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Music Therapy as Procedural Support for Young Children Undergoing Immunizations: A Randomized Controlled Study

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THE FLORIDA STATE UNIVERSITY
COLLEGE OF MUSIC

MUSIC THERAPY AS PROCEDURAL SUPPORT FOR YOUNG CHILDREN
UNDERGOING IMMUNIZATIONS: A RANDOMIZED CONTROLLED STUDY

By
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To William Miller Swedberg (1924-2009),
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ABSTRACT

Children undergoing medical procedures frequently experience severe distress, which may be ameliorated through procedural support music therapy. Parent and nurse behaviors have been noted to influence child behaviors during medical procedures, yet no prior studies were found which examined the impact of procedural support music therapy on caregiver behaviors. The purpose of the present study was to examine the effects of a live, cognitive-behavioral music therapy intervention on the distress and coping behaviors of young children undergoing immunization, as well as the behaviors of parents and nurses. Participants were children between the ages of 48 and 72 months ($N = 58$) who underwent immunizations, as well as their parents and the nurses who administered the immunizations. Each parent completed a demographic inventory describing their child's previous medical experiences. The researcher classified children as "high distress" or "low distress" based on parents' responses to the demographic inventory. Parent/child dyads were then randomly assigned to receive music therapy ($n = 29$) or standard care ($n = 29$) during their immunization, with an equal number of high distress ($n = 10$) and low distress ($n = 19$) children assigned to each condition. Afterward, each parent rated their child's distress compared to previous medical experiences and rated the level of pain their child experienced on a scale from 0 to 10. All procedures were videotaped. Research assistants created transcripts from the videotapes of procedures. Trained observers watched the videos and labeled each child and adult behavior using the categories of the Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R). Child behaviors were classified as coping, distress, or neutral. Parent and nurse behaviors were classified as coping-promoting, distress-promoting, or neutral. Rates and proportions of child and adult behaviors were calculated.

A series of Mann Whitney U tests revealed that, compared to children in the control group, children in the music therapy group showed significantly higher rates and proportions of coping behaviors during the preparation phase of the immunization (prior to the first needle injection) and during the procedure phase, $p < .05$. The two groups did not differ significantly in rates and proportions of child coping behavior during the recovery phase (after the final needle injection). Children in the control group showed significantly higher rates of distress behaviors during the procedure phase and during the recovery phase and higher proportions of distress behaviors during the procedure phase. The two groups did not differ significantly in rates of

child distress behaviors during the preparation phase or in proportions of child distress behaviors during the preparation or recovery phases.

Parents of children in the control group showed significantly higher rates and proportions of distress-promoting behaviors during all three phases of the procedure compared to parents of children in the music therapy group. The two groups did not differ significantly in the rates or proportions of parent coping-promoting behaviors during any of the three phases. Nurses who treated children in the music therapy group showed significantly higher proportions of coping-promoting behaviors during the procedure phase compared to nurses who treated children in the control group. The two groups did not differ significantly in the rates or proportions of nurse behavior during any other phases.

There were no significant differences between groups in the lengths of phases of treatment, nor were there significant differences in parents' ratings of their children's pain. Parents of children in the music therapy group reported that their child's level of distress was less than during previous medical experiences, while parents of children in the control group reported that their child's level of distress was greater than in the past. Results indicate that a live, cognitive-behavioral music therapy intervention has potential benefits for young children, their parents, and their nurses during immunizations.

CHAPTER ONE

INTRODUCTION

In the United States, certain diseases that once posed huge health risks, such as polio, have become rare, due to the process of childhood immunization, which is the means by which a child becomes protected against a disease. According to the Centers for Disease Control and Prevention (CDC), immunization is often accomplished through vaccination, the injection of a killed or weakened infectious organism that stimulates the development of antibodies against the disease (CDC, 2011a). Typically, vaccinations must be administered multiple times in order to render a child immune. Although vaccination is technically a step in the immunization process, the terms “immunization” and “vaccination” are often used interchangeably, and for the purposes of this paper, the term “immunization” will refer only to vaccinations accomplished through needle injections.

Because young children have weakened immune systems compared to adults, the CDC recommends that immunization begin in infancy. As of 2011, vaccinations against 14 separate diseases were recommended to protect children under 6 years of age. Because several combination vaccines protect against more than one disease with a single injection, 10 vaccines are currently recommended for young children: hepatitis B (HepB), rotavirus (RV), diphtheria/pertussis/tetanus (DTaP), haemophilus influenzae type b (Hib), pneumococcal (PCV), inactivated poliovirus (IPV), influenza, varicella, measles/mumps/rubella (MMR), and hepatitis A (HepA). In order for these vaccines to be effective, children should receive two to six doses of each vaccine (CDC, 2011b). This results in a total of 36 separate injections of vaccines recommended for all children before age 6 (CDC, 2011c).

In any given year, millions of children receive immunizations. For instance, a report from the CDC indicates that during the 2009-2010 school year, more than 2.9 million kindergartners were immunized against polio (CDC, 2010). The CDC estimates that this number represents approximately 95% of children entering kindergarten. Because unimmunized children put the entire community at risk of rare diseases reemerging, the CDC highly recommends that all parents of eligible children adhere to their proposed immunization schedule (CDC, 2011c).

Many children receive multiple shots in the same doctor visit because of CDC recommendations and parents' desire to reduce the number of appointments and co-payments.

Simultaneous administration, or giving a child all of the immunizations for which he or she is eligible during the same visit, is recommended by the CDC in order to increase the likelihood that a child will receive all of their scheduled vaccinations (CDC, 2011c). According to the CDC schedule, children may be eligible for up to nine vaccinations at one time between 12 and 15 months (CDC, 2011c). Although the CDC recommendations state that healthcare providers may be somewhat flexible in scheduling immunizations in order to avoid having too many injections in one visit, they state that “there is no exact limit on the number of injections” administered simultaneously (CDC, 2011c, p. 6).

Despite CDC recommendations regarding simultaneous administration, responses of children, parents, and healthcare providers indicate that the pain from receiving multiple injections in a single visit is of great concern. In a study of preschool children undergoing immunizations, Noguchi (2006) found that children who received four or more shots reported significantly more pain than children who received three or fewer shots. A survey conducted by Taylor and colleagues found that among more than 13,000 parents surveyed, two thirds felt that their infant or toddler should receive no more than two vaccinations in a single office visit (Taylor et al., 2002). Parents’ concerns about multiple shots during the same visit were shared by healthcare providers in a survey conducted by Madlon-Harper and Kay (1994). After surveying 46 physicians, 42 nurses, and 342 parents of children under age 6, Madlon-Harper and Kay found that 59% of physicians, 71% of nurses, and 76% of parents believed that children should receive no more than two injections in the same office visit. Pain and side effects were the main concerns for respondents, who felt that three injections were too many for a child to receive simultaneously. The results of a more recent survey conducted by Kennedy, Basket, and Sheedy (2011) found that the pain associated with receiving several shots during one doctor visit was parents’ primary concern related to vaccinating their child. More than 44% of 475 parents surveyed expressed this concern, while other common side effects, such as fevers, were of concern to fewer parents (28.3%). Thus, CDC recommendations appear to be at odds with child, parent, physician, and nurse preferences regarding simultaneous administration of immunizations.

Given the importance of administering all pediatric immunizations to prevent the spread of disease and concerns related to high levels of pain inherent in recommended immunization practices, finding and implementing effective pain management techniques during pediatric

vaccinations is an important consideration. Procedure-related pain in children is closely related to anxiety that children feel about receiving injections. Pain and anxiety that children feel during medical procedures may manifest in distress behaviors. In order to better understand the impact that pediatric immunization can have on young children, it is important to understand what is meant by the terms “pain,” “anxiety,” and “distress.”

Defining Pediatric Pain, Anxiety, and Distress

The definition of pain put forth by the International Association for the Study of Pain (IASP) states that pain is “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (IASP Taxonomy Working Group, 2011, para. 1). Varni, Blount, Waldron, and Smith (1995) describe four types of pain that children may experience: pain associated with a chronic disease (such as cancer or hemophilia); pain related to a physical injury or trauma (such as a burn or a fracture); pain not associated with a chronic disease or physical injury (such as migraine or tension headaches); and pain that is related to a medical or dental procedure (such as an injection or surgery). The present paper focuses on discussions of the fourth type of pain described by Varni et al.: pediatric procedural pain.

Anxiety is defined in the Fourth Edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) of the American Psychological Association (APA) as “the apprehensive anticipation of future danger or misfortune accompanied by a feeling of dysphoria or somatic symptoms of tension” (APA, 2000, p. 820). The extent to which the constructs of pain and anxiety overlap is unclear. Although the common definitions of pain and anxiety both mention physical and emotional states, for the purpose of this study, pain will refer to physical sensation while anxiety will refer to an emotional state. The term “distress” has been used to encompass both the physical and emotional aspects of pain. Merriam Webster's dictionary defines distress as “suffering of the body or mind: pain, anguish” (Merriam-Webster, 1997, p. 226).

Assessment of pain, anxiety, and distress may be accomplished through self-report, behavioral observation, or physiological measures (von Baeyer & Spagrud, 2007). Each individual experiences and expresses pain and anxiety somewhat differently, which makes self-report measures useful in understanding how an individual feels during a medical procedure. However, young children do not always express pain and anxiety verbally and they are not

always capable of understanding the instructions of self-report measures. Because of these challenges that young children face in utilizing self-report measures of pain and anxiety, measurement of physiological states and behavioral observation useful tools in understanding and comparing levels procedure-related pain and anxiety in young children. Physiological measures of pain and anxiety may include heart rate, oxygen saturation, systolic and diastolic blood pressure, salivary cortisol, and respiration rate. Measuring physiological changes may be misleading due to high levels of individual differences in physiological baselines, and the medical devices used to measure these changes may cause increases in anxiety for young children. Certain observable behaviors have repeatedly been associated with individuals' reports of pain and anxiety, and have also been linked to changes in physiological measures (Blount et al., 1989; Jay, Ozolins, Elliott, & Caldwell, 1983; Katz, Kellerman, & Siegel, 1980). For the purpose of this paper, the terms "distress" and "distress behaviors" will be used interchangeably to refer to vocalizations, verbalizations, facial expressions, movements, and other non-verbal behaviors which are observable indicators of pain and anxiety in children undergoing medical procedures. High levels of pain, anxiety, and distress have been documented in children receiving injections as part of the immunization process.

Young Children's Responses to Immunizations

Taddio and colleagues report that immunization is the most common painful medical procedure experienced by children and that younger children report more pain during vaccinations than older children or adults (Taddio et al., 2009). In a study of 150 children undergoing routine vaccinations between the ages of 15 to 18 months and 4 to 6 years, 20% of children showed distress behaviors during the preparation for the procedure that were classified as serious, severe, or panic (Jacobson et al., 2001). During the injection itself, 97% of children between the ages of 15 and 18 months and 44% of the children between the ages of 4 and 6 displayed serious distress behaviors or worse. In another study, Cassidy and colleagues observed that approximately 20% of 5-year-old children undergoing immunizations experienced clinically significant pain, defined as pain that required intervention (Cassidy et al., 2002). In a study by Blount et al. (1992), 56% of preschool children who underwent immunizations required restraint. Frank, Blount, Smith, Manimala, and Martin (1995) found that children between the ages of 4 and 7 displayed nearly twice as many distress behaviors as coping behaviors. Although many

children experience immunization-related distress regardless of their age, a survey of nurses conducted by Ives and Melrose (2010) found that school-aged children in the kindergarten age range and older show distress behaviors that make immunizing them particularly difficult. Because kindergarten age children receive multiple shots, may be difficult to immunize, and frequently show distress behaviors during immunizations, this paper focuses on children between the ages of 4 and 6.

The aforementioned studies indicate that a great number of children experience extreme pain, anxiety, and distress as the result of vaccinations. Because the pain, anxiety, and distress experienced by children during the immunization process has important implications for the well-being of the children themselves, as well as their community at large, it is important to investigate interventions that may help reduce pediatric procedural pain, anxiety, and distress.

CHAPTER TWO

REVIEW OF LITERATURE

Long-term Effects of Pediatric Procedural Pain and Distress

Pain, anxiety, and distress are unavoidable parts of life, yet unmanaged pain during pediatric immunizations can have negative long-term effects on children. Anticipatory fear regarding future medical procedures, increased pain sensitivity, decreased effectiveness of topical analgesics, and difficulty completing future procedures are all potential long-term effects of such events (Taddio et al., 2009). Distressing immunization experiences may also lead to fear and avoidance of medical procedures during adulthood (Pate, Blount, Cohen, & Smith, 1996) and needle phobias (Taddio et al., 2009).

Experiencing pain, anxiety, and distress during immunizations may cause greater anticipatory distress leading up to future injections. Cohen et al. (2001) found that fourth-graders anticipated greater distress than they actually experienced during a three-injection vaccination series. Children who received distraction or a topical anesthetic during their immunization reported no difference in distress at the time of the injection, but 6 months after the final vaccination recalled experiencing less distress during both intervention conditions compared to standard care. These results indicate that anticipatory distress is a common experience for young children and that interventions aimed at relieving distress may provide a buffer against formation of negatively distorted memories.

Needle phobia is one possible outcome of negative medical experiences. The DSM-IV-TR has diagnostic criteria for extreme needle phobia, known as a specific phobia of the blood-injection-injury type (APA, 2000, pp. 443-449). This phobia tends to begin in childhood and is frequently the result of experiencing or observing a traumatic medical experience. Those who avoid seeking medical treatment to the point that it interferes with their overall functioning may meet the criteria for this diagnosis. Hamilton, who has written an extensive report on needle phobia, reviewed literature on its prevalence among various populations, and estimated that more than 10% of the U.S. population has needle phobia (1995).

Negative experiences during early pediatric medical procedures may also result in non-adherence to recommended vaccination schedules. Children who are not up to date on their immunizations place others in society at risk of contracting serious diseases. A documented

outbreak of measles in the United States between 1989 and 1991 has been linked to low rates of immunization in children (The National Vaccine Advisory Committee [NVAC], 1991).

Healthcare providers play an important role in ensuring that children are up to date on their immunizations to prevent outbreaks like this from reoccurring; however, many healthcare professionals have concerns about administering immunizations in accordance with CDC's guidelines, particularly to children who show high levels of distress while undergoing injections.

Effects on Health Care Providers and Parents

Pediatric vaccinations can be difficult for the providers who administer them (most often nurses). A survey of Canadian nurses conducted by Ives and Melrose (2010) identified four themes relative to nurses' experiences with needle-resistant children. First, the experience of immunizing children who are fearful and resistant of needle injections is frequently stressful for nurses. Second, nurses often experience an ethical dilemma when children are strongly resistant and parents are overly forceful with their children. Third, parent responses occasionally make it difficult and unsafe for nurses to vaccinate children. Finally, insufficient resources are available to help nurses cope with these challenging situations. In the study by Ives and Melrose (2010), children who were kindergarten age and older were reported to be the most challenging for nurses to vaccinate.

The concerns of healthcare professionals regarding pediatric distress related to immunization need to be addressed, given the routine nature of childhood vaccinations. Although estimates of the prevalence of extreme immunization-related distress among preschool children vary from 20 to 56% (Blount et al., 1992; Cassidy et al., 2002; Jacobson et al., 2001), even by the most conservative estimate, over half a million preschool children in the U.S. could be classified as needle resistant. Add to this the number of infants, toddlers, grade-school children, and adolescents who also show needle-resistant behavior, and it is clear that needle-related distress poses a serious challenge for nurses and other healthcare professionals.

Parents, who are often present during their child's immunization, may experience anxiety upon seeing their child in distress. The ability of researchers to use imaging technology may help shed light on physiological changes related to anxiety caregivers may experience when watching their child undergo a medical procedure. A study by Singer and colleagues found that participants watching a loved one experience pain showed activation in the brain regions related

to the emotional experience of pain, as measured by functional magnetic resonance imagery (Singer et al., 2004). Because anxiety is an emotional response, this finding may provide a neurological basis for the fact that many parents tend to experience anxiety while watching their child undergo an immunization.

In addition to changes in brain activity, parents watching their child undergo a medical procedure may experience other physiological changes. In a study by Smith, Shah, Goldman, and Taddio (2007), parents of children under 18 who underwent an intravenous cannulation (IV start) showed significant increases in heart rate and anxiety. Morelius, Theodorsson, and Nelson (2009) found that changes in parents' salivary cortisol levels, a common physiological measure of stress, and anxiety ratings after their 3-month-old infant received an immunization were correlated with infant's crying time. Thus, watching one's child receive an immunization tends to have both emotional and physiological effects on the child's parent or caregiver.

Meyerhoff, Weniger, and Jacobs (2001) measured the intangible costs of pain and emotional distress that infants experience during vaccinations. They found that parents of 1- to 7-month-old infants receiving between one and four injections indicated a willingness to pay (WTP) median value of \$8.14 and a mean value of \$30.28 per injection to eliminate the associated pain and emotional distress. There was great variation in what parents were willing to pay, indicating that parents place widely different values on the level of pain and distress their infants experience. Low-income parents reported a willingness to pay more (though not significantly more) than high-income parents, and parents of younger children indicated a willingness to pay more than parents of older children. Using the more conservative median WTP value of \$8.14 per injection, the authors estimate that the annual cost of injection-related pain and distress in the United States is approximately \$317 million, assuming an annual birth rate of 3.9 million children receiving 10 injections in the first year of life. The annual cost increases to \$1.18 billion when calculated using the mean WTP value. This intangible cost of pain experienced during pediatric immunizations is one absorbed by the children undergoing vaccinations and their parents, and is often a cost that is not taken into consideration when healthcare organizations make recommendations regarding childhood immunizations.

In short, not only can unmanaged procedural pain and anxiety have negative long-term effects on the children who experience it, but healthcare professionals and parents who participate in childhood immunizations are also affected by children's distress during pediatric

medical procedures. For these reasons, it is important to develop and study effective pain- and anxiety-management techniques for procedural support. Recent research has uncovered various physical, pharmacological, psychological, and combined interventions that aim to decrease pediatric pain and distress associated with immunizations.

Overview of Physical, Pharmacological, and Psychological Interventions

In recent years, an interdisciplinary expert panel, the Help ELiminate Pain in KIDS (HELPinKIDS) Team, was formed to develop guidelines for pain management during childhood immunizations. The HELPinKIDS Team offers a “3-P” approach, which includes pharmacological, physical, and psychological treatments. Due to the work of the HELPinKIDS Team (Chambers, Taddio, Uman, & McMurtry, 2009; Shah, Taddio, & Reider, 2009; Taddio et al., 2009; Taddio et al., 2010) and others who have conducted reviews on pain treatments (DeMore & Cohen, 2005; Powers, 1999; Schechter et al., 2007; Uman, Chambers, McGrath, & Kisely, 2008), evidence-based recommendations are available regarding specific interventions to help alleviate pain and distress during immunizations. In a summary of the findings of the HELPinKIDS team, Taddio et al. (2010) utilize the grading system developed by the Canadian Task Force on Preventive Health Care to identify the level of evidence and grade of recommendation for each of the physical, pharmacological, and psychological intervention reviewed (Taddio et al., 2010; U.S. Preventive Services Task Force, 2008). The grading system developed by the Canadian Task force is similar to the criteria used by the U.S. Preventive Services Task Force. In both the Canadian and American systems, a Level A grade means that there is good evidence to recommend a practice, while Level B indicates there is fair evidence to recommend a practice. Clinicians are advised to offer Level A or Level B services to their patients when appropriate. Level C practices are those with conflicting evidence, while Levels D and E, according to the Canadian system, have fair or good evidence against their use, respectively. The American system does not specify a Level E, but defines Level D practices as those having *at least* fair evidence against their use. In both systems, Level I practices are those with insufficient evidence to make a recommendation for or against a practice (Taddio et al., 2010; U.S. Preventive Services Task Force, 2008).

In a review of pharmacological and combined treatments for pediatric immunization-related pain, Shah et al. (2009) identified the use of a topical local anesthetic as a Level A

intervention. In designing the physical components of the injection procedure, Taddio et al. (2009) recommended using the least painful vaccine formulation available where differences between brands exist (Level A). Taddio et al. (2010) recommended *against* positioning the child in the supine position (Level E). In Taddio's 2010 review, other physical interventions which reached Level B criteria included administering the least painful vaccine first when two or more injections are to be given, stroking the skin prior to the injection, and using a rapid intramuscular technique without aspiration during administration (Taddio et al., 2009, 2010). An earlier review by Schechter et al. (2007) proposed that using the deltoid (upper arm) as the injection site, using a needle between 7/8 inches and 1 1/4 inches in length, producing pressure at the injection site, and administering two vaccines at the same time are all Level B physical interventions for alleviating pediatric pain during immunizations.

In addition to pharmacological and physical interventions, recent investigations into psychological interventions have identified several effective treatments for pediatric immunization pain. Uman et al. (2008) provide definitions for various cognitive interventions (cognitive distraction, preparation, and coping self-statements) as well as behavioral interventions (behavioral distraction, breathing exercises, rehearsal, and positive reinforcement). Combined cognitive-behavioral therapy, or CBT, involves the use of at least one cognitive intervention and at least one behavioral intervention (Uman et al., 2008). Schechter et al. (2007) reported that Level A psychological treatments for reducing pain during pediatric immunizations exist, including preparing children for injections well in advance using developmentally-appropriate terminology, using distraction techniques during injections, and having parents maintain a calm, matter-of-fact demeanor without the use of reassurance. Based on the review criteria of Chambers et al (2009), breathing exercises, child-led distraction, nurse-led distraction, and combined cognitive behavioral interventions are recommended practices, while parent coaching and parent-led distraction require further investigation before conclusions can be drawn about their effectiveness at reducing pediatric pain and distress. Taddio and colleagues (2010) offer a different point of view based on their systematic review, which suggests that parent-led distraction or coaching; clinician-led distraction techniques; child-led distraction techniques; slow, deep breathing or blowing; and combined psychological interventions all meet Level B criteria. In the review by Taddio et al. (2010), telling children "it won't hurt," which is an example of reassurance, meets the criteria for a Level D treatment.

Factors Affecting Children's Responses to Medical Procedures

The large bulk of the research on pain responses of children undergoing medical procedures has occurred in the last 30 years. Much of the early research in this area has been explicative in nature, meaning that it has focused on correlations between variables related to pain responses (Blount, Bunke, & Zaff, 2000). More recently, scholars have begun implementing more treatment outcome research on interventions designed to reduce pain and distress in children undergoing medical procedures. Much of this research is based on the Proximal-Distal Model of Child Coping and Distress During Acute Medical Procedures (see Figure 1) proposed by Blount, Bunke, and Zaff (1999, 2000) and based on the work of Varni et al. (1995). This model incorporates the findings of previous explicative research identifying proximal and distal factors related to children's pain responses during medical procedures. Proximal factors are those variables that are immediately present and most likely to directly impact the child's expression of coping or distress behaviors during a medical procedure. Proximal factors include parent and staff behaviors that promote coping behavior or elicit distress behavior. These factors accounted for 38% of the variance in child coping behavior and 55% of the variance in child distress in a study of preschool children receiving immunizations (Frank et al., 1995). Distal factors are less apparent variables that may be related to child distress and/or coping behaviors, yet may be unchangeable. Distal factors include the child's age, gender, characteristics of the child's psychological state, the parent's psychological state, and family dynamics.

The distal variables of child temperament, coping style, age, gender, previous medical experiences, parental presence, parent anxiety, and parent behavior have been associated with pediatric procedure-related pain and anxiety to varying degrees (Blount, Bunke, & Zaff, 1999; 2000). Because much of the research on distal factors related to childhood procedural pain was conducted with hospitalized children undergoing major painful procedures, caution must be taken when generalizing these findings to studies of children undergoing routine, minor, outpatient procedures such as immunizations. The present review of literature is limited to research involving routine medical procedures (immunizations and venipuncture) or lab-induced pain, rather than chronic illness (bone marrow aspirations or lumbar punctures, which have been reported to be extremely painful) or operations that require hospitalization.

Figure 1. Proximal-Distal Model of Coping and Distress during Acute Medical Procedures (from Varni et al., 1995, p. 115)

Child Temperament Factor

Thomas and Chess (1977), two pioneers in the development of temperament theory and research, define temperament as concerning the way in which an individual behaves. They equate temperament to behavior style, stating that the term “refers to the *how* rather than the *what* (abilities and content) or the *why* (motivations) of behavior” (Thomas & Chess, 1997, p. 9). Through years of longitudinal research, Thomas and Chess described nine categories of temperament: activity level, rhythmicity, approach/withdrawal, adaptability, threshold of responsiveness, intensity of reaction, quality of mood, distractibility, and attention span/persistence. They grouped various combinations of scores in these nine categories into three constellations of temperament: easy children (regular, positive approach, high adaptability, mild or moderately intense positive mood), who constituted 40% of the sample they studied; difficult

children (irregular, negative withdrawal, non- or slow-adaptability, intense negative mood), who comprised approximately 10% of their sample; and slow-to-warm-up children (negative mild responses with slow adaptability and less irregularity than difficult children), who made up about 15% of their sample. Thomas and Chess point out that—although not all children fall into one of these constellations and there is wide variability in the degree to which children manifest characteristics of their constellation—these characteristics are observable early in a child's development and remain fairly stable over time (Thomas & Chess, 1977).

In their early writings on temperament, Thomas and Chess (1977) pointed out the relevance of child temperament in health care practices; however, a review of literature on pediatric temperament and pain responses conducted almost 30 years later by Ranger and Campbell-Yeo (2008) identified only eight studies that addressed pain-related temperament. Only one of these articles examined the influence of temperament on the effectiveness of an intervention designed to decrease pediatric procedural pain and distress; the rest of the studies reviewed were descriptive in nature. Only three studies could be found which examined the role of temperament in pain responses of children undergoing immunizations (Bustos, Jaaniste, Salmon, & Champion, 2008; Jacobson et al., 2001; Schechter, Bernstein, Beck, Hart, & Scherzer, 1991).

In a study on temperament conducted by Bustos et al. (2008), parents of 50 infants receiving 6-month immunizations were assigned to receive either information about distraction techniques they could use to help their infant cope with the injections or standard care. They found that, compared to infants classified as having an easy temperament, infants whose parents rated them as having a more difficult temperament cried significantly longer after receiving an immunization and showed significantly more pain based on a facial coding system. Infants who received standard care cried significantly longer than infants whose parents received training. Parents of infants with difficult temperaments, but not parents of children with easy temperaments, used more coping-promoting behaviors after receiving information about coping-promoting techniques to help their infant during the immunization. Greater use of coping-promoting behaviors by parents was, in turn, associated with less crying from their infants. The authors speculated that parents of difficult infants may have been better prepared to implement the coping-promoting techniques they learned because they perceived a greater need for the intervention than did parents of easy infants.

Results from the study by Jacobson et al. (2001) indicate that the associations between temperament and procedural distress observed in infants may not generalize to older children. In their study, significant correlations were found between aspects of temperament (namely, shyness, intensity level, physical sensitivity, and activity level) and observed distress for younger children (15 to 18 months) but not for older children (4 to 6 years). Because temperament is thought to be relatively stable across one's lifespan, the results of the studies by Jacobson et al. indicate that temperament may be a predictor of distress for toddlers but other factors are stronger predictors of distress for preschool children.

Schechter et al. (1991) conducted a study on predictors of pediatric procedural distress in which 65 children who received immunizations at age 5 and their parents served as participants. Prior to the immunization, parents completed questionnaires regarding their child's temperament and typical reactions to medical situations. Parents also completed a survey regarding their parenting style and beliefs about pain. Finally, parents were asked to make a prediction regarding their child's response to the upcoming immunization. Children's procedural pain and distress were evaluated using behavioral and self-report measures. Children who were less adaptable and more rhythmic tended to show more distress. Although children classified as "difficult" also tended to be more distressed, the authors found that parents' predictions of the level of distress a child would display during an immunization were the best indicators of the child's actual distress, and were better predictors than any of the nine subscales of the temperament measure utilized.

In their review of studies on child temperament and medical procedures, Ranger and Campbell-Yeo (2008) discussed the importance of better understanding the impact of temperament on pain in order to provide a better "goodness-of-fit" with regard to temperament when treating children undergoing painful procedures. However, the authors reported that there is currently not enough information to provide evidence-based recommendations on matching treatment to temperament style in clinical practice. While temperament indicators may be useful in choosing interventions for young children, recent studies have identified other modifiable factors-such as coping style-that have a more profound impact on outcomes during medical procedures.

Coping Style Factor

Research on the ways in which children cope with medical procedures has produced mixed results and is complicated by the utilization of varying terminology across studies. In 1964, Byrne described the repression-sensitization (R-S) dimension of coping, which assesses whether a person tries to escape from anxiety by using avoidance (repression) or focuses on the anxiety by approaching or seeking out information (sensitization). The terms “information avoiders,” “deniers,” “avoiders,” and “blunters” have also been used to describe repressors, while “information seekers,” “vigilants,” and “monitors” are other terms used to describe sensitizers (Blount, Davis, Powers, & Roberts, 1991). Repressors have also been said to use the coping style of “avoidance,” while sensitizers use the “approach” coping style (Hubert, Jay, Saltoun, & Hayes, 1988).

