Prehospital Analgesia INtervention PAIN Trial Task Order 0006

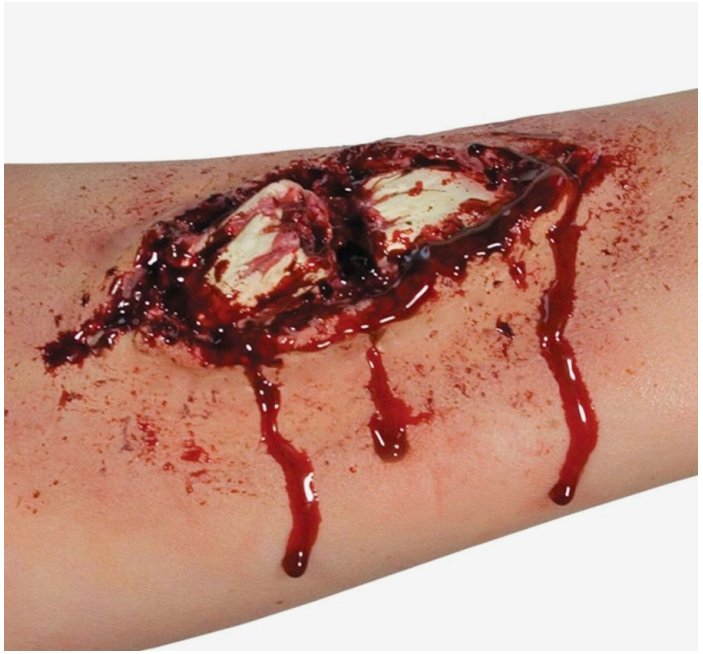
EMS Training

10 SLIDES

Study background and significance

Pain Management in Trauma

Safe?
Effective?
Inclusive?
Downstream Consequences?



Current standards: NAEMSP (National EMS Physicians)

Guidelines for Managing Pain in Trauma:

- Assess with Numerical Rating Score (NRS)
- Use opioids (morphine, fentanyl)
- Reassess
- Re-dose if necessary
- Refrain if patient is altered, hypotensive, or not breathing effectively

What we know already:

- Narcotic pain medications can lower blood pressure, decrease oxygen levels or result in airway management,
- Pain management in trauma patients with moderate to severe pain with compensated shock may be associated with a higher risk of mortality.

Why look at Ketamine?

- Effective analgesic
- Low risk of side effects (hypotension, hypoventilation)
- Comparisons of Ketamine to opioids in ED and OR demonstrate similar pain relief with fewer adverse effects

Study Details

- Clinical trial that compares **fentanyl vs. sub-dissociative ketamine** for the treatment of pain in the prehospital (EMS) setting
- Multicenter - participating sites across the US
- Randomized 1:1 ratio - equal chances of patients receiving fentanyl vs. ketamine
- Double-blinded - neither patients nor the study team will know which pain medicine was given
- Total to be enrolled = 994 (497/arm) across 30+ EMS services
- Looking only at trauma patients in compensated shock

Study Outcomes

- **Big Picture:** Effectiveness of analgesia, patient safety, and patient mortality
- Study Outcomes
  - Frequency of analgesia-associated hemodynamic instability and respiratory depression
  - Exposure to opioids in prehospital setting and at 24-hours
  - Anxiety and PTSD assessments in the acute phase of care and long-term
  - Incidence of long-term opioid use

Why PAIN is important to the DoD

Prolonged Field Care

Resource restrictions

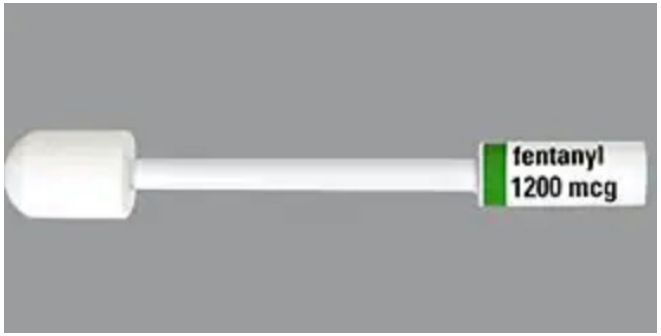
Limited monitoring capability

Opioid dependency

Pain Management for Trauma:

Civilian trauma pain management:

Military Trauma pain management:



These provide limited options which is why the **Department of Defense** is looking for safe pain management solutions.

