

EFFICACY OF EMLA CREAM IN REDUCING VENIPUNCTURE PAIN IN A  
SHORTER APPLICATION TIME IN THE PEDIATRIC POPULATION

A Research Grant Proposal

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Submitted in partial satisfaction of  
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Abstract

of

EFFICACY OF EMLA CREAM IN REDUCING VENIPUNCTURE PAIN IN A SHORTER  
APPLICATION TIME IN THE PEDIATRIC POPULATION:

A RESEARCH GRANT PROJECT

By

Stephanie Huang

Venipuncture such as blood draw and intravenous (IV) access are commonly performed in the emergency department (ED) as a diagnostic and treatment intervention. The pain associated with these procedures is inadequately treated and poorly managed in the ED despite safe and effective topical anesthetics, which are available. Effective procedural pain management is essential in reducing physical pain and prevention of psychological and emotional trauma children experience with venipuncture. Research has been done and shows Eutectic Mixture of Local Anesthetics (EMLA) cream is fully effective after application of 60 minutes. However, a sixty minute application time might not be feasible in the ED. The purpose of the study is to evaluate if EMLA cream is as effective at 15 minutes and 30 minutes as it is at 60 minutes. This will be a quantitative, randomized, and One Way ANOVA design study. A convenience sample of 969 pediatric patients' ages 5 to 12 years old who visit the Sharp Chula Vista Emergency Department (SCVED) will be utilized for this study. Samples will be categorized into three groups with different EMLA cream application times: group 1 at 15 minutes, group 2 at 30 minutes, and group 3 at 60 minutes. The Wong-Baker Faces Pain Rating Scale (WBFPRS) and patients' heart rate (HR) will be used for pain assessment before and after EMLA intervention. The One-Way

ANOVA test will be used to determine if there is a change in pain level and heart rate in the means of the three groups. The f-test statistic will be used to evaluate main effects. If a significance is found, a Bonferroni post hoc will be performed to determine which of the timed EMLA group means is different by comparing one group against the others. The study will use a significant level of  $p \leq 0.05$  with a confidence interval of 95%.

Key Words: EMLA cream, pain, pediatric population, procedural pain, topical anesthetic, venipuncture

### *Statement of Problem*

Venipuncture pain is inadequately and poorly managed with an underutilization of safe and effective topical anesthetics available in the pediatric population in the ED. This can lead to an increase in physical pain and is psychologically and emotionally traumatic for children to experience.

### *Sources of Data*

According to the National Institute of Health (NIH), the prevalence of pain and inadequate pain management in patients is well-documented (n.d.). NIH encourages interdisciplinary and multidisciplinary research in the understanding of pain and the treatment available to those suffering in pain. NIH supports research in identifying effective pain management in multiple areas such as intervention involving combinations of pharmacological, non-pharmacological, self-management and behavioral interventions. Furthermore, interventions to reduce pain that are customized to the group and tailored to the individual, new methods to manage pain in cognitively impaired individuals or those unable to verbalize their pain, new techniques for managing pediatric pain, and clinical trials to establish best pain management practice are encouraged (National Institute of Health, n.d.).

### *Conclusions Reached*

Currently, there is a lack of research being performed with evaluating the efficacy of EMLA cream in reducing venipuncture pain in a shorter application time in the pediatric populations in the ED. Due to the fast pace of the ED and the need for rapid diagnostic tests and intravenous hydration, sixty minutes of EMLA cream application time may not be realistic in the ED. Furthermore, increased nurse to patient ratios need time efficient strategies. Therefore, the

study to evaluate the efficacy of EMLA cream in reducing venipuncture pain in the pediatric population at a shorter timeframe in the ED is being proposed.

Denise Boren, Committee Chair

Denise Boren, PHD, RN

5/10/2016

Date

## DEDICATION

To my daughter, Amanda Lee, you are my aspiration and motivation in life!

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## CHAPTER ONE: INTRODUCTION

Pain is one of the main symptoms that prompt patients of all ages to come to the hospital seeking health care treatment. These patients' pain can further be aggravated by various treatment procedures such as intravascular access and blood draw. Pain is a complex phenomenon because the experience of pain is very individualized and can be influenced by various factors. Factors such as past pain experiences, present coping skills, fear, parental anxiety and reaction can influence the child's perception of pain. According to the International Association for Study of Pain, pain is defined as "an unpleasant sensory or emotional experience associated with actual or potential tissue damage, or described in terms of such damage"(2012). Pain management in the pediatric population presents challenges for Advance Practice Nurses (APNs) and nurses because most children are unable to express their pain subjectively and accurately. As a result, infants and young children's pain is often undertreated and untreated (Clark, 2011). According to a study conducted by Kellogg, Fairbanks, O'Connor, Davis and Shah (2012), patients younger than 2 years with severe pain received less analgesics than teenaged patients with severe pain. This can lead to long-term chronic pain and physiological and behavioral consequences (American Medical Association (AMA), 2013; Clark, 2011; Helms & Barone, 2008).

Effective pain management in the pediatric population is essential in the physical and psychological healing process of health. According to Huth and Moore (1998), "pain management is central to the domain of nursing, and a nurse-initiated holistic reassessment is paramount to pain control" (p.28). Thus, pain is considered the fifth vital sign. Although there are many clinical practice guidelines that guide APNs and nurses in the management of pain, there is still a gap in the treatment of pain especially in the pediatric population. The role of an

APN is to advocate and identify effective pain measures in reducing procedural pain in the pediatric population.

## **Background**

Many children experience acute pain as the result of injury, illness and diagnostic or therapeutic procedures (Shavit, Hadash, Knaani-Levinz, Shachor-Meyouhas, & Kassis, 2009) in the acute care environment. Procedural pain is defined as “the unpleasant sensory and emotional experience that is produced by an act or activity directed at or performed on an individual with the object of improving health, treating disease or injury, or making a diagnosis” (Ortiz, Lopez-Zarco, & Arreola-Bautista, 2012, p.2701). Procedural related pain in the pediatric population is underutilized despite the availability of topical analgesics (Cregin et al., 2008). Cregin et al. (2008) reported an “inadequate interventions to minimize pain for initial procedures results in a stronger pain response with subsequent painful procedures even when adequate analgesia is administered” (para.1). Young children are unable to fully express their pain during these invasive procedures, which contributes to improper pain management during invasive procedures. Invasive procedures such as blood collection and intravenous injection are the most painful physically, psychologically and emotionally traumatic for children to experience (Huff et al., 2009). Many preschoolers who do not comprehend the logic for these painful procedures might perceive them as a punishment for their bad behavior (Ahn et al., 2013). This can lead to long-term psychological and behavior problems.

Ortiz, Lopez-Zarco, and Arreola-Bautista (2012) conducted a prospective, descriptive and cross sectional study to investigate the prevalence of procedures that can induce anxiety or pain in children at the ED. A total of 252 children and adolescents ages 8-16 years old were asked to rate their pain and anxiety using a 100-mm visual analogue scale. The study showed peripheral

catheterization and vascular puncture were the most frequently reported procedural pain. Fifty-eight children rated peripheral catheterization as severe, 55 children rated as moderate, and 58 rated as slight. This finding is significant because peripheral catheterization and vascular puncture are often performed in the emergency department. The study found procedural pain and anxiety in children remained inadequately and poorly managed.

EMLA cream is a local anesthetic cream consisting of lidocaine 2.5% and prilocaine 2.5% and has shown to be effective in reducing pain or distress of common pediatric procedures such as venipuncture, venous cannulation, and lumbar puncture (AMA, 2013; Huff et al., 2009; Shavit et al., 2009). EMLA cream was the first topical anesthetic available and it has been extensively used and studied. EMLA cream is used topically on intact skin and takes full effectiveness after 30-60 minutes of application.

Sharp Chula Vista Medical Center (SCVMC) is a 343-bed community hospital and the ED sees about 60 pediatric patients a month. SCVMC is not a children's hospital but it does have a neonatal intensive care unit. The average ED waiting time is about one hour and 49 minutes. SCVMC does use EMLA cream as a topical anesthetic agent but its use is not in the standardized protocol in the ED. Currently, there is no procedural pain protocol for the pediatric population in the ED. Venipuncture pain is the most traumatic and painful procedure for children and most distressing for parents or caregivers. Pain is also one of the main measures of patient and parent satisfaction and venipuncture pain is often rated as the least effectively managed in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS).

To improve clinical practice, patients and parents satisfaction, APNs need to advocate effective use of current topical anesthetics to develop protocol and implementation to increase

the use of topical anesthetics during venipuncture procedures. Currently, there is a lack of research conducted in assessing the feasibility of EMLA cream at a shorter timeframe.

Therefore, research to evaluate the effectiveness of EMLA cream in reducing venipuncture pain in a shorter application time in the ED is being proposed.

### **Statement of the Problem**

Venipuncture pain is inadequately and poorly managed with an underutilization of safe and effective topical anesthetics available for the pediatric population in the ED. This can lead to an increase in physical pain and is psychologically and emotionally traumatic for children to experience.

### **Aim of Proposal**

To evaluate the effectiveness of EMLA cream in reducing venipuncture pain in shorter application time for the pediatric population in the ED. According to EMLA manufacture, the cream takes effect in 30-60 minutes. Currently, there is a lack of research conducted in assessing the feasibility of EMLA cream in a shorter timeframe of 60 minutes or less that are feasible to implement in the ED.