In a comparison of various tools for measuring approach and avoidance, Bernard, Cohen, McClellan, and MacLaren (2004) discuss several challenges in measuring and conceptualizing children's coping styles. They point out that approach and avoidance coping styles may not have the same meaning for children that they do for adults. Bernard et al. also summarize research which suggests that for adults, avoidance behavior may be more adaptive for coping with brief pain, such as that experienced during minor medical procedures, while approach behavior may be more optimal for coping with recurrent pain, such as that associated with a chronic illness.

Because optimal styles of coping with medical procedures appear to depend to some extent on developmental factors and to be specific to the type of pain experienced, a closer look at the research on coping styles of children undergoing medical procedures is warranted. Many of the studies on coping style involve children who are hospitalized (for a review, see Blount, Davis, et al., 1991). Being admitted to the hospital may be an anxiety-provoking experience, even when medical procedures are not being administered; therefore, children who are hospitalized may have pain associated with an illness or injury that compounds their procedure-related pain. For these reasons, findings from studies on how hospitalized children cope with procedural pain and anxiety may not generalize when discussing coping styles of children undergoing minor outpatient procedures such as immunization. Only one study that discussed coping styles of children receiving vaccinations could be found (Lim, 2006). Since the vast majority of young, healthy children undergo repeated immunizations, further research on how children cope with immunization-related pain and anxiety is warranted.

Lim (2006) conducted a study of 118 children between the ages of 3 and 11 who received standard care, low-distraction, or high-distraction while undergoing venipuncture. Low distraction consisted of watching a movie on a hand-held DVD player, while high distraction consisted of watching a movie using special goggles into which the movie images were projected and listening to the audio via headphones. Results indicated that children who used an approach coping style tended to experience significantly less pain than children who used an avoidance coping style. Children used the Child Approach-Avoidance Rating Scale-Revised, a picture-based self-report measure, to indicate their preferred coping style. Approximately equal numbers of children reported using an approach coping style, avoidance coping style, and a third mixed coping style.

In discussing coping styles of hospitalized children, Blount, Davis, et al. (1991) pointed out that although sensitizers, or those who use approach coping techniques, appear to cope better with medical procedures than repressors, the avoidance behaviors displayed by repressors may in themselves be indicative of distress. He suggests that active distraction, which has been shown to be an effective coping technique, should be differentiated from avoidance, which may in itself be a distress behavior.

A study by Tsao, Fanurik, and Zeltzer (2003) is relevant here-although it did not involve pain related to childhood immunizations-because it investigated the coping styles of healthy children experiencing minor lab-induced pain (a cold pressor task). In this study, 64 children between the ages of 8 and 10 years who received training in distraction as a way to cope with pain showed higher tolerance to the cold pressor task than children who received sensory-focused training. This difference in tolerance was found regardless of baseline coping style reportedly preferred by the children (distracting versus attending); thus, even children who reported that they preferred using an approach/sensitizing coping style were able to tolerate pain better when they received training in the use of distraction, which was previously considered an avoidance/repressing behavior. Furthermore, a preference for using distraction was found during a similar task in a 2-year follow-up study, indicating that a brief training in the use of distraction as a coping style can have long-term effects on pain tolerance (Tsao, Fanurik, & Zeltzer, 2003).

Although their study was conducted with children undergoing lumbar punctures or bone marrow aspirations, which are reportedly far more painful than routine immunizations, research by Smith et al. (1989) has interesting implications in designing pain- and distress-management

treatments based on children's preferred coping styles. In the study by Smith et al., children undergoing bone marrow aspirations or lumbar punctures showed less distress when they were trained to use a coping style that did not match their stated preference for how they cope. These results support the idea that ensuring that children have a variety of coping styles to choose from may help decrease procedural distress.

Age Factor

Children's definitions of pain are different from those of adults, and tend to follow developmental patterns (Craig, McMahon, Morison, & Zaskow, 1984; Ross & Ross, 1988). Ross and Ross (1988) discuss children's concepts of pain in relation to Piaget's developmental stages. During the sensorimotor phase, which occurs from birth until roughly age 2, children begin to develop verbal descriptors of pain as they develop language skills, and their pain experiences may help them learn to discriminate between self and environment. During the pre-operational stage, which occurs between ages 2 and 7, children are egocentric and may think that others experience their pain as they do. Children of this age may view pain as punishment for something they have done, and have minimal abstract thinking ability. Between the ages of 7 and 12 years, children experience the concrete operational phase, during which they become more aware that others have experiences different from theirs. Children in this phase may think logically but not yet abstractly. Finally, during the formal operations phase, which occurs from age 12 into adulthood, children can engage in abstract thinking and deductive reasoning (Ross & Ross, 1988).

Through a series of interviews with children of various ages, Gaffney and Dunne (1986) observed that children's definitions of pain changed with age in ways that appear to follow Piaget's stages of development. Children in the formal operations stage (11 to 14 years) tended to display a more abstract, generalized understanding of pain with discussion of pain's psychological aspects, compared to younger children, who tended to focus on the concrete, sensory aspects of pain (Gaffney & Dunne, 1986).

Several studies indicate that children under 7 years of age tend to show more pain and distress than older children undergoing immunizations (Broome & Endsley, 1989b), with the children under the age of 2 showing the greatest distress during the needle injection (Jacobsen et al., 2001). In Broome and Endsley's (1989b) study of children between the ages of 3 and 9 years

receiving immunizations, younger children consistently tended to show more distress than older children, although differences could not be compared meaningfully because of different numbers of children in each age group. In the study by Jacobson et al. (2001) that compares the distress of children in two different age groups who underwent immunizations, children between 15 and 18 months experienced more immunization-related distress than 4- to 6-year-olds.

Despite the fact that younger children tend to show more distress behaviors, nurses have reported that children kindergarten aged and older are more difficult to immunize (Ives & Melrose, 2010), possibly because the distress behaviors that older children do show may be more forceful and difficult to control. These results suggest that techniques to manage pain and distress for children should be developmentally appropriate. Although more recent research indicates that other factors may moderate or override effects of age, age is an important variable to consider when measuring procedural pain and distress in young children. Tools for measuring pain and distress, as well as interventions developed for pain and distress management, should be designed based on the developmental age of the children being targeted. Furthermore, studies of children across age groups should consider age as a covariate. Another possible covariate of children's expression of pain and distress is the gender of the child.

Gender Factor

The research literature on gender differences in the immunization-related pain and distress of preschool children shows mixed results. One study indicated that boys and girls aged 4 to 6 did not differ in the amount of pain they reported after an immunization (Lander, Fowler-Kerry, & Hill, 1990). Another study found that 5-year-old girls took longer to calm after receiving an immunization (Schechter et al., 1991). Still another study showed that boys between ages 3 and 6 showed significantly more distress than girls during an immunization (Megel, Houser, & Gleaves, 1998); however, half of the children in this study received a music distraction intervention, which may have been partly responsible for the gender difference in that females tend to respond better than males to music interventions in medical treatment (Standley, 2000). Both of the two aforementioned studies that found differences in the pain and distress of boys and girls during immunizations found differences in behavioral measures of distress, while no gender differences in child-reported pain were found in either of these studies.

A retrospective study conducted by Pate, Blount, Cohen, and Smith (1996) examined gender and other distal factors to determine their relative impact on adults' medical pain, fears, and coping effectiveness. In this study, 147 students between the ages of 17 and 21 who were enrolled in an undergraduate psychology class completed a survey regarding past and present medical experiences. Through the use of a regression model, Pate and colleagues determined the extent to which participants' temperament, age, gender, and childhood medical experiences predicted their medical fear, pain, coping effectiveness, and avoidance of medical care as adults. Although temperament, age, and gender appeared to have some effect on adult responses to medical care, factors related to previous medical experiences, including child pain, child fear, and child coping effectiveness, were the best predictors of adult reactions to medical procedures. For instance, with regard to adults' medical fears, gender and distractibility (an aspect of temperament) accounted for only 3% and 4% of the variance respectively, while fear and pain experienced during childhood medical experiences accounted for 40% of the variance. This finding suggests that variables related to previous medical experiences, particularly the quality and quantity of such experiences, are important distal factors to consider in examining children's ability to cope with future medical experiences.

Quality of Previous Medical Experience Factor

Dahlquist et al. (1986) examined the impact of the quantity and quality of children's previous medical experiences in a study of 79 children between the ages of 3 and 12 who underwent medical examinations and throat cultures. Parents were asked to estimate the number of previous throat cultures, medical appointments, dental appointments, and hospitalizations the child had undergone, as well as the child's reaction to each. Children were then assigned to one of five groups: a sensory information group, a coping skills group, a combined group, an attention control, or a no-treatment control. The three intervention groups received training before the throat culture. The attention control group participated in conversation with the researcher prior to their throat culture, whereas the no-treatment control group received standard care during the time leading up to the throat culture. All children received standard care (without additional coaching or distraction) during their medical examination and throat culture. During the throat culture, children in the attention control group who had previous negative medical experiences demonstrated significantly more behavioral distress than children who had positive

or neutral previous medical experiences. Children who had had negative experiences became more distressed during their throat culture after participating in age-appropriate conversations related to non-procedure related topics. The authors speculate that the conversation put them at ease prior to the throat culture, and they were then surprised by and unprepared for the procedure. In contrast, children with negative previous medical experiences who received sensory information, coping skills training, or a combination of the two showed similar low levels of distress as children who had had positive or neutral previous medical experiences. Although quality of previous medical experience was related to distress in this study, the number of medical procedures a child had previously undergone was not in itself related to child distress behaviors (Dahlquist et al., 1986).

Frank et al. (1995) performed a regression analysis to determine the impact of children's previous medical experiences, parent and staff behaviors, and the mother's trait anxiety (or anxiety that is pervasive rather than situation-specific) on the coping and distress behaviors of 77 children between the ages of 4 and 7 who received immunizations. Parent behaviors (both coping and distress promoting) explained 25% of the variance in child coping behavior, while staff behavior (primarily coping promoting) accounted for an additional 13% of variance. Parent behavior (primarily distress promoting) accounted for 53% of the variance in child distress behaviors, while staff behavior did not contribute significantly to child distress. Children's previous medical experiences accounted for only 4% of the variance in child distress. Mother's trait anxiety did not significantly contribute to either model. Regression models such as this one can help researchers and clinicians understand the complex triadic interaction that occurs during pediatric immunizations. Based on these models, parent and staff behavior have a greater impact on children's behavior than parent trait anxiety or the child's previous medical experiences, with parent behaviors being primarily responsible for the child's coping and distress behaviors. Parent distress-promoting, coping-promoting, and neutral behaviors were significantly correlated with similar behaviors performed by the staff, indicating that parents and staff have the potential to influence each other's behavior during pediatric immunizations, even without specifically being directed to do so (Frank et al., 1995). Numerous studies have investigated the complicated interactions that occur between children, their parents, and staff during medical procedures. Since 4- and 5-year-old children may receive immunizations in school settings without their

parents present, early studies on procedural pain and distress examined whether parental presence had an effect on child distress.

Parental Presence Factor

Shaw and Routh (1982) studied the impact of mother's presence on the behavior of children undergoing immunizations. Their study consisted of similar experiments with two age groups: 20 children between 18 and 26 months (1 to 2 years) of age and 20 children between 59 and 67 months (4 to 5 years) of age. Half of the children in each age group were randomly assigned to have their mother present during their immunization, while mothers of children in the second group left the treatment room when the nurse entered to administer the child's injection. Children's behavior was coded using a modified Frankl Scale, which allows for classification of behavior using global ratings of various degrees of "positive" or "negative" behavior. The authors also used a researcher-developed scale of specific child behaviors, including crying/screaming and playing with toys. Toddlers in the mother-absent group showed significantly more distress, particularly crying, when their mother left, but showed slightly less distress during the actual injection compared to children in the mother-present group. For preschool children, those whose mothers were present showed significantly more distress during and immediately after the injection than children whose mothers were absent. Children whose mothers were present tended to cry during the injection and fuss immediately afterward.

Gonzalez et al. (1989) followed up on the work of Shaw and Routh (1982) and examined the effects of either parent's presence on self-report and physiological aspects of child injection-related distress, in addition to behavioral measures. Participants in the study by Gonzalez et al. were 47 children between the ages of 13 months and 7 years of age who underwent immunizations. Heart rate was recorded throughout the procedure using an electrocardiogram. Younger children in this study (under the age of 4) were analyzed separately from older children. In accordance with the results of Shaw and Routh's (1982) study, children whose parent was absent showed significantly more distress, particularly crying, requesting emotional support, and muscular rigidity, when their parent left the room. In addition, children whose mothers were absent had significantly higher heart rates when their parents left compared to children whose parents were present. During the actual injection, older children whose parents were present showed significantly more behavioral distress, particularly crying, compared to children whose

parents were absent. Although the younger children had the same tendency during the injections, the group differences did not reach statistical significance for younger children. Although heart rate was highly correlated with distress scores ($r = .64$) during injections, heart rate differences between the mother-present and mother-absent groups were not significant. The results of the studies by Shaw and Routh (1982) and Gonzalez et al. (1989) are inconclusive, and indicate that parent presence may sometimes, but not always, increase children's procedural distress.

In the study by Gonzalez et al. (1989), the majority of older children (86%) who were asked their preference reported that they would rather have their parent present during future injections. This preference regarding parental presence supports the findings of an earlier study by Ross and Ross (1984) in which the authors reported that the majority of children would like to have a parent present during medical procedures, although the children were unable to tell what parents could do to be helpful in such situations. Gross et al. (1983) suggest that children associate their parent's presence with comfort, and that crying and distress behaviors are a signal to the parent of the child's need for comfort. Yet during medical procedures, a parent's power to help their child is diminished, which causes an increase in the child's distress behaviors because their usual level of crying is not obtaining the desired result.

More recent studies have examined the effects of several moderating variables in order to help make sense of the equivocal results of earlier studies on parental presence during medical procedures. Vervoort et al. (2008) studied the effects of parental presences on children's pain behavior, as measured by facial expression, during laboratory induced pressure pain. Children between the ages of 9 and 15 ($N = 84$) completed a questionnaire designed to measure catastrophic thinking about pain. They were later randomly assigned to experience pressure pain while being observed by either one of their parents or a stranger. Children who frequently had catastrophic thoughts about pain showed equal expressions of pain regardless of who was observing, while children with infrequent catastrophic thoughts about pain showed significantly more pain while their parent was observing than while a stranger was observing. The authors suggest that parental presence is a discriminating factor in the expression of pain for some children, but not for those who have frequent catastrophic thoughts about pain.

In addition to children's frequency of catastrophic thoughts, parent characteristics appear to play a moderating role in determining whether children express more or less pain when their parents are present. In a 1989 study by Fishman, Cook, Hammock, Gregory, and Thomas (as

cited in Blount, Davis, et al., 1991), 39 mothers of children undergoing dental treatment were classified as either “high-fear” or “low-fear.” Half of the mothers in each group were assigned to be present during their child's dental procedure while the other half were to be absent. Children whose mothers were highly fearful showed more distress when their mother was present, while children of mothers in the low-fear group showed more distress when their mother was absent. The findings of this study suggest that the parent's fear has a strong effect on their child's distress during medical procedures. It is possible that parental fear is linked to child catastrophizing. Further study is needed to examine whether levels of parental fear and child catastrophizing are associated and the degree to which each one predicts whether children express more pain when their parents are present. Parental fear may be related to parental state anxiety, which has been the subject of several studies on parents of children undergoing medical procedures.

Parental Anxiety and Behavior Factors

Higher levels of parental state anxiety have been associated with higher levels of pain, anxiety, and distress in children undergoing anesthesia induction prior to surgery (Davidson et al., 2006), intravenous cannulation in the emergency department (Smith, Shah, Goldman, & Taddio, 2007), and immunization (Broome & Endsley, 1989). In the study of children undergoing intravenous cannulation conducted by Smith et al. (2007), caregivers' anxiety and distress-promoting behavior predicted 34% of the variability in child-reported pain. Caregiver distress-promoting behavior predicted 31% of the variability in child distress. In addition, 51% of the variability in child distress during recovery was predicted by caregiver heart rate and anxiety during the procedure and caregiver distress-promoting behavior after the procedure (Smith et al., 2007). These results support the findings of Frank et al. (1995) regarding the importance of parent behavior in predicting child distress, and demonstrate that self-report and physiological measures of parent anxiety are related to measures of observable distress-promoting behaviors. Findings from another study, however, support the relationship between child behavior and parent behavior during medical procedures, but not necessarily the relationship between child behavior and maternal anxiety (Broome & Endsley, 1989a).

Broome and Endsley (1989a) examined associations between the self-reported anxiety of mothers, mothers' ratings of their children's anxiety, and the observed behavior of 83 mother-child dyads with preschool children who underwent immunizations. Parents' ratings of their own

anxiety were moderately correlated with their ratings of their children's anxiety. In addition, parents' ratings of their children's anxiety were slightly correlated with children's distress behavior, although parent anxiety and child behavior were not correlated. During their child's immunization, the majority of mothers used reassurance, now shown to be a distress-promoting parental behavior during medical procedures. Among mothers who were highly reassuring with their children, approximately half of their children showed high distress. Taken together, results of the studies by Smith et al. (2007) and Broome and Endsley (1989a) indicate that the effects of parental anxiety on children's pain perceptions and behavior during immunizations may be moderated by parent behaviors, which may be considered coping-promoting or distress-promoting. Parent behavior leading up to a medical procedure, even before arriving at the doctor's office or hospital, may affect child behavior.

In another study by Broome and Endsley (1989b), they examined the effects of maternal presence and child-rearing style on the distress of 138 children between the ages of 3 and 9 who underwent immunizations. Children were randomly assigned to either have their mother present or absent during an initial interview and to either have their mother present or absent during the injection. There was no significant difference in child distress during the immunization based on mother's presence. However, children whose mothers were present during the interview were significantly more distressed than children whose mothers were absent. Regardless of whether the parent was present, children whose parents were classified as authoritative (having high control and high warmth) showed significantly less distress during the immunization compared to children whose parents were classified as authoritarian (high control and low warmth), permissive (low control and high warmth), or non-responsive (low control and low warmth). The authors suggest that perhaps authoritative parents told their children what to expect during the immunization and prepared them to cope with the procedure, although further research is needed to investigate this claim.

Findings from the study by Jacobson et al. (2001) support the idea that parents who prepare their preschool children for immunizations can help decrease their children's distress. In their study, 4- to 6-year-old children who were not told about their vaccination in advance and who had shown distress at a recent medical visit showed significantly more distress during immunizations. In addition, children whose parents reported that they typically showed distress during vaccinations or predicted that their child would show distress tended to display more

distress. Blount et al. (2009) recommend the provision of some, but not extensive, developmentally-appropriate information to preschool children one week to one day in advance of undergoing a medical procedure. This type of behavior is difficult to measure through observation, so researchers must rely on parents' reports of whether or not they discussed the upcoming vaccination in advance with their child or helped them prepare for it.

Studies have shown challenges of using self-report measures to ascertain parents' procedure-related behaviors. A study by Cohen, Manimala, and Blount (2000) questioned parents of 55 children between the ages of 4 and 6 regarding how they typically interact with their child when he or she undergoes painful medical procedures. Children and parents were then videotaped while the child received an immunization, and behaviors were coded as coping-promoting or distress-promoting. Parents tended to overestimate how often they engaged in therapeutic behavior with their child. There was no relationship between parents' reports of behavior during the vaccination and their actual behavior. Parent behaviors were significantly related to child distress behaviors. Results of this study suggest that observing parent behavior during immunizations is important when researching distress-management techniques for children receiving vaccinations, as parent behaviors are associated with child distress.

Certain types of parent behavior have been identified as distress-promoting, largely due to the research of Blount and colleagues, who performed time lag analyses on videos of children undergoing medical procedures to determine which adult behaviors tended to precede child distress and coping behaviors (Blount et al., 1989). Parent behaviors were classified into three broad categories (coping-promoting, distress-promoting, and neutral) with multiple subcategories. Distress-promoting behaviors included making reassuring comments, apologizing, making empathic statements, giving control to the child, and criticizing. Coping-promoting behaviors included non-procedural talk or humor to the child and commands to use coping strategies. Adult neutral behaviors were behaviors that were neither distress- nor coping-promoting. Neutral behaviors included humor or non-procedural talk directed toward adults, procedural talk to adults, commands to engage in procedural activities, notice of the procedure to come, behavioral commands to the child, checking the child's status, child's general condition talk, child's general status comments, praise, and commands for managing the child's behavior (Blount et al., 1989). Blount and colleagues developed an assessment called the Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R), which describes and classifies child,

parent, and staff behavior using the categories and sub-categories identified through their research (Blount et al., 1989). In summary, results of many studies report a high association between adult distress-promoting behaviors and child distress behaviors, as well as between adult coping-promoting behaviors and child coping behaviors (Blount et al., 1989; Blount, Landolf, et al., 1991; Blount, Sturges, & Powers, 1990; Frank et al., 1995). Further research indicates that children may respond differently to various types of parent and staff behavior during different phases in the medical procedure (Blount et al., 1990; Blount et al., 2009), and that children benefit from having a variety of coping skills to choose from, depending on the phase of the medical procedure (Blount et al., 2009).

Phases of Medical Procedures

Researchers have classified phases of medical procedures in various ways, but they all generally describe at least three phases corresponding with before, during, and after the procedure. Blount et al. (2009) divide the period before the medical procedure into Phase One, the preparatory phase, which may occur in the weeks or days leading up to the procedure, and Phase Two, the anticipatory phase, which occurs immediately before the procedure. After Phase Three (the procedure), Blount et al. (2009) describe two phases: Phase Four, the recovery phase, which occurs immediately post-procedure, and Phase Five, the completion phase, which may occur minutes to hours after the procedure.

Blount and colleagues have published evidence-based recommendations for psychological interventions during specific phases of medical procedures to decrease pediatric distress (Blount et al., 1990; Blount et al., 2009). During Phase One, the preparatory phase, older children (over the age of 5 years) should be provided with information about the procedure and given opportunities to ask questions and practice coping techniques. Younger children may benefit from receiving less information during this phase, and information should be delivered in a way that is developmentally appropriate for their level of understanding. During Phase Two, the anticipatory phase, information giving should decrease and the focus should be on distraction and non-procedural talk. During Phase Three, the procedure, distraction should continue and parents and/or staff should coach the child to use coping techniques such as deep breathing. During Phase Four, the recovery phase, the focus should be on allowing the child to recover and providing distraction or resuming normal activities as appropriate. Finally, during Phase Five,

the completion phase, the focus should be on returning to normal, everyday activities (Blount et al., 2009).

These evidence-based, phase-specific recommendations for helping children cope with medical procedures highlight the importance of the words and behavior of parents and staff in meeting the ever-changing needs of children during potentially painful, anxiety-provoking experiences.

Cognitive-Behavioral Treatments for Pediatric Procedural Pain and Distress

As previously mentioned, research by Frank et al. (1995) showed that parent and nurse behaviors contributed to child distress and coping to a greater degree than other factors, paving the way for outcome research on the use of cognitive-behavioral techniques designed to modify parent, nurse, and child behaviors during medical procedures. The effects of cognitive-behavioral interventions on child pain and distress during medical procedures have been examined in numerous studies and several reviews (Chambers et al., 2009; DeMore & Cohen, 2005; Powers, 1999; Uman et al., 2008). Cognitive-behavioral treatments-including breathing exercises, relaxation, distraction, teaching cognitive coping skills, filmed modeling, reinforcement or incentive, behavioral rehearsal, and active coaching-have been considered well-established treatments in alleviating pediatric procedure-related pain for over a decade (Powers, 1999). Recent reviews have examined the relative benefits of various types of cognitive-behavioral treatment for needle-related procedures (Uman et al., 2008) and have sought to determine which treatments are the most effective for children undergoing immunizations (Chambers et al., 2009; DeMore & Cohen, 2005). In a critical review by DeMore and Cohen (2005), the authors examined research on the use of distraction interventions and concluded that distraction is an effective treatment for alleviating child immunization-related distress and pain. Another systematic review examining randomized controlled studies of psychological interventions for pediatric needle-related pain noted that distraction, combined cognitive-behavioral interventions, and hypnosis had the largest effect sizes compared to control conditions (Uman, Chambers, McGrath, & Kisely, 2008).

In the most recent review of pain and distress management treatments for children undergoing immunizations, cognitive-behavioral interventions were classified as breathing exercises, distraction (child-led, nurse-led, or parent-led), suggestion, and combined cognitive-

behavioral interventions, which included two or more of the aforementioned treatments. Of these cognitive-behavioral treatments, breathing exercises, child-directed distraction, nurse-led distraction, and combined cognitive-behavioral interventions were found to be effective treatments for decreasing pain and distress during child immunizations (Chambers et al., 2009). Specific studies pertaining to preschool children (between the ages of 3 and 6) undergoing immunizations are discussed here in detail, although each of the systematic reviews mentioned included studies of both older and younger children.

Breathing Exercise Interventions

Various types of age-appropriate breathing exercises have been examined in studies of children undergoing immunizations, including pretending to blow the pain away, using a party blower or pinwheel, and blowing bubbles (Bowen & Dammeyer, 1999; French et al., 1994; Krauss, 1996; Manimala, Cohen, & Blount, 2000; Sparks, 2001). In a study by French and colleagues (1994) of 149 children between the ages of 4 and 7 undergoing immunizations, those who were taught to blow out air while pretending to blow the pain away during immunizations showed significantly fewer pain behaviors compared to children in a standard care control group.

In a study by Bowen and Dammeyer (1999), 80 children between the ages of 3 and 6 undergoing immunizations were assigned to one of three groups: a party blower group, a pinwheel group, and a standard care control group. Children in the two treatment groups were instructed by the nurse to either blow on a party blower or a pinwheel during their injection. Children in the party blower condition reported significantly less distress than children in the other two groups, although parent and nurse ratings of the effectiveness of the three conditions did not vary significantly.

Bowen and Dammeyer (1999) offer a five-pronged rationale for the use of toys such as pinwheels and party blowers in distracting preschool children undergoing immunizations. Their rationale suggests the following: 1. toys are concrete and therefore more appealing to children in the pre-operational stage of development than abstract instructions or imagery; 2. children have positive associations of playing with toys, which will compete with the distress of the procedure; 3. playing with a toy is incompatible with distress behavior; 4. when children play with toys, their parents tend to be less distressed, which may subsequently reduce the child's distress; and 5.

children who are distracted by playing with a toy may not even notice that an injection is taking place, as the procedure tends to be brief.

Krauss (1996) studied the effects of a videotaped modeling treatment on the distress of 50 children between the ages of 4 and 7 who underwent immunizations. Behavioral distress was measured using the Child Medical Distress Scale. Children in the treatment group watched a videotape with their parent that showed the child how to use a party blower to cope with the immunizations they were to receive. All children received a party blower to bring with them when they went into the treatment room for their injection, so that the nurses who administered the immunizations were blind as to the child's group assignment. Boys in Krauss' study did not show a difference due to treatment, but girls in the experimental group showed significantly less distress than girls in the control group. Krauss speculated that the female model in the videotapes may have influenced the coping abilities of the girls more than the boys.

In a study by Manimala, Cohen, and Blount (2000), parents of 82 children between the ages of 3 and 5 who were to receive immunizations were randomly assigned to receive either training in reassuring their child, training in distracting their child, or received no training (standard care control). Parents who received distraction training were given several ideas of ways to distract their child prior to the procedure (coloring, putting together a puzzle, talking about non-medical topics, etc.) and shown how to coach their child to take deep breaths using a party blower during the injection. Children whose parents received distraction training reported experiencing significantly less fear compared to children in the control group. Parents who received training in reassurance had greater expectations of being able to help their child during the injection, yet after the procedure they reported being significantly more upset than usual when compared to parents in the control and distraction groups. Children in the reassurance group demonstrated significantly more verbal fear and verbal pain than children in the other groups, and were three times as likely as children in the distraction group to be restrained.

Sparks (2001) conducted a study on two types of distraction with 105 children between the ages of 4 and 6 who underwent immunizations. Children were randomly assigned to receive either touch, bubble blowing, or standard care during their immunization. Children in the intervention groups reported significantly less pain than children in the control group, although differences between the touch and bubble blowing conditions were not significant. Based on the results of the aforementioned studies on the use of breathing exercises with children undergoing

immunizations, teaching children to use breathing exercises, either on their own or with the use of an age-appropriate toy such as a party blower, a pinwheel, or bubbles, can reduce both perception of pain and expression of distress behaviors.

Distraction Interventions

Child-directed. Since training and coaching children in the use of breathing exercises takes time, other studies have investigated the use of child-directed distraction interventions which do not utilize parent or nurse coaches to help manage the pain and distress of children receiving vaccinations. Of these studies, three utilized recorded music as distraction (Fowler-Kerry & Lander, 1987; Megel, Houser, & Gleaves, 1998; Noguchi, 2006). Fowler-Kerry and Lander (1987) studied the effects of suggestion versus music distraction on self-reported pain of 200 children between the ages of 4 and 6 receiving immunization. Children were randomly assigned to receive music distraction, music distraction plus suggestion, suggestion, or standard care during their immunization. The music used was recorded music delivered via headphones. Children in the suggestion group were told that the procedure would hurt less. Children in the music distraction group reported significantly less pain than children in the suggestion group. In a study by Megel et al. (1998), 99 children between the ages of 3 and 6 were assigned to listen to recorded lullabies or to receive standard care while undergoing an immunization. Although no differences were found in heart rate, blood pressure, or self-reported pain, children in the music group showed significantly less behavioral distress.