Fentanyl and Ketamine

Fentanyl **1 mcg/kg**	Inclusion for both Trauma activation Shock Index ≥ 0.9 Pain score ≥ 5 (CPOT ≥ 2)	**Ketamine** **0.25mg/kg**
Bradycardia Bradypnea / Apnea Hypotension Dependence	Side Effects / **Contraindications**	Nystagmus Hallucinations Laryngospasm Muscle spasms
Binds: **opioid receptors** (reduces pain and respiratory effort) **histamine receptors** (vasodilation, itching)	Mechanisms of Action	Binds: **NMDA** (dissociation and pain relief) **Blocks Serotonin** (reduces spinal pain signals) **Increases Norepinephrine**

Completely different mechanisms of action

Study Drug

- Double-blinded, pre-filled syringes of study drug
  - 2 syringes in each kit contain same medication
  - Equal volumes of administration
  - Concentrations selected for weight-based dosing
  - Up to 2 doses/patient (one dose per syringe)
  - 15 min between doses
  - Slow push (over 2 minutes)

IV Ketamine (0.25mg/kg) vs
Fentanyl (1mcg/kg)

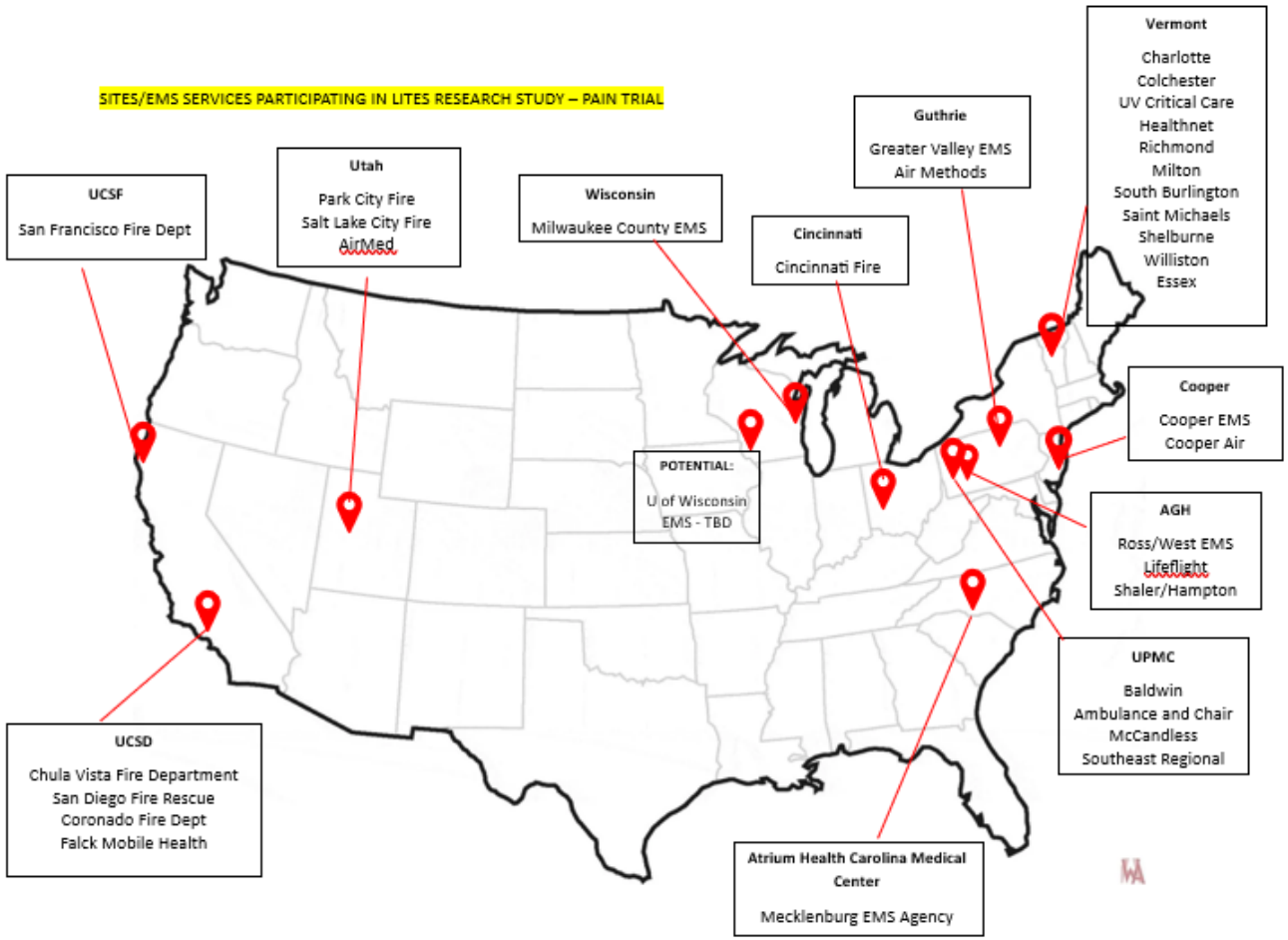
Outcomes of Interest

Prehospital outcomes: the incidence of adverse events such as hypoxia, hypotension, the need for airway management, allergic reactions, emergence, laryngospasm, dysphoria, pruritis, nausea, and pain assessments (NRS or CPOT).

In hospital outcomes include trauma bay pain scores, number of analgesic doses needed to reduce pain level to NRS<5 or CPOT<2, total 24-hour opioid use, and blood alcohol level (if drawn). Those who consent for follow-up will include PTSD and anxiety screen.

Follow up outcomes includes a three and six month follow up for PTSD, anxiety, pain, and opioid use.

