon, (2006) used an experimental design. They additionally used valid and reliable instruments to measure distress, which increases internal validity of the studies. They also share some of the same limitations. Both of these studies were

generalizable to similar areas and settings, they may not represent outcomes of children in other countries or those in an acute care setting. A limitation unique to Kolk et al. was noted: it was unclear which participants received topical anesthetic cream prior to the procedure. "Injected right away" implies that control participants received no intervention. Interpretation of this finding is therefore a challenge because whether distress was lower among prepared children due to the effects of the topical anesthetic cream, the verbal parent preparation, or both is unclear. These studies showed different results with regard to effects of procedural preparation. This could be related to study procedures and interventions that were different among groups. A new finding in this literature review is that both of these groups of scientists considered the child's physical comfort (topical anesthetic), psychospiritual comfort (distraction through preparation), and sociocultural comfort (caregiver presence)- a more holistic approach to procedural comfort. This progress therefore further indicates the importance of qualitative research on procedural holistic comfort in young children.

Three groups of researchers used child blowing distraction exercises in their routine multimodal approach. Lal, McClelland, Phillips, Taub, and Beattie, (2001) tested the effects of topical anesthetic cream versus placebo in children receiving an interactive blowing distraction. In a similar study Caprilli et al. (2012) also examined the effectiveness of a blowing technique and topical anesthetic cream while adding caregiver presence. Burgess, Nativo, and Penrose (2014) investigated the effects of a blowing exercise and topical vapocoolant spray on pain in children receiving immunizations.

Lal et al. (2001) recruited a convenience sample of 27 children, age 4-8 years, receiving routine venipuncture at an outpatient lab in the United Kingdom. This was a randomized, double-

blind controlled trial. All needle sticks were placed in a vein on the back of the child's hand (dorsum) and topical anesthetic was used. The distraction intervention was described as instructing the child to slowly count to five followed by blowing air into a windmill. This technique was preformed repeatedly until the completion of the procedure. Children were also sitting in their caregivers lap so they could "cuddle" (p. 155). There was not a significant difference in pain score between the two groups (p= .07) and no differences were found with or without EMLA anesthetic cream. The pain scores, however, were low in both groups throughout the procedure, indicating the effectiveness of distraction. Results here suggest that a blowing distraction integrating the use of a toy windmill may be beneficial but that additional topical anesthetic may provide little pain relief.

Burgess et al. (2014) used a similar intervention of blowing play. In this study researchers examined the pain and distress effects of children using a party blower before and during and during a routine procedure. Each child also received pain prophylaxis with a vapocoolant topical anesthetic spray. Theses nurse scientists present the results of a quality improvement program initiated in a primary care practice. Thirty children (age 4 to 6 years) receiving up to five routine vaccinations were recruited from a Pennsylvania community health center. A quasi-experimental one group pre-test post-test design was used. Caregivers/children were given a pre-immunization and post-immunization survey with questions directed at the assessment of pain and distress. This survey included a VAS for distress and the Wong & Baker FACES scale that caregivers were instructed to "help" their child answer for pain. Caregivers also assisted children in answering the distress assessment on the VAS by indicating the "typical level of distress expressed by the child" (Burgess et al., 2014, p. 3). Significant decreases in pre-test and post-test distress among caregivers and children were found. No significant decreases in pain were found.

Strengths of this study include the rigorous design and the use of valid and reliable instruments. Limitations include the caregivers assisting children in self-report, a lack of discussion on sample power, the varying number of vaccinations received, and non-random sampling of participants. Lal et al. (2001) showed similar non-significance with blowing distraction and pain scores.

Caprilli et al. (2012) also used a blowing distraction but added a different interactive component. Researchers examined the effectiveness of soap bubble blowing on distress and pain among 60 children (age 3 to 6 years) undergoing venipuncture blood sampling in a hospital located in Italy. This study was a randomized controlled trial, including a control and treatment group. Children in the control group received standard supportive care in addition to pharmacological treatment with topical anesthetic cream. Caregivers were encouraged to accompany children for procedures for support. Those in the treatment group received the topical anesthetic as well as the soap bubbles distraction intervention. Results revealed significantly lower pain (p=.007) and distress (p=.001) scores among children who received the soap bubble blowing intervention. Like several of the studies in the review, findings from Caprilli et al. (2012) indicate that younger children experience higher levels of pain and distress. Additionally, the researchers found that caregivers became less supportive during the procedure as the age of the child increased. The results of this study were similar to Burgess et al. (2014) with regard to significant reduction in child distress but different with regard to pain outcomes. These findings suggest that blowing soap bubbles provides better physical and psychospiritual procedural comfort for children than the party blower or windmill blowing distraction alone.

Lal et al. (2001) and Caprilli et al. (2012) had strengths and weaknesses associated with their studies. Both studies were randomized controlled trials. Validity and reliability of one pain instrument used by Lal et al. is unknown. Caprilli et al. (2012), however, did use valid and

reliable tools. Neither group of researchers addressed sample power analysis. Lal et al. (2001) and Caprilli et al. (2012) found similar results indicating the likelihood that a multifaceted approach including blowing exercises may enhance holistic procedural comfort in children. But, these results are only generalizable to pain and more research is indicated to test whether these blowing exercises address the comfort needs of the whole patient. As in other reviewed studies, these researchers addressed more than simply the physical aspect of comfort. They incorporated the use of distraction, play, topical pain medicine, and presence or touch of a caregiver. An instrument to measure this holistically, however, is not available. The qualitative findings from this dissertation study will help to advance nursing science with regard to measuring pediatric procedural holistic comfort outcomes.

Hematology/Oncology Diagnosis. Invasive needle procedures are a frequent occurrence for children with hematological and oncological diseases. Three studies in this review included a multifaceted approach among patients with cancer and or a blood disorder. This is a special population because, as previously discussed, the comfort needs of patients diagnosed with a chronic illness may not be the same as those individuals without it. One of the studies included child self-selected distractors as a comfort intervention, another used virtual reality, and the last compared effectiveness of a heated pillow and bubble blowing.

One group of nurse scientists examined the effects of a nonpharmacological distractor intervention and pharmacological topical anesthetic on comfort components- pain, distress, and fear among children with a chronic illness (Windich-Biermeier, Sjoberg, Dale, Eshelman, & Guzzetta, 2007). Fifty pediatric patients between 5 and 18 years with cancer were included. Using a repeated measures comparison group design, variables at baseline, during, and after routine port access or venipuncture were assessed. Validity and reliability were discussed or are

documented for all but one of the instruments used in this study: an investigator-developed instrument called the IV-Poke Questionnaire. This instrument addressed caregiver and participant experiences with the nursing procedures. Participants in the intervention group chose a specific distractor treatment: bubbles, music table, handheld video game, an I-Spy book, or virtual reality glasses. Participants in the control group received standard encouragement and analgesic only. Windich-Biermeier et al. (2007) found that fear (p< .001) and distress (p= .03) were significantly lower in the treatment group. Pain, however, was not significant (p= .68) but showed similar scores between groups over time. These findings are important because pediatric patients may still have some level of comfort through less fear and less distress even if they are also having pain. Again, comfort has been described as more than the absence of pain (Kolcaba, 2013).

In a very similar study involving patients diagnosed with cancer, the researchers investigated levels of fear, distress, and pain among 28 children needing routine port access in Sweden (Heden, Von Essen, & Ljungman, 2009). In this study- like Kolk et al. (2000), Tak & Van Bon, (2006), Lal et al. (2001), Caprilli et al. (2012) and Windich-Biermeier et al. (2007)- pharmacological and nonpharmacological treatment were used to enhance elements of comfort.

All children received two port access needle punctures. The first port access included standard care with topical analgesic only. The second port access included the treatment intervention. Participants were randomized to two different treatment groups for the second port access: intervention with a heated pillow or intervention with soap bubble blowing distraction. Measurements of variables were done at baseline with standard care and again after being randomized to a treatment group, becoming their own control. The results of this study replicated those of Windich-Biermeier et al. (2007). Both fear (p< .05) and distress (p< .05) were lower in

the soap bubble blowing group and fear was lower (p< .05) in the heated pillow group when compared to standard care alone. Pain was not affected by the interventions. Looking at these results, it may be possible that blowing bubbles may be helpful with a psychospiritual comfort (distress and fear) among children with cancer, but not necessarily physical comfort.

Another multifaceted approach to comfort among children with a hematology or oncology diagnosis was used in a mixed methods design by researchers in Sweden. Nilsson, Finnstrom, Kokinsky, and Enskar (2009) investigated the effects of virtual reality distraction and a topical anesthetic spray or cream on needle-related pain and distress. Forty-two pediatric oncology patients were recruited and assigned to a control or intervention group. Semi-structured interviews were conducted with all of the children in the intervention group. Interviews took place directly after the procedure to prevent recall bias (Nilsson et al., 2009).

Quantitative findings did not reveal significant differences among reported pain and distress between the control and intervention groups. This is dissimilar to the results of studies by Wolitzky et al. (2005) and Gold et al. (2006) who also examined the effects of virtual reality during invasive pediatric procedures. Qualitative data added to the understanding of outcomes of the virtual reality distraction. Two themes emerged in the qualitative interview content analysis:

(a) the virtual reality game should correspond to the child and the medical procedure, and (b) children enjoyed the virtual reality game and found that it did distract them during the procedure. The first theme was characterized by responses such as: "I didn't understand how to go forward when you pushed the button," and the game "was corny" (p. 105-106). Whereas the second theme included the following comments: "I didn't think of the pain" and "it was fun to play" (p. 106). The difference in results of this study may relate to a usability or age appropriateness issue.

This is important when evaluating child holistic comfort because age and developmental level will affect comfort outcomes.

Windich-Biermeier et al. (2007), Nilsson et al. (2009), and Heden et al. (2009) all explored the use of a multifaceted approach among hematology and oncology patients. Strengths of these studies include the use of valid and reliable measures and the strong designs. Heden et al. used one type of procedure, which increases control. Windich-Biermeier et al. (2007) used five different distractors, decreasing control. It is important to note here, especially among patients with chronic illness, that participants in two of these studies did not show decrease in pain even though they had decreased distress and fear. This means that a child can be less fearful and feel less distressed or anxious but still be hurting. It is furthermore an indication that a child can feel psychospiritually comforted (less fear and distress) but still have physical pain. In this dissertation study, children were able to describe some of these perceptions of their venipuncture procedure.

Multimodal Burn Treatment. Two studies that emerged in the review examined the effects of electronic distraction techniques on pain receiving acute burn dressing changes. One group of Australian researchers investigated the effectiveness of a hand-held multimodal distraction device (MMD) and an off the shelf hand-held video game (Miller, Rodger, Bucolo, Greer, & Kimble, 2010). The MMD device demonstrated an interactive animated 3D content about a child with a burn. These interventions were coupled with the standard protocol of oral narcotic medications administered (for those who required it) prior to the wound dressing procedures. Caregivers were present for additional child support during procedures.

Miller et al. (2010) evaluated pain reduction in 80 children age 3 to 10 years during a period of three consecutive burn dressing changes. Valid and reliable instruments were used. The

participants were randomized to one of four groups: (a) use of hand held video game, (b) use of MMD procedure preparation (before procedure), (c) use of MMD distraction (during procedure), or (d) standard care. Miller et al. (2010) show that the MMD procedural preparation and MMD distraction significantly reduce pain scores compared to standard care and a hand-held video game during burn dressing changes. The randomized controlled design adds to the strength of this study. Additionally, repeated measures over time with increased or sustained effects of the intervention add to internal validity. Generalizability is a problem here since this device was only tested on patients receiving burn care and it is relatively new in the literature. Additionally, it was not clear how many patients received standard care with oral narcotics, which could affect pain outcomes.

An earlier study closely related to Miller et al. (2010) revealed similar results. This study was conducted: (a) in the same hospital, (b) with three of the same researchers, (c) with a similar intervention, and (d) with a comparable patient population (Mott, et al. 2007). Differences noted were the inclusion of one treatment and one control group and the device used for distraction. Mott et al. (2007) tested the effectiveness of an animated augmented reality game in combination with a sedation or analgesic treatment and found significantly lower pain scores (p= .006) among children in the treatment group. The results of these two studies examining comfort outcomes in patients with acute burns are important. This again reiterates the central importance that procedural holistic comfort needs will be different for all children, depending not only age or developmental level, but also health circumstances.

Children with HIV. Children with cancer and hematological diseases were not the only individuals with chronic illness found in this review. Distress and pain among children diagnosed with human immunodeficiency virus (HIV) was also investigated. Schiff et al. (2001) evaluated

the effectiveness over time of a multicomponent pain intervention. Pain and distress levels secondary to routine venipuncture among children diagnosed with HIV were measured in a single group at four different time periods. Forty-seven participants (age 4 to 12 years) were recruited from an immunology clinic where each child received routine blood work every 3 months for T-cell count and viral load. The mixed intervention included topical anesthetic cream application, relaxation techniques and breathing exercises, distraction with bubble blowing or a pinwheel, and parental involvement. Results indicated reduced behavioral distress and reported pain over time (Schiff et al. 2001). Again, researchers found that younger age was correlated with having higher distress and pain level. As in the study by Kolk et al. (2000), the presence of several distractor interventions makes it a challenge to conclude which interventions decreased pain and anxiety the most. With repeated measures of distress and pain among children in the same group, participants served as their own control. The rigorous statistical analysis with a repeated measures design also increases the overall strength of study findings.

Summary and Gaps in the literature

The literature review helps establish what is known and not known regarding pediatric procedural holistic comfort. Evidence supports the use of various distraction techniques during invasive nursing procedures for decreasing anxiety, distress, fear, and pain. Music therapy had positive effects on comfort but perhaps with venipuncture and blood sampling more than with burn care, dressing changes and suture removal. The use of a Kaleidoscope was efficacious in one large sample study but showed no significant decreases in pain and distress in an even larger scale sample. More research is indicated in this area. Breathing techniques or blowing away pain/distress and soap bubble blowing also seem to be effective which is a feasible way for nurses to provide child comfort.

The use of modern interventions such as virtual reality lowers distress and pain in some children but not others. More research is indicated for this newer technology. Television passive distraction shows mixed results. One study conducted among children in India revealed that cartoons were effective comfort interventions during procedures and in other reviewed studies researchers found no statistical significance. It could be that ethnicity or culture plays a role in level of distraction and reduction in pain and distress. Another study incorporated distraction with an iPad and showed decreased distress levels in children. More research is also indicated in the area of screen time. Caregiver coaching, distraction, and presence show beneficial effects and appear to decrease pain and distress/anxiety among children undergoing painful procedures. A multifaceted approach including more than one intervention targeting overall cognitive, emotional, and physical comfort also shows mixed results. In some studies researchers found positive effects but in other studies no significant findings were reported. One of the most important findings in this review is that younger children experience higher rates of pain, anxiety, fear, and distress related invasive nursing procedures. This certainly indicates that younger children, such as those in the preoperational stage of development, may have more holistic procedural comfort needs.

There are additionally essential details on pediatric holistic procedural comfort that the literature does not reveal. It is possible that for a child, comfort means more than the absence of pain. Additionally, none of the studies reviewed examined the use of environmental comfort factors such as temperature setting, giving the child a choice of where the procedure is performed, noise level, adding pleasant smells to the procedure location, etc. True comfort measures and the meaning of procedural comfort to a young child can be better understood with the completion of this dissertation study. Another important gap noted is the limited evidence

focused on investigating the experiences of procedural holistic comfort in children of various ethnic and racial backgrounds.

Not to be discounted is the perception of child comfort as described by primary caregivers. Caregivers who know and understand their children have a unique perspective of holistic procedural comfort for a child. This gap in the literature was also addressed in this dissertation study. Additionally, more knowledge on the experiences of children undergoing invasive nursing procedures and what measures would provide holistic comfort to children during these times is needed. The qualitative research in this dissertation study suggests important procedural comfort needs described by children and their caregivers. An understanding of holistic comfort from the child's point of view is significant. Following this extensive review on comfort development and procedural comfort interventions, the following gap was addressed in this dissertation study: what are the descriptions of holistic comfort related to invasive nursing procedures as perceived by young children and their caregivers?

Chapter Three: Methods

In this study, holistic comfort was explored as it relates to an invasive nursing procedure described by young children and their caregivers. Research on pediatric pain, distress, fear, and anxiety related to nursing procedures is immense, but lacks a clear understanding about holistic procedural comfort and its role. Additionally, concept analyses, theory development, and research studies on comfort in the adult population are present in the literature. Holistic comfort focuses on the whole person and includes more than simply addressing the physical needs of patients. This is especially true when considering the procedural comfort needs of young children, who often lack the reasoning to understand why an invasive procedure is necessary. Most of the literature focusing on comfort in children, however, has not been represented as holistic and often has been related more to the experience of pain alone. A major gap in knowledge is the vague understanding of how procedural holistic comfort is defined by young children. In this chapter, discussion related to the research design, procedures for recruitment, sample, data collection, data analysis, and interpretation are presented. Ethical issues including the protection of human subjects will also be discussed.

Overview

A venipuncture is considered a painful, anxiety provoking, and fearful intervention for children. In order to holistically assess what procedural holistic comfort is to children experiencing it and the caregivers who observe it, these individuals were asked. In this qualitative descriptive study children age 5 to 7 years, in preoperational stage of development, and their caregivers, were recruited from a hospital outpatient laboratory. Once necessary consent and assent were obtained, child participants were interviewed using age appropriate questions after his or her venipuncture procedure was completed. At the closing of the child

interview, children were asked (in an age appropriate manner) to draw and talk about two pictures: one picture of what it was like to get the venipuncture or "shot," and another picture of things that would have made them feel better about the venipuncture. This drawing task was added to give child participants an additional means of communication and to evoke rich detail in their descriptions. Caregivers who were willing to participate were also interviewed directly after their children. One Caregiver who participated alone due to lack of child assent was interviewed directly after the procedure. Main caregivers of children have a unique perspective regarding what procedural comfort is to their child and how it can be best attained. These caregivers were encouraged to describe their discernments of pediatric procedural holistic comfort

Study Design

A qualitative descriptive design described by Sandelowski (2000; 2010) was used and is appropriate for this study because this type of research is used by scientists who seek to understand descriptions of a natural phenomenon, particularly research related to human behavior. Although there is quantitative research on interventions that may enhance comfort in children, the missing element was the descriptions of holistic comfort from the child's perspective. These essential perspectives can validate what interventions remain or do not remain effective. The most appropriate method of obtaining knowledge from young children related to this phenomenon was through a semi-structured interview process.

According to Sandelowski (2000) a qualitative descriptive approach gives a summary of occurrences and accounts in terms described by the participant. Descriptions of holistic procedural comfort were captured and interpreted as the children and caregivers explained them. Qualitative descriptive, like all qualitative research, is interpretive (Sandelowski, 2010). But it is

typically less interpretive than other forms of qualitative research such as phenomenology, ethnography, or grounded theory, hence leading the researcher toward a more fundamental elucidation of participant-described manifestations (Sandelowski, 2000). This essentially means the researcher stays very close to the data or "data-near" (Sandelowski, 2010, p. 78) in order to best generate findings in line with participant imageries. In a later article, Sandelowski revisits qualitative description and offers important recommendations for researchers, which will be discussed in the data collection and data analysis section of this chapter.

Preliminary Work

For the purposes of this study preliminary pilot data were collected from two five-year-old sibling children (twins). This was done in order to gain a better understanding of the interview process with children, the interview time, and a child's ability to answer the questions asked. There were several differences in this preliminary work that were not similar to this dissertation study: (a) the interview took place with twin siblings who preferred to be interviewed together instead of separately, (b) the interview was several days after an invasive procedure took place for the children, not directly after it, (c) the procedure that the children discussed was immunization injections and not a venipuncture, (d) the interview took place in the children's' home, not a medical facility, and (e) the children were known to the researcher.

The PI wore conservative attire to the pilot interview and sat on the floor with her legs crossed because the child participants asked her to sit this way. The PI began the interview by thanking the children for letting her talk with them. During the interview questions, children were sitting in front of the PI but slightly above her on their bed. When the interview questions began, the children were respectful of one another, allowing each other to explain their answers. It is important to note that there were specific questions that the children in the pilot interview

did not comprehend. These questions were removed for the dissertation study. If the child does not understand an interview question then it would have been a challenge to obtain appropriate descriptions. For example, the following question was not well received by the twin children and it was excluded: "Was there anything going on with your body that you didn't like during the shot; maybe not just the needle- but something else?" On the contrary, there were probing questions that the PI asked during the pilot interview, which did elicit rich data. These questions were added or revised for the dissertation study. For instance, the following question evoked important information from the twin children and so it was revised and included: "What would have made the shot even better for you or maybe other little kids too?" A full list of original and revised pilot questions can be found in Appendix A. The child pilot interview questions lasted approximately 15 minutes. Discoveries from this preliminary work included important information on how to conduct the dissertation study. Additionally, the interview questions included detailed descriptions of things that enhanced child procedural comfort as well as things that they described as needing improvement. The words are transcribed here exactly as the child said them. First, the children alluded to things that made them feel better during the venipuncture, including the procedure being nearly done, bandages provided, and their mother:

"Yea, uh, when it it was almost finished! I really liked the band-Aids too and we both got 4 shots and we had two (band-Aids) on one (arm) and two (band-Aids) on the other arm."

"Momma... she kinda makes us feel better... yea and she kisses us... and hugs us."

Then both children discussed additional comforters that would have made them feel better. They describe things that they did not have with them during the procedure that they thought would have helped. This included a soft blanket and stuffed animals/soft toys:

"Ummmm... um... yea my blanket... this one feels as soft as it could possibly feel.

Um... um... this, this, and that... all three of these right here... um this is Mary, this is Jesse, and that's Sadie May... they kinda make me feel better."

Next, the children gave details about the procedure room. They discussed how room décor would help their experience. They also talked about their environment during the procedure including noise level. Moreover, they described details about the room including how small it seemed.

"If there was butterfly paint on the room it would make it better, and ladybugs with smiles, and polka dots, and of course wings... and trees with owls."

"Well I kinda got bothered by all the noise... like... well I dunno it was just kinda noisy."

"No... No, it was just a small room... like if there was something around one of our beds, that's the whole room."

The supplementary pilot question that asked the child to draw a picture of a time they felt really good was well received: both children were able to draw a picture and explain this

experience. One child captured a picture of a time when she was out on a boat with her family while the other child explained a time when she was eating her favorite kind of ice cream. It was clear the children understood the purpose of the drawing task. Nonetheless, it was also clear that both drawings did not necessarily elicit descriptions of procedural holistic comfort. Therefore, the drawing task was changed for this dissertation study to elicit a more holistic description of comfort related to the invasive procedure.

Procedures

Ethical Considerations

This study was conducted after Institutional Review Board (IRB) approval was received from both the University of Tennessee- Knoxville and the children's hospital where participant recruitment took place. The principal investigator and all committee members signed a confidentiality agreement before the study began (See Appendix B). No interview was conducted until informed consent and assent was obtained. Children are a vulnerable research population. If the child did not assent to participation at any time during the study, even if their caregiver consented, the child was removed and all of their data collected were destroyed. This happened once in the course of the study. Equally as important, even if the child assented to participate in the study, the caregiver was required to first sign consent for the child to be included.

Risks associated with participating in this study for both the children and caregivers were relatively low. These risks included: (a) respondent burden due to the time consuming process of participating and waiting for the completion of interview(s), and (b) the potential emotional or psychological encumbrance that recalling the invasive procedure may cause. The research interventions were commensurate to those already in place for the venipuncture procedure, which is ordered by the child's physician/practitioner.

There were positive aspects to interviewing children. "Interviewing youthful respondents gives them voice to their own interpretations and thoughts rather than relying solely on adult interpretations of their lives" (Eder & Fingerson, 2002, p. 181). Qualitative interpretation and exploration with caregivers also provided important perspectives. Benefits of participation in this dissertation study included: (a) letting participants share their story, (b) giving the participants opportunity to see their perspectives as valuable, and (c) helping others by advancing science on comfort in children.

Young children appreciate immediate enjoyment and tangible items. For this reason a gift basket with a small stuffed animal, a Kaleidoscope, blowing bubbles, stickers, crayons, and a coloring book was given to each child participant for their time. These items were chosen based on the existing evidence to support their alleviation of pain, fear, and distress discussed in the literature review. The value of each basket was approximately \$20. Caregiver participants were also given a gift for their time- a \$20 VISA gift card.

Sample

This study was conducted on a sample of children age 5 to 7 years in Piaget's preoperational stage of child development and their primary caregivers. The PI originally aimed to recruit children between the ages of 4 and 7 years but no 4-year-old children were recruited. This young age group was chosen based on the current literature and evidence to support that younger children suffer higher levels of distress, fear, and pain than older children, which could lead to lower levels of comfort, requiring increased comfort needs. No age range was set for caregivers.

Child patients were included if they: (a) needed a medical venipuncture procedure, (b) were age 4 to 7 years, (c) spoke English, and (d) were able to draw pictures. Child participants

were excluded if they were: (a) under the influence of any controlled substances within the previous 8 hours, with the exception of stimulants to treat deficit disorders, (b) unable to verbally communicate due to neurological, developmental, or cognitive delays, (c) seriously acutely ill, hurt, overly distressed, or in crisis of any kind, and or (d) known personally as a friend, family member, acquaintance, or professionally as a patient to the PI. Caregiver participants were eligible for inclusion if they: (a) were primary caregivers of an eligible child participant, (b) spoke English, and (c) agreed to participate in the data collection process and sign the consent forms. Caregiver participants were excluded if they were: (a) unable to verbally communicate due to neurological, developmental, or cognitive delays, (b) known personally or professionally to the PI, and or (c) under the influence of any controlled substances within the previous 8 hours, and or alcohol in the last 4 hours.

At no time during the course of the study did the PI learn of a primary caregiver using illegal drugs. If this had been found the appropriate social services and possibly the department of children services would have been notified. This is for the safety and protection of both the caregiver and minor child. The decision to include only English speaking participants is supported by the large percentage of families served by the children's hospital that are English speaking. Both child and caregivers were recruited as dyads, but those children or caregivers wishing to participate alone (whom gave consent/assent) were also independently eligible. This situation was noted once in the course of the study when a child did not assent but a mother still wished to participate. Thirteen child participants and 15 caregiver participants were recruited. Unexpectedly, in some instances, child interviews lasted a little longer (10-40 minutes) than caregiver interviews (10-20 minutes). Two child interviews were outliers from the rest in that they lasted approximately 30-40 minutes when the remaining interviews lasted 25 minutes or

less. There was also a caregiver interview outlier. One married mother and father wished to participate but only if they were interviewed together due to time constraints. The decision was made by the PI to include the married couple in order to let their descriptions be known and their story to be told. Both caregivers signed individual consent and demographics were collected for each. Additionally, both mother and father were each given a separate \$20 VISA gift card for participation.

Participant Recruitment and Setting

Child and caregiver participants were recruited using purposive and convenience sampling. Participants were purposefully chosen in this study because each child was in need of an invasive venipuncture procedure ordered by a licensed medical provider. Additionally, participants were conveniently selected from a population of many pediatric patients who were in an outpatient laboratory for a venipuncture. Recruitment for this study and the participant interviews took place in a freestanding children's hospital in the Southeastern United States.