Unlike the two previous studies on the use of recorded music as child-directed distraction during pediatric immunizations, Noguchi's 2006 study used an interactive recorded music intervention. Noguchi (2006) studied 62 children between the ages of 4 and 6 who underwent immunizations. Children were randomly assigned to receive either a focused-attention listening task with music, a comparable listening task using spoken words instead of music, or standard care. The researcher, who was a board-certified music therapist, trained children in using the focused-attention listening task (with or without music) prior to the immunization. During the immunization, the researcher remained with children in the two intervention groups to prompt them to engage in the focused-listening task. Children in the music group showed less distressed behavior and reported less pain than patients in the non-music groups, although the differences were not significant. Parent and staff behavior may have had an impact on child distress

behavior. Although adult behavior was not examined as a variable, the author mentions that part of the protocol for keeping the child focused during the listening task was to provide reassurance, which may have been distressing. Regardless of this potential confounding variable, children in the music group tended to show less distress during the injection phase, particularly children who received four or more shots.

In another study of the use of child-directed distraction during immunizations, Cassidy and colleagues (2002) studied the effects of watching TV on the distress of 5-year-olds ($N = 62$) undergoing an immunization. Participants were randomly assigned to watch an age-appropriate musical cartoon (distraction) or receive standard care with a blank television screen (control). There were no significant differences between groups on any of the measures of pain, anxiety, or distress. Children who looked at the TV rather than the needle tended to demonstrate fewer pain behaviors, yet children in the distraction group were not more likely to look at the TV compared to children in the control group. This may indicate a need for additional time spent teaching children coping skills (such as looking at the TV) prior to immunizations. It may also be helpful to have adults coach children in the use of distraction *during* immunizations.

Parent-led. Two studies could be found in which parents were trained to coach their preschool children during immunizations, with somewhat contradictory results (Gonzalez, Routh, & Armstrong, 1993; O'Laughlin & Ridley-Johnson, 1995). Gonzalez, Routh, and Armstrong (1993) assigned mothers of 42 children between the ages of 3 and 7 to receive training in the use of distraction (non-procedural talk with the child), reassurance, or a minimal-treatment control prior to their child's immunization. During immunizations, children whose mothers had been trained to use distraction techniques showed significantly less distress, particularly crying, than children of mothers in the other two conditions. Children of mothers in the reassurance group did not differ from children of control mothers. Findings of this study support the use of training interventions that teach parents how to distract their children during immunizations.

O'Laughlin and Ridley-Johnson (1995) conducted a study on the effects of the level of the mother's involvement on the behavioral distress of children between the ages of 4 and 6 undergoing immunizations. Mothers were randomly assigned to one of four groups: mother absent, mother present and watching, mother present and involved as usual, or mother present

and acting as a trained coach. Prior to their child's immunization, mothers who received training in coaching their child were asked to read a handout with directions about how to distract their child during the shot. Five suggested methods of distraction were given: counting, singing, pointing out an object in the room, speaking a rhyme or poem out loud, or another specified method of the parent's choice. Mothers and their children were asked to decide together on one method of distraction to use during the injection. Children whose mothers were present and watched the procedure displayed significantly less behavioral distress than children whose mothers were involved in the procedure as usual, which often meant helping hold the child. Although not significantly different, children whose mothers coached them and children whose mothers were absent showed less distressed behavior than children of mothers who were involved as usual. The authors suggest that the absence of an effect based on the distraction coaching intervention is due to ineffective implementation of distraction. Although parent distress-promoting behaviors were not measured in this study, it is possible that children of mothers who watched the procedure showed less distress than children in other conditions because asking the parent to watch the procedure decreased their use of distress-promoting behaviors such as reassurance.

Taken together, these studies suggest that when correctly implemented, training parents to use distraction techniques can help children during immunizations. However, the lack of a significant difference in child distress for children of mothers who received distraction training in the study by O'Laughlin and Ridley-Johnson (1995) underscores the difficulty of effectively and efficiently training parents in distraction training. Training nurses to coach children in the use of distraction techniques during medical procedures is another approach to decreasing distress during immunizations that has been the topic of several studies.

Nurse-led. Although several studies have investigated the effects of training nurses to coach children during immunizations (see Chambers et al., 2009), only one of the studies involved preschool children (Cohen, Blount, & Panopoulos, 1997). Cohen et al. (1997) studied the effects of nurse coaching with and without parent/child training to engage children in a distraction intervention during immunizations. Participants were 92 children between the ages of 4 and 6 and one of their parents. Parent-child dyads were assigned to one of three groups: a standard-care control group, a nurse-led distraction group, or a nurse and parent-led distraction

group. The distraction intervention involved watching an animated cartoon. Children in the standard care control group displayed significantly more distress behaviors and fewer coping behaviors than children in the two intervention groups, which did not differ significantly from each other. Children in the intervention groups also required significantly less restraint. Parents and nurses in both intervention groups displayed significantly more coping-promoting and fewer distress-promoting behaviors compared to the standard care control group. Results of this study indicate that training nurses to coach children during immunizations, which is more efficient than training parents, may be equally as effective.

Combined Cognitive-Behavioral Interventions

Several studies have examined combinations of various cognitive-behavioral interventions to improve outcomes for children undergoing immunizations, including the aforementioned studies by Cohen et al. (1997), which combined nurse coaching with parent and child training, and Fowler-Kerry and Lander (1987), which combined music as distraction and suggestion. Cohen et al. (2002) studied the effects of training children to use deep breathing and positive self-talk prior to undergoing immunizations. Sixty-one children between the ages of 3 and 7 were randomly assigned to receive training in coping skills or standard care. Prior to their vaccination, children in the coping skills training group watched a brief video through which they were taught “snake breathing,” or breathing while making a hissing sound. They were also encouraged to make positive statements such as “I am cool and calm.” After watching a gender-matched model perform these two skills, children were asked to demonstrate them at least three times prior to completing the training. Child training did not significantly contribute to child coping or distress behavior. Nurse behaviors were the strongest predictors of child coping behaviors, while parent behaviors were the strongest predictors of child distress behaviors. Parent distress-promoting behavior was significantly correlated with child ratings of pain and distress. Parent distress was the strongest predictor of children's fear of future shots. Results of this study indicate that training children to use coping skills during a vaccination is not sufficient in decreasing distress behaviors or promoting coping behaviors if nurses and parents are not trained to use coping-promoting behaviors (e.g. encouraging deep breathing).

Blount et al. (1992) studied the effects of teaching phase-specific coping techniques (distraction prior to the immunization and using party blowers to encourage deep breathing

during the injection) to parents on the behavioral distress of 60 children between the ages of 3 and 7 who underwent injections. During their children's injections, parents who received training in coping techniques used significantly more commands to engage in coping strategies and fewer distress-promoting behaviors than untrained parents. Children whose parents received training used significantly more deep breathing when using the party blowers and fewer distress behaviors. Children whose parents underwent training were also rated as using more approach behaviors and required restraint less often than children in the control group. When working with trained families, staff used more commands to use coping strategies than they did when working with untrained families. These results indicate that coping style is something that can be modified and may be considered a state rather than a trait. In addition, training in various coping skills that are specific to the phase of the medical procedure (i.e., preparation, procedure, or recovery) may be an effective technique in decreasing procedural distress in children.

In summary, current evidence suggests that those designing effective cognitive-behavioral treatments for alleviating immunization-related pain and distress in preschool children should consider having the nurse or another trained member of the healthcare staff help coach the child to use a variety of different coping strategies during different phases of the procedure. Effective coping strategies include age-appropriate preparation for the immunization, teaching the child to use breathing exercises, and using music, movies, toys, or non-procedural talk to provide distraction during immunizations. Although all of these recommendations represent evidence-based best practices, training nurses to use a combination of cognitive-behavioral techniques and varying their use during different phases of the immunization may be time consuming. In addition, it may not be possible for a nurse to remain with the child to teach breathing exercises or provide non-procedural talk prior to the procedure, given the other tasks related to the child's doctor visit that he or she may be completing (e.g. conducting a urinalysis, preparing the syringes for administration of the vaccinations, and checking in other patients). During the immunization, nurses not only have the responsibility of safely and accurately administering the injections but also frequently restraining the child, which can be a difficult task when working with needle-resistant preschool children. Having another healthcare professional who would focus solely on coaching the child during each phase of the immunization is a delivery model that has potential to reduce pediatric pain and distress related to the vaccination process. Board-certified music therapists would be highly qualified to fill this role, given their

training in the use of cognitive-behavioral treatment and their ability to use live music as distraction.

The use of live, interactive music therapy conducted by a board-certified music therapist has been shown to be of greater benefit to patients in medical settings (Standley, 2000) and during medical procedures (Walworth, 2003). Recent research on the use of live music interventions conducted by board-certified music therapists indicates that this type of procedural support has potential benefits for children, their parents, and staff conducting medical procedures, including pediatric immunizations.

Procedural Support Music Therapy Interventions

In a meta-analysis on music research with pediatric patients, Standley and Whipple (2003) found an overall effect size of .64 for children younger than 21 years of age, indicating that music therapy generally has a positive and significant effect on the medical treatment of pediatric patients. Pain and anxiety reduction during pediatric procedures were two objectives documented in the quantitative research literature included in the meta-analysis. Live music therapy was shown to alleviate pediatric pain, anxiety, distress, and fear during both invasive and non-invasive procedures (Barton, 2008; Callahan, 2004; Malone, 1996; Walworth, 2003; Whitehead-Pleaux, Baryza, & Sheridan, 2006). In a systematic review of randomized, controlled trials involving the use of music therapy during pediatric medical procedures, a significant reduction in pain and anxiety was found for participants who received music therapy (Klassen, Liang, Tjosvold, Klassen, & Hartling, 2008). Studies were classified as active if a music therapist engaged the child in a live music interaction, while passive music therapy involved the use of recorded music. Only 5 out of the 19 studies reviewed included the use of active music therapy. Klassen et al. (2008) conducted a meta-analysis on a subset of the trials reviewed, including two studies on active music therapy and seven studies on passive music therapy. Significant effects were found for passive but not active music therapy compared to a control condition, although further analysis revealed a therapist effect in one of the studies of active music therapy. These results highlight the need for more research on the use of active music therapy during pediatric medical procedures, with particular emphasis on the techniques used by the music therapist.

In a recent article, Ghetti (2011) conducted a philosophical inquiry on approaches to the provision of music therapy as procedural support and discussed the theories behind such approaches. Ghetti provides a definition of music therapy as procedural support, stating that it is “the use of music and aspects of the therapeutic relationship to promote healthy coping and decrease distress in individuals undergoing medical procedures” (Ghetti, 2011, p. 4). In addition to providing a clear definition of music therapy as procedural support, Ghetti describes three approaches to music therapy that have been discussed in the research literature: musical alternate engagement, integration, and music-assisted relaxation. Musical alternate engagement (MAE) is often confused with distraction. Unlike distraction, which seeks to remove the child's focus from the procedure entirely, MAE engages the patient in music while supporting their need to attend to the procedure at times. Integration seeks to help the child focus on their bodily sensations, including pain, and uses the music to express their pain. During music-assisted relaxation, the music therapist may use deep breathing, progressive muscle relaxation, and imagery to help decrease pain and anxiety. Ghetti's article helps define terminology and presents a rationale for further research on the efficacy of specific music therapy techniques. The terminology used by Ghetti to describe music therapy approaches has not been used widely in studies of procedural support music therapy to date. For this reason, the original terminology used to describe the music therapy intervention in each study is reported here, rather than attempting to define each study in Ghetti's terms. However, it should be stated that none of the studies using an experimental or quasi-experimental design to study the efficacy of music therapy as procedural support investigated the use of the integration approach (focusing the child's attention on their pain and physical sensations). Further research on integration is necessary before adopting this approach in clinical music therapy practice.

Callaham (2004) found that pediatric patients undergoing hemodialysis who received live music therapy reported significantly less pain and anxiety, and showed fewer distressed behaviors during all phases of hemodialysis. Whitehead-Pleaux, Baryza, and Sheridan (2006) found that pediatric burn patients who received live music during a donor site dressing change reported decreased fear over the course of the procedure, while patients who did not receive music reported increased fear. Children who received music therapy also showed significantly less anxiety as measured by a decrease in heart rate when compared to the control group, which showed a trend towards increased heart rate during the procedure.

A comprehensive music therapy pediatric procedural support clinical program was developed by Walworth (2003) to meet a hospital-wide initiative to decrease the amount of sedation administered to pediatric patients during procedures including computed axial tomography (CT) scans, echocardiograms, electroencephalograms (EEG), and intravenous (IV) starts. Walworth (2005) published a cost-benefit analysis of procedural support music therapy in pediatric healthcare settings and concluded that music therapy can decrease the need for sedation during pediatric procedures, such as CT scans and echocardiograms; reduce procedural times; and decrease the number of staff members needed for the procedures. Live music therapy was highly cost effective and actually reduced medical costs by a greater amount than the added expense of the board-certified music therapist. In Walworth's report, the music therapy pediatric procedural support program had a 95% success rate for completing non-invasive and invasive pediatric procedures without sedation.

A study by Barton (2008) examined the effects of live music therapy on children between the ages of 5 and 12 ($N = 40$) undergoing invasive and non-invasive procedures in an inpatient hospital and emergency center. Children randomly assigned to the live music therapy condition received live music as distraction during their procedure. The children also received coaching from the music therapist in the use of breathing exercises set to music, using familiar, patient-preferred songs as well as original songs composed by the music therapist. Children in the control group received standard care. Results indicated that children in the music therapy condition showed a trend toward lower self-report anxiety and pain ratings, although the difference between groups did not reach the level of significance. Children in the control group displayed more than three times as many distress behaviors as children in the music therapy group, although the ratio of distress behaviors per minute was not calculated and this comparison was not analyzed statistically. The lack of significant difference between self-report measures may be due in part to a small sample and a wide variety of procedures (CT scans, IV starts, laceration repairs, incision and draining, foreign object removal, and breathing treatments) in two different hospital settings (inpatient hospital and emergency center). In Barton's study, ninety-four percent of parents who completed patient satisfaction surveys felt that their child benefited from receiving music therapy services during their emergency procedure, while 100% of parents said that their child enjoyed music therapy, that music therapy improved their satisfaction with their hospital experience, and that they would like to receive music therapy services during

future procedures. The positive comments from the parents and the trend toward decreased pain, anxiety, and distress for children in the live music therapy group warrant further study in this area.

A study by Pfaff, Smith, and Gowan (1989) examined the distress of six children between the ages of 6 and 15 years who received music-assisted relaxation during bone marrow aspirations. Using a within-subjects design, Pfaff et al. recorded a baseline procedure for each participant and then provided music-assisted relaxation during a subsequent bone marrow aspiration. During the music-assisted relaxation condition, a music therapist coached each participant in relaxation exercises while the child listened to a recording of music they had previously selected from several options offered by the music therapist. Pfaff et al. (1989) found that children tended to have less anticipatory fear, less actual fear and pain, and less anticipatory behavioral distress when they received music-assisted relaxation compared to a baseline procedure, although differences were not significant. The lack of significant differences may be attributable to the small sample size and the wide range of ages and numbers of previous medical experiences inherent in the sample.

In a 1996 study of 40 hospitalized children under the age of 7 years who received various types of needle insertions, including intravenous starts, venipuncture, injections, and infant heel sticks, children showed similar levels of distress regardless of the type of needle insertion (Malone, 1996). In this study, children were randomly assigned to either a music therapy intervention group or a standard care control group. During the music therapy intervention, the music therapist provided live music throughout the procedure and coached the child to engage in breathing exercises during the needle insertion phase. In addition to other child-preferred songs, Malone utilized an original song called “Sparky the Dragon” with children in the intervention group. This song incorporated cues for children to take a deep breath during the needle insertion phase. This type of preparation for the procedure is consistent with the type of age-appropriate preparation using minimal information for young children described by Blount et al. (2009). Results indicated that children who received live music therapy as a distraction while undergoing needle insertions showed significantly less behavioral distress than patients who received standard care.

Summary

As the aforementioned studies suggest, there is a growing body of literature that supports the use of music therapy as procedural support for hospitalized children. Music has also been used to assist with routine immunizations in outpatient settings. However, the research in this area has utilized recorded music rather than live music therapy, and music treatments have either been child-directed or implemented by healthcare staff other than music therapists (e.g. nurses). As was mentioned earlier, children who listened to recorded music during pediatric immunizations had less behavioral distress (Megel et al., 1998) and reported less pain (Fowler-Kerry & Lander, 1987).

Rationale for the Present Study

The one study that this researcher was able to find regarding procedural support music therapy implemented by a music therapist during immunizations utilized recorded music and did not address parent/staff behavior (Noguchi, 2006). The effects of live music therapy treatment combined with cognitive-behavioral interventions on coping and distress behaviors in children undergoing routine immunizations have not yet been examined in the research literature. In addition, no music therapy research could be found which included parent and nurse distress- and coping-promoting behaviors as dependent variables. Given the effectiveness of live music therapy and cognitive-behavioral interventions during other pediatric procedures (Barton, 2008; Malone, 1996; Walworth, 2003), further research on the effects of live music therapy during pediatric immunizations is warranted.

Purpose Statement

The purpose of this study was to examine the effects of a live cognitive-behavioral music therapy intervention on distress/coping behaviors and lengths of treatment phases for preschool children who underwent routine immunizations. Parents' and nurses' coping/distress-promoting behaviors and parents' ratings of their children's distress and pain were also measured to see if the music therapy treatment affected these outcomes. The following research questions were investigated:

Research Questions

1. Are there differences in the rates or proportions of coping behaviors or distress behaviors displayed by young children undergoing immunizations when receiving music therapy versus standard care?

H₀: There will be no significant differences in the rates and proportions of coping behaviors displayed by young children undergoing immunizations who receive music therapy and those who receive standard care.

H₁: Children who receive music therapy will display significantly higher rates and proportions of coping behaviors compared to children who receive standard care ($p < .05$).

H₀: There will be no significant differences in the rates and proportions of distress behaviors displayed by young children undergoing immunizations who receive music therapy and those who receive standard care.

H₁: Children who receive music therapy will display significantly lower rates and proportions of distress behaviors compared to children who receive standard care ($p < .05$).

2. Are there differences in the rates or proportions of coping-promoting or distress-promoting behaviors displayed by parents whose children undergo immunizations while receiving music therapy versus standard care?

H₀: There will be no significant differences in the rates and proportions of coping-promoting behaviors displayed by parents of young children undergoing immunizations who receive music therapy and those who receive standard care.

H₂: Parents whose children receive music therapy will display significantly higher rates and proportions of coping-promoting behaviors compared to parents of children who receive standard care ($p < .05$).

H₀: There will be no significant differences in the rates and proportions of distress-promoting behaviors displayed by parents of young children undergoing immunizations who receive music therapy and those who receive standard care.

H₂: Parents whose children receive music therapy will display significantly lower rates and proportions of distress-promoting behaviors compared to parents of children who receive standard care ($p < .05$).

3. Are there differences in the rates and proportions of coping-promoting behaviors or distress-promoting behaviors displayed by nurses administering immunizations to children receiving music therapy versus standard care?

H₀: There will be no significant differences in the rates and proportions of coping-promoting behaviors displayed by nurses who administer immunizations to young children while receiving music therapy or standard care.

H₃: Nurses who administer immunizations to children who receive music therapy will display significantly higher rates and proportions of coping-promoting behaviors compared to nurses who administer immunizations to children who receive standard care ($p < .05$).

H₀: There will be no significant differences in the rates and proportions of distress-promoting behaviors displayed by nurses who administer immunizations to young children while receiving music therapy or standard care.

H₃: Nurses who administer immunizations to children who receive music therapy will display significantly lower rates and proportions of distress-promoting behaviors compared to nurses who administer immunizations to children who receive standard care ($p < .05$).

4. Are there differences in the lengths of treatment phases (preparation, procedure, and recovery) for young children who undergo immunizations when receiving music therapy versus standard care?

H₀: There will be no significant differences in the lengths of treatment phases of young children who receive music therapy and those who receive standard care while undergoing an immunization.

H₄: Children who receive music therapy will have significantly shorter recovery phases after undergoing immunizations compared to children who receive standard care ($p < .05$).

5. Are there differences in parents' ratings of the distress their children experience during immunizations (relative to previous medical experiences) for parents of children who receive music therapy during immunizations versus parents of children who receive standard care?

H₀: There will be no significant differences in parents' ratings of child distress (relative to previous medical experiences) for parents of children who receive music therapy and parents of young children who receive standard care during immunizations.

H₅: Parents whose children receive music therapy will rate their children's distress as significantly better than during previous experiences compared to parents whose children receive standard care ($p < .05$).

6. Will parents' ratings of the level of pain experienced by their child differ based on whether the child received music therapy or standard care during their immunization?

H₀: There will be no significant difference in parents' ratings of their child's pain for parents of children who receive music therapy and parents of children who receive standard care during immunizations.

H₆: Parents whose children receive music therapy will rate their children's pain as significantly lower than parents whose children receive standard care ($p < .05$).

CHAPTER THREE

METHOD

Approval to conduct the present study was obtained from the Human Subject's Committees at the Florida State University and the Institutional Review Board at Tallahassee Memorial Healthcare (see Appendices A and B) and from administrators and medical staff at the other two sites, which did not have affiliated Institutional Review Boards. The Tallahassee Memorial HealthCare Institutional Review Board required a consent form for their healthcare site which was different from the consent form required by the Florida State University for the other two healthcare sites. Consent forms are included in Appendices C and D.

Design

This study utilized a posttest-only control group design with a stratified sample and random assignment. Children who participated in the study were classified as either "high distress" or "low distress" based on their parents' responses to a question on a demographic inventory which asked parents to rank their child's typical level of distress during doctor visits. The children were then randomly assigned to a music therapy intervention group ($n = 29$) or a standard care control group ($n = 29$).

Participants

Participants were pediatric patients ($N = 58$) between the ages of 4 and 6 years (48.1 and 70.8 months) who were scheduled to undergo routine immunizations at one of three healthcare sites in the southeastern United States, the parent(s) or guardian(s) who accompanied each child ($N = 62$), and the nurse(s) or nurse practitioner(s) who conducted or assisted with the immunizations ($N = 19$). In order to meet inclusion criteria, children had to be between 48 and 72 months of age, accompanied by at least one English-speaking parent or legal guardian, and scheduled to receive at least one injection during their doctor visit.

A total of 72 parents were asked to participate in the study. Of the 72 parents approached, 10 parents (14 %) declined to participate. Of those 10 parents who declined, two did so because of time constraints; two did not want their children to be videotaped; two had children who did not want to be videotaped; one said their child did not get distressed and did not need music

therapy; one did not want to agree to participate without consulting their spouse, who was absent; and two did not give a reason. Two parent/child dyads (one in the music therapy group and one in the control group) who consented to participate did not complete the study because the parents elected for their children to get the flu mist instead of the flu shot, which was the only vaccination the children were scheduled to receive. One child who had been assigned to the music therapy group did not complete the study because their parent decided to come back another day for the vaccination due to time constraints. One parent/child dyad was removed from the study because the injection that the child received was not an immunization but involved a different procedure. This left a total of 58 parent/child dyads who participated in the study. Eighteen nurses and one nurse practitioner participated in this study, although for simplicity they are referred to as nurses throughout the remainder of this paper.

A power analysis was conducted to determine the necessary sample size for this study. In DeMore and Cohen's systematic review (2005), effect sizes for behavioral measures of cognitive-behavioral interventions used to decrease distress during pediatric immunizations ranged from 0.5 to 0.97. It was determined that in order to detect an effect size of 0.7 (which is approximately the midpoint in the range of effect sizes identified in DeMore and Cohen's review) with a power level of 0.8 (a commonly accepted level) and an alpha level of .05 (one-tailed), 52 participants were needed. Because several participants who completed the present study had some missing data, a total of 58 participants were recruited for the study to ensure at least 52 complete data sets. Two participants in the control group did not have complete data because of a video camera malfunction. Parents of three children (two in the control group and one in the music therapy group) did not provide ratings of their children's pain. The father of one child in the music therapy group did not provide a rating of his daughter's distress because he had never been to the doctor's office with her and therefore could not compare her distress to previous medical experiences. Participants with missing data were included in the portions of the analysis for which data were available.

Gender and Level of Distress

Thirty-one (53%) of the children who participated in the study were female and 27 (47%) were male. Nineteen (66%) of the 29 children in the music therapy group were female while only 12 (41%) of the 29 children in the control group were female. As mentioned earlier, gender

differences in young children's responses to immunizations have been observed, although no clear conclusions can be drawn from the extant literature (Lander, Fowler-Kerry, & Hill, 1990; Megel, Houser, & Gleaves, 1998; Schechter et al., 1991). In the present study, parents' ratings of children's reactions to previous doctor visits were considered as better predictors of child distress than gender, because previous research indicates that quality of previous medical experiences is more closely related to children's level of procedural distress than gender (Pate, Blount, Cohen, & Smith, 1996). Based on the parents' ratings of their child's typical reaction to doctor visits, the researcher classified children as "low distress" or "high distress." Although the gender distribution between the music therapy and control groups is unequal, the ratio of high distress to low distress children in each group was the same. Ten children in each group (34%) were classified as "high distress," while 19 children in each group (66%) were classified as "low distress." Gender and distress classifications are shown in Table 1.

Table 1

<i>Gender and Distress Classifications</i>				
Demographic	Category	Music Therapy	Control	Total
High Distress	Male	3	7	10
	Female	7	3	10
	Total	10	10	20
Low Distress	Male	7	10	17
	Female	12	9	21
	Total	19	19	38

Parent/Guardian Demographics

Of the 58 children who participated in this study, 54 had only one parent or guardian present during their immunization, whereas four had two parents or guardians present. Guardians present included mothers, fathers, grandmothers, and aunts. Parent/guardian demographic information is summarized in Table 2.

Table 2

Parent/Guardian Demographics

Guardian Present	Music Therapy	Control	Total
Mother	20	22	42
Father	5	4	9
Mother and father	1	2	3
Grandmother	1	1	2
Mother and grandmother	1	0	1
Aunt	1	0	1

Previous Medical Experiences

A demographic inventory was used to ascertain children's age, gender, and quantity/quality of previous medical experiences (see Appendix E). Question 1 asked parents to estimate how many times their child had been to the doctor's office (less than 10, 11 to 20, or 21 or more) and to rate their child's typical reaction to doctor visits on a 7-point Likert-type scale (-3 = very negative, 0 = no reaction, 3 = very positive). The 7-point Likert-type scale was adapted from an assessment of pediatric medical history used by Bijttebier and Vertommen (1998). Children whose parents rated their typical reaction to visits to the doctor's office between 0 and 3 were subsequently classified as "low distress" while children whose parents rated their child's distress between -3 and -1 were classified as "high distress." Question 2 asked parents to specify how many times their child had been to the emergency room or the hospital, and then to rate their child's typical reaction to these experiences using the same 7-point Likert-type scale. It was determined that the music therapy and control groups were similar with regard to previous medical experiences. Data regarding children's previous medical experiences are shown in Table 3.

Table 3

Previous Medical Experiences

Demographic	Category	Music Therapy	Control	Total
Number of doctor visits	Less than 10	6	8	14
	11 to 20	19	17	36
	21 or more	4	4	8
Reaction to doctor visits	<i>M</i> ^a	0.74	0.86	0.80
	<i>SD</i>	1.75	1.71	1.71
Number of hospital/ER visits	<i>M</i>	1.53	1.70	1.62
	<i>SD</i>	1.57	1.70	1.62
Reaction to hospital/ER visits	<i>M</i> ^a	0.20	0.05	0.00
	<i>SD</i>	1.68	1.88	1.76

^a On the 7-point Likert-type scale ranging from -3 (very negative) to 3 (very positive), these means fall between 0 (no reaction) and 1 (slightly positive).

Number of Shots Administered

The CDC currently recommends that children between the ages of 4 and 6 years receive five separate immunizations to help prevent diphtheria, tetanus, and pertussis (DPT); polio (through the inactivated poliovirus vaccine or IPV); measles, mumps, and rubella (MMR); varicella; and influenza (Centers for Disease Control and Prevention, 2011a). It is recommended that the influenza vaccine be administered annually, and it is often given at the same time as the other four vaccines if the child's office visit falls during flu season (October to February). At Sites One and Two, children were routinely given all of the vaccines recommended for children between ages 4 and 6 at their four-year well-child check, while these vaccines were given to

children at Site Three at their five-year well-child check. Children received between 1 and 5 shots ($M = 3$, $SD = 1.44$). Again, groups were fairly similar with regard to the number of shots administered during the study. Frequency data for the number of shots administered are shown in Figure 2.

Figure 2. Number of shots administered

Music Therapist

The researcher served as the music therapist for 48 of the participants (23 experimental and 25 control), whereas the board-certified music therapist who served as a research assistant served as a music therapist for 10 of the participants (six experimental and four control). Both music therapists had had at least one year of experience providing pediatric procedural support music therapy and had undergone advanced training in the use of medical music therapy with infants and children, as designated by the NICU-MT (Neonatal Intensive Care Unit Music Therapist) credential.

Setting

Participants were recruited from three healthcare sites in the southeastern United States between October 2011 and April 2012. Site One was a family medicine practice in an urban region of North Florida. Site Two was a family medicine clinic housed within a regional medical

center in urban North Florida that serves many patients from nearby rural areas. Site Three was a pediatric practice affiliated with a hospital in a rural area of South Georgia. Site One did not accept Medicaid patients. Approximately 90% of all patients treated at Site Two received Medicaid and 75% of all patients treated at Site Three received Medicaid or another government subsidized health insurance program for low income families that did not qualify for Medicaid. The number of participants recruited from each healthcare site is shown in Table 4 and was similarly distributed between groups.

