How Does the Utilization of Non-pharmacologic Pain Management Techniques Affect Pain Outcomes and Long-term Memories in Young Children During Painful Procedures?

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Abstract

Background: A child's pain is different from pain experienced as adults. Different emotional and psychological factors can affect the child's pain comprehension and stimulate their response to pain. Procedural pain can have long-term negative effects on children. It may cause increased pain sensitivity, fear, and avoidance of healthcare as adults. Parents may also experience anxiety during their child's procedure, which may increase their child's perceived pain.

Problem: This DNP project aimed to implement and evaluate the usage of the *Buzzy* device during painful procedures of children ages three through six years at this pediatric hospital. Distraction can be used to decrease pain perceptions in children and parents, which could positively affect long-term memories.

Interventions: The nurses utilized *Buzzy* with children aged three to six years of age needing venipuncture. Staff provided a pain survey to each patient who received *Buzzy* before and during a painful procedure. Parents were contacted at 2 weeks and 1-month post-procedure to assess pain perceptions.

Results: Ninety-six patients participated in the study. An 84.6% response rate was acquired from the surveys. Ninety-seven percent of parents and patients surveyed reported decreased pain with venipuncture using *Buzzy*. Pain perceptions decreased with the use of *Buzzy* both short-term and long-term.

Conclusion: The positive response from patients and parents demonstrates *Buzzy* may be used to decrease pain perceptions in children and families. The success rate shown in this study will aid in distraction techniques used as pain management to be added to evidence-based practice in the future.

Keywords: distraction techniques, pediatric pain, *Buzzy*, pain perceptions, vibration

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Introduction

Children do not experience pain in the same way as adults. Children have fewer coping skills and can exhibit a more significant emotional and behavioral response to perceived pain experiences(Bahorski et al., 2015). Some professionals have misconstrued how young children perceive pain. They have theorized that children have an underdeveloped nervous system that does not allow them to feel pain. Other misconceptions include that children can not remember painful experiences and assess their pain level (Bahorski et al., 2015). Assessing pain levels in children can be omitted during venipuncture because of difficulties associated with the assessment. The developmental and age level also makes a difference in how children perceive pain (Bahorski et al., 2015). Children often remember the pain associated with venipuncture as a negative experience. Procedural pain is preventable but tends to be dismissed by healthcare practitioners(Bahorski et al., 2015). Failure to provide pain management can have adverse psychological and physical effects. Adverse effects can include a fear of doctors, lack of trust and can instill negative long-term memories (Taddio et al., 2010). Psychological and emotional distress, the development of needle phobia that extends into adulthood, and healthcare avoidance are a few fine examples of the adverse effects of pain during venipuncture(Taddio et al., 2010). According to Taddio, 25% of adults have a needle phobia that began in childhood, and approximately 10% of the population decline needle-sticks due to their intense fear of needles (Taddio et al., 2010).

Advanced practice providers have the responsibility of assessing and minimizing pain during procedures. Techniques, such as cold or vibration in the toddler population, decrease perceptions of pain. In addition, distraction techniques help toddlers retain positive long-term memories and instill trust with healthcare professionals (Taddio et al., 2010).

Background

Children often state that getting blood drawn is an excruciating and scary procedure. An apprehension of needles does not disappear after childhood. Many adults also have an extreme fear of needles ((McMurtry et al., 2015)). The inability to forget negative thoughts, images, or memories is difficult for some individuals and can be a source of psychological distress. These fears can develop into a phobia where all procedures are feared. Forgetting is not always a cognitive failure but a means of coping with negative experiences (Marche et al., 2015). Thus, our ability to control what we remember, and what we forget, is likely important for a person's emotional well-being (Marche et al., 2015). Memories of painful experiences can have a profound impact on subsequent anxiety and pain coping behavior (Marche et al., 2015). Negative memories can increase children's distress and anxiety concerning upcoming medical procedures, lead to negative attitudes about and avoidance of necessary medical care, initiate chronic pain syndromes and facilitate the persistence of pain conditions into adulthood (McMurtry et al., 2015). These fears can develop into a phobia where all procedures are feared (Marche et al., 2015). Evidence-based pain management strategies implemented during venipuncture could have decreased fear and anxiety levels. If children receive several repetitive painful procedures in childhood, a greater risk of extreme needle fear is probable (McMurtry et al.,2015). A bad experience involving a needle can become embedded in a child's brain and stored as a negative

long-term memory (McMurtry et al.,2015). Negative memories of pain can be as problematic in their impact on health and suffering as the actual pain experience (Marche et al., 2015).

Pain Perception

The International Study for the Association of Pain (IASP) defines pain as " an unpleasant sensory and emotional experience associated with or resembling that associated with, actual or potential tissue damage" (Breivik, 2002). Patients learn pain concepts from their personal experiences. Pain from physical, psychological, and spiritual factors affect perceptions (Breivik, 2002). Perceptions of pain could be decreased with improved pain management.

Children under 3 years of age cannot adequately verbalize about intensity, location, and characteristics of pain they experience. Toddlers are in the preoperational stage of thinking. They understand that pain is hurt. They do not relate pain to illness. Toddlers may feel pain as a punishment for bad behavior (Garra et al., 2010; Marwaha, 2017). The fear factor is a large contributor to the experience of pain in toddlers. Toddlers may become very quiet and inactive while in pain or may become very active (Mills, 2016). Interpreting toddlers' behavior may be difficult due to exacerbating factors such as separation anxiety, and the memory of previous painful experiences. Sometimes toddlers manifest their pain and fear through aggressive outbursts (Mills, 2016). Anticipatory fear becomes evident about six to twelve months of age. The central nervous system develops which increases the cognitive capacity allowing a memory of injections which causes an anticipatory response. Anticipatory responses cause fear of pain (Mills, 2016). An increase in motor control as myelination of motor nerves progresses as children age. Pain levels increase as motor control develops in children (Mills, 2016). Imaging studies report higher metabolic activity and functional connectivity in the thalamus and sensory

cortices for patients experiencing episodic pain (Victoria & Murphy, 2016) The enhanced integration of sensory information caused a decreased behavioral response to acute noxious stimuli but heightened withdrawal responses to pain from consecutive needle-sticks (Victoria & Murphy, 2016). One study on pain in infants found they have short-term pain associated with needle-sticks. The study also stated that memories of previous pain are apparent by six months of age (Mills, 2016).

There are long-term effects caused by pain experienced in childhood. Needles are routinely given from the first year of life, particularly for vaccinations. Current recommendations state that healthy children receive 20 to 30 immunizations before the age of 18 years (Birnie et al., 2018). For children with acute or chronic illnesses, needle procedures are even more frequent for the assessment and management of their conditions and are reported as the most distressing part of treatment (Birnie et al., 2018). Failure to adequately manage pain and distress during needle procedures can lead to the development of significant needle fears, which often begin in early to middle childhood and persist into adulthood (McMurtry et al., 2015). Fear of needles can also contribute to vaccine hesitancy and medical non-adherence (Taddio et al., 2010) Unalleviated pain in early developmental results in reductions in autonomic and hormonal responses to pain and stress that persist into adolescence and adulthood (Victoria & Murphy, 2016). Experiences of pain in early life increase general pain thresholds to acute stimuli but exaggerate responses to severe and persistent noxious stimuli (Victoria & Murphy, 2016). Early life pain also results in long-term changes in stress. In response to procedural pain, heart rate and cortisol levels of infants are high but become blunted as the number of skin-breaking procedures increases (Victoria & Murphy, 2016). Early life pain reprograms the hypothalamic-pituitary-adrenal axis, putting preterm infants at higher risk for developing maladaptive responses to

anxiety- and stress-provoking stimuli. (Victoria & Murphy, 2016). If pain is not addressed and treated early on, it can greatly impact a child's quality of life by interfering with mood, appetite, school attendance, academic performance, and participation in sports and other extracurricular. extracurricular activities. Unrelieved childhood pain can enhance a child's vulnerability to pain later in life (Victoria & Murphy, 2016). Pediatric pain is also associated with increased risk for physical and psychological symptoms such as fatigue, sleep disorders, depression, and anxiety (Groenewald et al., 2015).

Children experience pain result from painful invasive procedures such as venipuncture. Unrelieved pain may cause complications of disease and slowness in recovery. The psychological signs of pain during venipuncture were anxiety, stretching muscles, weeping, screaming, crying, biting on lips, and refusal. (Inan & Inal, 2019) Children using distraction techniques displayed physiological responses of deceased pulse rate decreased respiratory rate, and a reduction in body temperature (Inan & Inal, 2019). Exposure to pain in young children without adequate pain management has negative long-term consequences, including increased morbidity and mortality (Friedrichsdorf & Goubert, 2020). Repeated exposures to pain in children are associated with reduced cognition and motor function (Friedrichsdorf & Goubert, 2020). Previous studies have shown that exposure to pain early in life even heightens the risk for developing chronic pain, anxiety, and depressive disorders in adulthood. Therefore, adequate management of child pain is imperative to maintain a high quality of life throughout the lifespan (Ramira et al., 2016).

Providers should include onset, duration, severity, and location of pain in every assessment (Ramira et al, 2016). The prevalence of pain can be as high as 95% in the toddler population (Grout et al., 2018). All patients have a right to pain management regardless of their

age. Pain responses can have long-term effects on perception, coping, and anxiety in children. Effective pain management reduces stress, decreases hospital costs, and increases self-esteem in the pediatric population (Grout et al., 2018). Toddlers are at risk for inadequate pain management due to their lack of communication and coping skills. Pain needs to be managed appropriately in pediatrics to improve perceptions that affect their quality of life as an adult.

Cost Analysis

The costs for this project were minimal in comparison to the savings that could occur. Distraction techniques have been shown to decrease procedural time and shorten hospital stays (Bahorski et al., 2015).Distractions are interventions that require little time in the hospital setting, can be integrated into the daily workflow, and have positive implications for health outcomes when applied to a broader perspective (Bahorski et al., 2015) Pediatric pain-related conditions were associated with $11.8 billion in total incremental health care expenditures (Groenewald et al., 2015). Prior studies suggest that pediatric pain prolongs inpatient stay and increases costs (Tumin et al., 2018). There is evidence to suggest that parental coping is associated with child distress, which highlights the need for interventions that have the potential to decrease parental and patient distress (Tumin et al., 2018). Interventions that are cost-effective and sustainable are most appealing in the current healthcare environment.