### **Significance to Nursing**

The significance of the study is to improve clinical practice, improve patients and parents satisfaction with care, and to develop and implement effective procedural pain protocol in the ED.

## **Research Question**

The research question in the study is; is EMLA cream as effective in reducing venipuncture pain at 15 minutes and 30 minutes as it is after 60 minutes application time. Research has shown EMLA cream is effective in reducing venipuncture pain at a 60 minute application time. Therefore, 60 minutes is used to be the benchmark time in the study. Research has shown a 5 minute EMLA cream application time provided adequate IV cannulation pain relief in the adult population (Smith & Leonard, 2001). However, 5 minutes application time might be too short for the pediatric population. Therefore, a 15 minute application time, which is three times the adult strength, will be used for the study. Hopkins, Buckley, and Bush (1998) conducted a study to evaluate the effectiveness of EMLA cream in alleviating intravenous venipuncture pain in children between the ages of 1 and 5 years old. EMLA cream application times were between 30 and 300 minutes. The study showed EMLA cream provided effective analgesia when applied at a minimum of 30 minutes. Therefore, the study will use the same 30 minutes application times to compare its effectiveness against 15 minutes and 60 minutes.

There are two aims for the proposed study. The first aim is to assess if there is a statistical significant change in pain level and heart rate in the three groups. The second aim is to identify the optimal EMLA cream application time.

## **Hypothesis**

A hypothesis is made that one of the groups will have a statistically significant difference from the others. This hypothesis will be accepted if there is a significant change in pain level and heart rate in 15 minutes and 30 minutes compared to the 60 minutes application time. If there is no significant change in pain level and heart rate, the hypothesis will be rejected. This

indicates that 15 minutes and 30 minutes EMLA cream application time are as effective as 60 minutes in reducing venipuncture pain.

### **Research Variables**

The independent variable is time of EMLA cream. The dependent variables are change in pain level and heart rate within and between the three groups. The measureable outcomes are a change in HR and pain level reported by patients post EMLA intervention.

### **Barriers**

There are barriers that prevent the use of EMLA cream in the ED. A lack of time is a major barrier as most nurses and physicians deem 30-60 minutes after application time is too long. Another barrier is EMLA cream causes initial blanching and vasoconstriction that may affect successful intravenous catheterization (IV) (Huff et al., 2009). This may result in multiple IV venipunctures instead of one. As a result, an IV procedure that is supposed to be atraumatic became a traumatic one for the pediatric patients.

Other barriers include limited access and the need for a physician order (Baxter et al., 2013; Ortiz et al., 2012). Nurses' beliefs and attitudes can also be a barrier and affect their ability to manage pain adequately (Rieman & Gordon, 2007; Stanley & Pollard, 2013). A nurse's belief that pain is to be expected in children during a hospital stay often leads to suboptimal pain management. Melliush and Payne (2006) conducted a quantitative study on 45 nurses' views about the experience of pain during venipuncture by infants and toddlers, and the pain management techniques they use. The result showed there is a gap between theory and practice. The study showed that nurses' believe infants and toddlers feel more pain than older children. The study also demonstrated nurses have a broad knowledge of pharmacological and non-pharmacological techniques for pain management such as the use of topical anesthetic

cream, having parents present during procedures and use of distraction as age appropriate to draw attention away from pain. However, only 64% of nurses suggested the use of topical anesthetic cream prior to the procedure and only one nurse mentioned the use of glucose administration for infant care. Some nurses believed the use of topical anesthetic cream should not be used on infants and the use of cream was time consuming.

## CHAPTER TWO

### **Literature Review**

Many researches have shown EMLA as an effective topical anesthesia in reducing procedural pain at 60 minutes application time in both adult and pediatric populations. Very few research studies have been done to evaluate the effectiveness of EMLA cream in reducing venipuncture pain in less than 60 minutes application time. These research studies have used EMLA cream as an independent variables and pain level as their dependent variable.

A single blind, randomized, controlled study was conducted by Shavit, Hadash, Knaani-Levinz, Shachor-Meyouhas, and Kassis (2009) on patients ages 12 to 16 years old in the emergency room. The study was performed to examine the efficacy and safety of LidoDin cream in reducing pain associated with venipuncture by comparing it with the proven EMLA cream. The pain was assessed immediately after the procedure was done using the Visual Analog Scale (VAS). The one-way analysis of variance was used to compare the VAS scores. The results showed EMLA is equally safe and effective as compared to the new topical anesthetic cream LidoDin when both creams were applied at a duration of 60 minutes.

Another double-blind, randomized, controlled study was done to compare the analgesic efficacy of EMLA and lidocaine iontophoresis for peripheral venous cannulation (Moppett, Szypula & Yeoman, 2004). Twenty-eight patients had EMLA cream applied to the dorsum of one hand for 60 minutes followed by sham iontophoresis. The sham cream was applied for 60 minutes followed by 10 minutes of 2 mA iontophoresis with lidocaine 4% and epinephrine on the other hand. An anesthetist, who was not aware of the treatment allocation, inserted 18G cannula into veins of both hands within 5 minutes of completion of iontophoresis. Patients rated on the amount of pain using a 10 point verbal rating scale. The result showed pain scores were

lower for the EMLA treated hands than for the iontophoresis hand ( $p=0.023$ ). There was one reported intolerable burning sensation from iontophoresis. There were also reported cases of common but brief episodes of erythema and paresthesia on the iontophoresis side. The study concluded that EMLA has a superior quality of analgesia even though lidocaine iontophoresis's effect is quicker than the EMLA cream.

A barrier of EMLA cream use is that it causes vasoconstriction, which affects the nurse's ability to visualize the vein (Huff et al., 2009). However, research shows otherwise. A prospective, randomized, non-blinded study conducted by Baxter et al. (2013) was used to determine if placing EMLA cream at ED triage improves venipuncture success. The study consisted of 267 samples aged 0-18 years. The result showed patients with EMLA application perceived less pain with venipuncture and improved venous access rate when the cream was applied within 1 to 2 hours in the emergency department. However, this length of time may not be feasible for the fast pace of the ED and can potential keep patients longer than needed. At Sharp Chula Vista Medical Center ED, physicians' goal is to assess, diagnose, and dispose patients accordingly within 1-2 hours. This is to increase patients' satisfaction score by decrease the length of ED stay, decrease over crowding, and free up ED beds for acutely ill patients.

Huff et al. (2009) conducted a descriptive, quantitative design study to investigate whether the application of heat placed to a child's potential IV site after the application of EMLA cream decreases vasoconstriction. A convenience sample of 30 Caucasian children ranging in age from 8-12 years old was included in the study at a pediatric hospital. A vascular ultrasound directly measured the vein prior to and 1 hour after EMLA cream application and 2 minutes after heat application. The children's pain level was obtained immediately prior to and after venipuncture using the Wong-Baker Faces pain rating scale. The result showed there was a

significant increase in vein visualization from pre-application of heat to post application of heat. It also showed there was an 80% success rate with the first attempt of IV insertion. This indicates heat application can counteract the adverse effect of vasoconstriction that exists with EMLA cream.

Tak and Bon (2005) conducted an experiment to study the effects of EMLA and a placebo cream on reported pain and observed distress associated with venipuncture, and to investigate effects of procedural information before and distraction during venipuncture in the outpatient center in the Netherlands. A total of 136 Dutch children, 73 boys and 63 girls between 3 and 12 years of age participated in the study under five experimental and a control condition reported their pain at venipuncture on visual scales. The application of the EMLA cream or the placebo conditions was done by a double-blind procedure. Children who received the cream intervention spent one hour in the waiting room with their parents while they waited for the EMLA cream to reach its effect. The Oucher scale was used to measure pain with children younger than 6 years and the Visual Analogue Scale was used with children of 6 years and over. A research assistant administered both scales immediately after the venipuncture. The result showed EMLA cream is effective in reducing the pain associated with venipuncture ( $p < 0.05$ ). The placebo cream diminished the reported pain but the effect of the EMLA cream was greater. The study found procedural information and distraction showed no effects on reported pain.

Ahn et al. (2013) conducted a pre- and post-test design study to assess the effects of EMLA cream on pain response of preschoolers during venipuncture. The study was done on hospitalized children between the ages of 36-72 months during the period of July 2010 to November 2010. The study measured pain response during venipuncture by using the Faces

Pain Rating Scale on children, the procedural behavior checklist by nurses, and the visual analog scale by mothers in addition to measure children's pulse rate and oxygen saturation level. The results showed the EMLA cream was effective in decreasing the pain response during venipuncture when applied for 60 minutes.

A repeated-measures design study of 32 premature infants was conducted by Hui-Chen et al. (2013) to assess the effectiveness of the EMLA cream in minimizing venipuncture pain in neonatal intensive care units. The study used the scores of the Neonatal Pain, Agitation and Sedation Scale (N-PASS) measured before, during and 10 minutes after venipuncture with and without EMLA cream use. The result showed a significant decrease in N-PASS scores during venipuncture with EMLA cream use, using the paired t-tests. There were not any significant changes in N-PASS scores before, during and 10 minutes after venipuncture with EMLA cream using the analysis of repeated analysis of variance.