Table 4

<i>Number of Participants from Each Healthcare Site</i>			
Healthcare Site	Music Therapy	Control	Total
Site One	6	3	9
Site Two	14	16	30
Site Three	9	10	19

Participants met with the music therapist and completed consent forms in the waiting room at their respective healthcare site or, if the waiting room was crowded, in the treatment room. Treatment rooms at the three healthcare sites were similar with regard to arrangement of furnishings. Each treatment room had an exam table, a lamp, a chair, a rolling stool, and a sink with a counter. Two of the treatment rooms at Site Three had a window, while treatment rooms at Sites One and Two were windowless. One of the treatment rooms at Site One had a small table with several children's toys on it.

Independent Variable

The independent variable for this study was a single-session music therapy intervention which included live music and cognitive-behavioral techniques as procedural support during immunizations. The music therapy intervention was led by the researcher or a research assistant, both of whom were board-certified music therapists. During the music therapy intervention,

basic information about the immunization was presented to children prior to the procedure through a developmentally-appropriate song and story. Before the procedure, children were also taught to take deep breaths as a coping technique and encouraged to practice doing so in advance of the immunization. Children were engaged in active music making immediately before the immunization to provide distraction. During the procedure, children were encouraged to take deep breaths and focus on the music therapist. After the procedure, children were encouraged to play instruments, listen to the music, and sing in order to facilitate recovery.

Children in the control group received standard care without the music therapy intervention during their immunizations. Standard care consisted of administration of immunizations carried out per healthcare site protocols, including preparation for immunizations, administration of immunizations, and recovery from the procedure. Standard care immunizations were administered by nurses, with the potential for assistance from parents and other healthcare staff as necessary. Although the music therapist was present for standard care immunizations, the music therapist did not interact with the children, parents, or nurses during control group procedures.

Dependent Variables

Dependent variables included children's distress behaviors, children's coping behaviors, adult distress-promoting and coping-promoting behaviors, parents' ratings of children's distress compared to previous medical experiences, parents' ratings of children's pain, and length of the phases of treatment. Children's distress behaviors were measured using the CAMPIS-R. Distress behaviors coded by the CAMPIS-R included crying, screaming, verbal resistance, requesting emotional support, verbal fear, verbal pain, verbal emotion, and information seeking.

Children's coping behaviors, as measured by the CAMPIS-R, included audible deep breathing, nonprocedural talk by the child, humor by the child, and making coping statements. In addition, singing and playing musical instruments were defined as coping behaviors, although these were not included in the CAMPIS-R. The rationale for including singing and playing instruments as coping behaviors was that these behaviors are non-procedural activities similar to those defined as coping behaviors in other studies (Blount et al., 1989). Operational definitions of child distress and coping behaviors are included in Appendix F.

Adult behaviors were those behaviors displayed by parents and nurses that have been shown to promote either distress or coping in children undergoing medical procedures (Blount et al., 1989). According to the CAMPIS-R, adult distress-promoting behaviors included reassuring comments, apologies, empathic statements, giving control to the child, and criticism. Adult coping-promoting behaviors, as measured by the CAMPIS-R, included nonprocedural talk to the child, humor directed to the child, and commands to use coping strategies. Operational definitions of adult distress- and coping-promoting behaviors are included in Appendix G. An example of a transcript/coding form for coping, distress, coping-promoting, and distress-promoting behaviors is included in Appendix H. The CAMPIS-R also includes measures of child and adult neutral behaviors, which are defined for the purposes of this paper as behaviors that are not indicative of coping/coping-promotion or distress/distress-promotion. Neutral child and adult behaviors were coded in the present study and used to calculate the proportions of child coping/distress and adult coping-promoting/distress-promoting behaviors. However, neutral behaviors were not analyzed statistically because the research questions focused solely on coping, coping-promoting, distress, and distress-promoting behaviors.

Parents' ratings of their children's distress (relative to previous medical experiences) were measured using a researcher-developed post-procedure questionnaire (see Appendix I) modeled after that used by Manimala, Blount, and Cohen (2000). Parents' ratings of their child's overall level of pain during the procedure were measured by the Universal Pain Assessment Tool (see Appendix J). For assessment purposes, treatment was divided into three phases. The first phase (preparation) began when the nurse entered the treatment room to administer the immunization(s). During preparation, the nurse collected the necessary equipment and helped position the child for the immunization, either in a seated or a supine position on the treatment table. This first phase ended when the child was appropriately positioned for the procedure. The second phase (procedure) began immediately after the child was positioned for the procedure and included the needle injection(s). This phase ended when the final needle injection had occurred. The third phase (recovery) began at this point and ended either when the child demonstrated their final distress behavior or when the child left the treatment room, whichever occurred first. Lengths of treatment phases were measured in minutes and seconds by the time elapsed function on the video recorder.

Measures

The Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R) was used to measure child and adult distress and coping behaviors. In a review of assessments of pediatric coping and stress, the CAMPIS-R and the assessment from which it was derived (the original CAMPIS) were the only assessments classified as a “well-established assessment that guides treatment” (Blount et al., 2008, p. 1029). The CAMPIS-R has been reported to have high levels of convergent and predictive validity, as well as sensitivity to change (Blount et al., 1997; Blount et al., 2008). Cohen et al. (2008) also classified the CAMPIS and CAMPIS-R as well-established assessments of pediatric pain. Inter-rater reliability for the CAMPIS-R (calculated using Cohen’s kappa) was reported by Blount et al. (1997) to be between .72 and .91 for child behaviors, between .65 and .82 for parent behaviors, and between .88 and .92 for staff behaviors. The lowest reliability was reported for child neutral (.72), parent neutral (.65), and parent coping promoting (.78) behaviors; reliability for all other behaviors exceeded .80.

Previous studies utilizing the CAMPIS-R have utilized both rate metrics-the number of a specific type of behavior divided by the length of the observation period (Frank et al., 1995; Powers et al., 1993)-and proportion metrics-the number of a specific type of behavior divided by the total number of behaviors exhibited by the individual being observed (Blount et al., 1992). Blount and colleagues report that both metrics have advantages and disadvantages, stating that proportions “more accurately reflect the types of vocalizations emitted by children and adults producing low, as well as high, numbers of vocalizations within any time period” (Blount et al., 1990, p. 40). However, rates of behavior may be useful in determining the cause for changes in proportions of behavior. For instance, if a child shows an increase in the proportion of coping behavior from one phase of a medical procedure to the next, without knowing the rate it is not clear whether this change in proportion was due to an increase in coping behavior, a decrease in distress behavior, or a change in neutral behavior. Both rate metrics and proportion metrics for CAMPIS-R behaviors were calculated in the present study.

A researcher-designed post-procedure questionnaire was used to assess parents’ ratings of their child’s distress during the procedure relative to previous medical experiences. Parents were asked to rate their child’s level of distress during the present immunization compared to previous medical experiences on a 7-point Likert-type scale (-3 = much worse, 0 = the same, 3 = much better). Parents of children in the music therapy group were asked to complete a researcher-

designed satisfaction survey to assess their perceptions of the music therapy intervention. A similar survey was used by Barton (2008) and Chorna (2010) to assess the satisfaction of hospital patients and their parents upon receiving music therapy during a medical procedure. Post-procedure questionnaires for the music therapy and control groups are included in Appendix I.

The University of California at Los Angeles (2004) Universal Pain Assessment Tool was used to measure parents' ratings of their child's pain (see Appendix J). Chan (2007) reports high content validity (1.00) and test-retest reliability (.89) for this measure, which is widely used in clinical settings. This measure links the Wong-Baker Facial Grimace Scale (Wong & Baker, 1988), a verbal descriptor scale, an activity tolerance scale, and a 10-point Likert-type scale. Although many studies on interventions have utilized self-report measures of pain for young children, researchers often report that preschool children have difficulty understanding how to use these measures and/or require extensive training to use them appropriately (Chen, Zeltzer, Craske, & Katz, 1999). Additionally, young children may confuse anxiety or fear with pain. In a study by Goodenough (1999), children under the age of 8 did not discriminate between the pain they experienced during a medical procedure and the unpleasantness of the procedure, while older children were able to differentiate between the sensory and affective aspects of their perceptions of the procedure. Parents' ratings of their child's pain have been used as alternatives to children's reports of pain in research on pediatric medical procedures (Schechter et al., 1991). High correlations have been reported between children's and parents' ratings of the pain children experience (Schneider & LoBiondo-Wood, 1992). Therefore, due to the age of children in this study, the parents' rating of their child's pain was selected as a dependent measure.

Procedure

Healthcare staff at the three sites notified the researcher when a child who met study inclusion criteria had an appointment scheduled for an immunization. When patients who met the criteria for inclusion in the study came to their doctor's office for their appointment, the researcher met with each child's parent or legal guardian prior to the procedure to explain the nature of the study, obtain informed consent, and obtain demographic information. Children also gave verbal assent to be videotaped and, if assigned to the music group, were asked if they would like to participate in music. The nature of the study was also explained to the healthcare staff

performing immunizations for children included in the study, and their consent was obtained and documented.

Each parent was asked to fill out the demographic inventory, indicating the child's date of birth, gender, and number of previous doctor visits, emergency room visits, and hospitalizations. Parents were also asked to rate their child's reaction to previous doctor visits and emergency room visits/hospitalizations on a 7-point Likert-type scale (-3 = very negative, 0 = no reaction, 3 = very positive). Children whose parents rated their reaction to previous doctor visits at 0 or higher were considered "low distress" while children whose parents rated their distress at less than 0 were considered "high distress." The researcher then randomly assigned each participant to a music therapy intervention group ($n = 29$) or a standard care control group ($n = 29$).

The music therapy intervention was either implemented by the researcher or a research assistant, both of whom were board-certified music therapists who had undergone advanced clinical training in the use of music therapy in pediatric medical settings. For the purposes of this paper, the researcher and the research assistant are referred to collectively as "music therapists." Only one music therapist was present for each immunization. The music therapists practiced the original songs utilized in the study (see Appendix K) together and reviewed the music therapy treatment protocol to ensure consistency.

A music therapist met with children and parents/guardians in the music therapy intervention group prior to the immunization to develop rapport and assess music preferences. The music therapist set up a video camera on a tripod in the treatment room where the procedure was to take place, which recorded the child, as well as the parent(s), the music therapist, and the healthcare staff during the procedure. The music therapist taught children in the music therapy group cognitive-behavioral coping skills and engaged in music activities immediately before, during, and after the immunization. The researcher remained in the room to hold and monitor the video camera during procedures for participants in the standard care control group but did not interact with the child, child's parents, or staff.

Upon completion of the procedure, parents were asked to complete the questionnaire comparing their child's present level of distress to previous medical experiences (-3 = much worse, 0 = the same, and 3 = much better). Parents of children in the music therapy group were also asked to complete the satisfaction survey, indicating their perceptions of the music therapy

treatment. Parents were then asked to rate their child's level of pain during the procedure using the Universal Pain Assessment Tool.

Videos of procedures were transcribed by three research assistants who were either graduate or senior undergraduate music therapy majors. Research assistants underwent a three month training period during which they met once a week to receive instruction and practice in transcribing videos and coding them using the Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R). Training continued until observers achieved at least 80% agreement in coding practice videos. Each transcript was reviewed for accuracy by two research assistants and the researcher. Research assistants then independently reviewed each transcript while watching the corresponding video and classified each statement on the transcript using the CAMPIS-R.

Interrater Reliability

Interrater reliability was calculated by having a second research assistant independently code 20% of the videos. Six videos were randomly selected from each treatment group for reliability coding. Reliability was calculated using the formula: agreements divided by the sum of agreements plus disagreements (Madsen & Madsen, 1998). Reliability coefficients ranged from .80 to .91 with a mean of .85, which was deemed an acceptable level of reliability and is comparable to the levels of interrater reliability reported by Blount et al. (1997) for the CAMPIS-R.

Music Therapy Intervention

The music therapy intervention utilized different songs and cognitive-behavioral techniques within each phase of the medical procedure, consistent with the recommendations of Blount et al. (2009). During the preparatory phase, the music therapist presented an introductory song, a song to teach deep breathing, information provision, and additional songs as distraction. During the procedure phase, the music therapist provided coaching and music as distraction. During the recovery phase, the music therapist presented a new instrument and additional songs. After the child had recovered and no longer displayed distress behaviors, the music therapist presented a goodbye song to aid with completion of the procedure.

Introductory song. The purpose of the first song was to build rapport with the child and engage them in the music experience. A familiar song was used because it was hypothesized that hearing a song that the child recognized would help put him or her at ease and normalize the environment. The music therapist offered the child an instrument. Children were allowed to select a maraca decorated with a picture of a cartoon from a popular children's movie. The music therapist asked the child if they had any favorite songs or, if not, suggested a popular upbeat children's song (e.g. Old MacDonald or Twinkle, Twinkle, Little Star). The music therapist then played the song and encouraged the child to play and sing along, praising the child for any kind of participation.

Song to teach deep breathing. The music therapist then sang a narrative song based on a traditional song about an Austrian who went yodeling, changing the word "Austrian" to either "princess" or "dragon," depending on the child's preference. The song had four cues for the child to breathe deeply to imitate a character in the song, during which the music therapist encouraged the child to practice taking deep breaths (see Appendix K).

Information provision. Once the child seemed at ease, engaged in the music, and had practiced the coping technique of taking deep breaths, the music therapist introduced an age-appropriate story that provided some information about the immunization and how to cope with it. The music therapist produced a story book called "Me and My Dragon" (Biedrzycki, 2011) but did not read the story. Instead, she showed select pictures from the story which corresponded to scenes from the narrative song entitled "Sparky the Dragon" (Malone, 1996; see Appendix K).

Additional songs as distraction during preparation. If there was additional time before the nurse entered to administer the injection(s), the music therapist engaged the child in singing and playing instruments with additional age-appropriate songs, such as "I'm Going to Shake my Sillies Out," "Old MacDonald," "Leader of the Band," and "If All the Raindrops." A high level of participation from the child was encouraged in order to provide distraction and prevent the child from becoming anxious prior to the procedure.

Coaching during procedure. During the immunization(s), the music therapist positioned herself so that she was on the opposite side of the child from the nurse administering the injections. She sang the “Yodeling Song” and attempted to time the cues for deep breathing with the administration of the injections. She encouraged the child to look at her and take deep breaths on cue.

New instrument during recovery. Immediately after the last injection, the music therapist brought out a new instrument that had proven to be highly motivating for young children (e.g. an ocean drum, lollipop drum, or rainstick). When presenting the ocean drum, the music therapist sang a song called “The Beads go ‘Round and ‘Round,” which has many instances when the music pauses and then resumes (see Appendix K). The music therapist paused the music to gain the child’s attention, since the music therapist had previously observed that often a child in distress would stop crying in order to hear what would happen after the pause. It should be noted that the music therapist did not instruct children to stop crying or provide reassurance. Rather, a highly motivating musical experience was offered to create an incompatible response with distress behaviors and hasten recovery. When the child appeared calm, the music therapist praised the child for any use of coping behaviors. Even if the child had displayed primarily or solely distress behaviors during the injection, the music therapist reminded the child of the purpose of the immunization by calmly stating, “You got through it and now those shots will help keep you from getting sick, just like Sparky the Dragon.” Reminding children of the purpose of the procedure was deemed important in order to prevent children from mistakenly associating procedural pain with punishment, which is a common connection made by young children (Ross & Ross, 1988).

Goodbye song. When it was time for the parent and child to leave the treatment room, the music therapist played one final song for the child to say goodbye (see Appendix K). The goodbye song repeated the phrase “music time is over and we all had lots of fun” several times and encouraged the child to join in by saying “woo!” This song was presented to reinforce the positive aspects of the experience so that hopefully these would be more salient in the child’s memory than the negative experience of getting a shot. Finally, the music therapist concluded the session by offering the child a sticker featuring an animal that had been mentioned while singing

“Old MacDonald.” After concluding the music therapy session, the music therapist administered the post-procedure questionnaire and the Universal Pain Assessment Tool.

CHAPTER FOUR

RESULTS

Preliminary Analysis

Demographic information was examined to determine whether the music therapy group and the control group were different with regard to healthcare site, gender, music therapist, age, number of shots, number of previous doctor visits, reactions to previous doctor visits, number of previous hospitalizations/emergency room visits, and reactions to previous hospitalizations/emergency room visits. An alpha level of .05 was used for all statistical comparisons. Chi-square tests were used to analyze data at the nominal level (healthcare site, gender, and music therapist). The music therapy group and the control group were not significantly different with regard to healthcare site, $\chi^2 (5, N = 58) = 1.19, p > .05$, gender, $\chi^2 (3, N = 58) = 3.66, p > .05$, or music therapist, $\chi^2 (3, N = 58) = .48, p > .05$. Mann-Whitney *U* tests were used to analyze data at the ordinal level (number of doctor visits, reaction to doctor visits, and reaction to hospitalizations/emergency room visits). The two groups did not differ significantly with regard to the number of doctor visits, $z = 0.38, p > .05$, typical reaction to doctor visits, $z = -0.26, p > .05$, or typical reaction to hospitalizations/emergency room visits, $z = 0.79, p > .05$. A series of *t*-tests was used to analyze data at the intervallic level (age, number of shots, and number of hospitalizations/emergency room visits). The groups were not significantly different with regard to age, $t (56) = -.31, p > .05$, or number of shots, $t (56) = .63, p > .05$. Complete demographic information is included in Appendix L.

Distributions for rates and proportions of distress and coping behaviors were examined. Data for both rates and proportions were positively skewed due to a high number of zero values. Because the data were not normally distributed, non-parametric tests were used to analyze data. A series of Mann-Whitney *U* tests was used to determine whether the music therapy and the control group differed with regard to rates and proportions of coping and distress behaviors, parent ratings of distress and pain, and recovery time. Effect sizes (*r*) were calculated based on the *z*-scores associated with the Mann-Whitney *U* values, using the formula described by Field (2009).

Data Analysis of Child Behavior

Rates and Proportions of Child Coping Behavior

Children in the music therapy group showed significantly higher rates of coping behaviors during the preparation phase, $z = 3.18$, $p = .001$, $r = .42$, and the procedure phase, $z = 3.16$, $p = .001$, $r = .42$, compared to children in the control group. Therefore, the null hypothesis regarding child coping behavior was rejected. During the recovery phase, differences in rates of coping behaviors did not reach statistical significance, $p > .05$ (see Figure 3).

Figure 3. Rates of child coping behavior

Children in the music therapy group showed significantly greater proportions of coping behaviors during the preparation phase, $z = 4.30$, $p < .001$, $r = 0.57$, and the procedure phase, $z = 3.63$, $p < .001$, $r = 0.49$, compared to children in the control group (see Figure 4). No significant differences were found in the proportions of coping behaviors displayed by children during the recovery phase, $p > .05$.

Figure 4. Proportions of child coping behavior

Rates and Proportions of Child Distress Behavior

During the preparation phase, differences in the rates of distress behaviors did not reach statistical significance, $p > .05$. Compared with children in the music therapy group, children in the control group showed significantly higher rates of distress behaviors during the procedure phase, $z = -2.76$, $p = .003$, $r = -0.37$, and the recovery phase, $z = -2.99$, $p = .001$, $r = -0.40$ (see Figure 5). Therefore, the null hypothesis regarding child distress behavior was rejected.

Figure 5. Rates of child distress behavior

There were no significant differences in the proportions of distress behaviors displayed by children during the preparation or recovery phases, $p > .05$ (see Figure 6). Children in the

control group showed significantly greater proportions of distress behavior during the procedure phase, $z = -1.76$, $p = .04$, $r = -0.24$. Means, standard deviations, and Mann-Whitney test results for rates and proportions of child behavior are shown in Tables 5 and 6, respectively.

Figure 6. Proportions of child distress behavior

Table 5

Means, Standard Deviations, and Mann-Whitney Test Results for Rates of Child Behavior

Behavior	Phase	Music Therapy		Control		<i>N</i>	<i>z</i>	<i>p</i>	<i>r</i>
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>				
Coping	Preparation	4.78	3.09	2.21	2.84	(29, 27)	3.18	.001 *	0.42
	Procedure	3.39	2.43	1.68	2.43	(29, 27)	3.16	.001 *	0.42
	Recovery	1.02	1.53	1.29	1.46	(29, 27)	-0.66	.25	----
Distress	Preparation	0.84	1.81	3.89	6.16	(29, 27)	-1.56	.06	----
	Procedure	5.97	4.52	11.43	7.50	(29, 27)	-2.76	.003 *	-0.37
	Recovery	5.91	3.88	13.60	14.06	(29, 27)	-2.99	.001 *	-0.40

* Indicates statistical significance, $p < .05$.

Table 6

Means, Standard Deviations, and Mann-Whitney Test Results for Proportions of Child Behavior

Behavior	Phase	Music Therapy		Control		<i>N</i>	<i>z</i>	<i>p</i>	<i>r</i>
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>				
Coping	Preparation	0.73	0.34	0.28	0.31	(29, 27)	4.30	< .001 *	0.57
	Procedure	0.40	0.28	0.14	0.19	(29, 27)	3.63	< .001 *	0.49
	Recovery	0.12	0.18	0.10	0.14	(29, 27)	0.01	.5	----
Distress	Preparation	0.10	0.21	0.29	0.41	(29, 27)	-1.49	.07	----
	Procedure	0.56	0.30	0.69	0.33	(29, 27)	-1.76	.04 *	-0.24
	Recovery	0.71	0.32	0.70	0.31	(29, 27)	0.19	.42	----

* Indicates statistical significance, $p < .05$.

Data Analysis of Parent Behavior**Rates and Proportions of Parent Coping-Promoting Behavior**

Differences in the rates of parent coping-promoting behavior did not reach statistical significance during the preparation, procedure, or recovery phases, $p > .05$ (see Figure 7).

Figure 7. Rates of parent coping-promoting behavior

No significant differences were found in the proportions of coping-promoting behaviors displayed by parents during any of the three phases, $p > .05$ (see Figure 8). Therefore, the null hypothesis regarding parent coping-promoting behavior was not rejected.

Figure 8. Proportions of parent coping-promoting behavior

Rates and Proportions of Parent Distress-Promoting Behavior

Parents of children in the control group showed significantly higher rates of distress-promoting behaviors during the preparation phase, $z = -2.61$, $p = .005$, $r = -0.35$, the procedure phase, $z = -2.80$, $p = .003$, $r = -0.37$, and the recovery phase, $z = -2.99$, $p = .001$, $r = -0.40$ (see Figure 9). Therefore, the null hypothesis regarding parent distress-promoting behavior was rejected.

Figure 9. Rates of parent distress-promoting behavior

Compared to parents of children in the music therapy group, parents of children in the control group showed significantly greater proportions of distress-promoting behaviors during the preparation phase, $z = -2.61$, $p = .005$, $r = -0.35$, the procedure phase, $z = -2.18$, $p = .01$, $r = -0.29$, and the recovery phase, $z = -2.53$, $p = .01$, $r = -0.34$ (see Figure 10).

Figure 10. Proportions of parent distress-promoting behavior

Means, standard deviations, and Mann-Whitney test results for rates and proportions of parent behavior are shown in Tables 7 and 8, respectively.

Table 7

Means, Standard Deviations, and Mann-Whitney Test Results for Rates of Parent Behavior

Behavior	Phase	Music Therapy		Control		<i>N</i>	<i>z</i>	<i>p</i>	<i>r</i>
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>				
Coping-promoting	Preparation	0.81	1.38	0.72	1.08	(29, 27)	0.02	.49	----
	Procedure	1.48	1.97	2.05	1.96	(29, 27)	-1.31	.1	----
	Recovery	1.75	2.46	2.05	3.3	(29, 27)	0.20	.42	----
Distress-promoting	Preparation	0.00	0.00	1.09	2.46	(29, 27)	-2.61	.005 *	-0.35
	Procedure	0.70	1.51	3.46	4.65	(29, 27)	-2.80	.003 *	-0.37
	Recovery	1.52	4.35	4.48	5.62	(29, 27)	-2.99	.001 *	-0.40

* Indicates statistical significance, $p < .05$.

Table 8

Means, Standard Deviations, and Mann-Whitney Test Results for Proportions of Parent Behavior

Behavior	Phase	Music Therapy		Control		<i>N</i>	<i>z</i>	<i>p</i>	<i>r</i>
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>				
Coping-Promoting	Preparation	0.20	0.30	0.08	0.11	(29, 27)	0.78	.22	----
	Procedure	0.32	0.36	0.21	0.23	(29, 27)	0.46	.32	----
	Recovery	0.24	0.31	0.11	0.15	(29, 27)	1.28	.10	----
Distress-Promoting	Preparation	0.00	0.00	0.09	0.15	(29, 27)	-2.61	.005 *	-0.35
	Procedure	0.11	0.20	0.26	0.27	(29, 27)	-2.18	.01 *	-0.29
	Recovery	0.14	0.28	0.27	0.23	(29, 27)	-2.53	.01 *	-0.34

* Indicates statistical significance, $p < .05$.

Data Analysis of Nurse Behavior

Rates and Proportions of Nurse Coping-Promoting Behavior

No significant differences were found between the rates of nurse coping-promoting behaviors in any of the three phases, $p > .05$ (see Figure 11).

Figure 11. Rates of nurse coping-promoting behavior

Nurses who treated children in the music therapy group showed significantly greater proportions of coping-promoting behaviors during the procedure phase, $z = 2.33$, $p = .01$, $r = 0.31$, compared to nurses who treated children in the control group (see Figure 12). Therefore, the null hypothesis regarding nurse coping-promoting behavior was rejected. No significant differences were found in the proportions of coping-promoting behaviors displayed by nurses during the preparation or recovery phases, $p > .05$.

Figure 12. Proportions of nurse coping-promoting behaviors

Rates and Proportions of Nurse Distress-Promoting Behavior

No significant differences were found between the rates of nurse distress-promoting behaviors in any of the three phases, $p > .05$ (see Figure 13).

Figure 13. Rates of nurse distress-promoting behavior

There were no significant differences in the proportions of distress-promoting behaviors displayed by nurses during any phase (see Figure 14). Therefore, the null hypothesis regarding nurse distress-promoting behavior was not rejected. Means, standard deviations, and Mann-Whitney U results for rates and proportions of nurse behavior are shown in Tables 9 and 10, respectively. Raw data for CAMPIS-R rates and proportions can be found in Appendix M.

Figure 14. Proportions of nurse distress-promoting behaviors

Table 9

Means, Standard Deviations, and Mann-Whitney Test Results for Rates of Nurse Behavior

Behavior	Phase	Music Therapy		Control		<i>N</i>	<i>z</i>	<i>p</i>
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>			
Coping-promoting	Preparation	3.32	6.01	3.73	7.58	(29, 27)	-0.02	.49
	Procedure	4.14	4.81	4.28	5.87	(29, 27)	0.16	.44
	Recovery	2.45	4.61	3.95	5.17	(29, 27)	-1.51	.07
Distress-promoting	Preparation	0.04	0.21	0.48	1.45	(29, 27)	-0.95	.17
	Procedure	1.62	2.16	2.59	3.04	(29, 27)	-1.28	.10
	Recovery	3.25	6.41	4.22	5.83	(29, 27)	-1.54	.06

Table 10

Means, Standard Deviations, and Mann-Whitney Test Results for Proportions of Nurse Behavior

Behavior	Phase	Music Therapy		Control		<i>N</i>	<i>z</i>	<i>p</i>	<i>r</i>
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>				
Coping-Promoting	Preparation	0.19	0.26	0.16	0.20	(29, 27)	0.33	.37	----
	Procedure	0.30	0.22	0.17	0.19	(29, 27)	2.33	.01 *	0.31
	Recovery	0.13	0.17	0.18	0.17	(29, 27)	-1.18	.12	----
Distress-Promoting	Preparation	0.004	0.02	0.03	0.07	(29, 27)	-0.95	.17	----
	Procedure	0.13	0.13	0.14	0.16	(29, 27)	0.05	.48	----
	Recovery	0.20	0.28	0.25	0.25	(29, 27)	-0.93	.18	----

* Indicates statistical significance, $p < .05$.

Lengths of Treatment Phases

No significant differences were found between the music therapy group and the control group with regard to the length of the preparation phases, procedure phase, or recovery phase, $p > .05$. The groups did not differ significantly in the total lengths of procedures (see Figure 15). Therefore, the null hypothesis regarding lengths of treatment phases was not rejected. Means, standard deviations, and Mann-Whitney test results for lengths of phases of immunizations are shown in Table 11. Raw data for lengths of treatment phases are included in Appendix N.

Figure 15. Lengths of phases of immunizations (in seconds)

Table 11

Means, Standard Deviations, and Mann-Whitney Test Results for Lengths of Treatment Phases

Phase	Music Therapy		Control		N	z	p
	M	SD	M	SD			
Preparation	75.79	53.06	71.56	33.15	(29, 27)	-0.41	.34
Procedure	126.83	134.61	99.52	78.28	(29, 27)	0.74	.23
Recovery	65.17	70.17	63.33	52.09	(29, 27)	-0.59	.28
Total	267.45	204.21	234.41	110.63	(29, 27)	0.00	.50

Note. All values are in seconds.

