1) Protocol Title

Comparison of 2 application techniques for LET (lidocaine 4%; epinephrine 0.1%; tetracaine 0.5%) gel used prior to simple laceration repair

2) HSC Review History

n/a

3) Investigators

Kelly D. Young, MD, MS
Joshua Siembieda, MD
Manpreet Singh, MD

4) Objectives*

Describe the purpose, specific aims, or objectives.
State the hypotheses to be tested.

Primary outcome: To compare pain scores during laceration repair with first suture placement using standardized visual analog scale (VAS) between 2 different topical local anesthetic application techniques for using LET gel. Specifically, we are looking to see if applying LET gel 3 times, spaced 10 minutes apart (triple LET) provides superior anesthesia to one 30 minute application (single LET). Single LET is the current standard method of application.

Secondary outcomes:

1) To compare provider satisfaction scores using a Likert scale between the triple LET and single LET application techniques.
2) To compare parental satisfaction scores using a Likert scale between the triple LET and single LET application techniques.
3) To compare the need for additional local anesthetic infiltration between the triple LET and single LET application techniques.

Hypothesis: We believe that applying LET gel 3 times over a 30 minute period will provide superior anesthesia to one 30 minute long application.

4) Background*

Describe the relevant prior experience and gaps in current knowledge.
Describe any relevant preliminary data.
Provide the scientific or scholarly background for, rationale for, and significance of the Human Research based on the existing literature and how will it add to existing knowledge.

Preventing pain in the pediatric emergency department is a high priority. Studies have shown that sub-therapeutic anesthesia may result in more procedural complications, increased sensitivity to pain in the future, and increased anxiety related to medical care.[1]

LET gel has been shown to be safe and effective when used prior to wound repair.[2]

At our institution, the current method used to apply the LET gel is one 30 minute application. This it the standard application method. However, other institutions anecdotally report using different application techniques with superior results, specifically, applying the LET gel 3 times, in 10 minute intervals over a 30 minute period.

There are no studies comparing these 2 application techniques. We have only anecdotal reports that the triple LET application technique decreases patient pain and reduces the need for additional anesthetic infiltration.

5) Setting of the Human Research

Describe the sites at which your research team will conduct the research. If applicable, describe:

We are a county hospital with a Pediatric ED, level 1 trauma center that sees ~24000 patients aged < 21 years annually. We have Pediatric Emergency Medicine (PEM) trained physicians, PEM fellows, pediatric and emergency medicine residents, family medicine residents, medical students, and pediatric nurse practitioners working in our pediatric emergency department.

Identify the site(s) where your research team will identify and recruit potential subjects.

We will identify and recruit potential subjects from those presenting to the Pediatric Emergency Department.

Identify the site(s) where your research procedures will be performed.

The research will be conducted within the Harbor-UCLA Medical Center Pediatric Emergency Department.

Composition and involvement of any community advisory board.

N/A

7) Resources Available to Conduct the Human Research

Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

We are a county hospital with a Pediatric ED, level 1 trauma center that sees ~24000 patients aged < 21 years annually. Of these there are a number who will present with a laceration requiring repair.

We will be studying a convenience sample of patients requiring simple laceration repairs; enrollment will be centered around availability of investigators.

Sample size calculations revealed that enrolling 22 patients per group would have 90% power to detect a 1 point difference in visual analog pain score (range 0-10) between groups with a standard deviation of 1, using a two sample t test with an alpha of 0.05. We estimate that the enrollment will be complete within 1 year after IRB approval.

Describe the time that you will devote to conducting and completing the trial within the agreed trial period.

The Principal Investigator will devote ~5 hours a week/month to conducting this study. The fellows involved will devote ~20 hours a week/month.

Describe the number and qualifications of your staff, their experience in conducting research, their knowledge of the local study sites, culture, and society.

We will have 2 fellows enrolling patients in the Pediatric ED.

Drs. Young, Siembieda, and Singh developed the study design and will be involved in data collection, analysis, and manuscript preparation.

All members of the research team have completed CITI training. The team includes:

Kelly Young MD, MS, FACEP, FAAP: Dr. Young is a pediatric emergency medicine fellowship trained Clinical Professor of Pediatrics, the pediatric emergency medicine fellowship director, and has a Master of Science in Epidemiology and experience in research regarding pain with procedures. She is a reviewer for eight journals, an associate editor for Annals of Emergency Medicine, has been principal investigator or co-investigator on several projects including as recipient of a K23 award. She has coauthored 13 peer-reviewed manuscripts.