The previous studies on the effectiveness of EMLA cream were conducted based on the application time of at least 60 minutes. Some healthcare providers may choose not to use EMLA cream simply because of this reason. However, a study did show that EMLA cream is effective in achieving analgesia after an application time of 30 minutes. The study used a randomized, placebo-controlled, double-blind method to examine the efficacy of EMLA cream with respect to alleviation of venipuncture pain at intravenous induction of general anesthesia and to identify the optimal application time (Hopkins, Buckley, & Bush, 1988). The study was done with 111 children between the ages of 1 to 5 years old. An operating department assistant using both the verbal rating scale and the visual analogue scale for pain assessment. The result also showed significantly lowered pain scores in children treated with EMLA cream. This was the only study that was done to evaluate the effectiveness of EMLA in shorter application times. Research was

also done showing that a 5-minute application of EMLA was adequate to reduce pain associated with intravenous cannulation in the adult population (Smith, Holder, & Leonard, 2002). Smith, Holder, and Leonard (2002) conducted an experimental study by comparing perceived levels of pain associated with IV between an experimental group who received a 5 minute application of EMLA cream to a control group who received a 5 minute application of a placebo cream. The study consisted of 40 patients undergoing ophthalmic surgery that required an IV intervention. The Verbal Numerical Scale was used to report the level of pain perception post IV intervention. The T-test was computed to assess differences in the level of pain perception with IV cannulation between the two groups and showed significant difference in the experimental group treated with EMLA cream (t-value=-3.35, p=.002).

### **Summary**

According to literature, most EMLA research has been conducted at 60 minutes application time. There has been little to no research conducted to investigate the potential effectiveness of EMLA cream in a shorter timeframe in the pediatric population. Therefore, there is a need for further studies to evaluate the efficacy of EMLA in a shorter application time in the pediatric population (Rogers & Ostrow, 2004) in the ED.

### **Conceptual Framework**

The conceptual framework used to guide the proposed study is the concept of pain (see Figure 1). According to Montes-Sandoval (1999), the critical attributes of pain are described as a dominating, unpleasant, distressful, unwanted, and uncomfortable experience. Pain is a neurophysiological, psychological and socio-cultural response to a noxious stimulation. Pain is a variable, subjective and difficult to explain sensation that cannot really be shared or perceived by others. It is an aversive sensation to an actual or potential threat of injury or damage to body

and/or mind. Pain is expressed in the form of verbal and/or non-verbal communication and a unique experience that serves as a protective mechanism for self-preservation. It is also a reciprocal interaction with anxiety and mental misperception leading to distressful thoughts (Montes-Sandoval, 1999). Based on these critical attributes, APNs need to not only assess a patient's pain subjectively if possible; they also need to assess a patient's physical, psychological and cultural display of pain.

The antecedents of pain are identified as “emergence of an internal or external circumstance that creates noxious stimuli to the nociceptor, which cause discomfort, the patient is aware of the discomfort physically or psychologically, and the patient perceived the noxious stimuli as pain” (Montes-Sandoval, 1999, p. 940). This implies pain is individualized and it is what the patient says it is. However, this concept of pain will be a challenge in the younger pediatric population. Many in the pediatric population are unable to express their discomfort appropriately due to their cognitive and language development. A two year old child will not be able to verbally express his or her experience of the discomfort to the nurse the way a nine year old child can. Therefore, age appropriate and reliable tools should be used to measure children's pain.

The consequences of pain consist of the “individual either with verbal or non-verbal communication demonstrates neurophysiological, psychological and/or socio-cultural responses to the perception of pain” (Montes-Sandoval, 1999, p. 940). The individual may or may not have adequate pain relief response. The individual may also use available protective coping mechanisms in an attempt to maintain self-preservation. The individual will receive various forms of intervention by others in an effort to relieve or to cope with the pain. Lastly, the individual's pain will either decrease, increase or remain the same. Negative consequences such

as fear and anxiety can place additional strain on the body and can occur because of poor pain management. Prevention of such consequence is the goal in managing pain. Anticipation of a child's need and frequent monitoring of the effectiveness of the intervention is essential in preventing these negative consequences.

The empirical referents are identified as subjective and objective. The subjective empirical referents are verbal and non-verbal experiences and expressions of feelings that are observable and measurable behaviors (Montes-Sandoval, 1999). These behaviors can be silence, crying, or withdrawal from social interaction. The objective empirical references of pain is manifested physiologically such as vomiting, increased heart rate and elevated blood pressure. These indicators are easily observed, assessed and measured using various instruments. APNs can utilize the knowledge of the concept of the subjective and objective indicators in assessing the pediatric population more accurately.

### **Summary**

Based on the concept of pain, venipuncture is a noxious stimuli that a child will perceive as painful. This perception and the actual venipuncture will result in pain and manifest as subjective and objective symptoms. The study will measure a child's objective symptoms using the HR because it can be easily obtained. The subjective symptom will be measured using the WBFPRS, a reliable self-reporting scale. A self-report of pain measurement should be used to measure a patient's pain if possible because pain is subjective and it is what the patient says it is.

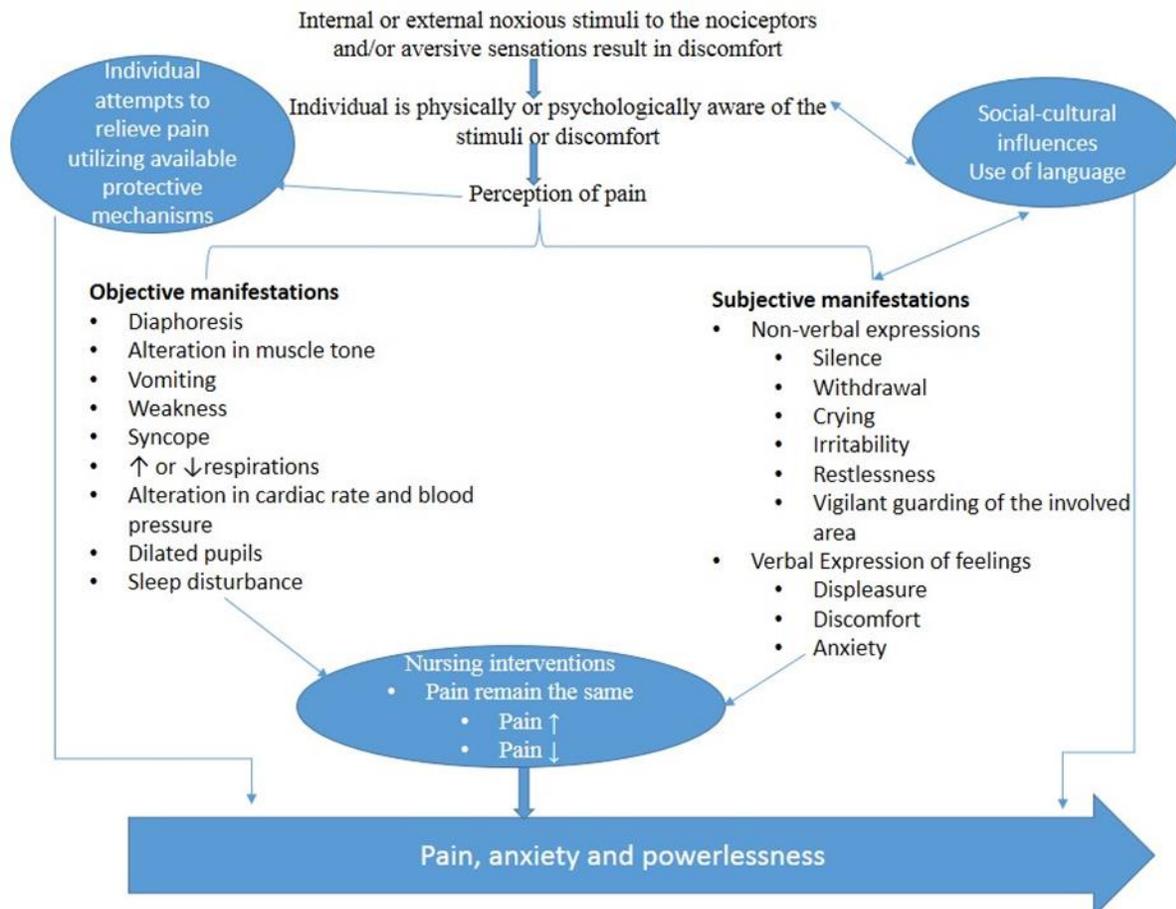


Figure 1. The Concept of Pain.

## CHAPTER THREE

### **Methodology**

#### **Design**

This is a quantitative and One-Way ANOVA designed study. The research question in this study is; Is EMLA cream as effective in reducing venipuncture pain in 15 minutes and 30 minutes as it is in 60 minutes application time. The purpose of this question is to assess if there is a significant change in pain level and heart rate between the three time groups. Therefore, a One-Way ANOVA design is used to determine whether a statistically significant difference in the means of the three groups exist (Kellar & Kelvin, 2013). A hypothesis is made that at least one of the groups will have a statistically significant difference from the others. A measurement of pain and HR level before and after EMLA cream treatment will be obtained using the same sample.