Parents' Ratings of Children's Distress and Pain

Parents of children in the music therapy group rated their children's level distress as significantly better than during previous procedures, $z = 3.57$, $p < .001$, $r = 0.48$, compared to parents of children in the control group. Parents in the music therapy group rated their children's distress relative to previous medical experiences at 1.18 ($SD = 1.54$), which falls between 1 (slightly better), and 2 (better) on the 7-point Likert-type scale ranging from -3 to 3. In contrast, parents in the control group rated their children's distress relative to previous medical experiences at -0.41 ($SD = 1.60$), which falls between 0 (the same) and -1 (slightly worse) using

the same 7-point Likert-type scale (see Figure 16). Therefore, the null hypothesis regarding parents' ratings of distress was rejected.

Figure 16. Parents' ratings of children's distress

There was no significant difference between the music therapy group and the control group regarding parents' ratings of pain (see Figure 17). Therefore, the null hypothesis regarding parents' ratings of pain was not rejected. On average, parents of children in the music therapy group rated their children's pain at 3.18 ($SD = 1.88$) on a scale of 0 to 10, with 10 being the worst pain. Parents of children in the control group rated their children's pain at 4.46 on average ($SD = 3.10$). Scores between 3 and 6 are considered "moderate pain" (University of California at Los Angeles, 2004). Means, standard deviations, and Mann-Whitney test results for parent ratings of distress and pain are shown in Table 12. Raw data for parents' ratings of distress and pain are included in Appendix O.

Figure 17. Parents' ratings of children's pain

Table 12

Means, Standard Deviations, and Mann-Whitney Test Results for Parents' Ratings of Distress and Pain

Rating	Music Therapy		Control		N	z	p	r
	M	SD	M	SD				
Distress	1.18	1.54	-0.41	1.60	(28, 29)	3.57	< .001 *	0.48
Pain	3.18	1.88	4.46	3.10	(28, 27)	-1.55	.06	----

* Indicates statistical significance, $p < .05$.

Satisfaction Survey

Parents in the music therapy group responded to four questions related to their satisfaction with the music therapy treatment. Responses indicated that the majority of parents felt that their children benefitted (question one), that they (the parent) benefitted (question two), that music therapy improved their perception of the facility (question three), and that they would like to receive music therapy services in the future (question four). None of the parents surveyed indicated that they had received music therapy previously. Responses to satisfaction survey questions from parents in the music therapy group are shown in Figures 18 through 21.

Did your child benefit from music therapy?

Figure 18. Parents' responses to satisfaction survey question one

Did you benefit from music therapy?

Figure 19. Parents' responses to satisfaction survey question two

Did music therapy improve your perception of this facility?

Figure 20. Parents' responses to satisfaction survey question three

Would you like to receive music therapy services again if you return to this facility?

Figure 21. Parents' responses to satisfaction survey question four

A series of chi-square goodness of fit tests were used to analyze responses to satisfaction survey questions. For questions one, two, and three, the responses “Yes, very much” and “Yes” were grouped together for analysis, since these would be considered positive responses. The responses “No opinion,” “Not really,” and “Not at all” were grouped together, since these would be considered neutral or negative responses. Parents of children in the music therapy group gave significantly more positive responses than neutral/negative responses to question one (“Did your child benefit from music therapy?”), $\chi^2(1, N = 29) = 11.18, p = .001$, question two (“Did you benefit from music therapy?”), $\chi^2(1, N = 29) = 11.18, p = .001$, and question three (“Did music therapy improve your perception of this facility?”), $\chi^2(1, N = 29) = 4.96, p = .03$. For question four, the responses “Maybe” and “No” were grouped together since these would be considered neutral or negative responses. Parents of children in the music therapy group gave significantly more positive responses than neutral/negative responses to question four (“Would you like to receive music therapy services again if you return to this facility?”), $\chi^2(1, N = 29) = 8.82, p = .003$. Results of chi-square tests for responses to satisfaction survey questions are shown in Table 13. Raw data from satisfaction surveys are included in Appendix P. Comments that parents noted on the post-procedure questionnaires are included in Appendix Q.

Table 13

<i>Responses to Satisfaction Survey Questions</i>						
Question	Positive Responses	Neutral/Negative Responses	<i>N</i>	<i>df</i>	χ^2	<i>p</i>
One	24	5	29	1	11.18	.001
Two	24	5	29	1	11.18	.001
Three	21	8	29	1	4.96	.03
Four	23	6	29	1	8.82	.003

CHAPTER FIVE

DISCUSSION

Interpreting the Dependent Measures

Child Coping Behavior

Children in the music therapy group showed significantly greater rates and proportions of coping behaviors during the preparation phase and the procedure phase compared to children in the control group, but not during the recovery phase. During the preparation and procedure phases, children in the music therapy group showed more than twice the proportion of coping behaviors than children in the control group (73% compared to 28% during the preparation phase; 40% compared to 14% during the procedure phase. During the recovery phase, children in the music therapy group showed comparable rates of coping behaviors to children in the control group (12% compared to 10%, respectively). The same trend was found for rates of child coping behaviors, with the music therapy group showing about twice the rate of these behaviors during the preparation and procedure phases but not during the recovery phase.

The lack of difference in children's coping behaviors during the recovery phase may be attributable to the way in which the phase was measured. In earlier studies, end of the recovery phase was defined as 1.5 minutes after the procedure (Jay, Ozolins, Elliot, & Caldwell, 1983), 2 minutes after the procedure (Blount et al., 1989), or when the child left the treatment room (LeBaron & Zeltzer, 1984). None of these definitions were appropriate for the present study since there was great variation in the length of time it took parent/child dyads to leave the treatment room, with some parents leaving before 1.5 minutes had elapsed. The length of time it took parent/child dyads to leave the treatment room was based in part on when the child appeared calm and in part on whether there was still business to be taken care of in the treatment room, such as waiting for test results, changing from a hospital gown into regular clothes, or filling out additional paperwork for the doctor's office. The decision to base the end of the recovery phase on the child's behavior was made to provide an accurate comparison in the length of time that it took children to calm regardless of other extraneous factors. Music therapists who led the sessions in the present study observed that children tended to show an increase in coping behaviors after the end of data collection, as evidenced by playing instruments and participating in music activities with the music therapist.

When comparing rates and proportions of coping and distress behaviors, it can be seen that children in the music therapy group showed more coping behaviors than distress behaviors during the preparation phase; however, for all other phases, children in both groups tended to show more distress behaviors than coping behaviors. This finding speaks to the distressing nature of immunizations for young children. In a previous study, children undergoing immunizations tended to show more than twice as many distress behaviors as coping behaviors during the procedure (Frank et al., 1995). In the present study, the rate of distress behaviors shown during the procedure phase by children in the control group was more than six times the rate of coping behaviors during the same phase. In contrast, children in the music therapy group showed less than twice as many distress behaviors compared to coping behaviors during the procedure, which is better than the results of the study by Frank et al. (1995) would have predicted. These results demonstrate that children who took part in the music therapy intervention positively engaged in a healthy, adaptive way of coping with painful stimuli before and during the immunization, which provided immediate benefits for the children and a potentially valuable long-term life lesson.

Child Distress Behavior

Children in the control group showed significantly higher rates of distress behaviors during the procedure phase and the recovery phase compared to children in the music therapy group, but significant differences were not found during the preparation phase. The control group showed a significantly higher proportion of child distress behaviors during the procedure phase compared to the music therapy group, but not during the preparation or recovery phases. The lowest proportion of child distress behaviors occurred during the preparation phase, with a greater proportion of distress behaviors occurring during the procedure phase and the greatest proportion of distress behaviors occurring during the recovery phase. Rates of distress behaviors increased from the preparation phase to the procedure phase for both groups and from the procedure phase to the recovery phase for the control group but not for the music therapy group. From the procedure phase to the recovery phase, distress behaviors decreased slightly for the music therapy group. This indicates that children in the music therapy group did not show the same increase in distress behaviors over the course of the session that children in the control group demonstrated, a clinically important finding.

The increase in distress behaviors from the preparation phase to the procedure phase is in accordance with the findings of previous studies, which show that children tend to demonstrate more distress during procedures than they do before the procedures (Blount, Sturges, & Powers, 1990). However, based on the results of previous studies, one would expect children's distress to decrease after the procedure phase, since the painful stimulus has been removed. The fact that in the present study the proportion of distress behaviors increased during the recovery phase may be related to the way in which the recovery phase was defined, as was previously discussed.

In the present study, the researcher attempted to video record the procedure until the child and parent left the treatment room in an attempt to capture the final distress behavior exhibited by the child. However, it was standard protocol at Site Three for children to wear a hospital gown during their well-check and immunizations. After the procedure, many parents at Site Three, particularly those in the control group, appeared to be in a hurry to leave the treatment room and expressed discomfort or appeared hesitant about having the child change out of their gown while being video-recorded. In order to respect the parents' privacy, if a parent or child appeared hesitant about changing out of their gown, the music therapist stopped video recording and left the room. For this reason, not all behaviors (coping and distress) may have been captured during the recovery phase.

Effect sizes for differences in child behaviors were greater for rates and proportions coping behaviors ($r = .42$ to $.57$) than they were for rates and proportions of distress behaviors ($r = -.24$ to $-.40$), indicating that music therapy treatment may increase coping behaviors to a greater degree than it decreases distress behaviors in children undergoing immunizations. Although not all differences were statistically significant, the fact that all differences between groups were in the predicted direction (more coping and less distress for the music therapy group) is indicative of the beneficial effects of the treatment. The music therapy procedure as designed would transfer directly to a clinical setting. This evidence-based procedure could dramatically reduce childhood trauma during vaccinations.

Parent Behavior

Research has shown that parent behavior during medical procedures influences child distress (Blount et al., 1989; Blount, Landolf, et al., 1991; Blount, Sturges, & Powers, 1990; Frank et al., 1995). In this study, music therapy parents showed significantly lower rates and

proportions of distress-promoting behavior during all phases, although no significant differences were found between groups in the rates or proportions of parent coping-promoting behavior. It is possible that parents engaged in fewer distress-promoting behaviors because they were observing their child's interactions with the music therapist. The lack of differences in coping-promoting behaviors indicates that parents may have taken a more passive role when the music therapist was present, demonstrating fewer distress-promoting behaviors but not replacing them with coping-promoting behaviors. Nevertheless, parents of children in the music therapy group showed more coping-promoting behaviors than distress-promoting behaviors during all three phases, while the opposite was true for control parents, who showed more distress-promoting behaviors than coping-promoting behaviors during preparation, procedure, and recovery. In previous studies (Broome & Endsley, 1989a; Cohen, Manimala, & Blount, 2000), parents who had not received instruction in the use of coping-promoting techniques tended to display distress-promoting behaviors, as did the control parents in the present study. The lower rates and proportions of parent distress-promoting behaviors noted for music therapy parents in the present study, in spite of the fact that parents did not receive training prior to the procedure, is a clinically important finding, since it makes it less likely that children will experience procedural distress as a result of their parents' behaviors.

Nurse Behavior

Nurses in the present study showed comparable rates and proportions of coping and distress-promoting behaviors regardless of their group assignment during the preparation and recovery phases. However, during the procedure phase, nurses in the music therapy group showed a significantly higher proportion of coping-promoting behaviors. This indicates that nurses in the music therapy group may have shown fewer neutral and distress-promoting behaviors during the procedure, which increased the proportion of coping-promoting behaviors without changing the rate of coping-promoting behaviors.

During the preparation and procedure phases, nurses in both groups displayed approximately two to three times as many coping-promoting behaviors as distress-promoting behaviors. During the recovery phase, however, nurses in both groups displayed more distress-promoting behaviors than coping-promoting behaviors. It is possible that the increase in nurse distress-promoting behaviors during the recovery phase was related to the increase in child

distress behaviors during this phase, although the way in which this phase was measured, as mentioned previously, may have influenced the rates and proportions of behaviors recorded.

The fact that nurses in both groups used similar rates of coping-promoting behaviors indicates that nurses may have learned coping-promoting techniques through prior experience or training and used them regardless of whether the music therapist was present. Since scheduling concerns and protocols at the three healthcare sites made it impossible to assign nurses to a single condition (music therapy or control), many of the nurses in the present study administered injections to children in both groups. It is possible that nurses who had administered an immunization to a child in the music therapy group behaved differently during future immunizations to children in the control group as a result. Indeed, the researcher observed several nurses who had previously been part of the music therapy condition coaching children during the control condition to “look at [music therapist]” or “look at the video camera,” which are coping-promoting behaviors that they may or may not have previously utilized. The fact that nurses interacted with children in both groups may be partially responsible for the similarities in nurse behavior between the control group and the music therapy group.

Lengths of Treatment Phases

Children in the music therapy group did not differ significantly from children in the control group in length of recovery. Children in the music therapy group had procedure phases that were on average 27 seconds longer than children in the recovery group, although a high degree of variation in the lengths of procedure phases in both groups made the difference in means non-significant. There are many factors that may influence the total length of treatment and the lengths of individual phases of an immunization. Before children receive vaccines, their parents are given written information about each vaccine and are required to sign forms indicating their consent for the immunizations. In the present study, at times the paperwork was completed before the nurse had prepared the shots and other times it took place after the nurse entered the room to administer the vaccines. The timing of completion of immunization-related paperwork appeared to be influenced by the nurses’ schedules and caseloads on a particular day. Therefore, factors out of the researcher’s control may have influenced the length of the preparation phase.

Since the administration of vaccines occurs at the end of a child's well-patient visit, the parent and child may have been waiting for a considerable amount of time for the immunization. Again, this is related to the schedule and caseload on a particular day. If a parent and child had been waiting a long time or if there were many other patients waiting to be treated, the researcher observed that nurses appeared to work faster during all phases of the procedure. On days that were not particularly busy, nurses who treated children in the music therapy group occasionally asked to hear songs that the music therapist and children had been singing during the preparation phase. While this seemed to have the effect of building rapport between the child and the nurse and increasing coping-promoting behavior among nurses, it may have also increased the length of the preparation phase for the music therapy group.

During two music therapy sessions at Site Three, it became necessary for the nurse to re-administer one of the shots because the child did not get the full dosage due to arm movement. This made it necessary for the nurse to leave the room during the procedure phase to get another vaccine, increasing the length of the procedure. During several sessions in both the music therapy and the control groups, the nurse had to leave the room to get another nurse to assist with restraining the child, which also increased the length of the procedure.

Parents' Ratings of Distress

Parents of children in the music therapy group indicated that their child's level of distress was better than usual, while parents of children in the control group tended to rate their children's distress as slightly worse than usual. This trend among the control group supports the claims made in previous research that children between 4 and 6 years of age show high levels of distress during immunizations (Blount et al., 1992; Frank et al., 1995; Jacobson et al., 2001), which may make it more difficult for nurses to immunize them compared to children of other ages (Ives & Melrose, 2010).

In spite of the difficulties inherent in preschool immunizations, parents of children in the music therapy group tended to report that their children were less distressed than during previous medical experiences. This suggests that at the very least, music therapy may improve parents' perceptions of their children's immunization experiences and, coupled with other behavioral measures of child distress, indicates that music therapy decreases children's distress.

Parents' Ratings of Pain

Parents' responses when asked about their children's pain indicated that parents understood the distinction between pain and anxiety. This is important, since children under the age of 8 tend to confuse the two concepts. When asked to rate her child's level of pain, the parent of a "high distress" child in the control group commented that she did not think that the shots were very painful for her child, but that her child had been fearful and anxious regardless of the pain. Parents of children in the music therapy group and the control group reported that their children experienced similar levels of pain, although parents in the music therapy group tended to report that their children were less distressed than usual.

There were several differences between the immunization protocols at the three healthcare sites which could have had an effect on the child's pain. It is unlikely that these variables influenced the measures of overall treatment effects in this study since the distribution of music therapy and control participants was fairly even among healthcare sites, but these practices still warrant discussion. At Sites One and Two, nurses positioned children in a supine position, while at Site Three, children were positioned in a seated position. At Site One, after asking children to lie back on the treatment table, one nurse would cross the child's hands over their chest and gently restrain them while a second nurse administered the injection(s) in the child's thigh(s). At Site Two, the nurse usually asked the parent to hold the child's arm while the nurse administered the shot(s) in the child's thigh(s), only asking another nurse for assistance if the child was extremely resistant. At Site Three, the nurse would administer the vaccine(s) in the child's deltoid(s), only asking the parent or another nurse to help restrain the child if the child resisted.

In spite of variations in practices among the three healthcare sites that may have caused great variation in parents' reports of their child's pain, children in the music therapy group reportedly experienced slightly less pain than children in the control group, on average. Future research including one healthcare site with a standard protocol for physical positioning of children during immunizations could better examine the child's level of pain. Regardless, in the present study children in the music therapy group showed less distress in spite of variations in perceived pain.

Parent Satisfaction

The majority of parents in the music therapy group reported that their child benefited from music therapy and that they (the parent) benefited from music therapy. In addition, most parents indicated that music therapy improved their perception of the facility and that they would like to receive music therapy in the future. There were no parents who responded “not at all” to the first three survey questions, regarding whether they or their child benefited from music therapy and whether it improved their perception of the facility. Likewise, there were no parents who said they definitely would not like to receive music therapy in the future. Responses of parents whose children received music therapy indicate that they valued the music therapy treatment as part of their child’s doctor visit, and would like for music therapy to be incorporated into future healthcare experiences.

Limitations of the Present Study

The relatively small sample size is one limitation of the present study. Because the study was conducted at three different healthcare sites, the sample was heterogeneous with regard to immunization practices utilized, including the positioning of the child (supine or seated) and the location of the needle injection (deltoid or thigh), although participants from the three healthcare sites were evenly distributed between the music therapy and control groups. Threats to internal and external validity are discussed further.

Threats to Internal Validity

The post-test only control group design with random assignment utilized effectively controlled for all single group threats to internal validity (history, maturation, testing, instrumentation, attrition, and regression to the mean), as well as the majority of multiple-group threats to internal validity (selection and its interactions with history, maturation, testing, instrumentation, and regression).

It is possible, but unlikely, that an interaction between selection (or group assignment) and attrition could have influenced the results of the study. If differential rates of attrition occurred between the music therapy and control groups, then this threat could have affected the results. However, of the two parents who elected for their child to receive the flu mist after learning which group their child was in, one was in the music therapy group and one was in the

control group. All other parents who declined to participate did so before they were randomly assigned to a group, minimizing the likelihood of effects from the threat of a selection-attrition interaction.

Trochim (2006) discussed four types of social interaction threats to internal validity that should be considered in research where members of one group are aware of the condition which another group is undergoing. These social interaction threats warrant discussion here since members of the control group in the present study were aware that they were not receiving music therapy. The first of these is the threat of diffusion or imitation of treatment. As previously discussed, several nurses administered immunizations to children in both groups, which may have resulted in diffusion or imitation. Diffusion or imitation of treatment tends to have the effect of minimizing the difference between treatment and control. Therefore, if diffusion or imitation did occur, it appears that it did not eliminate all treatment effects, since significant differences were found for child, parent, and nurse behavior. However, it is possible that greater differences between the two groups would have been found had nurses only performed immunizations under a single condition.

Compensatory rivalry, another social interaction threat to internal validity, could have occurred if children, parents, or nurses in the control group behaved differently than normal in an effort to demonstrate how well they could cope without music therapy. This threat also tends to minimize the treatment effect, which was evident in spite of the possibility of compensatory rivalry. However, as with diffusion or imitation of treatment, it is possible that greater differences would have been found if the control group was unaware that another group was receiving music therapy.

Resentful demoralization is another social interaction threat to internal validity. This could have occurred if children, parents, or nurses in the control group were angry that they were not assigned to the music therapy group and in effect gave up on attempts at coping during the procedure. This would have the effect of exaggerating differences between the groups. While technically possible, the likelihood that this occurred is small because of the negative effects this would have had on the child, parent, and nurse during the immunization. The researcher observed that parents and nurses appeared to try in earnest to help their children cope during immunizations in the control condition.

Another possible threat to internal validity is compensatory equalization of treatment. If the music therapist, doctor, or nurse had offered something outside of standard care to members of the control group to compensate for their group assignment, this could have influenced the results. This threat would also have the effect of minimizing the treatment effect. This is not applicable in the present study since the control group was given standard care.

The threat of experimenter effects was minimized by having two different music therapists administer the treatment, with each music therapist working with children under both conditions; however, since one therapist performed more of the treatments than the other, it was not possible to compare outcomes statistically to examine experimenter effects. This is an area for future research and replications of the present study could include analysis of experimenter effects.

Threats to External Validity

Although threats to external validity are a real potential for most if not all clinical research studies, the fact that the present study took place in doctors' offices during standard immunization procedures rather than in a lab makes a good case for the ecological validity of the study. Although there was no pre-test to raise concerns about an interaction effect of testing and treatment, it is possible that completing the demographic inventory or the knowledge that the parent would be completing a post-procedure questionnaire influenced behavior during the study. Likewise, the threat of reactive arrangements is possible, as with any study, since children, parents, and nurses may behave differently when they are not being studied. Multiple treatment interference is possible for the nurses, who may have been in both the experimental and the control conditions. The threat of an interaction effect between selection and treatment is minimized by the use of three diverse healthcare sites, but further testing would be necessary to determine whether the results generalized to other settings.

Limitations of the CAMPIS-R

The CAMPIS-R functioned well as a measure of distress and coping behaviors in the present study with one exception. It should be noted that the behavior of one of the parents of a child in the music therapy group seemed to necessitate the creation of a new code for adult behavior. During the preparation, procedure, and recovery phase, the parent in question behaved

in a way that appeared hostile to the nurses assisting with the immunization, criticizing and at times yelling and swearing. Although these behaviors were directed at other adults, both of the research assistants who viewed the video agreed that many of this parent's behaviors did not fit into the neutral category. The research assistant who coded the video decided that the comments made by the parent in this video fit into two newly defined categories: "Hostile Non Procedure Related Talk to Adults" and "Hostile Procedure Related Talk to Adults". Hostile Non-Procedure Related Talk to Adults was defined as talk that does not pertain to the treatment procedure that is delivered to other adults with a negative, critical, or aggressive tone. Hostile Procedure-Related Talk to Adults was defined as talk that directly pertains to the current treatment procedure that is delivered with a negative, critical, or aggressive tone. The research assistant further categorized these newly defined behaviors as neutral and distress-promoting, respectively, based on observations of the child's reactions to the parent's behavior. Although the parent was speaking to the nurse with a hostile tone before the shots were administered, the child was disengaged from what the parent was saying, showed no visible or audible signs of distress, and engaged with the music therapist when prompted, displaying a high frequency of coping behaviors. However, when the parent engaged in hostile procedure-related talk to the nurse administering the shots, the child showed an increase in distress behaviors such as crying, squirming, kicking, and screaming. Based on these observations, Hostile Non-Procedure Related Talk to Adults was coded as neutral and Hostile Procedure Related Talk to Adults was coded as distress-promoting.

It may not be feasible or necessary to include Hostile Non-Procedure Related Talk to Adults or Hostile Procedure Related Talk to Adults in future studies using the CAMPIS since they appear to be low-incidence behaviors, making it unlikely that a sequential analysis could be conducted to determine whether they tend to promote distress in children. Nonetheless, there was agreement among the music therapist who implemented the treatment, the research assistants who reviewed the video, and the researcher that these behaviors did not fit under the existing CAMPIS behavior categories. This transcript was included in the analysis because rates of child and nurse behaviors were similar to those of other participants in the music therapy group, in spite of the parents' behaviors. If this parent's unusual behavior had an effect on the rates of child and nurse behavior during this session, it would have most likely minimized the treatment effect of the music therapy intervention.

Implications for Clinical Practice

The results of the present study indicate that children, parents, and nurses can benefit from a live, cognitive-behavioral music therapy intervention as procedural support during preschool immunizations. In the present study, parents showed fewer distress-promoting behaviors during the music therapy condition in spite of the fact that they received no instruction or training regarding reduction of distress-promoting behaviors. This indicates that music therapy may be an efficient alternative to lengthy parent-training programs designed to teach adults how to coach children during medical procedures. Parents in both groups did not spontaneously use high rates of coping-promoting behaviors, indicating that additional training may be necessary to help parents use coping-promoting behaviors. However, parents' decreased use of distress-promoting behaviors, which may have been the result of parents listening to the music therapist rather than attempting to reassure their child, provided better outcomes for children than standard care, as evidenced by children's use of more coping behavior and less distress behavior. In other words, decreases in parent distress-promoting behaviors benefit children even without increases in parent coping-promoting behavior.

In practice, music therapists could find ways to efficiently model coping-promoting behaviors for parents without adding to the length of the family's visit to the doctor's office. Parents and children often have periods of time when they wait for the nurse to bring them to the treatment room and when they wait for the doctor to come see them while in the treatment room. These are times when a music therapist could begin interacting with the child and showing the parent ways to use coping-promoting techniques instead of distress-promoting behaviors. The use of a live, cognitive-behavioral music therapy intervention to model coping-promoting behaviors for parents could help increase positive responses from parents during their child's future medical procedures.

The present study makes a case for music therapy to be included as a service offered in outpatient pediatric or family medicine clinics. A music therapist working full-time in an outpatient pediatric clinic could provide procedural support music therapy to children of various ages receiving immunizations, allergy shots, throat cultures, and other invasive office procedures. Children who have had traumatic medical experiences may become distressed during doctor visits regardless of whether they are undergoing an invasive procedure. During the present study, some children cried upon seeing the doctor. One child in the control group reported being

in pain when the nurse placed the hearing probe up to her ear for her hearing test. Infants being weighed by the nurse during a well-baby check-up frequently cried upon being held by a stranger in an unfamiliar setting. Music therapy has the potential to normalize the environment of outpatient pediatric clinics, and with further research and demonstration of clinical benefits, could become a standard part of pediatric care.

Suggestions for Future Research

Future research should examine the effects of live, cognitive-behavioral music therapy procedural support interventions on children of different ages, since the research literature indicates that toddlers and school-aged children also show pain and distress during immunizations. It is recommended that adaptations of the present intervention for children of different ages should use music that is age-appropriate and use language and interactions that are matched to the child's developmental stage.

Physiological measures of anxiety and pain are often measured during medical procedures. While these measures can provide useful information, the use of heart rate monitors, oxygen saturation monitors, sphygmomanometers to measure blood pressure, and other tools for measuring physiological characteristics may invoke additional distress in children, creating a threat to external validity. Therefore, future studies investigating physiological measures during immunizations should do so as unobtrusively as possible.

It would be informative to survey nurses regarding their perceptions of music therapy to determine whether they perceived benefits for children, parents, and the nurses themselves. In previous studies, nurses have reported that although they thought cognitive-behavioral interventions were effective at decreasing children's distress and pain, they preferred to use standard protocols because of the time and effort involved with implementing cognitive-behavioral interventions. In the present study, several nurses made requests for music therapy services for children who did not meet the study's inclusion criteria due to age. When the music therapist came to a healthcare site after not having been there the previous day, nurses frequently commented, "We needed you here yesterday" to help a child who showed distress during immunizations. Although these anecdotes suggest that nurses found the intervention helpful, surveying nurses regarding their perceptions of music therapy interventions for children undergoing immunizations is an important area for future research.

Following-up with children who previously received music therapy during an immunization would be helpful to determine whether these children show differences in behaviors during subsequent immunizations. It would also be of interest to investigate whether improving children's early medical experiences leads to long-term decreases in trauma which can create needle phobias and avoidance of medical treatments in adulthood. A study by Cohen et al. (2001) found that fourth-graders who received a cognitive-behavioral intervention during immunizations remembered the experience as being more positive than other immunizations when surveyed six months later. In the present study, the music therapist saw the parent of one child-who had previously received music therapy-during a subsequent doctor visit. The parent told her daughter, "Look, it's the music lady," at which point the child smiled and waved to the music therapist. Whether other children in the music therapy group have positive memories of receiving music therapist and whether the coping skills they learned transfer to future procedures are areas for future research.

In conclusion, this study demonstrates that the use of an evidence-based, developmentally appropriate, cognitive-behavioral intervention using live music can effectively facilitate the delivery of medical treatment. Learning coping behaviors during an early medical procedure has the potential to help children develop healthy attitudes about medical care. When incorporated with standard care during immunizations for young children, live music therapy has the potential to normalize and humanize a potentially threatening environment, improving the experience for children, their parents, and members of the healthcare staff.

APPENDIX A

Florida State University Human Subjects Committee Approval

Office of the Vice President For Research
Human Subjects Committee
Tallahassee, Florida 32306-2742
(850) 644-8673, FAX (850) 644-4392

APPROVAL MEMORANDUM

Date: 10/10/2011

To: Olivia YINGER [REDACTED]

Address: 1180
Dept.: MUSIC SCHOOL

From: Thomas L. Jacobson, Chair

Re: Use of Human Subjects in Research
Music therapy as procedural support for young children undergoing immunizations: A
randomized controlled study

The application that you submitted to this office in regard to the use of human subjects in the research proposal referenced above has been reviewed by the Human Subjects Committee at its meeting on 08/10/2011. Your project was approved by the Committee.

The Human Subjects Committee has not evaluated your proposal for scientific merit, except to weigh the risk to the human participants and the aspects of the proposal related to potential risk and benefit. This approval does not replace any departmental or other approvals, which may be required.

If you submitted a proposed consent form with your application, the approved stamped consent form is attached to this approval notice. Only the stamped version of the consent form may be used in recruiting research subjects.