Joshua Siembieda, MD: Dr. Siembieda is a pediatric emergency medicine fellow with prior research experience. He completed his residency in pediatrics. He anticipates completing his fellowship in June 2017.

Manpreet Singh, MD: Dr. Singh is an ultrasound fellow in the emergency department. He completed his residency in emergency medicine. He has prior research experience and is involved in several studies in the emergency department.

Describe your facilities.

Facilities: Harbor-UCLA Medical Center has an 18 bed pediatric emergency department that sees about 24,000 patients per year.

Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.

We do not anticipate the need for any additional medical or psychological resources for the subjects as a result of our research. The patients will be consented for two known techniques of LET gel application, both of which are considered appropriate for pre-laceration repair analgesia. Treatment will not be withheld from the subjects.

Describe your process to ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

The investigators will meet regularly to discuss the status of the study and their roles and duties.

8) Prior Approvals

Describe any approvals that will be obtained prior to commencing the research. (E.g., school, external site. funding agency, laboratory, radiation safety, or biosafety approval.)

CITI training and IRB approval as required by LA BioMed. No additional product approvals will be required.

9) Study Design

a) Recruitment Methods

Describe when, where, and how potential subjects will be recruited.

Subjects will be identified on a convenience sample basis when a study investigators are available. When a study investigator is available, the patient will be identified on ORCHID, the patient/family will be approached by the treating clinicians and asked for permission for the researcher to approach and discuss the study.

Describe the source of subjects.

The source of potential subjects will be those presenting to the Pediatrics ED with a laceration requiring repair and meeting the study inclusion criteria.

Describe the methods that will be used to identify potential subjects.

Subjects will be identified on a convenience sample basis when a study investigators are available. When a study investigator is available, the patient will be identified on ORCHID, the patient/family will be approached by the treating clinicians and asked for permission for the researcher to approach and discuss the study.

Describe the amount and timing of any payments to subjects.
Subjects will not be compensated for their participation in this study.

Describe materials that will be used to recruit subjects. Include copies of these documents with the application. For advertisements, submit the final copy of printed advertisements. When advertisements are taped for broadcast, provide the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the HSC reviews the final audio/video tape.
There will be no advertisements.

b) Inclusion and Exclusion Criteria*

Describe how you will screen for eligibility.
When a study investigator is available, the patient will be identified on ORCHID, the patient/family will be approached by the treating clinicians and asked for permission for the researcher to approach and discuss the study.

Describe the criteria that define who will be included or excluded in your final study sample.
Inclusion Criteria:

- Patients with simple (≤ 3 cm) lacerations who are ≥ 7 years old and ≤ 18 years old, for whom the physician plans to close the laceration using simple superficial interrupted sutures.

Exclusion Criteria:

- Lacerations involving the hands, feet, genitals, tongue, mucus membranes, nose, ears, or occurring over joints.
- Patients who are developmentally delayed or have a disability preventing them from giving a reliable pain score.
- Patients whose primary language is other than English or Spanish.
- Patients for whom procedural sedation is required.
- Patients receiving intranasal or oral midazolam or inhaled nitrous oxide.

c) Local Number of Subjects

Indicate the total number of subjects to be accrued locally.
If applicable, distinguish between the number of subjects who are expected to be enrolled and screen, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)
We will be recruiting subjects on a convenience sample basis. We have calculated the need to recruit 22 subjects in each arm, for a total of 44 subjects, to have a 90% power to detect a 1 point difference in pain score, with an alpha of 0.05.

d) Study-Wide Number of Subjects*

If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.
N/A

e) Study Timelines*

Describe:

- *The duration of an individual subject's participation in the study.*

- *The duration anticipated to enroll all study subjects.*
- *The estimated date for the investigators to complete this study (complete primary analyses)*

The enrolled patients will be involved in the study through the duration of the consent process, laceration repair, and time needed to obtain pain score after procedure. There will be no follow-up beyond the ED visit.

Estimated date to complete enrollment is 1 year after IRB approval.