#### **Setting**

The study will be conducted at Sharp Chula Vista Emergency Department on Mondays, Fridays, and Saturdays from 10 am until 6 pm to recruit participants. These days and times are considered the busiest days in the ED. The participants will be randomly assigned a number and placed into three groups. The first participant who met the inclusion and exclusion criteria will be assigned to Group 1, second participant will be assigned to Group 2, and third participant to Group 3 etc.

## **Limitations**

A potential threat to internal validity is obtaining a true and accurate before pain level in a child due to the possibility that seeing the presence of the nurse with a needle catheter will cause a child to rate pain higher. To prevent this threat, each child's before pain level will be measured prior to seeing a nurse with the catheter. Another limitation is an unpredictable change in a child's status with a waiting time of 60 minutes. The primary investigator would have no control or way of knowing if the child's condition worsens during the waiting period.

Some limitations of the One-Way ANOVA design are all assumptions must be met and a One-Way ANOVA only reveals whether there is a significant mean difference among the three groups. If there is a statistical significance, further testing is needed to identify which of the group means are different. The assumptions of the one-way ANOVA are:

- The measures of the characteristic of interest constitute an independent random sample.
- The group variable has three or more categories.
- The variable measuring the characteristic of interest is normally distributed.
- The variable measuring the characteristic of interest is a continuous interval or ratio variable.
- There is homogeneity of variance among all of the groups (Kellar & kelvin, 2013, p. 154).

If any of these assumptions are violated, a one-way ANOVA cannot be used, and a nonparametric test will have to be explored for the study.

## **Sample**

The target population will be the pediatric population ages 5 to 12 years old. This is a convenient and random sampling study. The triage nurse will randomly select participants in the ED. A sample size of 969 will be used in the study and recruitment will end when 969 samples are reached. Sample sizes are calculated for the *F* test, a One-Way ANOVA design for between factors, within factors, and for interaction for large effect size of 0.10, alpha level of 0.05, power of 0.8 for 2 measurement points for the three groups using the statistical software G Power 3.0.

The inclusion criteria for samples are: a need to have blood drawn or intravenous catheterization intervention, has no allergies to lidocaine products, and has a triage acuity level of 3 or 4 based on a 1-5 level acuity scale. A triage acuity level of 1 means a patient needs immediate intervention such as intubation. A level 2 means a patient is unstable and can deteriorate. A level 3 means a patient is stable but might need intervention such as IV and other diagnostics to rule out a disease and a level 4 means a patient is stable and might need only one intervention such as a blood draw, and a level 5 means a patient does not need any intervention. The exclusion criteria for samples are: mentally challenged children, children that have an eczema condition, and hemodynamically unstable children.

## **Measurement Methods**

The WBFPRS will be used to measure children's pain (see Appendix A). The WBFPRS is a self-report tool that is used by asking children to point to the face on the scale that best matches how they feel about their pain. It ranges from 0 to 10 with faces showing different degrees of pain. The scale's greatest strength is that it is widely preferred by children of all ages, parents and practitioners when compared to other faces pain scales (Melby, McBride, & McAfee, 2011; Tomlinson, Baeyer, Stinson, & Sung, 2010). The reliability and validity of the scale was

0.74 and 0.60 during its development (Ahn et al., 2013). The WBFPRS can be a challenge on children who do not cry or who are taught not to cry when in pain (Ortiz et al, 2012). Children may be hesitant to pick a higher score of pain because it shows tears. This may lead to under scoring of the child's pain and may lead to instrumental bias. However, this bias was not supported by research among different age groups. A literature review conducted by Tomlinson, Baeyer, Stinson, and Sung (2010) supported the reliability and validity of the Faces Pain Scales for the assessment of pain intensity in children ages 4-12 years old. The study stated WBFPRS "exceeds conventional requirement for validity of research tools and shows excellent inter-scale agreement even in 4 year old children" (Tomlinson et al., 2010, p. 1186). This was further supported by Garra et al. (2009) study of validating the use of the WBFPRS on children ages 8-17 years old in the pediatric emergency department as an excellent measure of treatment effect in school-aged children and adolescents.

A pulse oximeter will also be used to measure children's heart rate. According to Polit and Beck (2012), bio-physiological measurement is highly reliable, valid, and extremely useful in clinical nursing studies. The measurement of heart rate is an indicator for physiological pain response. It is also known for its general simplicity and validity for measuring acute and sharp pain (Ahn et al., 2013). A higher level of heart rate indicates more pain.

### **Data Collection Process**

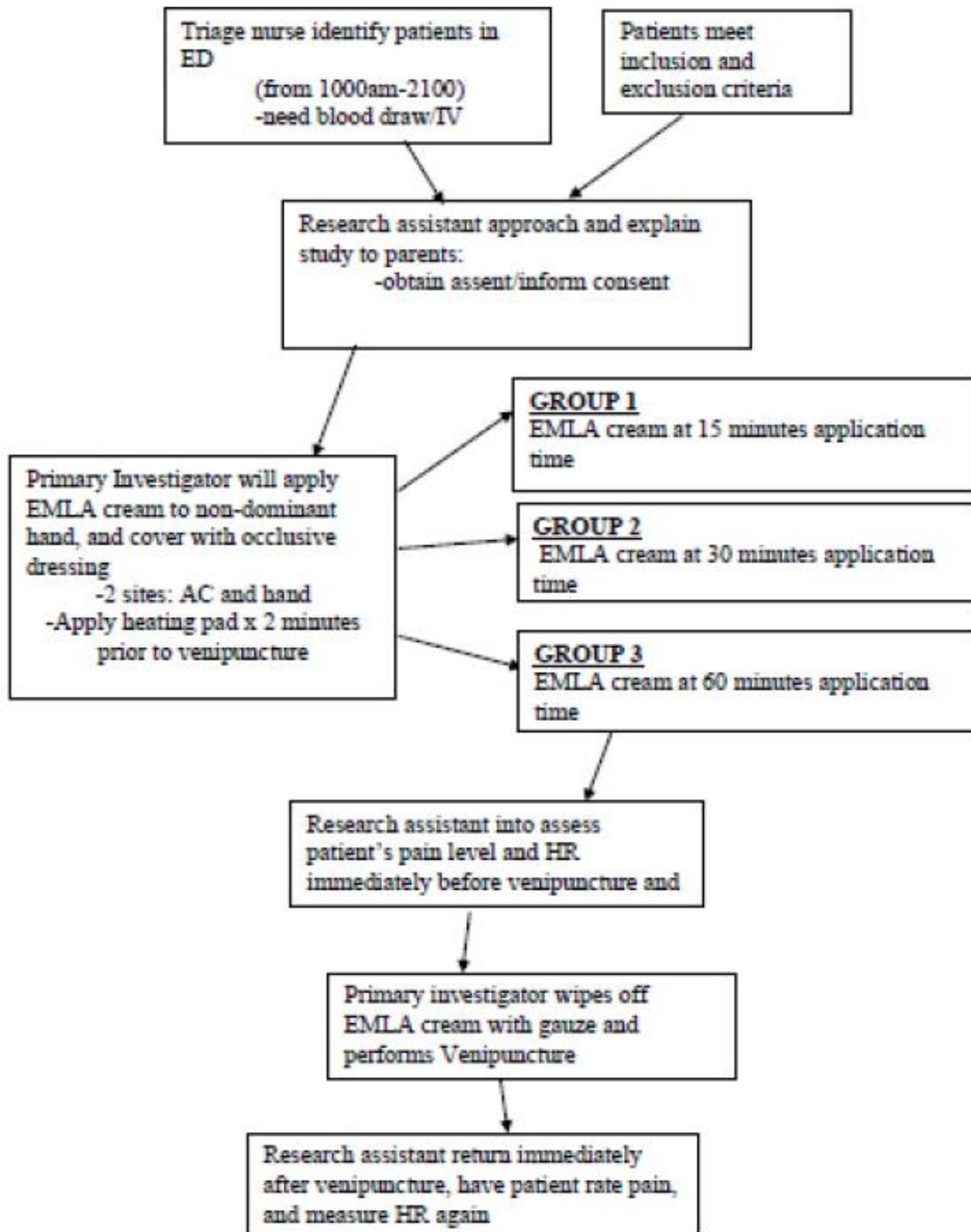
The data collection will be obtained at SCVED on Monday, Friday and Saturday from 10 am until 6 pm because that is the busiest time in the ED. Prior to the study, in-service training about the study will be provided to the nursing staff and physicians. The triage nurse will identify patients that might need a blood draw or IV intervention based on their chief complaint and assess the patients' inclusion and exclusion criteria. If the patient meets the criteria, a

research assistant who speaks both English and Spanish, when needed, will explain the purpose of study to parents while in triage. The research assistant will obtain assent from children and consent from parents. Parents will be informed that the patient's name will be anonymous.