Recruitment took place specifically in the clinical laboratory of the medical center.

Interviews were conducted in a designated room within the Neurodiagnostic department, which is directly across from the clinical laboratory. Involvement of these departments was discussed with the PI and permitted by the appropriate coordinators. Burden on these departments and their staff was minimally invasive. The lab coordinator (and his phlebotomy supervisor), permitted staff to disperse study recruitment flyers to potential participants on days of recruitment. Clinical laboratory staff was also permitted to direct potential participants to the interview room if they asked. Other questions concerning the study were directed by staff to the PI. The director for the Neurodiagnostic department permitted the use of this available room in the Neurodiagnostic area up to four times weekly. This was scheduled on prior approved days when the room was not

otherwise needed for outpatient Neurodiagnositic procedures and to avoid occupancy conflict.

When potential participants arrived to the Neurodiagnostic department, the staff directed them to the appropriate interview room. Questions asked by caregivers to the Neurodiagnostic lab personnel about the study were directed to the PI.

As a licensed practitioner in the area, the PI often orders lab work on patients that attend the study setting (children's hospital). As outlined in the exclusion criteria, patients or caregivers that were known by the principal investigator personally or professionally would have been excluded. This instance did not occur in the course of the study. As previously mentioned, there was one instance where a child did not wish to participate but the caregiver did. In this case, the consenting adult (meeting criteria) wishing to participate was included so his/her voice and experiences could be heard and contribute to science on procedural holistic comfort in children.

Upon arrival to the hospital, children and their caregivers were registered at the admitting desk and were then sent to the clinical laboratory for their intended procedure. After arriving to the laboratory, caregivers also registered with a lab attendant who collected pertinent information regarding the child's name and the procedure ordered by the child's provider. The lab attendant distributed a recruitment flyer (see Appendix C) to all potential participant caregivers with children who checked in at the laboratory for a venipuncture procedure. This flyer briefly explained inclusion criteria, exclusion criteria, benefits, and where to go for the interview directly after the venipuncture procedure if they wished to participate. The flyer also stated that caregivers would be asked about controlled substance use, alcohol consumption, and drug use. Dispersing the flyer in the laboratory allowed both the caregiver and child time while in the waiting room followed by time in the procedure room to consider participation. This also allowed caregivers and children to contemplate participation privately, without the presence of

the PI. Potential participants were then directed to the Neurodiagnositic lab. The PI was not present with the child or caregiver for the venipuncture procedure. This was decided because the child may have associated the procedure experience (one which could have been negative) with the PI directly if she were present in the room at the time of the venipuncture. This in turn could have affected the child's level of trust in the PI as well as the ability to elicit rich descriptions during child interviews.

Both child and caregiver interviews were held in the same location: a quiet room in the hospital, removed from the noise of a busy unit or department. If the caregiver identified him or herself and their child as meeting inclusion criteria and showed up to the interview room after their child's procedure, then the PI briefly explained the purpose of the study and supplied the caregiver with an informed consent form (see Appendix D). Any questions that arose were answered to ensure participants were well informed. Once consent was signed the PI gave the caregiver a demographic questionnaire (Appendix E) to complete. Although not all of the information found in the demographic questionnaire was used as inclusionary criteria, three of the questions (age, language, and medications) could have been used to identify possible ineligible participants. No participants were ineligible. Each caregiver signed separate consent on the same form for his/her own participation and for the participation of his/her minor child.

Once caregivers consented to his/her own and his/her child's participation then child assent was obtained. After explaining the purpose and importance of child assent to the caregiver, the PI then pursued assent from the child in a scripted format (see Appendix F) that was read aloud to all children. No signed assent forms were collected to further protect a child's identify and provide even more confidentiality. Whenever possible, assent was discussed with the child while he/she was turned away from their caregiver to avoid caregiver coercion. If the

child was more comfortable in the presence of his/her caregiver and did not wish to be separated from the caregiver, then assent was pursued while the caregiver was close. The PI listened very closely during discussion of the assent/consent process to words used by the child or the caregiver, which were then included/substituted in the interview to communicate. If at anytime during recruitment the child would have appeared frightened or distressed then he/she would have been immediately be excluded. This instance did not happen. The PI ensured that all inclusion and exclusion criteria were properly discussed with each caregiver prior to consent, assent, and preceding all interviews.

Data Collection

Once caregiver consent and child assent was obtained the interview procedures began. Interviews with children and caregiver participants were conducted in a semi-structured format. An interview protocol was used for both children and caregivers as Creswell (2009; 2013) recommends (see Appendix G and H respectively). This protocol consisted of an introduction, age appropriate interview instructions, asking the interview questions, probing the child and caregiver to elicit detail in descriptions, and a thank you statement. Notes were taken during all interviews. Following child and caregiver interviews, a more specific summary of field notes were also written. In this dissertation study field notes were defined as those notes taken during and after interviews. This included anything specific about the child or caregiver interview that pertinent in transcription, something that stood out about the interview or participant, certain words and phrases, where the interview took place, possible interruptions or unusual occurrences, nonverbal cues that could not be caught on audiotape, and researcher reactions. These field notes include only pseudonyms for identification and were used in conjunction with transcripts to help elucidate the most rich and accurate descriptions.

Sandelowski (2010) recommends incorporating the expert descriptions and explanation of other researchers for research procedures. Recommendations for data collection and data analysis by Hsieh and Shannon (2005) were also used. These researchers advise open-ended questions when conducting content analysis. Hsieh and Shannon's recommendations for data analysis will be discussed in more detail in the analysis section of this chapter.

Child Interviews. Children are a unique population, which is important to consider when interviewing them. Questions asked of an adult would not be appropriate to ask of a young child due to their developing cognition and limited comprehension of abstract information. Eder and Fingerson (2002) experts in sociology and strategic research analytics- discussed techniques and important factors to reflect on when working with children. The following elements help conduct a more successful child interview: (a) assess and recognize the issue of power imbalance between the child and the interviewer, (b) observe the child for a little while and make informal conversation prior to officially starting interview questions, and (c) incorporate more than one method of communication in the interview to enhance data collected and verify analyses.

Including verbal interview questions and a drawing task in this dissertation study was a suitable way to include more than one method of communication for child participants.

Researchers must understand that children are fundamentally controlled by adults and are naturally disadvantaged and disempowered due to their age and inability to be the researcher, only the researched (Eder and Fingerson, 2002). "Reciprocity" (p. 185) may help minimize power imbalance during child interviews. This reciprocity can be encouraged by allowing the child to ask the interviewer questions that they have in the informal beginning conversation and by providing a gift to show the child appreciation for his/her time and what they have described.

Questions and the style of the interview were tailored to the child's developmental level and cognitive abilities. Interviews with children began after arrival to the interview room following the venipuncture procedure but only after consent/assent was obtained. Child interviews were conducted directly after venipuncture procedures to help prevent recall bias.

These interviews lasted until the child voiced they were ready to be "done" (Average was about 20 minutes). Again, the interview room was a private location in the hospital and was conducive to having uninterrupted conversation. Upon entering the room, there were 7-8 age appropriate toys on a carpet tile lying on the floor. These toys were well received by children and were intended to support the child participants as they warmed up to the interview location. The toys were also used to help entertain siblings or other children present with caregivers. Once the dissertation study and write up is complete, these toys will be donated to the Child Life department at the children's hospital.

Verbal consent to be audio recorded was also obtained from both child and caregiver participants. Children were permitted to sit anywhere in the room that was safe. The PI always sat across from the child, at their level, arms unfolded, knees facing them, often smiling but also with facial expressions that represented empathetic responses to the child's descriptions. These facial expressions communicated that the researcher was feeling *with* the child. The PI was dressed without a lab coat, in conservative clothing, such as apparel that a child's teacher might wear.

Although children age 5 to 7 years are developmentally similar. There may have been slight cognitive differences in the 5-year-old children (preschool/Kindergarten) compared to the 6 and 7-year old children (school age). Child communication and dialogue with the PI was changed because of the preliterate and literate difference. It was not a requirement in this study

for the child to be literate. It was essential to recognize the subtle differences in these ages with regard to interview style.

The PI started by adjusting her speaking tone to gentle, softer level when interviewing the 5-year-old children. Intermittently, the PI would echo phrases of the child in his/her own words to stimulate full understanding (by the PI) and wait for the child's nod or verbal approval that it was correct. When interviewing the older school age participants, the PI also employed a soft tone, but additionally denoted a proud, verifying quality in her voice, indicating understanding of the child's independence. Manners of speaking were adapted during the interview depending on each individual child's needs. The PI similarly repeated what the school age child said in his/her own words to encourage full researcher understanding.

Before the Child Interview. Each child received an 8 oz. bottle of Nestle Pure Life water prior to beginning the interview. Before any child interview questions began the PI first calmly and kindly addressed the caregiver to explain how important it is that they let the child speak freely and to avoid interjecting at any point during their child's interview. The PI explained that this was essential to the child's communication of descriptions and perceptions of procedural holistic comfort. The PI also explained what the caregiver had to say was important. However, the PI reminded caregivers that everything they had to say about their child's experience could be heard in their own interview if they participated. After this short discussion with the caregiver, attention was turned to the child. The PI attempted to put the children at ease by engaging in light conversation and encouraging the child to play with the toys. Children were also asked if they had any questions for the PI before starting the interview. This was done to level the power imbalance and to provide reciprocity. Tissues were placed at close reach for the child in case they needed these for any reason during the interview.

It was very important to briefly establish what the child was bringing to the interview emotionally and cognitively. Children have varying individual circumstances and personal experiences. Some children experienced a physical, social, or psychological trauma in the previous week, month, or more before the venipuncture procedure. Some children had underlying emotional concerns or resolving family dynamic problems while others appeared to have ongoing supportive and collaborative family environments. Simple questions were asked to get an idea of the child's personal background. These questions included: (a) "how did you feel when you woke up today", (b) "has anything made you happy lately," (c) "Has anything made you sad lately?" (d) "has anything made you mad/angry lately?" The PI sought to obtain background information on how the child was feeling at the time of the interview about general life circumstances.

Beginning the Interview. Preschool and school-age children may not have understood the word "comfort" if it was addressed by the PI. Since defining comfort for the child was not the goal of the research (rather defining it from their experiences and descriptions), questions were asked using words that they would understand. This may include sentences with words such as: feel, better, good, fun, like, or happy. These words were selected based on their presence among already existing child descriptions documented in the literature. Clarification or rephrasing of a question occurred when it was needed. When indicated, the child's own words were used for probing questions or were substituted in subsequent interview questions. Children often refer to any needle puncture as a "poke" or "shot" so these familiar and understandable words were used in the protocol questions. Field notes began during the child interview. The following were semi-structured questions presented to the child participants:

- 1. Can you tell me about what it was like for you to get a shot today?
- 2. Is there anything or anyone you can think of that made you feel better about the needle poke you had done today?
- 3. Who is here with you today? Did he/she do anything to make you feel better?
- 4. Was there anything you liked or didn't like about the room where you were poked with the needle?
- 5. Was there anything or anybody else you wish you had with you to make you feel better today?
- 6. Did you feel too hot, or too cold, or just perfect in the room where you had the shot?
- 7. Did you like the chair or table you were on when you got the shot done?
- 8. What would have made the shot even better for you or maybe other little kids too?
- 9. Can you think of anything that would make you feel better right now?

 After interview questions were completed the children were asked to participate in another form of communication with the PI- drawing and dialoguing about pictures.

Drawing Task. As mentioned earlier, more than one communication method was used in this study with children. A drawing technique was added as an accompanied artistic approach. Children were asked to draw two pictures (See Appendix I) related to procedural holistic comfort. This drawing technique was important because children had the opportunity to communicate their experience and perspective in a way that helped elicit rich descriptions of procedural holistic comfort. The pictures themselves were not analyzed in this dissertation study. In the informed consent however, caregivers were informed that these drawings would be saved and possibly used for a future photo analysis study.

The drawing task helped to stimulate more verbal data from the child. The child received crayons from his/her respective gift basket and a blank piece of white copy paper. The child was first asked to draw a picture of what it was like to get the needle poke today. Then the PI asked the child to talk about their first picture. Next, the PI flipped the copy paper over and asked the child to draw a picture of whatever he/she thought would make him/her feel better when they were receiving the needle poke or what would have made him/her feel better about it. This technique complemented the data received through verbal interview questions. Three children preferred to end their interview session and descriptions prior to beginning the second drawing. As a result, only one drawing was discussed for these three participants. Among these three, one child preferred only to draw a picture of a house and nothing else because he felt he could draw this well.

Pictures drawn were kept on site in a locked briefcase along with signed consent/assent. Immediately when possible the pictures were digitalized and scanned into the PI's digitally locked computer. The original hard copy pictures were then destroyed. Any personal identifiers such as names found on the drawn pictures, were marked out to protect the child's identity. Again, these pictures were not analyzed in this study, but consent was obtained to keep them for possible future research. Interviews with the child participants ended when he/she indicated there was nothing more to describe and when the child was ready to terminate the session. Once the pictures were drawn/described and the child had nothing left to say, the remaining items in his/her gift basket were given. While the children were exploring the items in their basket, or with toys on the carpet tile, the caregiver interview, if consented, commenced.

Caregiver interviews. Arguably, primary caregivers spend the most time with their child in comparison to others. The knowledge and ability of these caregivers to describe their child's

needs is instrumental in defining procedural holistic comfort for young children. The adult interviews were also conducted in a semi-structured format. The PI explicitly used and explained what was meant by the word "comfort" in the caregiver protocol. Once the child interview was complete, the PI turned her attention to the caregiver. Initially, the caregivers were asked if they had any questions before the interview began or if there was anything that would make them feel more comfortable. Each caregiver received a 16 oz. Nestle Pure Life bottled water prior to beginning questioning. Again, tissues were placed at close reach for use at anytime. The PI began by implementing the caregivers interview protocol (Creswell, 2009; 2013). This started with an introduction followed by asking the interview questions, probing the caregiver to elicit detail in descriptions, and then ended with a thank you statement. The PI sat across from the caregiver in a similar fashion with unfolded arms, knees forward facing, and legs crossed at the ankles. The speaking tone was pleasant, respectful, and validating. As in the child interviews, a soft tone with empathetic facial expressions was used when appropriate. Field notes were taken during caregiver interviews as well. The following semi-structured questions were asked to caregiver participants:

- 1. Overall, How was the needle procedure for your child today?
- 2. What made your child more comfortable today before the needle stick?
- 3. What do you think comforted your child *during* the needle stick?
- 4. Did anything comfort your child *after* the needle stick or do you think a reward might make them feel better later?
- 5. What could have been done to make your child feel more comfortable with this procedure overall- either before, during, or after?
- 6. Tell me what normally makes your child feel more comfortable or better when he/she

is unhappy, hurting, or not feeling good?

- 7. Tell me about a time when your child recovered from feeling bad or uncomfortable?
- 8. Is your child coping with anything emotionally or physically traumatic right now that might affect how they may have experienced comfort with the needle stick today?

Data Management

All interview data were digitalized into a computer file as soon as it was possible. This information was stored on a computer with a digital access code to protect all participants' private information. Signed consent forms are held in a locked cabinet in the office of the dissertation chair at the college of nursing on the University of Tennessee, Knoxville campus. Pseudonyms were assigned by the PI and these were matched to each participant. No real names appear anywhere except on the original consent/assent and on a roster that matches pseudonyms to the consent. This roster is an electronic file stored on the PI's digitally locked computer.

All interviews with both child and caregivers were audio-recorded with a batteryoperated digital recorder. A second backup digital recorder was also used for each interview.

Extra batteries were kept at all times and a sound check was completed prior to every interview
to ensure equipment was functioning properly. Transcripts and other pertinent data were also
stored in the computer software program NVivo for Mac. This program cannot be accessed
without the digital access code on the PI's computer. The University of Tennessee Blackboard
site was available for transfer of study data and information if requested among the PI and
committee members only. Blackboard runs under SSL encryption to protect all information
moving through (to and from) the system. Blackboard can only be accessed by someone with a
valid NetID and password.

Each committee member was asked to sign a research team confidentiality agreement for the protection of participants and their private information. Prior to converting content (field notes, drawings, and roster) to digital files, and on site before, during, and after interviews, the data were stored in a locked briefcase only accessible by the PI. The briefcase was kept in a safe place in the interview room with the PI during interviews and in the PI's home in between interviews. All data in the briefcase were converted digitally or delivered to the dissertation chair in room 239 of the College of Nursing. Any study data, except the photos/drawings, including transcripts, field notes, audiotapes, and the pseudonym roster will be destroyed once the study is complete.

Data Analysis

In this dissertation study (as in many qualitative studies) data analysis began during the process of data collection. As previously mentioned field notes were taken during and after every interview. Additionally, audio recordings were listened to soon after individual interviews were complete to add supplemental information to field notes and begin early interpretation of insights. After several interviews these insights and interpretations began to repeat themselves. After the 11th child interview the PI found no recurring insights. Two more child interviews were conducted to verify this and again no new insights emerged. Among caregivers no new insights in descriptions were found by the completion of the 12th interview. Three more interviews were conducted following this to confirm and again no new insights were found. With these recurring child and caregiver perceptions and a lack of new descriptions the PI determined that data saturation had been reached.

Child and caregiver interviews were initially analyzed separately as two different populations. After saturation was reached for both child and caregiver participants, results from

both groups were compared for content. This was decided because it is important to distinguish between child and caregiver perspectives. The process of data analysis recommended by Sandelowski (2000; 2010) and the more specific descriptions of conventional content analysis by Hsieh and Shannon (2005) were used. Similar to Sandelowski, Hsieh and Shannon (2005) state that content analysis is the method of data analysis to use when descriptions of a phenomenon are desired. According to Hsieh and Shannon, (2005) conventional content analysis is also appropriate when limited research exists on the phenomenon under investigation. This dissertation study addresses the missing rich individual child and caregiver descriptions of procedural holistic comfort among children in the preoperational stage of development.

Coding. In qualitative descriptive research, the investigator uses thematic content analysis. This type of analysis is "a dynamic form of analyzing visual and verbal data that is oriented toward summarizing the information content" (Sandelowski, 2000, p. 338). In content analysis the themes result only from the interview data and are generated from a collection of codes from the descriptions provided by the research participants (Sandelowski, 2000). All interviews were transcribed verbatim and each transcript was read and re-read line-by-line. A paid professional conducted the transcription. This hired individual signed a confidentiality agreement prior to beginning any transcript work (see Appendix J). Transcripts were sent using a secure site as soon as possible after each interview during the course of the study. Coding analysis began once transcribed data were available. As Hsieh and Shannon recommend, the PI started analyzing with no pre-existing theory, categories, or codes. Rather, codes were created from the existing data then sorted into categories of meaningful clusters and descriptions. These were generated from like phrases, words, and meanings, which were developed carefully and interpreted into themes. This process of coding and analysis was completed until all transcripts

were complete. Although, this study was not a grounded theory design, some of the concepts of coding and comparing once interview data becomes available stems from the ideas of experts in this area. The researcher in this study used a process of analyzing prior to the completion of data collection while "constantly redesigning and reintegrating notions as material was reviewed" (Glaser & Strauss, 1967).

Philosophical Assumptions

As previously described in chapter one, qualitative descriptive research is found within the naturalistic inquiry paradigm. The following philosophical assumptions were made for this study:

- Participants should be interviewed in a familiar setting with no manipulations by the
 researcher. In this instance, the familiar (natural) setting was a medical facility where a
 practitioner ordered a venipuncture procedure that would have been performed with or
 without the study being conducted.
- 2. No predetermined definitions of child procedural comfort were made and no variables to measure were fixed.
- 3. Several realities and truths regarding the description of comfort related to invasive nursing procedures should emerge from the data.
- 4. The children, caregivers, and the principal investigator have an interrelated and interactive relationship, which were concurrently influenced.

Maintaining Rigor

Various steps recommended by Guba & Lincoln (1981), Creswell (2013), Sandelowski (1986), and Beck (2009) were employed to enhance trustworthiness and validity in this dissertation study. The goal of these steps was to help maintain credibility (truth-value),

dependability (stability of data over time), and confirmability (objectivity of findings). First, rich descriptions of procedural comfort from both child and caregiver participants were evoked. Additionally, a reflexivity statement was completed to openly recognize and share researcher views and potential biases related to the phenomenon under study (See Appendix K). Peer debriefing was also conducted whereby peers questions were answered regarding the methods, meanings, and interpretations of procedural holistic comfort in children. Consistency is determined by a researchers audit-trail (Guba & Lincoln, 1981; Sandelowski, 1986). The PI in this study sustained a clear trail of decisions in data analysis so that other researchers could audit the analysis and likely arrive at the same conclusions. Lastly, external auditing was completed with an experienced researcher who is not affiliated with the study to examine whether the interpretations were supported by the data. Transferability/fittingness is another aspect of trustworthiness and essentially represents the moving of findings across contexts. This element of rigor is more difficult to maintain given the population of young children and the specific focus on invasive nursing procedures. However, children in this study were outpatient (like the majority of pediatric patients who receive venipuncture procedures) and they were close in diversity to the entire state of Tennessee. This increases fittingess of findings. Additionally, some generalized and broad comfort findings may be elicited among children, which would, in fact, be more transferable.

Chapter Four: Findings

In this chapter a report of the study findings are presented. This will begin with a summary of the demographic data collected for all child and caregiver participants involved. Demographic information collected included age, gender, race, sex, education/grade, and medications. Basic descriptive statistics were used to analyze and explain the demographic data. Next, child and caregiver descriptions of holistic comfort related to a venipuncture procedure will be presented with overarching themes and their associated less abstract categories. There were additional findings outside the scope of this study; nonetheless these findings are pertinent and significant to report here.

Demographic Characteristics

Twenty-eight total participants were interviewed in this study. Of these 28 participants, 15 were adult caregivers who consented for themselves to participate. Two of the caregivers who participated were the biological mother and father of the same child participant. Fourteen caregivers also gave consent for their minor child to participate. One child did not assent to participation and therefore was excluded, leaving 13 total child participants. A summary of demographic characteristics with caregivers and their corresponding child is found in Table 1. One caregiver is listed singly as her child did not assent.

Children

Children between the ages of 4 and 7 years were recruited for the study but no children 4 years of age participated. Children were fairly even with regard to gender representation. Seven male children (53.8%) and 6 female children (46.2%) were interviewed. Children were also nearly evenly distributed with regard to age: 4 children (30.8%) were five-years-old, 5 children

Table 1. Participant Pseudonyms, Demographic Data, and Child/Caregiver Dyads

Table 1. Participant Pseudonyms, Demographic Data, and Child/Caregiver Dyads				
Participant	Age	Race	Gender	Education
	(yrs)			1
Minnie Mouse	7	White	Female	2 nd Grade
Ms. Potts		White	Female	High School
(Biological Mother)				
Cleo	6	White	Female	1 st Grade
Fairy God Mother		White	Female	8 th Grade
(Grandmother/Guardian)				
Thumper Rabbit	6	White	Male	1 st Grade
Sarafina Lion		White	Female	Some College
(Biological Mother)				
Queen of Hearts		White	Female	Some College
(Biological Mother)				
Princess Tiana	5	Black	Female	Kindergarten
Eudora		Black	Female	High School
(Biological Mother)				
Aladar Dinosaur	5	White	Male	Kindergarten
The White Queen		White	Female	Graduate School
(Biological Mother)				
Flower Skunk	7	White/Black/Hispanic	Female	2 nd Grade
Mama Odie	,	White	Female	Some College
(Legal Guardian-Adopting)				
Chip	5	White	Male	Preschool
Darling		White	Female	Bachelors Degree
(Biological Mother)		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		8
Abu Monkey	6	White	Male	1 st grade
Aphrodite		White	Female	Some College
(Biological Mother)		1,11100		20110 2011080
Jasmine	7	White	Female	2 nd Grade
Esmeralda	,	Asian	Female	Some College
(Biological Mother)		7 101411	Temare	Some conege
Sophia the First	6	White	Female	1 st Grade
Madam Mim		White	Female	High School
Baymax		White	Male	High School
(Biological Mother/Father)		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	1,1010	111511 5011001
Prince Eric	7	White	Male	2 nd Grade
Lady	'	White	Female	Some College
(Adopted Mother)		***************************************	1 Ciliale	Some Conege
Mowgli	6	Black	Male	1 st Grade
Calypso		Black	Female	Some College
(Biological Mother)		DIACK	Temate	Some Conege
Bashful	5	White	Male	Preschool
·		White	Female	
Daisy (Riological Mother)		vv IIILE	remale	Some College
(Biological Mother)				

(38.4%) were six-years-old, and 4 children (30.8%) were seven-years-old. Two children (15.4%) were in preschool, 2 children (15.4%) were in Kindergarten, 5 children (38.4%) were in 1st grade, and 4 children (30.8%) were in 2nd grade. Ten children (76.9%) were reported by caregivers as being White/Caucasian and 2 children (15.4%) were reported as being Black/African American. The last child was reported as being Black/African American, White/Caucasian, and Hispanic (7.7%). Three children were reported as being on medications at the time of the interview. No children were excluded due to medication. One child had taken Allegra. Another child had taken Concerta (controlled substance for ADHD), Clonidine, and Cephalexin, and the last child was also taking Cephalexin. Caregivers were asked about alcohol and drug consumption for their minor children. All caregivers reported that their child had no alcohol consumption, no illegal drug use, and no use of controlled substances with the exception of stimulant medications to treat deficit disorders.

Caregivers

All but one of the caregivers was female (n=14; 93.3%). One father (6.7%) consented for an interview that was conducted with his wife. As previously explained, this couple wished to participate together. Ages among caregivers varied. Seven (46.6%) caregivers were age 26-35 years, six (40.0%) caregivers were 36-45 years, one (6.7%) caregiver was age 46-55 years, and another caregiver (6.7%) was at or over 56 years. Two outliers were noted in age: both being at or over the age of 46 years. Education among caregivers was varied: High school/GED (n=4 or 26.6%), Some College (n = 8 or 53.3%), a Bachelor Degree (n= 1 or 6.7%), Graduate School (n=1 or 6.7%), and although it was not an option on the demographic sheet, one caregiver (n=1 or 6.7%) reported completing no High School but up to 8th grade. Twelve participants were White/Caucasian (80.0%). Two participants were Black/African American (13.3%), and one was

Asian (6.7%). No caregiver was excluded due to medication use. All caregiver participants were also asked about alcohol and drug use. Every caregiver reported no alcohol consumption in the last 4 hours, no illegal drug use, and no use of controlled substances in the last 8 hours.

Caregivers reported being on other medications: (a) one caregiver was taking metoporol, (b) another caregiver was taking citalopram, (c) one caregiver used metformin, Januvia, and cetirizine, (d) and the last caregiver reported being on "Thyroid" medication. Caregivers were asked about medications to be certain they did not meet exclusion criteria with the use of controlled substances in the last 8 hours. Amongst the primary caregiver participants was: one biological father, 11 biological mothers, one legally adopted mother, and two legal guardians-one caregiver who was also the child's grandmother and one female who was in the process of adopting the minor child.