LiTES



Participating Sites

- Allegheny Health Network in Pittsburgh
- University of Pittsburgh Medical Center
- University of Cincinnati Medical Center
- Cooper University Hospital
- University of California San Diego
- University of California San Francisco
- Medical College of Wisconsin
- University of Utah
- University of Vermont Medical Center
- Donald Guthrie Foundation
- Atrium Health Carolina Medical

7 SLIDES

Study Criteria

Inclusion/Exclusion Criteria

Inclusions
Transport after injury to a participating PAIN Study trauma center
Patient w/ compensated shock as defined **equal to or greater than 0.9. (SI ≥0.9)** *
IV pain medication indicated by pain score (**NRS ≥ 5 or CPOT ≥ 2**) prior to arrival at the trauma center

Exclusions
No IV access
Age < 18
All females < 50
Known prisoner (in police custody, detained, or cuffed)
SBP >180 mmHg at time of enrollment
Advanced airway management prior to 1st dose
Known allergy to fentanyl citrate or ketamine hydrochloride
Pain treatment contraindicated by local protocol *
Objection to study voiced by subject or family member at scene
Wearing “no pain study” bracelet

*Pain medication should not be given to patients if your local protocol does not indicate for medication to be given (for example, if in decompensated shock)

Shock Index Reference Table

Shock Index = Heart rate/Systolic BP

Compensated shock SI ≥ 0.9

SI = HR/BP	Heart Rate											
Systolic pressure	70	80	90	100	110	120	130	140	150	160	170	180
80	**0.9**	**1.0**	**1.1**	**1.3**	**1.4**	**1.5**	**1.6**	**1.8**	**1.9**	**2.0**	**2.1**	**2.3**
85	0.8	**0.9**	**1.1**	**1.2**	**1.3**	**1.4**	**1.5**	**1.6**	**1.8**	**1.9**	**2.0**	**2.1**
90	0.8	**0.9**	**1.0**	**1.1**	**1.2**	**1.3**	**1.4**	**1.6**	**1.7**	**1.8**	**1.9**	**2.0**
95	0.7	0.8	**0.9**	**1.1**	**1.2**	**1.3**	**1.4**	**1.5**	**1.6**	**1.7**	**1.8**	**1.9**
100	0.7	0.8	**0.9**	**1.0**	**1.1**	**1.2**	**1.3**	**1.4**	**1.5**	**1.6**	**1.7**	**1.8**
105	0.7	0.8	**0.9**	**1.0**	**1.0**	**1.1**	**1.2**	**1.3**	**1.4**	**1.5**	**1.6**	**1.7**
110	0.6	0.7	0.8	**0.9**	**1.0**	**1.1**	**1.2**	**1.3**	**1.4**	**1.5**	**1.5**	**1.6**
115	0.6	0.7	0.8	**0.9**	**1.0**	**1.0**	**1.1**	**1.2**	**1.3**	**1.4**	**1.5**	**1.6**
120	0.6	0.7	0.8	0.8	**0.9**	**1.0**	**1.1**	**1.2**	**1.3**	**1.3**	**1.4**	**1.5**
125	0.6	0.6	0.7	0.8	**0.9**	**1.0**	**1.0**	**1.1**	**1.2**	**1.3**	**1.4**	**1.4**
130	0.5	0.6	0.7	0.8	0.8	**0.9**	**1.0**	**1.1**	**1.2**	**1.2**	**1.3**	**1.4**
135	0.5	0.6	0.7	0.7	0.8	**0.9**	**1.0**	**1.0**	**1.1**	**1.2**	**1.3**	**1.3**
140	0.5	0.6	0.6	0.7	0.8	**0.9**	**0.9**	**1.0**	**1.1**	**1.1**	**1.2**	**1.3**
145	0.5	0.6	0.6	0.7	0.8	0.8	**0.9**	**1.0**	**1.0**	**1.1**	**1.2**	**1.2**
150	0.5	0.5	0.6	0.7	0.7	0.8	**0.9**	**0.9**	**1.0**	**1.1**	**1.1**	**1.2**
155	0.5	0.5	0.6	0.6	0.7	0.8	0.8	**0.9**	**1.0**	**1.0**	**1.1**	**1.2**
160	0.4	0.5	0.6	0.6	0.7	0.8	0.8	**0.9**	**0.9**	**1.0**	**1.1**	**1.1**
165	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.8	**0.9**	**1.0**	**1.0**	**1.1**
170	0.4	0.5	0.5	0.6	0.6	0.7	0.8	0.8	**0.9**	**0.9**	**1.0**	**1.1**
175	0.4	0.5	0.5	0.6	0.6	0.7	0.7	0.8	**0.9**	**0.9**	**1.0**	**1.0**
180	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.8	**0.9**	**0.9**	**1.0**

If at any time the SI index is ≥ 0.9, patient can be enrolled!