After obtaining assent and consent, the primary investigator (PI) will come in and apply EMLA cream on the patient on the non-dominant arm. The PI will apply 2.5 grams of EMLA cream to a 5 cm region around the area of needle site and cover the area with a Tegaderm dressing. This will be performed on two sites: antecubital and the hand. The PI will document the time of application on the Tegaderm dressing. The samples will be randomly divided into three groups. Group 1 with EMLA cream application time of 15 minutes, group 2 with an application time of 30 minutes and group 3 with an application time of 60 minutes. The participants will be sent to the waiting room with his or her parents until their application time is complete. Five minutes before the application time of 15 minutes, 30 minutes and 60 minutes are completed; the PI will call the child into a room and apply a heating pad to the IV sites for 2 minutes. This protocol is to promote successful IV cannulation by increased vein visualization in the patient and prevent venous vasoconstriction EMLA cream might cause (Huff et al., 2009). Immediately prior to venipuncture, the research assistant will come in the room and ask the patient to rate his or her pain on the WBFPRS. The research assistant will also measure the patient's HR using the pulse oximeter by placing it on the finger on the opposite arm where EMLA cream was applied. The research assistant will document the data on the data collection sheet and leaves the room. Then, the PI will come into the room, wipe off the EMLA cream with gauze, assess the patient's skin condition, and perform the venipuncture on the patient. Immediately after venipuncture, the research assistant will return to the room and reassess the patient's pain level and HR. The research assistant will document before and after pain level and

the HR on the timed venipuncture data collection sheet (See Appendix G, H, & I). See Figure 2 below.

Figure 2. Data Collection Process



## **Data Management**

All samples will remain anonymous and a number will be randomly assigned to each sample. Paper records will be stored in a locked cabinet in the ED manager's office. Data will not leave the manager's office unless it has been de-identified. A One-Way ANOVA statistical test will be used for analysis.

## **Date Coding and Scoring**

Demographic data such as age, sex, race, skin condition, body temperature, and history of previous venipuncture will be obtained and documented. Age will be treated as an interval scale and recorded in years. Sex will be treated as a nominal scale and placed into two categories: 0-male and 1-female. Race will be treated as a nominal scale and placed into five categories: 1-Caucasian, 2-African American, 3-Hispanic, 4-Asian, and 5- Other. History of previous venipuncture will be treated as a nominal scale and placed into three categories: 0-never, 1-once, 2-two or more times. Skin condition will be treated as a nominal scale and placed into three categories: 1-dry, 2-moist, 3-diaphoretic. Body temperature will be treated as a nominal scale and placed into two categories: 0-afebrile and 1-febrile. Skin condition and body temperature are important histories to obtain from parents and patients because they let the PI know whether the patient is dehydrated or not. These variables are beyond the PI's control and can affect the access and success of IV cannulation in patients. The WBFPRS will be coded with 0 being no hurt on the left to 10 being hurts worse to the right and will be treated as ratio scale. A SPSS 20 quantitative software program will be used for data coding and scoring.

## Data Analysis

Data analysis will begin with a careful examination of the univariate frequency distributions for each variable. Bivariate relationships will be examined using a correlation metric. Nonlinear relationships will be identified and variables will be transformed as indicated for the techniques that require a linear and/or normal distributions. Nonparametric techniques will be investigated in the case of such violations.

Frequency distributions for demographics (i.e. age, gender, hx of venipuncture) and variables of interest will be explored. Variables will be stratified into three different groups and statistically significant differences between the groups will be reported pre and post EMLA cream intervention using a One-Way ANOVA for each of the dependent variables. All statistical tests will be considered significant at  $p < 0.05$  (two-tailed) unless otherwise specified. **Table 1** describes the analysis plan of the proposed project.

**Table 1: Analysis Plan**

Aim: Efficacy of EMLA cream in reducing venipuncture pain in a shorter application time in the pediatric population in the ED			
Objective	Variables	Statistical technique	Analysis
1. Perform a historical assessment & evaluation of prior ER or hospital visits for blood draw or intravenous intervention in a sample of patients that comes in the ED.	1. age 2. gender 3. race 4. hx of venipunctures 5. Skin condition 6. Body temperature	Descriptive	1. Measures of central tendencies (mean, median and mode) 2. Frequency distribution (normality)
2. Answer the question: is EMLA cream as effective in reducing venipuncture pain in 15 minutes and 30 minutes as in 60 minutes application time?  a. Objective of the question is to assess if there is a statistical significant change in pain level and heart rate between the three groups.	1. Time of EMLA cream 2. Pre & Post pain level within the groups 3. Pre & Post heart rate within the groups 4. Pain level differences between the groups	One-Way Analysis of Variance will be used to determine if there is a statistically significant relationship between time of EMLA cream, pain level and heart rate.	1. The <i>F</i> - test statistic will be used to evaluate main effects. 2. If <i>F</i> - test is significant, a Bonferroni <i>post hoc</i> will be performed to determine which of the group means are different.

The *f*-statistic test will be used to evaluate the statistical significance. The *f*-test is considered significant if the between-group variance is greater than the within-group variance (Kellar & Kelvin, 2013). Thus, the hypothesis will be accepted. Then, a Bonferroni *post hoc*

test will be computed to determine which of the three group means are significantly different from each other.

### **Bias**

The study will be using a convenience sample at SCVMC ED that might not be representative of the whole population.

### **IRB/Ethical Considerations**

The pediatric population is a vulnerable population and they will be safeguarded by obtaining assent and informed consent from parents. Parents will be present at all times with the child. Parents will be informed their child will be randomly placed in the three timed groups. Parents will be informed that research has shown 5 minutes provided adequate analgesic in venipuncture pain in the adults (Hopkins, Buckley, & Bush, 1998). However, a 15 minutes application is used for the study because a 5 minutes application time might be too short for the pediatric population. Therefore, a 15 minute application time will be studied for its effect since it is three times the amount it took to provide effective analgesic in the adult population. Thirty minutes and 60 minutes EMLA cream application time will also be used for the study because research has shown 30-60 minutes provided full effectiveness in reducing venipuncture pain (Ahn et al, 2013; Baxter et al., 2013; Huff et al., 2009; Moppett, Szypula & Yeoman, 2004; Shavit, Hadash, Knaani-Levinz, Shachor-Meyouhas, & Kassis, 2009; Tak & Bon, 2005). Parents will also be informed that the child can still receive EMLA treatment even if they do not consent to participate in the study. Software and data will be locked in a password-protected computer. Hard copies will be locked in a safe cabinet in the manager's office.

## **Summary**

Venipuncture pain management in the pediatric population is essential in reducing children's physical and psychological responses. Many children come to the ED with pre-existing pain, which can be further aggregated by venipuncture procedures. To prevent short term and long term negative effects of venipuncture in children, APNs need to advocate the use of topical anesthesia such as EMLA. Although procedural pain in the ED cannot be eliminated; it can be reduced and minimized. Every child deserves to have pain free procedures as much as possible.

## CHAPTER FOUR

### **Grant Elements**

#### **Potential Grants**

Currently, the National Institute of Health is offering three grant awards to promote research in the areas of pain management. The first grant is PA-13-117 (R03), which is a small grant program. This grant provides research support specifically limited in time and amount for studies in categorical program areas. It provides flexibility for initiating studies that are short-term projects and are non-renewable. This grant would be feasible for a pilot study. The second grant is PA-13-118 (R01), which is a research project grant. This grant supports a discrete, specified, and circumscribed project to be performed by the named investigator in an area representing his or her specific interest and competencies. This grant is not limited in dollars but must reflect the actual needs of the proposed project and the project can be renewed. The third grant is PA-13-119 (R21), which is an exploratory/developmental research grant award. This grant has a restricted level of support and time but does encourage the development of new research activities in categorical program areas. This grant cannot be renewed and project period can be requested up to two years with direct costs of no more than \$275,000.

#### **Final Grant**

The final grant that is chosen is the PA-13-118 (R01) because the proposed grant is a research project with a specific interest in venipuncture pain management in the pediatric population in the ED.

## **Budget Justification**

The budget cost for the entire grant proposal will be \$131,607. The total direct and indirect costs include hiring a Primary investigator, research assistant, statistic and mentor consultant, computer and supplies, and traveling costs for dissemination of findings (see Appendix F).

## **Personnel Costs**

Stephanie Huang, RN, BSN, MSN will serve as the primary investigator on this project. Stephanie is an emergency nurse with a Master's degree and 15 years of nursing experience. She will assist in data collection and analysis, team meetings, presentation to the IRB, coordinating efforts of personnel and review of the budget on the project. She will work with research assistant and consult with subject matter experts on the intervention study. She will devote 8 hours a day for 3 days a week of her time to the grant for the duration of the project. She will be compensated at rate of \$45 per hour for a total of 96 hours per month over one year for a total of \$51,840.

A research assistant will be hired for the project and will be paid \$17 an hour. The research assistance hired will be fluent in both English and Spanish due to the majority of population that comes to SCVMD ED is Hispanic. The research assistant will work alongside with the primary investigator's schedule. The estimated cost for a research assistant is based on a total of 96 hours a month over one year for a total of \$19,584.

The primary investigator will seek the expertise of a statistics consultant and a research mentor for guidance in this project. A qualified statistics consultant is necessary to ensure statistical and data analysis are accurately analyzed. She will be provided 10 hours of consultation over the one year research period at the rate of \$100 per hour for a total of \$1000

consultation fee. A research mentor will also be necessary for mentoring the primary investigator to ensure the research is safely implemented. The research mentor will provide 12 hours of consultation over the one year period at the rate of \$100 per hour for a total of \$1200.