Holistic Comfort Descriptions

Many descriptions of holistic comfort among child and caregiver responses were gathered. As previously explained, caregivers and children were originally analyzed separately. After this separate analysis it was interpreted that comfort descriptions between the two groups were similar, resulting in identical overall themes. Child and caregiver categories of comfort (within the themes) were either similar, different, or independent. The overall discoveries of this study led to the following four overarching themes of holistic comfort related to venipuncture procedures: *Body Comfort, Cognitive and Emotional Comfort, Comfort in the Procedure Surroundings*, and *Comfort Play*. Table 2 outlines all of the overarching themes and their corresponding categories among child and caregiver descriptions. As a necessity in the qualitative descriptive design, the PI stayed "data-near" when naming categories. Participants

Table 2. Overall Themes and their Corresponding Child and Caregiver Categories

Theme	Child Categories	Caregiver Categories
Body Comfort Cognitive and Emotional Comfort	-Hugs and Holding -Physiological Needs -Getting Over The Hurt Spot -Clinician Secrets -Family and Friends -Rewards Made me Happy -Self Help -Special Security	-Avoiding Hurt -Hunger-Thirst-Rest -Medicine -Loving Physical Touch -Comfort of Others -Distraction and Connection -Earn a Treat -Once it was Over it was Over -Preparing for the Procedure -A Good Nurse
Comfort in the Procedure Surroundings Comfort Play	-What Feels Comfy -What would Look Better -Games and Enthusiasm -Toys and Stuffed Animals	-Child Friendly Environment -Procedure Atmosphere -Something to Do

own words were used in many instances while interpreting categories. The overall themes are presented individually with explanation and references. Categories of comfort are examined at the level of each theme. The categories of child comfort descriptions are addressed first. This will be followed by categories of caregiver comfort descriptions, including a comparison with child descriptions, when appropriate. Examples of comfort descriptions from each category in their respective group of participants are included and referenced by pseudonym.

Body Comfort

The theme body comfort related to the child's somatic needs revolving around the venipuncture procedure. Children and caregivers described body comfort as an experience that was desired or necessary related to the human body system, structures or parts of the body, or improvement/satiation in body function, sensation, and feelings.

Children. Three categories of body comfort were discovered in child responses. Children were detailed in explaining the positive effects of various types of body comfort while additionally describing the negative aspects of missing these desired comforts. These categories included: *hugs and holding, physiological needs,* and *getting over the hurt spot.* Two of these categories were named specifically from child descriptions.

Hugs and Holding. Being held anywhere on the body and giving or receiving hugs were sources of body comfort for children. Children experienced this kind of comfort from a primary caregiver, immediate family member, or extended family member. Several children mentioned their caregiver, often times their mother, held their hand during the venipuncture procedure or in preparation of the procedure.

Jasmine: "Yeah. I holded her [mother's] hand and it didn't' even hurt because I, I was holding still... holding my moms hand... she was holding onto mine... I'm gonna draw my mom holding my hand...that made me feel better..."

Prince Eric: "Well, she [mother] did let me um, in the waiting um, well she did hold my hand..."

Princess Tiana: "She [mother], she wa um, she was holding my hand... because she she made me, she made me feel better... she was ha, she was holding my hand."

The above children communicated the simple gesture of hand holding as comforting in the time of his/her procedure. Other children talked about the importance of hugging. Two children discussed hugging siblings. Another child yearned for the presence of a favorite aunt. She further talked about an important hugging ritual that her aunt often gives her.

Aladar Dinosaur: "Well, if, if I can get hurt and I cry, my uh, my sister would always hug me... yeah and even at like a shot when I cry, she gives me hugs... That's my sister. She's 8-years-old [child discussing his drawing]... That's me, I'm 5-years-old... Well I couldn't, on the other paper, I was trying to make us hug [child explaining he was attempting to drawn himself and his sister hugging but instead he explains it to the PI].

Chip: "Uh huh, because she [younger sister] hugged me while I was getting my, my, hurt, like um I got poked."

Princess Tiana: "She [child's aunt], she um, when she goes to work, she hugs me because when I go to school, she um, gives me a hug so loving and then when I leave and then when she comes back, she gives me some more hugs."

With these descriptions it is apparent that from a young child's perspective, acts of hugging and holding with significant others is meaningful and comforting to the body during a venipuncture procedure.

Physiological Needs. Another source of body comfort described by children was in relation to various physiological body needs. Descriptions and discussion focused on wanting to eat and drink, elimination habits, and sleep/being tired were mentioned. One child said he needed to go to the bathroom prior to the procedure and that he did in fact get to use the bathroom before his procedure began.

Aladar Dinosaur: "I need... I need, well when I was waiting in the room, I had to go potty... I did go potty before I had the shot."

Aladar Dinosaur talked about using the bathroom before his venipuncture which provided him some relief. Other children discussed food and drink specifically, including the types of food that would satiate and or satisfy their hunger. Wanting to eat or drink was described by children as occurring before or after the venipuncture procedure.

Jasmine: "And I'm getting a drink of water. I really wanted a drink of water. That's what I want... Hm, mama I'm hungry... yeah food would make me feel better like I know how to draw like, let me remember, like mashed potato and corn. I know how to draw corn."

Aladar Dinosaur: "I would like, I would like to see food on the wall [in the exam room] ... I love steamed broccoli! ...Ah, I want, I want the ones that you can eat ... I can eat the wall, like I can eat the stuff on the wall."

The two children above very richly described hunger and thirst experienced before and after the procedure showing these are important comfort needs surrounding a venipuncture. Another physiological comfort need described by children revolved around sleep. Several children reported that they felt tired, sleepy, or even "woozy" after they awoke the morning on the day of their procedure. One girl discussed feeling sad because she had a nightmare about a monster the night before the procedure. Another boy described feeling strange and not getting sufficient sleep.

Aladar Dinosaur: "Oh [I felt] kind of weird. I, I haven't ah, slept until well ah, un until it was almost dawn... I was feeling like kind of strange."

Cleo: It was, I was still asleep [this morning] ... I was sad, it made me sad one night because of I had a dream ... yeah, it and because when I had a dream that a monster was at my door."

Clearly, adequate sleep before an invasive procedure can be comforting to children in the preoperational stage of development. The above combined physiological descriptions by children represent basic human needs: hunger, thirst, sleep, and elimination. Children describe these somatic or body comfort needs as occurring before, during, or after the invasive venipuncture procedure.

Getting Over the Hurt Spot. The last category of body comfort described by children was getting over "the hurt spot." This type of comfort specifically related to the venipuncture site, venipuncture supplies, and the child's opinions about these elements related to the procedure.

Many children talked about materials used by the clinician when initiating and completing the blood sampling. Some children found comfort in the band-aids and the dressing.

Princes Tiana: "Because, ba, band-aids are pretty and band-aid make me feel better... um... pink, pink... because it will, it'll if um you don't put a band-aid on it, um bu um you um, the blood um, the blood will leak out... I can smell my band-aid right now... Yeah, it smells like, like the doctors!"

Aladar Dinosaur: "That little wash cloth...um they put a band-aid over it...because the, they [band-aids] get over the hurt spot."

A band-aid or some form of dressing is used in all venipuncture procedures. Children finding comfort in these things is significant since the dressing can be easily provided and coordinated. Other children described finding more comfort in removing the procedure materials. One girl discussed her disapproval of the band-aid smell as well as the adhesive sensation. She also

reported the discomfort associated with the application of the tourniquet and feeling better after the clinician removed this. Another child described his thoughts on the band-aid and the unwanted body sensations he felt connected to it – "sticky and itchy".

Jasmine: Here... it [band-aid and dressing] doesn't smell that good... and it's squishy yuck and it's sticky... it smells like gas in cars... Can I take it off? [child asks her mother] ... Because it stinks! ... Yup, that stinks... some people said the part of that thing that holds it up [the tourniquet] is the worst part and I say that too... that was so hard like I'm oh oh oh they're squishing my arm."

Thumper Rabbit: "It feels like, it feels sticky... cause it does... can I ask my mom something first? [child then directs question to his mother] Can I take this [band-aid/dressing] off? It's making me itchy...see this [venipuncture site now uncovered] is where they poked me."

Venipuncture dressings can be removed just as easily as they are applied. If some children find the persistent presence of a dressing or band-aid uncomfortable then taking the dressing off for enhanced comfort can be offered, granted the site is assessed as clear by the clinician.

Caregivers. Four categories of body comfort were uncovered in caregiver responses. These categories included: *avoiding hurt, hunger-thirst-rest, medicine,* and *loving physical touch*. Three of these categories were named using caregivers' own words. One category, *medicine,* was independent. Descriptions of medicine were only interpreted in the caregiver participant group as children did not mention this as a source of comfort.

Avoiding Hurt. Avoiding hurt was similar to getting over the hurt spot category in child descriptions. Caregivers however focused their descriptions on the actions of the child and or clinician. Caregivers were specific in recounting what their children did or what the clinician could have done to avoid the hurt associated with the venipuncture procedure. Many caregivers described their child's distressing actions, child refusal to cooperate with the procedure, fighting back on the part of the child prior to and during the procedure, and details about the procedure that made the hurt experience worse for the child. One father explained himself being witness to and a participant of holding his daughter down for a procedure process.

Baymax: "She don't like needles, never has been and like my wife said... its took me, her (wife), two or three techs, and, and two nurses, and a doctor to hold her, so I mean when she don't want the needle or something injected, she uh, she's hard to handle."

The description above suggests that avoiding distress and pain when possible would provide comfort to this fathers' child. Another mother described her daughter's pain experience with the venipuncture. She associated this with: the lengthy time spent by the clinician trying to find the best location to insert the needle, the child's waiting and enduring while trying to access a vein, and calling another clinician in for consult during the procedure. This mother describes how preventing these technical details would have been more comforting to her child.

Ms. Potts: "They went from arm to arm and tried to figure which arm to get it out of and then they had to wiggle around the needle a little. Um, that was probably the worst part, the hunting... but they just kept, you know going, trying to figure out which arm and then she did

have to call um somebody else in there to figure out what's the minimum (blood) she could get...
the thing they use on her arm (tourniquet), she did, started to hurt cause it had to be left on so
long."

In the above statement it is clear that actions by the clinician such as avoiding vein "hunting," being more prepared, and monitoring the length of time the tourniquet is in place would be comforting to a child.

Hunger-Thirst-Rest. Caregivers, like their children alluded to satiating hunger and thirst as a comfort need related to the venipuncture procedure. Caregivers also described the exhaustion caused by the long day and the process of the venipuncture. The perception of the child being "tired" was expressed by caregivers as a concern that the child needed rest from the day, not necessarily sleep. This was similar but not completely consistent with child descriptions of being sleepy, needing more sleep, or inadequate sleep upon awakening in the morning. Unlike children, no caregivers were aware of or discussed their child's elimination needs. Some caregivers described the dissatisfaction associated with not being able to offer their child a meal before the procedure.

Fairy God Mother: "I just discussed with her and told her you know she can't eat or drink anything... She didn't really like that. She was complaining all the way down here I'm hungry, I'm hungry."

It is clear in the above description that food is portrayed as a source of comfort to hunger before the venipuncture procedure. One caregiver explained the thirst and fatigue effects on her child's body after experiencing the process of the procedure day: leaving their home in the morning, going to her child's pediatrician's office, going to the hospital, following through with the procedure, and finally participating in the interview where they received their first drink in several hours.

Lady: "Yes, it's been a long morning... but, we did go to the doctor... so they said from there they wanted so many blood tests that they felt it was best to come here (hospital)... you know and you follow through (with the procedure) and then, and he's (child) pretty tired. He's, he's really, we left this morning at 9, yea 9 and this (water bottle received during the interview) is his first drink... I'm like oh we need to get a drink."

Medicine. Caregivers were the only participants to describe the comforting effects of topical "medicine." These medicines offered comfort to the body by preventing or alleviating pain. One mother discussed the use of Neosporin as a source of comfort to her child's pain in times of injury. It is clear in this description that applying cream to a wound can comfort her child.

Eudora: "Lets go inside and put some medicine on it... Um, she's real skittish about pain. She don't like pain so... you know Neosporin cream, Ill put it on there.

Only one caregiver participating in the study reported the use of procedural pain prophylaxis- a standard of care recommended for children by various medical and nursing experts. This mother first went to her child's pediatrician's office to have "numbing lotion" applied to his skin on

potential venipuncture sites. The mother described the positive effects of the topical anesthetic cream for her child's procedure. This is significant as analgesic cream is readily available in most inpatient/outpatient medical centers.

The White Queen: "We went by our pediatrician's office and they gave me the numbing... the lotion... and I think without that, it would not have been perfect... But I was really really shocked because of the numbing medicine. I mean he sat there and watched it and didn't flinch..."

Loving Physical Touch. Similar to child descriptions, caregivers very frequently described various acts of "loving physical touch" beyond hugs and holding. Caregivers recognized this physical touch as something that comforted or would have comforted their children before, during, or after the venipuncture procedure. Physical touch descriptions included: cuddle, snuggle, rock, in our arms, in my lap, touching, loving on, affectionate, kissing on the cheeks or forehead, holding, and holding hands. One distinct dissimilarity was noted between child and caregiver descriptions of comfort loving touch: the persons providing the touch. Children described receiving hugs and holding comfort from caregivers, siblings, as well as extended family. Whereas primary caregivers described comfort through physical touch provided only by themselves. One mother described how all of her children appreciate sitting in her lap during something tense.

Darling: "...I mean I think that's all my children, comforted either sitting in my lap with some, you know something uneasy coming, yeah... kisses and holding is usually the path, physical touch.

Many caregivers accompany children for venipuncture procedures. The potential for procedural comfort offered by these individuals is significant. Another mother described cuddling and snuggling as "all" she does to comfort her son when he is in need. The only biological grandmother participant (legal guardian) recounted her perception of providing comfort via "loving on her" granddaughter in the laboratory lobby prior to the procedure.

Sarafina Lion: "Um, whenever he sick and stuff like that, we just usually will take him and we'll cuddle and talk... I mean that's all we do is just snuggle, yea we just snuggle.

Fairy God Mother: "I was sitting out there in the lobby and she jumped over my lap and I was loving on her... I will have to love on her."

Cognitive and Emotional Comfort

Another overarching theme of procedural holistic comfort described by children and caregivers was cognitive and emotional comfort. This theme was found to have the most frequently occurring codes and categories between both participant groups. Emotional and cognitive comfort was often interpreted as occurring together so they were merged. Children and caregivers described cognitive and emotional comfort as a process of making the child feel better through actions, expressions, feelings, or thought processes that stimulated the child before, during, or after the venipuncture procedure.

Children. Five categories of cognitive and emotional comfort were interpreted among child descriptions. These categories included: *Clinician Secrets, Family and Friends, Rewards*

Made me Happy, Self-Help, and Special Security. Three of these categories were named in part by children's words used to describe the comfort source.

Clinician Secrets. Various clinicians were responsible for performing the invasive venipuncture on child participants in this study. Children described in detail the many things the clinician did or said to comfort them before and during the procedure. No child made negative comments directed at the clinician. This was an unexpected finding. It is reasonable to expect that children in the pre-operational stage of development would cognitively associate a negative experience, a painful and distressing experience, with the person (clinician) performing the procedure. All negative comments by children were directed in some way at the procedure itself ("the shot, the poke, shot stuff, or labs"), or the supplies for the procedure ("the needle, butterfly, or rubber band"). Basic child descriptions of the clinician were numerous: "nice, good, lady, man, woman, liked", and "brown skin". It is also important to indicate that several children sketched the clinician in their drawing with a smiling face. More elaborate descriptions of comfort from clinician secrets were also noted. One child described emotional comfort from the clinician who told her that holding still was the "secret" to feeling no pain.

Jasmine: "...She told me what is this [described the procedure] and she told me what's the secret of um how its not gonna hurt...it's because not not moving that much."

This above described interaction between the child and the clinician is suggested as significant and comforting to the child. Another child associated his clinician's performance with an even higher level of cognition.

Chip: "Um, a lady with ah um, a Halloween shirt on... Um, well she made me better because I didn't, we didn't know what, made me like, made me like you know like what it was when I was itching to death."

Chip was diagnosed with moderate to severe atopic dermatitis (eczema) and was having blood work that day to help determine the possible allergens causing his skin disease. Atopic dermatitis is often characterized by pruritus, scratching, excoriation, and dryness. He described the comfort of knowing the clinician was there to help him get "better" and determine the cause of his intense itching. It is evident that the child perceived the clinician as helpful and comforting. One child described his appreciation for positive reinforcement. It is clear that the child emotionally responded and found comfort in the clinician's supportive pledge to the child's self-esteem.

Prince Eric: "[I] like her because she complimented how brave I was... she said other kids didn't be that brave, they were scared...I was the only one um, that was brave."

Family and Friends. Children specifically reported people, including family and friends, as a source of comfort surrounding the venipuncture procedure. Primary caregivers, immediate family, extended family, as well as friends were all interpreted as sources of comfort. In this category children did not focus on physical or body interventions, rather the comfort that comes from having a significant interpersonal relationship with the described individual. This comfort was understood as support, presence, mental images, and encouragement. Children described actual or desired cognitive and emotional comfort from people perceived as important to them. Similar to the hugs and holding category, it is clear that children considered individuals beyond

the role of a primary caregiver as significant to their venipuncture procedure. Short descriptions of these significant people were made: a "darker brown dad," a "special nana," a "loving auntie," a "cousin" who has ears like the "poof of a elephant," and a "friend" that "wanted me to come over." Children also described mothers and siblings. When asked, children described emotional comfort and how their mothers' presence and encouragement made them feel better during the procedure.

Sophia the First: "She [mother] had me to look toward her.

Aladar Dinosaur: "Um, she [mother] was in, she was right there in the ba, in the thing. I was on, was right over there."

Caregiver presence is clearly a form of comfort to children during times of invasive procedure.

This is also easily accomplished as caregivers are often present for invasive procedures. Children were also asked about missing individuals during the procedure- someone they wished was there with them. One child described thinking of her baby sister and wishing for her older brother.

Another child described wishing her absent father was in the room during her procedure.

Sophia the First: "Mm daddy, I wish daddy was in the room with me."

Cleo: "I think of my baby sister and it made me feel good... [child also described wishing she had her brother present] ... my brother but he's at school... because I wished he was with me... because he's my brother."

Rewards Made Me Happy. Children described the comforting effects of receiving rewards before or after the venipuncture procedure. They reported various feelings associated with rewards such as happiness, longing for, excitement, and thankfulness. The rewards however were not seen by children as merited. They were viewed more as an affectionate gift. Children did not expect these rewards because they endured the venipuncture procedure. Instead they showed great appreciation and excitement for them. Children described how "chocolate, cookies, Starbucks, smoothies, money, stickers," and more made them feel better before or after the venipuncture procedure. One child described, in great detail throughout his interview, how his reward of stickers and the various types of stickers received after the procedure made him feel better.

Thumper Rabbit: "Well after [the procedure], I got some stickers but I got some [stickers], hang on, let me clean my back pocket... I'm a show the first ones [stickers] that I got... I got I Skylander one that was first... Ah. Uh oh. Oh my gosh, I lost that one. Anyway, I um... um I, I had Crusher [name of a Monster Jam truck] but I lost him, but I had more. See I got Monster [Jam], these were the first ones and then I had Crusher what even it was my other one... and then these were my 2nd ones right here, Swamp Force [another Monster Jam truck name]."

Another child was asked to draw something that made him feel better or something he wished he had with him during the venipuncture procedure. Over several minutes, the child pondered. He then talked to the PI/himself, described his drawing, and disclosed the name of his sweet treat in excitement.

Aladar Dinosaur: "Something I wish I had with me... Something I wish I had with me... Well, what's going on [the paper] ... I'm gonna use this, this color [crayon] for the topping... [humming] and then the straw... Let me get the cream on the top. Done... A chocolate milkshake!"

Self-Help. Children described various acts leading to their own provision of cognitive and emotional comfort before, during, or after the venipuncture procedure. This category included descriptions of thought processes, personal choices, learning, substituting a negative perception for a positive one, protecting oneself, and being proud of oneself.

Some children reported making the personal decision to "hold still" before and during the procedure. Another child reported feeling "good" because she "didn't cry" suggesting she took pride in her ability to withhold tears. One boy described being "scared" but also stated he thought his blood in "that little tube was cool" indicating a self-provoked shift from dissonance to satisfaction. The emotional comfort of the procedure being done was also described: "I don't have to do it again," felt less nervous "after" it was done, "felt good when she took it out." The importance of learning and returning to school was described as a desired cognitive comfort after the venipuncture procedure. One girl spoke richly about wanting to get back to school that day to "learn" the "Quran" and various texts found in this holy book. She recited one of these passages in Arabic during the interview. The Arabic passage was not transcribed.

Jasmine: "If school is over when I get out... which I really don't want to miss it. I wanna learn my Quran. You don't know what that means right? (child asks the PI if she knows what the Quran is]. Can I tell her the Sur-Al-Fatiha? [child then seeks permission from her mother to

speak a passage from the Quran and the mother nods in acceptance]. This is how you start...[child recites the entire prayer in Arabic for the the PI] ... it was, it's Sur-Al-Fatiha.

Another child described comforting himself through self-protection. When asked if there was anything he would have liked to have with him from his home, the boy explained how his "table" could provide him protection and "hiding." It is clear from this description that the child confidently describes the importance of comfort through reducing his fear and feeling more secure.

Mowgli: "My table... ah, I will push it up like this... and then nothing... where people can't give me a shot! A whole bunch of table surrounding me... and then I'd be hiding."

Special Security. Another category of cognitive and emotional comfort interpreted among child descriptions was comfort through special security. Many children described belongings that provided them a unique kind of emotional comfort. These special entities involved a mix of different child possessions, even live animals, and were described as more than simply objects of fun or entertainment. They were communicated and interpreted as being extraordinary and meaningful to the child. One child described the special relationship she has with her "cat gabby" and reported that she wished her cat was with her during the venipuncture procedure. One boy, on several occasions, described his stuffed penguin "Poofy" who makes him feel better "so much." He additionally chose to sketch the stuffed penguin as a source of comfort during the drawing task and chose to give the PI his drawing so she could "remember" the stuffed animal.

Thumper Rabbit: "My penguin named Poofy... Yeah look look, and he's a stuffed animal and he is ah from the Aquarium... cause he's so fluffy.... Watch this it's my best buddy Poofy's feet [child telling PI to look at his drawing of the stuffed penguin]... he always makes me feel better...Next time when I come here I'll bring Poofy... this, my friend right here [Poofy] will make me more than anything feel better... You know why I'm wanting you to have that picture and keeping it [child asks PI]? Cause I want you to remember what Poofy is."

Another child described the emotional comfort he received during his venipuncture from a blanket that he has had since he was born. The blanket is called his "Bee Bee". The child was holding and caressing the "Bee Bee" at the time of the quote.

Aladar Dinosaur: "My Bee Bee ... Well I use it at night and it's snuggly It's a blanket ... I can snuggle the hurt spot ... I can put my Bee Bee over the hurt spot (child then places part of the Bee Bee directly over his venipuncture site)."

Caregivers. Six categories of cognitive and emotional comfort were discovered among caregiver descriptions: *Comfort of Others, Distraction and Connection, Earn a Treat, Once it was Over it was Over, Preparing for the Procedure,* and *A Good Nurse.* Five of the six categories in this theme were named all or in part from caregivers' verbatim descriptions.

Comfort of Others. Caregivers, like children, described the emotional and cognitive comfort of family and loved ones surrounding the venipuncture procedure. No caregiver discussed comfort provided by their child's friends as children did. Comfort provided by family members and primary caregivers was mentioned often. But, a new comfort from social and

fellowship support systems was also described. Caregivers elaborately communicated the comfort of others. They achieved this through describing the understanding and perception of safeguarding their child through others. This comfort included support, encouragement, presence, availability, reassuring, protection, and love. Verbatim emotional and cognitive procedural comfort descriptions such as: "having mommy there, consoling her, let her cry it out, comforting words, I'll do it with her, to feel protected, she wanted me and sissy to go, you're doing good, she like somebody to be proud of her, and family love" were all noted among caregiver responses. One mother described the importance of having the people her daughter loves the most in the room during the venipuncture procedure. She admitted that her sister (the child's aunt) is better at calming her daughter and they (her child and her sister) have a close bond. She also discussed her own efforts to console and comfort her child during the procedure.

Eudora: "She was calling out for my sister... Auntie ah Jackie yeah. She's, she's like real, more I guess like calmer... Yeah, that's her [the child's] favorite auntie so she [child] was mainly looking out for her [during the procedure] and stuff so but, but yeah just me consoling her and making sure she's ok. Just telling her everything's gonna be alright... But, she's [the child], she's just like, she's real sensitive and emotional so that extra type of comfort and love from the ones that she love the most, that's probably what you know, that would um, help her out, as far as, being comfortable in the room.

The only male caregiver (father) in the study described comfort his daughter receives in times of pain or distress from people who are close to her outside of family. This comfort was available through the family church and more specifically church leaders.

Baymax: "She [the child] has ah, pastor's wife and our pastor that she can go to and and talk with and and just loves her just like that she was their own... And church, she's the same way about church.

Distraction and Connection. Caregivers frequently described ways children were comforted through distraction away from the procedure. Additionally, some of these comforts offered an important, almost restorative, connection to the child. This category is in some ways similar to the special security that children discussed. But, it is different in the underlying purpose described. Caregivers specifically describe distraction as a technique. They explain the importance of diverting the child's attention as a method of comforting. Children did not state or imply distraction as a means of comfort. This could be related to the child's age, developmental level, and cognitive abilities. It could also be that children do not think diversion is the comfort; rather the stimulation or inspiration of the distractor is comforting. Caregivers specifically stated the words "distraction, get their mind off it, mind occupying, occupies him, and pointing out things in the room." One mother described her anticipation of what the day would be like and the comforting effects of counting beads as a distraction to her son before the procedure.

Darling: ... I mean walking in, I already knew that he would already tense up knowing that it was a doctor's atmosphere... Um, he didn't seem to [tense up] as much as I thought. With the distraction of this [counting beads], we did pretty good... We honestly were completely distracted by this [beads] ... all the way up to the moment [the procedure began] so."

Another mother described the distraction her child received during the procedure from a particular blanket named "Bee Bee." At the same time the mother described the important connection the child has to this blanket.

The White Queen: "The Bee Bee fixes everything... Um, like he's here because of stomach pains... And he's been putting the blanket [Bee Bee] under his shirt against his stomach to make his stomach better. But the Bee Bee, he has to have the Bee Bee [with him during the procedure]... We never had a pacifier... we had a Bee Bee."

When asked about what would have made the procedure better for his child, a father described the distraction and connection of a doll that his daughter has. The father indicated innocently and occasionally teasing his daughter about the doll.