If the project has not been completed by 8/8/2012 you must request a renewal of approval for continuation of the project. As a courtesy, a renewal notice will be sent to you prior to your expiration date; however, it is your responsibility as the Principal Investigator to timely request renewal of your approval from the Committee.

You are advised that any change in protocol for this project must be reviewed and approved by the Committee prior to implementation of the proposed change in the protocol. A protocol change/amendment form is required to be submitted for approval by the Committee. In addition, federal regulations require that the Principal Investigator promptly report, in writing any unanticipated problems or adverse events involving risks to research subjects or others.

By copy of this memorandum, the Chair of your department and/or your major professor is reminded that he/she is responsible for being informed concerning research projects involving human subjects in the department, and should review protocols as often as needed to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

This institution has an Assurance on file with the Office for Human Research Protection. The Assurance Number is FWA00000168/IRB number IRB00000446.

Cc: Jayne Standley, Advisor
HSC No. 2011.6797

Office of the Vice President For Research
Human Subjects Committee
Tallahassee, Florida 32306-2742
(850) 644-8673, FAX (850) 644-4392

APPROVAL MEMORANDUM (for change in research protocol)

Date: 11/1/2011

To: Olivia YINGER [REDACTED]

Address: 1180
Dept.: MUSIC SCHOOL

From: Thomas L. Jacobson, Chair

Re: Use of Human Subjects in Research (Approval for Change in Protocol)
Project entitled: Music therapy as procedural support for young children undergoing immunizations: A randomized controlled study

The form that you submitted to this office in regard to the requested change/amendment to your research protocol for the above-referenced project has been reviewed and approved.

Please be reminded that if the project has not been completed by 8/8/2012, you must request renewed approval for continuation of the project.

By copy of this memorandum, the chairman of your department and/or your major professor is reminded that he/she is responsible for being informed concerning research projects involving human subjects in the department, and should review protocols as often as needed to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

This institution has an Assurance on file with the Office for Human Research Protection. The Assurance Number is FWA00000168/IRB number IRB00000446.

Cc: Jayne Standley, Advisor [jstandley@music.fsu.edu]
HSC No. 2011.7326

APPENDIX B

Tallahassee Memorial HealthCare Institutional Review Board Approval

Tallahassee Memorial HealthCare

Office of Research
Institutional Review Board 1300 Miccosukee Road
Tallahassee, Florida 32308
(850) 431-5676
(850) 431-6052 Fax

September 21, 2011

Olivia Swedberg Yinger, MME, MT-BC
Florida State University
College of Music
Tallahassee, FL 32306-1180

Dear Ms. Swedberg Yinger:

Following your presentation to the Institutional Review Board (IRB) at Tallahassee Memorial HealthCare (TMH) on September 20, 201, IRB # 2011-29 Titled: Music therapy as procedural support for young children undergoing immunizations: A randomized controlled study, v2, 9/2/2011 was unanimously approved with the provision that the modifications indications are made and may be submitted to the IRB Chair for consideration using expedited review guidelines. The approval expires on September 19, 2012.

IRB # 2011-29 Music therapy as procedural support for young children undergoing immunizations: A randomized controlled study

Principal Investigator: Olivia Swedberg Yinger, MME, MT-BC

Informed Consent: Pending Requested Changes to include:

- Changing "the records of this study will be kept private and confidential to the extent permitted..." to "...the extent required..."
- A time frame for how long the protected health information will be kept and a description of how it will be destroyed.

Protocol: Pending Requested Changes to include:

- Clarification whether or not that the researcher and music therapist are the same person.
- Correction of the age of the child participating to correlate with the age designated in the informed consent, e.g., 48-72 months.

Other Forms Reviewed: Pending Requested Changes to include:

- Demographic Form – give the parents categories to check for number of previous doctor visits and hospitalization/ED visits.
- Application: Section G b) Age range of subjects: 4-6 years (48 to 72 months), 18 and older. Clarify what population constitutes the 18 and older group.

FWA #00006166

Tallahassee Memorial HealthCare, Inc. Institutional Review Board is organized and operates according to ICH-GCP standards and applicable laws and regulations.

Other Materials Reviewed and Approved: Parent Post-procedure Questionnaire, Universal Pain Assessment, Video Observation Form 1, Child Coping, Child Distress, Child Neutral, Parent or Staff Coping Promoting, Parent or Staff Neutral, Parent or Staff Distress Promoting, Video Observation Form 2, Children's Hospital Eastern Ontario Pain Scale (CHEOPS), TMH Consent to Photograph and Publish, and Confidentiality Agreement for Video Observers.

Reporting Requirements:

- Report to the IRB any planned change in the study or informed consent and do not implement any change without receiving prior approval, except to eliminate immediate hazard;
- Report to the IRB any unanticipated problems involving risks to subjects;
- Report to the IRB any new information on the project that adversely influences the risk/benefit ratio;
- Report to the IRB any serious or unexpected adverse events;
- Report to the IRB any major protocol violations within ten days. Minor protocol deviations may be reported at the time of the Study Progress Report (Application for Renewal). Maintain a log throughout the year and establish a plan of correction to minimize the deviations.
- Report to the IRB when the study is terminated or completed and submit a summary of the study findings.

Please request approval for advertising copy, recruitment flyers, publications, that appear in any medium prior to use.

Supplemental Reporting Requirements: None

Expiration Date: September 19, 2012

Continuation Review Date: September 19, 2012

Continuation Review Requirements: At the time of renewal please check the Office of Research/IRB intranet site to ensure that you have the most current edition of the IRB Forms. The investigator must submit a completed Study Progress Report Application and supporting documentation packet to the Office of Research/IRB one month prior to the approval expiration date. Please note the expiration date of the study and compare it to the IRB Meeting Schedule to ensure timely review and processing of the study file prior to the fully convened IRB meeting and inclusion of your request for renewal on the appropriate agenda. If you have any questions about the forms or submitting them, please contact Mary Sandell, Regulatory Readiness Coordinator at (850) 431-5676.

FWA #000006166

Tallahassee Memorial HealthCare, Inc. Institutional Review Board is organized and operates according to ICH-GCP standards and applicable laws and regulations.

As the principal investigator you are responsible for ensuring compliance with the study protocol, the applicable IRB at TMH Guidelines and Code of Federal Regulations set forth by the Department of Health and Human Services. The IRB Guidelines and forms required to comply with reporting requirements are available on the TMH Intranet.

Enclosed are the forms which were reviewed and approved by the board and have the IRB approval stamp for this year.

Sincerely,

Cynthia Blair
Administrative Liaison/IRB

Modifications Request

Changes (amendments/modifications) to a protocol may not be initiated without prior IRB approval except, when necessary to eliminate immediate hazard to subjects.

Click on Modifications for guidance (Section 8.5).

This form must be typed or it will be returned.

Date: 11/1/2011 PI: Olivia Swedberg Yinger Phone: 850-443-8703 Email: oliviaswedberg@gmail.com

Study Coordinator: Same as PI Phone: Email:

IRB #: 2011-29 Study Title: Music therapy as procedural support for young children undergoing immunizations: A randomized controlled study

Check items submitted for IRB approval. Attach revisions/amendments as appropriate.

Personnel changes: Indicate which personnel are to be added or removed from the study. If NEW PERSONNEL are added provide documentation indicating the individual's qualifications to participate in research, Medical Staff Office Privileges and signed Conflict of Interest Questionnaire IRB Form 3 for each new person.

Action	Obtaining Informed Consent		Name	Resume/CV Submitted	
Remove Add	Yes	No		Yes	No
Remove Add	Yes	No		Yes	No
Remove Add	Yes	No		Yes	No
If this is an investigator initiated study involving an investigational drug, submit a revised FDA Form 1572.					

Protocol Updates/Amendment(s): It is required that you attach:

- A detailed summary from the investigator describing the changes and how they impact on the patient care/treatment,
- If minor changes only, please summarize.
- A complete copy of the revised protocol with revision date of .
- Any relevant documentation.

Consent form changes: It is REQUIRED that you attach:

- A copy of the revised consent form with revision date of 10/31/2011.
- A summary of changes.

ALL CHANGES MUST BE HIGHLIGHTED (Strikethrough and Underline).

Investigator Brochure - Changes must be highlighted (Strikethrough and Underline). If changes are more than minor in detail, attach a detailed summary of the changes requested. Pharmacy received a copy of the Investigator Brochure Yes No Comments:

Other (recruitment materials, survey instruments, etc.):

The modifications, if approved and implemented, **will not** result in a change of the risk benefit/ratio nor will they affect a change in the study's overall objectives.

Signature of Principal Investigator

Olivia Swedberg Yinger/ 11/1/2011
Print Name/Date

The above changes have been reviewed by Expedited Procedures
Approved ☒ Deferred ☐ Referred for further review by ☐

Convoked Full Board ☐

Larry C. Deeb, IRB Chair

Date

APPENDIX C

Florida State University Consent Forms

FSU Behavioral Consent Form

Music therapy as procedural support for young children undergoing immunizations: A randomized controlled study

You are invited to be in a research study of the effects of live music therapy on child and adult behaviors during child immunizations. You were selected as a possible participant because your child is between 48 and 72 months of age and will be undergoing an immunization. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by Olivia Swedberg Yinger, MME, MT-BC, NICU-MT, a doctoral student studying music therapy at the Florida State University College of Music under the direction of Dr. Jayne M. Standley.

Background Information:

The purpose of this study is to examine the effects of music therapy on child and adult behaviors during child immunizations.

Procedures:

If you agree to be in this study, you will be asked to fill out a form answering questions about your child's age, sex, and previous medical experiences. Next, you and your child will be randomly assigned to either an experimental group or a control group. The experimental group will receive music therapy during the child's immunization, while the control group will receive standard care during the child's immunization. All procedures will be videotaped. Afterward, you will be asked to fill out two forms answering questions about your perceptions of the procedure and your child's reactions during the procedure. This will take approximately 5 minutes.

For children in the music therapy treatment group, the music therapist will meet with the child before the procedure and will remain in the treatment room during the immunization. The music therapist will engage the child in live music play activities at appropriate times throughout the procedure. Later, the videotapes will be reviewed by trained observers who will be advanced students in music education/music therapy from FSU. All observers will sign agreements to maintain confidentiality regarding what is seen in the videotapes.

Risks and benefits of being in the Study:

A possible risk of participation in this study is that you or your child could become uncomfortable during the videotaping or, for participants in the experimental group, your child could become upset by the music. If this happens, you or your child may stop participation in the study at any time by telling the researcher that you do not want to continue or that you would like to stop videotaping.

FSU Human Subjects Committee approved on 10/31/2011 Void after 08/08/2012
HSC # 2011.7326

The information that you provide could help researchers better understand ways to help children cope with medical procedures. Also, for those in the experimental group, one potential benefit is that music therapy may help distract your child during the procedure.

Compensation:

There is no additional cost to you to participate in this study. You will not receive any compensation for being in this research study.

Confidentiality:

The records of this study will be kept private and confidential to the extent permitted by law. In any sort of report we might publish, we will not include any information that will make it possible to identify a subject. Research records will be stored securely and only researchers will have access to the records. Video recordings of procedures will be kept on the Principal Investigator's computer, which is password protected. Your video recording will be labeled with a code number, and your name and your child's name will not be attached to it.

Voluntary Nature of the Study:

Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future medical care or your current or future relations with Florida State University. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Contacts and Questions:

The researcher conducting this study is Olivia Swedberg Yinger. You may ask any question you have now. If you have a question later, you are encouraged to contact the researcher at Florida State University College of Music, Tallahassee, FL 32306-1180 (address [REDACTED]-mail). You may also contact the Faculty Advisor for this study, Dr. Jayne M. Standley, at 850-644-4565 (phone) or jstandley@music.fsu.edu (e-mail). If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), you are encouraged to contact the FSU IRB at 2010 Levy Street, Research Building B, Suite 276, Tallahassee, FL 32306-2742, or 850-644-8633, or by email at humansubjects@magnet.fsu.edu.

You will be given a copy of this information to keep for your records.

Statement of Consent:

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature

Date

Signature of Investigator

Date

FSU Human Subjects Committee approved on 10/31/2011 Void after 08/08/2012
HSC # 2011.7326

FSU Behavioral Consent Form

Music therapy as procedural support for young children undergoing immunizations: A randomized controlled study

You are invited to be in a research study of the effects of live music therapy on child and adult behaviors during child immunizations. You were selected as a possible participant because you are a member of the healthcare staff who will be assisting with procedures for children and parents enrolled in this study. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by Olivia Swedberg Yinger, MME, MT-BC, NICU-MT, a doctoral student studying music therapy at the Florida State University College of Music under the direction of Dr. Jayne M. Standley.

Background Information:

The purpose of this study is to examine the effects of music therapy on child and adult behaviors during child immunizations.

Procedures:

If you agree to be in this study, immunizations that you perform on children who are enrolled in this study will be videotaped. You will be included in these video recordings.

Later, the videotapes will be reviewed by trained observers who will be advanced students in music education/music therapy from Florida State University (FSU). All observers will sign agreements to maintain confidentiality regarding what is seen in the videotapes.

Risks and benefits of being in the Study:

A possible risk of participation in this study is that you may be uncomfortable with the music or being videotaped. If this happens, you may stop participation in the study at any time by telling the researcher that you would like to stop the music or the videotaping.

One potential benefit is that music therapy or the presence of the video camera may help distract the child, making the procedure easier for you to perform. However, there is no guarantee that this will happen. The information that you provide could help researchers better understand ways to help children cope with medical procedures.

Compensation:

There is no additional cost to you to participate in this study. You will not receive any compensation for being in this research study.

Confidentiality:

The records of this study will be kept private and confidential to the extent permitted by law. In any sort of report we might publish, we will not include any information that will

FSU Human Subjects Committee approved on 10/31/2011 Void after 08/08/2012
HSC # 2011.7326

make it possible to identify a subject. Research records will be stored securely and only researchers will have access to the records. Video recordings of procedures will be kept on the Principal Investigator's computer, which is password protected. Your video recording will be labeled with a code number, and your name and your child's name will not be attached to it.

Voluntary Nature of the Study:

Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future medical care or your current or future relations with Florida State University. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Contacts and Questions:

The researcher conducting this study is Olivia Swedberg Yinger. You may ask any question you have now. If you have a question later, you are encouraged to contact the researcher at Florida State University College of Music, Tallahassee, FL 32306-1180 (address) [REDACTED] (e-mail). You may also contact the Faculty Advisor for this study, Dr. Jayne M. Standley, at 850-644-4565 (phone) or jstandley@music.fsu.edu (e-mail). If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), you are encouraged to contact the FSU IRB at 2010 Levy Street, Research Building B, Suite 276, Tallahassee, FL 32306-2742, or 850-644-8633, or by email at humansubjects@magnet.fsu.edu.

You will be given a copy of this information to keep for your records.

Statement of Consent:

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature

Date

Signature of Investigator

Date

FSU Human Subjects Committee approved on 10/31/2011 Void after 08/08/2012
HSC # 2011.7326

APPENDIX D

Tallahassee Memorial HealthCare Consent Forms

Informed Consent Form

Title of Project: Music therapy as procedural support for young children undergoing immunizations: A randomized controlled study

Principal Investigator: Olivia Swedberg Yinger, MME, MT-BC, NICU-MT

Participant (Child's) Printed Name: _____

This is a research study. Research studies include only people who want to take part. This form gives you information about this research, which will be discussed with you. It may contain words or procedures that you do not understand. Please ask questions about anything that is unclear to you. Discuss it with your family and friends and take your time to make your decision.

1. Purpose of the Research:

The purpose of this study is to examine the effects of music therapy on child and adult behaviors during child immunizations and influenza vaccinations. You were selected as a possible participant because your child is between 48 and 72 months of age and will be undergoing an immunization or influenza vaccination at Tallahassee Memorial HealthCare (TMH) Family Medicine. This study is also being conducted at another doctor's office in Tallahassee, as well as a doctor's office in Bainbridge, Georgia. About 60 children, 60 parents/guardians, and 60 healthcare staff will take part in this research nationwide. About 45 children, 45 parents/guardians, and 45 healthcare staff are expected to take part in the study at TMH Family Medicine.

2. Procedures to Be Followed:

If you agree to be in this study, you will be asked to fill out a form answering questions about your child's age, sex, and previous medical experiences. Next, you and your child will be randomly assigned to either an experimental group or a control group. The experimental group will receive music therapy during the child's immunization, while the control group will receive standard care during the child's immunization. All procedures will be videotaped. Afterward, you will be asked to fill out two forms answering questions about your perceptions of the procedure and your child's reactions during the procedure. This will take approximately 5 minutes.

For children in the music therapy treatment group, the music therapist will meet with the child before the procedure and will remain in the treatment room during the immunization. The music therapist will engage the child in live music play activities at appropriate times throughout the procedure.

Later, the videotapes will be reviewed by trained observers who will be advanced students in music education/music therapy from Florida State University (FSU). All observers will sign agreements to maintain confidentiality regarding what is seen in the videotapes.

FSU Human Subjects Committee approved on 10/31/2011 Void after 08/08/2012
HSC # 2011.7326

Informed Consent Form

3. Discomforts and Risks:

A possible risk of participation in this study is that you or your child could become uncomfortable during the videotaping or, for participants in the experimental group, your child could become upset by the music or uncomfortable being videotaped. If this happens, you or your child may stop participation in the study at any time by telling the researcher that you do not want to continue or that you would like to stop videotaping.

4. Possible Benefits:

a. Possible benefits to you and your child:

For those in the experimental group, one potential benefit is that music therapy may help distract your child during the procedure. However, there is no guarantee that music therapy will help children in the experimental group.

b. Possible benefits to others:

The information that you provide could help researchers better understand ways to help children cope with medical procedures.

5. Other Options that Could be Used Instead of this Research:

You do not have to take part in this research study. If you do not want your child to participate in the study, they will receive standard care services during their immunization or vaccination.

6. Time Duration of the Procedures and Study:

If you agree for your child to take part in this study, you will be asked to fill out paperwork before their immunization, which will take approximately five minutes, and additional forms afterwards, which will take approximately five more minutes. Participation in this study does not require any additional time on your part during the immunization or vaccination procedure.

7. Statement of Confidentiality:

a. Privacy and confidentiality measures

The records of this study will be kept private and confidential to the extent required by law. Information that you provide on the data collection forms will be labeled with a code number, and the key that matches your child's name with the code number assigned to your child's record will be kept in a locked file cabinet in the Principal Investigator's office. On the research data forms, your child will not be identified by name; instead, the assigned code number will be used to identify your child's information. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Video recordings of procedures and data for analysis will be kept on the Principal Investigator's computer, which is password protected. Your video recording will be labeled with a code number, and your name and your child's name will not be attached to it. Trained observers (graduate students in music education/music therapy at FSU) who view the videos for data analysis will sign a confidentiality statement before

FSU Human Subjects Committee approved on 10/31/2011 Void after 08/08/2012
HSC # 2011.7326

Informed Consent Form

watching the videos, stating that they will not share content of the videos with anyone other than the Principal Investigator.

b. The use of private health information

A video recording of your child's immunization or vaccination will be made if you choose to participate in this study. You will also be asked to provide your child's sex and date of birth, and complete questionnaires about your child's previous medical experiences and about the current medical experience. No other health information about you or your child will be collected if you choose to be part of this research study.

Health information about you will be collected if you choose to be part of this research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information and may share it without your permission.

To participate in this research you must allow the research team to use your health information. If you do not want us to use your protected health information, you may not participate in this research. Your permission for the use, retention, and sharing of your identifiable health information will continue indefinitely. Data collection forms will be shredded after the results of the study have been analyzed and within one year of collection. Video recordings and protected health information will be maintained indefinitely by the researcher for use in potential follow-up analysis.

If you choose to participate, you are free to withdraw your permission for the use and sharing of your health information at any time. You must do this in writing. Write to Olivia Swedberg Yinger and let her know that you are withdrawing from the research study. Her mailing address is: Florida State University College of Music, Tallahassee, FL 32306-1180.

If you withdraw your permission:

- We will no longer use or share medical information about you for this research study, except when the law allows us to do so.
- We are unable to take back anything we have already done or any information we have already shared with your permission.
- We may continue using and sharing the information obtained prior to your withdrawal if it is necessary for the soundness of the overall research.
- We will keep our records of the care that we provided to you as long as the law requires.

The research team may use the following sources of health information.

- Video recording of your child's procedure
- Your responses to study questionnaires

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HSC # 2011.7326

Informed Consent Form

Representatives of the researcher or designee may use your health information and share it with other specific groups in connection with this research study.

- The Institutional Review Board at TMH

The above people/groups may share your health information with the following people/groups outside TMH for their use in connection with this research study. These groups, while monitoring the research study, may also review and/or copy your original records.

- The Office of Human Research Protections in the U. S. Department of Health and Human Services
- The FSU Human Subjects Protection Office
- The researcher's major professor and committee members, who are faculty of the FSU College of Music
- Trained observers who are graduate students in music therapy/music education

We will do our best to make sure that the personal information in your medical record will be kept private. However, because of the need to release information to the above parties, absolute confidentiality cannot be guaranteed. Once your personal health information is released, it may be redisclosed and no longer protected by federal privacy regulations. Your personal information may also be given out if required by law and in rare circumstances may be subpoenaed by a court.

8. Costs for Participation:

a. Costs:

There is no additional cost to you for your child to participate in this study.

b. Treatment and compensation for injury:

Every effort to prevent injury as a result of your participation will be taken. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. It is the policy of this institution to provide neither financial compensation nor free medical treatment for research-related injury.

Costs for the treatment of research-related injuries will be charged to your insurance carrier or to you. Some insurance companies may not cover costs associated with research studies. If for any reason these costs are not covered by your insurance, they will be your responsibility. You will also be responsible for any deductible, co-insurance and/or co-pay. You will not lose any legal rights by signing this form.

9. Compensation for Participation:

You will not receive any compensation for being in this research study.

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HSC # 2011.7326

Informed Consent Form

10. Research Funding:

The institution and investigators are not receiving any funds to support this research study.

11. Voluntary Participation:

Taking part in this research study is voluntary. Your child does not have to participate in this research. If you choose to have your child take part, you have the right to stop at any time. If you decide not to have your child participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which your child is entitled. The healthcare staff may take your child out of the research study without your permission. One possible reason for this would be if medical complications arise that prevent your child from being able to receive music therapy.

12. Contact Information for Questions or Concerns:

You have the right to ask any questions you may have about this research. If you have questions, complaints, or concerns or believe that you or your child may have developed an injury related to this research, contact Olivia Swedberg Yinger at 850-██████████ (phone), Florida State University College of Music, Tallahassee, FL 32306-1180 (address), or ██████████ (e-mail). If you have questions regarding your rights or your child's rights as a research participant or you have concerns or general questions about the research or about your child's privacy and the use of your child's personal health information, contact the research protection advocate, Cynthia Blair, Administrative Liaison/IRB, Tallahassee Memorial HealthCare, (850) 431-5676. You may also call this number if you cannot reach the research team or wish to talk to someone else. You may also contact the Faculty Advisor for this study, Dr. Jayne M. Standley, at 850-644-4565 (phone) or jstandley@music.fsu.edu (e-mail). If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), you are encouraged to contact the FSU IRB at 2010 Levy Street, Research Building B, Suite 276, Tallahassee, FL 32306-2742, or 850-644-8633, or by email at humansubjects@magnet.fsu.edu.

Informed Consent Form

Signature and Consent/Permission to be in the Research

Before making the decision regarding enrollment in this research you should have:

- Discussed this study with an investigator,
- Reviewed the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Participant's Legally Authorized Representative: By signing below, you indicate that you give permission for the participant (your child) to take part in this research.

Signature of Participant's Legally Authorized Representative	Date	Time	Printed Name
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(Signature of Participant's Legally Authorized Representative is required for people unable to give consent for themselves.)

Description of the Legally Authorized Representative's Authority to Act for Participant (for example, "parent" or "guardian")

Person Explaining the Research: Your signature below means that the subject met all inclusion criteria, consent was obtained prior to any study procedures, you have explained the research, including procedures and requirements, viable alternatives, and risks, to the participant/participant representative and have answered any questions he/she has about the research, enrolled the subject in the study and given them a copy of the consent.

Signature of person who explained this research	Date	Time	Printed Name
--	------	------	--------------

(Only approved investigators/research coordinators and those trained in obtaining research informed consent and familiar with this research may explain the research and obtain informed consent.)

FSU Human Subjects Committee approved on 10/31/2011 Void after 08/08/2012
HSC # 2011.7326

CONSENT TO PHOTOGRAPH AND PUBLISH

The undersigned hereby authorizes Tallahassee Memorial HealthCare and my physician(s) to photograph or permit other persons to photograph or interview (name of patient) _____ while a patient at Tallahassee Memorial HealthCare facility or regarding care previously received while a patient at a Tallahassee Memorial HealthCare facility. The undersigned agrees that the hospital and my physician(s) may use and permit other persons to use the negatives or prints prepared from such photographs for the purposes and manners deemed appropriate. The undersigned agrees that these photographs and interviews may be used for purposes including, but not limited to, dissemination to hospital staff, physicians, health professionals and members of the public for educational, treatment, research, scientific, public relations and charitable purposes and that such dissemination may be accomplished in any manner and that such use is subject only to the following limitations:

The undersigned has entered into this agreement in order to assist scientific treatment, educational, public relations and/or charitable goals and hereby waives any right to compensation for these uses by reason of the foregoing authorizations, and the undersigned and his or her successors or assigns hereby hold the hospital, its employees, my physician(s) and any other person participating in my care and their successors and assigns harmless from and against any claim for injury or compensation resulting from the activities authorized by this agreement.

The term "photograph" as used in this agreement, shall mean motion picture or still photography in any format, as well as videotape, video disc and any other means of recording and reproducing images. The term "interview" as used in this agreement, shall mean any health care related or other personal information that I may disclose verbally or in writing during the course of an interview.

The undersigned may be a patient or a patient's family member who is participating in a health care activity or event sponsored by TMH. Such events are typically held for specific groups of individuals who have certain health care diagnoses, interests or questions.

Upon my authorization for the use of my picture or any information which I may have disclosed to TMH or to the media during interviews or participation in health care activities or events, I understand and consent to the possibility that protected health information may be disclosed to the public by virtue of the photograph, interview or my presence and participation.

Date: _____ Time: _____ AM/PM

Signature: _____
(patient/parent/guardian)

If signed by other than patient, indicate relationship: _____

Witness: _____

Original: Medical Record

Copy: Patient

Informed Consent Form

Title of Project: Music therapy as procedural support for young children undergoing immunizations: A randomized controlled study

Principal Investigator: Olivia Swedberg Yinger, MME, MT-BC, NICU-MT

Participant's (staff's) Printed Name: _____

This is a research study. Research studies include only people who want to take part. This form gives you information about this research, which will be discussed with you. It may contain words or procedures that you do not understand. Please ask questions about anything that is unclear to you. Discuss it with your family and friends and take your time to make your decision.

1. Purpose of the Research:

The purpose of this study is to examine the effects of music therapy on child and adult behaviors during child immunizations and influenza vaccinations. You were selected as a possible participant because you are a member of the healthcare staff of the Tallahassee Memorial HealthCare (TMH) Family Medicine Residency who will be assisting with procedures for children and parents enrolled in this study. This study is also being conducted at another doctor's office in Tallahassee, as well as a doctor's office in Bainbridge, Georgia. About 60 children, 60 parents/guardians, and 60 healthcare staff will take part in this research nationwide. About 45 children, 45 parents/guardians, and 45 healthcare staff are expected to take part in the study at TMH Family Medicine.

2. Procedures to Be Followed:

If you agree to be in this study, immunizations that you perform on children who are enrolled in this study will be videotaped. You will be included in these video recordings.

Later, the videotapes will be reviewed by trained observers who will be advanced students in music education/music therapy from Florida State University (FSU). All observers will sign agreements to maintain confidentiality regarding what is seen in the videotapes.

3. Discomforts and Risks:

A possible risk of participation in this study is that you may be uncomfortable with the music or being videotaped. If this happens, you may stop participation in the study at any time by telling the researcher that you would like to stop the music or the videotaping.

4. Possible Benefits:

a. Possible benefits to you:

One potential benefit is that music therapy or the presence of the video camera may help distract the child, making the procedure easier for you to perform. However, there is no guarantee that this will happen.

b. Possible benefits to others:

The information that you provide could help researchers better understand ways to help children cope with medical procedures.

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Informed Consent Form

5. Other Options that Could be Used Instead of this Research:

You do not have to take part in this research study. If you do not want to participate in the study, the researcher will not be present for any immunizations that you perform, and will not videotape or provide music therapy.

6. Time Duration of the Procedures and Study:

If you decide to participate in this study, you will be asked to put a copy of the child/parent's consent forms in their physical medical chart. Participation in this study does not require any additional time on your part during, before, or after the immunization or vaccination procedure.

7. Statement of Confidentiality:

a. Privacy and confidentiality measures

The records of this study will be kept private and confidential to the extent required by law. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Video recordings of procedures and data for analysis will be kept on the Principal Investigator's computer, which is password protected. Your video recording will be labeled with a code number, and your name will not be attached to it. Trained observers (graduate students in music education/music therapy at FSU) who view the videos for data analysis will sign a confidentiality statement before watching the videos, stating that they will not share content of the videos with anyone other than the Principal Investigator.

b. The use of private health information

A video recording of you performing an immunization or vaccination will be made if you choose to participate in this study. No other health information about you or your child will be collected if you choose to be part of this research study.