Gaining the cooperation of the child and family is essential for a successful interaction that encompasses the child and family and considers the child's age, developmental level, cognitive and communication skills, and culture (Tumin et al., 2018). Using distraction can reduce the time and staff members needed for a procedure and can save costs. Distraction techniques may decease or avoid the use of opioids or anxiolytics, decrease recovery time, and adverse events (Victoria & Murphy, 2016). Distraction techniques used to decrease procedural

pain management in children are cost-effective, easy to use, and have no side effects (Erdogan & Aytekin Ozdemir, 2021). An overall decrease in needle-related phobias may contribute to improved compliance with preventative care as the patient ages, leading to a decrease in future disease, positively impacting families, employers, insurance companies, local hospitals, and the community at large

Problem Statement

Currently, pediatric units in the Midwest have no cold and vibration pain management protocols. The purpose of this project is to create the initial steps to develop a pain management protocol with toddler venipunctures by assessing patient and parent perception of *Buzzy* effectiveness for children three to six years of age. There is evidence that negative experiences related to pain in children can harm future healthcare experiences (Olsen & Weinberg, 2017). Toddlers have the right to pain management before, during, and after any painful procedure (Olsen & Weinberg, 2017). Pharmacological and non-pharmacological interventions are available to aid in pain management (Olsen & Weinberg, 2017). There are distraction techniques and tools available to use with young children undergoing venipuncture. The utilization of distraction techniques used during painful procedures will provide valuable data in this study. These improvements should promote self-esteem and positive long-term memories in toddlers (Dastgheyb et al., 2018). There is a Child Life Specialist assigned to each unit. These specialists exist to mentor staff and patients on distraction techniques. There is no current protocol for using cold or vibration during venipuncture on every patient. Long-term memories and pain perception could be improved while using cold and vibration. These improvements should promote self-esteem and positive long-term memories for this age group (Dastgheyb et al., 2018).

A stakeholder is an individual or group that is affected by a project or can influence implementation and long-term sustainability of a project (Hussain et al., 2018). Key stakeholders in this project include patients, parents, nurses, child life specialists, and providers. Patients are stakeholders because their life will be affected by the healthcare decisions that are made. Distraction techniques reduce pain, decrease cost, and increase patient satisfaction and pain perceptions. Pain that is controlled in childhood improves pain perceptions and health outcomes through adulthood. Parents act as advocates for their children. They have a legal right to participate in decision-making about their child's health care to ensure that health care is provided to meet the family's needs and preferences. Parents should be involved in all healthcare decisions made for their children. Parents should have the opportunity to improve their personal control over their child's health care and their own life circumstances (Aarthun et al., 2018) A parent's active involvement in medical decision-making and provision of sufficient and consistent information empowered the parents to increase their active involvement in decisions about their child's medical care. A parents' ability to cope with the parental role in the hospital appeared to be strengthened by promoting their perception of life as meaningful, comprehensible, and manageable (Aarthun et al., 2018). Nurses are stakeholders because they are the primary advocates for patients and their families. Nurses are internal stakeholders responsible for ensuring high-quality patient care. Nurses function by translating evidence into practice while caring for patients (Kallio et al., 2018). Child life specialists are stakeholders because their expertise is in distraction techniques to decrease pain in children. Child life specialists focus on the optimal development and well-being of infants, children, adolescents, and young adults while promoting coping skills and minimizing the adverse effects of hospitalization, health care encounters, and other potentially stressful experiences (Romito et al.,

2020). Physicians act as stakeholders by serving as facilitators of shared decision-making. Patients benefited from shared decision-making in terms of patient satisfaction and engagement. Research outcomes that would encourage the use of shared decision-making include patient engagement, mitigation of risk, and patient satisfaction (Schoenfeld et al., 2016). Stakeholders play a major role in ensuring the successful adoption of evidence in healthcare. Their support is necessary because they provide the resources, skills, and knowledge required for positive patient outcomes. Potential benefits for stakeholders included increased improvement in satisfaction and health outcomes, decreased hospital stay, and decreased cost.

Search Methodology

Cochrane, CINAHL, and PubMed databases were used in the literature search. The search was related to distraction involving pediatric patients published within ten years from the beginning of the scholarly project. The following were the terms applied to the search, pain perception, parent's perception, pediatric, distraction therapy, multimodal distraction, analgesia, intravenous, pain, fear, vibration, *Buzzy*, and analgesia. In addition, keyword combinations included coping and pain, pediatrics and pain, distraction and coping, toddlers and pain perception, young children and pain perception, children and distraction techniques, children and *BUZZY,* pediatrics and distraction methods, anxiety, and pediatrics. A variety of these keyword combinations were searched within each of the databases. All electronic searches were included from the years 2010-2021. Inclusion criteria consisted of studies investigating non-pharmacological pain-relieving strategies for procedure-related pain for children. Articles focusing on intravenous, or prescription pain relief were excluded. A total of 38 peer-reviewed articles, all with quality ratings of A (high quality) or B (good quality) were critiqued, evaluating

the strength and quality of the evidence as well as identifying major patterns, trends, and gaps in the literature ((Logan et al., 2008). Articles that focused on chronic pain or opioid medications for pain relief were eliminated. Ten articles did not meet the criteria and were excluded. Most of the articles reviewed were systematic reviews of randomized controlled trials or literature reviews. Articles that were determined to have a quality rating of C were eliminated from inclusion as their results are not reliable and cannot be applied to future studies. The final set of evidence was comprised of 26 articles, all with quality ratings of A or B quality (Logan et al., 2008). Research studies were graded based on their level of consistency, conclusions, results, recommendations, sample size, and ability to apply results. Non-research studies were graded based on the outlined objectives, results, recommendations, and conclusions (Logan et al., 2008).

Review of Literature

The need for improved pediatric pain management during venipuncture is the focus of this literature review. The review will begin with a discussion of the gate control theory of pain. The panel will be followed by reviewing developmental considerations and how it correlates to pediatric pain perception. Finally, the review will conclude with a discussion of procedural anxiety in the pediatric population. The gate control theory of pain was used to understand venipuncture pain reduction in children through vibration and cold applications (Bergomi et al., 2017; Bahorski et al., 2015; Thrane et al., 2016). The gate control theory proposes that "pain is transmitted from the peripheral nervous system to the central nervous system where a gating system modulates it in the spinal cord" (Thrane et al., 2016). Vibration stimulates receptors to close the "fast pain gate" by presynaptic inhibition at the spinal cord (Thrane et al., 2016).). Cold blocks pain signals and raises the body's overall threshold for pain (Thrane et al., 2016). Buzzy

provides optimal pain relief via the gate control theory with its vibrating motor and ice pack by stimulating the nerves with cold and vibration to close the “fast pain gate” (Moadad et al., 2016). Several randomized control trials analyzed refer to the gate control theory of pain as a method for understanding the process of procedural pain reduction in children using vibration and external cold analgesia (Canbulat, Ayhan, Inal, 2015; Potts, 2017; Inal & Kelleci, 2017; Moadad et al., 2015; Schreiber et al., 2015). Tactile stimulation via vibration is purported to stimulate the A-beta mechanoreceptors, which close the "fast pain gate” by presynaptic inhibition at the dorsal horn of the spinal cord (Canbulat, Ayhan, Inal, 2015; Potts, Davis, Elci, & Fein, 2017; Inal & Kelleci, 2017; Moadad et al., 2015; Schreiber et al., 2015). External cold analgesia stimulates the C fiber while blocking the delta pain signals and raises the body’s overall threshold for pain (Canbulat, Ayban, Inal, 2015).

Buzzy effectively combines vibration and cold, significantly reducing venipuncture pain in children (Moadad et al., 2016). *Buzzy* is an FDA-cleared device widely used for pain reduction during needle-stick procedures in the pediatric population (Canbulat et al., 2015). It is a vibration and pulsation device attached to an ice pack applied directly to the injection site. *Buzzy* is placed on the injection site for 30 to 60 seconds and then immediately moved proximally to the injection point so that the infusion can take place (Ballard et al., 2018). The continuous application of cold affects the C fibers within the spinal cord and consequently blocks the pain signal from the A-delta fibers, reducing the painful sensation (Inal & Kelleci, 2012). Thus, *Buzzy* is a combination of vibration and external cold analgesia, which significantly reduces injection pain in children (Baxter, Cohen, McElvery, Lawson, & von Baeyer, 2011; Canbulat et al., 2015; Inal & Kelley, 2017; Moadad, Potts et al., 2017; Schreiber et al., 2016; Whelan et al., 2014). B*uzzy* provides optimal pain relief via the gate control theory with its vibrating motor and ice pack, by

stimulating the nerves with cold and vibration to close the “fast pain gate” (Canbulat, Ayhan, Inal, 2015; Inal & Kelleci, 2017; Moadad et al., 2015; Potts,2017; Schreiber et al., 2015).

As children age and develop, so does their capacity to describe the pain (Giordano et al., 2019). At four years of age, children can use a pain scale, utilizing facial expressions to indicate their pain. (Giordano et al., 2019). It is necessary for pediatric pain scales to be age and developmentally appropriate to obtain accurate pain assessments to manage pain (Giordano et al., 2019) effectively. The Wong-Baker FACES Pain Rating Scale is a helpful tool that has been successfully used in children ages three to eighteen years to measure acute pain (Moadad et al., 2019). It is a continuous outcome measure consisting of a 100-mm scale from 0 to 100 with low and high-end points of no pain and worst pain. Pain can be measured by self-report, biological markers, and behavior. Pain is subjective; therefore, self-report is the best if available (Garra et al., 2010). It may be difficult to measure the degree of pain in a young child, especially toddlers because of their level of cognitive and language development. The FACES Pain Scale provides a useful method of describing pain perceptions (Garra et al., 2010). Faces scales use a series of facial expressions to illustrate a spectrum of pain intensity. Numerous face-based rating scales are available. Faces scales are ordinal outcome measures consisting of a limited number of categorical responses ordered in a specific pattern (Garra et al., 2010). The FACES Pain Scale has been shown to be a reliable and valid measure of acute pain in pediatric patients. Facial expression drawings are a popular method of pain severity assessment in pediatric populations. that help illustrates a spectrum of pain intensity (Garra et al., 2010). A randomized control trial indicated that age was an essential factor associated with child pain, suggesting that younger children reported higher pain scores (Thrane et al., 2016). The study postulated that parents and healthcare providers may underestimate pediatric anxiety related to venipuncture.

Fear and anxiety related to needle-stick procedures may not resolve over time and has the potential to cause delays in seeking medical care and treatment, as well as adherence to future medical procedures (Canbulat et al., 2015). The Children's Fear Scale has been widely utilized to assess pediatric anxiety related to venipuncture. Fear and anxiety related to needle-stick procedures may not resolve over time and has the potential to cause delays in seeking medical care and treatment, as well as adherence to future medical procedures (Canbulat et al., 2015). The Children's Fear Scale has been widely utilized through the literature as a reliable and valid tool for evaluating pediatric fear (Canbulat et al., 2015). Children's negative experiences during these routine procedures can have long-term negative consequences that may persist into adulthood. Outcomes can include increased pain sensitivity, negative responses to pain, low cognitive and motor development, and long-term traumatic memories (Thrane et al., 2019). Children who rated their anxiety as high during the venipuncture were more likely to have greater anxieties when talking about the exact procedure two weeks later (Noel et al., 2010). Children who rated their pain and anxiety as low during the venipuncture were also more likely to have decreased anxiety while talking about the procedure two weeks later. Evidence discovered by Noel et al. (2010) indicated the importance of keeping the pain and anxiety low for pediatric patients to help prevent exaggerated memories about possible medical procedures in the future.

