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# The J Tip Needleless System versus Standard of Care for Venipuncture: Comparison of Procedural Fear and Pain in Pediatric Patients.

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The J Tip Needleless System versus Standard of Care for Venipuncture:  
Comparison of Procedural Fear and Pain in Pediatric Patients.

Petronella Stoltz, DNP

University of Connecticut 2013

**Abstract**

Venipuncture procedures are fear inducing and painful for pediatric patients and are recognized as the leading cause of procedure-related pain in hospital settings and pediatric emergency rooms.

**Objective:** The comparison of procedural fear and pain related to venipuncture after the use of the J-tip needleless lidocaine system versus the standard of care (EMLA) in pediatric patients ages 8 years to 18 years. This randomized controlled trial investigated the effectiveness of a needleless system for instilling local anesthetic to numb the skin prior to venipuncture by measuring procedural fear and pain and comparing these outcomes to the standard of care (EMLA).

**Methods:** Pediatric patients aged 8 years to 18 years were randomly assigned to treatment with the J-tip needleless system or to the standard of care (EMLA) prior to venipuncture. Patients rated procedural fear and the pain of the venipuncture procedure using the Children's Fear Scale (CFS) and a Visual Analog Scale (VAS).

**Results:** Of the 150 children enrolled, 75 were randomized to the J-Tip group and 75 were randomized to the EMLA group. An analysis of variance for repeated measures (RM-ANOVA) was conducted to compare the effect of the J- tip needleless devices to EMLA on pediatric procedural fear with three different measurements using the Children's Fear Scale. The results showed that there was no significant interaction

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between the treatment groups for procedural fear. Both groups showed a reduction in fear using the Children's Fear Scale from the three time periods which were pre treatment, prior to initiation of venipuncture and post venipuncture.

An independent T-Test was used to compare the effect of the J- tip needleless devices to EMLA on pediatric pain using a Visual Analog Scale. There was a statistically significant difference in the pain scores between the EMLA and the J-Tip group.

Conclusion: This randomized control study found that there was statistically significant difference between the J-Tip and standard of care (EMLA) for pediatric pain and but no statistical difference in procedural fear. The results supported that standard of care (EMLA) provided more effective local anesthetic for venipuncture.

The J Tip Needleless System versus Standard of Care for Venipuncture:  
Comparison of Procedural Fear and Pain in Pediatric Patients.

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B.S.N., Long Island University 1997

M.S.N., University of Pennsylvania, 1999

A Dissertation Presented in Partial Fulfillment

Of the Requirements for the Degree

Doctor of Nursing Practice

at the

University of Connecticut

2013

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2013

Approval Page

Doctorate of Nursing Practice Dissertation

The J Tip Needleless System versus Standard of Care for Venipuncture:  
Comparison of Procedural Fear and Pain in Pediatric Patients.

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2013

## Dedication

This dissertation is dedicated to my children, Cheyenne, Brandon and Skye, who provided me with motivation, love and hugs through this process. Without Cheyenne's ongoing support, advice and cheerleading this journey may never have been completed. Thank you all for your love and support every step of the way and for understanding why we ate so much pasta.

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## Chapter One

Children presenting to the emergency department or a pediatric hospital are faced with many challenges. Venipuncture is one of the most painful and fear inducing procedures for pediatric patients and is recognized as the leading cause of procedure-related pain in hospital settings and pediatric emergency rooms (Kennedy, Luhman, Zempsky, 2008; Zempsky, 2008). Unfortunately, studies have highlighted the fact that pain assessment and management practices are commonly deficient in hospital and emergency room settings (MacLean, Obispo & Young, 2007; Young, 2005).

With the current focus on improving management of procedural pain in the pediatric population, institutions and researchers have begun to examine barriers to adequate procedural pain management in pediatric patients as well as the long term effects of untreated pain (Young 2005). MacLean, Stevens and Young (2007) examined the gap between procedural pain management treatments available and actual practice in a pediatric emergency department. There was a belief by surveyed staff that the use of the topical anesthetic and the required length of time before effective pain relief would disrupt the patient flow. Young (2005) found the staff in the pediatric emergency room often felt rushed, and the emergency room culture seemed to reflect the practice of holding down a patient and quickly performing the procedure as the most compassionate alternative available.

Zempsky (2008) identified barriers to procedural pain management and included lack of knowledge of available modalities and perceived time constraints as major issues. The American Academy of Pediatrics task force on Pain in Infants, Children and Adolescents and the American Pain Society (2001) examined the assessment and management of pain and concluded that education of all pediatricians is essential for appropriate and accurate assessment of pain in

children. Their recommendation is aimed at optimal and ethical assessment and treatment of pain in children and a reduction in the barriers to pain management.

The actual pain of the procedure combined with the anticipation and fear of the pain, contributes to the complexity of the phenomenon (Humpreys, Boon, Chiquit van Linden van den Heuvel and Van de Wiel, 1992). Pain is perceived as a threat and a loss of control, creating an intensely stressful and fearful environment for the child. “Fear is defined as a present oriented state to fight against an immediate threat” (Hugart, McGarth and Pardos, 2011, p.1). In the pediatric patient, pain associated with venipuncture procedures is perceived as a direct threat to themselves and therefore patients experience procedural fear, which precedes the actual procedure. Studies in both the pediatric and adult populations have examined the impact of procedural fear and the subsequent reaction to the actual procedures. The research findings have identified an association between higher fear of pain and a greater negative reaction to the procedure (Carpenter, 1990) as well as a “poorer adjustment to persistent pain”(Hugart, McGarth & Pardos 2011; Martin, McGarth, Brown & Katz, 2007; Tsao, Allen, Evans, Lu, Myers & Zeltzer, 2009; Vervoort, Eccleston, Goubert, Buysse & Crombez, 2010).

Research has shown that pain from venipuncture procedures can be significantly reduced with the use of local anesthetics and the use of non pharmacological interventions. In a study by Ellis, Sharp, Newbrook and Cohen (2004) the researchers surveyed nurses working in a pediatric inpatient setting to address concerns about not adequately controlling pain from needlestick procedures. The researchers concluded that integration of topical anesthetics and a number of non pharmacological strategies were beneficial in reduction of pain and distress associated with needle pain. Of local anesthetic options, EMLA® has become the standard of care in most

pediatric inpatient units and emergency rooms. As technology changes in the area of pain management, new options have become available to reduce pediatric patients' pain and discomfort during painful procedures. These options include the transdermal injection of buffered 1% lidocaine via the J-tip needless system, the use of iontophoresis, which is a technique using a small electric charge to deliver a medication such as lidocaine or other chemical through the skin, vapocoolant, a spray used for cooling of both superficial and deep tissues, and multiple different anesthetic and topical creams (Galinkin, Rose, Harris & Watcha, 2002; Zempsky, 2008).

Non-pharmacological interventions include education, procedural preparation and distraction provided by Child Life Therapist, who are health care specialists especially trained in age appropriate medical teaching as well as distraction techniques, can be extremely beneficial (Cavendar, Goff, Hollon & Guzzetta, 2004; Duff, 2005). These inpatient services are often available 24 hours a day to support patients undergoing painful procedures. The child life specialist in combination with the parents and the use of distraction are essential in successful preparation for the child and to decrease the fear of the unknown (Cavendar, Goff, Hollon & Guzzetta, 2004; Duff, 2005).

In conjunction with non-pharmacological support, the use of local or topical analgesia to help decrease the pain and discomfort that accompanies venipuncture procedures is beneficial to children (Cavendar, Goff, Hollon & Guzzetta, 2004; Duff, 2005, Committee on Psychological Aspects of Child and Family Health, 2001). Unfortunately, many children treated in the emergency room, inpatient setting and pediatric intensive care unit often receive no pain management for intravenous cannulation or venipuncture procedures due to the urgent need for

the procedure, either for the continuation of care or secondary to rapid deterioration in the child's condition, requiring immediate intervention. The reasons for inadequate pain management in the emergency room includes the myth that children do not experience pain, fear of over sedation and the use of inappropriate tools to assess the child for fear and pain (Zempsky, Cravero, Committee on Pediatric Emergency Medicine and AAP section on anesthesiology and Pain Medicine, 2004). The pressure to initiate therapies and the growing trend of shortened wait times or time to treatment in the emergency room increases the pressure on staff to proceed to venipuncture without use of local topical anesthetics, despite the overwhelming support for pre-procedural pain management reflected in the literature base.

### **Background of the Problem**

In patients requiring painful procedures, such as venipuncture, for the treatment of medical conditions or illnesses, extreme fear and pain can result. This is especially true in the pediatric population (Kennedy, Luhmann & Zempsky, 2008; Zempsky, 2008). Unfortunately, venipuncture is often a necessary procedure for blood work, fluid administration, medication or management of pain. Strategies to minimize trauma associated with invasive procedures, both physically and psychologically, has been an ongoing challenge for health care providers (Kennedy, Luhmann, & Zempsky, 2008).

The procedural fear and resultant pain related to venipuncture procedures has been identified in the literature as creating dissatisfaction for patients and families, as well as mistrust of the health care providers. In a survey conducted by Walsh and Bartfield (2006) of parent's presenting to the emergency room with their children, 89 percent of parents expressed a desire for painless placement of an intravenous device. Of parents who responded to the survey, 65%

were willing to stay an extra hour to ensure a procedural fear free and pain free placement of the intravenous catheter. Remarkably, 77 percent were prepared to pay extra for this assurance.

Studies examining painful cancer treatment procedures in pediatric patients have documented an association between children who have negative memory experiences surrounding procedural pain and those who will experience greater pain during procedures later in life (Kennedy, Luhmann, & Zempsky, 2008). Weismann, Bernstein and Schechter (1998) explored the effects of inadequate analgesia for procedures and the effect children experienced for subsequent procedures. Although a small study with a sample size of only 21 subjects, the researchers concluded that in pediatric patients, especially those younger than 8 years, initial inadequate analgesia led to difficulty with adequate analgesia requirements for subsequent procedures. These researchers concluded that it is essential to adequately treat any pain including venipuncture pain to reduce the negative impact of other painful experiences.

Currently the standard of practice in many hospitals and emergency rooms is to offer a topical anesthetic containing Lidocaine 2.5% and Prilocaine cream 2.5% (EMLA) as a means of pre-treatment for procedural pain. This preparation is known as EMLA (AstraZeneca UK Limited and Affiliates) and is one of few pharmacological options available for children. To ensure full effect of this topical anesthetic it must be applied 60 to 90 minutes prior to venipuncture procedures. Additionally, to prevent vasoconstriction of the superficial vessels, venipuncture should not be initiated for an additional 15 minutes after removal of the EMLA (Friedman, Fogelman, Nouri, Levine & Ashinoff, 1999; Zempsky, 2008).

Although there have been studies that demonstrate the effectiveness and ease of use for EMLA as well as relatively low cost (Friedman, Fogel, Nouri, Levine and Ashinoff, 1999;

Taddio, Gurguis and Koren, 2002), there have also been a number of studies that have shown the side effects and barriers to using Lidocaine 2.5% and Prilocaine cream 2.5%. These side effects include including vasoconstriction, allergic reaction, itching, and minor cases of dermatitis. Barriers include a delay in time to treatment, due to the time requirement for EMLA to produce optimal effective analgesia (Carceles, Alonso, Garcia-Munoz, Najera, Vila & Castano, 2002; Friedman, Fogelman, Nouri, Levine & Ashinoff, 1999; Kuwahara & Skinner, 2001; Moreau & Zonderman, 2000; Zempsky, 2008).

In busy emergency rooms and in pediatric intensive care units, the urgency of venipuncture procedures, necessary for phlebotomy or placement of an intravenous access device, often means that the 60 to 90 minute time lapse required to establish optimal effectiveness of EMLA is not a viable or a realistic option (Zempsky, 2008). Other barriers to the use of EMLA include vasoconstriction of superficial vessels leading to extreme difficulty in venipuncture and uneven topical application, leading to questionable efficacy of the drug. These confounding issues sometimes require multiple intravenous sites to be prepped, resulting in further discomfort secondary to tape removal following EMLA application (Kuwahara & Skinner, 2001; Moreau & Zonderman, 2000; Zempsky, 2008).

Other options for procedural pain pre-treatment are often not readily available in hospitals and may require specialized training of staff. These include: iontophoresis, which is a technique using a small electric charge to deliver a medicine such as lidocaine or other chemical through the skin; vapocoolant, a spray used for cooling of both superficial and deep tissues; and multiple different anesthetic / topical creams (Galinkin, Rose, Harris & Watcha, 2002; Zempsky, 2008). A 1% lidocaine subcutaneous injection has also been documented as a potential pain

relief agent, but this can be uncomfortable and also involves use of a needle (Zempsky, 2008).

As a result of these barriers to use, venipuncture is often done without a topical or local agent to ease the pain, despite the Joint Commission 2012 standards, as well as recommendation from the American Academy of Pediatrics (American Academy of Pediatrics Committee on Psychological Aspects of Child and Family Health, 2001; Young 2005; Zempsky, 2006).

A review article by Zempsky (2008) discusses findings from the literature that have identified “needle sticks” not only as the most common cause of pain in the hospitalized child, but also the second most common identified cause of “worst pain” as self-reported by pediatric patients. The American Academy of Pediatrics, the Intravenous Nurses Association, and the American Pain Society have all identified the need for pre venipuncture treatment to decrease the incidence of pain and extreme distress for pediatric patients (American Academy of Pediatrics Committee on Psychological Aspects of Child and Family Health, 2001; The infusion Nurses Society, 2006; Zempsky, 2008). These organizations make strong recommendations for the use of local anesthetics prior to venipuncture procedures and have issued policy statements to support the need to provide pharmacological and non-pharmacology pain relief for procedural pain in pediatric patients.

The long term effects of procedural fear and untreated pain are significant. Evidence that untreated pain has tremendous impact on a child throughout their lives is fast becoming a more clearly understood phenomenon. Pain is experienced early in life can impact patient pain perceptions throughout their lives (Kennedy, Luhmann & Zempsky, 2008). For example, Taddio, and associates (1995) evaluated the pain responses to vaccinations in two groups of circumcised boys. One group had been circumcised with pain management and the second

group had no pain management. The group without pain management for circumcision had a longer period of crying and increased pain reaction to both four and six month vaccinations as compared to the group that had pain management for the procedure.

In pediatric and young adult patients, needle phobia is a potential outcome of untreated venipuncture procedures. Needle phobia is considered a true medical diagnosis (Hamilton, 1995). The Diagnostic and Statistical Manual of Mental disorders considers needle phobia as a true medical condition and classifies the diagnosis in the category of blood injection injury phobias (American Psychiatric Association, 1994; Kennedy, Luhmann, Zempsky 2008). True needle phobia is experienced by approximately ten percent of the population (Hamilton 1995). Studies in the pediatric population have shown a correlation between procedural fear associated with venipuncture and other medical procedures, and negative memory experiences. Patients with phobia can exhibit extreme adverse affects from venipuncture including fainting, tachycardia, and increases in stress hormone levels (Hamilton 1995; Pate, Blount, Cohen & Smith, 1996). Research on the negative impacts of poor venipuncture pain control has been used to support the need for improved practices to prevent the development of needle phobia and increased procedural fear in children long term.

A relatively new product on the market, the “J-Tip Needleless Injection System” (National Medical Products, Inc, Irvine, CA) is a carbon dioxide driven, needleless system, which delivers 0.2mg of buffered 1% lidocaine via transdermal administration. This syringe device delivers the medication rapidly and painlessly and has demonstrated effectiveness in providing local anesthesia in approximately 3 to 5 minutes in some studies (Jimenez, Bradford, Seidel, Sousa &

Lynn, 2006; Zempsky, Bean-Lijewski, Kauffman, Koh, Malviya, Rose, Richards & Gennevois, 2008).