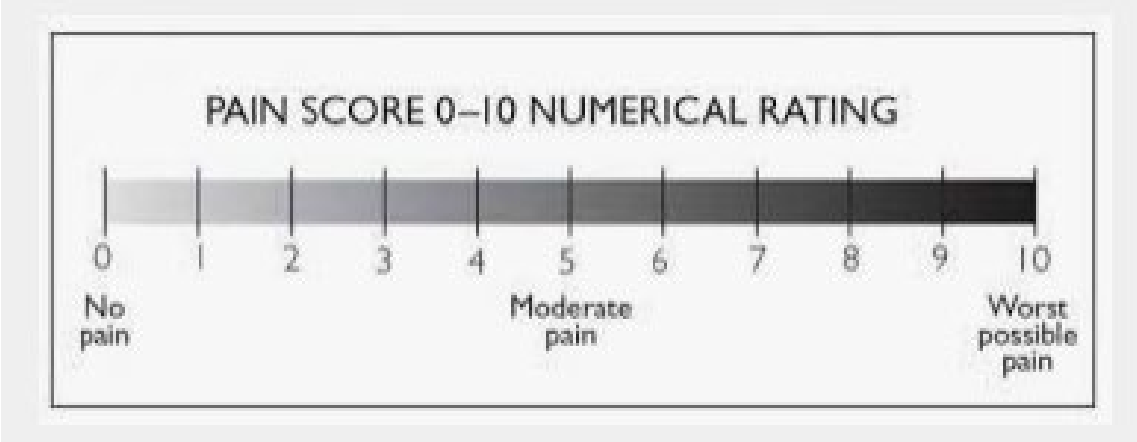
Review: Numerical Rating Scale (NRS)

- Ask patients to choose a number between 0 and 10 that fits best to their pain intensity

- Zero usually represents ‘no pain at all’

- The upper limit of 10 represents ‘the worst pain ever possible’

- For this study, subject is eligible if **NRS ≥ 5**



Review: CPOT Pain scale

Non-Verbal or Critically ill Patients (e.g., Intubated Patients)

Critical Care Pain Observation Tool (CPOT) score is used to assess pain in nonverbal patients.

1. Each of the four categories are scored 0-2.
2. Total score is between 0 and 8.

Indicator	Score	Intubated	Not Intubated
Vocalization / Compliance with Ventilator	0	Tolerating ventilator or movement	Talking in normal tone or no sound
	1	Coughing but tolerating	Sighing, moaning
	2	Fighting ventilator	Crying out, sobbing
		All Patients	***Description***
Facial Expression	0	Relaxed, neutral position	*No muscle tension observed*
	1	Tense	*Presence of frowning, brow lowering, orbit tightening and levator contraction or any other change (e.g., opening eyes or tearing during nociceptive procedures)*
	2	Grimacing	*All previous facial movements plus eyelid tightly closed*
Body Movements	0	Absence of movements or normal position	*Does not move at all or normal position (movements not aimed toward the pain site or not made for the purpose of protection)*
	1	Protection	*Slow, cautious movements, touching or rubbing a pain site, seeking attention through movements*
	2	Restlessness / Agitation	*Attempting to sit up, moving limbs or thrashing, not following commands, striking at staff, trying to climb out of bed*
Muscle Tension	0	Relaxed	*No resistance to passive movements*
	1	Tense, rigid	*Resistance to passive movements*
	2	Very tense or rigid	*Strong resistance to passive movements or incapacity to complete them*
TOTAL	# / 8		

- Typically used by critical care
- Assesses pain in nonverbal patients
- Scale is between 0-8
- For this study, subject is eligible if **CPOT ≥ 2**

Let's review the details of the exclusion criteria

EXCLUSION CRITERIA

1. Patients without IV access (cannot give this drug through IO)
2. Pediatrics: Age <18 years
3. Prisoners: transferred from jail, in police custody, **or hand-cuffed**
4. Potentially pregnant people: **Females < 50 years old**

Contraindications

5. Hypertensive subjects: SBP > 180 at time of enrollment
6. Known allergy to either fentanyl or ketamine
7. Any contradiction to pain meds based on local protocol (eg. hypotension)

Prior intervention given

8. Advanced airway prior to 1st dose of pain meds

Participant choice

9. Objection to the study voiced by subject/family at the scene
10. Wearing a "NO PAIN STUDY" bracelet (see next slide)

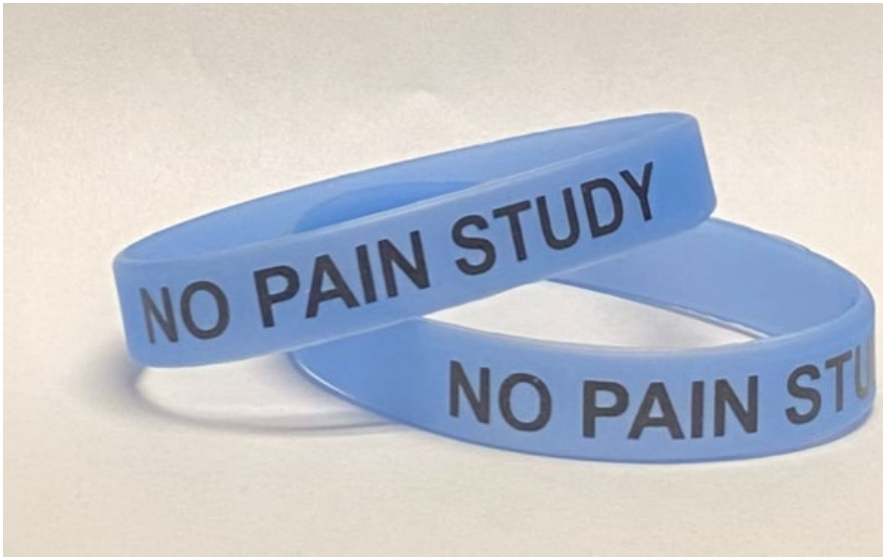
NOTE
If you find out later that a subject meets an exclusion criteria (after giving them the first dose) please do not give the second dose. Revert to clinical care

Example 1: You find out that patient is actually 48y/o female and not 52 as originally thought.