Buzzy has proven to significantly reduce anxiety and distress experienced by children undergoing venipuncture (Erdogan et al., 2021). Utilizing *Buzzy* for children undergoing venipuncture will reduce stress decrease pain levels, and improve pain perceptions (Erdogan et al., 2021). Positive pain perceptions improve cognitive processes, brain function, mental health, cardiovascular function, and overall quality of life (Marche et al., 2015). Evidence of additional

positive characteristics was also included throughout the primary studies, such as an increased percentage of successful venipunctures, improved cooperation, and lessened stress in pediatric patients (Buratti et al., 2015).

Theoretical Framework

The Prescriptive Theory of Acute Pain Management was founded in 1988. This theory was developed to aid in pain management for infants and children (Huth & Moore, 2007). Recommendations from the Acute Pain Management Guideline Panel of 1992 and Good and Moore's Model of Acute Pain Management (Huth & Moore, 2007). The purpose of this theory is to provide physicians and advanced practice providers guidelines for effective interventions to reduce the perception of pain in infants and children (Huth & Moore, 2007). In addition, this theory includes guidelines for effective therapeutic interventions (Huth & Moore, 2007).) Interventions are based on several factors, including the infant or child's physical, psychological, and developmental levels. Other factors, such as gender, ethnicity, and culture, are also used to determine the best method to decrease pain in each infant or child (Huth & Moore, 2007). The theory considers pain as assessed by the child, parents, and advanced practice providers. The theory also considers the child and parent's satisfaction with pain reduction. The theory indicates that pain management and satisfaction with pain reduction are successfully achieved by using specific assessment strategies, therapeutic pain relief interventions, and reassessments of the child's pain (Huth & Moore, 1998).

This theory provides an evidence-based framework that can structure this DNP project to address pain reduction during venipuncture in small children. It provides guidelines for using cold and vibration via Buzzy as a therapeutic tool for reducing pain during painful procedures.

Buzzy is a promising intervention to reduce pain in children (Baxter et al., 2011). This battery-operated motorized device is bee-shaped with removable wings of ice. *Buzzy* was used on pediatric patients during needle-related procedures in the ED (Baxter et al., 2011). The nurse or child life specialist will perform an initial pain assessment considering factors such as developmental level, age, and culture. The nurse will teach the parent and child about *Buzzy* and its use and then implement the non-pharmacologic adjuvant (i.e., *Buzzy)* during the child's venipuncture (Huth & Moore, 1998).

According to Good and Moore's Model of Acute Pain Management, pain management plans are best developed when a balance between analgesia and side effects is created to control acute pain (Good, 1998). Management of acute pain is achieved by using multimodal interventions, attentive care, and patient participation (Good, 1998). *Buzzy* will be used as a multimodal intervention to regulate pain with nominal side effects. As a part of attentive care, The Wong-Baker FACES Scale and the Children's Fear Scales will be used to rate pain and fear perceptions. The child will subjectively rate their own pain and fear perceptions (Good, 1998).

Vibration is useful in pain management and prevention (Bahorski et al., 2015) as it blocks the afferent nerve fibers from transmitting the sensation of pain to the brain. *Buzzy* also allows local cold therapy to stimulate nociceptive pain fibers, blocking the sensation of pain from reaching the brain. Lastly, in another seminal study by Bukola and Paula (2017), distraction has been identified as an effective pain intervention with pediatric patients. Specifically, distraction effectively relieves procedural pain (Bahorski et al., 2015; Bukola et al., 2017). The nurse or child life specialist will reassess pain after venipuncture using the Wong-Baker FACES pain scale to assess the child's pain level (Garra et al., 2010). The parents will be provided with a survey to evaluate their child's pain and satisfaction with pain reduction techniques used during

venipuncture. This theory will assist by setting guidelines for the appropriate use of cold or vibration to decrease pain in children undergoing venipuncture. Minimizing pain during venipuncture should result in increased positive outcomes for the parent and child. Parents will be given a survey two weeks and four weeks after their procedure to compare their perceptions of pain control and patient satisfaction over time. Trusting relationships should be improved between advanced practice providers and their patients and families. Children should have a decreased perception of pain, which should help them create better long-term memories of pain associated with venipuncture procedures. In conclusion, the dissemination of this evidence may enhance best practices in pain management and prevention

Gap Analysis

Distraction techniques can decrease pain in young children during painful procedures. The proposed new practice consistently uses distraction techniques based upon the child's age and developmental level to decrease pain during painful procedures such as venipuncture. In children, ages three through six, cold and vibration are effective at reducing pain during venipuncture. Barriers to the implementation of the proposed best practice are gathering 100 participants to volunteer for the study. Obtaining voluntary consent from the child's parents may become a secondary barrier in the study. Cold and vibration, used as distraction techniques, will be offered to children participating in the study. Pain levels in all children undergoing venipuncture. Current policy does not state that a pre- and post-pain assessment should be performed with venipuncture procedures. In this study, all children will be assessed using the Wong-Baker FACES pain scale for children (Garra et al., 2019). Staff members need to agree to evaluate pain pre routinely and post-procedure with every venipuncture performed. A barrier may be the education of staff on pain assessments and data collection. Best practices will be used

with the new proposed approach to mandate pain assessments with each venipuncture (Potts et al., 2017).

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One strength of this project was that staff felt that the intervention was easily incorporated into the daily workflow and made a positive impact on the care that the patient and family experienced while in the hospital. The hospital already has an ample supply of *Buzzy* devices on each unit. This practice could decrease procedure times while increasing child and parent satisfaction. This intervention takes little time or effort to implement, is cost-effective, supported by parents and staff, and provides increased comfort during a very common pediatric

procedure. The use of distraction techniques to improve pain perceptions in children and parents is a growing need and a cause for action. There are many strengths associated with addressing these needs, such as the potential for improved long-term patient outcomes, increased patient satisfaction, and an improved understanding of pain management. Therefore, its implementation into practice should be further considered.

A limitation of this study is the potential lack of transferability. This study was conducted on toddlers in a hospital setting. It is unknown if the results would be transferable to other age groups or healthcare settings. *Buzzy* was the only distraction tool used in the study. It is unknown if other distraction techniques would produce similar results. This project used subjects from a vulnerable population, therefore, IRB approval took longer than expected. The number of participants was limited due to a shortened time frame. A larger sample size may have made the project more statistically significant.

Goals, Objectives, and Expected Outcomes

This project will determine the efficacy of cold and vibration to decrease pain perception in young children. Research has shown that children who have positive experiences related to healthcare can form trusting relationships with healthcare professionals as adults. These patients seek out care more often and have improved health outcomes as adults. Current practice allows distraction techniques to be offered to children showing signs of anxiety before painful procedures. This study is being conducted to show that all children should be offered distraction techniques before any medically necessary painful procedure. Patients and their families will assess pain levels pre- and post-venipuncture procedures using the Baker-Wong FACES pain scale (Garra et al., 2019). Fear levels will be assessed using the Children's Fear Scale (Dastgheyb et al., 2018). A post-survey assessing patient and family satisfaction will utilize the

Likert Scale from the Pediatric Pain Assessment Survey. The study will analyze results from Riley Children's Hospital in Indianapolis, Indiana, for six weeks (Srouji et al., 2010).

Project Design

This project is a nonrandomized, quasi-experimental study performed in an acute care unit of a tertiary care hospital over six weeks. This quality improvement (QI) project focused on implementing and evaluating the usage of the *Buzzy* device during venipuncture of pediatric patients. The project was limited to children between the ages of 3 and 6 years who received venipuncture or IV insertion at the clinical site. The estimated sample size (n = 100 patients) was based upon an approximate rate of 3 patients (ages three-six years) per day per provider. Pain perceptions will be evaluated by survey pre- and post-blood draw or IV insertion. A follow-up survey will be completed by parents one-month post-procedure. The data used from this study will be used as a quality improvement DNP scholarly project. Qualitative data from the Wong-Baker FACES pain scale, the Children's Fear Scale, and the Pediatric Pain Assessment Survey will be used to collect data (Garra et al., 2010).

The study will access data from participants at Riley Children's Hospital in Indianapolis, Indiana. The hospital is an inpatient facility. Children in the hospital will be asked to volunteer to participate in the study. Children from ages three to six will be included in the study. Exclusion criteria included children with cold sensitivity, Raynaud's, or Sickle Cell disease, or who had impaired skin integrity, as they were listed as contraindications for using *Buzzy* (Moadad et al., 2016). A brochure describing the device was provided to parents with eligible children undergoing venipuncture or IV insertion. The child also had to give voluntary assent to participate in the study (see Appendix B). On week one the nursing and child life specialist staff received an email regarding the project and mandatory individualized training sessions. During

the second week, fliers were distributed explaining staff roles and responsibilities in the study. In the first two weeks of the study, the standard protocol was followed, and staff decided which patients were offered distraction techniques during painful procedures. During week three, the study protocol went live. Two *Buzzy* devices were available in a designated refrigerator in two storerooms. A nurse or child life specialist offered *Buzzy* to children ages three through six years undergoing venipuncture on the unit and documented that they completed the intervention on their designated "Weekly Nurse *Buzzy* Log". Each staff member also distributed a *"*Pediatric Pain Survey" (see Appendix E) for parents and patients to complete together and submit in a security box post-procedure.

Measurement Instruments

All participants will have pain levels assessed via the Wong-Baker FACES pain scale for children (Garra et al., 2019). The Wong-Baker FACES Pain Rating Scale was used to quantify patient's pain rating pre-procedure and post-procedure. This tool has been previously used, tested, and found to be reliable by Garra et al., (2010) with 95% confidence interval [CI] = 0.86 to 0.93 while the original creators of this scale indicated a validity of 60% and reliability of 87.5% (Wong & Baker, 1988). The Wong-Baker FACES scale is copyrighted; however, permission was not needed for healthcare students, the Wong-Baker FACES Pain Rating Scale was used to quantify patient's pain rating post- immunization and retrospectively from previous immunizations. This tool has been previously used, tested, and found to be reliable by Garra et al., (2010) with 95% confidence interval [CI] = 0.86 to 0.93 while the original creators of this scale indicated a validity of 60% and reliability of 87.5% (Wong & Baker, 1988). The Wong-Baker FACES scale is copyrighted; however, permission was not needed for healthcare students.