In three clinical trials in both adult and pediatric patients, statistically significant results demonstrated that pain scores were lower in patients who received pre-procedural pain management via the J-tip device than those in control groups (Jimenez, Bradford, Seidel, Sousa & Lynn, 2006; Zempsky, 2008). These effects were especially remarkable in pediatric populations. In a research study by Jimenez, Bradford, Seidel, Sousa and Lynn (2006) comparing the needle free injection system of lidocaine to EMLA for pediatric PIV placement, the researchers concluded that the J-tip group had less pain than the EMLA group, which had statistically significant findings ( $p < .0001$ ). However, the same statistical results were not seen in the adult population (Jimenez, Bradford, Seidel, Sousa & Lynn, 2006; Zempsky 2008). The adult studies showed no difference between EMLA and J-Tip venipuncture pain.

Currently there is no “gold standard” for choice of procedural pain management prior to venipuncture in the pediatric population, despite recommendations from The American Pain Society, the American Academy of Pediatrics, the Emergency Nurses Association, the World Health Organization and The Joint Commission. Practices among hospitals, units and individual providers vary from EMLA for the older pediatric patient to no intervention at all. The literature demonstrates agreement by experts from the medical and nursing communities for the need to appropriately manage procedural and venipuncture pain, although no agreement on best practice currently exists.

The J-tip 1% buffered Lidocaine system has demonstrated effectiveness as a method of pain control in pediatric patients in comparison to no analgesia in early studies (Auerbach, Tunik

& Mojica, 2009). Additionally, a number of studies that examined patient satisfaction and perception of pain and trauma of venipuncture revealed a favorable preference towards the lidocaine injection system (Peter, Scott, Watkin & Frasure, 2002; Spanis, Both, Koenig, Sikes, Gracelt, & Kim, 2008; Zempsky, 2008). Due to the extensive use of venipuncture in the pediatric patient population and the increasing concern by providers and governing bodies for appropriate pain control in pediatric patients, the exploration of alternative rapid onset methods to provide pain relief during venipuncture is warranted.

Fear is defined in the medical literature as a negative emotion that is thought to arise as an alarm to a dangerous and/or life threatening situation. (Hugart, McGarth & Pardos, 2011; Rachman, 1998). Traditional fear in children undergoing venipuncture has been referred to as “distress” (Duff 2003) but there is strong evidence that children regard venipuncture as one of the most fearful experiences while in a hospital (Humpreys, Boon & Chiquit van Linden van der Heuvell, 1990; Schechter, Blackson & Pachter, 1997). There were no studies that actually measured fear in children with reference to EMLA. Anxiety and distress was measured.

“Needle pain” has been identified by researchers as one of the most feared experiences on the part of pediatric patients. In combination, procedural fear can increase the pain sensation (McMurtry, Noel, Chambers & McGarth, 2011). Procedural fear impacts children in many different ways, including physiologically increasing pain perceptions, (Rhody & Meagher, 2003) increased emotional distress, and increased autonomic stimulation (Hugart, McGarth & Pardos, 2011). Unfortunately the studies comparing procedural pain management has not measured the actual phenomena of procedural fear. The literature does support that measures need to be taken to decrease procedural fear in pediatric patients.

In the pediatric literature there have been a small number of studies comparing the use of EMLA to the J-Tip. Auerbach, Tunik and Mojica (2009) studied the J-Tip jet device to determine whether this device and lidocaine would decrease self reported pain in children undergoing needle insertion in the emergency room. The researcher had 2 stages in the research project and concluded that the J-Tip provided better pain control for venipuncture than EMLA or no pain medications.

Jimenez, Bradford, Seidel, Sousa and Lynn (2006) compared the needle free injection system of lidocaine to EMLA for pediatric PIV placement. These researcher concluded that the J-Tip provided better pain control for venipuncture than EMLA.

As the requirements for pre procedural pain management by Joint Commission has increased there is a need for pediatric institutions providing healthcare and researcher to examine the viable options available currently.

### **Significance**

Nurses are often faced with the need to perform venipuncture procedures in pediatric patients for emergency purposes, whereby delay for the purposes of utilizing EMLA for the procedure is not feasible. Venipuncture often causes extreme anxiety in both the patient and the family and leads to many issues including increased procedural fear and overall dissatisfaction with the hospital experience for the child and family. EMLA has been shown to have many barriers to use as has been described (Kuwahara & Skinner, 2001; Moureau & Zonderman 2000; Zempsky, 2008). Previous studies in the pediatric population have shown that effective pain management decreases the traumatic effects of venipuncture procedures and reduces the amount of pain experienced by the child (Zempsky, 2006; Zempsky, 2008).

Children who are fearful or have an anxious family makes the task of placing a peripheral intravenous access device much more difficult for nurses and often can lead to a number of staff required to hold the child for repeated, unsuccessful procedural attempts to access the vein. The environment for the child is already loud and chaotic as well as unfamiliar and the feeling of physical restraint by hospital staff leads to increase fear and distress (Young, 2005). The family may perceive the venipuncture procedure as a particularly difficult one for their child, whereupon future visits, these parents have increased fear and anxiety due to the perception that the “child has terrible veins and they can never get them” (Ellis, Sharp, Newbrook & Cohen, 2004). These research findings support the need to provide ethical, humane and pain free care prior to procedures in pediatric patients. The challenges of working with the fearful child or family can lead to failed access, the need for placement of a surgical intravenous access device or peripherally inserted central venous catheters (PICC), which are far more invasive procedures, requiring anesthesia or moderate sedation. Another potential result of unsuccessful placement of peripheral intravenous access devices can be emergent placement of an intraosseous line, as well as numerous bruises and injuries to the child’s skin and vessels; all contributing to repeated painful procedures. Additionally, when repeated attempts for successful placement of intravenous access devices are required, there is an increased risk of accidental needle sticks to staff.

Venipuncture procedures remain a source of significant pain and discomfort in pediatric patients (Young, 2005; Zempsky, 2008). Barriers to pain management and control include lack of knowledge among healthcare providers and inconvenience to the providers when having to wait for the EMLA to take effect (American Academy of Pediatrics, Committee on Psychosocial

Aspects of Child and Family Health, 2001). The J tip may be an effective and safe solution to this dilemma in the pediatric population, in both the inpatient and outpatient setting, for the reduction of pain experienced during venipuncture. The use of the J-tip has been shown in studies to be safe and to reduce all of the above negative effects of venipuncture (Jimenez, Bradford, Seidel, Sousa & Lynn, 2006).

### **Theoretical Framework**

The middle range Theory of Unpleasant Symptoms, by Lenz and Pugh (1997) served to guide the development of this research project. This theory included three categories of variables, all relevant to the proposed study. These variables were identified as effecting the occurrence, intensity, timing, distress level, and quality of symptoms. The three categories are, physiologic, psychological, or situational. In this theory each category is affected by level of distress, duration, intensity, quality of symptom, and the affect on the patient (Lenz & Pugh, 1996). These factors overlap and affect the patient and family (Lenz, Pugh, Milligan, Gift, & Suppe, 1997). The theory can be used as a foundation for guiding practice.

Lenz and Pugh (1997) describe the unpleasant symptom as multi dimensional. The authors also clearly state that the unpleasant symptom is individualized and although one patient may find it extremely distressing, another person may not be bothered by it at all. This is further complicated by differences in descriptions of the symptoms and previous experiences. This theory examines not only the symptom, but also encompasses other influencing factors and the interaction of the symptoms with other aspects of care of the patient.

With pediatric venipuncture, procedural fear and pain occur and, as a result of these unpleasant symptoms, there are a number of resulting physiologic, psychological and situational

factors to be considered. The physiological symptoms that may occur include intense pain, vasoconstriction, hyperventilation, fainting, tachycardia and hypertension. Psychological factors that symptoms include distress, anxiety, fear, mistrust of healthcare providers and behavioral issues. Contributing and situational factors would include one's previous experiences, family anxiety, presence of support persons including child support, use of pain management tools, skill of nursing staff and preparation of the patient for the procedure.

Understanding the effects of the unpleasant symptoms will assist nursing staff caring for the patient to recognize, anticipate and intervene early to reduce the negative effects of venipuncture procedures. By reducing the factors that are affected by the unpleasant experience or symptom, the effects and outcomes will be beneficial by reducing procedural discomfort, reducing procedural fear and facilitating improved care for the child. The concepts of this theory related well to the processes of procedural pain in the pediatric patient. Additionally, the theory also explained the complexity and need for identification and management of symptoms in the earliest stages. The theory is very adaptable to clinical practice and change.

In a clinical setting it is essential that the healthcare provider attempts to decrease patient's procedural fear and anxiety by preparing the patients and family appropriately. This preparation includes addressing questions and being extremely selective with the words used to describe venipuncture. Avoiding words such as "needles" or "sticking" that have negative impacts on the child, using age appropriate interventions and providing appropriate pain management the access will induce fewer unpleasant symptoms. By reducing the unpleasant symptom or symptoms, the effect will decrease alterations in homeostasis and procedural fear,

supporting cooperation and participation while at the same time increasing or continuing trust in the health care provider.

### **Purpose of Study Change**

The purpose of the study was to:

Implement a new device to deliver preprocedural pain medications to a child prior to venipuncture and to evaluate procedural fear and procedural pain scores among subjects when receiving standard of care (EMLA) for procedural pain verses the J-tip device. The J-tip is a needless device that can be used to transdermally deliver 1% buffered lidocaine prior to venipuncture and can be administrated by nursing staff. This system can be used in both the inpatient and outpatient population. Due to rapid onset of effect, the J tip system may decrease current barriers to pre-medication for procedural pain and decrease pain and procedural fear associated with venipuncture for pediatric patients.

### **Study Questions**

Research questions addressed during the conduct of this study were:

- 1). Is there a difference in procedural fear scores among pediatric patients requiring venipuncture with the use of the J-Tip Needleless system as compared to the standard of care (EMLA)?
- 2). Is there a difference in pain scores among pediatric patients requiring venipuncture with the use of the J-Tip Needleless system as compared to the standard of care (EMLA).

### **Definition of Key Terms and Variables**

*Conceptual definition: Fear*

A negative emotion that is thought to arise as an alarm to a real or perceived danger and/or life threatening situation (Rachman 1998; Hugart, McGarth, & Pardos 2011).

*Operational definition: Fear*

For the purpose of this study, procedural fear was measured by the Children's Fear Scale (Hugart, McGarth, & Pardos, 2011). Subjects selected a fear face ranging from zero to five. A face of zero represented no procedural fear and a face of five indicated extreme procedural fear.

*Conceptual definition: Pain*

Pain is a subjective experience of an unpleasant sensory or emotional experience associated with actual or potential tissue damage (Merskey and Bogduk, 1986).

*Operational definition: Pain*

An unpleasant sensation associated with damage to the body. For the purpose of this study, pain was measured by subjects scores on a Visual Analog Scale (VAS). Subjects marked a pain level on a line and this mark was measured on ranging from zero to 100 mm scale with zero representing no pain and 100mm being severe scale. This scale was used for children 8 years and older.

*Conceptual definition: Venipuncture*

The transcutaneous puncture of a vein by a sharp rigid stylet or cannula with a flexible plastic catheter to withdraw blood or instill fluid and/or medication (Dorland's Medical Dictionary for Health Consumers. © 2007).

*Conceptual definition: J-tip 1% Needleless injection syringe(National Medical Products, Inc, Irvine, CA)*

Carbon Dioxide activated syringe containing 0.2mL buffered Lidocaine to introduce 1% buffered lidocaine. This device was used to inject transdermally, prior to the initiation of venipuncture procedures.

*Conceptual definition: Buffered Lidocaine*

Mixture of 3mL Sodium Bicarbonate with 10 mL of 1% lidocaine that was drawn into the J tip syringe for administration at the site of the venipuncture 1 to 3 minutes prior to procedure.

*Conceptual definition: EMLA 2.5% Lidocaine and 2.5% Prilocaine ( AstraZeneca UK Limited and Affiliates).*

Topical anesthetic cream consisting of 2.5% Lidocaine and 2.5% Prilocaine.

**Summary**

Venipuncture in the pediatric population is a frequent invasive procedure required for appropriate patient care in both the inpatient and outpatient settings (Zempsky, 2008). There is increased knowledge and recognition that venipuncture is an extremely painful and fear provoking process for pediatric patients (Duff, 2003; McMurtry, Chambers & MaGarth, 2011; Papa & Zempsky 2010). The purposes of this practice change were to implement and evaluate the effectiveness of a J-Tip to deliver pre-procedural pain medication to a child prior to venipuncture for local anesthetic effect to reduce procedural pain, as well as compare pain scores and procedural fear scores among subjects when receiving standard of care (EMLA) for procedural pain verses the J-tip device.

Procedural fear is currently recognized as a phenomenon that can have long term negative impacts on children and may affect their response to pain, response to pain medication and affect their medical care. Untreated procedural fear can lead to needle phobias and further issues into adulthood. The literature and current research supports the need for the healthcare provider to address procedural pain and procedural fear for all pediatric patients and to provide

ethical, humane and safe care as well as eliminate the gap in available and actual practice for venipuncture (Bhargava & Young 2007; MacClean, Obispo & Young 2007; Young, 2005).

Currently there are a growing number of options for treatment of procedural pain management. There is ample knowledge regarding the existence and management of both pain and procedural fear and the impact of untreated venipuncture pain (Committee on Psychological Aspects of Child and Family Health, 2001). Implementation into our standard protocols and practice guidelines as well as education of the staff is essential to achieve the goal of a reduction in unpleasant symptoms experience for pediatric patients.

## Chapter II

### **Literature Review**

Children requiring hospitalization or visits to the emergency room are often subject to venipuncture procedures, via either venous cannulization or placement of intravenous access devices. The procedure and process of venipuncture is well described in the literature as a significant source of pain and procedural fear for children receiving medical care (Papa & Zempsky, 2010; Young, 2005; Zempsky, 2008). In addition to the pain associated with venipuncture, the process of venipuncture is also viewed by many children as being the most fearful aspect of hospital and emergency room visits (Duff, 2003; McMurtry, Chambers & MaGarth, 2011; Papa & Zempsky 2010). In a survey conducted by Papa & Zempsky (2010) nursing staff agreed that improved pain management for venipuncture pain leads not only to improved the hospital experience for the child and family but also to increased nursing job satisfaction. There is recognition within the literature and by leading experts that procedural fear and pain related to venipuncture needs to be addressed to improve care provided to children and their families.

There are many factors that affect the degree of procedural fear and pain that children experience. Some procedural fear is expected as a normal developmental milestone. Lack of adequate assessment tools and inability to properly evaluate developmental stages, or the constellation of symptoms presented to an unknown provider, affect the evaluation or decision of pain medication choices (Zempsky, Cravero, and Committee on Pediatric Emergency Medicine and Section on Anesthesiology and Pain Medicine, 2004). Children develop coping strategies, but many children are unable to develop effective coping strategies, resulting in high levels of

procedural fear, pain, and behavioral distress. Procedural fear and pain results in traumatic venipuncture procedures, which may involve the child being restrained or sedated, which leads to further distress for all involved (Duff, 2003; Young, 2005).

Changing nursing practice requires careful review of the literature and current evidence based practices. The initial literature review for the proposed study was conducted by computer based search using the Cumulative Index to Nursing and Allied Health Literature (CINAHL). Articles initially from 1995 to 2011 were reviewed. Key words that were used for this literature search included: Venipuncture, peripheral intravenous access, PIV, procedural pain, pediatric procedural pain, EMLA, J-tip, buffered lidocaine, local anesthetic jet injections.