Baymax: "...She's got a baby that she calls "Baby Doll," that she's ah, had from the time that she was ah, a baby and she sleeps with her aaaaaaaaall the time and all, ah I pick on her a little bit over it. I said "No, she (the baby doll) gonna sleep with daddy [then the child will respond and say]. No, she ain't she's sleeping with me."

Earn a Treat. Cognitive and emotional comfort also included an "earned treat" before or after the venipuncture procedure. This is very similar to the rewards made me happy category described by children and many of the same types of treats/rewards were described between both the caregiver and child groups. Both food or drink and non-food or non-drink treats were described. Verbatim comfort treats described by caregivers included things such as: "ice cream,

popsicles, McDonalds, junk food, milkshake, Starbucks, gummies, whatever she wants, stickers, and money." One of the major differences noted in this category was less description of child emotions tied to the treat. Children often tied feeling outcomes (ex: happiness or thanksgiving) with the rewards and they did not describe expectations of receiving a treat. Caregivers focused less on the emotional outcomes of giving the treats and more on the underlying cognitive justification or the incentive of providing a treat. The treat was earned because his/her child would be enduring or had endured a venipuncture procedure. One mother described the comforting effects of promising her daughter a tasty post-lunch. Hot chocolate from Starbucks was also described as comforting.

Eudora: "I just told her you know we're going to the doctor and you know after we get done, you know for her being good, we're gonna go get something to eat, probably go to the Burger King."

The White Queen: "... After we left the pediatrician's office, he was screaming bloody murder because he had the Band-Aid (tegaderm adhesive with topical anesthetic cream beneath) on... We got Starbucks to calm him down to get here."

Another mother described the importance of her son earning a treat after the venipuncture because of his bravery with the procedure.

Lady: "You know when they're having to do extra stuff... You want to get enough that you know they feel they've earned it and he definitely earned it. He was so brave. You know you earn a treat when you're brave."

Treats and rewards described by caregivers in this category are significant in this study because these are simple but seemingly comforting options for children related to a venipuncture procedure.

Once it was Over it was Over. Caregivers described the child's cognitive comfort of knowing the venipuncture procedure was done. "Once it was over it was over" is a category of descriptions that explain the importance of no longer enduring the discomforts associated with the venipuncture. This perception was found to a lesser extent among children's descriptions in the self-help category. The importance of the procedure being "over" was a larger insight among the caregiver group. One mother describes her son's readiness to leave upon the completion of his procedure. Another mother explains the conflict of watching her child in distress but describes the relief of seeing him manage well after the venipuncture.

Queen of Hearts: "As soon as the shots are you know done and administered you know then he's fine... Oh I think as soon as the needle's out and once that bandage is on there, wrapped up, he knows he can go... yeah cause he's... he knows he gets to go out"

Darling: "It, it bothers me to see him get so stressed about it but I mean... he coped fine after so I'm good with that."

It is clear by the above descriptions that ending the procedure offers comfort to children. This is significant to the caregiver and child procedure experience as the knowledge could provide comfort in advance.

Preparing for the Procedure. Caregivers made numerous references to the cognitive comfort associated with caregiver-induced, and to a lesser extent, child-induced preparation for the procedure. This category of comfort was different because caregiver strategies for preparing their child were not discovered among child descriptions. Child-induced preparation was found in the self-help category of cognitive and emotional comfort described by children.

The types of preparation described by caregivers were at times opposite. These opposites were still however forms of preparation and thus in the same category. Some caregivers described preparing their child by fully explaining the procedure details. Other caregivers characterized their preparation strategy as simply avoiding any explanation. Although these two approaches to preparing a child are different, they are still methods of preparation that caregivers feel work best for his/her child. One mother described the comfort associated with not burdening her child with knowledge about the procedure until they got into the exam room.

Eudora: "I really didn't tell her what was going on until like we actually got into the room so that kind of made it more easier... until they done it (the venipuncture)... I think by me not saying anything to her... before hand... actually eased it."

Another mother described the comforting effects of providing a different kind of preparation- a more explanative and informative one.

Mama Odie: "And then when they [doctor's office] told us, I tried to explain it to her. You know they're gonna have to take some blood out, you know... you have to try to prepare her for anything new."

Self-preparation on the part of the child was described by one mother as the act of her son offering his arm to the clinician willingly for the venipuncture.

Lady: "He knew what was going on... and he was a little nervous you know when they started...
but you know he gave his arm and ah... yeah."

Many caregivers described preparation as a source of procedural comfort. This is a significant way that caregivers can be involved in the comfort care that children receive prior to invasive procedures.

A Good Nurse. The last category of cognitive and emotional comfort was "a good nurse." This category of comfort was described by caregivers as things that clinicians can do or did do before, during, and after the venipuncture to make the procedure experience more comforting for children. This category of cognitive and emotional comfort was similar to the clinician secrets category found among child descriptions. There was however no descriptions of clinician technical skill by children. Another difference noted here is that one caregiver did make negative comments specifically about the clinician performing the venipuncture on her child. This is unlike children who reported no negative descriptions about the clinician. This one caregiver also made positive comments about the same clinician. The summative descriptions from caregivers regarding the "good nurse" revolved around comfort from clinician demeanor, rapport, skill, and

talk. One mother described the comfort of demeanor with "sweet talk" provided by the clinician during her child's venipuncture.

Ms. Potts: "The lady was real sweet talking to her... you know... the sweeter they, the, that comforts em."

Another mother described the clinician providing comfort through building a rapport with her son by talking to him about things that he may find interesting and entertaining.

Lady: "Um, they were very nice. Extremely nice to him. Um, talked not only about what she was doing but also about being a vampire and you know something he could relate to... and then he talked to her [the clinician] about being a werewolf."

Caregivers also described the importance of clinicians spending caring time with their children.

One grandmother shares her perception on the significance that clinicians have with invasive procedures.

Fairy God Mother: "It just wasn't you know like some one went in there [procedure room] and didn't say anything and just poked her [child] and went on... cause there are people like that... I think they think some people thinks kids don't have feelings but I think the personality on the nurses is a... it's good... for our kids"

A contrasting and less positive description of the clinician was also noted. This suggests similar caregiver expectations with suitable clinician demeanor, talking, and rapport. One mother described this experience with the clinician as being good at his job but lacking in other areas.

The White Queen: "The guy that did it was very good but he wasn't real calming and soothing feeling... and he was quick, I mean he was nice but usually with kids, your used to somebody being overly friendly... that is the way you deal with a kid."

The perception of clinician importance was evident in both child and participant descriptions. This is significant because a clinician may not know how essential his/her role is in comforting a child before, during, and after a venipuncture procedure.

Comfort in the Procedure Surroundings

Another overarching theme of this study was comfort in the procedure surroundings. This type of holistic comfort was characterized by elements within the context of the child's environment. This surrounding comfort was in some way related to the child's venipuncture procedure from beginning to end. Descriptions of comfort in the procedure surroundings existed on a spectrum of various locations: some as general as the entire hospital and others as specific as the exam table the child sat on for the procedure.

Children. Two categories were interpreted among child descriptions of comfort in the procedure surroundings. Both of these themes were named in part by descriptions and actual words that children used to share his/her perceptions: *What Feels Comfy* and *What would Look Better*. The main insights of children in this theme originated from what felt more comfortable and the comfort that comes from looking at something pleasing, attractive, or enjoyable.

What Feels Comfy. Children made various descriptions related to feeling more comfortable. Accounts of satisfactory and unsatisfactory parts of the procedure table in the exam room were discussed. Room temperature of the entire hospital, the exam room, and even the bathroom was also described. Some children mentioned their views on the size of the procedure room. On numerous occasions children made recommendations on what they would have changed about their experience to make it feel better to them- hence feeling more "comfy." One child was asked if he remembered the room he was in when he had the venipuncture done. The child was able to communicate and summarize his feelings about the room in just one sentence.

Mowgli: "A little room with a whole bunch of shot thingies and stuff... where I got my needle."

Several children described their perceptions of the temperature in certain areas of the hospital. When asked what he/she thought about the temperature in the exam room, children reported feeling cold, hot, just right, or perfect. Children also described things that would have made them feel better about the temperature of the room if they communicated it as being uncomfortable.

Minnie Mouse: "Cold, this whole building [hospital] is cold!... Ah, a jacket, like kind of like my moms [would have made me feel better]. Mmm, if I had my mom's jacket [would make me feel better now] ... Cuz it's still cold even in here [interview room].

Another child, when asked, described the procedure room as being "hot." He then elaborated on his preference for temperature in the procedure room while also comparing it to another location in the hospital for clarification.

Thumper Rabbit: "[The procedure room felt] Hot. I would like it warm but not cold like the bathroom... it was a lot cold [in the bathroom]."

Children described the procedure table in various ways. Some children perceived the table as too hard while others perceived it as soft. One child went even further and described his dislike for the noisy crunching sounds of the paper on the procedure table.

Prince Eric: "Yeah um, it was, well um it wasn't comfortable because of that paper on it... Um, well first of all it um, it makes, it does, it's not um like, it makes uncomfortable and it also and also when it makes that um those noises, it kind of hurts my ears... Um um just like um like a sa like a soft sheet [would be better].

While drawing a picture of his experience with the venipuncture procedure, the same child draws the procedure table. He makes recommendations and states his preference for something else on top of the table, something he finds more "comfy."

Prince Eric: "The mattress was green... and no pillow, and there was just like um, and here's and here's the paper... when I lay down on the bed [child's bed at home], um I usually has a pillow that's comfy so my head doesn't have to lay down on the mattress. The mattress is kind of hard."

Children thoroughly described ways in which the procedure room could feel more "comfy." This is significant because many of these descriptions can be easily implemented and developed to improve the overall comfort that children "feel" in a procedure room.

What Would Look Better. Children also described the visual aspects of their procedure surroundings- those that were aesthetically pleasing and those that were not. In this category, children discussed the waiting room, the laboratory floors, and the procedure room in great detail. Among these descriptions were perceptions of things that children were impartial to, they liked, or did not like. Suggestions for things that children would have liked to see instead, hence "what would look better" were also made. Children talked frequently about color preferences and recalled colors in their surroundings. Some examples of these verbatim references include: "my favorite color is blue, they were colorful, because I like the color red, I love pink the best and purple, I don't like the color yellow, I wanted blue, I like dark blues, hot pink and hot purple, colors and decorations, and it's gonna be colorful." It is also important to note here that color preference crossed over into the first theme of body comfort when children described band-aids (see p. 104). One child began talking about the floors in the laboratory and exam room. He described the colors on the floor and what colors he would have preferred while also relating this to something exciting to him- a fire fighter/officer.

Chip: "Nothing was on the floor there...only colors... I think it was just light blue and dark blue and all kinds of blue. [I Would have liked to see] red and orange [two of my favorite colors]...and in yellow because I, I really like fire.. like fi, like a fire cop!"

Painted decorations (in this case painted foot steps) on the floor of the laboratory caught the attention of one boy when he was walking to his exam room.

Prince Eric: "Actually the floor um, actually the floor um, I looked at that, I looked back and look at the footprints that were on the floor yeah... and then I looked back [again].

Child descriptions of various decorations in the exam room, waiting room, and laboratory were common. Children liked some of these decorations and did not like others. Children referenced liking "dinosaurs, flowers, fish, sparkles, UT Volunteer football decorations, diamonds," and more. One girl described the ceiling of her procedure room and suggested "what would look better."

Minnie Mouse: "Mmm it [the procedure room] had like cats and dogs on the ceiling... I kind of liked it... what would look better would be hearts."

The above description is important because it signifies children have various preferences with regard to an aesthetically pleasing atmosphere. This can be considered in the procedure environment. In another case, when one boy was asked what he liked about the exam room floors and walls, he stated there was "nothing."

Mowgli: "There was nothing!... white, white, white."

Another child described "creepy" decorations in the waiting room of the laboratory. This boy made it clear that he did not like the "weird" decorations, which were probably celebrating Halloween since this interview took place in October.

Aladar Dinosaur: "Um, well why do you have creepy stuff in, in the first place where you wait [waiting room]? …I just think that room ah, room is kind, kind of weird… Well, like I didn't like all that stuff on the window… uh, or those pumpkins."

The description above is also significant because it is a reminder that all children are different.

Procedure surrounding decorations may be pleasing to one child and frightening to another.

Caregivers. Caregivers also talked about comfort in the procedure surroundings. Two categories were found in this theme among caregiver descriptions. These two categories are: Child Friendly Environment and Procedure Atmosphere. One of these categories was named from caregivers' own words.

Child-Friendly Environment. Caregivers described various aspects of the child's surroundings they felt were or could have been more "child friendly." This description of a "child-friendly environment" was interpreted as environmental elements that a child would relate to or identify with more. As with children in the what would look better category, these descriptions focused on the visual aspects of the waiting room, laboratory, and exam room. One difference noted in this category among caregiver descriptions was the specific recommendation for more appropriate locations of décor. Various descriptions of the walls, floors, exam room overall, and suggestions for change were discussed. Several mothers made comments about

things that would have looked better in the exam room surroundings. One mother suggested a room design similar to the one that is in her child's pediatrician's office.

The White Queen: "Our pediatrician's awesome, office is awesome. Every room is decorated and I think… and it's floor to ceiling in their whole theme… and it's really great cause they [child patients] look at the… count the pigs on the wall… but that's…it it helps the child feel more secure in an area… like that… instead of coming in and oh gosh, we're in the hospital room… The white walls I think are probably not soothing."

Another mother described the placement of painted handprints on the back of exam room wall. She explains her son walking into the room and seeing the handprints only momentarily before having to face forward (away from the handprints) to have his procedure done.

Lady: "I think there were handprints on the walls [in the exam room]... But, if, if there were... um, they [handprints] were on the back wall and he's [child] facing forward so they're not gonna do any good so... You see it [handprints] when you walk in, but if the child's not gonna be looking there, they're gonna be looking at what, what he looked, what he told you he saw... because when you sit down, his back's to em [handprints on the wall].

Other caregivers talked about the child-friendly environment. One mother describes the beneficial effects of floor decorations in the laboratory. Decorations in this instance were advantageous given her child's "active" personality.

Esmeralda: "The steps [painted foot prints on the floor] ... She's an active person...like kind of jumping on the polka dots. They're actually steps not polka dots...So that's kind of got her...attention a lot so."

The descriptions above are significant because the way a procedure environment looks is clearly reassuring to a child. The surroundings in this environment can be modified to be more fitting to a child's needs and in turn enhance procedural holistic comfort.

Procedure Atmosphere. Caregivers also described the procedure atmosphere. This category was similar to the child category of what feels comfy and included caregiver comfort descriptions about size of the room, descriptions about the procedure table, and the temperature in the room. However, unlike children, caregivers described the procedure space and atmosphere as needing improvement.. When asked about the procedure room, one mother described her son's perspective of a small exam room and compared this room to others that she and her son have experienced.

Lady: "Um, his words exactly when we walked into it [procedure room].. and I'm gonna go by his words, um well it's a little small huh... Yeah to him [it's small] ... But it's not as big as a doctor's room ... It's not as big as the ER room ... that we ended up going to ... It's smaller so."

Similar to children, caregivers also discussed comfort of the temperature in the procedure room. However, unlike children, caregivers only discussed the temperature when they felt it was too cold for their child. Caregivers did not discuss the procedure atmosphere being hot. When

asked what could have been done to make the procedure experience better for her child, one legal guardian described the room being warmer.

Mama Odie: "They could have made it warmer... As a matter of fact, it's kind of cold in here [interview room] ... Yeah and you know she has a shirt, she has an undershirt, and a jacket and then she has a coat too ... She's a very cold natured child."

Comfort related to the procedure table was also discussed. One mother described her child's positioning for the venipuncture procedure and how this positioning resulted in less comfort. She thought that a chair would offer more comfort than a table.

Ms. Potts: "...Well she had to sit there for a for a little while since she was, you know, and her legs were danglin off the table... better to sit on than the, you know they might be more comfortable instead of just sitting out in the open on a table. I don't know... little kids...um, a soft chair [would be better] ... Ah, ah a chair, which I know with small babies and things that's hard... but um, I think, I think a kid would feel better in a chair instead of just kind of feeling like they're vulnerable up sitting on that table..."

The atmosphere of the procedure is evidently an area that can enhance holistic comfort among children experiencing a venipuncture. As previously stated, it is also an area that can be easily changed in order to improve overall procedural comfort for children.

Comfort Play

Comfort play in the final overarching theme. Comfort from "play," with the objects described in this study, is related to recreation and hobbies that a child or someone in earlier stages of development would likely enjoy. Children were far more detailed, specific, and varied in their descriptions of "play" in this theme. In fact, only one category of comfort play was found among caregiver descriptions. Additionally, caregivers included some descriptions of comfort play that children did not mention. Nonetheless, the descriptions by children and caregivers in this theme were comparable. This suggests that caregivers perceive their child's expectation of comfort from play to be similarly important. Both participant groups described various belongings, gifts, or objects that offer entertainment.

Children. Two categories of comfort play were described by children. These categories included: *Games and Enthusiasm* and *Toys and Stuffed Animals*. Both of these categories were named in part by verbatim descriptions by children. It was noted that children were particularly excited about the comfort sources in these categories.

Games and Enthusiasm. The child category of games and enthusiasm is filled with descriptions of various activities and sources of amusement that could be used before, during, or after the venipuncture procedure. Children also described topics that they were enthusiastic and excited about. This enthusiasm included objects, subjects, or brand names that children liked or labels that could in some way be related to play or playful. Examples of references by children in this category include "fun, games, bubbles, free drawing, brachiosaurus, Monster Jam, Michael Jordan," mom's "phone," and "my phone." Many new advancements and game applications are now available on various mobile phones. One child described his phone as a source of comfort play.

Mowgli: "My phone... Ah, cause I like to play games on it... I have angry birds and mind craft and stuff."

Another child expressed enthusiasm and enjoyment with drawing several times during the interview. He also indicated self-confidence in his drawing abilities and wanting to draw something he is "good at."

Aladar Dinosaur: "I know how to draw. I know how to draw some stuff... I can draw very well...Well, I really want to draw something I'm really good at... I can make it like this [child begins drawing]."

Some girls were enthusiastic about princesses. One child drew the princess on her bracelet when asked to draw something that made her feel better or would make her feel better about her procedure.

Cleo: "This is the princess... it's right here on my bracelet...It's this one with the yellow dress...and there was a another one [princess] right here and that's ah there's flowers on it [the dress] ... And that's my bracelet."

Toys and Stuffed Animals. Children also described comfort associated with novelty toys, action figure toys, and stuffed animals. This comfort need or expectation was expressed as occurring before, during, or after the venipuncture procedure. Many children talked about enjoying the toys that were left for them to play with (provided by the PI) on the carpet tile

during the interview. Many children played with these toys during and after their interview.

Other children talked freely about their own stuffed animals or toys from home as well as stuffed animals given to them by the laboratory staff. One boy was playing with a ninja turtle action figure provided on the carpet tile. When this boy was asked what he would have liked to have with him during his procedure he described a stuffed toy at home like the action figure.

Bashful: "Um, um my Ninja Turtle... I do have a stuffed animal Ninja Turtle. He's Michelangelo crawling like this [Child picks up the ninja turtle action figure and gestures him crawling] ... Yeah [crawling] on a sheet ... And it has a button right here (child points to the back of the ninja turtle toy) and it, and it, and it lights up a at the, in the dark.

Another child described the comforting effects of an activity set. During the drawing task, the boy was asked to create a picture of things he wish he had during his venipuncture or things that made him feel better about his procedure. He chose to draw and describe a Safari train tabletop activity he played with in the waiting room of the Neurodiagnostic lab after his procedure.

Prince Eric: "Ok. Hm, mm hm, wait that's not what the color is [child looking for a crayon]. It's kind of brown. This is the tr, this is um, train thing...that I played with...Yeah and just...and here's some tracks [train tracks]... and and that goes in to here [describing the drawing]... and that arch thingy that's his, that's his safari park."

Many children wanted stuffed animals with them as a comfort source during and after the venipuncture procedure. Among these, several children wished for a stuffed animal they did not

have. One girl described a stuffed owl that her mother bought for her in the gift shop right after her procedure was over. She stated in her interview that she wished she was holding the stuffed animal during her venipuncture. Note here with the description below, how color preference (from the theme of comfort in the procedure surroundings) also crosses over into the comfort play theme.

Jasmine: "It's an owl and the best part I love about it, it's pink... It's fluffy and the kind of thing that looks oh so adorable... Yeah it is."

Other children said the laboratory staff gave them stuffed animals as gifts after their procedure.

One child described staff giving him a squeaking stuffed cat and how he wished he had it during his venipuncture.

Bashful: "I wish I would have that with me when I was in my room today [Child points to stuffed animal in his mothers arms and takes it from her hands]... It's a kitty who'll squeak, squeak."

Caregivers. Caregivers described one category of comfort play. This category was: Something to Do. The comfort play category of something to do was closely named and lifted from data and descriptions by caregivers. Children were very specific and elaborate with their descriptions of comfort play. Caregivers however were more general in their explanations of things to do before, during, and after the procedure.

Something to Do. Comfort descriptions in the category of something to do centered on different activities, toys, stuffed animals, and games. This category was similar to both of the

child categories but the descriptions were less frequent. Caregiver descriptions in this category did not include mention of specific games as in child descriptions. Additionally, caregiver descriptions here included playful activities that children did not mention such television, beads, sitting and reading, a toy chest, and art. Caregivers made recommendations to include more of their described comfort play measures in the hospital laboratory or procedure room. Several caregivers described the comforting effects of television watching. One legal guardian described the beneficial effects of television.

Mama Odie: "Well, if they had given her a TV and turned it on, she'd had zoned out, probably wouldn't even felt the stick [venipuncture needle insertion]. She can zone out on anything whatever [laugh] ... Yeah, she can kind of go into her own world sometimes."

When asked about things that may have been helpful or comforting in the laboratory or procedure room, one mother described how she recalls no toys, activities, or anything her son would have enjoyed.

Calypso: "I didn't, I don't even remember if there was any toys or anything... in there... where we went and got the um, where you got the blood at [laboratory]... No, there wasn't anything in there... We talked to some people in there and he laughed and joked with the man [the clinician] but I don't think there was anything in there for him to do."

Several caregivers, like their children, made references to stuffed toys. Caregivers described comfort from stuffed bears, stuffed monkeys, a stuffed lamb, and stuffed animals in general. One mother recognized that a stuffed teddy bear her child had at home might have been comforting if she (child) would have had it for her venipuncture.

Eudora: "Um, maybe she was, she has a teddy bear that she just got... Maybe if she would brought that [teddy bear], that might have helped...to comfort her a little bit more."

Another mother said her child would have appreciated some stuffed animals in the room during his venipuncture. At the same time the mother admitted that the child mentioned bringing his stuffed animals with him to the procedure the day before. However, she mentioned that she did not remember this until after the procedure was over.

Sarafina Lion: "It, maybe, if he [child] brought his stuffed animals. I know you [caregiver looking at child] mentioned it yesterday. Didn't dawn on us till he just said it."

Supplementary Findings

The purpose of this study was to explore perspectives of children age 4 to 7 years and their caregivers regarding procedural holistic comfort. In the interview protocol however, questions were asked and child drawings were made that led to findings beyond the purpose of the study. Perspectives of the needle procedure itself and child background information was also described. Again, these additional findings were not anticipated. They are nonetheless still

significant to report because they are elements that may affect the procedural holistic comfort of the child.

Perspectives of the Venipuncture Procedure

Both children and caregivers spoke about other perspectives related to the needle procedure. This is not a surprising finding considering it may be challenging for any individual to describe what makes them feel better without also explaining what first made them feel worse. Numerous participants, both children and caregivers, perceived some aspect of the venipuncture as negative or uncomfortable for the child. Descriptions of feelings, sensations, thoughts, and emotions related to the venipuncture are important to report in order to improve overall holistic comfort. Similar and dissimilar perspectives were noted among children and caregivers. These descriptions were reported by both participant groups. The perspectives were focused on how the child perceives the process of a venipuncture procedure.

Children described venipuncture procedures as producing anger, anxiety, distress, fear, opposition, pain, and sadness. Caregivers described seeing anticipation, anxiety, distress, embarrassment, fear, opposition, pain, and building resilience. Children did not describe embarrassment, anticipation, or building resilience and caregivers did not describe anger or sadness. Children did in fact describe a form of self-help through feelings of happiness, contentment, and satisfaction (emotional comfort) when the venipuncture was over. No child however described the experience of bouncing back, toughness, pushing through, or unanticipated strength that is often seen with building resilience. These resilient descriptions were only communicated by caregivers.

Children were asked if anything has made them sad or angry/mad recently and several of them described the venipuncture as a source of anger or sadness. Many perspectives of the

venipuncture were similar between the two groups. Both caregivers and children described the venipuncture as a source of anxiety, distress, fear, opposition, and pain. Dissimilarities were also noted. Caregivers describe observations of distress related to the venipuncture above all other perspectives while children described pain the most. It is possible that caregivers think distress and pain are mutually exclusive but this is not known. It is also possible that children chose not to describe themselves in periods of distress as caregivers did. Fear was the most salient response in the sample as both caregivers and children described this evenly. Perspectives that were infrequently described (however still noted) among children include anger, anxiety, and opposition. Infrequent descriptions among caregiver perspectives include embarrassment and opposition. A more detailed list of child and caregiver perspectives and the associated codes/quotes can be found respectively in Tables 3 and 4.

Table 3. Perspectives of Venipuncture Procedure: Children

Participant	Perspective	Quote/Code
Abu Monkey (6 y/o White Male)	Anger	I: Has there anything that's made you angry lately? The shot? You're pointing to your arm right now, I can see that. P: I got a shot (venipuncture)!
Bashful (5 y/o White Male)	Anger	I: How about has there been anything lately that's made you kind of sad or mad? P: Um, getting the shot (venipuncture).
Thumper	Anxiety	P: Yeah, but a little nervous (about the venipuncture).
(6 y/o White Male) Thumper	Anxiety	I: When did you feel not
Thumper	Anxiety	nervous anymore?
(6 y/o White Male)		P: After (the venipuncture).
Mowgli (6 y/o Black Male)	Distress	I: You got a wide open mouth so you're saying, what are you saying here" P: Ahhhhhhh! (Child demonstrates a screaming sound referring to himself while in the lab room)
Sophia the First	Distress	I: Were you crying? No? P: No, but I was yelling.
(6 y/o White Female)		
Aladar Dinosaur	Fear	P: Well, I felt kinda kinda
(5 y/o White Male)		happy and kind of scared.
Aladar Dinosaur	Fear	P: Well, I was feeling a little
(5 y/o White Male)		scared.
Jasmine	Fear	P: Mm, like at first I was so
		scared. I thought it was gonna
(7 y/o White Female)		be a big shot (venipuncture).