Estimated date to complete data analysis and manuscript is 2 years after IRB approval.

f) Study Endpoints*

Describe the primary and secondary study endpoints.
Describe any primary or secondary safety endpoints.

Primary endpoint: To compare pain scores during laceration repair with first suture placement using standardized visual analog scale (VAS) between 2 different topical local anesthetic application techniques for using LET gel. Specifically, we are looking to see if applying LET gel 3 times, spaced 10 minutes apart (triple LET) provides superior anesthesia to one 30 minute application (single LET).

Secondary endpoints:

1) To compare provider satisfaction scores using a Likert scale between the triple LET and single LET application techniques.
2) To compare parental satisfaction scores using a Likert scale between the triple LET and single LET application techniques.
3) To compare the need for additional local anesthetic infiltration between the triple LET and single LET application techniques.

g) Procedures Involved in the Human Research*

Describe and explain the study design.

Provide a description of all procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks. Include procedures being performed already for diagnostic or treatment purposes and differentiate between these and the procedures performed solely for the research.

Once patients are identified and consent is obtained, they will be randomized to one of two groups. One group will have LET gel applied to the laceration one time for a duration of 30 minutes. The other group will have LET gel applied 3 times, at 10 minute intervals. Between applications, the excess gel on the surface of the skin will be gently wiped off, and a new strip of LET gel will be applied. The laceration repair will proceed in a normal sterile fashion, using standard irrigation and debridement techniques. Laceration repair will occur within the 15 minutes following the 30 minute period of LET application to the wound. The patient will be asked to rate his/her pain immediately after the first suture is placed or attempted using the visual analogue scale (VAS, range 0-10). The decision to use any additional anesthetic infiltration will be left to the performing provider. There will be 2 nurses involved in the study. One nurse will be the patient's primary nurse and will be administering the LET gel (so will not be blinded, but will not be involved in data collection). The other nurse will be obtaining the VAS immediately (Appendix 3) after the first suture is placed, using a pre-prepared script (Appendix 3) and standardized technique. The nurse or research assistant will also be blinded as to the method of LET gel application. The provider performing the laceration repair will be blinded. The research assistant will not be blinded and will coordinate all involved providers and nurses, will ensure correct timing in LET gel administration, and laceration repair timing.

The investigator will interview for demographic data, ensure proper application of LET gel according to randomized group, observe laceration repair, record use of additional anesthesia, (including all data collection on data form).

Describe procedures taken to lessen the probability or magnitude of risks.

Risks to the patient are minimal given that LET is routinely used in the pediatric ED and has been shown to be efficacious. To minimize risk, patients and/or clinicians can withdraw from the study at any time.

Identify which procedures are being done as part of the Human Research and which are being conducted anyway for other reasons.

The randomization to the timing and number of applications of LET gel is being done specifically for this study as are the VAS post placement of first suture. Repair of the laceration will be done as part of standard of care.

Describe all drugs and devices used in the research and the purpose of their use, and their regulatory approval status.

LET gel is compounded by our pharmacy using the formula shown in Appendix 2.

Describe the source records that will be used to collect data about subjects. Attach all surveys, scripts, and data collection forms.

The attached survey forms can be seen in Appendices.

Describe what data will be collected including long-term follow-up.

There will not be any long-term follow up.

a) Data and Specimen Banking*

If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.

We are not banking data for future sharing or use.

List the data to be stored or associated with each specimen.

N/A

Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

We are not banking data for future sharing or use by outside researchers.

b) Data Management *

Describe the data analysis plan, including any statistical procedures.
Provide a power analysis.

The study hypothesis is that there will be at least a 1 point difference in pain score. Sample size is calculated such that the study will have a power of 90% to detect a 1 point difference in pain scores using a two sample t test with an alpha of 0.05.

Describe the steps that will be taken secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.

Original data forms and consent forms and scales will be kept in a locked office. We will not record any identifiers as defined by HIPAA on our data forms and scales. We will assign a random unique study identification number to each subject and this number will be used rather than the subject's name on the data forms and in our database/excel spreadsheets. We will not maintain a link between the study ID number to each individual; however will still seek individual permission to collect and use protected health information using a PHI authorization.

Data will be entered into password protected excel files and analyzed using SAS statistical analysis software. Excel files will be de-identified using study numbers; no patient names or identifiers will remain. Study numbers will be used to enter into excel files. Only the study investigators will have access to the data forms and files. All investigators will be trained in confidentiality, CITI training.