The search was then expanded to OVID for evidence based practice and research using the same key terms as the initial search and research articles from 1996 to 2011. The search for EMLA and J-tips yielded 34 papers. Lidocaine yielded 20, 332 studies, the majority of were not applicable to initiation of venipuncture. The search was then narrowed further to remove non English papers and non-human only studies. The search was then narrowed further to EMLA, J-tip and lidocaine topical for venipuncture, pediatric pain, and procedural fear in the pediatric population.

The following review of the literature represents a synthesized, integrative review of the current state of the science. Discussion of the literature base pertaining to the theoretical framework is presented below, followed by presentation of the empiric literature pertaining to the specific variables of interest. Finally, the chapter concludes with a brief summary of key points.

### **Review of the Theoretical Literature**

The theoretical framework selected for the proposed study is the middle range Theory of Unpleasant Symptoms, developed by Lenz and Pugh in 1995. There are three major components in this theory: the symptom that the individual is experiencing, the influencing factors that give rise to or affect the nature of the symptom, and the consequence of the symptom (Lenz, Pugh, Milligan, Gift & Suppe, 1997). The effects that the symptom has on the physiological aspect of the patient, as well as the psychological and environmental aspects of the patient and the multidimensional affects that the symptom can have on the patient outcomes, both immediately and in the long term.

Symptoms are defined by the Theory as “perceived indicator of change in normal function as experienced by the patient and are the red flags of threats to health” (Lenz, Pugh, Milligan, Gift & Suppe, 1997, p.15). The Theory examines symptoms in a multidimensional context. For example pain may be examined in multiple dimensions including intensity, which includes how strong the symptom of pain is and the amount of pain perceived by the patient, developmental interpretation of pain, previous experiences, and degree of fear present and parental support.

Pain, which would represent the symptom that the patient conceptualizes as a multidimensional experience, is evaluated by using age appropriate scales or tools that are tested and reliable as well as descriptions by the patient. The time that the patient has been experiencing the unpleasant symptom needs to be considered when evaluating and assessing patients. In evaluating the pain or symptom it is essential to include how long the symptom has been present, the intensity of the symptoms and whether the symptoms stay constant or vary. The amount of distress caused by the symptom has to be closely evaluated, often providing

assistance in the guidance of therapy. The symptom, in this case, the pain and the effect that the pain has on the patient, is the factor or dimension that contributes the most to the quality of life for the patient (Lenz, Pugh, Milligan, Gift & Suppe, 1997).

Pain is known to be subjective and varies among people with many factors influencing pain perception. In the pediatric patient, developmental age, disabilities, understanding, culture and family influences make pain a challenge to assess accurately (Walco, 2010; Weismann, Bernstein & Schechter, 1998). When assessing pain in the pediatric population, it is absolutely essential to use developmental age appropriate tools to evaluate the physiological symptoms, intensity, duration and distress caused by the procedural fear and pain. This assessment must include all aspects of the symptom including psychological and environmental influences. Cultural and parental input is essential as parents may have a unique insight into the patient's response to pain or unique ways of describing pain. Culturally, patients may respond differently to pain and interpretation may be difficult for the health care provider caring for the patient.

Influencing factors play a role in the unpleasant symptoms, which is very important in the understanding how a pediatric patient experiences pain. Physiologically, procedural fear and concerns regarding the venipuncture procedure, as well as the perceived pain and distress can lead to difficulty accessing the vessel, vasoconstriction, increased heart rate, apnea and occurrence of trauma to the child (Papa and Zempsky, 2010). Psychologically, there is concern for needle phobia, increased fear, anxiety, and depression (Duff, 2003, Walco, 2008; Weisman, Bernstein and Schechter, 1998). If psychological factors can be managed, research findings suggest effectiveness in reducing the symptom (Lenz, Pugh, Milligan, Gift & Suppe, 1997).

Parents and the hospital or emergency room environment can often affect a child's level of procedural fear. Being placed in a small room, in an unknown environment, with numerous people and unknown aspects of care, leads to situational factors that affect the child and symptoms. The situational and emotional factors includes the words used by health care professionals to describe venipuncture, being held down by one or two strangers, not being allowed access to familiar objects of comfort, lack of proximity to parents, or visualization of needles. The unpleasant feeling of fear due to the environment and the unknown can lead the child to have physiological and psychological symptoms including tachycardia, nausea, vomiting, uncontrollable behavior and poor coping skills (Walco, 2008). These factors can all negatively impact the experience of venipuncture and fear for a child and their family.

The Theory of Unpleasant Symptoms (TOUS) describes how proper recognition and management of all three components, physiologic, psychological, and environmental, are necessary to improve clinical outcomes. If pain and procedural fear in the pediatric patient is assessed with age appropriate tools, skill and sensitivity, then the outcome of the patients experience and the long term impact will be positive. With proper evaluation and resources, such as child life support services and appropriate pre procedural pain management, preparation for the procedure can be optimized. Parents may be able to assist in comforting the child or explaining to the child, whereby reducing procedural fear. Age appropriate words may help to decrease the procedural fear and anxiety about the procedure. If inappropriate management occurs then the long term effects of pain can include mistrust of the health care professional, needle phobias, injury to the vessels, multiple needle sticks and medical complications including

stress, apnea and hematoma (Kennedy, Luhmann & Zempky, 2010; Walco, 2008; Weisman, Bernstein & Schechter, 1998).

Liehr (2005) suggests that unpleasant symptoms are subjectively experienced indicators affecting performance, which are described specifically by timing, quality, intensity, and distress and are influenced by physiological, psychological, and situational factors. The notion of pain as a subjective experience is supported in the research literature. Liehr (2005) postulates that the Theory of Unpleasant Symptoms explains that persons in varied situations can experience common symptoms, and that symptoms are individual phenomena occurring in family and community contexts.

Liehr (2005) states that in practice, unpleasant symptoms are operationalized by symptom assessment, management, and relief intervention. In research, symptoms can be described using a symptom scale, which measures duration, quality, and intensity of the symptom, as well as the symptom experience (Liehr, 2005). When considering the concept of pain, there are various subjective as well validated and age appropriate scales to measure pediatric pain. These tools can be utilized in the clinical setting to give guidance to the health care provider for appropriate management of the unpleasant symptom and reevaluation of the effectiveness of the intervention.

Tyler and Pugh (2009) applied the Theory of Unpleasant Symptoms to patients undergoing Bariatric Surgery. Their study used the theory to evaluate and manage post operative patients with a multidisciplinary team to encompass all three components of the theory. This paper highlights the essential aspects of the consequences of an untreated unpleasant symptom on both cognitive and functional activities and ultimately the outcome. Pain is multidimensional therefore, early recognition and treatment can ensure multidisciplinary interventions to provide

comfort and decrease both pain and procedural fear with positive outcomes for patients. This theory can give health care providers a clearer understanding of the characteristics of the unpleasant symptoms and the factors that interact or affect the patient psychologically, physiologically, and situationally (Tyler & Pugh, 2009).

“Needle pain” has been identified by researchers as one of the most feared experiences on the part of pediatric patients. In combination, procedural fear can increase the pain sensation (McMurtry, Noel, Chambers & McGarth, 2011). Procedural fear impacts children in many different ways, including physiologically increasing pain perceptions, (Rhody & Meagher, 2003) increased emotional distress, and increased autonomic stimulation (Hugart, McGarth & Pardos, 2011). From a psychological perspective, there is well documented research evidence supporting a phenomenon of catastrophic thinking in children and the subsequent development of needle phobias, extreme distress, and panic to the perceived threat to self (Hugart, McGarth & Pardos, 2011). Children with procedural fear become more fearful and reactive to the environment leading to increases in fear. If the unpleasant symptom of procedural fear is recognized early on in the assessment phase and is managed effectively, venipuncture procedures will have less of a negative impact or long term effect on children and their families.

### **Review of the Empirical Literature**

The purpose of the proposed study was to compare the effectiveness of the J-Tip needleless system, which delivers 1% buffered Lidocaine to the current standard of care, the topical anesthetic EMLA (prilocaine and lidocaine formula) for management of procedural fear prior to venipuncture procedures, as well as pain relief during venipuncture. In this review, aspects of EMLA and the J-tip device were examined for effectiveness, ease of use, rapid onset

of anesthesia, and incidence of reported side effects. An additional concept included barriers to use for EMLA and the J-Tip needleless system with 1% buffered lidocaine as reported by providers. The variables of interest were effects of EMLA and the J-Tip needleless system on procedural fear and pain in pediatric patients undergoing pediatric venipuncture procedures.

In an effort to establish the need for the proposed study and to articulate the state of the current scientific evidence, an extensive literature review was conducted. There were only limited quantitative randomized control trial (RCT) studies on the J Tip buffered lidocaine use in pediatrics. There were a number of articles discussing the scientific knowledge of procedural pain and pharmacological interventions to improve clinical outcomes and practice. Research on adult venipuncture pain studies, and general pediatric procedural pain was included in the review in light of the limited literature available pertaining to the pediatric population.

### **Pediatric procedural fear**

Fear is discussed in many articles related to procedural pain but the definition of fear and the method of measuring the actual phenomenon have not been well documented until recently. There has been growing effort by pediatric psychology practitioners to evaluate and explore methods of assessing and measuring fear accurately. In the current literature there were two articles published using a new, well validated tool similar to the pediatric FACES scales to measure pediatric fear.

McMurray, Chambers and McGarth (2011) clearly defined fear as a negative emotion that is thought to arise as an alarm to a dangerous and life threatening situation. These researchers investigated the psychometric properties of the Children's Fear Scale with young school aged children. In this study children and parents were videotaped during venipuncture

and completed fear and pain ratings immediately after the procedure. The study was a convenience sample of 100 subjects between the ages of 5 years and 10 years were included in the study.

The study setting was an outpatient laboratory and the study required the completion of one of three fear scales at the completion of the venipuncture. The three scales used by the subjects were the Children's Fear Scale, the Faces Pain Scale – Revised and the Children's Anxiety and Fear Scale. Parents were only required to complete the Children's Fear Scale. Two weeks after the experience the subjects and parents then completed the same scales. The authors concluded that the Children's Fear Scale was a valid and reliable measurement for measuring and evaluating pediatric procedural fear.

Humphrey, Boon, Chiquit van Linden van der Heuvell and van de Wiel (1992) evaluated 223 children undergoing venipuncture to gain scientific data on the occurrence of acute behavioral distress in children that are undergoing venipuncture. The study used trained observers and a behavioral observation scale to examine the levels of distress experienced by the children undergoing venipuncture. The instruments used for this study was the Groningen Distress scale for distress measurements and a VAS for "pain and nervousness". Approval was obtained for the study from the medical ethics board. All children requiring venipuncture were included. There was no required informed consent and the parents were notified of the ongoing study by posters in the pediatric units. Children were observed in two phases, the first section occurring in the preparatory phase and the second observation phase occurring during the actual venipuncture. The researchers used a one to five observational scale to evaluate the children's level of distress and had these scales completed by trained observers. During the study, using

the Groningen Distress Scale, the researchers observed that 113 children out of 223 children were rated as having a three or higher score which was interpreted as a high level of distress. The researchers found significance  $p < .001$  correlation  $r = .87$  in the preparatory phase and the actual venipuncture phase. The researchers also found significant  $p < .0001$  correlation  $r = .57$  of the VAS with distress. Therefore, the researchers concluded that high levels of distress and procedural fear during venipuncture was common, and that these levels of distress correlated with age. Based on age related findings, the researchers recommended that toddlers and pre-adolescents should be targets for new interventions to reduce distress during venipuncture. The researchers found that distress decreased with age and maturity but that the process of venipuncture still caused some distress in adolescents. The authors if this study did not identify study limitations (Humphrey, Boon, Chiquit van Linden van der Heuvell and van de Wiel, 1992).

The need to decrease the fear of needles is essential as this fear can have lifelong health impacts. There is an opportunity and need for health care professionals to take steps to diminish the procedural fear of needles and to be active in the prevention of the development of needle phobia (Nir, Paz, Sabo and Potasman, 2003). Nir, Paz, Sabo and Potasman (2003) designed a study to evaluate fear of injection in young adults as related to vaccinations. The study site was a travel clinic in Jaifa, Israel that was responsible for providing health services to over 2000 travelers a year. The researchers had 400 travelers, with a mean age of 25 years; at a travel clinic participate in the study with a mean age of 25 years. Questionnaires were given to each of the subject regarding their fear of needles or injections. Questions asked about include bad past experiences, value of immunizations, time, comfort and the need for empathy by medical staff. The researchers used logistic regression to predict two specific end points. The researchers

showed that fainting was associated with a bad past needle experiences, needle fear and unreasonable fear ( $p < .0001$ ). The researchers concluded that fear of needles and bad experiences potentially negatively impact the young adult

Procedural fear can be decreased to have less of an impact on the child. There are a number of interventions that can be used. Cavender, Goff, Hollon and Guzzette (2004) studied the effectiveness of parental involvement on pain, procedural fear and distress in the pediatric patient during venipuncture. This study had the purpose of determining the effectiveness of parental positioning and distraction on pain. This study used an experimental comparison group design. A convenience sample of 43 patients was enrolled in the study and the fear and pain of the children were evaluated by the patient, parents and child life specialists. Inclusion criteria was English speaking, ages between 4 years and 11 years, a medically transcribed order for venipuncture and consent. Exclusion criteria included chronic illness including cancer and cystic fibrosis and possible child abuse. In pediatrics, including the parents to hug and hold during procedures to ensure the child feels secure and as safe as possible is an effective intervention and provides comfort. In the study, fear was rated on a one to five scale. Wong Baker FACES scale was used to rate pain. Measurements were taken after the venipuncture had been completed. Using two groups the researchers found that a significant difference in fear between the two groups ( $p = .04$ ). A two tail t-test with p values less than .05 were considered statistically significant difference in fear. There was no statistical significance difference for pain between the two groups, but the self reported scores for the group receiving distraction and comfort position during the procedure was found to be lower. For fear the group receiving parental distraction and positioning their fear rated lower. Statistically this was not significant but the

researchers statistic probability was reported as  $p = .058$  and therefore concluded that fears scores were lower in the children that were distracted and held. Observed fear was statistically significant with a  $p = .04$  between the two groups. Fear score rating by a child life therapist were lower in the group receiving the experimental therapy of distraction and position. Fear is significant in a child and the study showed that correct techniques and a multidisciplinary approach to venipuncture decreases fear in children of all ages.

In Martin, McGrath, Brown and Katz, (2007) the researchers examined the role of fear of pain to personal pain relevance. The study uses an older tool known as the child version of the 20-item Pain Anxiety Symptom Scale (PASS). In this study, the children were asked to use the scale in reference to their own pain and for another acute pain that they did not have. Children reported fearful and catastrophic thinking for their own pain but not for other types of pain, suggesting that fear of pain is learned and not a generalized individual trait (Martin, McGrath, Brown & Katz, 2007). The authors concluded that pain-related fear may develop from one's chronic, personally meaningful, and emotionally laden own pain experiences. These findings support the need to consider fear as well as pain when addressing venipuncture in the pediatric pain and that unaddressed fear may be a consequence of inappropriate management of pre procedural pain management in the pediatric patient undergoing venipuncture.

Topical analgesia for treatment of venous access.