Table 3. Continued

Participant	Perspective	Quote/Code
Mowgli	Fear	P: That's why I backed up I
(6 / D1 1 M 1)		was trying to run (away from
(6 y/o Black Male)		the procedure room).
Mowgli	Fear	I: You maybe were a little bit
		scared. Right? Ok.
(6 y/o Black Male)		P: Yeah (scared), As soon as I
		saw them getting the stuff ready.
		ready.
Thumper	Fear	P: I was probably, I was a
(6 x/a White Mala)		little kind of scared.
(6 y/o White Male)		
Bashful	Opposition	P: I hate getting shots
		(venipunctures)
(5 y/o White Male)		
Cleo	Opposition	P: Was there anything that you
		didn't really like about it?
(6 y/o White Female)		P: It was a little ah wa she um,
		getting to stick it (needle) in me.
Aladar Dinosaur	Pain	P: Well, it (venipuncture) it
(5 y/o White Male)		hurted a little.
(3 y/0 winte Maie)		
Aladar Dinosaur	Pain	P: Because I can snuggle the
(5 / W/I:4 N. 1)		hurt spot (venipuncture site).
(5 y/o White Male)		
Aladar Dinosaur	Pain	P: I can put my Bee Bee
		(blanket) over the hurt spot
(5 y/o White Male)		(venipuncture).

Table 3. Continued

Participant	Perspective	Quote/Code
Aladar Dinosaur (5 y/o White Male)	Pain	P: Well, if, if I can get hurt and I cry, my uh, my sister would always hug me. Yeah and even at like a shot (venipuncture) when I cry, she gives me hugs.
Bashful (5 y/o White Male)	Pain	P:Because it hurt. I cry when I get em.
Chip (5 y/o Male)	Pain	P:She hugged me while I was getting my, my hurt, like um I got poked.
Jasmine 7 y/o White Female	Pain	P: Yep, it's just a little sting.
Jasmine 7 y/o White Female	Pain	P: That (tourniquet) was so hard like I'm "oh oh oh" they're squishing my arm.
Minnie Mouse	Pain	P: It kind of hurt when they put the rubber band.
7 y/o White Female Mowgli (6 y/o Black Male)	Pain	P: And then the table (procedure table) of hurt, ouchie, ouchie stuff.
Prince Eric 7 y/o White Male	Pain	P:When it (paper on the procedure table) makes that um those noises, it kind of hurts my ears.
Sophia the First 6 y/o White Female	Pain	P: Mm, I had to get labs. It hurt.
Abu Monkey (6 y/o White Male)	Sadness	I: How about anything that's made you kind of sad lately? P: The shot (venipuncture).

Table 3. Continued

Participant	Perspective	Quote/Code
Abu Monkey	Sadness	I: What kind of face is on your
		face? (Child drawing himself)
(6 y/o White Male)		Ah, that looks like a sad face.
		P: Cause the needle's in my
		arm.
Bashful	Sadness	I: How about has there been
		anything lately that's made
5 y/o White Male		you kind of sad or mad?
		P: Um, getting the shot
Mowgli	Sadness	I: Can you tell me anything
_		that's going on that's made
6 y/o Black Male		you feel really sad lately?
		P: Um, getting this (child
		pointing to venipuncture
		site) A shot

Table 4. Perspectives of Venipuncture Procedure: Caregivers

Participant	Perspective	Code/Quote
Darling (Mother, White Female)	Anticipation	I: Ok, So, he struggled the second he knew that P: Something (venipuncture) was (silence) I: Something was coming? P: Yes.
Lady (Adopted Mother, White Female)	Anticipation	P:You do not know what it's (venipuncture) going to feel like.
Lady (Adopted Mother, White Female)	Anticipation	P: So their anticipation of a needle is going to be something that burns like an injection and until they do it
Mama Odie (Legal Guardian, White Female)	Anticipation	P: She kind of got a little jumpy (waiting for the venipuncture) but she did not squirm.
Queen of Hearts (Mother, White Female)	Anticipation	P: Being his age so otherwise, I don't think anything would factor anything out cause he knows that needle's still coming. Once he hears the word "shot"
The White Queen (Mother, White Female)	Anticipation	P: Knowing that we were gonna have do this (venipuncture).
Darling (Mother, White Female)	Anxiety	P: I already knew that he would already tense up knowing that it was a doctor's atmosphere.
Lady (Adopted Mother, White Female)	Anxiety	P:And he was little nervous, you know, when they started.

Table 4. Continued

Participant	Perspective	Code/Quote
Mama Odie (Legal Guardian, White Female)	Anxiety	P: It was just the shock of the stick (venipuncture), the needle, a little bit that panicked her (child).
Sarafina Lion (Mother, White Female)	Anxiety	P: He (child) was a little anxious, nervous.
Calypso (Mother, Black Female)	Distress	P: He (child) did good till we got right there and got to the room (procedure room) and he seen everything (venipuncture supplies)and then he kind of flipped out on me.
Darling (Mother, White Female)	Distress	P: It, it bothers me to see him (child) get so stressed about it (venipuncture) but I mean
Darling (Mother, White Female)	Distress	P: Well, he (child) started screaming and crying and knew that he did not want to do the procedure (venipuncture).
Darling (Mother, White Female)	Distress	P: When she (clinician) put the rubber band on (tourniquet)that's what broke him (child) right there.
Baymax (Father, White Male)	Distress	P: It's took me, her (wife), 2 or 3 techs and and 2 nurses and a doctor to hold her (child), so I mean when she don't want the needle or something injected, she uh, she's hard to handle.

Table 4. Continued

Participant	Perspective	Code/Quote
Madam Mim	Distress	P: Um, so we did that and ah,
(Mother, White Female)		she (child) yelled you know a lil, you know once or twice.
Mama Odie (Legal Guardian, White Female)	Distress	P: Cause new experiences (venipuncture) for her (child) are very dramatic.
Ms. Potts	Distress	P: She's a (child) drama queen
(Mother, White Female)		so she flips out over everything.
Queen of Hearts	Distress	P: Well, ah they have to hold
		him (child) cause he will jerk
(Mother, White Female)		so as a parent, we have to
		hold him or help hold him.
The White Queen	Distress	P: And he (child) was freaking out.
(Mother, White Female)		
The White Queen	Distress	P: So he (child) was freaking
		out in the beginning
(Mother, White Female)		
The White Queen	Distress	P: That was after we left the
(Mother, White Female)		pediatrician's office, he (child) was screaming bloody murder.
The White Queen	Distress	P: I pretty much had to hold
(Mother, White Female)		him (child) down.
The White Queen	Distress	P: I have to hold him (child)
The winte Queen	Distress	down anything that we do like
(Mother, White Female)		that.
,		

Table 4. Continued

Participant	Perspective	Code/Quote
Fairy God Mother (Grandmother and Legal Guardian, White Female)	Embarrassment	P: I think with her (child), sometimes she just don't want people to know know Like if she goes to school Yeah, she don't want people to be questioning you know "What happened? Why you got this on your arm?
Calypso (Mother, Black Female)	Fear	P: He (child) was terrified of em (spinal Taps and Venipuncture).
Fairy God Mother (Grandmother and Legal Guardian, White Female)	Fear	P: We woke up 1:30 and you know she (child) got scared (about upcoming venipuncture procedure).
Lady (Adopted Mother, White Female)	Fear	P: But he (child) had a huge fear leading up to it that it (venipuncture) was going to be huge.
Lady (Adopted Mother, White Female)	Fear	P: It (fear) was huge It, it took him (child) over.
The White Queen (Mother, White Female)	Fear	P: So, he (child), but he was more afraid of what was gonna happen.
The White Queen (Mother, White Female)	Fear	P: He's (child) very fearful, so.
Eudora (Mother, Asian Female)	Opposition	P: She (child) don't like needles at all so.
Eudora (Mother, Asian Female)	Pain	P: Um, she's (child) real skittish about pain. She don't like pain.

Table 4. Continued

Participant	Perspective	Code/Quote
Baymax	Pain	P: Cause she (child) don't like
		needles, never has.
(Father, White Male)		
Ms. Potts	Pain	P: I think the thing they
		(clinicians) use on her arm,
(Mother, White Female)		she (child), did started to hurt
		cause it had to be left on so
		long.
Darling	Building Resilience	P: He (child) coped fine after
		so I'm good with that.
(Mother, White Female)		_
Lady	Building Resilience	P: So you know those kinds of
		things, but he (child) does,
(Adopted Mother, White		kids are amazing. They just
Female)		push right on through
Queen of Hearts	Building Resilience	P: but as soon as the shots are
		you know done and
		administered you know then
		he's (child) fine.
Sarafina Lion	Building Resilience	P: He usually does anytime he
		has blood drawn, shots, I
(Mother, White Female)		mean he's just in and out.

What the Child Brings to the Venipuncture

Children came to the venipuncture with a variety of backgrounds, experiences, and personal circumstances. This was looked at essentially as "what the child brings to the venipuncture." These various child backgrounds may lead to some differences in how the child experiences comfort. No causal or correlational analysis can be done in this study on comfort experiences in relation to child backgrounds. But, it can be expected that all children may experience comfort a little differently depending on their current and past experiences.

"What the child brings to the venipuncture" was a part of seven different situational categories. These categories included: family matters, grief and loss, health issues/illness, life stress/emotions, repeat invasive procedure, repeat venipuncture, and first venipuncture. Children were the only participants to report positive/optimistic situations (three occurrences). Certain children were in more than one situational category. Additionally, situations were described by children, caregivers, or both. There is a possibility that some circumstances were simply not described by caregivers or children. Table 5 outlines the specific background situations of caregivers and children and the children individually affected. A more detailed summary of the specific situations reported by caregivers and children are outlined in an explanation of situations and context in Table 6. It is also indicated in Table 6 whether the caregiver, the child, or both reported the circumstances.

Table 5. What the Child Brings to the Venipuncture: Situational Categories

Background Situations	Number of Affected Children	Specific Participants Affected
Family Matters	5	Cleo, Flower Skunk, Chip, Prince Eric, Thumper Rabbit
Grief and Loss	4	Jasmine, Princess Tiana, Cleo, Flower Skunk
Health Issues/Illness	9	Mowgli, Chip, Cleo, Prince Eric, Sophia the First, Flower Skunk, Thumper Rabbit, Aladar Dinosaur, Child that did not participate (caregiver Report)
Life Stress/Emotions	5	Cleo, Flower Skunk, Jasmine, Minnie Mouse, Child that did not Participate (Caregiver Report)
Repeat Invasive Procedure	7	Mowgli, Jasmine, Flower Skunk, Cleo, Aladar Dinosaur, Sophia the First, Child that did not Participate (caregiver report)
Repeat Venipuncture	6	Abu Monkey, Chip, Princess Tiana, Prince Eric, Sophia the First, Thumper Rabbit
First Venipuncture	3	Bashful, Aladar Dinosaur, and Flower Skunk

Table 6. Detailed Background Summary: What the Child Brings to the Venipuncture

Participant	Background Category	Background Description
Cleo (6 y/o F) *Reported by Child	Family Matters	Happy about Sibling growing and developing.
Flower Skunk (7 y/o F) *Reported by Child	Family Matters	Happy about Mother (Child currently being adopted).
Prince Eric (7 y/o M) *Reported by Child	Family Matters	Happy about relationships with family- brothers and grandfather (Child adopted).
Thumper Rabbit (6 y/o M) *Reported by Child	Family Matters	Child not happy with himself for misbehaving and being mean to his mother lately.
Prince Eric (7 y/o M) *Reported by Caregiver	Family Matters	Child Adopted 4 years agolife just now returning to normalcy.
Cleo (6 y/o F) *Reported by Caregiver	Family Matters	Younger sibling with various health problems (Child participant very close to this sibling).
Chip (5 y/o M) *Reported by Child	Family Matters	Self-esteem problem- relationship with brother. Brother hurts his feelings by not playing with him often.
Jasmine (7 y/o F) *Reported by Caregiver	Grief and Loss	Child's mother suffered the loss of stillborn twins 4 weeks prior. Child suffering loss greatly, as she was very happy about having siblings.
Princess Tiana (5 y/o F) *Reported by Caregiver and Child	Grief and Loss	Mother and father recently separated and father moved out of the family home. Child misses father being at home greatly.

Table 6. Continued

Participant	Background Category	Background Description
Cleo (6 y/o F) *Reported by Caregiver	Grief and Loss	Child dealing with frustration and sadness from absent biological parents. Child and sibling went into states custody and now grandmother has guardianship.
Flower Skunk (7 y/o F) *Reported by Caregiver	Grief and Loss	Child (custody of legal guardian in process of adoption) has 4 siblings; only has contact with one of the siblings due to social problems with biological parents and child/family temporary placement problems.
Mowlgi (6 y/o M) *Reported by Caregiver	Health and Illness	Child admitted to hospital with acute bacterial meningitis 2 weeks prior.
Chip (5 y/o M) *Reported by Caregiver and Child	Health and Illness	Child with chronic moderate to severe atopic dermatitis/eczema (allergic rash). Preoccupation with persistent and recurring itching and excoriation.
Cleo (6 y/o F) *Reported by Caregiver	Health and Illness	Child receives weekly allergy desensitization injections.

Table 6. Continued

Participant	Background Category	Background Description
Prince Eric (7 y/o M) *Reported by Caregiver	Health and Illness	Child with recurrent fevers for 15 days. Has been on several antibiotics and has seen an infectious disease specialist who is thinking disease likely a new onset Rheumatologic disease.
Sophia the First (6 y/o M) *Reported by Caregiver	Health and Illness	Child with chronic history of seasonal allergies and asthma with frequent exacerbations. Abdominal pain with vomiting for the last year. Several PCP visits and now GI and Allergy specialists collaborating in her care.
Flower Skunk (7 y/o F) *Reported by Caregiver	Health and Illness	Child with history of ADHD and Fetal Alcohol Syndrome after exposure to ETOH in utero.
Child not a participant in the study- did not assent. *Reported by Caregiver-Queen of Hearts (Mother, White Female)	Health and Illness	Child with unknown gastrointestinal disease and newly scheduled GI procedures.
Thumper Rabbit (6 y/o M) *Reported by Caregiver	Health and Illness	Child with seasonal environmental allergies - chronic rhinitis, runny nose, itchy eyes, etc.
Aladar Dinosaur (5 y/o M) *Reported by Caregiver and Child	Health and Illness	Child receives weekly allergy desensitization injections and has new onset stomach pains that his practitioner is investigating with blood work.

Table 6. Continued

Participant	Background Category	Background Description
Child not a participant in the study- did not assent. *Reported by Caregiver-	Life Stress/Emotions	Child recently transitioned from Pre-Kindergarten to Kindergarten and mother reports the stressful and
Queen of Hearts (Mother, White Female)		rigorous learning process that comes with this.
Cleo (6 y/o F) *Reported by Child	Life Stress/Emotions	Child reports recently struggling with "monster bad" dreams.
Flower Skunk (7 y/o F) *Reported by Child	Life Stress/Emotions	Child responds feeling angry with "me" because of other children "making fun" of her.
Jasmine (7 y/o F)	Life Stress/Emotions	Child reports feeling sad lately
*Reported by Child		because she "kept having nightmares" that wake her up and give her trouble sleeping.
Minnie Mouse (7 y/o F) *Reported by Caregiver	Life Stress/Emotions	Caregiver reported that child has a tendency to be overly dramatic in various circumstances.
		circumstances.
Mowgli (6 y/o M)	Repeat Invasive Procedure	Child recently (2 weeks prior) experienced 3 unsedated
*Reported by Caregiver		spinal tap procedures to collect cerebrospinal fluid for testing during acute bacterial meningitis diagnosis.
Jasmine (7 y/o F)	Repeat Invasive Procedure	Child with recent history of surgery on her ears and
*Reported by Caregiver		invasive procedures associated with this surgery.

Table 6. Continued

Participant	Background Category	Background Description
Flower Skunk (7 y/o F) *Reported by Caregiver	Repeat Invasive Procedure	Child with history of having several injections/vaccinations for school and being "uncontrollable" with this. In the recent past she additionally was tied down to the bed in an emergency room for her own safety during examination of a "severe" ear infection.
Child not a participant in the study- did not assent. *Reported by Caregiver-Queen of Hearts	Repeat Invasive Procedure	Child with history of vaccinations and "shots" in the past that he "normally" cries with.
Cleo (6 y/o F) *Reported by Caregiver	Repeat Invasive Procedure	Child receives weekly allergy desensitization injections.
Aladar Dinosaur (5 y/o M) *Reported by Caregiver and Child	Repeat Invasive Procedure	Child receives weekly allergy desensitization injections.
Sophia the First (6 y/o F) *Reported by Caregiver (Father)	Repeat Invasive Procedure	Father states child has had to be held down in the past by up to 5 people for an intravenous cannulation when she was admitted to the hospital.
Abu Monkey *Reported by Caregiver	Repeat Venipuncture	Mother reported child did "better" with this venipuncture than the previous one.

Table 6. Continued

Participant	Background Category	Background Description
Chip (5 y/o M)	Repeat Venipuncture	Mother reported that child has
*D . 11 . C		been blood tested for allergies
*Reported by Caregiver		"before" but they are doing
		the test again.
Princess Tiana (5 y/o F)	Repeat Venipuncture	Mother stated that the child
*Reported by Caregiver		did "better" than the previous
		time she had venipuncture
		done.
Sophia the First (6 y/o F)	Repeat Venipuncture	Mother stated that clinicians
11 0		have had to "poke around to
*Reported by Caregiver (Mother)		find the vein before" with a previous venipuncture.
(Wother)		previous vempuneture.
Thumper Rabbit (6 y/o M)	Repeat Venipuncture	Mother stated that child
Thumper tweete (c g/ c 1/1)		"usually" does well "anytime
*Reported by Caregiver		he has blood drawn."
Prince Eric (7 y/o M)	Repeat Venipuncture	Child stated "This is my
*D		third time."
*Reported by Child Bashful (5 y/o M)	First Venipuncture	Mother states this was the
Dasiiiui (5 y/0 Wi)	That vempuncture	"first time" he had a
*Reported by Caregiver		venipuncture so she "didn't
		know what to expect."
Elever Clovels (7/- E)	First Vanious stars	Mother man or de the table
Flower Skunk (7 y/o F)	First Venipuncture	Mother responds that this episode was the first time her
*Reported by Caregiver		child has had a venipuncture.
Aladar Dinosaur (5 y/o M)	First Venipuncture	Mother states this
*Danartad by Caraciyar		venipuncture episode was the
*Reported by Caregiver		first. Child "has never had a
		CBC before."

Findings Summary

The findings from this inductive study support the underlying tenets of Naturalistic Inquiry. Children and caregivers expressed multiple realities of procedural holistic comfort within the context of their own life circumstances and personal values. The researcher and participants were directly influenced by one another on the basis of these shared realities. Although it was not the guiding theory in this study, it is significant to note the parallel between Kolcaba's Comfort Theory and the themes of procedural holistic comfort interpreted in this study. Procedural holistic comfort was described by children and caregivers as: comfort to the body, comfort through cognition and emotions, comfort in the procedure surroundings, and comfort from play. Body comfort and comfort in the procedure surroundings are represented in Kolcaba's Physical and Environmental contexts of comfort. Cognitive and emotional comfort fits into Kolcaba's Sociocultural and Psychospiritual domains. Discoveries of pediatric holistic comfort surrounding a venipuncture procedure suggests new evidence, leads to the support and question of existing evidence, and spearheads the implementation of various implications to improve pediatric procedural care.

Chapter Five: Discussion

The purpose of this study was to explore procedural holistic comfort perspectives of children age 4 to 7 years and their caregivers. Twenty- eight interviews were conducted using a qualitative descriptive design directed by the philosophical/theoretical perspective naturalistic inquiry. Specifically, 13 children between the ages of 5 to 7 who experienced a venipuncture procedure and 15 primary caregivers who witnessed his/her child's venipuncture procedure participated. A thematic content analysis was conducted. There were four overarching themes among child and caregiver descriptions: *body comfort, cognitive and emotional comfort, comfort in the procedure surroundings,* and *comfort play*. This chapter presents a thorough discussion including findings related to preceding literature, various implications, contributions to science, limitations of the study, and future research.

Findings Related to Preceding Literature

Findings from this study support the discoveries of previous researchers. Other findings question the appropriateness of specific comfort interventions that have been earlier examined. This study additionally brings about new findings not yet reported in the literature and it expands upon some of the already examined comfort measures. In chapter two, comfort intervention studies occurred in four themes: music therapy, amusement and entertainment, caregiver facilitation, and a multifaceted approach. These themes will be reviewed and re-evaluated with a comparison discussion related to findings from this study. Previous literature on caregiver and child perspectives will also be compared to the supplementary findings of this dissertation study.

Music Therapy Revisited

Neither children nor caregivers described music therapy, music listening, or music intervention as source of comfort related to venipuncture procedures in this study. One child

liked to sing but recurrent descriptions of music, as a holistic procedural comfort source was not supported. A systematic review by Klassen et al. (2008) showed that music may decrease anxiety and pain (facets of comfort) among children experiencing various invasive nursing, advanced nursing, and medical procedures. Results are mixed however, about invasive clinical procedures, such as venipuncture, commonly performed by nurses.

Much as this dissertation study suggests, Press et al. (2003) and Noguchi (2006) found that music distraction revealed no significant effects on pain or distress with venipuncture or immunizations respectively. Similarly, Whitehead-Pleaux, et al. (2006; 2007) found no significant decreases in pain or distress with music therapy related to various nursing wound dressing changes and suture-related procedures in the United States. Caprilli et al. (2007) did, however, find significant outcomes of reduced pain and distress with live music during venipuncture procedures in hospitalized Italian children. Based on previous literature and the qualitative findings of this study, music therapy may or may not be a source of procedural holistic comfort for children in the preoperational stage of development. The differences noted in this study and the previous literature on music therapy could be related to geographical locations, age differences, the procedure setting (hospitalization, emergency department, or outpatient), and ethnic or cultural background. It unknown if music offers procedural holistic comfort in much younger or much older age groups, such as infants or adolescents. Qualitative research focusing on procedural holistic comfort in these age groups has not yet been conducted. Additionally, quantitative research is missing due to the lack of a valid and reliable pediatric instrument to assess procedural holistic comfort.

Amusement and Entertainment Revisited

Toys. Both children and caregivers in this study described sources of amusement and entertainment for comfort related to venipuncture. Toys were frequently discussed as sources of comfort play before, during, or after the procedure. While many of the descriptions were specific, some were explained simply as "toys." Carlson et al. (2000) and Tufekci, et al. (2009) found different results with a Kaleidoscope distraction. Carlson et al. (2000) found no significant decrease in fear, pain, or distress in hospitalized children during IV insertion or venipuncture. Tufekci, et al. (2009) found significant reduction in pain among children receiving an outpatient routine venipuncture. No children or caregivers described Kaleidoscopes specifically in this dissertation study. Dahlquist et al. (2002a) investigated the effects of an interactive electronic toy and found significant reduction in behavioral distress during pediatric chemotherapy injections. The sample and setting of Tufekci, et al. (2009) is more closely associated with the sample and health care setting of this dissertation study but Tufekci, et al.'s research was conducted in Turkey. Dahlquist et al.'s sample was in the United States but researchers included children with cancer having a different invasive procedure. Nonetheless, evidence from this study and previous literature suggests that Kaleidoscopes, interactive toys, and perhaps other novelty toys may offer comfort play related to pain and distress among young children receiving outpatient venipuncture. In this study pediatric procedural holistic comfort occurred in four main areas. So examining effects on one or two dependent variables (pain and distress) as completed in several of these intervention studies, is not a holistic measurement of comfort.

Screen Time. Caregivers and children described television and interactive phone application games as a source of procedural comfort play in this dissertation study. The effects of screen time on pain, fear, anxiety, and distress has been previously documented. Cassidy et al.

(2002) found that a cartoon television intervention did not reduce pain in 5-year-old children receiving immunizations. Unlike Cassidy et al., MacLaren & Cohen (2005) found that passive television watching significantly decreased distress levels among young children receiving presurgery (outpatient) venipuncture in the United States. James, et al. (2012) showed a decrease in both pain and distress during venipuncture with an animated cartoon intervention among children in India. The findings of James, et al. (2012) and MacLaren & Cohen (2005) are similar to this dissertation study given the enhancement of comfort components and the procedure investigated. It is difficult to distinguish if Cassidy et al.'s insignificant results are unlike the findings of this dissertation study. Television may be a source of comfort play for children during procedures but not necessarily reduce pain- the only dependent variable Cassidy et al. measured.

Advanced forms of screen technology have significant effects on areas of procedural comfort in children. Both Wolitzky et al. (2005) and Gold et al. (2006) found children receiving needle procedures experienced less pain with an electronic virtual reality intervention. Shahid et al. (2015) showed that iPad movies or interactive games during routine immunizations can significantly reduce anxiety, fear, and crying time in children while also increasing caregiver satisfaction with pain control. The findings from this qualitative dissertation study and previous literature indicate the use of interactive tablet devices, virtual reality, and television intervention may increase procedural comfort play or body comfort through a decrease in anxiety, fear, pain and or distress. These electronic devices do not however, offer the relational experience of touch and interaction that children report as comforting to the body during procedures.

Live Animals. The presence and touching of live animals was described in this dissertation study as a source of cognitive and emotional comfort- a method of special security. Only one previous study investigated the use of live animals during procedures. Vagnoli et al.

(2014) examined the effects of a live dog on pain and distress during venipuncture procedures for children in Italy. No effects on pain were noted but significant reduction in distress was found. Given the findings of this study and the very recent study conducted by Vagnoli et al., the presence of live animals may increase the emotional or cognitive comfort, but not body comfort, of children during venipuncture procedures.

Caregiver Facilitation Revisited

Caregiver presence and Coaching. Previous literature focused on the effects of caregiver facilitation and presence during invasive nursing procedures. Numerous descriptions of caregiver presence, physical touch, hugs and holding, encouragement, and talk were described as sources of body comfort and cognitive or emotional comfort by caregivers and children in this dissertation study. Kleiber, et al. (2001) found no significant reduction in pain or distress during IV insertion with a parent coaching distraction intervention. Significantly reduced procedural distress was noted among children diagnosed with a chronic illness in two other studies using parent coaching and distraction (Dahlquist et al., 2002b; Pringle et al. 2001). Two previous studies examined caregiver assisted positioning in the emergency department with venipuncture (Cavender, et al., 2004) and IV insertions (Sparks, et al., 2007). Cavender et al. found no significant differences in self-reported fear or pain, and no differences in behavioral distress. Sparks et al. showed significantly reduced distress. Caregivers in this study described cognitive/emotional comfort through preparation with either: (a) explanation of the procedure beforehand, or (b) no explanation of the venipuncture procedure at all. Caregivers providing programed and learned preparation as instructed by researchers shows little benefit for holistic comfort at this time. With the caregiver and child descriptions in this study and previous

literature, it appears that caregiver presence alone and touch does offer cognitive, emotional, or body comfort to children during procedures in the preoperational stage of development.

Caregiver Facilitation and Entertainment. Bellieni et al., (2006) and Matziou, et al. (2013) investigated toys and television with caregiver facilitation during venipuncture. The intervention study by Bellieni et al. showed significant decreases in pain from TV but not from caregiver distraction. Matziou, et al. showed significantly reduced pain and distress among children who had a caregiver present. The qualitative evidence from this dissertation study coupled with the results from previous studies suggests that caregiver presence and caregiver physical touch decreases child distress during invasive nursing/clinical procedures and may reduce pain. Thus, caregiver facilitation with the use of additional comfort distraction and play interventions may enhance the body, emotional, and or cognitive procedural holistic comfort of children. Since some of these studies also incorporated the use of toys with caregiver facilitation, evidence from this literature also supports an increase in comfort play during invasive procedures.