Example 2: After giving first dose, 15 minutes later, patient now has BP of 182/90.

Opt-out bracelets

- Handed out to general public during the community consultation/disclosure process.
- More commonly seen in blood product research
- Please honor if you come across a patient wearing this bracelet



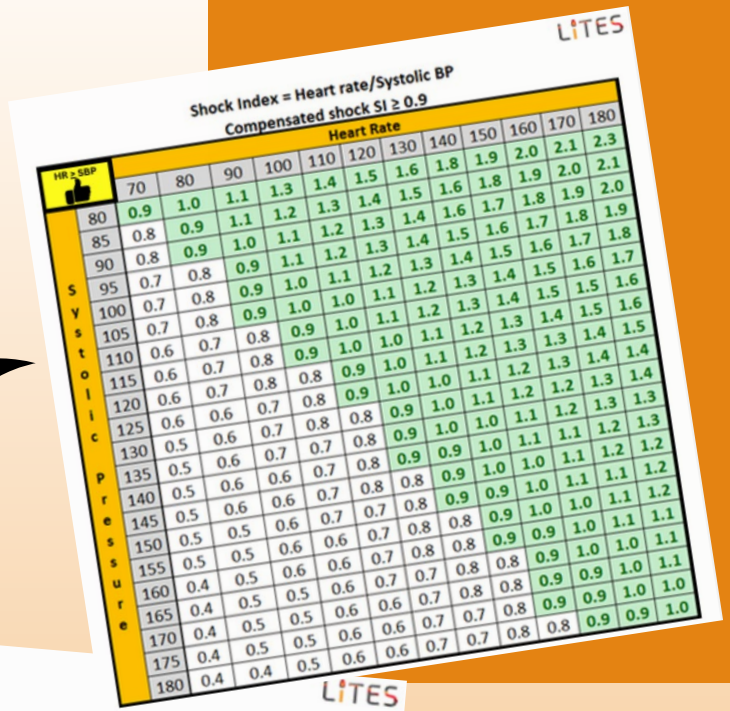
IF the patient simply expresses an objection to receiving either pain medication, they should be excluded.

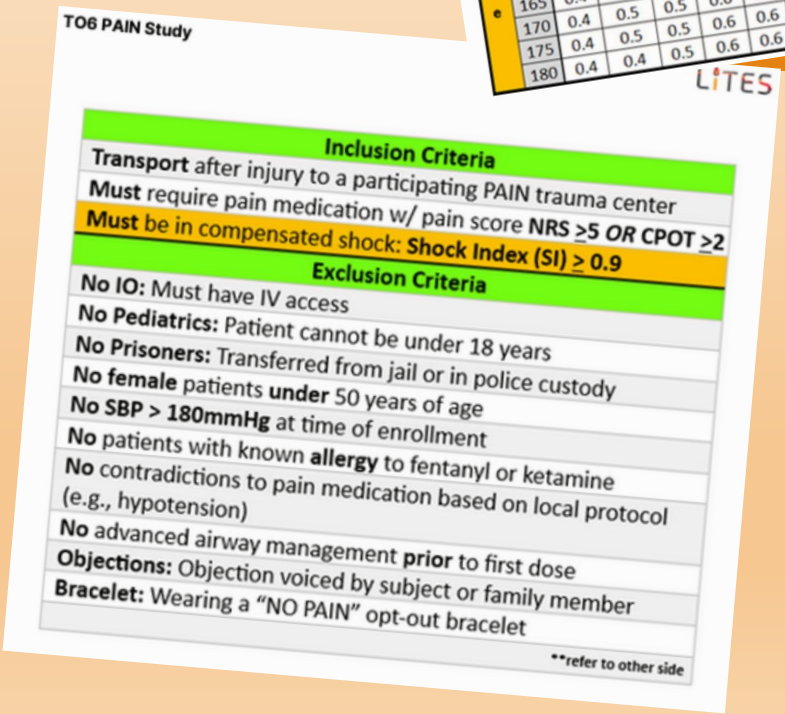
For example, if they say they don't want a narcotic, please honor and document in run sheet.