#### *EMLA*

EMLA, a topical anesthetic cream consisting of 2.5% Lidocaine and 2.5 % of Prilocaine, is considered the current standard of practice within many institutions, however the barriers to use of EMLA, as well as the length of time necessary for effective pain relief are significant in

the practice setting. EMLA requires an application time of 60 minutes until full effectiveness of local anesthesia is achieved (Kleiber, 2002, Moreau, Zonderman, 2000, Zempsky 2008). Many practitioners have identified the need to explore alternatives to EMLA that increase ease for use, comparative efficiency, and safety (Kennedy, Luhmann & Zempsky, 2008). Staff many not have 60 minutes to wait for the complete effects of the EMLA prior to needing to perform venipuncture and intravenous cannulation (Young, 2005).

A prospective, randomized, and single-blind study compared EMLA applied for 60 minutes verses EMLA applied for 90 minutes prior to venipuncture procedures (Gad, Olsen, Lysgaard and Culmsee, 2004). The study has a sample size of 60 Caucasian children, aged 6-12 years requiring intravenous cannulation. The children were allocated to either a 60-minutes application of anesthetic cream followed by intravenous cannulation (Group A) or to a 90-minutes application followed by an interval of 30 minutes before cannulation (Group B) prior to cannulization. The subjects did not receive any further sedation or analgesia prior to the intravenous cannulization. The children scored their pain by a faces scale with four faces. The group of subjects who received EMLA application 90 minutes prior to the procedure had significantly less discomfort with venipuncture as compared to the group who received EMLA for only 60 minutes (Mann-Whitney test,  $p=.01$ ). The researchers did not identify limitations in this study (Gad, Olsen, Lysgaard and Culmsee, 2004).

MacLean, Obispo and Young (2007), retrospectively reviewed the charts of patients requiring painful procedures in a busy pediatric ED were reviewed. There were 1727 procedures performed of which 859 patients that underwent venipuncutre. There were 777 patients (90%) whom received venipuncture and had no documented pain management interventions and only

seven patients (less than 1%) had received a topical anesthetic prior to venipuncture. Most of these patients received venipuncture within 30 minutes of the physician order being placed. All the data was analyzed after entry into an excel sheet and analysis with SAS software. A primary reason identified by the researchers for not using topical anastesthesia was concern over delaying procedures while waiting for the topical anesthetic to take effect ( MacLean, Obispo &Young, 2007).

If used appropriately and per manufacturer recommended time frames, studies overall do support that EMLA significantly reduces pain for venipuncture in the pediatric population (Goldsmith, 1999, Russell, Doyle, 1997). In a double blinded RCT, determinants for the success and failure of EMLA were evaluated. This study had two arms and was a double blinded study (Lander, Hodgins, Nazarali, McTavish, Ouellette and Friesen, 1996). The sample was 258 children between the ages of 5 years and 18 years. The subjects had EMLA or placebo applied for 90 minutes prior to the start of the venipuncture. The subjects were not aware which treatment they received prior to the initiation of the venipuncture. The researchers concluded that there was a significant reduction in pain at time of venipuncture in 84% of the subjects and 51% reduction in pain in the peripheral venous patients. One of the identified determinants in success of the pain control was the length of time the EMLA had been applied. The researchers concluded that EMLA applied and left in place for less than 90 minutes had less successful pain control (Lander, Hodgins, Nazarali, McTavish, Ouellette and Friesen, 1996).

A study using a multicenter, double-blind, randomized, placebo-controlled parallel group trial with a sample size of 161 children between the ages of 4 years and 6 years undergoing standard DPTP immunizations in private office pediatrician office settings evaluated the

effectiveness of EMLA in the reduction of pain associated with intramuscular immunization (Cassidy, Reid, McGarth, Smith, Brown and Finley, 2001). Inclusion criteria included appropriate age, required DPTP scheduled immunization, ability to complete pain assessment and informed consent by guardian. Children with sensitivity to EMLA, active dermatitis or open wound, fever or acute illness that prevented vaccination administration, developmental delays, language barriers, receiving an analgesia or sedative twelve hours prior to the procedure, congenital or idiopathic methemoglobinemia or sulfonamide therapy were excluded from the study. The subjects received either an EMLA or a placebo patch prior to the immunization. Informed consent was obtained by the researchers prior to the day of appointment for the subject. On arrival at the pediatrician's office the parents rated their children's pain and anxiety related to the immunization process using a VAS scale. At this point a placebo or EMLA patch was applied. There was standardization within the protocol for site application and procedure for immunization administration. Immediately after the immunizations the subject was asked to rate their level of pain using a self reporting faces scale. The researchers used the Mann-Whitney U-test to detect differences between the two groups. Alpha was set at .05. The tests and relative risk test were used to compare proportions for clinically significant self-reported pain. To examine for potential mediators the researchers used a spearman correlation test was used. The potential mediators of pain were identified as, gender, previous medical experience and patch adhesion. Alpha was set at .01 for the correlations. There was a small to medium (28) effect size (Cohen's  $d = .45$ , all subjects;  $d = .42$ , excluded subjects omitted) for EMLA on children's self-reported pain. The EMLA patch caused a 26% reduction in the number of children who reported clinically significant pain. The researchers concluded that the EMLA patch reduced immunization pain

from 43% to 17%, a decrease of 50% of the total group experiencing significant pain. The EMLA group in this study had statistically less discomfort and pain associated with the immunization than the placebo group. There were no reported major adverse reactions in the study. There were a few documented cases of pallor of the skin or mild skin reactions. There was no significance in skin reactions when the researchers examined correlations between the two groups.

In a randomized control study on peripherally inserted central catheters by Fry and Aholt (2001), researchers compared the effectiveness of the local anesthetic, buffered lidocaine and no interventions prior to the placement of a peripherally inserted line. The purpose of the proposed study was to evaluate whether buffered intradermal lidocaine or EMLA reduce pain experienced as compared to no anesthesia in adult patients requiring placement of a peripheral inserted central catheter. Inclusion criteria included placement of catheter by an experienced nurse, ability to understand and complete a visual analog score, no allergies to any of the medications used and were older than 18 years. Formal institutional review board approval was obtained for this study and all patients consented prior to inclusion. The sample size for the study was 42 subjects, aged 19 to 79 years. Subject's pain was evaluated with a Visual Analog Score (VAS) and a McGill Pain questionnaire. A lower VAS score was considered the goal of appropriate pain relief. The mean VAS score for subjects receiving buffered lidocaine scored was 3.3, as compared to the 6.4 for the EMLA cream group, and 7.3 in the control group. The researchers concluded the differences for the VAS were not statistically significant ( $p = .12$ ) between the three groups. The McGill scale results were analyzed for the same subjects; the mean scores were 1.5 for the 1% buffered lidocaine group, 1.7 for the EMLA cream group and 3.4 for the

control group. The researchers concluded that there was a statistically significant difference ( $p = .034$ ) between both therapies compared to no therapy. Benefits discussed in this paper included low cost and nearly pain free injections. Disadvantage cited included needing special equipment and pharmacy to make the mixture resulting in a time consuming process for the pharmacy personnel. This study demonstrated efficacy of EMLA for pain relief and patient satisfaction, but researchers emphasized the intervention disadvantages included a long wait time for full effect and cost of EMLA (Fry, Aholt, 2001).

With current trends in pain control and management of pre procedural pain and anxiety the literature supports EMLA as a viable option with many positive qualities including ease of use and affordability. Unfortunately, the literature does reflect and support many of the disadvantages of EMLA, including 60 minute application time prior to venipuncture, concerns for systemic absorption in the neonate and younger pediatric patients, concern for venous constriction and some of the dermalogical side effects.

*Pharmacological approaches to reducing venous access pain in children.*

Needle pain causes significant distress in the pediatric patient. The pain related to venipuncture can cause a significant negative impact on the child later on in life and through to early adulthood. Compliance by staff with recommendation for pain control is an area of poor compliance (MacLean, Obispo & Young, 2007).

In a study by Bhargave and Young (2007) the researchers surveyed a number of pediatric emergency rooms with fellowship programs for the purpose of evaluating pain and sedation medication use for procedural scenarios. Surveys were sent to 51 academic pediatric fellowship programs with a return of 38 (75%) surveys. IRB approval was obtained form all institutions.

The researchers used descriptive statistics to present categorical variables. Of the 51 responses the researchers found that in high volume emergency rooms there was a 67% use of pre venipuncture pain medication but in low volume emergency rooms there was only a 26% use of interventions ( $p = .013$ ). Limitations of this study included small sample of emergency rooms, no international hospitals were included and therefore the researchers felt that the generalizability was reduced. The authors concluded that venipuncture pain was one of the least treated pediatric procedures and that there was room for improvement in this area (Bhargave and Young, 2007).

Barriers towards use of interventions included lack of knowledge for available treatments, time constraints and urgency of line placement, inconvenience and inappropriate pain assessment (Zempsky 2008). When addressing pharmacological interventions and treatment of the venipuncture pain, there are a number of factors essential to successful implication and use of the therapy. These include good medication safety profile, ease of use, readily available to staff, reasonable cost, convenient application and high efficacy (Zempsky, 2008). In venipuncture, all of the above factors are important as well as minimal systemic absorption, minimal disruption or delay in the medical procedure and no adverse effect on the success rate of the venous access procedure. Zempsky (2008) concluded that there are a number of effective and safe choices available but concluded with the availability of new rapid onset anesthetic products is increasing and the use of local anesthetics is becoming more practical.

The choices for pain management prior to venipuncture are well documented in the literature. However, as a general limitation, many studies have been conducted in exclusively adult populations. Therefore, due to this limitation a review of both the pediatric and adult-population studies were included in the review for this study.

*J-Tip Needleless Device*

The standard exclusion criteria for most of the following studies were: analgesic use within 6 hours of admission: Glasgow Coma Scale less than 15: a baseline Visual Analog Score greater than 20 or lidocaine allergy. The researchers used the Visual Analog Score (VAS) for evaluation of pain before and after the initiation of the peripheral intravenous access in all the following studies.

Spanos, Booth, Koenig, Sikes, Gracely and Kim (2008) in a randomized controlled trial compared the anesthetic effectiveness of the J-tip needleless jet injection of 1% buffered lidocaine to the effectiveness of ELA-Max for peripheral venous insertion. The study was conducted at a large tertiary-care children's hospital over a one-year period. IRB and consent was obtained for the study. Subjects were children 8 to 15 years of age with a sample size of 70. In addition to the previously defined exclusion criteria used children were excluded from this study if they were unable to use the VAS adequately or correctly, did not speak English or had a neurological condition. Subjects presented to the emergency room and required placement of a peripheral intravenous device. Subjects were randomized to the J-tip group (35) or to the ELA-Max group (35). VAS was used to evaluate the children's pain level. For concurrent validity of the VAS use in this study, the researchers videotaped the children and an observer blinded to the treatment reviewed the videos. The researchers found a high correlation between the VAS score and facial expression. A VAS score with a difference of 10 mm was considered by the researchers to be clinically and statistically significant ( $p < .05$ ) for this study. The VAS was not significantly different for pain scores between the two groups at the start of the study but after peripheral intravenous insertion there was a significant difference ( $p < .0001$ ) with pain

being lower in the J-tip group. The researchers concluded that the J-tip was more effective in the pain control for PIV insertion. The researchers data showed that the 74% of the J-tip group had a VAS of 0 with use of the J-tip and 91% had a VAS of less than 10mm. Limitations in the study were identified as an unequal distribution of children, with a predominant distribution of African Americans in the ELAMAX group, gauge size for needle insertion was not standardized and no follow up or documentation of complications was reported.

Auerbach, Tunik and Mojica (2009) studied the J-Tip jet device to determine whether this device and lidocaine would decrease self reported pain in children undergoing needle insertion in the emergency room. The study design was a randomized double blinded single dose placebo controlled study. The study examined needle insertion pain for children between the ages of 5 and 18 years of age. Exclusion criteria included: Glasgow Coma Scale less than 15; local skin infection; altered level of consciousness; lidocaine allergy; and neurological sensory deficit or developmental delay condition. In the first phase of the study, the participants were either pretreated with jet delivered lidocaine or jet delivered placebo prior to venipuncture. In the second phase of the study, there was no treatment for the control group. The study included a sample size of 150 children between 5 years and 18 years. There were 75 per group initially, and another 47 were enrolled in the second phase of the study as the control group (no procedural pain management provided). The researchers used a chi-square to analysis the categorical independent variables. The pain scores were reported as means with standard deviation of 28mm and a confidence interval of 95%. At the completion of data collection for the third group of subjects a one way analysis of variance was used to determine differences in needle insertion pain between the three groups. A student T-test was used to compare primary outcomes and pain

score between individual scores. For this study statistical significance was set at  $p < .05$ . In this study the difference between the jet lidocaine and the placebo needle insertion pain was not significant ( $p = .227$ ). The needle insertion pain for the control group in phase two of the study was statistically significant and clinically lower in the placebo and jet lidocaine group ( $p < .005$ ). Limitations to this study included lack of research control of parental presences and distraction, use of child life presences, provider skill levels; no control for length of time of EMLA placement and a single location for this convenience study causing concern about generalizability of the study (Auerbach, Tunik and Mojica (2009)).

Jimenez, Bradford, Seidel, Sousa and Lynn (2006) compared the needle free injection system of lidocaine to EMLA for pediatric PIV placement. This study was conducted in a large tertiary children's hospital. IRB approval and informed consent was obtained. The researchers used simple randomization design for their study. The study had two groups with a total of 116 subjects between the ages of 7 years and 19 years. Exclusion criteria were allergy to either Lidocaine or EMLA, diagnosis of methemoglobinemia, treatment with sulfa drugs, pre operative analgesia, sensory deficits in upper extremities and intellectual disabilities. Tools used for the study data collection was a VAS to evaluate the subjects' level of discomfort, with 0 representing no pain and 10 representing worst pain. Pain was rated at two different stages: time of removal of tegaderm from EMLA application or time of lidocaine application with the J- Tip and then at completion of venipuncture. Patients were randomly assigned to EMLA group (59) or J-Tip group (57). This study was terminated after one hundred and sixteen patients were recruited. Variables for this study included pain at time of peripheral intravenous cannulization and number of attempts at venipuncture until successful placement of the peripheral venous device.

The researchers had initially projected that a sample group of two hundred would be required. This sample size was based on a projected difference of 20% between the two groups for successful cannulization and a power of 80% with a 0.05 level of significance. Study enrollment was terminated early because of significant difference in VAS scores despite similar IV cannulation rate. The researchers calculated that continuation of the study had a less than 10% chance of changing the results. The J-tip group had a lower VAS than the EMLA group at time of peripheral intravenous insertion which was statistically significant ( $p = .0001$ ). The researchers controlled for inadequate time of EMLA by removing any patient that had EMLA applied for less than 30 minutes prior to PIV insertion. The results remained statistically significant after removal of the subjects from the analysis ( $p = .0013$ ). Limitations identified in the study included extended EMLA times after application (exceeding the recommended 60 minutes) and disproportionate representation of preteen and adolescents. The authors did compare cost of the J-tip to EMLA and found that the J-tip did not increase costs for the hospital (Jimenez, Bradford, Seidel, Sousa and Lynn, 2006).

### **Summary**

The literature clearly identified that the child receiving venipuncture experiences procedural fear and pain. These experiences impact many aspects of the child's life including causing behavioral issues and potential for needle phobias. The Theory of Unpleasant Symptoms discusses the need to identify and evaluate the impact of "unpleasant sensations or feelings". By evaluating the psychology, physiological and environmental aspects that impact a child undergoing venipuncture the opportunity to intervene appropriately is present and the negative impact of the unpleasant symptom can be prevented.