Anxiety levels will be assessed with the Children's Fear Scale. Finally, patient and family satisfaction will be evaluated via a completed pre-survey and post-surveys from the Likert Scale manufactured by the Pediatric Pain Assessment Survey (Zanolin et al., 2016). SPSS will be used for data analysis. First, demographic, and descriptive data were analyzed using means, standard deviations, and percentage values. Next, Fisher's exact test of independence was used to compare the differences in the distribution of responses within the survey. This test is often used with small samples and serves as an alternative to the Chi-Square test. The results of the tests that were used made an inference whether the utilization of *Buzzy* helped improve parental perceptions of their children's pain during invasive procedures.

Pain levels and pain perceptions will be assessed with the Pediatric Pain Survey. Children frequently describe pain as the most distressing aspect of disease or hospitalization, and it can negatively impact their wellbeing and future development (Vagnoli et al., 2019). The questionnaires were administered after each venipuncture. Parents were requested to fill out a questionnaire on the perceptions of pediatric pain management and the use of distraction. Institutional review board approval was obtained. The survey provided qualitative data to assess pain perceptions in children and parents. Parents were asked to describe their child's pain. They were then given a list of words to choose from to describe their child's pain or emotions felt while in pain. Examples of words used were throbbing, uncomfortable, sharp, sad, sore, and miserable. Lastly, they were asked if they felt their child's pain was controlled or decreased due to *Buzzy*. Pain is a subjective experience, and, how individuals react to a new episode of pain is shaped and influenced by previous experiences. Cognitive processes and emotions are used to interpret pain. This process combines to form pain perceptions. Individuals show differences in their ability to regulate emotions as well as their perceptions about pain, their judgments about

the seriousness of pain, and their sense of control over pain. Negative pain perceptions that have been shown to put patients at the risk of a poor prognosis are negative interpretations of pain, and fear avoidance. Assessing pain perceptions may be even more important than reaching a definitive diagnosis or explaining what factors contributed to pain onset (Bergomi et al., 2018).

Data Collection

The Marian University IRB reviewed the project and determined that the project did not constitute human subjects research and did not require IRB review. The project site's IRB guidelines were followed for the submission of the requested documents for their determination. The project's information form was developed per the project site's guidance and IRB recommendation. A one-page introductory form was provided to participants, and implied consent was granted upon completing the pretest. The potential risks and benefits of participating in this study were explained to participants in the project's introductory portion. The potential benefit to participants was an increase in knowledge regarding pediatric pain assessment and management. Participants were also informed of the potential benefit of improved self-efficacy when caring for pediatric patients after project participation. The risk of participating in this study was described as minimal, with the main risk being a breach of confidentiality. This risk was minimized by assigning a unique code to each participant. The list of codes was stored separately from the survey answers in a secure database on the PI's private computer, accessible only by the PI. All email and paper invitations for participation contained the PI's contact information to streamline questions or concerns.

Data analysis took place between June 2021 and August 2021 and involved descriptive statistics in the International Business Machines (IBM) Statistical Package for the Social Sciences (SPSS). Data was downloaded into Excel and was analyzed using descriptive statistics.

Participant demographic characteristics were analyzed. Descriptive statistics were used to assess for differences pediatric pain perceptions by examining baseline, immediately post-intervention, and 1-month follow-up. Children between the ages of three to six years of age will be included in the study. Patients having a "critical" status were eliminated from this study. Parental consent will be obtained from all parents before participants were enrolled in the study. Child assent must also be received before any child is enrolled in the study. Participants will be nonrandomized. The study will be conducted over a six-week time frame. In the first two weeks, painful procedures will be performed using the current hospital policy. All participants will be offered cold or vibration during a blood draw or IV insertion in the following four weeks. Once a limit of 100 participants or the 6-week timeframe ends, the study will no longer be conducted. All data will remain secure and confidential. All computers use SSL layering for security. Data collected from the study will be kept on a spreadsheet in a locked drawer in the nine west charge nurse office at Riley Hospital. Participation in the study is strictly voluntary. Participants may leave the study at any time they choose. Staff members will be educated on obtaining parental consent and collecting data protocols. The nurse used the "Weekly Nurse *Buzzy* Log" to document *Buzzy* use.

During weeks three through six, the QI Project Leader reviewed and entered the data into an Excel spreadsheet each week. Data analysis included descriptive statistics. During the project's implementation phase, human subjects were protected by keeping the data collected anonymous, and no identifiable information was recorded. The documents were stored in a file cabinet and an Excel file was saved on a password-encrypted computer at the organization. At the end of each shift, each nurse submitted the "Weekly Nurse *Buzzy* Log" to the nurse manager, who filed the logs until the start of the next business day. The Marian University Institutional

Review Board approved the project. As no pain management protocol for painful procedures existed previously at this organization, there was a clear need for the practice change to occur, which was a driving force in the project's sustainability.

Data Analysis

Qualitative pain data will be assessed with data retrieved from the Wong-Baker FACES pain scale for young children (Garra et al., 2016). Patient satisfaction data will be reviewed from the Pediatric Pain Survey (Zanolin et al., 2016). Parents of the patients completed the surveys. The Pediatric Pain Survey (Zanolin et al., 2016) evaluated the parents' perceptions of their children's satisfaction, anxiety, pain, as well as the staff's helpfulness during an injection or a venipuncture. The child's assent was necessary before they participated in the study. Data will be analyzed with SPSS software. During the QI project, a total of 135 patients were offered *Buzzy* (see Table 2). Ninety-six patients used the device, and 39 patients declined to participate in the study. (See Table 2). A total of 384 Pediatric Pain surveys were collected (see Appendix E). For question number one: "Were you satisfied with your child's venipuncture process using *Buzzy?"* Approximately ninety-seven percent of respondents answered "Yes," while 3% answered "No." For question number two: "Did you find Buzzy to be helpful?" nearly eighty-nine percent of respondents answered, "Yes," while 11% answered "No." Finally, for question three: "Would you opt to use *Buzzy* again in the future, for your child's vaccinations?" ninety-one percent of respondents answered "Yes," while 9% answered "No." This quality improvement project supports implementing the *Buzzy* device during painful procedures in a pediatric inpatient setting. After this QI project, 96.9% of parents reported satisfaction with their child's pain management experience, which well surpassed the long-term project goal of fifty percent (see Table 3). Perceptions of pain and patient satisfaction seemed to remain constant 1-month post-

procedure, with a patient satisfaction score of 95.8%. Two families reported decreased satisfaction one-month post-procedure. Ninety-one percent of parents surveyed in this QI project indicated that they would opt to use *Buzzy* for their child's pain management in the future (see Table 3). This result was like that of Redfern, Chen, and Sibrel (2018), who found that 88% of parents of children who used *Buzzy* during painful procedures desired to use the device in the future. The sample size collected during the study was limited. Therefore, the distribution of responses for each survey item was examined for each gender using Fisher's exact test of independence. Along with the quantitative data collected throughout the study, open-ended survey comments were also collected and reviewed. This section allowed parents to openly express how they felt about their respective children's experiences. Out of the surveys that were collected from the parents left comments. These included the following: "The injection was much needed. She was able to relax and felt better afterward;" also, "He did get seven pokes today, so he was probably more distressed than normal." The other comments from the control group said the following: "Want to say thank you. I know my kid is easygoing, but you guys made her feel even more comfortable. The successful results achieved by this QI project warrant consideration for applicability to other healthcare clinics seeking methods of pain reduction for children undergoing painful procedures. Results of this study confirm the efficacy of the Buzzy device in reducing procedure-related pain and speak to the success and usefulness of this QI project. The support for Buzzy will aid in the project's sustainability. Implications for future research include using the device on a younger population of patients (i.e., six months and older). Suggested next steps include: (1) incorporation of this device as a standard of care during painful procedures at the hospital (2) development of a pain management protocol to include Buzzy; (3) integration of Buzzy usage within nurse orientation training; (4) implementation of an electronic

health record function that would prompt nurses to use Buzzy before painful procedures and track the device's usage among patients. The time required from IRB submission to the written proposal will be approximately three months.

Results

There were ninety-six participants who completed the pre-survey; and ninety-two participants completed the 1-month follow-up surveys. The final project population consisted of ninety-two out of ninety-six (95.8%) possible participants who completed the baseline and immediate post-intervention surveys. Of those ninety-six participants, eighty-eight participants (91.7%) participated in the 1-month follow-up. Multiple emails were sent to remind participants to complete the 1-month follow-up to increase participation. The demographic information was described using frequency and means/standard deviations... Comparison of the categorical variables was performed by way of the Pearson's c2 test. A p-value of <0.05 was statistically significant. Overall, the results concluded that children's perception of pain was less in the non-pharmacological intervention groups compared with no intervention. Buzzy® was highly effective in children that were younger than six years of age ($p = 0.04$). The level of pain was assessed in each child using the Wong Baker FACES pain rating scale and verbal reports. The data were then analyzed using the SPSS software 22. The p value less than 0.05 was considered significant in this study. The comparison between the pain levels was analyzed using t test, while the demographic data were compared using frequency and chi-square tests. The results showed that self-reported procedural pain levels were significant between the study groups ($p = .001$). The distraction group had significantly lowered pain levels ($p = .001$) than the non-intervention group. Prior to implementation of the intervention, data were collected for two weeks to obtain the average pain rating score of children receiving vaccinations that were between the ages of

three and six years. The reason that this comparison is taking place is to identify not only the need for intervention for pain but also to assess how high the average pain perception is rated. Currently, the hospital has no comfort measures in place for children that are receiving routine venipuncture procedures. Since venipuncture is one of the largest routine pain-producing procedures in children it is important to identify interventions that can help limit the pain that is caused during these procedures. A t-test was completed for comparison of pre-intervention and post-intervention pain scored for both pain scales. A t-test was also used to compare pre-intervention and post-intervention demographic information on patient age and number of venipunctures. A chi-square statistical analysis was completed for comparison of the rest of the demographic information which included patient gender, previous painful procedures, and patient race.

Participants that were three years and older, scored their pain rating using the Wong-Baker FACES scale. This scale rates pain on a scale from 0 to 10 using increments of two. Each number coincides with a picture of a cartoon face depicting the amount of pain that the participant might be in after vaccination. The participant was asked to select which pictures accurately depicts the amount of pain that was experienced. A chi-square for independence was completed to compare scores from the pre-intervention group to the post-intervention group. The mean for the pre-intervention group was 3.5 (Sd = 0.71), and the mean for the post-intervention group was 1.5 (Sd = 0.71). No significant difference between the pre-and post-intervention group was found (x^2 (3, N=10) = 5.94, $p > 0.05$).