Multifaceted Approach Revisited

Previous researchers using a multifaceted approach incorporated pharmacological and non-pharmacological interventions to enhance comfort. Several descriptions of non-pharmacological interventions for comfort surrounding venipuncture procedures were interpreted in this study. Some of these interventions previously studied were not described by children, such as soap bubbles or party blowers and pinwheels. Again, children did specifically state "toys" and "games." These two descriptions could include various active entertainment interventions. Additionally, caregiver participants in this dissertation study described the body comforting effects of specific topical pharmacological interventions.

Caregiver Facilitation and Topical Anesthetic. Kolk, et al. (2000) and Tak & Van Bon, (2006) used a preparation technique and topical anesthetic for children undergoing venipuncture. Significant decreases in distress were found related to EMLA cream and parent preparation in Kolk et al. (2000). Slightly different findings were noted in Tak & Van Bon-EMLA cream decreased distress at the time of injection only with no effects of parental preparation. Topical medications alone may provide procedural body comfort for children as described by caregivers in this dissertation study. Additionally, descriptions in this study and results from previous studies suggest that the combined use of caregiver facilitation and topical anesthetic medications may increase body, cognitive, and or emotional comfort related to invasive procedures in a young child.

Topical Anesthetic with Blowing Distractions. Lal, et al. (2001), Burgess, et al. (2014), and Caprilli et al. (2012) respectively used windmill blowing, a party blower, and soap bubble blowing distractions with a topical anesthetic in their routine multimodal approach. Lal et al. found no significant reduction in pain during venipuncture. Burgess, et al. (2014) found no reduction in pain with immunizations but found significant decreases in distress. Caprilli et al. found significant decreases in pain and distress with venipuncture. Although all blowing distractions have not been found as significant, limited dependent variables were measured. Additionally, no children specifically mentioned soap bubble blowing as a source of comfort play in this dissertation study. Children were particularly excited however, to receive the blowing bubbles in their gift baskets. Given the review of evidence, soap bubble blowing and a party blower may enhance body or cognitive and emotional procedural comfort in young children.

Toys/Activities with Topical Anesthetics. Other studies have investigated pharmacological interventions with toys or entertaining activities. Both Windich-Biermeier et al. (2007) and Heden, et al. (2009) examined effects of topical anesthetic and various distraction activities. These researchers found fear and distress (but not pain) significantly decreased. Heden, et al. (2009) also investigated comforting effects of a heated pillow and found significant decreases in fear. Nilsson, et al. (2009) found no significant decreases in pain or distress among Swedish children receiving virtual reality with a topical anesthetic. Some qualitative data from this same study showed the game was "fun" and children "didn't think of the pain."

Additionally, Nilsson, et al. found the game may have been difficult to manage for some children and perhaps not age appropriate for others. Toys and activities in combination with topical medications may provide children cognitive, emotional, and play procedural comfort. It is also separately noted that a heated pillow may provide comfort in the procedure surroundings due to warming temperatures or the pillow being close to the child's body.

Entertainment with Oral Analgesia. Children and caregivers did not describe oral analgesic medications for comfort in this dissertation study. Two groups of scientists previously examined the effects of electronic toy distraction and oral analgesic/narcotic on child pain during acute burn dressing changes. Miller, et al. (2010) and Mott, et al. (2007) showed significant decreases in pain scores among children who received the electronic toy/augmented reality distraction and analgesic medication. Schiff et al. 2001 showed reduced behavioral distress and reported pain over time with the following: topical anesthetic cream, relaxation techniques, breathing exercises, distraction with bubble blowing or a pinwheel, and parental involvement. Virtual reality mixed with oral analgesia seems effective at reducing pain in children with burn care. There is not enough evidence to suggest its effectiveness with enhancing body or play

comfort with venipuncture procedures. Additionally, oral analgesia is not standard of care for invasive pediatric needle procedures.

Child and Caregiver Procedure Perspectives Revisited

Many perspectives of invasive procedures found in the literature were also found in this qualitative study. Some perspectives were new. In this dissertation study children and caregivers described venipuncture procedures as producing feelings of anger, anxiety, anticipation, distress, embarrassment, fear, opposition, pain, resilience, and sadness. Children and caregivers have previously described, narrated, and or reported fear, anxiety, distress, coping, pain, and opposition as perceptions of invasive procedures. Forsner, et al. (2009) investigated the meaning of being afraid in children under medical care and found an overarching theme of being "threatened by the monster." In a phenomenological study, researchers found that caregivers lived with their child's fear of invasive procedures related to a cancer diagnosis (Anderzen-Carlsson, et al., 2007).

Very similar to the descriptions of children in this dissertation study, Hodgins and Lander (1997) found venipunctures made children "scared, nervous, not good, terrible, sad, and angry." Child feelings of opposition to procedures were similarly reported in Forsner, et al. Parallel to the results of this study are findings of Karlsson, et al. (2014) who showed that caregivers saw support during needle-related procedures as a means of "keeping the child under the protection of one's wings." Evidence suggests that invasive pediatric nursing and related clinical procedures are viewed as undesirable events that break through the personal, psychological, and physiological boundaries of children.

Significance and Contribution to Science

The qualitative evidence from this study provides new documented insights on procedural holistic comfort management for children in the preoperational stage of development. As previously discussed some of the findings from this study were reported through other empirical works. This is the first study to investigate qualitative procedural holistic comfort evidence through descriptions of children and their caregivers. Findings from this study help bridge the gap of an unrecognized understanding of comfort related to invasive pediatric procedures. Pediatric procedural holistic comfort is made up of various holistic elements including the body, emotions, cognition, surroundings, and play.

Comforting Interpersonal Relationships. Previous research has shown mixed results on the comforting effects of caregiver preparation, coaching, distraction, or presence. Thus, the evidence of caregiver comfort during pediatric procedures is unclear. Some literature suggests that caregiver presence and or intervention reduces anxiety or pain while other literature shows no decrease at all. In this study both caregivers and children describe the definite cognitive, emotional, and body comforting effects of actions by primary caregivers before, during, and after a venipuncture procedure. Both participant groups frequently described the importance of caregiver touch, presence, a glance, and talking to the child through the procedure. This evidence offers the missing qualitative data needed to support caregiver presence, encouragement, and touch during pediatric procedures. This includes the frequent description of touch, holding and encouragement from persons other than primary caregivers. The comforting effects of extended family members and friends are additionally meaningful to children in times of pediatric venipuncture procedures. This has not been previously studied.

Significance of the Clinician. Qualitative evidence from this study delivers a new and critical awareness: the clinician who performs the invasive procedure is important to the child. Both caregivers and children described the various comforting interventions by the clinician including rapport, talk, technical skill, and caring. No child in this study stated anything negative about a clinician. Children, as a whole, were able to associate the clinician with positive impressions, appreciation, altruism, and even gratitude. Caregivers similarly described the meaningful effects of clinician comforting interventions. The importance of the clinician was frequently communicated in both participant groups.

Color Preferences. Until now the significance and comforting effects of a child's color preference surrounding an invasive venipuncture procedure has not been documented. The concept of color preference crossed more than one theme in this qualitative study. Children discussed color enjoyment, preference, and appreciation involving the: body and the procedure site (band-aids and gauze/coband dressings), procedure surroundings (the exam room décor and laboratory), and play time before, during, and after the venipuncture (stuffed animals, games, and activities). Adult preconceived notions and stereotypical assumptions of color preferences for children are made. For example: boys like blue and red while girls like pink and purple. As a result the boy will get a blue band-aid and the girl will a pink band-aid. This dissertation study offers more evidence on child preferences and significance of color, shades, and hues related to a child's venipuncture procedure experience.

Significance of Procedure Surroundings. Research investigating comfort outcomes of enhancing/altering invasive procedure surroundings have not been widely studied in the pediatric population. It is common for pediatric health care setting administrators to incorporate the use of age appropriate décor in patient rooms, procedure rooms, ancillary departments, or general

locations. This dissertation adds more specific evidence on child and caregiver recommendations for enhancing comfort of the procedure environment. Both participant groups described comfort in the procedure surroundings such as: (a) child tolerance of or contentment with room temperature, (b) age and developmentally appropriate decorations and embellishments, and (c) the immediate procedure space such as comfort components of an exam table, supply counter space, or furniture in the room. This new qualitative evidence shows child satisfaction in the procedure surroundings is a component of holistic comfort and that it is essential to the overall venipuncture experience.

Physiological Procedure Needs. Children and caregivers described hunger, thirst, rest, sleep, and elimination comfort needs related to the venipuncture procedure. These necessities are well known as basic needs for survival. But, they have never before been documented as procedural holistic comfort needs or interventions- sources of comfort that could provide a better overall venipuncture procedure experience for the child. Physiological needs surrounding a venipuncture are not generally thought of as requiring nursing or clinical intervention. However, assessing and addressing these basic needs is primary to child health and appropriate for nursing and clinical staff to complete.

Holistic Procedural Comfort. This is the first study to investigate comfort surrounding the whole child related to an invasive venipuncture procedure. Before this study the understanding of pediatric holistic procedural comfort was limited, defined only in part by previous adult comfort literature and procedure comfort intervention studies to reduce fear, anxiety, distress, and pain. This study shows that comfort related to an invasive venipuncture procedure is, in fact, desired and described by children and caregivers as holistic- incorporating comfort on the body, with emotional and cognitive responses, from surroundings, and through

play. One significant finding from previous literature coupled with the results of this study is that various procedural comfort interventions may have positive effects on one or more areas of procedural holistic comfort. For example, just because a child does not experience less self-reported pain with caregiver presence during a venipuncture, does not indicate that the child received no comfort from their caregiver. Similarly, a child who self-reports less procedural pain with a topical anesthetic may still have other areas of discomfort such as needing to use the bathroom or not having a caregiver present. This is important because it cannot be assumed that children will receive total comfort from one, two, or even three interventions. A 5-year-old girl in no pain may still wish she had her favorite baby doll to squeeze. A 6-year-old smiling boy may still want his father to hug him, and a seven-year-old screaming girl may not be hungry or thirsty. Foremost, the procedural comfort of a child is a holistic experience. The pediatric holistic procedural comfort findings from this study have various implications in nursing and across numerous health and social science disciplines.

Study Implications

The implications from this qualitative study are multidimensional and include possibilities for innovation in procedural practice, organizational and administrative policy, nursing practice, methodology, and theory. Many of the recommended improvements and/or new developments discussed here can be implemented in a timely manner, with low cost, ease of administration, and minimal duty burden to healthcare staff. These findings could be extended to outpatient medical centers and could benefit children in acute care settings, intensive care, primary care, palliative and end-of-life care, school-based nursing, and sub-specialist clinics.

Procedural Implications

Pharmacological Procedural Treatments. In this study, topical anesthetic (numbing) cream was a source of procedural body comfort. As explained in the introduction of this dissertation there are many barriers that prevent adequate pediatric procedural care including time management, proper assessment of child needs, provider and nurse collaboration, nursing knowledge, and nurse attitudes (Ellis, Sharp, Newhook, & Cohen, 2004; Ely, 2001; Latimer, Johnston, Ritchie, Clarke, & Gilin, 2009; Manworren, 2000; Rieman & Gordon, 2007; Robins, 2007; Ware, Bruckenthal, Davis, & O-Conner-Von, 2011). The safety and efficacy of various topical pain prophylaxis medications has long been known. Increasing the use of these treatments may include nursing/clinical education, protocols, and empowering nurses to deliver this care (Bice, Wyatt, and Gunther, 2014). In a sample of 13 children in this study only one mother said topical anesthetic analgesic was used during the venipuncture procedure. In this instance the anesthetic was applied by the child's primary care office, not the laboratory staff. The results of this dissertation study suggest prophylactic pharmacological treatments is still being underused by nurses/clinicians during routine procedures. Advocacy is a fundamental part of the nursing/clinician procedural care process and involves the healthcare worker identifying his or her own role in providing this care (Vaartio, Leino-Kilpi, Suominen, & Puukka, 2008). This study reinforces the benefits of safe, effective, readily available, and cost effective procedural pain treatments that increases procedural body comfort in children and contribute to overall improved pediatric procedural care.

Caregiver Consultation. Findings from this study suggest a need for change in the process of venipuncture and other routine clinical pediatric procedures. In the previously discussed study by Ljungman, et al., (2006), researchers merged the perspectives of caregivers

and children on pain associated with cancer because they were so similar. In this dissertation study caregiver and child descriptions were similarly alike and merged into themes. Like previous research suggests, this study indicates primary caregivers have a special understanding of their child. Primary caregivers can in many instances anticipate their child's procedural holistic comfort needs. Children also discussed the comfort associated with having primary caregivers or other important individuals with them during the procedure. Given these findings it would be beneficial for clinicians to consult with caregivers about child comfort prior to the start of invasive pediatric procedures. Caregivers should also be given the option to accompany his/her child for the procedure to provide sources of holistic procedural comfort.

Permitting Color Choices. Child color preference is another finding with implication. The description of color preference or color enjoyment/appreciation was frequently found among child descriptions in this study. These child color preferences were also noted among descriptions about the procedure surroundings such as the exam room or laboratory. Both boys and girls showed a particular excitement for his/her "favorite" color or colors "liked." In an older study centered on genetic psychology, researchers found 5-6 year-old children associated various emotional responses to different colors (Boyatzis & Varghese, 1994). Similar to this dissertation study, researchers also found boys were more likely to prefer darker colors and girls were more likely to prefer brighter colors. A simple clinician task that should be considered when providing invasive procedures is to allow children to choose color preference whenever possible during the course of the procedure process. Examples of these color choices may include exam room colors, band-aids, procedure site dressings as well as stickers or other rewards provided with the procedure.

Considering Physiological Needs. In this study children described feelings of hunger, thirst, and needing to use the bathroom. They additionally described food, drink, and using the toilet as comfort measures that could be implemented to make them feel better. Children and caregivers described specifically wanting food in the procedure room or directly after the procedure. Carnevale and Guadreault (2013) explored child experiences and found that children who were hospitalized in a pediatric intensive care unit used food as a source of comfort. Children are frequently instructed to be fasting for venipuncture lab work which could lead to hunger and thirst before, during, and after the procedure. Some children are seen at a pediatric specialist or a primary care office prior to their procedure leaving longer periods of time without food, drink, or even a bathroom break. Clinicians performing procedures should ask and offer children (when clinically indicated) if they wish to use the bathroom, if they would like a drink, or if they would like a snack in the designated appropriate and food-safe areas. This is in part an organizational implication as the decision to stock and distribute drinks such as water, juice, or milk, and snacks such as crackers, "gummies," (described in study findings), or cereal bars would need organizational and administrative approval.

Organizational Implications

Providing Environmental Décor and Embellishments. Both participant groups in this study perceived a colorful, decorative, embellished, and age appropriate environment as comforting. Children frequently described their fondness of wall and floor décor, pictures, paintings, and door hangings. Children perceived these decorations as something that would make him/her feel better about the overall venipuncture procedure. Caregivers additionally described recommendations for more or different exam room decorations, child themes, and a "child-friendly" surrounding.

In a qualitative study focused on hospital environments researchers found adult patients desired a "homely welcoming atmosphere, a good physical design, and a supporting environment" (Douglas & Douglas, 2004). The official journal of the American Academy of Pediatrics published information on a Child-Friendly Healthcare Initiative (CFHI) focused on the "physical, psychological, and emotional well-being of children attending healthcare facilities" (Southhall, et al., 2000, p. 1054). One of the standards in this document specifically mentioned "child-friendly décor" (p. 1058). The initiative included a focus on the environment which should help to prevent anxiety and fear in children attending health care facilities. Healthcare organizations can positively affect child comfort in the procedure surroundings by adding various and perhaps exaggerated decorations, trimmings, accessories, painting, embellishments, ornaments, and other child-friendly elements to the procedure environment. These elements may provide extra comfort with sensations through visual and tactile enhancement for the child.

Providing Procedure Comfort Objects. In this dissertation study children and caregivers described stuffed animals, baby dolls, toys, and other objects that provide holistic comfort through comfort play. Much like this study, Carnevale and Guadreault (2013) showed critically ill children found comfort with stuffed animals. In several instances children and caregivers reported the laboratory offering stuffed animals as a gift to the child after the venipuncture procedure was complete. However, children reported wishes of having that same stuffed animal gift (or stuffed animals from their home) in the procedure room with them.

Instead of offering children a snuggly stuffed animal reward after enduring the invasive procedures, organizations and staff should consider providing a hospitable stuffed animal gift before the invasive procedure. This simple evidence-based change could increase procedural holistic comfort through play in children experiencing a venipuncture or other invasive pediatric

procedures. Additional implications from this study involving sources of comfort play in the organization were also found.

Providing Entertainment. As previously discussed, children found games, activities, mobile phone applications, electronic devices, and toys as added sources of comfort play throughout the venipuncture procedure process. Caregivers and children both described the lack of toys, play sets, or other sources of entertainment from the time they entered the laboratory to the time they exited procedure room. Various comfort interventions with novelty toys, electronic devices, or activities were discussed in the findings related to preceding literature. Organizations and administration should consider providing entertainment and comfort play sources in the waiting room of the laboratory, the procedure/exam room, and on the way out as the child exists the laboratory. Providing these extra sources of entertainment may help to keep a child's mind on "play" instead of the negative emotions and cognitions associated with a "shot." Providing these sources of entertainment and play must also be implemented through nursing practice changes.

Practice Implications

Comfort Recommendations with Referral. Every invasive procedure begins with an ordering practitioner or nursing/clinician standing orders. Findings from this dissertation study offers evidence for enhancing procedural holistic comfort beginning with the referring nurse/clinician. Caregivers and children frequently described sources of body comfort, cognitive/emotional comfort, and comfort play that they wanted during the procedure. Many of these comfort sources were objects, belongings, or items children wished they had from home. Caregivers often described being unprepared for the venipuncture procedure due to time constraints, unknown need for blood sampling, and short notice. Many children were sent

directly to the laboratory for the blood sampling after attending a pediatric specialist or primary care visit.

A very easily administered, feasible, and cost effective way referring nurses and clinicians can aid in a child's comfort associated with procedures starts with early communication to the caregiver. When referring a child for a procedure or making future appointments where procedures are anticipated, nurses and other clinicians should discuss the importance of bringing favorite toys, stuffed animals, activities, security objects, or games for the child. Additionally, the body comfort and cognitive/emotional comfort associated with special interpersonal relationships or even beloved people was described as significant to children in this study. Caregivers should be asked to consider who among immediate and extended family members is the most comforting to the child. This/these persons would be best to accompany the child to the invasive procedure to ensure optimal holistic comfort.

Methodology Implications

Pediatric Qualitative Research. Although this study was not the first to include children or caregivers as participants, there were particular successful study procedures that should be discussed. Limited qualitative nursing research exists in children younger than 8-years-old. This may be, in part, related to the assumption that cognitive abilities and developmental level would not permit successful or rich interviews in children this young. However, children as young as 5-years-old were successfully interviewed in this dissertation study. Discussions with children lasted on average 20-25 minutes. This is quite a long time considering a child's attention span, his/her willingness to continue talking, and the inherently dull and monotonous experience of answering questions asked by adult researchers. Children gave rich and elaborate descriptions of procedural holistic comfort and on several occasions surprised the PI with acts and statements of

maturity. Exploratory research including children in the preoperational stage of development or younger should be considered whenever a child's experience or perspective is desired instead of simply interviewing caregivers or adults instead of the child.

Provision of Interview Toys. In this study 7-8 age appropriate toys were placed on a carpet tile in the interview room prior to the child and caregiver arriving for the interview. These toys were offered as means of play and a source of warming up to the environment. The toys included: a model jet, a baby doll with accessories, two Barbie dolls with accessories, an interactive healthcare instrument set (thermometer, stethoscope, and reflex hammer), matchbox cars, a stuffed teddy bear, an ice cream parlor set, and various action figures. These toys proved successful at keeping children engaged and active during the interviews. Children commented on enjoying the carpet tile toys and some asked the PI if the same toys would be in his/her gift basket. Children also verbalized the ability to play with toys and talk at the same time. Despite the attention to playtime with toys, child participants were still able to focus on answering questions and invoking discussion. This simple procedure is an age appropriate and "child-friendly" tool that can be implemented in qualitative research with children regardless of study purpose.

Drawing Pictures. Eder and Fingerson (2002) suggest incorporating more than one method of communication in child interviews to enhance data collected and verify analyses.

Nurse scientists have previously conducted studies using child drawings during exploratory qualitative research. But, this research is limited in the areas of young child experiences.

Carnevale and Guadreault (2013) incorporated the use of drawing pictures in their study. In their study younger children actively engaged in drawing pictures of themselves while critically ill.

Carnevale and Guadreault found that adolescents did not want to draw in their study. In this

dissertation study, children were asked to draw two pictures- one of themselves getting the venipuncture and another of comfort measures that would have made or did make them feel better during the venipuncture. All children participated in the drawing task, even if they chose not to draw what was asked or to finish drawing before both pictures were complete. This activity was a successful way to elicit descriptions and allow for rich discussion between the child and the PI regarding procedural holistic comfort. Findings from this study and Carnevale and Guadreault (2013) suggest that younger children may respond well to a drawing activity in qualitative research while older adolescent children may not want to participate in it.

Theoretical Implications

Development of a Conceptual Model. The results of this inductive or theory-building study have implications for creating a new conceptual model. A working framework could be developed and modified with continued research on the concept of holistic procedural comfort. With a valid and reliable measurement instrument, this concept may be operationalizable and tested for nursing and patient outcomes. Similarly, with more research, innovation, and the development of propositions to connect concepts, it is possible that a midrange theory of pediatric procedural holistic comfort could be composed and later tested.

Kolcaba's Comfort Theory. Kolcaba's comfort theory was not the guiding framework in this qualitative study. However, it is through her research and the works of others that comfort has become known and accepted as holistic- incorporating the whole person. As previously discussed in the literature review, Kolcaba (1991; 1992; 1994; 2013) developed a midrange theory of holistic comfort in nursing. Recalling this theory is characterized by three different states of comfort- relief, ease, and transcendence, these states occur in four different domains-physical, psychospiritual, environmental, and sociocultural. Kolcaba's research has not focused

on children and she has not completed any research with child participants. However, findings from this study conducted with children replicate some of the findings of Kolcaba's concept analysis and holistic theory of comfort. For example, procedural holistic comfort in this study was found to exist in the child's environmental context, physical context, and sociocultural or psychospiritual context. With more research, Kolcaba's holistic comfort theory can be expanded to include experiences of comfort for children as well as a child's particular, age appropriate, and developmentally appropriate holistic comfort needs.

Future Research

Several areas for future research are still noted after conducting this study. First, comfort interventions during invasive pediatric nursing/clinical procedures are currently aimed at alleviating pain, fear, distress, and anxiety. Comfort during these painful procedures is largely defined by reducing pain. Part of the problem here is that many scales used to measure comfort are traditionally designed to measure pain, which is not holistic. This dissertation study addresses the procedural holistic comfort needs of children. More research addressing procedural holistic comfort with other invasive procedures including, but not limited to, urinary catheterizations, nasogastric tube insertions, port-a-cath central line access, IV cannulation, lumbar punctures, wound dressing changes, suture placement, suture removal, and more is needed. In order to conduct intervention studies with children who experience invasive procedures a tool must be developed. Narratives exploring the experiences of caregivers who witness invasive pediatric clinical procedures and children who experience frequent invasive procedures is also needed.

The General Comfort Questionnaire measures comfort in adults (Kolcaba, 1992) and this tool has been adapted for other areas of health and healthcare. In order to understand levels of comfort and holistic comfort outcomes in children, a measurement instrument for childhood

procedural comfort is needed. A sequence of studies with this measurement instrument will be needed. This sequence begins with a pilot study conducted on a small sample of children to assess the feasibility and utility of the tool. Next, a lager scale validity and reliability study should be conducted. If the instrument shows acceptable validity and reliability for a beginning psychosocial instrument then intervention studies can begin.

Comfort has been extensively studied in adults (Dowd et al., 2000; Dowd, et al., 2007; Kolcaba, et al., 2004, Kolcaba, et al., 2006; Kolcaba & Fox, 1999; Kolcaba and Steiner, 2000; Wagner & Kolcaba, 2006). Holistic comfort needs exist in many areas of a child health, across various age groups, and in various cultural groups, races, and ethnicities as these important elements could affect how a child experiences comfort. Disparities research and pediatric holistic comfort outcomes is also absent from the literature. Comfort connected to other areas of child experiences with health and healthcare also needs exploring. For example, research is needed on the holistic comfort needs related to procedures otherwise not known as painful but also not enjoyable. This may include ancillary or radiology testing such as magnetic resonance imaging (MRI), computed tomography (CT), simple radiographs (x-ray), electroencephalograms (EEG), polysomnography (sleep study), treadmill electrocardiograms (ECG), and nuclear medicine studies.

Holistic comfort related to child health states is a significant area of research that is needed. Children with chronic illnesses may experience comfort differently than other children. Holistic comfort research is needed in children diagnosed with various diseases such as cancer, cystic fibrosis, HIV, chronic kidney disease, diseases causing neurological impairment, congenital heart disease, trisomy 21, diabetes, juvenile rheumatoid arthritis, asthma, musculoskeletal disease, autism spectrum disorders, obesity, depression, and ADHD.

Additionally, the holistic comfort needs of children receiving End-of-Life care is a significant area of research indicated for children to have a more peaceful death. Novak et al., (2001) looked at holistic comfort needs in adults at the end-of-life but research in the pediatric population is lacking.

Lastly, studies investigating new theories are essential in nursing. Quantitative research involving testing of propositions in a pediatric procedural holistic comfort theory (when it is developed) is needed. This can be done when the theory includes operationalizable or measurable concepts. Additionally, through child and caregiver descriptions it was evident in this dissertation study that some clinicians may have provided more procedural holistic comfort than others. A grounded theory study is needed to evaluate the following research question: what is the social process of becoming a nurse who regularly provides procedural holistic comfort.

Study Limitations

This study has limitations. Qualitative descriptive research is an appropriate design to implement when little is known about a subject (Sandelowski, 2000;2010) and when pure descriptions of a phenomenon are desired. It has been argued however, that "pure descriptions," even when described by participants may be impossible (Neergaard, Olesen, Andersen, & Sondergaard, 2009, p. 2). This is related to the fact that the element of interpretation, regardless of the descriptive method, is still present (Neergaard, et al., 2009; Sandelowski, 2000; 2010). In this study descriptions and perspectives of holistic comfort related to a clinical venipuncture procedure were explored. The PI stayed very close to the data as required by the method.