Procedural fear is less well-researched than procedural pain. These unpleasant symptoms may be synergistic or fear may influence self-report of procedural fear. Therefore, evaluation of both fear and pain may add to our knowledge. Fear scales have recently been developed and validated.

After an extensive review of the current literature, there appeared to be ample evidence to support the need for improved procedural pain management to decrease fear and pain of the venipuncture procedure in pediatric patients. The literature base supported the negative impact of inappropriate or no pain management for simple procedures such as venipuncture. Authors emphasized and study results highlighted the need for procedural pain management. As healthcare professionals, we have an ethical and a moral obligation to all the children we treat to provide best care and this includes pain free venipuncture.

The J tip or similar devices are reviewed in the literature. Studies in the pediatric population have shown that there is a statistically significant difference in procedural pain for the patient –tip use compared to EMLA or no pre procedural pain management. The research supported the rapid onset of the local anesthetic and the ease of use of the needleless systems. This is potentially an ideal system for use in the emergency room, inpatient setting, peri-operative setting or Pediatric intensive care setting. The J-tip buffered lidocaine offers a safe, effective and rapid pre procedural pain and has shown to facilitate successful placement of the intravenous line in some studies.

The barriers and limitation for the use of EMLA was well described and discussed in the literature. Although EMLA is effective in pain management, in the emergency room, pediatric intensive care unit and emergent or urgent situations, EMLA is not an appropriate choice due to

the 60 minute minimum delay for onset of action needed for effective therapy (American Academy of Pediatrics Committee on Psychological Aspects of Child and Family Health, 2001; Young 2005; Zempsky, 2006).

The Joint Commission and hospital agencies continue to improve pain management strategies in pediatric patients both in the desire to prevent discomfort as well as in light of the strong documentation of the negative impact through the lifespan of procedural pain. The Joint Commission has advocated pre procedural pain management for intravenous and venipuncture as a standard for pediatric in the upcoming 2012 accreditation standards. The determination of best practices for pediatric pre-procedural pain management and procedural fear reduction may assist in the future development of improved standards of care, and therefore supported the need for the study.

## Chapter 3

### **Methodology**

The American Society for Pain Management Nursing (ASPMN) has developed a position statement and clinical practice recommendations related to procedural preparation and comfort management. The ASPMN statement clearly recognizes and endorses the need for the assessment and plan to treat procedural fear and pain before painful procedures begins. The statement identifies that procedural fear and pain management is the responsibility of all health care professionals, including nurses. All healthcare providers have a responsibility and ethical obligation to advocate for optimal comfort to protect the best interests of the patient (Czarnecki, Turner, Manda Collins, Doellman, Wrona & Reynolds, 2011). Studies repeatedly have supported the notion that poor management of pain caused by medical procedures, including venipuncture, can negatively impact the patient and result in long term negative effects that may impact a patient throughout their lifespan.

Procedural fear and pain in pediatric patients remains an area in need of further research. As more products with rapid onset of action become available for use relieving children's procedural pain, more studies are needed to verify their efficacy. This research project examined and compared the use of two current therapies for venipuncture and the effect of these therapies on procedural fear and pain in the pediatric patient.

The study examined two research questions:

- 1). Is there a difference in procedural fear scores among pediatric patients requiring venipuncture with the use of buffered 1% lidocaine delivered by J-Tip Needleless system as compared to the standard of care (EMLA)?

2). Is there a difference in pain scores among pediatric patients requiring venipuncture with the use of buffered 1% lidocaine delivered by J-Tip Needleless system as compared to the standard of care (EMLA)?

### **Design**

The design for the study was a prospective, randomized control study design. The study involved a comparison of two treatments. Sealed numbered envelopes with random numbers assigned by the primary investigator were placed in the research unit. Subjects were randomly assigned by selection of a sealed envelope confirming treatment. Subjects were randomized to one of the treatment groups: 1) Standard of care group (EMLA) or 2) J-tip needleless system for buffered 1% lidocaine administration. The two group design was selected to compare the effectiveness of the standard of care compared to the buffered 1% lidocaine delivered by J-Tip needleless system.

### *Setting*

For this study the perioperative setting was selected for a convenience sample due to a high rate of subjects requiring venipuncture. The majority of surgical patients often require venipuncture prior to their respective surgical procedures, whereby making this setting an appropriate one for the proposed study.

The setting for the study was the perioperative suite at a free standing, nonprofit, university affiliated pediatric tertiary care hospital located in the northeast United States. The 147 bed hospital provides surgical treatment for approximately 10, 000 pediatric patients per year. This setting provides care to approximately 35 to 60 children a day requiring surgery or outpatient radiological studies. The perioperative services are provided to patients requiring

anesthesia or sedation for neurosurgery, cardiovascular surgery, orthopedics, urology, GI, ENT, general surgery services or radiology procedures requiring venipuncture. Registered Nurses, who are responsible for preoperative patient preparations, including venipuncture procedures, staff the Perioperative suites. Additionally, the Perioperative Child Life Specialists participate in the care of the preoperative patients by providing procedural preparation and support. This study was limited to this single site setting that has a high rate for use of venipuncture and EMLA as a standard of care for management of venipuncture.

### *Sample*

The target population for this study were children, ages 8 years to 18 years, presenting to the pediatric pre operative suite.

Power analysis was used to determine that a sample size of 150 patients with 75 patients per treatment group was required to determine a medium effect size at 80% power (Cohen's  $d=.5$ ) when applying an independent samples t test to compare the standard of care to the needleless J-tip system. This estimate used a 5% threshold for statistical significance, calculation of a 2-tailed p-value and the possibility of 15% of the subjects not completing the study.

Sample size calculations were based on previous studies in which the needleless system was used. In the study by Zempsky, Bean-Lijewski, Kauffman, Koh, Malviya, Rose, Richards and Gennevios (2008) a 135 patient per group was needed to indicate a difference in pain score with a 90% power using a 5% significance for a 2-sided test.

### **Sample Recruitment**

All children, 8 years to 18 years, presenting to the pediatric preoperative suite at the study site for the study who required venipuncture were screened for inclusion in this project. This study was limited to a single unit that had a high rate of usage for use of venipuncture and EMLA. Subjects were recruited for approximately four months, or until a minimum of 75 patients had been enrolled in each of two treatment groups.

#### *Inclusion and Exclusion Criteria*

For the purposes of this project all children ages 8 years to 18 years of age who presented to the pediatric pre operative suite and who required venipuncture were eligible for participation. Patients were excluded from recruitment into the study if they exhibited local skin infections, had insufficient cognitive skills that precluded their ability to use the CFS or VAS to complete the study tools, history of allergy to local anesthetic, tape or adhesive dressing, had a port or central access in place, had venipuncture at the site within two weeks, met criteria for anesthetic gas or previously enrolled in the study. All the subjects in the study were admitted through the Peri-operative day surgery suite. No emergent or inpatient were included in study as these children all already had established access prior to entering peri-operative suite.

#### **Instruments**

The Instruments selected for this project were the Children's Fear Scale to evaluate level of procedural fear and the Visual Analog Scale to assess pain.

#### **Children's Fear Scale (McMurtry, Chambers, McGarth, 2011)**

The Children's Fear Scale was chosen for the study due to its validity to measure the variables and the ease of use. The tool consists of five faces across a horizontal axis (See Children's Fear Scale, Appendix five). Each face shows a different fear expression, with the left-

most face marked as number one representing an expression interpreted by the developers as no fear at all. As the faces are depicted sequentially to the right side of the page, there is a slow progression to represent increased fear the fifth face being worst fear possible, on the far right. The Children's Fear Scale (CFS) was based on the FACES anxiety scale developed by McKinley and Madronio (2008). The researchers, McKinley and Madronio found support for construct validity, inter-rater reliability and test – retest validity.

In a subsequent study, results supported inter-rater reliability and test–retest reliability of the CFS for measuring children's fear during venipuncture (McMurtry, Noel, Chambers, McGrath 2011). Assessment of construct validity was shown to also have high concurrent convergent validity with another self reported measure of fear (Time 1:  $r_s = .73$  and  $p < .001$ ). For the CFS inter-rater reliability was found to be  $r = .51$  and  $p < .001$  and test – retest reliability was  $r_s = .76$  and  $p < .001$  for measuring children's fear during venipuncture. The CFS was also found when compared to another self reporting measure of fear, to have moderate discriminate validity (Time 1:  $r_s = -.30$  and  $p < .005$ ). The conclusion of the instrument development study was that the CFS was reliable and accurate for evaluating a child's level of fear (McMurtry, Chambers & McGrath, 2011). The CFS tool is notable for the ease of use and adaptability to all age groups making it appropriate for the evaluation of procedural fear in the pediatric population. The CFS is a useful tool as it gives nursing staff and health care providers a way to accurately evaluate a child's procedural fear and to anticipate an appropriate therapy to facilitate effective pain management or to reduce fear for the child prior to venipuncture.

### **Visual Analog Scale**

The Visual Analog Scale is a self assessment psychometric response scale. Use of the VAS scale requires subjects to select from a choice of 0 to 10 on a horizontal scale (see Visual Analog Scale, Appendix six). The rating is 0 for no pain and 10 for worst or most severe pain ever. This tool will be used for the measurement of pain in pediatric patients aged 8 years to 18 years old, who meet the study inclusion criteria and who provide informed consent and assent to participate in the study.

The VAS scale has been chosen specifically for the study, as the instrument had been shown to be valid, reliable and frequently used in similar studies of pre procedural pain management interventions with children 8 – 18 years of age. Extensive evidence supporting that the VAS pain ratings are valid indicators of children's pain experience exists. In a study by Gallagher, Bijurr, Latimer and Silver (2002) the VAS was studied to assess the tools validity and reliability for measuring acute abdominal pain. The researchers had 96 subjects in the study and provided 432 paired measures on the VAS scale. The measurements were taken one minute apart. In the study by Bijur, Silver and Gallagher (2001) the interclass correlation coefficient for all paired VAS scores was 0.97 (95% CI = 0.96 to 0.98). Further analysis using the Bland Altman analysis showed that 50% of the paired measurements within 2mm of each other, 90% within 9mm and finally 95% with 16mm. These findings were reproducible and therefore the researcher concluded that the VAS is a reliable and valid tool for acute pain assessment. Similar findings have been presented by other researchers specifically examining the VAS scale validity and reliability for evaluating acute pain (Gragg, et al, 1996). Children's VAS scores have been evaluated and have shown correlation with parent ratings of children's pain (Luffy & Grove,

2003; Varni, Thompson, & Hanson, 1987). Luffy and Grove (2003) found construct validity of  $r = .44$ ,  $r = .28$   $r = .44$  and  $p = < .001$  between parent and child, nurse and child and nurse and parent. Additionally, a reliability of  $r = .87$  was established. Additionally, health care providers who have been asked to rate pain in children using the VAS have shown correlated ratings (Gragg et al., 1996). VAS scores have been compared in numerous studies to other well validated pediatric tools and have shown to correlate positively. These tools include the Oucher Scale (Aradine, Beyer, and Thompson, 1988; Beyer and Aradine, 1987), the Eland Color Scale (Guariso, Mozrzymas, Gobber, Genini, Zancan and Zacchello, 1990), the Baker Wong faces scale, and the COMFORT Scale (van Dijk, de Boer, Koot, Tibboel, Passchier & Duivenvoorden, 2000).

Another rationale for selecting the VAS for the study was due to the ease of administration, low cost, familiarity by staff and the fact that the scale yields ratio-level data. The VAS has been recommended as most appropriate for children over 8 years of age (Stinson, 2006).

#### *Protection of Human Subjects*

IRB approval was obtained from the University of Connecticut (Appendix F) and from the IRB at the study site (Appendix G). Informed consent and assent for treatment documents (Appendix E) were approved by both IRB boards prior to beginning of study. Parents of all patients that met criteria in this study were asked for consent and all children were asked for assent if age appropriate for the treatment.

Participation in the study was on a voluntary basis. Participants were able to withdraw at any stage of the study without penalty. There was no financial compensation for participation in the study.

All data was collected by either the principle investigator, or CITI certified nurses employed in the perioperative setting. The completed data forms information was entered into a password protected database and was maintained by the principle investigator. The patient's right to privacy was protected at all times by limiting access to the data and identifiers of the information (Appendix D). Only de-identified data was collected. The instruments used in this study were assigned study numbers following return of completed study instruments.

### **Procedure**

Prior to the start of the project there was a required staff education session for all the perioperative Registered Nurses and Child Life Specialists. This staff education session included a description and explanation of the project, education on the use of the J-Tip needleless syringe use and functioning, experience with using the needleless system including time to practice using the device, and time for questions and answers to address concerns or questions from Child life and nursing staff in the study setting. On completion of the education of the staff and IRB approval the project and data collection portion was started. All staff involved in obtaining consent and participating in data collection were CITI trained and were trained on consent process for consistency throughout the process.

Upon admission to the perioperative waiting area, patients were screened for eligibility to participate in the study. If the patient met criteria, the parent and child were approached and asked if there may be an interest in participating in the study on a volunteer basis. The study was

explained to the patient and family. If the family agreed to participate, informed consent was obtained from the parent and assent if age appropriate from the child.

On admission to the assigned bed space in the preoperative area, the researchers completed a demographic form (Appendix A) and instructed the subjects on how to complete both the Children Fear Scale (Appendix B) and Visual Analog Scale (Appendix C) as per description below. The subjects were randomly assigned to a treatment by selection of a pre-filled envelope and were given a research number. A simple demographic data sheet was completed.

Subjects were instructed on how to complete the Children's Fear Scale in the following manner:

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 little 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 before [the needle]."

The Children's Fear Scale was administered at three stages during the process (diagram1). The subjects were required to complete a Children's Fear Scale instrument at completion of the consenting procedure. Then the subjects received the assigned treatment per sealed envelope. Five minutes prior to venipuncture the subjects completed a second children's fear scale tool. Appropriate wait times prior to venipuncture were 60 minutes in the EMLA group and 5 minute after the use of J-tip needleless system. Immediately after venipuncture occurred, the subjects were asked to complete a third Children's Fear Scale and a Visual Analog

Scale to assess their pain and discomfort from venipuncture. This completed the data collection phase for this study.

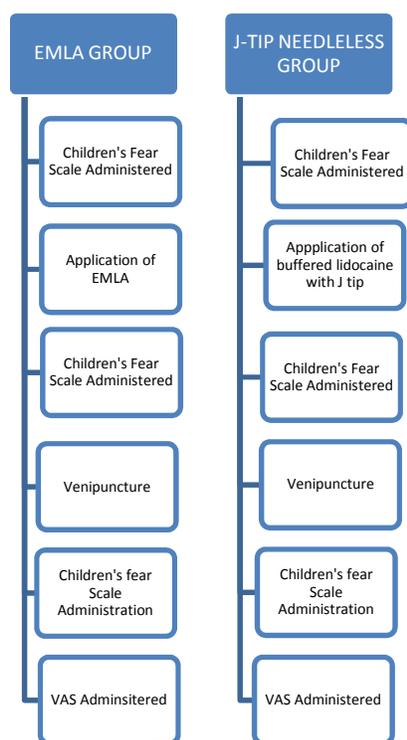
The subject was instructed on how to complete the Visual Analog Scale in the following manner:

Instruction to the patient: On this line with 0 for no pain and 10 for worst or most severe pain ever make a mark on the line to show how much pain you had when they put your IV in.

The collected data and demographics were entered into the password protected computer and the data was kept a locked filing cabinet in the researcher's office.