Materials for EMS – provided by coordinating center

- Posters for inside trucks
- Training placards for the station
- 8x10 Shock Index reference chart
- 3x3 Hang tags for each medic showing inclusion criteria and SI index reference chart
- Green drug wrap with reminder material around the kit

Hang-tags





10 SLIDES

Prehospital Enrollment Procedures

Intervention

If at any point a rescue medication is needed for pain management, EMS should provide and document appropriately in run sheet

1. Review that patient meets all inclusion/no exclusion criteria
2. Give one dose of blinded study drug (weight-based dosing) via slow IV push (approx. 2 min)
3. Reassess pain scale and need for pain management after 15 minutes
4. If still NRS ≥ 5, administer 2nd dose of blinded study drug
5. Continue to assess every 15 minutes
6. If patient still needs pain management, rescue medication is given based on local protocols
7. Once at hospital, waste any unused study drug, scan QR code, and leave empty drug kit package with ED staff for any clinical unblinding needs

Example Dosing (based on weight)

Fentanyl	70 Kg patient	Ketamine
1 mcg/kg dose	Dose	0.25mg/kg dose
10 mcg/ml syringe	Concentration	2.5mg/ml syringe
7 ml dose= 70 mcg	Delivery	**7 ml dose**= 17.5 mg

Administer 0.1 ml/kg

For example: 1 ml per 10 kg

70kg patient receives 7ml blinded study dose

*Each 20cc syringes have 10cc of product in them and since the graduations on the syringe are the whole 1 ml, we are requesting that medics dose to the 0.5ml of the weight base dose

EMS will Scan QR code with a phone/tablet

Outside package will have the QR code, and the EMS must enter the Kit number from outside package

PAIN Study Medication
STERILE ANALGESIC SOLUTION FOR INJECTION
10 mL Pre-Filled Syringe

Ketamine C-III 25 mg/10 mL (2.5 mg/mL)
or
Fentanyl C-II 100 mcg/10 mL (10 mcg/ mL)

LOT: 12345

EXP: 01/01/1900

Kit Number: 001

Scan QR Code to complete study reporting:

Directions: Administer 0.1 mL/kg IV, slowly over 2 minutes. Dose may be repeated after 15 minutes if patient continues to meet criteria.

Date Compounded: 01/01/1900
Store at Room Temperature
Excursions permitted -20°C to 40°C

Caution: New Drug - Limited by Federal (or United States) law to investigational use.

If treatment arm must be known, call either:
Dr. Jason Sperry 412-215-7025
Dr. Frank Guyette 412-651-1077

69194088861

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INCLUSION CRITERIA:

1. Transport after injury to a participating PAIN Study Trauma center
2. Patient w/ Compensated Shock (Shock Index ≥ 0.9 ….. for example ….. HR equal to or > Systolic BP)
3. IV pain meds indicated (Pain score ≥ 5 on scale of 0-10 … OR … Nonverbal Pain Score ≥ 2 [see back])

EXCLUSION CRITERIA:

- ☐ No IV access (cannot give drug IO)
- ☐ Age < 18 years
- ☐ Known prisoner
- ☐ **Females < 50 years old**

Contraindications (Do not give drug if…)

- ☐ SBP >180 at time of enrollment OR multiple instances of SBP < 90
- ☐ Contraindication to pain meds based on local protocol
- ☐ Allergy to either fentanyl or ketamine

EXCLUSION CRITERIA:

Prior interventions given (Do not give drug if…)

- ☐ Advanced airway prior to 1st dose of pain meds

Participant Choice

- ☐ Objection to study by subject/family at scene
- ☐ Wearing a "NO PAIN STUDY" bracelet

DOSE:

- **Administer 0.1 ml/kg slow IV Push over 2 minutes** (max. 10ml)
- May administer 2nd dose in kit 15 minutes after 1st dose (same pain criteria as above)

ALSO DON'T FORGET TO:

- ☐ Waste remaining drug in syringe per protocol
- ☐ **SCAN QR CODE** after transfer of patient care (**NOTE** KIT NUMBER IS ON BROWN OUTSIDE PACKAGE)
- ☐ Document enrollment (include kit #) in your trip sheet
- ☐ Document pain scores before & 15 minutes after drug given (redose as above), complications, and/or adverse events
- ☐ Place the brown outer package that the drug came in into the PAIN-Lites study box (in EMS room) or give to ER staff

Reminder "Green" drug wrap will accompany the drug

- Provides a checklist
- Has reminder for dosage
- Provides copy of the CPOT

…ly ill Patients (e.g., Intubated Patients)

…bservation Tool (CPOT) score is used to assess pain in nonverbal patients. …ur categories are scored 0-2. …etween 0 and 8.

		Intubated	Not Intubated
…with Ventilator	0	Tolerating ventilator or movement	Talking in normal tone or no sound
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TOTAL	# / 8		

Patients eligible if: SCORE ≥ 2

LiTES

Time of Enrollment

- Scanning of the QR code will generate an auto-email to site making them aware of the enrollment
- Time of Enrollment:
  - For subjects who meet all criteria and are administered medication: **date/time that medication is administered is time of enrollment**
  - If study drug is never administered for some reason, the time the subject met inclusion criteria will be used as time of enrollment

*A patient is considered ENROLLED once you **open the study drug kit.** So please do not open the kit until you have confirmed they are a good candidate*

Transparency

What if the patient or family member asks about the study drug?