Data will be kept for at least 3 years after completion of the research. This includes data collection forms, consent documents, etc. We will ensure that all data is de-identified at that time.

j) Confidentiality

Describe the local procedures for maintenance of confidentiality.

- *Where and how data or specimens will be stored locally?*

2. Original data forms and source documents will be kept in locked filing cabinet in a locked office in Building D9.

- *How long the data or specimens will be stored locally?*

3. Data will be kept until the youngest subject turns 18 years.

- *Who will have access to the data or specimens locally?*

4. Only investigators and research assistants involved in the conduct of this study will have access to the data.

- *Who is responsible for receipt or transmission of the data or specimens locally?*

5. The investigator and research assistants are responsible.

- *How data and specimens will be transported locally?*

Data will be secured using a password protected excel spreadsheet and accessible only by study personnel.

k) Provisions to Monitor the Data to Ensure the Safety of subjects*

This is required when Human Research involves more than minimal risk to subjects.

Because LET gel is used routinely in clinical practice and this study looks at 2 different methods of application, there is no more than minimal risk to the subjects. There is no more than minimal risk to involved nurses and physicians.

l) Withdrawal of Subjects*

Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

Describe any procedures for orderly termination.

Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

The subject will be withdrawn from the study at any time if the subject or legal guardian(s) choose to withdraw. If the subject is withdrawn after consent and data collection has already taken place, the data collected will be entered into the intention to treat group, but all further data collection will stop. A statement is included in the

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consent form that they must tell us if they do not wish us to use the data already collected and we will destroy it if we are still able to identify it as being from their child.

No procedures will be done should a subject withdraw from the study after application of the gel. Subjects will continue to receive standard of care.

10) Risks to Subjects*

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the HSC's consideration, describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.

If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.

It is assumed that the systemic absorption through topical use will be minimal. For example, commercially available combination of lidocaine+tetracaine (Pliagris) cream has pregnancy category B even though tetracaine alone is under category C due to lack of data

If applicable, describe risks to others who are not subjects.

The risks to the subject involved in the laceration repair are a function of the medical treatment required and not directly related to the study. The only foreseeable risk related to the study is a theoretical increase in pain, however, providers will provide additional anesthesia as they see appropriate. Also, a theoretical increase in total time in ED exists, however, based on current practices, no significant delays in ED stay time are foreseen. In actuality, because investigators will be following up with clinicians to make sure suturing begins within 15 minutes of completing the LET application, ED total time may actually be shorter for participants.

There are no foreseeable risks to involved providers. The nurses and providers in the Pediatric ER will know about the study and they may opt out of the study if they choose.

11) Potential Benefits to Subjects*

Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the HSC's consideration, the probability, magnitude, and duration of the potential benefits.

Indicate if there is no direct benefit. Do not include benefits to society or others

Potential benefits to individual subjects include possible decreased pain, lower requirement for additional injected local anesthesia, decreased ED length of stay (since timing of LET and laceration repair will be monitored by investigator).

12) Provisions to Protect the Privacy Interests of Subjects

Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

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Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

Indicate how the research team is permitted to access any sources of information about the subjects.

A provider will approach and ask patient and parent or legal guardian for permission for a researcher to approach patient/family. The investigator will discuss the study design with the family and assure that medical care will not be withheld as part of this study. The investigator will inform the patient and family that they can withdraw from the study at any time. The investigator will explain to the patient and family that the information recorded on the data collection forms will not include any direct identifiers and will only be accessible to the study investigators. The patient and family will be assured that their involvement in this study is completely voluntary, and their decision to take part in the study will not affect the care they receive.

All interactions with the subjects and their parent/legal guardian will take place in a private setting such as a private exam room.

13) Compensation for Research-Related Injury

If the research involves more than minimal risk to subjects, describe the available compensation in the event of research related injury.

There is no more than minimal risk to subjects. There is no anticipated research related injury expected and no compensation for subjects involved in the study.

14) Economic Burden to Subjects

Describe any costs that subjects may be responsible for because of participation in the research.

There will be no economic burden to the subjects. Subjects will be responsible for the costs of their visit to the Pediatric Emergency Department including the LET gel.