To make an accurate comparison of the two groups it was important to verify that the groups were similar regarding their age, race, and previous history of a painful procedure. A t-test was completed to compare both the pre-and post-intervention ages and the number of painful

procedures. The participants in the pre-intervention group had a mean age of 36 months (Sd = 2.23), and the mean age of the post-intervention group was 38 months (Sd = 2.87). No significant difference was found between the pre-and postintervention group ages (t (11, N=28) = 0.799, p > 0.05).

A chi-square test of independence was calculated comparing the genders of both the pre-and post-intervention groups. No significant relationship or difference was found between the two groups (x 2 (1, N=28) = 0.438, p > 0.05). Another chi-square of independence was calculated comparing the race of both the pre-and post-intervention groups. Again, no significant relationship or difference was found (x 2 (3, N=28) = 2.82, p > 0.05). Participants in both groups had never experienced previously painful procedures, and therefore there was not a need for any statically significant analysis as both groups were the same in this case. ANOVAs were performed. The results indicated that children reported higher scores when they did not have the "*BUZZY"* applied, F (2/45 = 7.07, p = 0.011, mothers also rated children's pain higher when the "*BUZZY*" was not applied, F (2/45 = 6.7, p = 0.014. Younger children had significantly higher pain scores in the "No *BUZZY*" group compared to the *"BUZZY*" group, F (2/19) = 8.96, p = 0.007, females had significantly higher scores in the "No *BUZZY*" group compared to the "*BUZZY*" group, F (2/21) = 14.59, p = 0.00. A multiple regression analysis found that only the *"BUZZY*" remained the only significant factor that predicted the pain scores of children.

Table 1

Differences in Pain Ratings for Child and Parents

	Buzzy	**No Buzzy**		
Variable	**Mean (+/-SD)**	**Mean (+/- SD)**	**F Value**	**p-Value**
Pain scale by child	2.32	4.40 (+/-3.0)	8.08	0.012
Pain scale by parents	3.52	4.98(+/- 3.25)	2.80	0.118

Since children younger than 7 years report more distress, pain intensity, and unpleasantness following a needle prick than older children, distraction may be more beneficial to this age group.

Table 2

Multiple Regression of Factors that are Predictors of Pain Perception

	Standardized	**Coefficients**		**Non-Standard**	**Coefficients**
	Beta	**t**	**p**	**B**	**Std. Error**
Constant		.468	.650	1.976	4.258
Age in Years	-0.464	-1.684	.108	-0.481	.276
Gender	-0.026	-1.24	.906	-0.158	1.284
Previous Procedures	.468	1.818	.106	1.222	.728
Child on Analgesics	-3.98	-1.705	.108	-2.366	1.387
Buzzy or No Buzzy	.398	2.293	.036	2.353	1.027
Prior Hospitalization	.144	.466	.649	1.016	2.183

"*BUZZY*" was more effective in the younger age group and in girls. It could well be that "*BUZZY*" is more effective in the younger age group who are easily distractible. Children with prior needle pricks may be more apprehensive about the procedure and welcomed *"BUZZY*" as a distracter whereas children with no prior hospitalization were not as likely to be distracted. Previous negative or painful experiences probably lead to elevated anxiety and pain experiences during future invasive medical procedures.

Strengths and Limitations

There were several strengths of this project that were evident. One of the largest strengths was the support from the clinical staff and site facilitator. They greatly believed in the need for

practice change and were excited to introduce the *Buzzy*® device to their patients. This made the project more successful in that they were willing to make the change. Similarly, patients and their families willingly accepted the use of *Buzzy*®. Several families expressed great satisfaction and a noticeable difference in their child during venipuncture. The project was also very easy to understand and not extremely time-consuming for the staff. This allowed for the project to be realistic in the hospital setting. Likewise, with only measuring one outcome it made it easy for the staff to learn the respective pain scales and place the pain score in the medical record. Only measuring a single outcome also made data collection and analysis more simplistic. An additional strength was also the affordability of the *Buzzy*® device. *Buzzy* can easily be cleaned off for reuse, making it a great product for busy healthcare facilities. The study did have some limitations. The sample size was limited to ninety-six participants. A larger sample may have provided stronger support to the hypothesis. The small sample size was constrained by the short timeline of the project. The project was not randomized because the children and/or families that participated knew they were receiving the use of *Buzzy*®. This could have caused some bias in reporting of pain scores between the two groups. The staff had to be aware of gaining consents and using the correct pain scoring scale for each participant. There were also some situations where consents were not obtained or scores were not recorded in the electronic medical record, thus causing a smaller sample size.

Conclusion

The purpose of this DNP scholarly project was to evaluate whether distraction techniques used during painful procedures improved pain perceptions for children and parents short-term and long-term. Positive pain perceptions lead to improved coping strategies and pain

management (Basten-Günther et al., 2018). Parental perceptions of pain in their children decreased as a response to the use of distraction techniques used during painful procedures. Patient satisfaction increased with the use of distraction techniques and patient satisfaction remained high over time. Improved pain perceptions in childhood increase the likelihood of receiving medical care and optimizing health outcomes as an adult. The results of this project supported the effectiveness of combination cryotherapy and vibration for painful procedures in children as was seen by the improvement in pain scores, which is consistent with current literature. Management of procedural distress through evidence-based distraction is simple, cost-effective, and can provide both short and long-term benefits. Evidence supports future research that might further examine the effectiveness of using distraction techniques for pain control management in the pediatric population. Distraction techniques seem to be an effective form of pain management in pediatrics that should become an evidence-based practice in the future.

References

Aarthu-n, A., Oymar, K. A., & Akerjordet, K. (2018). Parental involvement in decision-making about their child's health care at the hospital. *Nursing Open*, *6*(1), 50–58. https://doi.org/10.1002/nop2.180

Bahorski, J. S., Hauber, R., Hanks, C., Johnson, M., Mundy, K., Ranner, D., Stoutamire, B., & Gordon, G. (2015). Mitigating procedural pain during venipuncture in a pediatric population: A randomized factorial study. *International Journal of Nursing Studies*, *52*(10), 1553–1564. https://doi.org/10.1016/j.ijnurstu.2015.05.014

Ballard, A., Khadra, C., Adler, S., Trottier, E. D., & Le May, S. (2019). Efficacy of the buzzy device for pain management during needle-related procedures. *The Clinical Journal of Pain*, *35*(6), 532–543. https://doi.org/10.1097/ajp.0000000000000690

Basten-Günther, J., Peters, M., & Lautenbacher, S. (2018). Optimism and the experience of pain: A systematic review. *Behavioral Medicine*, *45*(4), 323–339. https://doi.org/10.1080/08964289.2018.1517242

Baxter, A. L., Cohen, L. L., McElvery, H. L., Lawson, M., & von Baeyer, C. L. (2011). An integration of vibration and cold relieves venipuncture pain in a pediatric emergency department. *Pediatric Emergency Care*, *27*(12), 1151–1156. https://doi.org/10.1097/pec.0b013e318237ace4

Bergomi, P., Scudeller, L., Pintaldi, S., & Dal Molin, A. (2018). Efficacy of non-pharmacological methods of pain management in children undergoing venipuncture in a pediatric outpatient clinic: A randomized controlled trial of audiovisual distraction and external cold and vibration. *Journal of Pediatric Nursing*, *42*, e66–e72. https://doi.org/10.1016/j.pedn.2018.04.011

Birnie, K. A., Noel, M., Chambers, C. T., Uman, L. S., & Parker, J. A. (2018). Psychological interventions for needle-related procedural pain and distress in children and adolescents. *Cochrane Database of Systematic Reviews*, *2020*(10). https://doi.org/10.1002/14651858.cd005179.pub4

Breivik, H. (2002). International association for the study of pain. *Journal of Pain and Symptom Management*, *24*(2), 97–101. https://doi.org/10.1016/s0885-3924(02)00465-7

Bukola, I. M., & Paula, D. (2017). The effectiveness of distraction as procedural pain management technique in pediatric oncology patients: A meta-analysis and systematic review. *Journal of Pain and Symptom Management*, *54*(4), 589–600.e1. https://doi.org/10.1016/j.jpainsymman.2017.07.006

Canbulat, N., Ayhan, F., & Inal, S. (2015). Effectiveness of external cold and vibration for procedural pain relief during peripheral intravenous cannulation in pediatric patients. *Pain Management Nursing*, *16*(1), 33–39. https://doi.org/10.1016/j.pmn.2014.03.003

Dastgheyb, S., Fishlock, K., Daskalakis, C., Kessel, J., & Rosen, P. (2018). Evaluating comfort measures for commonly performed painful procedures in pediatric patients. *Journal of Pain Research*, *Volume 11*, 1383–1390. https://doi.org/10.2147/jpr.s156136

Erdogan, B., & Aytekin Ozdemir, A. (2021). The effect of three different methods on venipuncture pain and anxiety in children: Distraction cards, virtual reality, and buzzy® (randomized controlled trial). *Journal of Pediatric Nursing*, *58*, e54–e62. https://doi.org/10.1016/j.pedn.2021.01.001

Ferland, C. E., Eduardo, V., & Ingelmo, P. M. (2018). Acute pain management in children. *Current Opinions in Anesthesiology*, *31*(3), 327–332. https://doi.org/doi: 10.1097/ACO.0000000000000579

Friedrichsdorf, S. J., & Goubert, L. (2020). Pediatric pain treatment and prevention for hospitalized children. *PAIN Reports*, *5*(1), e804. https://doi.org/10.1097/pr9.0000000000000804

Garra, G., Singer, A. J., Taira, B. R., Chohan, J., Cardoz, H., Chisena, E., & Thode, H. C. (2010). Validation of the wong-baker faces pain rating scale in pediatric emergency department patients. *Academic Emergency Medicine*, *17*(1), 50–54. https://doi.org/10.1111/j.1553-2712.2009.00620.x

Giordano, V., Edobor, J., Deindl, P., Wildner, B., Goeral, K., Steinbauer, P., Werther, T., Berger, A., & Olischar, M. (2019). Pain and sedation scales for neonatal and pediatric patients in a preverbal stage of development. *JAMA Pediatrics*, *173*(12), 1186. https://doi.org/10.1001/jamapediatrics.2019.3351

Good, M. (1998). A middle-range theory of acute pain management: Use in research. *Nursing Outlook*, *46*(3), 120–124. https://doi.org/10.1016/s0029-6554(98)90038-0

Groenewald, C. B., Wright, D. R., & Palermo, T. M. (2015). Health care expenditures associated with pediatric pain-related conditions in the united states. *Pain*, *156*(5), 951–957. https://doi.org/10.1097/j.pain.0000000000000137