1. If the patient or family member has a concern about the medication, we have a script you can follow to help guide the conversation

2. If the patient or family member is uncomfortable with the study, DON'T ENROLL THEM.

Prehospital Analgesia INtervention (PAIN) Trial

Instructions:
Use in **rare** situations when it's feasible with patients (who are conscious and alert), it does not adversely affect patient care and/or transport, and injured person has met the study inclusion criteria with no exclusion criteria.

Script:

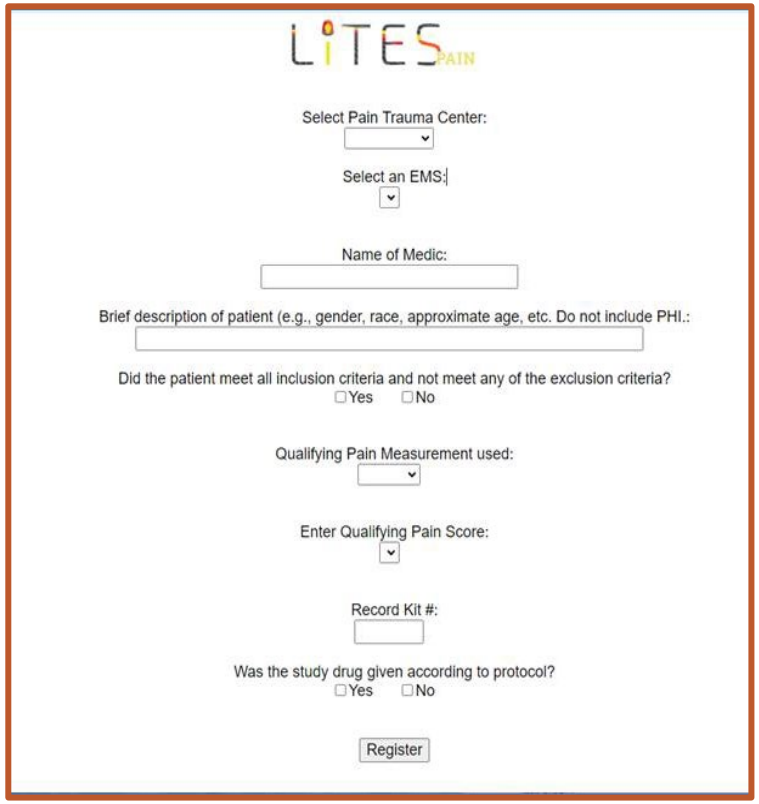
1. Our trauma system is participating in a research study to compare two medications, Fentanyl and Ketamine, which are both commonly used by EMS to treat pain.
2. If you say no to the study, we will treat you (or your loved one) according to our standard protocols, which may include giving these same pain medications.
3. The research group can give you more information at the hospital.

Each service's EMS medical director will dictate where to store and manage the scripts at your service

QR questions – complete once you transfer patient care

1. Trauma Center (or other)
2. EMS Service Name
3. Name of EMS clinician
4. Brief description (no HPI)
5. Yes/No evaluations of inclusion/exclusion criteria
6. Qualifying pain scale used
7. Number of pain score
8. Kit number (from outside package)
9. Yes/No was study drug given according to protocol

Verify you checked your R's
√ Right dose – based on weight
√ Right rate – slow IV push
√ Right route – IV only



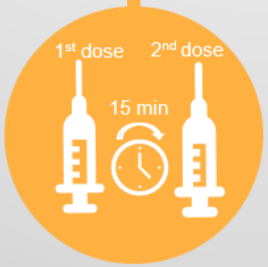
What to do if QR code doesn't work?

- Some scenes/landing zones might have terrible phone service.
- If this occurs, please take a picture of the KIT so you will have the QR code and Kit # readily available.
- Once you have a good signal, please scan the QR code and enroll the subject.
- Worst case scenario, have your supervisor contact your local research coordinator to make them aware of the enrollment in real time via email (please include lot and kit number)

Prehospital Analgesia Intervention Trial (PAIN)
EMS Flowsheet

Enroll trauma patients who meet all inclusions and no exclusions

Before giving pain medication to a trauma patient check to see if they qualify for the PAIN study