Diagram 1

*Study diagram for administration of VAS and CFS*



## Data Management

*Planned data management tools*

Data collected during this project was entered into SPSS software and analyzed using SPSS software for Microsoft Windows XP.

*Data Management*

Data included a description of the demographic characteristics of the sample population. Data from each of the pre and post tests were entered into the computer using SPSS software as it was collected. The researcher ensured accuracy of data entry through double checking of the data by a second investigator prior to entry into computer. Data was maintained on a password protected computer in a locked office and all paper copies were stored in a locked filing cabinet in the principle investigators office.

*Data Analysis*

Descriptive analysis was used to compare the demographic data of the subjects. Chi Square and independent t-test analysis were also used to compare the demographic data between the two study groups to examine the equivalence of the study groups. To answer the two research questions for the study, the following analysis were conducted:

*Research Question #1*

Is there a difference in procedural fear scores among pediatric patients requiring venipuncture with the use of the buffered 1% lidocaine delivered by J-Tip Needleless system as compared to the standard of care (EMLA)?

An analysis of variance for repeated measures (RM-ANOVA) was conducted to compare the effect of the J- tip needleless devices to EMLA on pediatric procedural fear with three different measurements using the Children's Fear Scale, this scale provided interval level data. During the

collection period there were three different data collection points on the Children's Fear Scale. These measurements were taken pre EMLA or J-Tip application, prior to venipuncture and post venipuncture. The fear score was used as the repeated factor for the analysis between the J-Tip lidocaine group and the EMLA group. The RM-ANOVA was used to compare the data.

### *Research Question # 2*

Is there a difference in pain scores among pediatric patients requiring venipuncture with the use of the buffered 1% lidocaine delivered by J-Tip Needleless system as compared to the standard of care (EMLA)?

An independent t-test analysis was selected to answer research question two. The study design selected utilized ratio-level data and will consist of two independent groups with equal sample size in each group and we tested the assumption that the data is from a normal distribution and that the two populations had the same variance and thus the same standard deviation between the two groups. The independent t-test was used to compare the means of the two groups of data sets.

### *Summary*

Pediatric venipuncture is well documented to be extremely stressful to a pediatric patient. The need for improved management of procedural fear and pain remains a challenge to pediatric staff. The purpose of this study was to examine the J-Tip needleless system compared to EMLA for the management of procedural fear and pain and to deliver optimal care to the patient. The research design chosen for this study was a randomized controlled study, which compared the effectiveness of the standard of care (EMLA) to the use of a new innovation the J-Tip needleless system upon children's procedural fear and pain scores in the preoperative setting.

An in-depth staff educational session was presented to the staff including child life specialists to ensure accuracy and understanding of the research project. All children admitted to the perioperative area who met criteria for the study were eligible. The data collection portion occurred over a four month period, or until 75 subjects had been recruited in each group. There was randomization to two groups during the data collection. The subjects were randomized to group one, who received the current standard of care (EMLA) or group two that received the J-tip needleless injection of 1% buffered lidocaine.

Instruments selected for use in the study, the Children's Fear Scale and the Visual Analog Scale, were reliable tools for measuring procedural fear and pain and are age appropriate for the sample group.

Findings from this study could identify an alternative therapy to the current standard of care to reduce fear and pain in the pediatric patient undergoing venipuncture. An alternative therapy to the current standard of care that has the advantage of rapid onset would be beneficial to children in the emergency department and in the critical care areas of the hospital that currently underutilize EMLA due to time constraints and need to rapidly gain intravenous access in a child.

## Chapter 4

### Results

The purpose of this study was to implement a new device to deliver preprocedural pain medications to a child prior to venipuncture and to evaluate procedural fear and procedural pain scores among subjects when receiving standard of care (EMLA) for procedural pain versus the J-tip device. A randomized control design was utilized for this study. The middle range Theory of Unpleasant Symptoms, by Lenz and Pugh (1997) served to guide the development and implementation of this research project.

Research questions addressed during the conduct of this study were:

- 1) Is there a difference in procedural fear scores among pediatric patients requiring venipuncture with the use of the J-Tip Needleless system as compared to the standard of care (EMLA)?
- 2) Is there a difference in pain scores among pediatric patients requiring venipuncture with the use of the J-Tip Needleless system as compared to the standard of care (EMLA).

### **Description of the Sample**

The sample was a sample of convenience. The setting was the perioperative suite at a free standing, nonprofit, university affiliated pediatric tertiary care hospital located in the northeast United States. All children admitted to the perioperative suite between the ages of 8 to 18 years of age were screened for eligibility from November 2012 to February 2013. A total of 150 subjects were recruited in this study. Each group had 75 subjects. Data collection took place over a period of 12 weeks.

Demographic data included gender, age and race. Participants were predominantly Caucasian, but the sample was otherwise evenly distributed by gender and age (Table 1). All, but 6 subjects (0.4%) were healthy, without co-morbid chronic conditions.

Table 1

*Characteristics of participants*

Participant demographics		EMLA	J-Tip	<i>p</i>
	N= 150	n = 75	n = 75	
<b>Gender</b>				
Male	78	43 (57%)	35(43%)	.25
Female	72	32(43%)	40(57%)	
<b>Age</b>				
8 – 10	14	8 (11%)	6 (11%)	.80
11-12	33	18(24%)	15(20%)	.73
13-14	39	16(21%)	23(31%)	.24
15-16	37	20(27%)	17(23%)	.74
17-18	26	13(17%)	13(18%)	1
Missing	1			
<b>Race</b>				
White / Caucasian	113	56 (75%)	57 (76%)	1
Hispanic / Latino	19	9 (12%)	10 (13%)	1
Native American	1	1 (1%)	0 (0%)	1
Asian	1	0 (0%)	1 (1%)	1
Hawaiian/ Pacific Islander	1	1 (1%)	0 (0%)	1
African American/Black	13	8 (6%)	7 (9%)	1
Prefer not to answer	2			
<b>Chronic Conditions</b>				
Asthma	1			
Anxiety	1			
ADHD	1			
Ulcerative Colitis	2			
Spherocytosis	1			

### **Effects of J-Tip system verses EMLA on Procedural Fear**

Research question #1: “Is there a difference in procedural fear scores among pediatric patients requiring venipuncture with the use of the J-Tip Needleless system as compared to the standard of care (EMLA)?”

An analysis of variance for repeated measures (RM-ANOVA) was conducted to compare the effect of the J- tip needleless devices to EMLA on pediatric procedural fear among three different time points using the Children’s Fear Scale. The three time points were: (1) time point 1, before use of the J-Tip or standard of care (EMLA), (2) time point 2, immediately prior to initiation of the intravenous device placement, and (3) time point 3, after successful placement of the intravenous device. The fear score among 3 time points was used as the repeated factor for the analysis and the intervention group (J-Tip lidocaine or standard of care - EMLA) was used as the between subject factor.

The RM-ANOVA showed a statistically significant difference in fear scores among 3 time points,  $F_{2,148} = 7.213$  and  $p = .002$  ( $< .01$ ) (Table 2). The pairwise comparisons showed no statistically significant difference among fear scores between time point 1 and 2 ( $p = .830$ ), but did show a statistically significant difference between time point 2 and 3 ( $p = .023$ ) and time point 1 and 3 ( $p = .009$ ). The RM-ANOVA showed that there was no significant interaction effect between the J-Tip needleless group and the standard of care (EMLA) group among 3 time points,  $F_{2,148} = 1.125$  and  $p = .314$ . Therefore it was concluded that there was no difference between the two groups in fear but that there was a similar reduction in fear from the time period one (pre venipuncture) to time period three (post venipuncture).

Table 2

*Children's Fear Scale Scores for EMLA and J-TIP*

Time period	J-Tip			EMLA		
	n	M	SD	N	M	SD
Pre intervention	75	1.25	1.175	75	1.11	1.226
Pre IV insertion	75	1.25	1.242	75	1.24	1.303
Post IV insertion	75	1.07	1.357	75	0.79	1.166

**Effects of J-Tip system verses EMLA on Pain**

Research question 2 “Is there a difference in pain scores among pediatric patients requiring venipuncture with the use of the J-Tip Needleless system as compared to the standard of care (EMLA)?”

After placement of the designated intravenous device as described, the subject was asked to complete a visual analog scale and place a mark on a scale of 0 to 10 to describe the degree of pain experienced from the intravenous device placement.

The assessment tool selected provided ratio-level data from two independent groups with a sample size of 75 in each group. We tested the assumption that the data was from a normal distribution and that the two populations had the same variance and thus the same standard deviation between the two groups.

An independent samples t-test was conducted to compare the pain scores for the EMLA group and the J-Tip needleless system. Levene's test showed that equal variance was not assumed; therefore the results from the analysis of equal variances not assumed were used. There

was a significant difference in pain scores between the EMLA group ( $M = 1.63$ ,  $SD = \pm 1.659$ ) and the J-Tip group ( $M = 2.99$ ,  $SD = \pm 2.586$ ),  $t(126.057) = -3.833$ ,  $p = .000$  ( $<0.001$ ) (see Table 3). Children who received EMLA had lower scores indicating less pain.

The frequency distribution table for pain intensity scores by intervention emphasizes an overall low patient rating for pain with the majority of patient reporting pain scores less than 2 and less than 36% percent of patients reporting pain scores greater than 3 (Table 4).

Table 3

*Pain scores for EMLA vs J-Tip*

	M	SD	t-test	P
EMLA	1.63	1.659	3.833	< .001
J-Tip	2.99	2.586		

Table 4

*Pain Score Distribution*

Pain Score	Frequency	Percent	EMLA	J-Tip
0	37	24.7%	23	14
1	29	19.3%	16	13
2	28	18.7%	20	8
3	22	14.7%	8	14
4	12	8%	3	9
5	6	4%	2	4

6	6	4%	2	4
7	4	2.7%	0	4
8	3	2%	1	2
9	1	.7%	0	1
10	2	1.3%	0	2

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### Summary

The current standard of care for venipuncture initiation is EMLA. This randomized control trial examined two research questions related to pediatric venipuncture. The first research question examined procedural fear scores among pediatric patients requiring venipuncture with the use of the J-Tip Needleless system as compared to the standard of care (EMLA). The study results showed no statistically significant difference between the J-Tip Needleless system as compared to the standard of care (EMLA) for procedural fear. A pairwise comparison showed that there was no significant difference in fear scores between time point 1 and 2, but there was a statistical difference between time point 1 and 3 and time point 2 and 3.

The second research question examined during this randomized control study was designed to compare pain scores among pediatric patients requiring venipuncture with the use of the J-Tip Needleless system versus the standard of care (EMLA). The results showed that there was a statistically significant difference between the two treatments with the standard of care group self reporting lower pain score intensity than the J-Tip group.

## Chapter 5

### **Discussion**

The purpose of this randomized control trial was to implement a new device to deliver preprocedural local anesthetic to a child prior to venipuncture and to evaluate procedural fear and procedural pain scores among subjects when receiving standard of care (EMLA) for procedural pain verses the J-tip device. This project included recruitment and education of 6 Peri-operative nurses as research assistants for the implementation and evaluation of the treatments. All nurses involved in the study received Collaborative Institutional Training Initiative (CITI) training prior to educational sessions as required by the institutional IRB for protection of human subjects.

The final sample consisted of 150 subjects between the ages of 8 to 18 years requiring intravenous device placements prior to surgery or procedures within the peri operative area. As a result of this randomized controlled trial, we found no statistically significant difference in procedural fear scores between the two groups. Using the Children's Fear Scale at 3 different time periods there was no statistical difference among the groups during time 1 and time 2 in how much procedural fear occurred but there was a statistically significant result between time and fear for time 1 and time 3.

The finding that there was no difference between the two groups but that fear decreased with the therapies was consistent with the current literature. There has been growing effort by pediatric psychology practitioners to evaluate and explore methods of assessing and measuring fear accurately. McMurray, Chambers and McGarth (2011) clearly defined fear as a negative emotion that is thought to arise as an alarm to a dangerous and life threatening situation.

“Needle pain” has been identified by researchers as one of the most feared experiences on the part of pediatric patients. In combination, procedural fear can increase the pain sensation (McMurtry, Noel, Chambers & McGarth, 2011). Procedural fear impacts children in many different ways, including physiologically increasing pain perceptions, (Rhody & Meagher, 2003) increased emotional distress, and increased autonomic stimulation (Hugart, McGarth & Pardos, 2011). From a psychological perspective, there is well documented research evidence supporting a phenomenon of catastrophic thinking in children and the subsequent development of needle phobias, extreme distress, and panic to the perceived threat to self (Hugart, McGarth & Pardos, 2011). Children with procedural fear become more fearful and reactive to the environment leading to increases in fear. If the unpleasant symptom of procedural fear is recognized early on in the assessment phase and is managed effectively, venipuncture procedures will have less of a negative impact or long term effect on children and their families.

Humprey, Boon, Chiquit van Linden van der Heuvell and van de Wiel (1992) evaluated 223 children undergoing venipuncture to gain scientific data on the occurrence of acute behavioral distress in children that are undergoing venipuncture. The researchers found that distress decreased with age and maturity but that the process of venipuncture still caused some distress in adolescents (Humprey, Boon, Chiquit van Linden van der Heuvell and van de Wiel, 1992).

The need to decrease the fear of needles is essential as this fear can have lifelong health impacts. There is an opportunity and need for health care professionals to take steps to diminish the procedural fear of needles and to be active in the prevention of the development of needle phobia (Nir, Paz, Sabo and Potasman, 2003). Nir, Paz, Sabo and Potasman in their study

concluded that fainting was associated with a bad past needle experiences, needle fear and unreasonable fear. The researchers' final conclusion was that fear of needles and bad experiences potentially negatively impact the young adult

Procedural fear can be decreased in such a way to have less of an impact on the child. There are a number of interventions that can be used. Cavender, Goff, Hollon and Guzzette (2004) studied the effectiveness of parental involvement on pain, procedural fear and distress in the pediatric patient during venipuncture. This study had the purpose of determining the effectiveness of parental positioning and distraction on pain. In pediatrics, including the parents to hug and hold during procedures to ensure the child feels secure and as safe as possible is an effective intervention and provides comfort. There was no statistical significance difference for pain between the two groups, but the self reported scores for the group receiving distraction and comfort position during the procedure was found to be lower. For fear the group receiving parental distraction and positioning their fear rated lower.

In Martin, McGrath study, children were asked to use the scale in reference to their own pain and for another acute pain that they did not have. Children reported fearful and catastrophic thinking for their own pain but not for other types of pain, suggesting that fear of pain is learned and not a generalized individual trait (Martin, McGrath, Brown & Katz, 2007). The authors concluded that pain-related fear may develop from one's chronic, personally meaningful, and emotionally laden own pain experiences. These findings support the need to consider fear as well as pain when addressing venipuncture in the pediatric pain and that unaddressed fear may be a consequence of inappropriate management of pre procedural pain management in the pediatric patient undergoing venipuncture.

Although multiple studies have raised concern that the noise of the J-Tip activation would increase fear, anxiety or distress in the child the literature did not investigate this finding. This study showed no difference in fear between the two groups.

There was a statistically significant difference between the two treatment groups related to pain scores. Using the Visual Analog Scale to evaluate pain experienced by the intravenous device placement the results were statistically significant with the EMLA group scoring lower on the pain scale than the J-Tip group.

The results of this study differed from the results of a number of pediatric research studies reviewed in the literature. The majority of the research studies reviewed concluded that the J-Tip had statistical significance over EMLA or ELA-MAX. Jimenez, Bradfordm Seidel, Sousa and Lynn (2006) completed a randomized control study with 116 patients comparing the J-Tip to EMLA. The researchers compared pain scores using a VAS after venipuncture initiation. The EMLA was in place for an average length of time of 69 minutes prior to initiation of venipuncture. The findings of this study showed lower pain scores in the J-Tip group than the EMLA group.