Grout, R. W., Thompson-Fleming, R., Carroll, A. E., & Downs, S. M. (2018). Prevalence of pain reports in pediatric primary care and association with demographics, body mass index, and exam findings: A cross-sectional study. *BMC Pediatrics*, *18*(1). https://doi.org/10.1186/s12887-018-1335-0

Hussain, M., Ajmal, M. M., Gunasekaran, A., & Khan, M. (2018). Exploration of social sustainability in healthcare supply chain. *Journal of Cleaner Production*, *203*, 977–989. https://doi.org/10.1016/j.jclepro.2018.08.157

Huth, M., & Moore, S. M. (1998). Prescriptive theory of acute pain management in infants and children. *Journal for Specialists in Pediatric Nursing*, *3*(1), 23–32. https://doi.org/10.1111/j.1744-6155.1998.tb00206.x

Inal, S., & Kelleci, M. (2017). The effect of external thermomechanical stimulation and distraction on reducing pain experienced by children during blood drawing. *Pediatric Emergency Care*, *Publish Ahead of Print*. https://doi.org/10.1097/pec.0000000000001264

Inan, G., & Inal, S. (2019). The impact of 3 different distraction techniques on the pain and anxiety levels of children during venipuncture. *The Clinical Journal of Pain*, *35*(2), 140–147. https://doi.org/10.1097/ajp.0000000000000666

International association for the study of pain. (1989). *Pain*, *36*(2), 1–8. https://doi.org/10.1016/0304-3959(89)90036-5

Kallio, T., Tevameri, T., & Vähätalo, M. (2018). Nurses' organizational roles—stakeholders' expectations. *Professions and Professionalism*, *8*(2), e1973. https://doi.org/10.7577/pp.1973

Logan, L., Hickman, R. R., Harris, S. R., & Heriza, C. B. (2008). Single-subject research design: Recommendations for levels of evidence and quality rating. *Developmental Medicine & Child Neurology*, *50*(2), 99–103. https://doi.org/10.1111/j.1469-8749.2007.02005.x

Marche, T. A., Briere, J. L., & von Baeyer, C. L. (2015). Children's forgetting of pain-related memories. *Journal of Pediatric Psychology*, *41*(2), 220–231. https://doi.org/10.1093/jpepsy/jsv111

Marwaha, S. (2017). Prevalence of principles of piaget's theory among 4-7-year-old children and their correlation with iq. *JOURNAL OF CLINICAL AND DIAGNOSTIC RESEARCH*. https://doi.org/10.7860/jcdr/2017/28435.10513

McMurtry, C., Pillai Riddell, R., Taddio, A., Racine, N., Asmundson, G. G., Noel, M., Chambers, C. T., & Shah, V. (2015). Far from "just a poke". *The Clinical Journal of Pain*, *31*(Supplement 10), S3–S11. https://doi.org/10.1097/ajp.0000000000000272

Mills, N. M. (2016). Acute pain behavior in infants and toddlers. In *Management of pain, fatigue and nausea* (pp. 52–59). Macmillan Education UK. https://doi.org/10.1007/978-1-349-13397-0_6

Moadad, N., Kozman, K., Shahine, R., Ohanian, S., & Badr, L. (2016). Distraction using the buzzy for children during an iv insertion. *Journal of Pediatric Nursing*, *31*(1), 64–72. https://doi.org/10.1016/j.pedn.2015.07.010

Noel, M., McMurtry, C. M., Chambers, C. T., & McGrath, P. J. (2009). Children's memory for painful procedures: The relationship of pain intensity, anxiety, and adult behaviors to subsequent recall. *Journal of Pediatric Psychology*, *35*(6), 626–636. https://doi.org/10.1093/jpepsy/jsp096

Olsen, K., & Weinberg, E. (2017). Pain-less practice: Techniques to reduce procedural pain and anxiety in pediatric acute care. *Clinical Pediatric Emergency Medicine*, *18*(1), 32–41. https://doi.org/10.1016/j.cpem.2017.01.007

Potts, D., Davis, K., Elci, O. U., & Fein, J. A. (2017). A vibrating cold device to reduce pain in the pediatric emergency department. *Pediatric Emergency Care*, *Publish Ahead of Print*. https://doi.org/10.1097/pec.0000000000001041

Ramira, M. L., Instone, S., & Clark, M. (2016). Pediatric pain management: an evidence-based approach. *The Journal of Pediatric Nursing*, *42*(1), 39–46. https://doi.org/https://login.forward.marian.edu/login?url=https://www-proquest-com.forward.marian.edu/scholarly-journals/pediatric-pain-management-evidence-based-approach/docview/1765381484/se-2?accountid=66430.

Redfern, R. E., Micham, J., Seegert, S., & Chen, J. T. (2019). Influencing vaccinations: A buzzy approach to ease the discomfort of a needle stick—a prospective, randomized controlled trial. *Pain Management Nursing*, *20*(2), 164–169. https://doi.org/10.1016/j.pmn.2018.07.001

Romito, B., Jewell, J., & Jackson, M. (2020). Child life services. *Pediatrics*, *147*(1), e2020040261. https://doi.org/10.1542/peds.2020-040261

Schoenfeld, E. M., Goff, S. L., Elia, T. R., Khordipour, E. R., Poronsky, K. E., Nault, K. A., Lindenauer, P. K., & Mazor, K. M. (2016). The physician-as-stakeholder: An exploratory qualitative analysis of physicians' motivations for using shared decision making in the emergency department. *Academic Emergency Medicine*, *23*(12), 1417–1427. https://doi.org/10.1111/acem.13043

Schreiber, S., Cozzi, G., Rutigliano, R., Assandro, P., Tubaro, M., Cortellazzo Wiel, L., Ronfani, L., & Barbi, E. (2015). Analgesia by cooling vibration during venipuncture in children with cognitive impairment. *Acta Paediatrica*, *105*(1), e12–e16. https://doi.org/10.1111/apa.13224

Shahid, R., Benedict, C., Mishra, S., Mulye, M., & Guo, R. (2014). Using ipads for distraction to reduce pain during immunizations. *Clinical Pediatrics*, *54*(2), 145–148. https://doi.org/10.1177/0009922814548672

Short, S., Pace, G., & Birnbaum, C. (2017). Nonpharmacologic techniques to assist in pediatric pain management. *Clinical Pediatric Emergency Medicine*, *18*(4), 256–260. https://doi.org/10.1016/j.cpem.2017.09.006

Sree, S. (2016). Pediatric pain management. In *Handbook of pain management in practice* (pp. 217–217). Jaypee Brothers Medical Publishers (P) Ltd. https://doi.org/10.5005/jp/books/12645_19

Srouji, R., Ratnapalan, S., & Schneeweiss, S. (2010). Pain in children: Assessment and nonpharmacological management. *International Journal of Pediatrics*, *2010*, 1–11. https://doi.org/10.1155/2010/474838

Taddio, A., Appleton, M., Bortolussi, R., Chambers, C., Dubey, V., Halperin, S., Hanrahan, A., Ipp, M., Lockett, D., MacDonald, N., Midmer, D., Mousmanis, P., Palda, V., Pielak, K., Riddell, R. P., Rieder, M., Scott, J., & Shah, V. (2010). Reducing the pain of childhood vaccination: An evidence-based clinical practice guideline. *Canadian Medical Association Journal*, *182*(18), E843–E855. https://doi.org/10.1503/cmaj.101720

Thrane, S. E., Wanless, S., Cohen, S. M., & Danford, C. A. (2016). The assessment and non-pharmacologic treatment of procedural pain from infancy to school age through a developmental lens: A synthesis of evidence with recommendations. *Journal of Pediatric Nursing*, *31*(1), e23–e32. https://doi.org/10.1016/j.pedn.2015.09.002

Tumin, D., Drees, D., Miller, R., Wrona, S., Hayes, D., Tobias, J. D., & Bhalla, T. (2018). Health care utilization and costs associated with pediatric chronic pain. *The Journal of Pain*, *19*(9), 973–982. https://doi.org/10.1016/j.jpain.2018.03.012

Vagnoli, L., Mammucari, M., Graziani, D., & Messeri, A. (2019). Doctors and nurses' knowledge and attitudes towards pediatric pain management: An exploratory survey in a

children's hospital. *Journal of Pain & Palliative Care Pharmacotherapy*, *33*(3-4), 107–119. https://doi.org/10.1080/15360288.2019.1686100

Victoria, N. C., & Murphy, A. Z. (2016). Exposure to early life pain: Long term consequences and contributing mechanisms. *Current Opinion in Behavioral Sciences*, *7*, 61–68. https://doi.org/10.1016/j.cobeha.2015.11.015

Whelan, H. M., Kunselman, A. R., Thomas, N. J., Moore, J., & Tamburro, R. F. (2014). The impact of a locally applied vibrating device on outpatient venipuncture in children. *Clinical Pediatrics*, *53*(12), 1189–1195. https://doi.org/10.1177/0009922814538494

Appendix A

Pediatric Pain Study

Pediatric Pain Perception Study

What is this study about?

You are being asked to volunteer in a quality improvement study performed by Sheryl Graybill, FNP/DNP student at Marian University. The purpose of this research is to assess the effects of distraction techniques used in young children on long-term pain perceptions. Studies have shown that children that have positive healthcare experiences in childhood develop more trust in healthcare as adults. Standard practice includes offering distraction techniques to children that show signs of anxiety before painful procedures. This study will assess the effect of offering distraction techniques to all children before painful procedures.

What will participation involve?

You are being asked to do the following. Complete the survey before a blood draw or IV insertion. Complete the same survey after the procedure. Complete a follow-up survey in 1 month to assess if your pain perceptions during your visit stayed the same or changed over time. The survey will take about 5-10 minutes to complete each time. The surveys contain questions about pain and pain perceptions. Your child will be asked to rate their pain by looking at pictures of cartoon faces. Any survey information you provide about your child will not be linked to any other data, or medical records.

What risks are involved in the study?

The main risks to you are those associated with the inappropriate disclosure of data collected. Every attempt will be made to keep all information secure and confidential.

Do you have to participate?

No, you do not! Your participation is completely voluntary. If you decide to participate, you can stop at any time you choose. If you choose not to participate or to discontinue your participation, you will not lose any benefit to which you are otherwise entitled.

Who can provide additional information if you need it?

Questions about the research aspects of this study can be directed to the principal investigator at sgraybill513@marian.edu or (765) 610-6939. Questions about the ethical aspects of this study or your rights as a volunteer should be directed to Marian IRB at IRB@ marian.edu.

How will your data be protected against any risks?

All information collected through the internet survey is done by using Secure Sockets Layer (SSL) data transmission lines. SSL encrypts, or scrambles, all survey data over the internet. Information will only be understandable when it reaches the investigator database.