Health information about you will be collected if you choose to be part of this research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information and may share it without your permission.

To participate in this research you must allow the research team to use your health information. If you do not want us to use your protected health information, you may not participate in this research. Your permission for the use, retention, and sharing of your identifiable health information will continue indefinitely. Data collection forms will be shredded after the results of the study have been analyzed and within one year of collection. Video recordings and protected health information will be maintained indefinitely by the principal investigator for potential use in follow-up studies.

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2011.7326

Informed Consent Form

If you choose to participate, you are free to withdraw your permission for the use and sharing of your health information at any time. You must do this in writing. Write to Olivia Swedberg Yinger and let her know that you are withdrawing from the research study. Her mailing address is: Florida State University College of Music, Tallahassee, FL 32306-1180.

If you withdraw your permission:

- We will no longer use or share medical information about you for this research study, except when the law allows us to do so.
- We are unable to take back anything we have already done or any information we have already shared with your permission.
- We may continue using and sharing the information obtained prior to your withdrawal if it is necessary for the soundness of the overall research.
- We will keep our records of the care that we provided to you as long as the law requires.

The research team may use the following sources of health information.

- Video recording of procedures that you perform

Representatives of the researcher or designee may use your health information and share it with other specific groups in connection with this research study.

- The Institutional Review Board at TMH

The above people/groups may share your health information with the following people/groups outside TMH for their use in connection with this research study. These groups, while monitoring the research study, may also review and/or copy your original records.

- The Office of Human Research Protections in the U. S. Department of Health and Human Services
- The FSU Human Subjects Protection Office
- The researcher's major professor and committee members, who are faculty of the FSU College of Music
- Trained observers who are graduate students in music therapy/music education

We will do our best to make sure that the personal information in your medical record will be kept private. However, because of the need to release information to the above parties, absolute confidentiality cannot be guaranteed. Once your personal health information is released, it may be redisclosed and no longer protected by federal privacy regulations. Your personal information may also be given out if required by law and in rare circumstances may be subpoenaed by a court.

FSU Human Subjects Committee approved on 10/31/2011 Void after 08/08/2012 HSC # 2011.7326

Informed Consent Form

8. Costs for Participation:

a. Costs:

There is no additional cost to you to participate in this study.

b. Treatment and compensation for injury:

Every effort to prevent injury as a result of your participation will be taken. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. It is the policy of this institution to provide neither financial compensation nor free medical treatment for research-related injury.

Costs for the treatment of research-related injuries will be charged to your insurance carrier or to you. Some insurance companies may not cover costs associated with research studies. If for any reason these costs are not covered by your insurance, they will be your responsibility. You will also be responsible for any deductible, co-insurance and/or co-pay. You will not lose any legal rights by signing this form.

9. Compensation for Participation:

You will not receive any compensation for being in this research study.

10. Research Funding:

The institution and investigators are not receiving any funds to support this research study.

11. Voluntary Participation:

Taking part in this research study is voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are entitled. The researcher may take you out of the research study without your permission. One possible reason for this would be if a child who you immunized was withdrawn from the study by their parent/legal guardian or healthcare staff.

12. Contact Information for Questions or Concerns:

You have the right to ask any questions you may have about this research. If you have questions, complaints, or concerns or believe that you or your child may have developed an injury related to this research, contact Olivia Swedberg Yinger at [REDACTED] (phone), Florida State University College of Music, Tallahassee, FL 32306-1180 (address), or [REDACTED] (e-mail). If you have questions regarding your rights as a research participant or you have concerns or general questions about the research or about your privacy and the use of your personal health information, contact the research protection advocate, Cynthia Blair, Administrative Liaison/IRB, Tallahassee Memorial HealthCare, (850) 431-5676. You may also call this number if you cannot reach the research team or wish to talk to someone else. You may also contact the Faculty Advisor for this study, Dr. Jayne M. Standley, at 850-644-4565 (phone) or jstandley@music.fsu.edu (e-mail). If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), you are encouraged to contact the FSU IRB at 2010 Levy Street, Research Building B, Suite 276, Tallahassee, FL 32306-2742, or 850-644-8633, or by email at humansubjects@magnet.fsu.edu.

FSU Human Subjects Committee approved on 10/31/2011 Void after 08/08/2012 HSC # 2011.7326

Informed Consent Form

Signature and Consent/Permission to be in the Research

Before making the decision regarding enrollment in this research you should have:

- Discussed this study with an investigator,
- Reviewed the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Participant's Legally Authorized Representative: By signing below, you indicate that you give permission for the participant (your child) to take part in this research.

Signature of Participant's Legally
Authorized Representative

Date

Time

Printed Name

(Signature of Participant's Legally Authorized Representative is required for people unable to give consent for themselves.)

Description of the Legally Authorized Representative's Authority to Act for Participant (for example, "parent" or "guardian")

Person Explaining the Research: Your signature below means that you have explained the research to the participant/participant representative and have answered any questions he/she has about the research.

Signature of person who explained
this research

Date

Time

Printed Name

(Only approved investigators/research coordinators and those trained in obtaining research informed consent and familiar with this research may explain the research and obtain informed consent.)

FSU Human Subjects Committee approved on 10/31/2011 Void after 06/06/2012 HSC # 2011.7326

**Tallahassee Memorial
HealthCare**

CONSENT TO PHOTOGRAPH AND PUBLISH – NON-PATIENT

The undersigned hereby authorizes Tallahassee Memorial HealthCare to photograph or permit other persons to photograph, videotape or interview me and to use or permit other persons or entities to use the photographs, video footage or interviews for educational, treatment, research, scientific, public relations, marketing and charitable purposes.

The undersigned agrees that these photographs and interviews may be used for purposes including, but not limited to, dissemination to hospital staff, physicians, health professionals and members of the public and that such dissemination may be accomplished in any manner and that such use is subject only to the following limitations:

The undersigned agrees that the hospital may use and permit other persons to use the negatives or prints prepared from such photographs for the purposes and manners deemed appropriate.

The undersigned waives any right to compensation for these uses by reason of the foregoing authorizations, and the undersigned and his or her successors or assigns hereby hold the hospital, its employees, my physician(s) and any other person participating in my care and their successors and assigns harmless from and against any claim for injury or compensation resulting from the activities authorized by this agreement.

The term "photograph" as used in this agreement, shall mean motion picture or still photography in any format, as well as videotape, video disc and any other means of recording and reproducing images. The term "interview" as used in this agreement, shall mean any health care related or other personal information that I may disclose verbally or in writing during the course of an interview.

The undersigned may be a patient's family member who is participating in a health care activity or event sponsored by TMH. Such events are typically held for specific groups of individuals who have certain health care diagnoses, interests or questions.

Upon my authorization for the use of my picture or any information which I may have disclosed to TMH or to the media during interviews or participation in health care activities or events, I understand and consent to the possibility that protected health information may be disclosed to the public by virtue of the photograph, interview or my presence and participation.

Date: _____ Time: _____ AM/PM

Print Name _____

Signature: _____

Witness: _____

APPENDIX E

Demographic Information Form

Demographic Form

Child's date of birth: _____

Child's sex: M F

1.) How many previous doctor visits has your child had? Please circle one:

Less than 10

11 to 20

21 or more

2.) How would you rate your child's typical reaction to previous doctor's visits? Please circle one:

-3
Very
negative

-2
Negative

-1
Slightly
negative

0
No
reaction

1
Slightly
positive

2
Positive

3
Very
positive

Additional comments:

3.) How many previous hospitalizations and emergency room visits has your child had?

4.) How would you rate your child's typical reaction to previous hospitalizations and emergency room visits? Please circle one:

-3
Very
negative

-2
Negative

-1
Slightly
negative

0
No
reaction

1
Slightly
positive

2
Positive

3
Very
positive

Additional comments:

APPENDIX F

Operational Definitions of Child Behaviors

Child Distress Behaviors

Crying: Crying sounds, usually unintelligible but can be double coded with verbal categories.

Examples:

1. "Sobbing"
2. "Boooohooohooo"
3. Crying sounds

Screaming: Vocal expression of pain at high pitch/intensity, usually nonintelligible but can be coded with other verbal categories. Examples:

1. Sharp, shrill, harsh, high tones
2. Shrieks
3. "Owwwh"

Verbal resistance: Any verbal expression of delay, termination, or resistance. Examples:

1. "Stop"
2. "No more"
3. "Don't"

Requesting emotional support: Verbal solicitation of hugs, hand holding, physical or verbal comfort by the child. Examples:

1. "Hold me"
2. "Momma please"
3. "Help me"

Verbal fear: Statement of being apprehensive or in fear. Examples:

1. "I'm afraid"
2. "I'm scared"

Verbal pain: Statement of pain, damage or being hurt. May be in any tense. Can be anticipatory as well as actual. Examples:

1. "Don't hurt me"
2. "It stings"
3. "You're killing me"

Verbal emotion: Statements other than fear or requesting emotional support which express the child's emotional state. Anger, self-pity, or resentment would be emotions conveyed here. This category is reserved for negative emotions only. Examples:

1. "Why does this have to happen to me."
2. "I hate you."
3. "I don't like doing this."

Information seeking: The child asks questions about the medical procedures. Examples:

1. "When will you stick me?"
2. "When will you be finished?"
3. "Will you let me know when you're ready to start?"

* From the CAMPIS-R (see Blount, 1990), retrieved from:

<http://psychology.uga.edu/people/bios/faculty/BlountDoc/Blount-CAMPIS%20&%20CAMPIS-R%20no%20affect.pdf>

Child Coping Behaviors

Audible deep breathing: Deep breathing that is used to cope with the procedures. Breathing that is part of the child's distress does not count.

Nonprocedural talk by the child: The child engages in talk that is in no way related to his or her current physical condition or the procedure. Examples:

1. "That cat was a girl."
2. "I was watching He-man the other day."
3. "School is going OK."

Humor by the child: This is the same category as in the Codes for Staff/Parent Behaviors, but with the child doing the talking.

Making coping statements: The child makes some statements which indicates courage or attempts to soothe himself or herself verbally. Examples:

1. "I'll be O.K."
2. "I'm Superman/woman."
3. "I can get an ice cream afterward."

* From the CAMPIS-R (see Blount, 1990), retrieved from:

<http://psychology.uga.edu/people/bios/faculty/BlountDoc/Blount-CAMPIS%20&%20CAMPIS-R%20no%20affect.pdf>

APPENDIX G

Operational Definitions of Adult Behaviors

Adult Distress-Promoting Behaviors

Reassuring comments: Procedures related comments that are directed toward the child with the intent of reassuring the child about his/her condition, or the course of the procedure.

These may be volunteered by staff and/or parents and may be in response to questions by the child or may reflect the child's comments. If procedure related information is repeated in response to the child's request for reassurance or emotional support, code these procedural notifications as reassuring comments. Examples:

1. "You're O.K."
2. "It's almost over."
3. "Just touching honey."

Apologies: Any statement relating a sense of sorrow or a sense of responsibility for the pain the child is expressing. These statements may occur prior to, during, or after a painful event, and may occur in conjunction with other verbal codes. Examples:

1. "Timmy, we don't like doing this either."
2. "I'm sorry this is taking so long."
3. "I wish I didn't have to hurt you."

Empathic statements: Statements which show an appreciation for the frame of reference of the person being spoken to. Examples:

1. "I know this is hard."
2. "I know this is taking a long time."
3. "I know it hurts."

Giving control to the child: Any statement to child denoting that child has control over some event to occur with relation to the procedure. Generally this includes staff suggestions where the child is given a choice about the procedure. "Can you breathe now?" is coded as coaching child to use coping strategy even though it has the impression of giving control to the child. Examples:

1. "Let me know when you are ready to start."

2. "Which side would you like to lie on?"
3. "Do you like it better when we tell you or don't tell you?"

Criticism: Any verbalization that finds fault or implies fault with the (a) activities, (b) products, or (c) attributes of the child. Criticisms include negatively evaluative adjectives or adverbs referring to the child, statements of disapproval, statements pointing out something wrong about the child or the child's behavior, and statements pointing out that the child is not doing something positive. Also included as Criticism are obvious sarcastic statements, if these are unaccompanied by laughter on the part of either the speaker or listeners. Usually, criticism is accompanied by a harsh voice tone. Examples:

1. "You didn't use you breathing that time like I told you to."
2. "Boy, you really controlled yourself that time." (After child let out a big scream).
3. "You're being a pain."

* From the CAMPIS-R (see Blount, 1990), retrieved from:

<http://psychology.uga.edu/people/bios/faculty/BlountDoc/Blount-CAMPIS%20&%20CAMPIS-R%20no%20affect.pdf>

Adult Coping-Promoting Behaviors

Non-procedural talk to the child: Talk that does not pertain to the treatment procedure or about the child's illness. Examples:

1. Conversations about the child's pet, siblings, parents, school, motorcycles, toys, etc.
2. Questions, unrelated to the child's illness or treatment, about the child's plans, wants, desires, etc.
3. Conversations about activities on the ward or about other children or staff members.

Humor directed to the child: Any statement that is clearly intended to be humorous and is primarily lighthearted in tone. Humor is often accompanied by laughter from the person making the statement and may evoke laughter in the patient or in other staff members. Sarcasm may be coded as humor if it is accompanied by laughter on the part of the speaker or on the part of the listener. Sarcasm is not coded as humor if it is accompanied by an anger or harsh tone of voice. Examples:

1. Outright jokes of the "one-liner" variety.
2. Statements that suggest purely facetious, outlandish, or outrageous ideas.
3. Statements that emphasize the humorous aspects of a situation or problem.
4. Statements which present lighthearted criticism of someone else in such a manner that would be lightly received (e.g., "Oh you silly duck!")
5. Laughter.

Commands to use coping strategies: Any orders, suggestions, or statements of a rule, which direct the child to engage in a coping behavior. These strategies are generally issued immediately prior to a painful event, and may suggest one (but not exclusively one) of the following: relaxation, distraction, use of coping statements, or deep breathing. An example such as "Can you breathe now?" is coded command to use coping strategy in spite of it giving the impression of control to the child. Examples:

1. "Use your deep breathing now."
2. "Imagine you are Superman and this is a test of your strength."
3. "Squeeze your mother's hand when you feel the bumble bee."

* From the CAMPIS-R (see Blount, 1990), retrieved from:

<http://psychology.uga.edu/people/bios/faculty/BlountDoc/Blount-CAMPIS%20&%20CAMPIS-R%20no%20affect.pdf>

APPENDIX H

Sample Transcript

Transcribed by: _____ Date transcribed: _____ Date reviewed: _____

Coded by: _____ Date coded: _____

Participant Code: _____ Video start time: _____ Video end time: _____

Treatment	Start: _____	End: _____	Total Length: _____
Preparation	Start: _____	End: _____	Length of Phase: _____
Procedure	Start: _____	End: _____	Length of Phase: _____
Recovery	Start: _____	End: _____	Length of Phase: _____

Child			Parent			Staff		
Coping	Neutral	Distress	Coping	Neutral	Distress	Coping	Neutral	Distress
CC	CN	CD	PC	PN	PD	SC	SN	SD

Verbalization	Code
MT: [singing] Sparky the dragon was sad because his fire went out. He went to the hospital deep in the woods to see if they could help.	
Child: [singing with MT, words unintelligible]	
MT: You remember that song very well!	
MT: Who did he see first?	
RN: I don't know, who did he see?	
MT: Nurse Doey the deer, is that right?	
Child: Mmm-hmm.	
MT: [singing] First he saw nurse Doey the deer and she made him open wide.	
RN: I'm washing your hand.	
MT: Is that cold? Does that feel cold?	
Child: Mmm-hmm.	
MT: [singing] She looked way, way down deep in his throat and then she said, "Oh my!"	
RN: [Laughter]	

Verbalization	Code
MT: And he sounded like this.	
MT: You remember the coughing part?	
MT: Do you want to help me cough?	
MT: [singing] Cough, cough, and a yak cough, cough and a yak, and a one two three, wheeze wheeze...	
Child: [singing with MT, words unintelligible]	
MT: [singing] Cough, cough and a yak, cough, cough and a yak, wheeze one, wheeze two, wheeze three	
MT: So she said, [singing] “Now try to see if your fire’s come back, now take a deep breath and see.”	
RN: It’s going to be a little pin prick.	
RN: Hold real still.	
Parent: Take a deep breath.	
Child: [audible deep breath]	
RN: Take a deep breath.	
MT: Take a deep breath.	
Child: [audible deep breath]	
MT: There you go, very good.	
RN: That’s good.	
RN: The worst is over.	

Note: This transcript is from a video that was used to train research assistants to transcribe and code videos. It was not included in analyses for the present study. Verbalizations made by the music therapist, although highlighted as “staff behaviors,” were not included in analyses. Nurse behaviors were the only staff behaviors analyzed. Rows were highlighted to make it easier for the person coding the transcript to identify the speaker for each verbalization.

APPENDIX I

Post-Procedure Questionnaires

Music Therapy Group

Parent Post-procedure Questionnaire

Please circle your response for each question.

1.) How was your child's level of distress during this immunization compared to previous medical experiences?

-3	-2	-1	0	1	2	3
Much worse	Worse	Slightly worse	The same	Slightly better	Better	Much better

2.) Did your child benefit from music therapy?

Yes, very much ~~Yes~~ No opinion Not really Not at all

3.) Did you benefit from music therapy?

Yes, very much ~~Yes~~ No opinion Not really Not at all

4.) Did music therapy services improve your perception of this facility?

Yes, very much ~~Yes~~ No opinion Not really Not at all

5.) Have you received or experienced music therapy services prior to this?

Yes No If yes, where? _____

6.) Would you like to receive music therapy services again if you return to this facility?

Yes Maybe No

Comments: _____

Control Group

Parent Post-procedure Questionnaire

Please circle your response for each question.

How was your child's level of distress during this immunization compared to previous medical experiences?

-3	-2	-1	0	1	2	3
Much worse	Worse	Slightly worse	The same	Slightly better	Better	Much better

Comments: _____

APPENDIX J

Universal Pain Assessment Tool

UNIVERSAL PAIN ASSESSMENT TOOL

This pain assessment tool is intended to help patient care providers assess pain according to individual patient needs. Explain and use 0-10 Scale for patient self-assessment. Use the faces or behavioral observations to interpret expressed pain when patient cannot communicate his/her pain intensity.

APPENDIX K

Original Songs used in Music Therapy Intervention

The Yodeling Song

* indicates places where the child takes a deep breath

Traditional
Adapted by Olivia Yinger

D A7 D

Oh a dra gon went yo del ing on a moun tain so high, when a

6 A7 D A7 D

long came a (pup py dog) in ter rupt ing his cry. Oh lee ah, oh lee ah koo kee ah,
(pret ty girl)
(march ing band)
(hur ri cane)

12 A7 D

oh lee ah koo koo, * (pant pant) Oh lee ah koo kee ah, oh lee ah koo koo * (pant, pant)
(blow kiss)
(boom boom)
(woosh woosh)

17 A7 D

Oh lee ah koo kee ah, oh lee ah koo koo, * (pant, pant) oh lee ah koo kee ah oh.
(blow kiss)
(boom boom)
(woosh woosh)

Sparky, the Dragon

April Batson Malone
Abridged by Olivia Yinger

The musical score is written for a single voice in the treble clef, with a key signature of one sharp (F#) and a 4/4 time signature. The melody is simple and repetitive, using a limited range of notes (D, E, F#, G, A, B). Chord symbols (D, G, A) are placed above the staff to indicate accompaniment. The lyrics are written below the staff, with line numbers 3, 5, 7, 10, 12, 14, 16, and 18 marking the beginning of new lines of music. The lyrics tell a story of a dragon named Sparky who is sad because his fire went out and he went to a hospital in the woods to see if they could help. He is then helped by a nurse who makes him open wide, and he coughs and yaks. The nurse tells him to take a deep breath and see if his fire comes back. Finally, his fire comes back because of help from the audience.

3 Spar ky the dra gon was sad be cause his fire went out. He
5 went to the hos pi tal deep in the woods to see if they could help
7 First he — saw Nurse Do ey the Deer and she made him op en wide. She
10 lis tened way way down deep in his throat and then she said, "Oh my!" Do you know what she heard? Cough,
12 cough, and a yak, cough, cough, and a yak, and a one two three, wheeze, wheeze! Cough,
14 cough, and a yak, cough, cough, and a yak, wheeze one, wheeze two, wheeze three. "Now
16 try and — see if your fire's come back. Now take a deep breath and see." So he
18 held back his head and he took a deep breath Take a deep breath.
All of a sud den his fire came back 'cause of help from you and me!

The Beads go 'Round and 'Round

Melody: Mexican Folksong

D A7

The beads go 'round and 'round. The beads go 'round and 'round. The

6 D A7

beads go 'round and 'round. The beads go 'round and 'round. Then you

10 D A7

shake it and shake it and shake it, _____ Shake it and shake it and shake it, _____

14 D

Shake it and shake it and shake it, _____ Shate it and shake it and STOP!

Goodbye Song (Bop Shoo Woo!)

Swing dotted eighth
and sixteenth notes

Jen Reece

E

Mu sic time is o ver and we all had lots of fun,___ bop shoo bop,___

4 A7

bop shoo woo!___ Mu sic time is o ver and we all had lots of fun,

7 E B7

___ bop shoo bop,___ bop shoo woo!___ Now it's time to say good bye, I

10 A7 E

sure had fun with you,___ bop shoo bop,___ bop shoo woo!

APPENDIX L

Complete Demographic Information

Music Therapy Group

ID	Age	Gender	MD Hx	MD Reaction	Hosp Hx	Hosp Reaction	Site	Guardian	Shots
A	54.5	F	11-20	-1.5	0	----	1	Mother	1
C	59.8	F	11-20	-1	2	-1	3	Mother	1
E	60.8	F	11-20	-2	2	-3	3	Mother	5
G	58.1	F	21+	2	2	0	3	Father	1
I	68	M	11-20	-1	4	-2	2	Father	1
J	52.2	F	< 10	2	0	----	2	Mother	3
K	58.7	F	11-20	1	0	----	1	Mother	1
L	49.4	M	21+	3	0	----	2	Father	5
M	57.4	F	11-20	2	0	----	1	Mother	2
N	67.9	M	11-20	1	4	-1	1	Father	1
S	61.9	M	11-20	1	1	0	1	Mother	4
X	66.1	F	11-20	2	2	1	3	Mother	1
Y	60.5	M	11-20	-2	2	0	3	Mother	5
Z	71.2	F	< 10	3	0	----	3	Mother	4
FF	48.2	M	11-20	2	3	2	2	Mother	4
GG	61.3	M	11-20	3	1	2	3	Mother	4
II	49.1	F	11-20	0	0	----	3	Mother	1
JJ	50	F	< 10	-1	2	-2	2	Mother	4
KK	50.3	F	21+	3	6	1	2	Mother	4
MM	48.9	M	11-20	2	3	2	2	Mother	4
OO	56.3	F	< 10	3	1	3	2	Aunt	4
PP	60.8	F	< 10	-1	1	0	3	Mother/father	4
UU	48.5	M	11-20	-1	0	----	1	Mother	5
ZZ	48.9	F	11-20	-2	1	0	2	Mother	3
AAA	50.8	F	11-20	-1	1	1	2	Mother	5
GGG	48.1	F	11-20	0	0	----	2	Father	4
HHH	55.8	F	21+	2	3.5	-2	2	Mother	3
III	62.3	F	< 10	2	3	2	2	Grandmother	1
JJJ	48.2	M	11-20	1	0	----	2	Mother/grandmother	4

ID = Participant code

MD Hx = Number of previous doctor visits

MD Reaction = Reaction to previous doctor visits

Hosp Hx = Number of previous hospitalizations/emergency room visits

Hosp Reaction = Reaction to previous hospitalizations/emergency room visits

Site = Healthcare site

Control Group

ID	Age	Gender	MD Hx	MD Reaction	Hosp Hx	Hosp Reaction	Site	Guardian	Shots
B	65.1	M	< 10	3	0	----	3	Grandmother	1
D	61	F	11-20	2	1	2	3	Mother	4
H	58.1	M	11-20	2	2	0	3	Mother	1
O	70.5	M	11-20	-1	2	-1	1	Mother	1
P	70.8	F	21+	-2	5	-2	2	Mother	1
Q	49.1	M	< 10	3	0	----	2	Mother	2
R	56.1	F	< 10	2	0	----	1	Mother	2
T	49.7	F	11-20	2	1	-1	3	Mother	1
U	48.8	M	11-20	2	1	3	2	Mother	4
V	49.3	M	< 10	-1	0	----	2	Mother	4
W	52.9	F	< 10	2	0	----	2	Mother	2
BB	65.4	F	21+	0	2	0	2	Mother	1
CC	55.1	F	11-20	-2	2	-2	2	Mother	4
DD	52.4	M	21+	2	0	----	2	Mother	3
EE	61.3	M	11-20	-1	2	-1	2	Mother	1
HH	62.2	F	11-20	1	1	-1	3	Mother	4
NN	49	M	11-20	2	1	3	2	Mother	4
QQ	49.1	M	11-20	-1	4	-1	2	Father	3
SS	60	F	< 10	2	5	-2	3	Mother	4
TT	52.3	M	21+	2	6	1	3	Mother/father	1
VV	60.5	M	11-20	-1	0	----	1	Mother	4
WW	50	M	< 10	-1	1	-1	2	Father	5
XX	61.4	M	11-20	2	1	2	3	Mother	4
YY	61	M	11-20	2	2	2	3	Mother	4
BBB	53.2	M	11-20	-2	4	-3	2	Mother	4
CCC	48.7	M	11-20	2	0	----	2	Father	3
DDD	62.1	F	< 10	-1	2	0	2	Mother	3
EEE	54.6	F	11-20	3	1	3	2	Mother/father	3
FFF	60.1	F	11-20	2	0	----	3	Father	4

ID = Participant Code

MD Hx = Number of previous doctor visits

MD Reaction = Reaction to previous doctor visits

Hosp Hx = Number of previous hospitalizations/emergency room visits

Hosp Reaction = Reaction to previous hospitalizations/emergency room visits

Site = Healthcare site

APPENDIX M

Raw Data for CAMPIS-R Codes

Music Therapy Group
Rates of Child Behavior, in Behaviors per Minute

ID	Coping			Distress		
	Preparation	Procedure	Recovery	Preparation	Procedure	Recovery
A	6.06	0.00	1.26	0.00	10.02	4.44
C	1.14	0.00	0.00	2.94	14.16	4.98
E	8.22	2.16	0.30	0.00	13.62	7.14
G	1.80	5.88	0.00	0.00	3.96	6.00
I	1.92	1.74	0.00	0.00	7.08	15.00
J	13.92	3.24	0.00	0.00	9.66	5.58
K	4.62	4.98	0.00	0.00	0.00	0.00
L	2.82	1.20	0.48	0.00	3.90	2.88
M	0.00	2.64	0.00	0.00	1.32	6.00
N	7.50	7.80	0.00	0.00	2.58	12.00
S	2.22	4.92	0.60	2.22	1.20	8.04
X	4.74	2.16	0.00	0.00	1.44	6.66
Y	0.36	3.12	0.00	0.00	1.80	5.34
Z	10.32	8.52	0.00	0.00	1.44	0.00
FF	5.04	2.70	3.30	5.58	6.36	2.16
GG	2.34	1.80	2.16	0.00	6.42	4.62
KK	0.00	9.06	5.46	0.00	2.82	5.46
II	5.64	4.14	0.00	0.00	4.14	0.00
JJ	4.50	3.78	0.00	0.00	4.50	3.36
MM	4.14	5.40	3.42	0.00	6.48	2.28
OO	7.80	2.40	2.58	0.00	1.62	6.36
PP	6.18	2.76	1.26	0.00	7.98	4.74
UU	4.26	2.28	4.14	4.26	9.12	4.74
ZZ	4.20	0.00	2.70	6.30	18.30	13.62
AAA	4.62	5.88	1.98	0.00	1.08	8.70
GGG	6.00	4.32	0.00	3.00	9.06	14.04
HHH	6.90	2.52	0.00	0.00	4.98	6.66
III	6.00	0.00	0.00	0.00	7.68	6.66
JJJ	5.22	2.76	0.00	0.00	10.32	4.02

Control Group
Rates of Child Behavior, in Behaviors per Minute

ID	Coping			Distress		
	Preparation	Procedure	Recovery	Preparation	Procedure	Recovery
B	2.40	0.72	0.00	0.00	15.90	9.84
D	2.58	3.36	3.54	0.00	6.36	3.54
H	9.18	1.56	0.00	0.00	3.06	60.00
O	0.00	10.74	0.00	0.00	0.00	0.00
P	1.74	1.20	4.02	7.92	27.60	10.68
Q	6.30	0.84	0.00	3.18	11.64	5.10
R	6.78	3.54	1.92	0.00	21.18	19.26
T	1.74	2.52	1.62	0.00	1.26	13.14
U	0.00	1.08	0.00	0.00	11.58	26.64
V	1.14	0.00	0.00	6.18	26.76	17.22
W	8.28	7.38	1.98	14.46	14.76	9.84
BB	----	----	----	----	----	----
CC	0.00	0.00	0.90	17.76	15.72	16.14
DD	0.00	1.86	0.00	0.00	4.32	3.84
EE	0.00	0.00	2.16	16.38	8.88	55.74
HH	0.96	2.16	2.58	0.00	12.48	10.26
NN	0.00	0.54	0.00	0.00	3.78	12.00
QQ	1.44	0.00	2.28	1.44	15.60	14.28
SS	1.14	0.30	3.00	1.14	6.66	4.98
TT	3.84	2.94	0.00	0.00	0.00	0.00
VV	0.00	0.00	0.00	0.00	7.38	9.78
WW	----	----	----	----	----	----
XX	7.14	0.54	3.42	0.00	17.88	12.48
YY	3.06	1.50	2.94	0.00	12.96	6.90
BBB	0.00	0.00	0.66	8.28	13.56	5.70
CCC	0.00	1.26	3.78	0.00	5.10	4.98
DDD	0.00	0.00	0.00	17.16	19.56	14.70
EEE	0.00	0.00	0.00	11.22	16.26	11.64
FFF	1.98	1.38	0.00	0.00	8.28	8.58