15) Consent Process

Indicate whether you will you be obtaining consent, and if so describe:

- *Where will the consent process take place*
- *Any waiting period available between informing the prospective subject and obtaining the consent.*
- *Any process to ensure ongoing consent.*
- *Whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, describe:*
  - *The role of the individuals listed in the application as being involved in the consent process.*
  - *The time that will be devoted to the consent discussion.*
  - *Steps that will be taken to minimize the possibility of coercion or undue influence.*
  - *Steps that will be taken to ensure the subjects' understanding.*

Consent will be obtained from the legal guardian(s) in the subject's room in the pediatric emergency department. Assents will be obtained from the patient as well.

Appropriate time will be given to the patient and legal guardian to complete the assent and consent process.

No process will be required to ensure ongoing consent since the researcher will be present from the time consent is obtained through the end of the subject's involvement in the study. The legal guardian(s) will be given written information about the consent process and study.

The consent process will follow the conditions of HRP-090.

Non-English Speaking Subjects

- *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
- *If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language.*

Spanish speaking families will be included in the study.

When enrolled, a consent form translated into Spanish will be used and either translational services or a trained observer fluent in Spanish will be used during the data collection and the consent process.

After IRB approval of the English consent, an identical Spanish consent will be prepared.

Waiver or Alteration of the Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

N/A

Subjects who are not yet adults (infants, children, teenagers)

- *Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the Human Research under the applicable law of the jurisdiction in which the Human Research will be conducted. (E.g., individuals under the age of 18 years.)*

  - *For research conducted in the state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

Parental permission will be obtained from:

- One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

Permission will be obtained from individuals other than parents if they are the legal guardians with documentation supporting this and not foster parents.

Assent will be obtained on all patients enrolled in the study. All patients will be at least 7 years old.

Assent will be documented with the child's signature (in writing) on the prepared and approved assent form.

Cognitively Impaired Adults

Describe the process to determine whether an individual is capable of consent.

N/A

Adults Unable to Consent

List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)

N/A

16) Process to Document Consent in Writing

Describe whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not, describe whether and how consent of the subject will be documented in writing.

Written consent will be obtained by the parent/legal guardian for all children enrolled. Assent will be obtained from all the subjects enrolled in the study. The written consent will follow "SOP: Written Documentation of Consent (HRP-091)." Adequate provisions will be made to solicit the permission of the legal guardian of the child.

17) Vulnerable Populations

If the Human Research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

The population involved in this study is a vulnerable population in that all subjects are children. The population of the pediatric emergency department at Harbor UCLA is a primarily economically and educationally disadvantaged population.

In order to minimize risks to this population the following safe guards will be added:

- The research assistant will verbally read the consent information aloud while the legal guardians read it to ensure that illiteracy does not prevent the legal guardians from understanding the study
- The research assistant will have the legal guardians verbalize back the study plan, what the study is for, and that they are allowed to withdraw their child at any time
- Legal guardians who are not able to consent will not have their child enrolled in the study.
- The physician providing care for the patient will not be involved in data collection, consent, enrollment.

- *Adults unable to consent* - **Excluded**
- *Individuals who are not yet adults (infants, children, teenagers)* **- Included**

- *Pregnant women* **– Included (permission will be sought from parent/legal guardian and their assent will be sought unless they are an emancipated minors as defined by Cal. Fam. Code §7002 and Cal. Fam. Code §7050(e) – pregnancy is not among conditions that emancipate a minor)**
- *Prisoners* **- Excluded**

18) Drugs or Devices

If the Human Research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

The study involves a medication which is routinely used in the pediatric emergency department. There will not be any special supply or storage of the medication for this study, as it is a standard, stocked medication in our department.

19) Multi-Site Human Research*

This is not a multi site research project.

20) Community-Based Participatory Research

Describe involvement of the community in the design and conduct of the research.
Note: "Community-based Participatory Research" is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has

the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities

Our goal is to reduce perceived pain in the pediatric emergency department. By comparing two different methods of topical anesthetic applications, we hope to discover a superior application method than is currently used in our ED.

21) Sharing of Results with Subjects

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared.

Study results will be available to study participants and nurses who participate after data analysis and manuscript preparation if they express a desire to collect information. If they express an interest, participants will be given the contact information of the primary investigator so they can email a request to receive a copy of the manuscript after publication.

References

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