In a randomized control study on peripherally inserted central catheters by Fry and Aholt (2001), researches compared the effectiveness of the local anesthetic, buffered lidocaine and no interventions prior to the placement of a peripherally inserted line. The purpose of the study was to evaluate whether buffered intradermal lidocaine or EMLA reduce pain experienced as compared to no anesthesia in adult patients requiring placement of a peripheral inserted central catheter. Subject's pain was evaluated with a Visual Analog Score (VAS) and a McGill Pain questionnaire. The researchers concluded the differences for the VAS were not statistically

significant between the three groups. The McGill scale results were analyzed for the same subjects and the researchers concluded that there was a statistically significant difference between both therapies compared to no therapy. This study demonstrated efficacy of EMLA for pain relief and patient satisfaction, but researchers emphasized the intervention disadvantages included a long wait time for full effect and cost of EMLA (Fry, Aholt, 2001). The J-Tip in this study showed statistical significance in that there were lower pain scores compared to no intervention.

Spanos, Booth, Koenig, Sikes, Gracely and Kim (2008) in a randomized controlled trial compared the anesthetic effectiveness of the J-tip needleless jet injection of 1% buffered lidocaine to the effectiveness of ELA-Max for peripheral venous insertion. The researchers concluded that the J-tip was more effective in the pain control for PIV insertion.

Auerbach, Tunik and Mojica (2009) studied the J-Tip jet device to determine whether this device and lidocaine would decrease self reported pain in children undergoing needle insertion in the emergency room. The study design was a randomized double blinded single dose placebo controlled study. The needle insertion pain for the control group in phase two of the study was statistically significant and clinically lower in the placebo and jet lidocaine group.

After an extensive review of the current literature, there appeared to be ample evidence to support the need for improved procedural pain management to decrease fear and pain of the venipuncture procedure in pediatric patients. The literature base supported the negative impact of inappropriate or no pain management for simple procedures such as venipuncture. Authors emphasized and study results highlighted the need for procedural pain management.

Although the results of this study differed from a number of previous studies in that the standard of care EMLA had statistically significant a better pain management, there was evidence that the J-Tip did provide effective pain management for venipuncture and should be considered a viable option if the clinical situation prohibits the appropriate time required for the effective application of EMLA. The limitations of this study may have affected the results although these limitations were similar in a majority of the reviewed studies. Another factor that could have affected the differences in the results of the reviewed studies and this study was that there was no or limited discussion on preparation of patient for procedure, parental presence and use of supportive therapies which can have an impact on both procedural fear and pain. In this study one of the identified imitations was that there were no controls for the presence of support services and parental supervision.

Studies in the pediatric population have shown that there is a statistically significant difference in procedural pain for the patient that has had EMLA or buffered lidocaine via the J-TIP compared to no pain management ( Fry & Aholt 2001, Auerbach, Tunik and Mojica 2009).

### **Adverse Events**

Use of lidocaine whether topical or transdermal has documented risk. During the study there was one complaint of stinging after the use of the J-Tip by one subject that resolved after 5 minutes. There were no other documented rashes or adverse events.

### **Implications for Practice**

Findings from this study offer support that procedural fear and pain management prior to venipuncture or placement of an intravenous device is important. EMLA use resulted in statistically lower self reported pain intensity with venipuncture than lidocaine instilled with the

J-Tip needleless device. EMLA was placed for 60 minutes on all the EMLA subjects to maximize effectiveness of the local anesthetic affect.

Unfortunately, in the different practice areas within the hospital setting, both outpatient and inpatient areas, the recommended 60 minute wait time for efficacy of EMLA is not always possible, as treatment delays may be clinically impractical. Studies support that time to effectiveness of EMLA is one of the major barriers to its use (The committee on Pediatric Emergency medicine and the Section of Anesthesiology and Pain medicine, 2004), MacLean, Obispo & Young, 2007, Young, 2005). Performing the procedure prior to the time of anesthetic effectiveness or without anesthetic results in inadequate or with no pain control prior to the placement of the intravenous device in the pediatric patient.

This study revealed that the current standard of care (EMLA) was more effective in providing local anesthetic and decreased pain with venipuncture. While the results of this study did not show that the J-tip had improved or equal pain management to EMLA, this device may be useful in cases where a 60-minute time delay is not an option. The introduction of an alternative form of pain control that has a rapid onset may be beneficial to the pediatric patient in the emergent or urgent setting where the 60 minute wait time for the EMLA to be at maximum effectiveness is not an option. In 2012 the Joint Commission endorsed a requirement for pre procedural pain management for all pediatric patients prior to intravenous insertions. The J-Tip can offer an alternative to current standard of practice when time prevents the use of EMLA. Despite the statistically significant difference in pain scores for EMLA and the J-Tip, the J-Tip did provide effective and rapid anesthesia prior to venipuncture and insertion of an intravenous device as evidenced by the mean pain score of 2.99 (SD 2.586).

As hospitals are exploring solutions to pain reduction for venipuncture, the J-Tip has additional advantages when there is a time limiting factor preventing the use of standard of care (EMLA). This study also revealed that procedural fear is a factor in the process of placing an intravenous device or initiating venipuncture. Although there was no significant difference in procedural fear between the two groups, there was a significant difference in fear score among the pre and post venipuncture scores. As nurses we need to be aware of the patients fear and utilize all available resources to manage and decrease fear. These resources include EMLA, J-Tip, appropriate words and teaching, child life services and distraction to reduce the procedural fear accompanying venipuncture.

### **Implications for further studies**

More research is needed regarding modifying and improving preprocedural pain control and factors affecting this phenomenon. Limitations of this study reveal several areas for future research. First, there is a need for more research regarding health care providers' interactions with the families and patients, use of environmental and non pharmacological methods to manage and reduce procedural fear and pain and preventing the development of long term complications such as needle phobias or fear and mistrust of health care providers. Outcome studies examining the effects of procedural fear and pain related to venipuncture in pediatrics are lacking in the literature. In addition there are a limited amount of studies examining the long term outcome and effects of interventions to treat pediatric venipuncture pain. Pain responses or reactions to subsequent venipuncture or needle procedure are a clinically important outcome that needs to be researched further.

A second area for further research is the appropriate selection of patients for the J-tip intervention. Further research on the potential use of the J-tip in the younger child for venipuncture pain control is recommended. Like this study, previous venipuncture research has been limited to children that are able to complete a self assessment tool. The limited J-tip literature examines the use of the J-tip in infants for lumbar puncture but there is almost no literature examining pain control in the infant or toddler using the J-Tip system. Further study for this age group would provide evidence to support standard of care for all pediatric patients.

Third, the limited ethnic and racial diversity in the convenience sample recruited for this study prevented analysis of results by ethnicity or race. Three African-American subjects who had been previously enrolled in the study requested enrollment when returning for a second procedure. All had received the J-Tip device and reported that they preferred this method of topical anesthetic placement for venipuncture. Their reported preference contradicts the study results, but suggests there may be racial difference in efficacy that was not able to be assessed given this patient sample.

Fourth, there is a small amount of pediatric studies evaluating nursing skills and competence related to years in practice. This was not assessed in the current study; and this area of nursing competency requires more research. Current nursing experience levels vary from novice to expert, but once staff completes orientation they assume similar roles and are considered to have similar procedural competence. Skill comparison for venipuncture site selection and successful placement of venipuncture devices has tremendous implications and further research is required.

Fifth, cannula size for the intravenous device initiation is not standardized or well researched. The Pediatric patients are often accessed with either a 24 gauge or a 22 gauge intravenous device based on the assessment of the vessel by the registered nurse inserting the device. The 24 gauge device has a smaller needle for insertion. Further studies are needed in this area to evaluate whether the insertion of a venipuncture device with a smaller needle may inflict less pain entering the skin and vessel.

As more products with rapid onset of action become available for relieving children's procedural pain, studies are needed to verify their efficacy in the pediatric population. These studies need to examine the risks and benefits of new therapies as compared to standard of care and cost to benefit ratios.

### **Implications for Policy**

Given the current emphasis and recommendation of the Joint Commission on the management of preprocedural pain management and the increasing awareness by the general public in viable options available for pain management, this is the ideal time for policy development and reeducation of all medical personnel. This study supports policy for current standard of practice but also presents a second option if time constraints prevent standard of care.

The findings in this study support the use of EMLA or standard of care for pre procedural pain management and present a second option that is less effective but an option if time does not permit the use of standard of care.

### **Implications for Education**

Ongoing educational initiatives and educational offerings are critical for practice changes to occur. Pediatric procedural fear and pain evaluation and prevention should become part of the

intake process for all patients. The introduction of an alternative to EMLA for patients that are limited by time and urgency of need for placement of a venipuncture device has the implication of introducing further education to staff on the importance of the management of procedural fear and pain.

The introduction of a new device and the findings from this study offer support for educating staff prior to practice changes. The education of staff on preprocedural pain management will ensure that there is appropriate local anesthetic used for children undergoing venipuncture, including for children that are unable to wait the required 60 minutes for the EMLA or standard of care to achieve maximum effect.

The use of standard of care verses J-Tip and the use of the J-tip syringe would potentially be incorporated into competency validations for all registered nurses as well as part of the orientation process for all new hires.

### **Limitations of the study**

There were several limitations to this study. First, there was not a normal distribution between the two groups of subjects. There were a larger percentage of white / Caucasian subjects than the other race in the groups. This may have impacted the study and was not a true representation of all the races. Therefore, findings from this study may not be generalizable to other races.

Second, cannula size for the intravenous device used was not standardized. The patients either received a 24 gauge or a 22 gauge intravenous device based on the assessment of the vessel by the registered nurse inserting the device. The 24 gauge device has a smaller needle for

insertion and, although further studies are needed in this area, the insertion of a venipuncture device with a smaller needle may inflict less pain entering the skin and vessel.

Third, there was no control for skill level or number of attempts by the registered nurse inserting the intravenous device. The PACU staff experience levels varies from novice to expert. There was inadequate documentation about number of attempts or reasons for multiple attempts. This limitation had potential to affect both the procedural fear and the pain scales.

Fourth, there was no expert or company educational representative available to assist in the training of the staff regarding the use and ideal placement of the J-tip for maximum pain relief. This may have impacted the subjects by differing techniques in use of the J-Tip device. Training was done by pamphlet and educational videos supplied by the manufacturer as well as the company website. Currently the J-Tip manufacturer and supplier are based out of California and currently do not have any company representatives in the northeast.

Lastly, children have different threshold for pain and experience pain levels differently. Although the most reliable tool available was used in the conduct of this study, there was concern that the variance in pain experiences that occur among children may affect or guide the pain score reporting. One subject verbalized feeling a pinch and scored 7 on the VAS. Although when questioning further it was not painful but rather discomfort, however the score of 7 was retained per protocol. This issue has been identified in other local anesthetic studies as a limitation (Auerbach, Tunik, Mojica, 2009). Some of the children had spent time with the child-life specialist due to their age or fear prior to the initiation of the EMLA or J-tip and had been prepared better than other patients. Some of the patients had been on a pre admission tour with child life for preparation for their upcoming surgery. Although the Child Life Specialist's

services are offered to all children many of the older children did not want this service or preparation for their venipuncture or surgery. There was minimal documentation of which of the subjects had received either of these two services and therefore it was not possible to control or account for these factors.

### **Summary**

Pediatric venipuncture is one of the most painful and feared procedures for pediatric patients and is recognized as the leading cause of procedure-related pain in hospital settings and pediatric emergency rooms (Zempsky, 2008). Appropriate pain management for venipuncture and minor procedures has become a focus of hospital accrediting organizations. Organizations are being encouraged to develop standards, policies and practice guidelines to manage venipuncture pain.

This study showed no statistically significant difference between EMLA and the J-Tip needleless system in procedural fear. The study did show statistically significance difference between the pre intervention and post venipuncture fear scores. Both EMLA and J-Tip are effective in managing pain prior to intravenous device. Although the EMLA group in this study had statistically significant results for less pain for venipuncture than the J-Tip group, the J-tip offers pre procedural pain management when there is not the opportunity to delay the procedure or venipuncture for an hour and therefore may be a viable alternative to no pain management when time does not allow for EMLA application.

As pediatric care providers it is essential that we provide the best care to our patients. Venipuncture has been identified by multiple studies as a significant source of pain and distress for children (Zempsky, 2008, Humphreys, Boon, van Linden van den Heuvill, van de Weil,

1992, Young , 2008). Barriers to use of pre procedural pain management includes lack of knowledge, time constraints, incompetence and lack of appropriate training for use of products available (Zempsky, 2008). Many of the available local anesthetics have been shown to be safe and highly effective in reducing pain and procedural fear. As health care providers we should be aware and educated on the effects both positive and negative of untreated venipuncture pain and make choices to reduce the pain and fear for a child requiring venipuncture.

### **Conclusion**

The literature supports that venipuncture is one of the foremost procedural fear provoking experiences for children and that failure to treat preprocedural fear and pain appropriately can lead to psychological and physiological symptoms. The purpose of this randomized control study was to examine and compare the standard of care (EMLA) to a new needless device for delivery local anesthetic prior to venipuncture. The study examined the procedural fear scores and pain experienced by the subjects exposed to venipuncture.

This study used the Theory of Unpleasant Symptoms as a clinical guide. Use of this theory yielded the desired effect of creating an awareness of the need for pre procedural pain management for venipuncture and the successful implementation of the study. Further evaluation and implementation of the J-Tip into the current standards will be explored as a result of this research study. Currently the standard of care (EMLA) should remain the optimal choice for venipuncture. When the 60 minute effectiveness time of EMLA is deleterious to the patient, the J-Tip provides another option for venipuncture pain management.

A survey suggested that nurses' perceived improved preprocedural pain management for venipuncture not only had a positive impact on children and families but also improved nurses'

performance and job satisfaction (Papa & Zempsky 2010). This study supports the use of the standard of care (EMLA) for pre procedural pain management and presents a reasonable alternative, the j-tip device, for circumstances in which the standard of care cannot be used due to time constraints.

Education and policy change is essential as is creating an awareness of the importance of preprocedural fear in the pediatric patient and the importance of providing effective pain management for venipuncture.

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## Appendix A

## Demographic form

Subject Number

Demographic Form

Gender

0 = Male

1 = Female

Age

Present Age

8 to 10 years

11 to 12 years

13 to 14 years

15 to 16 years

17 to 18 years

9999 = Missing

Race

Race Background

1 = Hispanic or Latino

2 = American Indian/Alaska Native

3 = Asian

4 = Native Hawaiian/Pacific Islander

5 = Black or African American

6 = White

9999 = Missing

Chronic Conditions

## Appendix B:

Children's Fear Scale (CFS; McMurtry et al., 2011)

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 little 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 little 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.



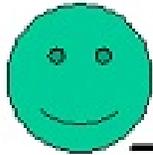
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McKinley, S., Coote, K., & Stein-Parbury, J. S. (2003). Development and testing of a faces scale for the assessment of anxiety in critically ill patients. *Journal of Advanced Nursing*, 41, 73-79. For more information: contact C. Meghan McMurtry at [cmcmurtr@uoguelph.ca](mailto:cmcmurtr@uoguelph.ca)

Appendix C:

Visual Analog Scale

Instruction to the patient: On this line with 0 for no pain and 10 for worst or most severe pain ever make a mark on the line to show how much pain you had when they put your IV in.