### **Equipment**

EMLA cream will be needed for the research to apply on patients arms. Estimated cost for one tube of EMLA cream (30gm) is \$50. Each sample will need 2.5 gm of EMLA cream on each of the two sites. For the samples of 969 patients, 162 tubes will be needed at the cost of \$50 each. The estimated cost of EMLA cream will be \$ 8,100. Large tegaderm dressings will be used to cover and keep the EMLA cream in place. One box of tegaderm dressing contains 50 dressings. Each sample needs two tegaderm dressing to cover two sites. A total of 40 boxes is needed at a cost of \$95 each box. The estimated costs for tegarderm is \$3,800. Heating pads will be purchased at the cost of \$1.05 each. Each participant will need 2 heating pads with the total cost of \$2035 for sample of 969. A pulse oximeter will be used to measure patients' heart rate level before and immediately after venipuncture. The estimated cost for a pulse oximeter is \$129. The total estimated equipment cost for the entire project will be \$14,064.

### **Supplies**

A laptop computer and printer are necessary for data input and analysis, reports and preparing necessary documents. A SPSS 20 software is necessary to run data analysis. Office supplies such as copy paper, general office supplies, and copier expenses are necessary for preparing documents such as consent forms and assessment tool. The total estimated cost for these supplies will be estimated at \$4,100 for the entire project.

**Travel**

Dissemination of research findings will be presented at the National Conference for Nurse Practitioners. Proposed budget of \$1500 estimated for round trip travel expense, including airfare and lodging, and conference cost.

**Timeline**

The grant proposal timeline will be one year. The primary investigator and assistant will be recruiting samples three times a week on Mondays, Fridays, and Saturdays. These days are the busiest in the ED and will be optimal to recruit the samples needed for the study.

**Dissemination of Findings**

The research findings will be disseminated to the emergency department pediatric committee at Sharp Chula Vista Medical Center and at regional and national nursing conferences. The research findings will also be submitted for publication in nursing journals.

Appendix A

**Wong-Baker FACES® Pain Rating Scale**



[www.wongbakerFACES.org](http://www.wongbakerFACES.org)

©1983 Wong-Baker FACES® Foundation. Used with permission.

Adopted from Wong-Baker Faces Foundation. *Wong-Baker Faces Pain Rating Scale in Spanish.*

Retrieved from <http://wongbakerfaces.org/faces-download-scalable-files/>

Appendix B

Demographic Survey Form				
<b>Ages</b>	<b>5-7 yrs</b>	<b>8-10 yrs</b>	<b>11-12 yrs</b>	<b>Total</b>
				969
<b>Racial Categories</b>				
	<b>Females</b>	<b>Males</b>	<b>Sex gender Not reported</b>	<b>Total</b>
Caucasian				
African American				
Hispanic				
Asian				
Other				
<b>Total of All Subjects</b>				969
<b>Hx of previous venipuncture</b>				
1. Never				
2. Once				
3. Two or more times				

--

**Demographic Survey Form**

<b>Demographic Survey Form</b>				
<b>Skin Condition</b>				
1. Dry				
2. Moist				
3. Diaphoretic				
<b>Body Temperature</b>				
0. Afebrile				
1. Febrile				

## Appendix C

### Parental Consent Form



# California State University SAN MARCOS

## Consent to Participate in Research

### Invitation to Participate

My name is Stephanie Huang. I am a student at California State University San Marcos and a Registered Nurse at Sharp Chula Vista Medical Center at the Emergency Department. I am conducting a study to find out if EMLA, a localized anesthesia cream, is as effective in reducing needle puncture pain in the emergency department in 15 minutes and 30 minutes as in 60 minutes. Research had showed 5 minutes application time provided adequate analgesic in venipuncture pain in the adults (Hopkins, Buckley, & Bush, 1998). However, a 5 minutes application time might be too short for the pediatric population. Therefore, a 15 minutes application time, which is three times the adult strength, will be used for the study. Thirty minutes and 60 minutes EMLA cream application time is also used for the study because research have showed 30-60 minutes provided full effectiveness in reducing venipuncture pain. This information will be used to create a standardized guideline for staff members in reducing and minimizing needle puncture pain in the pediatric population. The needed criteria for this study are blood draw or intravenous placement.

### Requirements of Participation (What you will be asked to do)

EMLA cream will be applied to your son or daughter's arm and it will be covered with a piece clear tape. Your son or daughter will be asked to leave the EMLA cream on for a specific amount of time at 15 minutes, 30 minutes, or 60 minutes. Your son or daughter will be asked to wait in the waiting area after the EMLA cream is applied on their hand. Five minutes before their application time is complete, your son or daughter will be called into a room and a heating pad will be applied to the two IV sites two minutes before their venipuncture. Your son or daughter will be asked to rate his or her pain on a picture pain scale before and immediately after his or her needle stick.

**Risks** are minimal in this study but include:

1. Possible skin irritation from the tape.
2. Possible skin reaction to the numbing cream site such as redness.



California State University  
**SAN MARCOS**

**Safeguards** to minimize risk include:

1. EMLA cream and the tape will be removed immediately if skin irritation or reaction occurs.

**Benefits**

The research involved with this study will benefit education as a whole in the pediatric medical field. Hospital administrators and Registered Nurses may find the information valuable and utilize the results to create a standardized guideline to reduce needle puncture pain in the emergency department.

**Voluntary Participation and Contact Information**

Your participation is entirely voluntary, and may be withdrawn at any time. There are no consequences if you decided not to participate. You may also request the use of EMLA cream even if you do not want to participate in the study.

This study has been approved by the California State University of San Marcos Institutional Review Board (IRB). If you have questions about the study, you may direct those to the researcher, Stephanie Huang at [huang020@cougars.csusm.edu](mailto:huang020@cougars.csusm.edu), (808) 382-XXXX, or the researcher’s advisor/professor, Dr. Denise Boren, [dboren@csusm.edu](mailto:dboren@csusm.edu), (760) 750 7550. Questions about your rights as a research participant should be directed to the IRB at (760) 750-4029. You will be given a copy of this to keep for your records.

\_\_\_\_\_ I agree for my child to participate in this research study

Participant’s Name \_\_\_\_\_

Parents’s Name \_\_\_\_\_ Parents’s Signature \_\_\_\_\_ Date \_\_\_\_\_

Researcher’s Signature \_\_\_\_\_ Date \_\_\_\_\_

Appendix D

Patient Assent Form



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**Assent to Participate in Research**

Dear Participant,

My name is Stephanie Huang. I am a student at California State University San Marcos and a Registered Nurse at Sharp Chula Vista Medical Center at the Emergency Department. I am conducting a research study and I want to know if EMLA cream, a localized numbing cream, will help to decrease needle pain in the emergency department.

In order to find out whether the EMLA cream works, I will be asking for your participation if the doctor decides you will need blood testing or needle placement in your vein for your visit today. A nurse will be applying a small amount of EMLA cream to two areas of your arm and cover it with clear tape. You will be asked to leave the EMLA cream on your arm for a specific amount of time. You will also be asked to rate your pain on a picture pain scale before and immediately after the needle stick.

**Contact Information**

This study has been approved by the California State University San Marcos Institutional Review Board (IRB). If you have questions about the study, you may direct those to the researcher, Stephanie Huang, Huang020@cougars.csusm.edu, (808) 382-XXXX, or the researcher’s advisor/professor, Dr. Denise Boren, Dboren@csusm.edu, (760) 750 7550. Questions about your rights as a research participant should be directed to the IRB at (760) 750-4029. You will be given a copy of this to keep for your records.

\_\_\_\_\_ I agree to participate in this research study

Participant’s Name \_\_\_\_\_ Participant’s Signature \_\_\_\_\_ Date \_\_\_\_\_

Researcher’s Signature \_\_\_\_\_ Date \_\_\_\_\_

## Appendix E: IRB Application



# California State University SAN MARCOS

## Application for Approval for Research Involving Human Subjects: Full or Expedited Review

### Submission Procedures:

1. The researcher completes application
2. If the researcher is a student, their faculty advisor must review the application and **sign the application in IRBNet**. Additional instructions can be found on the last page of this application. \*\*
3. The researcher submits the application and accompanying documents to IRBNet. <http://www.csusm.edu/gsr/irb/forms.html>  
For assistance completing this form, please review the resources located at [www.csusm.edu/irb](http://www.csusm.edu/irb).  
If you have any questions, please refer to the [IRB website](#) or contact the IRB staff at (760) 750-4029 or [irb@csusm.edu](mailto:irb@csusm.edu).  
Please answer each section completely and as concisely as possible. Use lay terms as IRB members have diverse backgrounds.