Nevertheless, interpretation was used in the thematic content analysis process, which could have affected participant "pure descriptions." Stabilization of this limitation was aimed for in the implementation of peer debriefing with dissertation committee members and the use of an

external researcher audit. These elements of rigor were conducted so researcher interpretations could be verified by researchers other than the PI.

Another limitation in this study is the unknown transferability across different populations and different age groups. Holistic comfort was explored in one child age group with one type of invasive procedure. These holistic comfort descriptions may be different among children who experience less invasive, more invasive, or traditionally non-invasive interventions. The majority of children are however not hospitalized for venipuncture procedures so this supports transferability. Moreover, according to the United Sates Census Bureau, in 2013 the diversity of Tennessee included 74.9% Caucasian individuals, 17.0% African American, 1.6% Asian, and 1.7% two or more races. This diversity is fairly similar to the demographics of the child and caregiver participants in this study further supporting transferability.

Varied child backgrounds could have affected the descriptions of procedural holistic comfort in this study. Some children in the study previously experienced a venipuncture or invasive procedure while others were experiencing this procedure for the first time. Additionally, certain children were coping with one or more of the following pressures: family matters, grief and loss, health issues/illness, and or life stress/emotions. Wavering past experiences may have affected the descriptions of holistic comfort among children and caregivers who had or had not previously been subjected to or witnessed the venipuncture. It is important to mention however, that despite the numerous experiences of children in this study, many of the descriptions of holistic comfort were the same.

There were additional limitations noted in the procedures and recruitment of the study.

First, the use of a single institution for recruitment restricts the findings to those participants

coming to a children's hospital, in one city of a much larger region. There are various institutions

and medical centers in the same area that children have blood sampling procedures. The differences among clinicians and invasive procedure policies may be different at various institutions, which could in turn affect child procedural holistic comfort. Next, recruitment may have been affected by the information provided in the recruitment flyer and informed consent. It was required by the University IRB to notify caregivers in the flyer that they would be asked about illegal drug use. It was then stated in the informed consent that any information found about illegal drug use would be reported to the appropriate department of children services. Caregiver fear of being reported to social services may have hindered participation. Attention bias may have also been a limitation. Some child participants may have assented, participated in, and responded in a particular way because they were receiving attention from the PI. Also, the VISA gift card and child toy basket offered for participation may have positively affected willingness of caregivers and children to participate. It was for this reason that a reasonable amount of \$20 and non-extravagant toys were chosen as gifts for study involvement.

Finally, one of the factors that could affect the outcomes and interpretations of this dissertation study is researcher bias. The PI is a Certified Pediatric Nurse Practitioner who has previously performed many venipunctures and other invasive procedures on children. The PI continues to frequently perform advanced nursing practice invasive procedures on infants, children, and adolescents in primary care currently. It is possible given the PI's personal and professional background, that the interpretations/outcomes of the study could have been affected. For this reason a reflexivity statement was completed prior to conducting the procedures and data analysis of the study so to separate the PI's opinions, attitudes, and beliefs about pediatric comfort prior to interviewing and coding. Again, peer debriefing and external audit was implemented in order to further support the interpretation of findings from this study.

Conclusion

Invasive pediatric clinical procedures are an unavoidable part of health care for many children. The negative aspects however related to these invasive procedures can be reduced or avoided through providing various comfort interventions. Many of these comfort interventions such as forms of entertainment, music therapy, caregiver facilitation, and a multifaceted approach to decreasing pain, distress, anxiety, and fear have been studied. Research in the area of holistic comfort related to invasive procedures in children was missing. Although comfort has been rigorously studied in the adult population, the definition and meaning of pediatric procedural comfort has been defined more by the absence of pain as opposed to a holistic concept focusing on the whole child. The significance of holism is unquestionable when nurses and other clinicians care for children. In this study the definition of *holistic* was inspired by previous researchers and was understood as an attitude of caring that acknowledges and treats the whole child, with careful consideration of all needs.

The purpose of this study was to explore perspectives of children age 4 to 7 years and their caregivers regarding procedural holistic comfort. Findings from this study suggest that the process of experiencing an invasive clinical/nursing procedure introduces more comfort needs than relief from fear, pain, distress, and anxiety. Children and caregivers described holistic procedural comfort as including body comfort, cognitive and emotional comfort, comfort in the procedure surroundings, and comfort play. Supplementary findings of the study included caregiver and child perspectives of feelings associated with venipuncture procedures. These perspectives included anger, anxiety, distress, fear, opposition, pain, sadness, building resilience, and embarrassment. Additional findings included various backgrounds of child experience.

These experiences were centered on having a venipuncture for the first time, having a repeated

venipuncture or invasive procedure, family matters, grief and loss, health issues/illness, and or life stress/emotions.

The findings from this study have implications in the areas of procedural practice, organizational policy and procedures, nursing practice, theory, and methodology. There are however questions about pediatric holistic comfort that remain unanswered. Future research should focus on exploratory and empirical studies investigating different populations such as children of various age groups, children with special health needs, disparate groups, and children of different ethnic or cultural backgrounds. With the findings from this study and future outcomes research, there is potential for enhancement of overall procedural holistic comfort in children. Adequate nurse and clinician-provided procedural comfort management is the right of every child. With this new knowledge and further research on holistic comfort, clinicians can avoid becoming metaphorically and mentally anesthetized, which has, in the past, rendered the problem of suffering during invasive pediatric procedures more difficult to manage. Most significantly, as a result of this study, beginning evidence exists with regard to care that focuses on ending associated anguish and enhancing holistic comfort related to invasive pediatric clinical procedures.

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Appendices

Appendix A: Original Preliminary and Revised Interview Questions

Excluded Questions

- 1. Was there anything that made you feel better right before you got the shot done?
- 2. Was there anything that made you feel better when you were in the middle of getting the shot?
- 3. Was there anything that made you feel better when the shot was all done?
- 4. Was there anything going on in the room around you that bothered before the shot or when you were getting the shot?
- 5. Was there anything going on with your body that you didn't like during the shot? Maybe not just the needle- but something else?
- 6. What would have made the chair or table even better for you or maybe other little kids too?
- 7. What do you think would have made the room even better for you or maybe for other little kids too?

Revised Questions

- 1. Is there anything or anyone you can think of that made you feel better about the needle poke you had done today?
- 2. Was there anything you liked or didn't like about the room where you were poked with the needle?
- 3. Was there anything or anybody else you wish you had with you to make you feel better during the needle poke today?
- 4. What would have made the shot even better for you or maybe other little kids too?

Appendix B: Dissertation Committee Confidentiality Pledge

Research Project Title:

Exploring Holistic Comfort in Children who Experience a Clinical Venipuncture Procedure

Principal Investigator:

April A. Bice MSN, RN, CPNP 10217 Boston Lane Knoxville, TN 37932 865-292-1430 abice@utk.edu

As a dissertation committee member for this research project, I understand fully that I will have access to confidential information collected during research participant interviews. The data has been disclosed by individual participants on good faith that their interview material would remain completely confidential. I understand that I must honor this confidentiality agreement and I hereby agree not to share any confidential information regarding this study with anyone except the principal investigator, April Bice, and other research team members who have also signed this pledge. A violation of this agreement would represent a serious breach of ethical standards, and so I hereby agree not to violate this confidentially pledge.

Dissertation Committee Member (Sign and Print Name Please)

Appendix C: Recruitment Flyer

Hello and thank you for reading this flyer! Please See below.

Is your child age 4 to 7 years old?	YES	NO
2. Will your child have a blood test done today?	YES	NO
3. Can you and your child speak English?	YES	NO
4. Does your child like to draw?	YES	NO

If you answered yes to all of these questions then you and your child may be fit to participate in a study about comfort for children during needle procedures. The purpose of this study is to find out more about what makes children comfortable during procedures such as blood sampling. Your child will not experience any more procedures or physically uncomfortable interventions for this study. Participation includes interviewing you and your child separately (but together in the same room) or interviewing only one of you (whichever you consent to). You will be asked about alcohol, controlled substances, and drug use. You or your child will not be eligible to participate if either of you has had any controlled substances in the last 8 hours and you will not be able to participate if you have had alcohol in the previous 4 hours. If you agree to participate your child will receive a gift basket full of toys and you will receive a \$20 VISA gift card today. The amount of time you will be needed for the study is roughly 30 to 60 minutes. If you are interested please go to the Neurodiagnostic room directly across from the lab as you exit the door and see April Bice after your child's procedure is done.

Thank you!

April A. Bice, Certified Pediatric Nurse Practitioner

Appendix D: Informed Consent

University of Tennessee Knoxville

Study Title: Exploring Holistic Comfort in Children who Experience a Clinical Venipuncture Procedure

INFORMED CONSENT STATEMENT

Hello!

You and your child are invited to be in a research study while you are here getting your child's blood test today. The main person over the study, April Bice, a doctoral student in the College of Nursing at the University of Tennessee, is interested in finding out what comfort means to young children who have invasive clinical procedures done. The purpose of this study is to learn more about what makes children comfortable with things such as blood sampling. Talking about this topic with you and your child will help answer these questions.

Information about Involvement in the Study

Interviews will be in the same room you are in right now about 15 minutes after your child's blood test. Interviews with children will be done first, followed by caregivers. While you the caregiver is being interviewed, the children will be in the same room playing with provided the toys if they wish. Questions will be asked to you and your child about the blood sampling today and comfort measures related to the procedure. Your child will also be asked to draw a picture today of things that did or would have made him or her feel better about the procedure today. If your child looks nervous or uncomfortable during the interview, the researcher will give them a break. If your child looks really upset or distressed the interview will be stopped. The length of time you will be in the study if you participate today is about 30-60 minutes. These interviews will be audio recorded with two digital recorders so that your interview(s) can be listened to again at another time. No additional testing or blood sampling is needed to participate in this study- only what has already been ordered by your child's doctor/practitioner. You will be asked to complete a short form about you and your child's age, gender, race, education, language, and medications. You will also be asked about alcohol and controlled substance or drug consumption in the last 4-8 hours.

About 12-15 child and 12-15 caregiver participants will be needed for this study. Your child can participate today if he or she is: 4-7 years old, having a medically necessary needle stick blood sampling test done today, and speaks English. Your child cannot participate if he or she is unable to talk for the interview or if he or she has taken any medications that may affect his/her comfort levels during the needle stick. You, the caregiver, will be able to participate if you speak English and if you sign this consent. You will not be able to participate if you cannot talk for the interview, or if you have had alcohol or controlled substances in the last 4 hours. There is no cost to you or your child for your participation in this study.

Risks and Benefits

Risks of being in this study for you and your child are pretty low. These risks include: (a) the burden of participating in and waiting for interview(s) to be finished, and (b) the possible emotional or psychological strain that talking about the blood sampling may cause. There are

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Parti	icin	ant's	in	itial	Q

also benefits to participating in this study. One direct benefit is the opportunity for you and your child to share your experiences. You are also indirectly helping with child comfort research.

Confidentiality

You and your child's interviews and private information found in the demographic form will be secured in a database on a digitally locked computer. It will be looked at only for the purposes of the study. We will only use you and your child's real name on the consent form. Consent forms will be kept in a locked cabinet at the College of Nursing. Only April Bice and her research team will have access to yours and your child's information. Information that is collected in the interviews today will be used in the main researcher's dissertation and possibly a publication in a peer-reviewed journal. All audio recordings will be destroyed when the study is complete. A digital or hard copy of the pictures drawn by your child will be kept for possible future studies. Any information that could identify your child will be removed from the pictures. Your identify will be kept confidential in all reporting of data with no reference to you or your child's name. If you or your child withdraw from the study before data collection is done your data will be destroyed and you will not receive the compensation gifts. If your child withdraws from the study, they will however receive a consolation gift. If during the course of the study it is learned that you are using illegal drugs, this will be reported to the appropriate social services and possibly the department of children services for you and your child's safety.

Contact Information

If you have questions at any time about the study, (or you experience adverse effects as a result of participating in this study) you may contact the main researcher, April Bice at (865)-292-1430. If you have questions about your rights as a participant, please contact the University of Tennessee, Office of Research Compliance at (865) 974-3466.

Participation

Your and your child's participation in this study is voluntary; you each may decline to participate without penalty. If you decide to participate, you may also withdraw from the study at anytime without penalty. Time is valuable and the researcher understands this. Your child will be given a gift basket with toys and activities and you will be given a \$20 VISA gift card for participating.

CAREGIVER CONSENT I have read the above information. I have received a copy of this form. this study.	I agree to participate in
Caregiver Participant's signature	Date
CONSENT FOR MINOR CHILD I have read the above information. I also consent for my minor child to	participate in this study.
Caregiver Participant's signature for minor child	Date
Child's Name (only if participating)	

Appendix E: Demographic Data Sheet

Caregiver Age	Child Age
18-25	4 years 5 years 6 years 7 years Child Race
Caregiver Race	Child Race
Black/African American White Asian American Indian Other (Specify)	Black/African American White Asian American Indian Other (Specify)
Caregiver Preferred Language	Child Preferred Language
English Spanish Other (Please Specify) Caregiver Gender	English Spanish Other (Please Specify) Child Gender
Male Female	Male Female
Caregiver Education	Current Grade of Child
High School/GED Some College Bachelor's Graduate School	None at this time 2 nd Grade Preschool 3 rd Grade Kindergarten Other 1 st Grade
Child and Caregiver Medications	Time Medication Last Taken
1. (Child) 2. (Child) 3. (Child) 4. (Child) 1. (Caregiver) 2. (Caregiver) 3. (Caregiver) 4. (Caregiver)	1. (Child)

Caregiver Relatio	nship to the Child	
Consent Number		

Appendix F: Child Assent Form

University of Tennessee Knoxville

Study Title: Exploring Holistic Comfort in Children who Experience an Invasive Clinical Procedure

Scripted Child Assent Form

Hello,

My name is April and I would like to help kids feel better during needle pokes. Don't worry—I won't poke you with a needle. You could help me by telling me what it was like today when you had your needle poke. If you want to help me then we will talk about your needle poke today. After that you can draw some pictures.

It might take about the same time for you to talk to me and draw pictures as it takes for you to watch your favorite TV show. You might get a little sad or scared to tell me about your needle poke or you might feel like it is taking too long to talk to me.

We are just going to talk. No matter what you say your answers will be good. You can ask me anything you want. You can take a break from talking or drawing any time if you want to. If you don't want to talk anymore or draw, that's okay. No one will be mad at you if you want to stop. If you want to talk to me and draw pictures about the needle poke, then you will get a basket of toys for helping me.

Will you talk to me and draw pictures about the needle poke you had done today?

Appendix G: Child Participant Script with Interview Questions

PI: Hello (child's name). It is very nice to meet you. My name is April and I am so glad you want to talk to me. I want to know what makes kids like you feel better when you get a shot or a needle stick like you got today. So I will ask some questions about that. Does that sound okay to you?

Await Child's response...

PI: This water (*PI will place the 8 oz. water bottle in front of the child*) is for you if you get thirsty while we are talking, okay?

Await Child's response...

PI: Here are tissues (point the tissues out to the child) if you need to blow your nose or wipe your face, or use them for anything else.

Await Child's response if any...

PI: You can draw some pictures today too. While you are drawing them or after you are done drawing, I will talk to you about the pictures. Okay?

Await Child's response...

PI: If at any time you start to feel a little nervous or scared and you would like a break just tell me and we will stop for a while. If you become very upset and you don't want to talk to me anymore at all then just tell me you don't want to talk anymore and we will stop. Okay?

Await Child's response...

PI: *Turning attention to and talking to caregiver*... I also want to thank you for allowing your child to talk to me today. I understand that your time and your child's time is very important and valuable. If I could please ask you to remain quiet during your child's interview and allow him/her to respond without interrupting that would be very helpful. It is important that I obtain all of your child's important perspectives on comfort related to the blood test he/she had done today.

Await Caregiver's response...

PI: *Turning attention back to the child*... Okay, before we start (child's name), do you have any questions for me?

Await Child's response...

PI: Okay (child's name), lets get started okay?

Await Child's response...

PI: How did you feel when you woke up today?

Await Child's response...

PI: Has anything made you happy, sad, or angry lately?

Await Child's response...

PI: Can you tell me anything else about you before we talk about the needle poke you had done today?

Await Child's response...

BEGIN PROCEDURAL COMFORT INTERVIEW QUESTIONS (When indicated, words will be substituted with the child's own stated words if they are different from the researcher's words. This will be done to help the child understand and communicate procedural comfort according to his/her own understanding of the event).

- PI: Can you tell me about what it was like to get a needle poke today? *Await Child's response... ask probing or clarification questions if indicated.*
- PI: Is there anything or anyone you can think of that made you feel better about the needle poke you had done today?

Await Child's response... ask probing or clarification questions if any.

PI: Who is here with you today? (*Pause for response*) Did he/she do anything to make you feel better?

Await Child's response... ask probing or clarification questions if indicated.

PI: Was there anything you liked or didn't like about the room where you were poked with the needle?

Await Child's response... ask probing or clarification questions if indicated.

PI: Was there anything or anybody else you wish you had with you to make you feel better today?

Await Child's response... ask probing or clarification questions if indicated.

PI: Did you feel too hot, or too cold, or just perfect in the room where you had the shot? *Await Child's response... ask probing or clarification questions if indicated.*

PI: Did you like the chair or table you were on when you got the shot done?

Await Child's response... ask probing or clarification questions if indicated.

PI: What would have made the shot even better for you or maybe other kids too?

Await Child's response... ask probing or clarification questions if indicated.

PI: Can you think of anything that would make you feel better right now?

Await Child's response... ask probing or clarification questions if indicated.

PI: Thank you for answering those questions. You did great! *The PI will then pull crayons* from the gift basket and hand them to the child with a piece of blank white 8.5 x 11 copy paper. (Child's name), now you can draw two pictures, okay?

Await Child's response...

PI: First, can you draw me a picture of what it was like getting the needle poke today? You can talk to me about this while you draw this picture or when you are done.

Await child to complete the drawing and or communicate the picture while drawing...

PI: *The following question will only be asked if the child chooses to remain quiet during the drawing of the picture:* Can you tell me about this drawing?

Await Child's response if applicable...

- PI: Now for the second picture will you draw me a picture of the things that make you feel better when you have a needle poke done? You also can draw things you wish you had today but you didn't.
- PI: The following question will only be asked if the child chooses to remain quiet during the drawing of the picture: Can you tell me about this drawing?

Await Child's response if applicable...

PI: We are all done (child's name). Thank you again so much for all of your help. This is because you helped me today (the PI will hand the child the gift basket of toys and activities). You can play with this while I talk to (caregiver's title). You can also play with the rest of those toys (PI will point to the carpet tile with toys on it) if you want to. Do you have any questions for me?

Await Child's response...

PI: Would you like to keep the pictures you drew for me today or would you like for me to keep them?

Await Child's response... If the child wishes to keep the drawn pictures then a digital photo of the pictures will be taken with the PI's personal iPad which is locked with a digital passcode (like the secure computer) prior to the child taking the pictures home with them.

END CHILD INTERVIEW AND TURN ATTENTION TO CAREGIVER INTERVIEW IF APPLICABLE.

Appendix H: Caregiver Participant Script with Interview Questions

PI: Hello (Caregivers name). Again, thank you so much for talking with me about your child today. I am going to ask you some questions about your child's blood sampling procedure. I will focus on what you think made your child comfortable with the needle procedure. Okay?

Await Caregiver's response...

PI: This water bottle (*PI will hand the caregiver a 16 oz. water bottle*) to drink throughout the interview if you get thirsty. There are also some tissues here (PI will point to tissue box) should you need them at anytime during the interview. If at anytime you feel you are having a hard time discussing the issues of your child's comfort and you need a break, then please do not hesitate to let me know. If you become distressed or upset and you do not wish to continue then simply let me know and we will stop the interview. Does this sound okay with you?

Await Caregiver's response...

PI: Before we begin the questions I did want to explain to you what I mean by comfort. Comfort means more than just relieving your child's pain. I want to know all of the things that you think help comfort your child during invasive clinical procedures such as the blood sampling he/she had done today. I am interested in the emotional, mental, environmental, and social comfort measures, no matter how small, that you believe help your child feel better, as well as the things that relieve his/her pain. Does this make sense?

Await Caregiver's response and answer accordingly...

PI: Do you have any questions for me?

Await Caregiver's response and answer accordingly...

BEGIN PROCEDURAL COMFORT INTERVIEW QUESTIONS:

PI: Overall, How was the needle procedure for your child today?

Await Caregiver's response and ask probing questions if indicated...

PI: What made your child more comfortable today before the needle stick? *Await Caregiver's response and ask probing questions if indicated...*

PI: What do you think comforted your child *during* the needle stick?

Await Caregiver's response and ask probing questions if indicated...

- PI: Did anything comfort your child *after* the needle stick or do you think a reward might make his/her feel better later?
 - Await Caregiver's response and ask probing questions if indicated...
- PI: What could have been done to make your child feel more comfortable with this procedure overall- either before, during, or after?
 - Await Caregiver's response and ask probing questions if indicated...
- PI: Tell me what normally makes your child feel more comfortable or better when he/she is unhappy, hurting, or not feeling good?
 - Await Caregiver's response and ask probing questions if indicated...
- PI: Tell me about a time when your child recovered from feeling bad or uncomfortable? *Await Caregiver's response and ask probing questions if indicated...*
- PI: Is your child coping with anything emotionally or physically traumatic right now that might affect how they may have experienced comfort with the needle stick today? *Await Caregiver's response and ask probing questions if indicated...*
- PI: That is all of the questions I have for you today. Again, thank you very much for helping me to understand your child's comfort related to procedures. Do you have any questions for me?

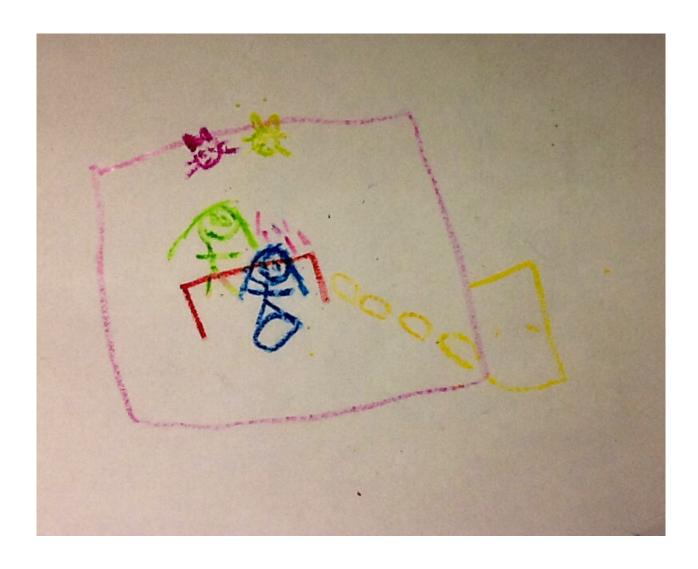
Await Caregiver's response...

PI: Well it was nice meeting you today. Here is a gift for your time (*PI will hand the \$20 VISA card to the caregiver*). If you have any questions for me, my number can be found at the bottom of the consent form that you signed today.

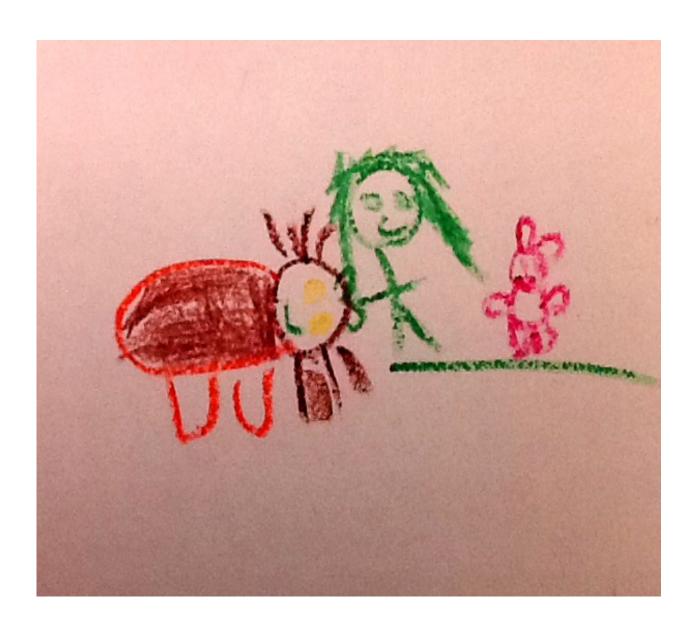
Await Caregiver's response and respond appropriately if indicated...