**No pain**



**Worst pain  
ever**

---

0 1 2 3 4 5 6 7 8 9 10

## Appendix D:

## Consent and Assent for Study

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES Connecticut Children's Medical Center

CCMC Principal Investigator: Petronella Stoltz APRN

**Collaborators :** Sandra Bellini, NNP, APRN, DNP; Renee Manworren, PhD, APRN, David Marcello, MD, Julie Veilleux, RN; Jen Coiffi, RN; Mary Beth Dautrich, RN; Theresa DeSocio, RN.; Daniel Novak, RN; Evelyn Buckley. RN

**Department:** Pediatric Critical Care Phone: (860)545-9805

**Title of Research :** The J Tip Needleless System Versus Standard of Care for Venipuncture: Comparison of Procedural Fear and Pain in Pediatric Patients.

(In this form “you” refers to “you and your child”.)

**Purpose of Research:**

We are conducting a research study designed to compare the effectiveness of management of pre procedural fear and pain management in the pediatric patient requiring venipuncture (blood draw or IV) by comparing the current standard of care (EMLA) numbing cream applied by hand to the J-Tip needleless system to numb the skin by air tight injector.

Your child is being invited to take part because s/he requires the placement of a peripheral intravenous device (IV).

In order to decide whether or not you wish your child to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures and possible benefits. Once you understand the study, you will be asked if you wish your child to participate; if so, you will be asked to sign this form.

**Procedures:**

If you agree to have your child take part in this study, one of the investigators will take an envelope that is sealed and upon opening the envelope will determine whether your child receives the standard of care (EMLA) or the J-tip needleless application of 1% lidocaine.

We will then explain the Children’s Fear Scale and the Visual Analog Scale to you and your child and ask your child to complete the scale prior to application the therapy.

Five minutes prior to venipuncture your child will be asked to complete a second children’s fear scale tool.

Appropriate wait times prior to venipuncture will be 60 minutes in the EMLA group and 5 minutes after the use of J-tip needleless system. Immediately after venipuncture occurs your child will be asked to complete a third Children’s Fear Scale and a Visual Analog Scale to assess their pain and discomfort from venipuncture. This will complete the studies data collection phase.

We will also collect information regarding your child from his/her medical records. This will include his/her age and race. All research data will be collected and entered into a password-protected electronic database maintained by the PI. Only individuals directly involved in this research study will have access to collected data. Individual patient

medical information obtained as a result of this study is considered confidential and disclosure to third parties is prohibited. Such medical information may be given to the patient's personal physician or to other appropriate medical personnel responsible for the patient's welfare.

All paper files will be stored in a locked file cabinet in a locked office and access is limited to members of the local study research team.

It is likely that data from this study will be published in scientific and medical journals and presented at scientific and medical conferences. In all such cases, project data will be presented in such a way that no participant could possibly be identified.

The duration of the participation in the study will only occur during this visit and participation is complete at the end of the final Children's Fear Scale and a Visual Analog Scale.

#### Risks and Inconveniences:

The J-Tip device is FDA approved for use to numb the skin (topical anesthetic). However, the 1% lidocaine can cause temporary redness, stinging and swelling at the application site.

This study will add an additional 15 minutes to your stay at Connecticut Children's Medical Center.

There is a small risk that confidential health information about you will inadvertently be released. Any information about your child obtained from this research will be kept as confidential (private) as possible.

#### Benefits:

While there may be no direct benefit to you for participation in this study the information we obtain from this study will help us provide an alternative therapy for pain management related to venipuncture (blood draws), that has rapid onset and that is painless to children. We will use the results of this study in planning for future alternatives to current standard of care that will aim to decrease the occurrence of painful venipuncture and blood draws in children. We expect that this trial will improve the care we provide to children who require venipuncture or peripheral venous access.

#### Alternative Treatments:

If you do not wish to participate, the following alternatives are available.

The standard of care (EMLA) or no topical pain management will be alternatives. The J-Tip needleless application of buffered 1% Lidocaine for pre-procedural pain management is not available at Connecticut Children's Medical Center.

#### Economic Considerations:

You will not be compensated for participation. The local anesthetic will be provided without cost to you or your insurance company.

#### Voluntariness and Right to Withdraw:

Your decision for your child's participation is voluntary. You may refuse to allow your child to participate, and you may withdraw your consent and discontinue your child's enrollment in the study at any time. Your decision whether or not to allow your child to participate will not affect your child's future medical care at Connecticut Children's Medical Center or any other benefits to which you are entitled.

You will be told of any medical consequences of withdrawing early from the study. You will also be told of any new information that may influence your willingness to continue your child's participation in the research.

#### Confidentiality:

The confidentiality of your child's records will be maintained in accordance with applicable state and federal laws. You may request that your child's records be released to your personal physician. However, no information that would reveal your child's identity will be released or published without your permission.

Information about your child and his/her health which may identify him/her may be used by or given to:

The Federal Drug Administration (FDA) .

Representatives from the Connecticut Children's Medical Centers Institutional Review Board (IRB) (The committee that reviews, approves and monitors research on human subjects).

Those individuals at Connecticut Children's Medical Center who are responsible for the financial oversight of research including billing and payments.

Members of the research team.

Connecticut Children's Medical Center Research Monitor.

If drugs and/or devices subject to the U.S. Food and Drug Administration (FDA) regulations are involved, it may be necessary for this consent form and other medical records to be reviewed by the FDA and the company providing the test substances.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

In Case of Injury:

If your child is injured as a direct result of participating in this study, please contact the Principal Investigator, *Petronella Stoltz* at (860)545-8468. However, you have not waived any legal rights to which you are otherwise entitled by participating in this research.

Any additional, non-emergency treatment related to this injury is available at Connecticut Children's Medical Center but such treatment will not be free of charge. For further information regarding treatment and compensation for injury, please contact the Principal Investigator, *Petronella Stoltz APRN* at (860)545-8468

Questions:

The Principal Investigator, Petronella Stoltz, APRN (name) is willing to answer any questions you may have about the study, or address any concerns or complaints, and may be reached at (860)545-8468. Future concerns or questions about this study may also be directed to Petronella Stoltz, APRN.

If you have questions about your child's rights as a research subject, or if you would like to discuss problems, concerns, or questions, obtain information, or offer input about a particular research study, you may call the Institutional Review Board Office at Connecticut Children's Medical Center at (860) 545-9980. In the event of a research-related injury, please contact Petronella Stoltz at (860)545-8468.

Please read the above information carefully and discuss this study with the principal investigator (or designee) and his or her staff. You may obtain information about the results of this study when it is completed, by contacting the principal investigator.

Based on the information provided, you agree to allow your child to participate in this study.

Upon signing, you will receive a copy of this form. All the questions you have at this time have been answered.

As the parent/guardian, I have legal responsibility for the care and custody of ( ). I willingly agree to allow my child, \_\_\_\_\_, to participate in this investigation, The J Tip Needleless System Versus Standard of Care for Venipuncture: Comparison of Procedural Fear and Pain in Pediatric Patients. The purpose, procedures, and length of my child's involvement have been explained to me.

---

Parent/Guardian or Subject if 18 or older

---

Date

---

Assent (Optional for older minors where no

---

Date separate assent is provided)

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Second parent signature line [*when required*  
by the IRB or Study Sponsor]

---

Date

I have fully explained to the parent/guardian or subject if 18 years of age or older, the nature and purpose of the above described research and the risks involved in its performance. I have answered and will answer all questions to the best of my ability. I will inform the participant of any changes in the procedure or the risks and benefits, if any should occur during or after the course of this study.

---

Investigator/Person Obtaining Consent

---

Date

---

Witness (where required)

---

Date

**Assent** [(for those participants capable of understanding the study in simplified terms and assenting in writing)]

Your nurse and parents have talked to you about being part of a study to lessen the pain that happens with IV starts. The purpose of this study is to see if the J-Tip needleless syringe with lidocaine works better than EMLA cream to make the pain less when your nurse starts the IV. You are being invited to take part in this study.

1. You will be asked to look at a Children's Fears Scale which has pictures of 5 different faces.
  - 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 little 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].
  - We will ask you at three different times to have a look at these faces and choose the one that shows how scared you are.
  - The three times will be after we get your permission, after we give you the numbing medicine and after your IV start.
2. After you have had your IV placed, your nurse will ask you to look at a straight line called a Visual Analog Scale.
  - On this line the 0 means no pain and 10 is worst or most severe pain ever.
  - We will ask you to make a mark on the line to show how much pain you had when your nurse put your IV in.
3. The researcher will keep the 3 Children's Fear Scales that you have drawn on and the Visual Analog Scale.

You may ask questions about this study at any time

You can decide not to be in the study, or after entering the study you can decide that you want to be taken out of it. Whatever you decide to do, your surgeon and nurse will not be angry with you and will continue to treat you as his/her patient.

---

Participant's Assent

---

Date

Reason why Participant did not sign: \_\_\_\_\_

---

## COMPARISON OF PROCEDURAL FEAR AND PAIN IN PEDIATRIC PATIENTS 93

**Documentation that Assent Was Sought** [for Younger Child or Subjects with Cognitive or Developmental Delays (where appropriate)]

[For younger participants or those with cognitive or developmental delays, verbal assent may be possible for some participants with sufficient ability to understand the study, and where feasible based on the nature of the study. The participant's verbal assent may be required (when feasible based on cognitive maturity, developmental maturity, and the context of the study) for research that does not offer the prospect of direct benefit. (Please refer to "INSTRUCTIONS" page 1 of this document.)

I am satisfied that Dr. \_\_\_\_\_ has discussed these procedures with my child in a manner and to an extent that is appropriate for his/her capacity to understand at the present time. My child has been informed of the procedures that will be performed, the reason for such treatment, and the associated risks. In addition, all of the alternative procedures have been described. In research that offers no prospect of direct benefit, my child's participation is voluntary.

---

Parent/Guardian

---

Date

Reason why verbal assent was not obtained: \_\_\_\_\_

---

Appendix E: HIPPA Form

Connecticut Children's Medical Center

Authorization to Use and Disclose Protected Health Information

for Research Purposes

Title: The J Tip Needleless System Versus Standard of Care for Venipuncture: Comparison of Procedural Fear and Pain in Pediatric Patients.

Sponsor (if applicable): None

Investigator: Petronella Stoltz APRN, Sandra Bellini APRN, NNP, DNP, Renee Manworren, PhD, APRN, David

Marcello, MD, Julie Veilleux, RN; Jen Coiffi, RN; Mary Beth Dautrich, RN; Theresa DeSocio, RN.; Daniel Novak,

RN; Evelyn Buckley. RN

Beginning April 14, 2003, Federal Privacy Laws require the study doctor to get your authorization (permission) to use or give out any health information that might identify your child.

1. What Protected Health Information (PHI) may be used, given, or otherwise accessed by others?

PHI to be collected in this study are :

- Your child's age
- Your child's gender
- Your child's race
- Any Chronic illnesses your child may have

2. Who may use, give out, or otherwise access PHI about your child?

- Connecticut Children's Institutional Review Board
- Research Monitor from Department of Research
- FDA and other government regulatory agencies

3. What will the information be used for?

- You/your child's PHI will be used for: examining if age, race, gender or chronic illness makes a difference in procedural pain or fear in children receiving intravenous s(IV) starts.

4. Will this form expire?

- This form will expire at the end of the study June 2013 .

5. May I revoke this authorization?

You may also revoke your permission in writing for the continued use of PHI about you/your child by sending your request to *Petronella Stoltz APRN*.

6. What will happen if you decide not to sign this form?

- It will not affect your treatment, or any benefits at Connecticut Children's for which you are eligible.
- You may not be allowed to participate in this research study.

7. Once this PHI is disclosed, it may no longer be protected under the Federal Privacy Rule.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Appendix F: IRB University of Connecticut letters of approval for study



University of Connecticut  
*Office of Research Compliance*

To: Roslyn Edson, SM, MA, CIP  
IRB Vice-Chair  
Director, Human Research Protection Program  
Connecticut Children's Medical Center  
Suite 2E  
80 Jefferson Street  
Hartford, CT 06106

From: Douglas Bradway, M.A., CIP   
Office for Research Compliance

Date: October 24, 2012

Re: Acceptance of IRB Review – Designation as IRB of Record

Protocol Title: Pain Free Pediatric Peripheral Intravenous Placements: J tip vs EMLA  
CCMC IRB Number: 12-084  
CCMC Principal Investigator: Petronella Stoltz, APRN  
UConn Co-Investigator: N/A  
UConn Student Investigator: Petronella Stoltz, APRN  
UConn Student Investigator Major Advisor: Sandra Bellini, DNP, APRN  
UConn Protocol Number: CCMC12-084  
UConn Proposal Number: N/A

On October 24, 2012, the Institutional Review Board of the University of Connecticut (UConn) accepted the review conducted by your institution for the study noted above. The Storrs IRB will accept the CCMC IRB review of the study noted above. Per the cooperative agreement in place, the IRB of the Connecticut Children's Medical Center will serve as the IRB of record for this study, and, therefore, be responsible for all continuing review and review of amendments. Additionally, the UConn IRB is to be informed of all instances of non-compliance or unanticipated problems, related to this study, should they occur.

Please forward copies of IRB approval letters and study related activities to the UConn Office of Research Compliance.

cc: Petronella Stoltz  
Sandra Bellini

*An Equal Opportunity Employer*

438 Whitney Road Extension, Unit 1246  
Storrs, Connecticut 06269-1246

Telephone: (860) 486-8802  
Facsimile: (860) 486-1044  
web: compliance.uconn.edu

APPENDIX G

IRB Connecticut Children's Medical Center Letter

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IRB Office  
860-545-9980  
860-545-8830 (fax)

Institutional Review Board  
**Expedited New Protocol Approval Notification**

October 22, 2012

Petronella Stoltz, APRN  
Pediatric Critical Care  
282 Washington Street  
Hartford, CT 06106

Re: CCMC IRB NUMBER **12-084**

Pain Free Pediatric Peripheral Intravenous Placements : J tip vs EMLA

**IRB APPROVAL DATE:** October 18, 2012

**IRB APPROVAL VALID THRU:** October 17, 2013

**PROGRESS REPORT DUE DATE:** September 17, 2013

Dear Ms. Stoltz:

The Connecticut Children's Medical Center IRB approved the above referenced study by expedited review on October 18, 2012 for a period of 12 months.

The Connecticut Children's IRB determined that this research satisfies the requirements of 45 CFR 46.111 and expedited review categories 45 CFR 46.110 1(b) (ii), (5) and (7).

**The signature of one parent on the consent form is required.**

**Assent is required for this research, as described in the IRB application.**

**Connecticut Children's IRB approval for this protocol will expire on October 17, 2013.** If you wish to request continuing approval of this study, you must do so by **September 17, 2013** by completing a Continuing Review form in IRBManager. The IRBManager website can be found at <https://login.irbmanager.com>.

Version Date: December 12, 2011

As the Principal Investigator, you are responsible for complying with reporting requirements as described in the HRPP Standard Operating Procedures that are posted on the HRPP Intranet site. For example, you are responsible for reporting unanticipated problems involving risk to subjects or others.

You are also responsible for obtaining IRB review and approval in writing before changes are made to approved protocols or consent forms unless the change is necessary to eliminate an immediate hazard to the subject (in which case the IRB must then be notified at once).



10/22/12

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Roslyn Edson, SM, MA, CIP  
IRB Vice Chair  
Director, Human Research Protection Program

Date

*All IRB correspondence addressed to the IRB Office should include your IRB protocol #.  
Connecticut Children's DHHS Federal-Wide Assurance Number is: FWA00004706*