Music Therapy Group
Rates of Parent Behavior, in Behaviors per Minute

ID	Coping-Promoting			Distress-Promoting		
	Preparation	Procedure	Recovery	Preparation	Procedure	Recovery
A	2.64	0.00	8.82	0.00	0.00	1.92
C	0.00	0.00	0.00	0.00	0.00	0.00
E	0.00	1.02	0.84	0.00	2.34	0.60
G	2.40	1.98	6.00	0.00	0.96	0.00
I	0.00	0.00	0.00	0.00	0.00	22.50
J	1.08	6.48	2.82	0.00	0.66	0.00
K	1.56	0.00	0.00	0.00	0.00	0.00
L	1.38	0.78	0.48	0.00	0.00	0.00
M	0.00	0.00	0.00	0.00	0.00	0.00
N	0.00	0.00	0.00	0.00	0.00	0.00
S	0.00	0.00	5.58	0.00	0.00	1.26
X	0.00	0.00	0.00	0.00	0.00	0.00
Y	0.66	1.32	3.54	0.00	0.78	0.00
Z	0.00	3.12	0.00	0.00	0.00	0.00
FF	5.04	0.00	1.14	0.00	1.80	0.00
GG	4.68	0.36	0.54	0.00	1.08	0.00
KK	0.00	2.10	0.00	0.00	0.72	5.46
II	0.00	3.12	0.00	0.00	0.00	0.00
JJ	0.00	1.02	0.00	0.00	0.00	6.66
MM	0.00	0.00	0.00	0.00	0.00	2.28
OO	0.30	1.62	3.84	0.00	0.00	0.00
PP	0.30	0.48	0.96	0.00	0.00	0.00
UU	2.28	0.78	3.54	0.00	0.00	0.60
ZZ	1.08	6.12	0.90	0.00	1.02	0.00
AAA	0.00	0.00	1.20	0.00	0.00	1.56
GGG	0.00	3.60	3.84	0.00	2.52	1.26
HHH	0.00	5.82	0.00	0.00	0.84	0.00
III	0.00	3.06	6.66	0.00	0.00	0.00
JJJ	0.00	0.00	0.00	0.00	7.56	0.00

Control Group
Rates of Parent Behavior, in Behaviors per Minute

ID	Coping-Promoting			Distress-Promoting		
	Preparation	Procedure	Recovery	Preparation	Procedure	Recovery
B	0.00	4.32	0.00	0.00	4.32	1.80
D	0.00	1.50	0.00	0.00	1.14	0.00
H	0.84	1.56	0.00	0.00	0.00	0.00
O	0.00	0.00	0.00	0.00	0.00	0.00
P	1.74	3.60	5.34	0.90	2.40	6.66
Q	3.18	1.68	1.26	0.00	5.82	3.84
R	0.96	1.74	2.28	0.00	0.00	7.68
T	0.00	0.00	0.00	0.90	0.00	0.00
U	0.00	0.00	0.00	0.00	0.54	0.00
V	0.00	0.00	2.40	1.68	19.38	11.88
W	2.04	4.20	0.00	4.14	4.20	2.94
BB	----	----	----	----	----	----
CC	0.00	7.38	3.30	10.50	5.52	8.64
DD	0.00	0.60	0.00	0.00	0.00	1.26
EE	1.62	0.00	10.74	4.38	0.00	25.74
HH	0.00	2.16	0.84	0.00	0.90	0.00
NN	0.00	1.08	0.00	0.00	2.16	4.26
QQ	0.00	3.60	5.28	0.72	9.60	7.38
SS	1.14	1.74	1.02	0.00	2.88	1.98
TT	3.84	1.44	0.00	1.26	0.00	0.00
VV	0.00	5.28	0.00	0.00	0.00	4.92
WW	----	----	----	----	----	----
XX	0.54	2.82	0.00	0.00	2.52	1.14
YY	0.00	3.54	10.80	0.00	12.96	7.86
BBB	1.50	0.00	0.96	2.28	7.74	3.48
CCC	0.00	2.58	8.76	0.00	0.00	3.78
DDD	0.00	0.00	2.46	2.16	6.96	12.24
EEE	0.00	0.00	0.00	0.54	3.42	0.00
FFF	1.98	4.44	0.00	0.00	1.08	3.42

Music Therapy Group
Rates of Nurse Behavior, in Behaviors per Minute

ID	Coping-Promoting			Distress-Promoting		
	Preparation	Procedure	Recovery	Preparation	Procedure	Recovery
A	12.18	16.68	11.40	0.00	6.66	2.52
C	5.22	2.94	0.00	1.14	2.46	3.36
E	0.72	2.46	1.14	0.00	4.02	5.16
G	0.00	5.88	0.00	0.00	0.96	0.00
I	0.00	1.74	7.50	0.00	1.74	0.00
J	0.00	0.00	0.00	0.00	0.00	0.00
K	11.52	4.98	0.00	0.00	0.00	0.00
L	2.82	1.20	1.92	0.00	0.42	2.40
M	7.50	7.98	18.00	0.00	0.00	0.00
N	7.50	15.66	0.00	0.00	0.00	24.00
S	24.42	12.24	6.48	0.00	3.66	1.56
X	0.00	4.26	13.32	0.00	2.16	19.98
Y	1.74	1.20	0.00	0.00	0.48	19.44
Z	1.92	2.52	0.00	0.00	0.00	0.00
FF	0.00	0.00	0.00	0.00	0.00	0.00
GG	0.00	7.50	1.38	0.00	2.52	0.54
KK	0.00	1.38	0.00	0.00	0.72	5.46
II	1.86	9.30	0.00	0.00	0.00	0.00
JJ	1.50	0.66	0.00	0.00	0.00	0.00
MM	0.00	0.00	0.00	0.00	1.62	2.28
OO	0.00	1.62	0.00	0.00	0.00	0.66
PP	0.30	4.32	0.00	0.00	2.28	1.26
UU	17.16	11.40	4.14	0.00	9.12	3.54
ZZ	0.00	0.00	2.70	0.00	1.02	1.80
AAA	0.00	1.08	0.42	0.00	0.00	0.42
GGG	0.00	1.44	2.58	0.00	1.44	0.00
HHH	0.00	0.00	0.00	0.00	0.00	0.00
III	0.00	1.56	0.00	0.00	3.06	0.00
JJJ	0.00	0.00	0.00	0.00	2.76	0.00

Control Group
Rates of Nurse Behavior, in Behaviors per Minute

ID	Coping-Promoting			Distress-Promoting		
	Preparation	Procedure	Recovery	Preparation	Procedure	Recovery
B	6.00	5.76	5.40	0.00	2.88	4.20
D	0.00	7.14	7.08	0.84	3.36	0.00
H	6.66	0.00	0.00	0.00	0.00	0.00
O	37.92	27.84	0.00	0.00	4.26	0.00
P	3.54	0.00	10.68	0.00	8.40	1.32
Q	9.48	4.14	5.10	0.00	3.36	0.00
R	10.62	14.10	11.94	0.00	12.36	9.60
T	5.28	6.24	4.92	0.00	4.98	5.76
U	0.00	2.76	0.00	0.00	2.22	13.32
V	0.00	0.00	1.80	0.54	0.00	1.80
W	0.00	1.08	1.98	0.00	1.08	0.96
BB	----	----	----	----	----	----
CC	0.00	0.00	0.00	0.00	0.48	0.90
DD	0.00	1.86	0.00	0.00	1.26	1.26
EE	1.98	0.00	21.42	6.42	6.66	25.74
HH	0.00	4.74	10.26	0.96	1.08	0.84
NN	0.00	3.78	0.84	0.00	3.24	5.16
QQ	0.00	0.00	3.00	0.00	0.00	2.28
SS	0.00	2.28	3.48	0.00	1.44	0.00
TT	7.68	5.88	0.00	0.00	0.00	0.00
VV	0.00	7.38	0.00	0.00	1.08	4.92
WW	----	----	----	----	----	----
XX	4.38	3.36	9.06	0.00	0.00	14.70
YY	4.56	2.04	6.90	0.00	2.52	5.88
BBB	0.00	0.00	0.30	0.00	0.96	1.56
CCC	0.00	6.36	0.00	0.00	0.00	4.98
DDD	0.00	0.00	2.46	4.26	6.96	4.92
EEE	0.00	0.00	0.00	0.00	0.00	3.90
FFF	2.52	8.82	0.00	0.00	1.38	0.00

Music Therapy Group
Proportions of Child Behavior

ID	Coping			Distress		
	Preparation	Procedure	Recovery	Preparation	Procedure	Recovery
A	0.875	0.000	0.222	0.000	1.000	0.778
C	0.286	0.000	0.000	0.714	1.000	0.818
E	0.793	0.133	0.029	0.000	0.828	0.714
G	1.000	0.600	0.000	0.000	0.400	1.000
I	0.250	0.200	0.000	0.000	0.800	1.000
J	1.000	0.250	0.000	0.000	0.750	1.000
K	1.000	1.000	0.000	0.000	0.000	0.000
L	1.000	0.231	0.143	0.000	0.769	0.857
M	0.000	0.667	0.000	0.000	0.333	1.000
N	1.000	0.750	0.000	0.000	0.250	1.000
S	0.333	0.800	0.071	0.333	0.200	0.929
X	1.000	0.300	0.000	0.000	0.200	1.000
Y	0.250	0.600	0.000	0.000	0.345	0.750
Z	1.000	0.833	0.000	0.000	0.139	0.000
FF	0.429	0.300	0.500	0.476	0.700	0.333
GG	1.000	0.217	0.296	0.000	0.783	0.630
KK	0.000	0.765	0.500	0.000	0.235	0.500
II	1.000	0.500	0.000	0.000	0.500	0.000
JJ	1.000	0.458	0.000	0.000	0.542	1.000
MM	0.778	0.455	0.600	0.000	0.545	0.400
OO	1.000	0.500	0.267	0.000	0.333	0.667
PP	0.863	0.245	0.174	0.000	0.714	0.652
UU	0.500	0.200	0.438	0.500	0.800	0.500
ZZ	0.400	0.000	0.158	0.600	1.000	0.789
AAA	1.000	0.762	0.185	0.000	0.143	0.815
GGG	0.571	0.300	0.000	0.286	0.625	1.000
HHH	0.857	0.231	0.000	0.000	0.462	1.000
III	1.000	0.000	0.000	0.000	1.000	1.000
JJJ	0.846	0.211	0.000	0.000	0.789	0.500

Control Group
Proportions of Child Behavior

ID	Coping			Distress		
	Preparation	Procedure	Recovery	Preparation	Procedure	Recovery
B	0.333	0.042	0.000	0.000	0.917	0.917
D	0.333	0.321	0.500	0.000	0.607	0.500
H	0.846	0.167	0.000	0.000	0.333	1.000
O	0.000	0.714	0.000	0.000	0.000	0.000
P	0.167	0.042	0.250	0.750	0.958	0.667
Q	0.500	0.059	0.000	0.250	0.824	1.000
R	0.778	0.143	0.091	0.000	0.857	0.909
T	1.000	0.667	0.091	0.000	0.333	0.727
U	0.000	0.077	0.000	0.000	0.808	1.000
V	0.143	0.000	0.000	0.786	1.000	1.000
W	0.333	0.318	0.167	0.583	0.636	0.833
BB	----	----	----	----	----	----
CC	0.000	0.000	0.050	1.000	1.000	0.900
DD	0.000	0.188	0.000	0.000	0.438	1.000
EE	0.000	0.000	0.029	0.932	1.000	0.765
HH	0.333	0.143	0.200	0.000	0.821	0.800
NN	0.000	0.100	0.000	0.000	0.700	0.933
QQ	0.222	0.000	0.130	0.222	1.000	0.826
SS	0.182	0.042	0.300	0.182	0.958	0.500
TT	0.600	0.286	0.000	0.000	0.000	0.000
VV	0.000	0.000	0.000	0.000	0.123	0.163
WW	----	----	----	----	----	----
XX	0.722	0.009	0.057	0.000	0.298	0.208
YY	0.667	0.203	0.250	0.000	0.864	0.583
BBB	0.000	0.000	0.100	1.000	1.000	0.900
CCC	0.000	0.143	0.429	0.000	0.571	0.571
DDD	0.000	0.000	0.000	1.000	1.000	1.000
EEE	0.000	0.000	0.000	1.000	1.000	0.857
FFF	0.267	0.102	0.000	0.000	0.612	0.417

Music Therapy Group
Proportions of Parent Behavior

ID	Coping-Promoting			Distress-Promoting		
	Preparation	Procedure	Recovery	Preparation	Procedure	Recovery
A	1.000	0.000	0.483	0.000	0.000	0.103
C	0.000	0.000	0.000	0.000	0.000	0.000
E	0.000	0.229	0.214	0.000	0.514	0.143
G	0.250	0.222	1.000	0.000	0.111	0.000
I	0.000	0.000	0.000	0.000	0.000	1.000
J	0.500	0.909	0.500	0.000	0.090	0.000
K	1.000	0.000	0.000	0.000	0.000	0.000
L	0.500	0.286	0.200	0.000	0.000	0.000
M	0.000	0.000	0.000	0.000	0.000	0.000
N	0.000	0.000	0.000	0.000	0.000	0.000
S	0.000	0.000	0.692	0.000	0.000	0.154
X	0.000	0.000	0.000	0.000	0.000	0.000
Y	0.087	0.378	0.667	0.000	0.216	0.000
Z	0.000	0.786	0.000	0.000	0.000	0.000
FF	0.450	0.000	0.067	0.000	0.400	0.000
GG	0.500	0.125	0.110	0.000	0.375	0.000
KK	0.000	0.750	0.000	0.000	0.250	1.000
II	0.000	1.000	0.000	0.000	0.000	0.000
JJ	0.000	0.176	0.000	0.000	0.000	0.400
MM	0.000	0.000	0.000	0.000	0.000	0.667
OO	0.167	0.500	0.353	0.000	0.000	0.000
PP	0.500	0.222	0.375	0.000	0.000	0.000
UU	0.500	1.000	0.667	0.000	0.000	0.111
ZZ	0.200	0.600	0.250	0.000	0.100	0.000
AAA	0.000	0.000	0.200	0.000	0.000	0.267
GGG	0.000	0.370	0.273	0.000	0.259	0.091
HHH	0.000	0.583	0.000	0.000	0.083	0.000
III	0.000	1.000	1.000	0.000	0.000	0.000
JJJ	0.000	0.000	0.000	0.000	0.846	0.000

Control Group
Proportions of Parent Behavior

ID	Coping-Promoting			Distress-Promoting		
	Preparation	Procedure	Recovery	Preparation	Procedure	Recovery
B	0.000	0.429	0.000	0.000	0.429	0.333
D	0.000	0.267	0.000	0.000	0.200	0.000
H	0.167	0.250	0.000	0.000	0.000	0.000
O	0.000	0.000	0.000	0.000	0.000	0.000
P	0.143	0.300	0.250	0.071	0.200	0.313
Q	0.250	0.111	0.200	0.000	0.389	0.600
R	0.100	1.000	0.171	0.000	0.000	0.571
T	0.000	0.000	0.000	0.125	0.000	0.000
U	0.000	0.000	0.000	0.000	0.125	0.000
V	0.000	0.000	0.082	0.086	0.808	0.408
W	0.125	0.308	0.000	0.250	0.308	0.429
BB	----	----	----	----	----	----
CC	0.000	0.471	0.164	0.647	0.353	0.433
DD	0.000	0.111	0.000	0.000	0.000	0.200
EE	0.148	0.000	0.227	0.407	0.000	0.545
HH	0.000	0.522	0.200	0.000	0.217	0.000
NN	0.000	0.182	0.000	0.000	0.364	0.455
QQ	0.000	0.231	0.259	0.143	0.615	0.481
SS	0.118	0.140	0.118	0.000	0.233	0.235
TT	0.429	0.200	0.000	0.143	0.000	0.000
VV	0.000	0.088	0.000	0.000	0.000	0.082
WW	----	----	----	----	----	----
XX	0.143	0.047	0.000	0.000	0.042	0.019
YY	0.000	0.152	0.524	0.000	0.554	0.381
BBB	0.167	0.000	0.167	0.250	0.800	0.611
CCC	0.000	0.500	0.467	0.000	0.000	0.200
DDD	0.000	0.000	0.105	0.091	0.455	0.526
EEE	0.000	0.000	0.000	0.077	0.800	0.000
FFF	0.286	0.356	0.000	0.000	0.089	0.400

Music Therapy Group
Proportions of Nurse Behavior

ID	Coping-Promoting			Distress-Promoting		
	Preparation	Procedure	Recovery	Preparation	Procedure	Recovery
A	0.560	0.455	0.514	0.000	0.182	0.114
C	0.529	0.214	0.000	0.118	0.179	0.250
E	0.100	0.253	0.059	0.000	0.413	0.265
G	0.000	0.500	0.000	0.000	0.083	0.000
I	0.000	0.250	0.333	0.000	0.250	0.000
J	0.000	0.000	0.000	0.000	0.000	0.000
K	0.789	0.333	0.000	0.000	0.000	0.000
L	0.400	0.429	0.129	0.000	0.143	0.161
M	0.200	0.429	0.300	0.000	0.000	0.000
N	0.500	0.857	0.000	0.000	0.000	0.333
S	0.688	0.416	0.396	0.000	0.125	0.094
X	0.000	0.200	0.400	0.000	0.100	0.600
Y	0.179	0.265	0.000	0.000	0.102	0.846
Z	0.333	0.692	0.000	0.000	0.000	0.000
FF	0.000	0.000	0.000	0.000	0.000	0.000
GG	0.000	0.583	0.278	0.000	0.194	0.111
KK	0.000	0.333	0.000	0.000	0.167	1.000
II	0.182	0.529	0.000	0.000	0.000	0.000
JJ	0.143	0.095	0.000	0.000	0.000	0.000
MM	0.000	0.000	0.000	0.000	0.333	0.667
OO	0.000	0.333	0.000	0.000	0.000	0.200
PP	0.250	0.413	0.000	0.000	0.217	0.444
UU	0.762	0.395	0.438	0.000	0.316	0.375
ZZ	0.000	0.000	0.200	0.000	0.167	0.133
AAA	0.000	0.333	0.333	0.000	0.000	0.333
GGG	0.000	0.250	0.250	0.000	0.250	0.000
HHH	0.000	0.000	0.000	0.000	0.000	0.000
III	0.000	0.100	0.000	0.000	0.200	0.000
JJJ	0.000	0.000	0.000	0.000	0.333	0.000

Control Group
Proportions of Nurse Behavior

ID	Coping-Promoting			Distress-Promoting		
	Preparation	Procedure	Recovery	Preparation	Procedure	Recovery
B	0.357	0.276	0.300	0.000	0.138	0.250
D	0.000	0.297	0.400	0.077	0.141	0.000
H	0.444	0.000	0.000	0.000	0.000	0.000
O	0.632	0.813	0.000	0.000	0.125	0.000
P	0.250	0.000	0.444	0.000	0.318	0.056
Q	0.333	0.135	0.108	0.000	0.108	0.000
R	0.314	0.381	0.378	0.000	0.333	0.305
T	0.300	0.250	0.194	0.000	0.200	0.226
U	0.000	0.156	0.000	0.000	0.125	0.667
V	0.000	0.000	0.273	0.056	0.000	0.273
W	0.000	0.200	0.167	0.000	0.200	0.083
BB	----	----	----	----	----	----
CC	0.000	0.000	0.000	0.000	0.063	0.500
DD	0.000	0.091	0.000	0.000	0.061	0.083
EE	0.096	0.000	0.278	0.308	0.600	0.333
HH	0.000	0.245	0.429	0.091	0.057	0.036
NN	0.000	0.292	0.111	0.000	0.2500	0.667
QQ	0.000	0.000	0.500	0.000	0.000	0.875
SS	0.000	0.151	0.206	0.000	0.094	0.000
TT	0.545	0.211	0.000	0.000	0.000	0.000
VV	0.000	0.123	0.000	0.000	0.018	0.082
WW	----	----	----	----	----	----
XX	0.308	0.056	0.151	0.000	0.000	0.245
YY	0.462	0.143	0.438	0.000	0.179	0.375
BBB	0.000	0.000	0.083	0.000	0.091	0.417
CCC	0.000	0.385	0.000	0.000	0.000	0.500
DDD	0.000	0.000	0.286	0.222	0.556	0.571
EEE	0.000	0.000	0.000	0.000	0.000	0.065
FFF	0.192	0.451	0.000	0.000	0.070	0.000

APPENDIX N

Raw Data for Lengths of Treatment Phases

Music Therapy Group
Length of Treatment Phases, in Minutes and Seconds

ID	Preparation	Procedure	Recovery	Total
A	1:09	0:18	1:35	3:02
C	1:43	2:03	1:48	5:34
E	2:48	7:46	3:30	14:04
G	1:39	1:01	0:10	2:40
I	0:31	0:34	0:08	1:13
J	0:56	1:33	0:43	3:12
K	1:18	0:12	0:00	1:30
L	0:43	2:33	2:04	5:20
M	0:16	0:45	0:10	1:11
N	0:16	0:23	0:05	0:44
S	0:27	0:49	3:14	4:30
X	0:38	1:24	0:09	2:11
Y	2:54	10:39	0:34	14:07
Z	1:33	3:32	0:00	5:05
FF	1:47	1:06	0:55	3:48
GG	0:51	2:48	3:40	7:19
KK	1:04	0:58	0:00	2:02
II	0:40	2:54	0:18	3:52
JJ	0:07	1:26	0:11	1:44
MM	1:42	1:51	0:53	4:26
OO	3:05	1:15	1:34	5:54
PP	3:05	4:23	3:10	10:38
UU	0:56	1:19	1:41	3:56
ZZ	0:57	0:59	1:06	3:02
AAA	0:13	2:43	2:32	5:28
GGG	1:20	2:46	0:47	4:53
HHH	1:44	1:12	0:09	3:05
III	0:10	0:39	0:09	0:58
JJJ	2:06	1:27	0:15	3:48

Control Group
Length of Treatment Phases, in Minutes and Seconds

ID	Preparation	Procedure	Recovery	Total
B	0:50	1:23	1:07	3:20
D	1:10	2:40	0:17	4:07
H	1:12	0:39	0:01	1:52
O	0:20	0:28	0:00	0:48
P	1:08	0:50	0:45	2:43
Q	0:19	1:12	0:47	2:18
R	1:02	0:34	2:36	4:12
T	1:08	0:48	1:13	3:09
U	1:47	1:49	0:09	3:45
V	1:47	1:05	1:41	4:33
W	0:29	0:57	1:01	2:27
BB	----	----	----	----
CC	1:03	2:10	3:21	6:34
DD	1:06	1:37	0:47	3:30
EE	2:30	0:27	0:28	3:25
HH	1:02	5:31	1:10	7:43
NN	1:05	1:51	1:10	4:06
QQ	1:23	0:50	1:20	3:33
SS	1:48	3:28	2:01	7:17
TT	0:47	0:41	0:00	1:28
VV	0:19	0:57	0:49	2:05
WW	----	----	----	----
XX	1:49	3:35	0:53	6:17
YY	1:19	3:56	1:01	6:16
BBB	1:20	1:02	3:10	5:32
CCC	1:14	0:47	0:48	2:49
DDD	0:28	0:43	0:49	2:00
EEE	1:47	1:10	0:31	3:28
FFF	2:00	3:37	0:35	6:12

APPENDIX O

Raw Data for Parents' Ratings of Distress and Pain

Music Therapy Group
Parents' Ratings of Distress and Pain

ID	Distress	Pain
A	2	3.5
C	0	5.0
E	1	5.0
G	1	0.0
I	2	2.0
J	-2	7.5
K	3	1.5
L	3	1.5
M	3	0.0
N	1	3.5
S	1	5.5
X	1	3.5
Y	1	5.5
Z	3	1.5
FF	3	5.0
GG	0	1.5
II	1	2.0
JJ	-1	3.5
KK	0	5.0
MM	-1	3.5
OO	3	2.5
PP	1	1.5
UU	1	----
ZZ	0	3.0
AAA	2	3.5
GGG	----	6.0
HHH	3	2.0
III	3	1.0
JJJ	-2	3.5

Control Group
Parents' Ratings of Distress and Pain

ID	Distress	Pain
B	2	7.5
D	0	1.0
H	2	2.0
O	3	0.0
P	0	5.0
Q	-1	1.5
R	-1	1.5
T	-1	7.0
U	1	5.5
V	0	0.0
W	-3	7.5
BB	0	0.0
CC	-3	2.5
DD	-2	3.0
EE	-3	----
HH	-2	5.0
NN	-1	7.0
QQ	0	1.5
SS	0	7.5
TT	0	0.0
VV	0	----
WW	-2	6.0
XX	0	6.0
YY	-1	7.5
BBB	0	5.5
CCC	2	5.5
DDD	0	10.0
EEE	-3	10.0
FFF	0	5.0

APPENDIX P

Raw Data from Music Therapy Satisfaction Surveys

Question One:
Did Your Child Benefit from Music Therapy?

ID	Yes, very much	Yes	No opinion	Not really	Not at all
A	X				
C		X			
E	X				
G		X			
I		X			
J			X		
K	X				
L	X				
M	X				
N		X			
S	X				
X				X	
Y		X			
Z	X				
FF	X				
GG				X	
II		X			
JJ	X				
KK	X				
MM				X	
OO	X				
PP		X			
UU		X			
ZZ		X			
AAA		X			
GGG		X			
HHH	X				
III	X				
JJJ			X		

Question Two:
Did You Benefit from Music Therapy?

ID	Yes, very much	Yes	No opinion	Not really	Not at all
A	X				
C		X			
E	X				
G				X	
I	X				
J		X			
K	X				
L	X				
M		X			
N				X	
S	X				
X			X		
Y			X		
Z	X				
FF	X	X			
GG			X		
II	X				
JJ	X				
KK	X				
MM	X				
OO		X			
PP		X			
UU	X				
ZZ	X				
AAA		X			
GGG		X			
HHH	X				
III		X			
JJJ		X			

Question Three:
Did Music Therapy Services Improve Your Perception of this Facility?

ID	Yes, very much	Yes	No opinion	Not really	Not at all
A	X				
C		X			
E		X			
G				X	
I		X			
J			X		
K			X		
L	X				
M	X				
N			X		
S	X				
X				X	
Y		X			
Z	X				
FF	X				
GG	X				
II				X	
JJ	X				
KK	X				
MM		X			
OO	X				
PP		X			
UU		X			
ZZ		X			
AAA			X		
GGG		X			
HHH	X				
III	X				
JJJ				X	

Questions Regarding Past and Future Music Therapy Services

	Have you received or experienced music therapy services prior to this? If yes, where?	Would you like to receive music therapy services again if you return to this facility?
A	No	Yes
C	No	Yes
E	No	Yes
G	No	Maybe
I	No	Yes
J	No	Maybe
K	No	Yes
L	No	Yes
M	No	Yes
N	No	Yes
S	No	Yes
X	No	Maybe
Y	No	Maybe
Z	No	Yes
FF	No	Yes
GG	No	Yes
II	No	Yes
JJ	No	Yes
KK	No	Yes
MM	No	Maybe
OO	No	Yes
PP	No	Yes
UU	No	Yes
ZZ	No	Yes
AAA	No	Maybe
GGG	No	Yes
HHH	No	Yes
III	No	Yes
JJJ	No	Yes

APPENDIX Q

Comments from Post-Procedure Questionnaires

Music Therapy Group
Parents' Comments

ID	Comment
A	I loved it, should definitely be a part of all immunizations.
G	Kids had fun.
I	Thank you.
K	Thank you- she loved it!
N	Will talk to son to see what he thought. A little concerned it might draw out the vac [sic] process rather than just keep it short and sweet. Nursing staff would have better idea of whether it helps.
Z	Great job!
FF	[Music therapist] is great! In the past, pain was a 12.
OO	I really love it and so did [child]. Thank you so much!
UU	I think it would have been different if their father were here. I'm a stay-at-home mom and they react differently to him.
ZZ	Didn't help during the immunization, but helped ease her anxiety leading up to the shots and shortened recovery time.

Control Group
Parents' Comments

ID	Comment
R	Seeing the needles.
V	He gets hysterical when a doctor does any work on him.
CC	[Child] is just frightened of any doctor visit, they are all equally stressful for her.
TT	He never has a bad reaction. He isn't scared of needles, apparently.
BBB	Hates shots. Had bad experience with previous visits so not sure how he acts because I'm never really in the room. But he cried pretty hard this time.

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