Full Review     
  Expedited Review     
 Proposed Start Date

**Project Title**

#### Faculty/Staff Investigator:

Name  Department/College   
 Phone Number  E-mail   
 Date CITI Completed

#### Student Investigator: *(if the student is the primary investigator) \*\**

Name  Department/College   
 Phone Number  E-mail   
 Date Training Completed 
 CITI       IRB Workshop

Faculty Advisor Name:  Department/College   
 Phone Number  E-mail  Date CITI Completed

#### Checklist: Check which of the following items are included, as applicable:

- Certification of Human Subjects Protection training for each researcher and the faculty advisor.
- Letter/email of organizational support. (Required if recruiting or interacting with participants at a specific site or through a specific organization outside of CSUSM.) If sent in an email, must include organization and position of the person who approved.
- Recruitment flier(s) or advertisements, scripts for radio or TV.
- Survey(s), questionnaires, or interview questions. If this is an online survey, please provide a pdf copy of the survey.
- Consent and/or child assent form(s) or information sheet(s).  
For online surveys, provide a pdf copy of the introduction/information screens.
  1. Provide unique forms for each population in your research.
  2. Use official letterhead or the masthead found in the samples on the IRB website
  3. Include contact information for the Researcher, faculty mentor, and IRB office.
  4. Be sure the information in your consent/information sheet MATCH your application information!
- Students Researchers ONLY:** Faculty advisor has approved the project and has signed the application in IRB Net.
- Ed.D Students ONLY:** Attach the required [UCSD-CSUSM-JDP IRB Cover Sheet](#), Please be sure to **sign** the form, scan it, and submit it with your application as a separate document.

## 1. Purpose of Project and Project Background

Describe your research question, including **why** the question is important, and **how** your study will attempt to answer it. Include how your literature review supports this with at least three citations. (Do not exceed one page--Use lay language.)

Venipuncture pain is inadequately and poorly managed with an underutilization of safe and effective topical anesthetics available in the pediatric population in the emergency department (ED). This can lead to an increase in physical pain and is psychologically and emotionally traumatic for children to experience. Many preschoolers might perceive painful procedures as a punishment for their bad behavior (Ahn et al., 2013). Poor management of pain can lead to long-term physiological and behavioral consequences (AMA, 2013, Helms & Barone, 2008). Topical anesthetics such as EMLA cream are underutilized in managing procedural pain. Inadequate interventions to minimize pain for initial procedures result in a stronger pain response with subsequent painful procedures even when adequate analgesia is given (Cregin et al., 2008). The purpose of this research is to evaluate the effectiveness of EMLA cream in reducing venipuncture pain at a shorter application time in the pediatric population in the ED. Researches have showed EMLA cream is effective in reducing venipuncture pain after 60 minutes of application (Ahn et al, 2013; Baxter et al., 2013; Huff et al., 2009; Moppett, Szypula & Yeoman, 2004; Shavit, Hadash, Knaani-Levinz, Shachor-Meyouhas, & Kassis, 2009; Tak & Bon, 2005). However, a 60 minutes application time might not be feasible to use in the ED. Currently, there is a lack of research that has been done to investigate the potential effectiveness of a shorter time frame. A study done by Smith and Leonard (2001) has showed a 5 minutes application time was adequate to reduce pain associated with intravenous cannulation in adults and Hopkins, Buckley and Bush (1998) study showed 30 minutes of EMLA application provided effective analgesia in relieving venipuncture pain. Therefore, this grant is proposed to assess whether EMLA cream is as effective in reducing venipuncture pain at 15 minutes and 30 minutes as in 60 minutes application time. The research will provide valuable data that will improve clinical practice, improve patients/parents satisfaction and prevent potential long term physical and psychological trauma in the pediatric population.

## 2. Recruitment Procedures & Participant Population

A) List the expected number of participants for each population group included in this study.

969

B) Describe all characteristics relevant to being selection of participants. (e.g., demographics, ethnicity, vulnerabilities, etc.) Explain why you are targeting this specific population.

The target population will be the pediatric population ages 5 to 12 years old that comes to the Sharp Chula Vista Emergency Department (SCVED). The pediatric group is a vulnerable population because they may not be able to fully express their pain and are unable to advocate for themselves in the use of localized anesthesia creams that are available in alleviating venipuncture pain. This specific age of 5 years and above are selected because a five years old child will be developmentally mature enough to rate his/her pain accurately on a pain scale. Thus, it will provide the study with more substantial results.

Demographics such as age, race, and sex, hx of venipuncture, skin condition, and body temperature will be obtained from the participants. All participants will remain anonymous.

The inclusion criteria for samples are: a need to have blood drawn or intravenous catheterization intervention, has no allergies to lidocaine products, and has a triage acuity level of 3 or 4 based on a 1-5 level acutely.

C) Indicate whether anyone might be excluded from participating and explain why.

The exclusion criteria for samples are: mentally challenged children, children that have an eczema condition, and hemodynamically unstable children. Mentally challenged children are excluded because they are developmentally not able to rate or express their pain accurately on a pain scale. Children with eczema condition might interfere with the visualization of their veins as well as possible further irritation of their skin condition with the application of EMLA cream. Hemodynamically unstable children are excluded because they need intervention right away and are unstable to wait for the application time for the study.

D) How will you find, recruit, or identify potential subjects? How will you select, from the volunteers, the final group of participants? Submit flyers, posters, or other oral or written invitations used to recruit potential participants.

Any pediatric samples ages 5 to 12 years old that come to the SCVED are eligible for the study as long as they met the inclusion and exclusion criteria.

E) Will you be offering an incentive?

Yes  No

If yes, please explain procedure for any incentives that will be offered. Include how much participants must do to be eligible to receive credit.

### 3. Informed Consent Process.

Explain for each population participating in your research.

See the IRB web page on [Informed Consent](#). See also [Language Requirements](#).

A) How and when will you explain the study and the required elements of Informed Consent? Will you be doing this or will it be handled by a research assistant?

A research assistant that speaks fluent in both English and Spanish, when needed, will be explaining the study to the parents and the patient after the triage nurse identified the patient have met the study criteria in triage. The research assistant will explain the study to the parents and patients in layman's term and provide sufficient time for them to ask questions. Once the parents and patients verbalized understanding of the study, they will be asked to sign a written consent prior to the study. A copy of the consent will be provided to the parents.

B) How much time will participants have to consider participating between the explanation described above, the receipt of the consent document, and the beginning of study?

Parents and the patient will have 20 minutes to consider participating in the study and can withdraw from the study anytime.

C) If there are subjects under the age of 18, how will the study be explained to them? How will parental consent and child assent be handled?

Parents will be provided a verbal and written informed consent. Once the parents consent for the patient to participate in the study, an assent will also be obtained from the patient. Both informed and assent consents will be explained in layman's term to the parents and participants in their primary language by a research assistant.

D) If you are requesting a Waiver of Consent or a Waiver of Documentation of Consent, explain why this waiver is needed. Outline alternative procedures for obtaining consent or providing study information (e.g., information sheet, introduction screen for web survey, etc.).

N/A

E) Indicate the primary language(s) of your participants. If any participants' is not fluent and comfortable with English, explain how you will ensure that participants' understanding of the activity for which they are giving consent.

SCVED have a high Spanish population. For parents and patients that speak Spanish as their primary language, a research assistant who speaks fluent Spanish will be explaining the purpose of the study and obtain informed and assent consent from them.

#### 4. Procedures and Methodology

Provide descriptions of each distinct procedure and each population group.

A) Provide a step-by-step explanation of your research activities and methodologies that involve human subjects. Be thorough.

Prior to the study, in-service training about the study will be provided to the nursing staff and physicians. The triage nurse will identify patients that might need a blood draw or IV intervention based on their chief complaint and assess the patients' inclusion and exclusion criteria. If the patient meets the criteria, a research assistant who speaks both English and Spanish, when needed, will explain the purpose of study to parents while in triage. The research assistant will obtain assent from children and consent from parents. Parents will be informed that the patient's name will be anonymous. After obtaining assent and consent, the primary investigator (PI) will come in and apply EMLA cream on the patient on the non-dominant arm. The primary investigator (PI) will apply 2.5 grams of EMLA cream

to a 5 cm region around the area of needle site and cover the area with a Tegaderm dressing. This will be performed on two sites: antecubital and the hand. The PI will document the time of application on the Tegaderm dressing. The samples will be randomly divided into three groups. Group 1 with EMLA cream application time of 15 minutes, group 2 with an application time of 30 minutes and group 3 with an application time of 60 minutes. The participants will be send to the waiting room with his or her parents until their application time is complete. Five minutes before the application time of 15 minutes, 30 minutes and 60 minutes are completed; the PI will call the child into a room and apply a heating pad to the IV sites for 2 minutes. This protocol is to promote success IV cannulation by increase vein visualization in the patient and prevent venous vasoconstriction EMLA cream might cause (Huff et al., 2009). Immediately prior to venipuncture, the research assistant will come in the room and ask the patient to rate his or her pain on the WBFPRS. The research assistant will also measure the patient's HR using the pulse oximeter by placing it on the finger on the opposite arm where EMLA cream was applied. The research assistant will document the data on the data collection sheet and leaves the room. Then, the PI will come into the room, wipe off the EMLA cream with gauze, assess the patient's skin condition, and perform the venipuncture on the patient. Immediately after venipuncture, the research assistant will return to the room and reassess the patient's pain level and HR. The research assistant will document before and after pain level and the HR on the timed venipuncture data collection sheet

Data analysis will begin with a careful examination of the univariate frequency distributions for each variable. Bivariate relationships will be examined using a correlation matrix. Nonlinear relationships will be identified and variables will be transformed as indicated for the techniques that require a linear and/or normal distributions. Nonparametric techniques will be investigated in the case of such violations.