When your data are entered into the computer files for analysis, your answers will be identified only by a special study identification number. If someone broke in from outside, it would be impossible for them to identify your data. To minimize the risk of anyone breaking into the data files, all files will be maintained on IU Health computers under HIPAA regulations. Data will be maintained until all research questions have been addressed.

The principal investigator will be responsible for storing all research records related to this study. The records will be stored in a locked drawer on the 9 West unit of Riley Children's Hospital in the charge nurse office. You may change your mind and revoke your permission to

further collect health information about you at any time. If you revoke your permission, no new health

Information about you will be gathered after that date. To review your electronically submitted survey or end further participation in this data collection effort, contact the principal investigator at sgraybill513@marian.edu or (765)-610-6939

What are the benefits of participating in this study?

Your participation in this study may decrease your child's pain perception during a painful procedure. Your participation is a critical step in developing policies and interventions for children experiencing pain during medically necessary painful procedures.

Study Contacts/Termination

You will be asked to complete a survey before and after your child's procedure, and one month after the procedure. The study will be conducted over six weeks. Participation is completely voluntary, but the principal investigator will greatly appreciate your involvement in this research effort to help better understand pain perceptions and their effect on long-term health outcomes.

_____

Printed Name

_____

Signature

_____

Today's Date

Appendix B

Child Assent Form

What is the Effect of the Use of Distraction Techniques during Painful Procedures?

My name is Sheryl Graybill, RN, FNP/DNP student, Marian University.

We are asking you to take part in a research study because we want to learn more about pain perceptions during painful procedures such as blood draws.

If you agree to be in this study, we will ask you to allow us to use a distraction technique to make your blood draw or IV insertion less painful.

Painful procedures such as IV insertion or blood draws may be necessary during treatment, but distraction techniques may help the procedure be more comfortable.

Please talk this over with your parents before you decide whether to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say "yes," if you don't want to be in this study, you don't have to participate. Remember, being in this study is up to you and no one will be upset if you don't want to do this. If you do participate and later change your mind, you can stop participating at any time. Nobody will be angry or upset with you.

You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me at 765-610-6939 or contact Marian IRB at

Signing your name below means that you agree to be in this study. You and your parents will get a copy of this form.

NAME OF STUDY PARTICIPANT:

Printed Name of Participant:_____

Signature of Participant:_____

Date: _____

SIGNATURE OF PERSON OBTAINING CONSENT: _____

In my judgment the participant is voluntarily and knowingly agreeing to participate in this research study.

Name of Person Obtaining Assent: _____

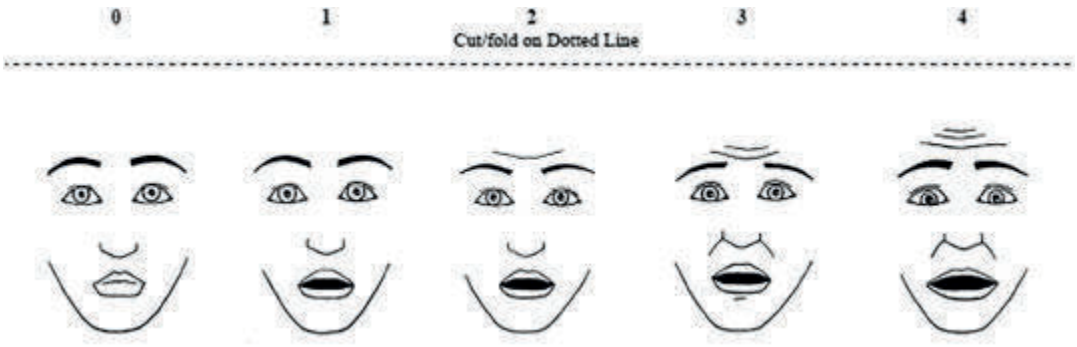
Contact Phone Number: _____

Signature of Person Obtaining Assent: _____

Appendix C

Children's Fear Scale

Figure 1



Instructions for Children: "These faces are showing different amounts of being scared. This face [point to the left-most face] is not scared at all, this face is a bit more scared [point to second face from left], a bit more scared [sweep finger along scale], right up to the most scared possible [point to the last face on the right]. Have a look at these faces and choose the one that shows how scared you were during [the needle]."

Instructions for Parents: "These faces are showing different levels of anxiety. This face [point to the left-most face] shows no anxiety at all, this faces shows a bit more [point to second face from left], a bit more [sweep finger along scale], right up to extreme anxiety [point to the last face on the right]. Have a look at these faces and choose the one that shows how much anxiety you felt during [the needle]." Score the chosen face from 0 to 4.

Sources: Please cite the CFS Initial Validation Study: McMurtry, C.M., Noel, M., Chambers, C.T., McGrath, P.J. (2011). Children's fear during procedural pain: Preliminary investigation of the Children's Fear Scale. Health Psychology, Advanced Access Online. Adapted from the (adult) Faces Anxiety Scale: McKinley, S., Coote, K., & Stein-Parbury, J.

Appendix D

Wong-Baker FACES Pain Scale

Instructions for Usage

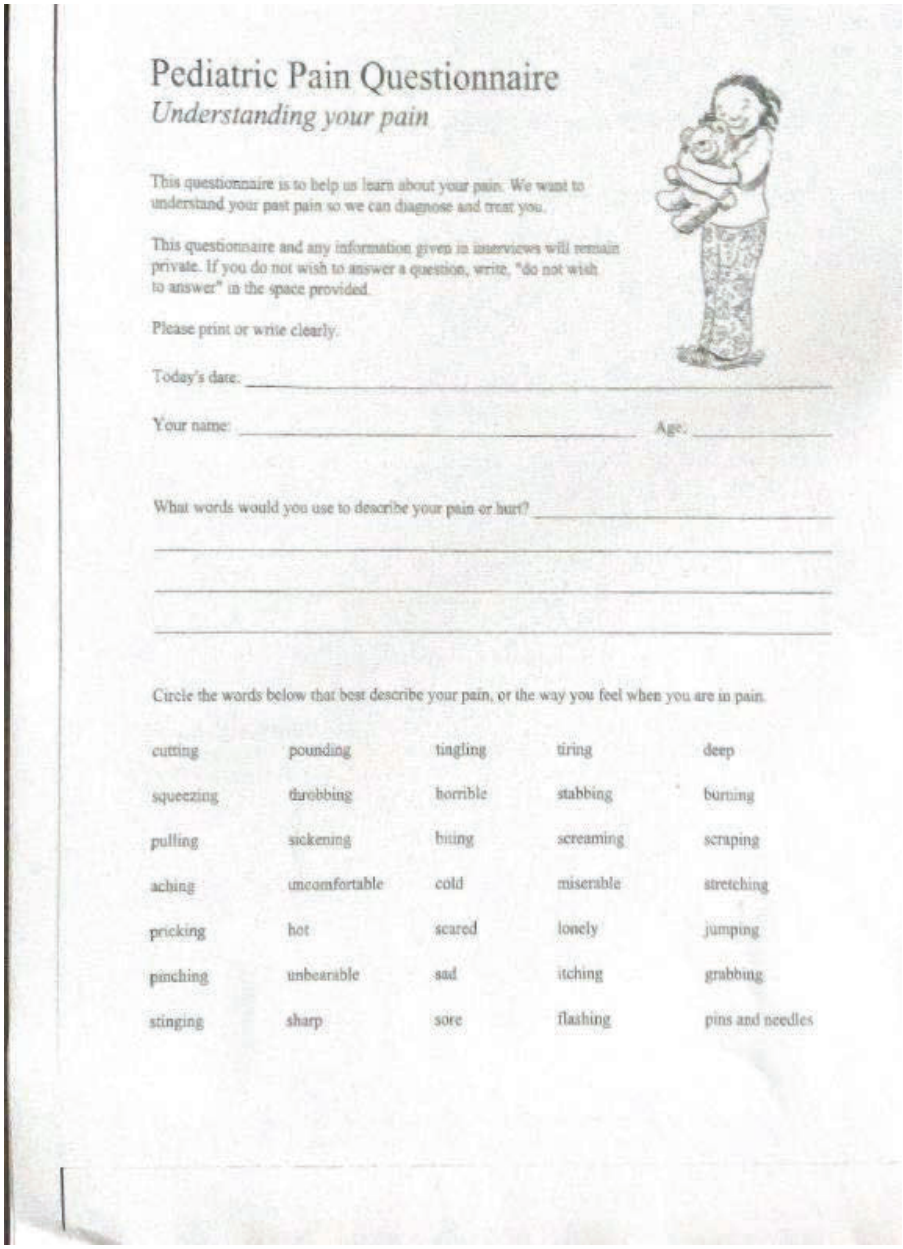
Explain to the person that each face represents a person who has no pain (hurt), or some, or a lot of pain.

Face 0 doesn't hurt at all. Face 2 hurts just a little bit. Face 4 hurts a little bit more. Face 6 hurts even more. Face 8 hurt a whole lot. Face 10 hurts as much as you can imagine, although you don't have to be crying to have this worst pain.

Ask the person to choose the face that best depicts the pain they are experiencing.

Appendix E

Pediatric Pain Survey



Pediatric Pain Questionnaire

Understanding your pain

This questionnaire is to help us learn about your pain. We want to understand your past pain so we can diagnose and treat you.

This questionnaire and any information given in interviews will remain private. If you do not wish to answer a question, write, "do not wish to answer" in the space provided.

Please print or write clearly.

Today's date: _____

Your name: _____ Age: _____

What words would you use to describe your pain or hurt? _____

_____

_____

_____

Circle the words below that best describe your pain, or the way you feel when you are in pain.

cutting	pounding	tingling	tiring	deep
squeezing	throbbing	horrible	stabbing	burning
pulling	sickening	biting	screaming	scraping
aching	uncomfortable	cold	miserable	stretching
pricking	hot	scared	lonely	jumping
pinching	unbearable	sad	itching	grabbing
stinging	sharp	sore	flashing	pins and needles

From the words you wrote or circled, which three words best describe the pain you are feeling right now?

_____

_____

_____

Rate **how you feel now**. If you have no pain put a mark at the end of the line by the happy face. If you have some pain, put a mark near the middle of the line. If you have a lot of pain, put a mark by the sad face.

Not hurting
No discomfort
No pain

Hurting a whole lot
Very uncomfortable
Severe pain

Rate **the worst pain you had this week**. If you had no pain this week, put a mark at the end of the line by the happy face. If the pain you had was some hurting, put a mark by the middle of the line. If the worst pain you had was a whole lot of pain, put a mark by the sad face.