END CAREGIVER INTERVIEW

Appendix I: Child Drawings



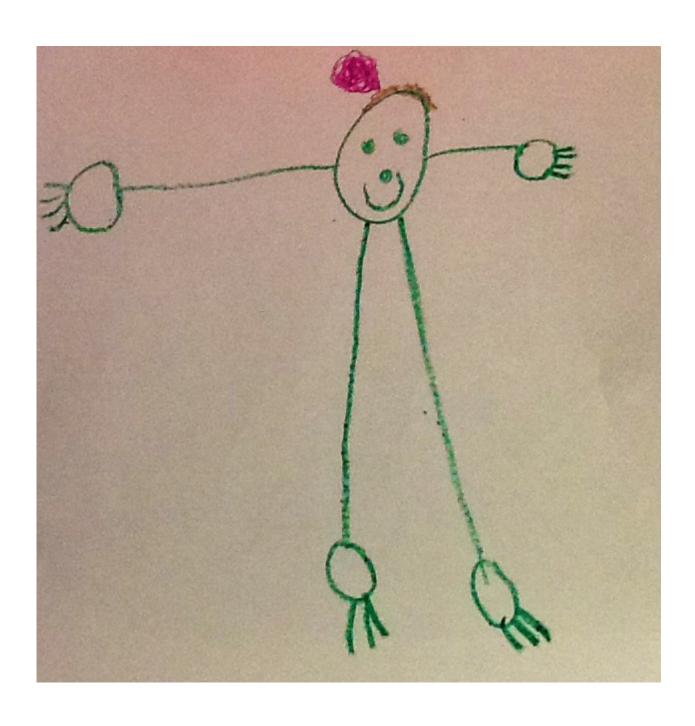
Minnie Mouse: Drawing 1 (Illustration of Procedure Experience)



Minnie Mouse: Drawing 2 (Illustration of Procedural Comfort)



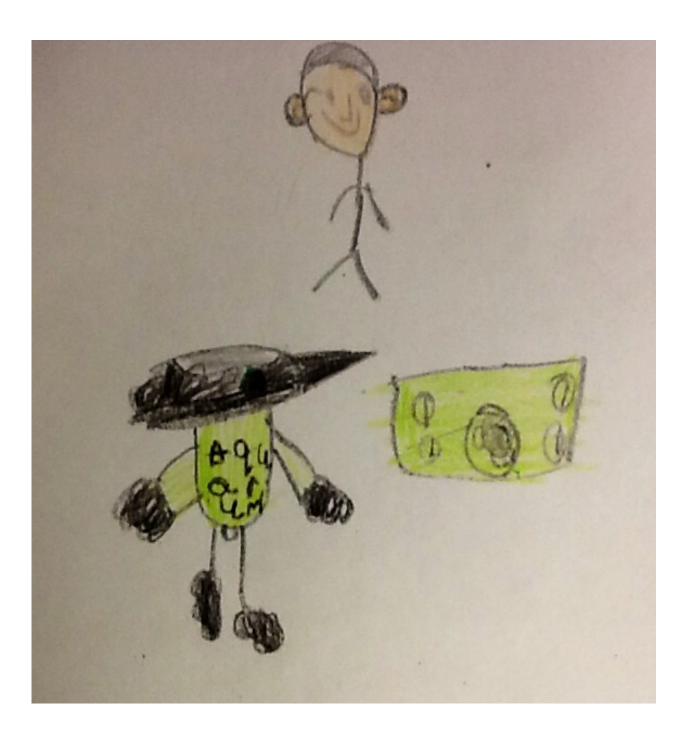
Cleo: Drawing 1 (Illustration of Procedure Experience)



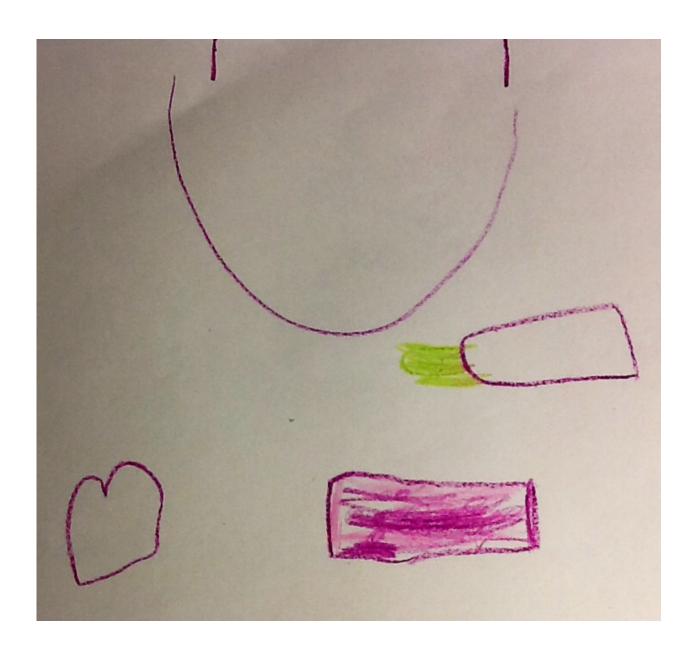
Cleo: Drawing 2 (Illustration of Procedural Comfort)



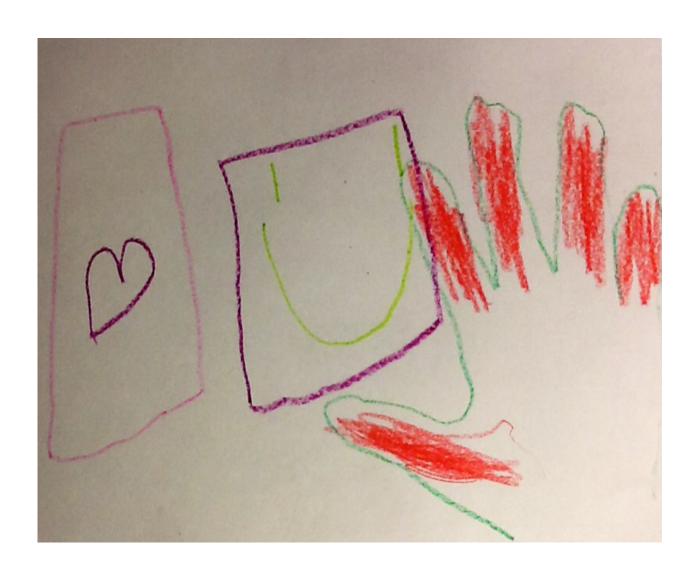
Thumper Rabbit: Drawing 1 (Illustration of Procedure Experience)



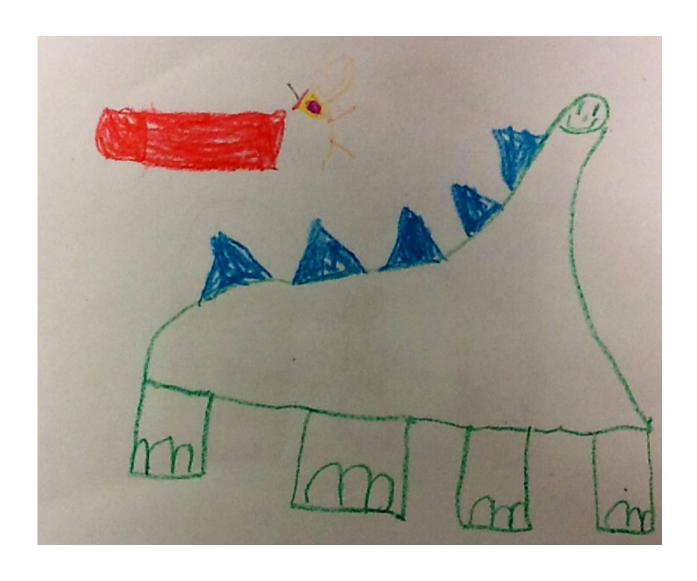
Thumper Rabbit: Drawing 2 (Illustration of Procedural Comfort)



Princess Tiana: Drawing 1 (Illustration of Procedure Experience)



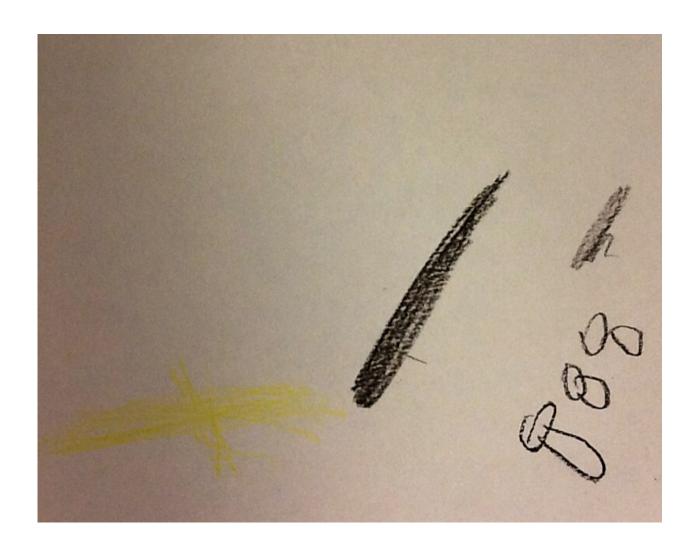
Princess Tiana: Drawing 2 (Illustration of Procedural Comfort)



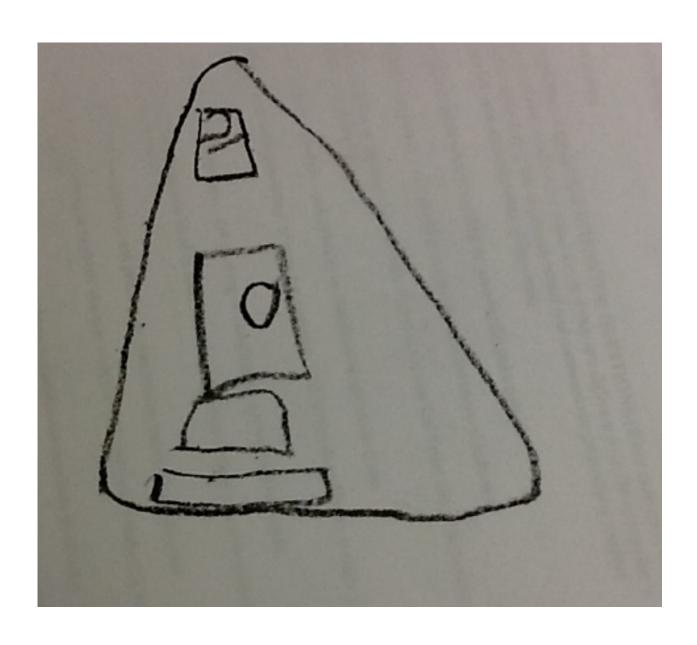
Aladar Dinosaur: Drawing 1 (Illustration of Child's Choosing and of Procedure Experience)



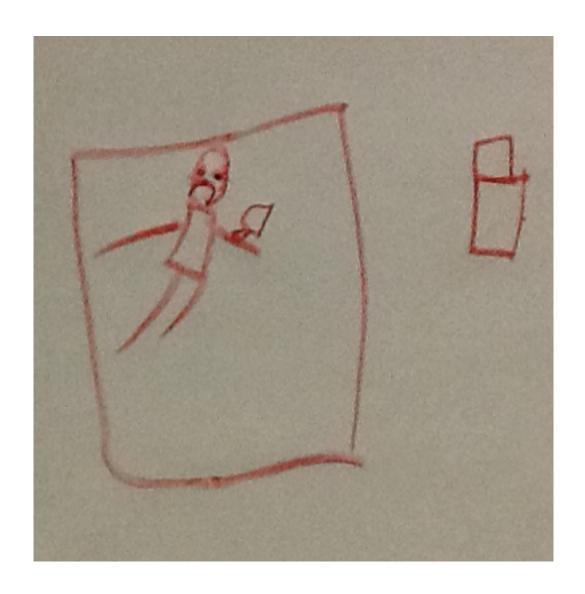
Aladar Dinosaur: Drawing 2 (Illustration of Procedural Comfort)



Flower Skunk: Drawing 1 (Illustration of Procedure Experience)



Chip: Drawing 1 (Illustration of Child's Choosing)



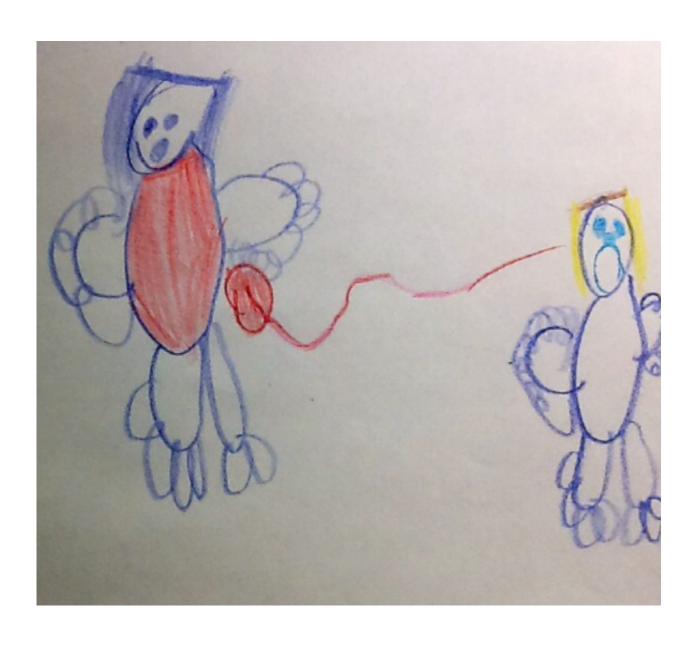
Abu Monkey: Drawing 1 (Illustration of Procedure Experience)



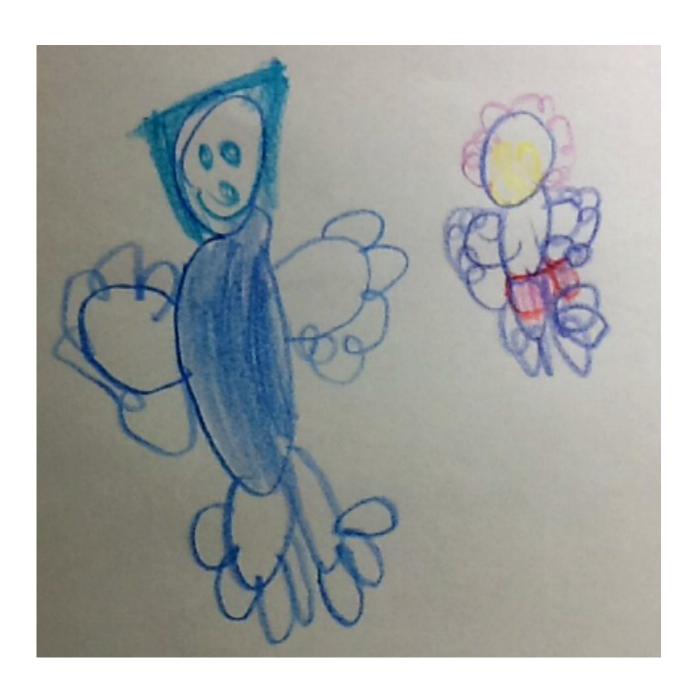
Jasmine: Drawing 1 (Illustration of Procedure Experience)



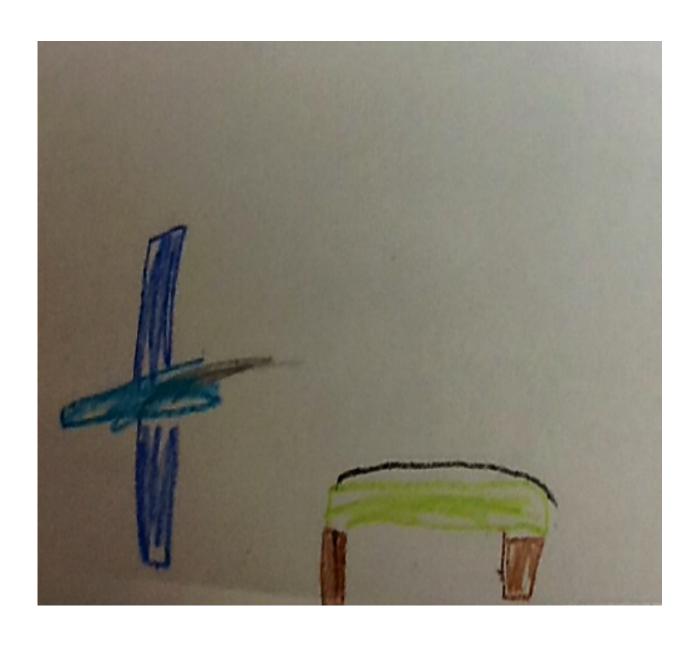
Jasmine: Drawing 2 (Illustration of Procedural Comfort)



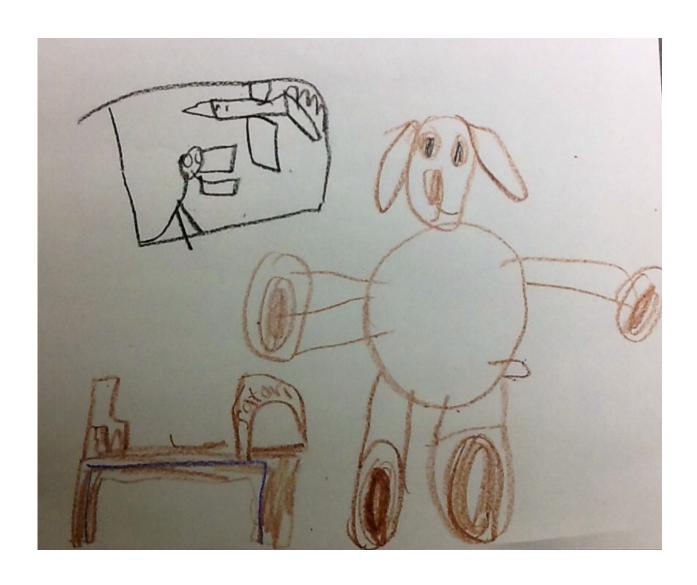
Sophia the First: Drawing 1 (Illustration of Procedure Experience)



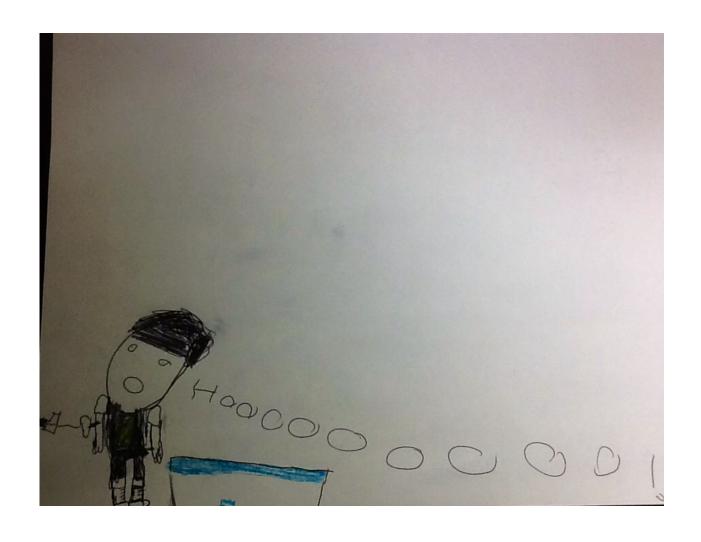
Sophia the First: Drawing 2 (Illustration of Procedural Comfort)



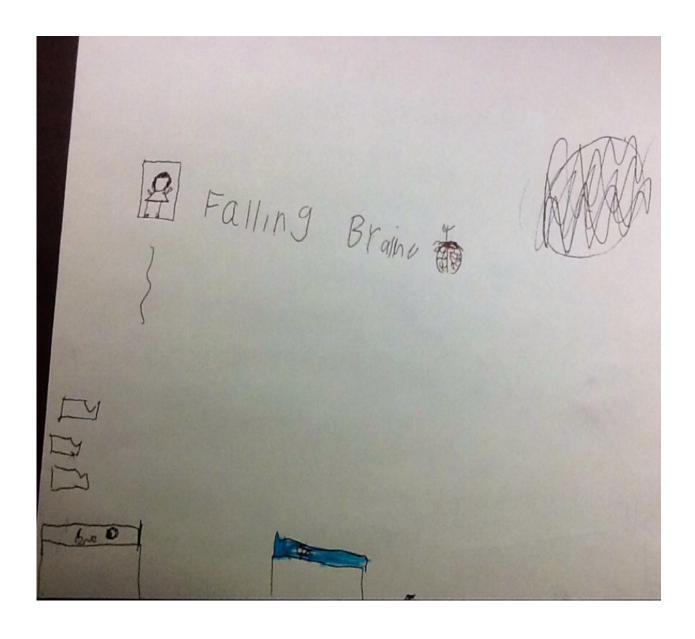
Prince Eric: Drawing 1 (Illustration of Procedure Experience)



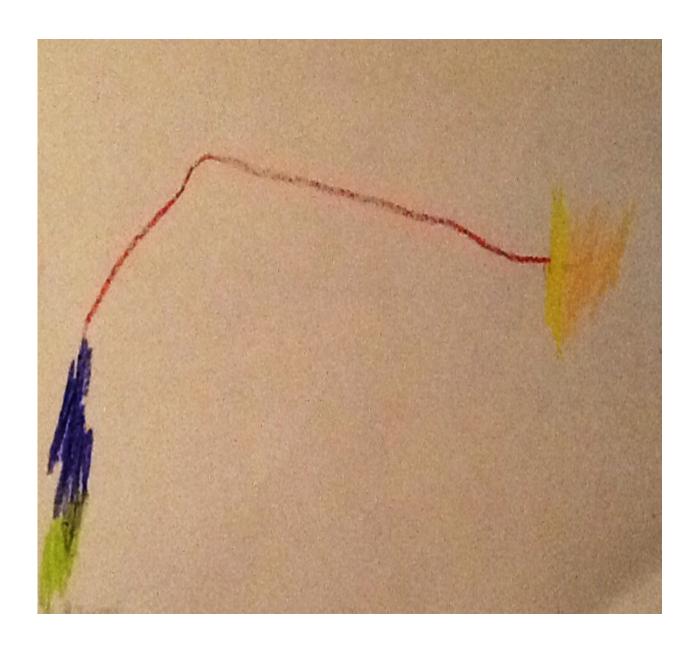
Prince Eric: Drawing 2 (Illustration of Procedural Comfort)



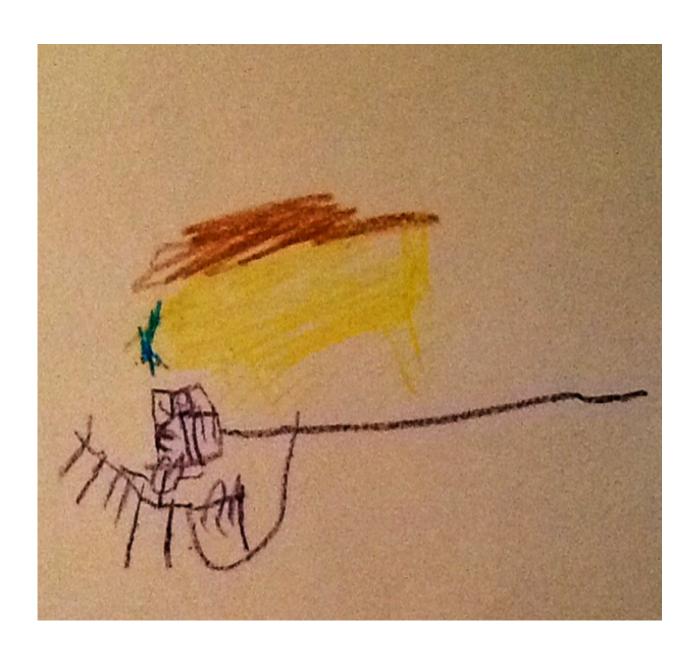
Mowgli: Drawing 1 (Illustration of Procedure Experience)



Mowgli: Drawing 2 (Illustration of Child's Choosing and Procedural Comfort)



Bashful: Drawing 1 (Illustration of Procedure Experience)



Bashful Drawing 2 (Illustration of Procedural Comfort)

Appendix J: Transcriber's Confidentiality Pledge

Transcribing Typist (Sign and Print Name Please)

Research Project Title:
Exploring Holistic Comfort in Children who Experience a Clinical Venipuncture Procedure
Principal Investigator:
April A. Bice MSN, RN, CPNP 10217 Boston Lane Knoxville, TN 37932 865-292-1430 abice@utk.edu As a transcriptionist for this research project, I understand fully that I will be hearing and typing information from confidential research participant interviews. I understand that the material on these tapes has been disclosed by individual participants on good faith that their interview material would remain completely confidential. I understand that I must honor this
confidentiality agreement and I hereby agree not to share any confidential information regarding this study with anyone except the principal investigator, April Bice. A violation of this agreement would represent a serious breach of ethical standards, and so I hereby pledge not to violate this confidentially pledge.

Date

Appendix K: Reflexivity Statement

Creswell (2013) defines reflexivity as the researcher awareness of values, experiences, and biases that are brought to a qualitative study. He further defines it as encompassing two parts: experiences that the researcher has with the phenomenon, and how these experiences shape the researchers interpretation. I think that comfort and the components of comfort are a basic human right that all individuals deserve regardless of age, gender, ethnicity, sexual orientation, medical history, race, or other social determinants. Perhaps my strong feelings on this issue stem from characteristically uncomfortable and painful experiences that I endured for much of my childhood and early adult life. I spent several years longing for comfort both during and while surviving childhood sexual assault/battery (beginning at age 6 and ending at age 11) and adult interpersonal/relationship violence (beginning at age 19 and ending at age 22). By the time I was 7-years-old and on into my teenage years, any clinical procedure I endured produced unexplainable torture for me, conceivably more than average. Then as a young victim of domestic violence I experienced urgent care, primary care, and emergency care visits leading to necessary nursing or medical procedures that frequently fashioned unnecessary suffering. Upon reflection I have come to the understanding that this suffering was possibly an effect of my concomitant abuse. I felt powerless and seemingly unable to obtain this comfort from others or produce it for myself. But, by my Heavenly Father's grace I survived. I was picked up out of my misery and given a glimpse of the oppression-free life that I deserved; the life I now have today. Upon my survival I became a part of the most caring, nurturing, comforting, and compassionate profession I have ever known- nursing.

I have been a registered nurse in the field of pediatrics for 11 years; eight years as a staff nurse in acute and emergent care and three years in my current position as a Certified Pediatric

Nurse Practitioner. All throughout my career as an RN, I have been responsible for completing several invasive nursing procedures. I would argue that I have completed more than the average nurse with my experience considering one of my positions was float or "skills nurse," meaning I was essentially deemed responsible for administering many uncomfortable, painful, and anxiety producing nursing procedures due to my technical abilities.

As I became a more experienced staff nurse I adopted an unfamiliar (an often unaccepted) philosophy on my nursing unit. Every patient who received an invasive procedure from me received a nonpharmacological and pharmacological comfort intervention. Other staff nurses would ask for my help with needle procedures and I would remind them to place EMLA cream (topical anesthetic) on the child for 30-60 minutes, or to have the quick relief topical anesthetic spray at the bedside. I would often bring music to the room and ask the child what kind of song they would prefer, encourage them to use whatever technology devices they enjoy, or put the TV on a channel of their choice. Additionally, I would always ask the child's caregiver to be present for procedures (if they wished) when many nurses felt uncomfortable having mothers, fathers, or other family members present to "monitor them." My co-workers would regularly complain to me that they did not have "time" to wait for these comfort interventions. But, I never stopped providing them. As an advanced practice nurse there are still invasive procedures that I perform on children. At all times, when it is appropriate and necessary, I consistently provide or facilitate comfort interventions as I believe it is the right of all children.

April Athena Bice earned her Bachelors of Science in Nursing from the University of Central Florida in 2004. Graduating with Honors in the Major, Mrs. Bice wrote an undergraduate thesis on recognition and treatment of pain in pediatric patients diagnosed with cancer. As an undergraduate student, she was a member of Sigma Theta Tau, Omicron Delta Kappa, Golden Key, and Tau Sigma Honor Societies. She was additionally recognized as *Who's Who Among Students at the University of Central Florida and Who's Who Among Students in American Universities* prior to graduating.

While working as a pediatric registered nurse she completed her Master's of Science in Nursing in 2011 at the University of Tennessee in Knoxville and was certified as a Pediatric Nurse Practitioner. She was again inducted into Sigma Theta Tau as a graduate student and received various health-related scholarships from the College of Nursing. Mrs. Bice was officially accepted as a PhD student at the University of Tennessee in 2012 and focused all of her research efforts on the phenomenon of inadequate management of pediatric procedural pain and comfort.

As a doctoral student Mrs. Bice has acted as a reviewer for *Issues in Mental Health Nursing* and was the lead author on a manuscript (Bice, Wyatt, & Gunther, 2014) published in *Pain Management Nursing*. This paper concentrated on "Increasing Nursing Treatment for Procedural Pain." She additionally considers herself an advocate for women and children victims of interpersonal violence and authored an OpEd published in the Knox News Sentinel (2013) focused on fighting domestic violence in the state of Tennessee. In February 2014 Mrs. Bice also presented a research poster at the national conference for the Southern Nursing Research Society on pediatric procedural comfort.

Mrs. Bice is currently living in Knoxville, Tennessee and is practicing as a Certified Pediatric Nurse practitioner in primary care. She is additionally employed as nursing faculty and teaches primarily through distance education. After graduating with her PhD, Mrs. Bice hopes to take on a full time faculty position at a research-focused university and continue her trajectory in the area of pediatric procedural holistic comfort management.