Frequency distributions for demographics (i.e. age, gender, hx of venipuncture) and variables of interest will be explored. Variables will be stratified into three different groups and statistically significant differences between the groups will be reported pre and post EMLA cream intervention using a One-Way ANOVA for each of the dependent variables. All statistical tests will be considered significant at  $p < 0.05$  (two-tailed) unless otherwise specified.

B) Where will the research will be conducted? Describe any risks or confidentiality issues related to using this location.

The research will be conducted at SCVED. There are no risks of confidentiality issues related to using this location.

C) State the specific dates/timeframe in which you plan to conduct your research.

The data collection will be obtained at SCVED from Monday, and Friday and Saturday from 10 am until 6 pm because that is the busiest time in the ED and will be optimal to recruit sufficient samples. The time frame for the study will be one year and specific dates is to be determined.

5. Participant Debriefing or Feedback.

If deception is involved in your research, participants should be debriefed about the nature of the study as soon as possible.  
Participants should be given the opportunity to request a copy of the results of the study/your final report.

A) Describe any feedback or information you will offer participants.

N/A. There is no deception involved in the study.

6. Risks

List risks for each population participating in the research and for each methodology.  
Please be sure the risks listed here match the risks mentioned in your consent letter or information sheets.  
Consider all risks very carefully. For more information on risks, see [Examples of Risk](#).

A) Explain potential risks to your participants. Risks may be physical, psychological (e.g., strong emotional reactions to research questions), or inconveniences (e.g., time required).

There are minimum risks in the study which include possible skin irritation from the tape and possible skin reaction to EMLA cream. There is an inconvenience in time due to the patient will be asked to leave the EMLA cream on for a specific amount of time up to 60 minutes.

B) Vulnerable Subjects: Select which, if any, of the following vulnerable subjects will be involved in your research.

- Pregnant women, human fetuses, neonates (see Federal Guidelines, 45CFR26, subpart B)
- Prisoners (see Federal Guidelines, 45CFR26, subpart C)
- Children (see Federal Guidelines, 45CFR26, subpart D)
- Other Vulnerable Populations such as persons with cognitive disabilities, economically or educationally disadvantaged persons, etc.

C) Describe and special risks to vulnerable populations or your population profile

There are no special risks to this vulnerable populations besides the risks that has been stated above. As a matter of fact, this population will benefit from the study because application of EMLA cream will help to decrease venipuncture pain vs no intervention at all.

D) List risks related to confidentiality of data. What could happen if an unauthorized person accessed the data? For instance, participant's identify or personal information could be known by others

There will not be a risk related to confidentiality of data because there will be no personal information that will be obtained from participants beside their age, race, and sex. All samples will remain anonymous and a number will be randomly assigned to each sample.

E) Will any **personal identifying data** be recorded? If so, what information will be recorded?  
(e.g., Social security number, drivers license number, student id, address, phone number, birth date, personal email address)

No personal identifying data will be recorded.

**7. Safeguard Procedures to Minimize Risks.**

A) Please respond to each risk that you listed in #6 above. State how you will minimize each risk and protect confidentiality.

- EMLA cream and the tape will be removed immediately if skin irritation or reaction occurs.

B) How you will safeguard data? Where/how will data be stored? Who will have access to the data? How will access be limited?

Hard copies will be locked in a safe cabinet in the manager's office. . Data will not leave the manager's office unless it has been de-identified. Software and data will be locked in a password-protected computer. The primary investigator will have sole access to the password and data.

C) List referrals and/or resources that may be offered if a participant has a strong emotional response or a physical injury (e.g., clinics or shelters, medical or psychological referrals).

N/A

**8. Study Benefits**

A) Discuss any potential individual and/or societal benefits. Note, often there is no direct benefit for the participants. However, the study may contribute to the literature and/or future research.

The research involved with this study will benefit education as a whole in the pediatric medical field. Hospital administrators and Registered Nurses may find the information valuable and utilize the results to create a standardized guideline to reduce

needle puncture pain in the emergency department.

B) Do the benefits from this study exceed the risks to participants? Please explain.

Yes, currently there is no standardized procedural pain protocol in treating venipuncture pain in the pediatric population. The use of EMLA cream prior to venipuncture will provide some if not effective pain relief compared to no intervention at all.

### 9. Researcher(s) qualifications and experience.

A) Briefly outline the primary researcher(s)'s qualifications and experiences relative to the subject of this research.

Stephanie Huang, RN, BSN will serve as the primary investigator on this project. Stephanie is an emergency nurse with a Bachelor's degree and 15 years of nursing experience. She have served as a former member of the Pediatric Committee at SCVED. She is also a member of the new hired RNs program where she provides lectures on pediatric emergencies. She will assist in data collection and analysis, team meetings, presentation to the IRB, coordinating efforts of personnel and review of the budget on the project. She will work with a research assistant and consult with subject matter experts on the intervention study. She will devote 8 hours a day for 3 days a week of her time to the grant for the duration of the project.

B) If this is a student project, include faculty sponsor's qualifications.

Dr. Denise Boren, PHD, Director of the Family Nurse Practitioner program at California State University of San Marcos.

C) If using student or research assistants, please state how you will ensure that these assistants are trained and qualified to assist. All assistants should complete the CITI training on the protection of human participants in research.

A research assistant will be hired for the study and will have 2 hours of training with the primary investigator prior to the study.

#### Time to Review:

Expedited reviews are reviewed by one committee member with an average approval time of approximately three weeks. Questions from reviewers and approval paperwork will be sent to the email address provided on the application at the time of submission.

Full reviews are reviewed by the full committee at an IRB meeting. Approvals on full reviews may take 4-6 weeks. Questions from the committee and approval paperwork will be sent to the email address provided on the application at the time of submission. All "full review" applications are copied to Risk Management.

#### Faculty Advisor Approval: \*\*

Once the student researcher has completed the application, they must e-mail their application to their faculty advisor for review. When the faculty advisor pre-approves the application, the student will upload their application and documents to IRBNet and share the package with the faculty advisor for official approval. The faculty advisor must have an account in IRBNet to approve the application. The faculty advisor will receive a notification via e-mail that the application package has been shared with them and that they need to sign off on the application package in IRBNet.

Instructions on sharing the project can be found on the IRBNet video training site. There is a section in the video called **Sharing This Project**. The link and the login for the training is on the CSUSM IRB website under **How to Submit to IRBNet**  
<http://www.csusm.edu/qsr/irb/forms.html>

## Appendix F

<b>BUDGET FOR ENTIRE PROPOSED PROJCT PERIOD: DIRECT &amp; INDIRECT COSTS</b>	<b>FROM</b>	<b>THROUGH</b>
	<b>TBD</b>	
	<b>Justifications for Costs</b>	<b>TOTAL</b>
<b>Primary investigator (Stephanie Huang)</b>	\$45 per hour for 96 hours a month ( 3 times a week) for a total of 12 months	\$ 51,840
<b>Research Assistant</b>	\$17 per hour for 96 hours a month for a total of 12 months	\$19,584
	Personnel costs plus Benefits at 40%	\$ 71,424 +1.40
	<b>Total Personnel Costs</b>	<b>\$ 99,994</b>
<b>Consultant costs</b>	1) Statistic consultant: \$100 per hour for 10 hours	\$1,000
	2) Research mentor: \$100 per hour for 12 hours	\$1,200
	<b>Total Consultant Costs</b>	<b>\$ 2,200</b>
<b>Equipment</b>	<b>Pulse oximeter x1 at \$ 129 each</b>	\$129
	<b>Tegaderm dressing: 1 box contains 50 dressings. Need 20 boxes for Sample of 969 at \$95 each box ; heating pads at \$1.05 each for 2 IV sites x 969 samples</b>	\$3,800 \$2,035
	<b>EMLA cream: 1 tube contain 30 gm; each Sample needs 5 gm for 2 sites application; 162 tubes needed at the cost of \$50 per tube</b>	\$8,100
	<b>Total Equipment Costs</b>	<b>\$14,064</b>
<b>Supplies</b>	Laptop computer, printer, SPSS IBM 21.0; computer CD; copier expenses; general office supplies; copy papers	\$4,100

APPENDIX F CONTINUES	FROM	THROUGH
BUDGET FOR ENTIRE PROPOSED PROJCT PERIOD: DIRECT & INDIRECT COSTS	TBD	
		Justifications for Costs
Travel	Lodging and gases for round trip to attend nursing conferences to present research findings.	\$1,500
	Total Direct Costs for Proposed Project Plus Indirect Costs at 8%	\$ 121,858 +1.08
	Total Direct/Indirect Costs for Proposed Project Period	\$ 131,607

Appendix G: Group 1 Data Collection Sheet

Sample	Apply EMLA @ 15 mins	Before Tx		After Tx	
		Pain	HR	Pain	HR
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					

Appendix H: Group 2 Data Collection Sheet

Sample	Apply EMLA @ 30 mins	Before Tx		After Tx	
		Pain	HR	Pain	HR
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					

Appendix I: Group 3 Data Collection Sheet

Sample	Apply EMLA @ 60 mins	Before Tx		After Tx	
		Pain	HR	Pain	HR
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					

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