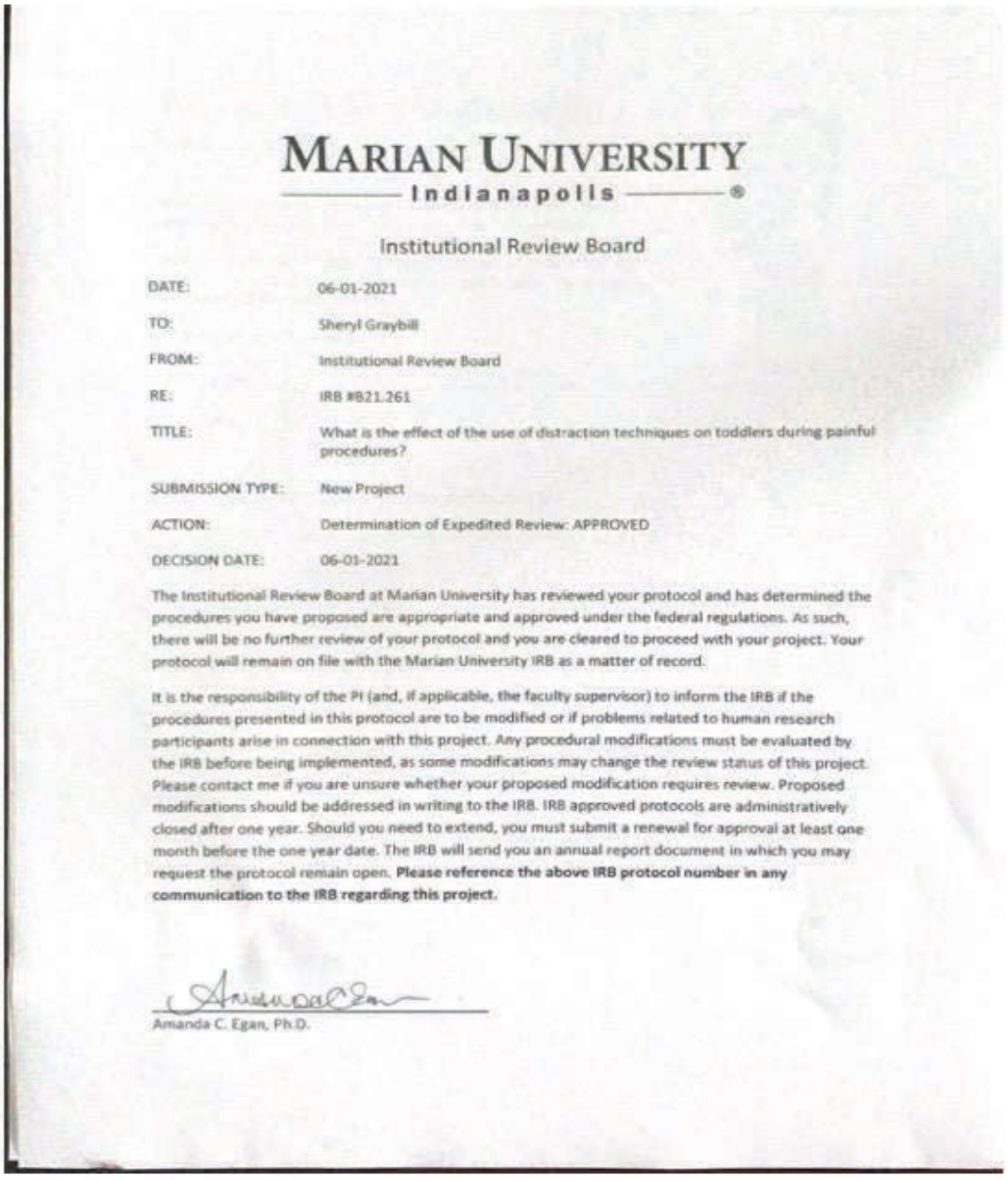
Not hurting
No discomfort
No pain

Hurting a whole lot
Very uncomfortable
Severe pain

From Hockenberry MJ, Wilson D, Winkelstein ML: Wong Essentials of Pediatric Nursing, ed. 7, St. Louis, 2005, p. 1259. Used with permission. Copyright Mosby.

Appendix F

IRB Approval



MARIAN UNIVERSITY
Indianapolis ®

Institutional Review Board

DATE:	06-01-2021
TO:	Sheryl Graybill
FROM:	Institutional Review Board
RE:	IRB #821.261
TITLE:	What is the effect of the use of distraction techniques on toddlers during painful procedures?
SUBMISSION TYPE:	New Project
ACTION:	Determination of Expedited Review: APPROVED
DECISION DATE:	06-01-2021

The Institutional Review Board at Marian University has reviewed your protocol and has determined the procedures you have proposed are appropriate and approved under the federal regulations. As such, there will be no further review of your protocol and you are cleared to proceed with your project. Your protocol will remain on file with the Marian University IRB as a matter of record.

It is the responsibility of the PI (and, if applicable, the faculty supervisor) to inform the IRB if the procedures presented in this protocol are to be modified or if problems related to human research participants arise in connection with this project. Any procedural modifications must be evaluated by the IRB before being implemented, as some modifications may change the review status of this project. Please contact me if you are unsure whether your proposed modification requires review. Proposed modifications should be addressed in writing to the IRB. IRB approved protocols are administratively closed after one year. Should you need to extend, you must submit a renewal for approval at least one month before the one year date. The IRB will send you an annual report document in which you may request the protocol remain open. **Please reference the above IRB protocol number in any communication to the IRB regarding this project.**

Amanda C. Egan, Ph.D.

Appendix G

Buzzy Instructions

How To Use Buzzy + DistrACTION Most Effectively

To improve pediatric procedural distress, address Fear, Focus, and Pain!

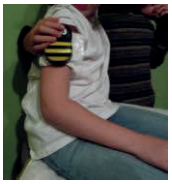
Fear: Children are less fearful when they know what's happening and feel in control. When asked if they're going to get a shot, avoid using the words pain or hurt. Instead, use the word "bother", and answer this way:

"Yes, but a lot of kids aren't that bothered the way we give them. Before you get them, I'll show you how we make them more comfortable now."

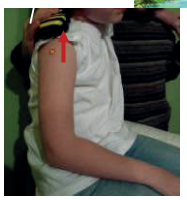
Before giving shots, let patients touch Buzzy, or press Buzzy on a hand or forearm, and lightly scratch the area distal to the Buzzy. "See how cold this is, and see how you can't feel so much anymore?"

Seeing for themselves and agreeing with you helps the child feel in control. Placing the child in a "position of comfort", e.g. with the parents arm around them, or facing them on a lap for younger children, also increases children's security.

Focus.* Helping a child focus elsewhere during procedures engages the same part of the brain that processes pain. Hold, give, or engage a parent to ask children questions on the back of DistrACTION Cards; memorize a question or two to get them started. The combination of a visual finding task and focus decreases pain.



Pain Relief: Just like holding a burn under running water, vibration and cold interrupt the sharp pain feeling. For best results, put the HARD frozen Ice Wings behind Buzzy, then press Buzzy on the injection site itself for about one minute. During the injection, having the parent, nurse, or older patient slide Buzzy just above the injection site (red dot) and hold it firmly in place blocks pain directly.



To emphasize, give the shot or start IV <u>while Buzzy is still buzzing and on the arm</u>.

*About 20% of children will want to watch the shots. Let them, this usually means they get some control watching, and the fear reduction from feeling in control helps reduce pain.

Appendix G

BUZZY Education

Venipuncture Pain Reduction Using a Vibrating, Cold Device

Potts D, Davis KF, & Fein JA
The Children's Hospital of Philadelphia, Philadelphia, PA

Introduction

IV insertion causes unnecessary pain and distress in children, which can have long-lasting detrimental effects. Based on the gate theory, a vibrating, cold device (VCD) applied to the extremity just before IV insertion may diminish pain and distress.

Background

Purpose: To test the effectiveness of a VCD in reducing pain associated with intravenous (IV) insertion

Objectives

1. Evaluate if VCD is as effective as topical lidocaine cream (TL) to reduce pain during IV insertion
2. Compare between VCD and TL groups:
   - self reported anxiety
   - caregiver and nurse satisfaction with IV insertion
   - time to complete IV insertion

Design: 2-arm randomized, controlled non-inferiority trial

Setting: Large, urban pediatric ED

Participants

- Age 4-18 years
- Able to complete pain/anxiety outcomes
- Require IV for care

Methods

- **VCD group**: Device applied over cold pack and remained in place until IV inserted/secured.
- **TL group**: Lidocaine cream placed on two potential sites and underwent IV insertion ≥30 min after cream applied.
  - Pediatric ED nurses with ≥ 1 year experience performed all IV insertions.

Standard of Care

- A coping plan tailored to the needs of the child by a Child Life Specialist (CLS).
- Caregiver(s) were at the bedside with no restrictions on interaction with the child.

Outcome Measures

- Self-reported pain and anxiety just prior to IV insertion and both self-reported and observed pain after the successful IV attempt.
- Caregivers and RNs completed satisfaction surveys

Instruments

- Faces Pain Scale Revised (FPS-R) - self-reported
- FLACC Behavioral Pain Assessment Scale for observed pain and distress
- Child's Rating of Anxiety for state and trait anxiety

Results

Demographics (n=224)	VCD	TL
Age in years (mean, IQR)	9.06 (4.96)	9.25 (5.85)
Sex (n, % male)	114 (51.3)	110 (48.7)
Race (n, %) Caucasian	77 (68.8)	66 (60.0)
Black/AA	24 (21.4)	34 (30.9)
Ethnicity Non-Hispanic , (n, %)	89 (80.9)	80 (74.0)
Trait Anxiety score preprocedure (mean, IQR)	0.9 (1.0)	0.5 (0.0)
FACES Pain Score preprocedure (mean, SD)	3.46 (3.2)	3.26 (3.3)

Post Procedure Outcomes	VCD	TL
FACES Pain Score (mean, SD)	3.5 (3.4)	3.4 (3.4)
FLACC Pain Score (mean, SD)	1.07 (1.61)	1.00 (1.46)
State Anxiety score (mean, IQR)	4.5 (7.0)	4.6 (6.5)
Time to complete in minutes (mean, IQR)*	**3.35 (2.0)**	**44.84 (13.5)**
Parent (% agree/strongly agree)		
• I am very satisfied with IV start	92%	95%
• Would use same methods in future	83%	86%
• Would recommend this method to others	85%	87%
RN: (% agree/strongly agree)		
• Method is a good way of dealing with IV pain	86%	86%
• Method did not adversely affect IV insertion	85%	90%
• Would recommend method to pts/families	89%	90%

* $p < 0.0001$; IQR = interquartile range; SD = standard deviation

Implications for Practice

- VCD was comparable to TL in managing pain and distress for children undergoing IV insertion with the added benefit of quick onset time.
- Treatment groups had equal self-reported state & trait anxiety.
- VCD and TL demonstrated equal satisfaction of caregivers or staff.
- ED clinicians should consider VCD as an effective option to manage pediatric IV insertion pain.