Administer blinded, pre-filled syringes of study drug

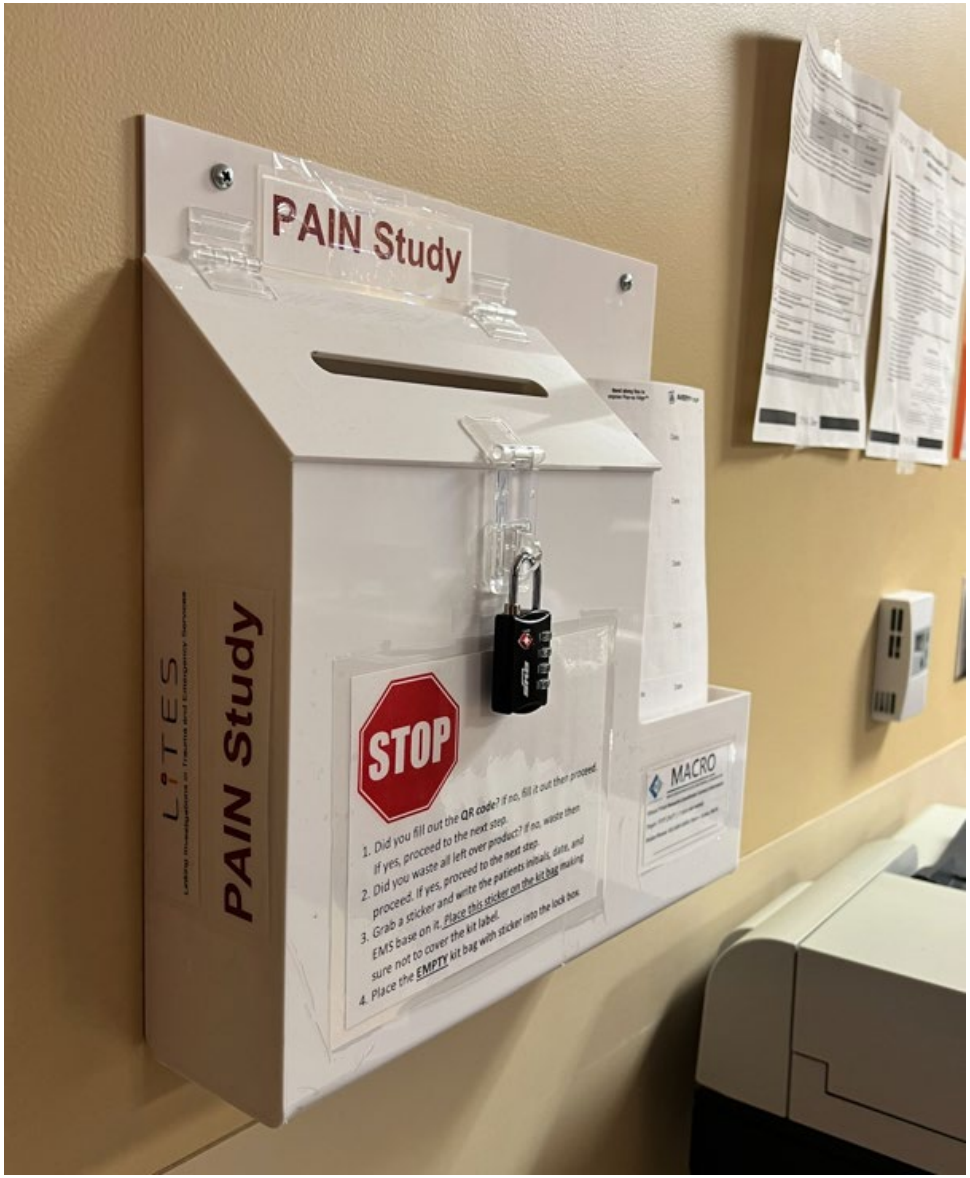
- Concentrations selected for weight-based dosing **0.1 ml/kg** (i.e. 1 ml per 10kg)
- Up to 2 doses/patient
- 15 min between doses

Transfer drug package with patient and waste unused drug

- Make sure empty package stays with patient
- Waste any unused drug from kit according to your protocol

Scan QR code to notify research staff of enrollment

- Answer 5 questions
- Include kit number
- Document enrollment, including kit number in your run sheet!



Drop box

When leaving the **empty drug packages** with the patient at the ED, some hospitals may have installed a “drop box” so you can mark the patient’s initials and leave the package there.

Check with your training coordinator to see if your ED has one installed.

Important Notes

- If the kit is opened and the medication is not administered for some reason, the QR code must be scanned and the subject will be enrolled as Intent to Treat
- Any unused medication will need to be disposed of properly according to EMS local protocol
- The empty drug kit package will need to be left with subject (not the syringes) to clinical staff to have unblinding information and for research to verify kit number sent in QR code survey

Drug Accountability

- Study drug kits must be tracked per FDA and DEA requirements.
- Sites and agencies are responsible for tracking kits, including which are given to enrolled patients, which are wasted, and which expire.
- Tracking medications will be consistent with record keeping and other responsibilities as required under 21 CRF 312.
- Treat the same as any other CONTROLLED SUBSTANCE. Must maintain a chain of custody.

Investigational Drug Responsibilities: (**documentation** is key!)

EMS

- EMS medical director orders drug (may be different for your site)

- Drug will come from your site or directly from Pine Pharmaceuticals

- Drug must be logged upon arrival

- Drug must be stored appropriately

- Drug must assigned to units

- Drug must be scanned via QR code when used (or even opened)

- Drug must be wasted appropriately

RESEARCH TEAM

- Ensure drug is ordered appropriately

- Maintain drug accountability log to follow chain of custody

- Collaborate with EMS to ensure DEA rules are being followed

- Receive email with enrollment information based on QR scans when drug is used

- Ensure family/patient is notified/consented about study drug administration

GOOD CLINICAL PRACTICE AND COMPLIANCE

6 SLIDES

Key Research Principles

This is Research!

General Rules in research are called Good Clinical Practice (GCP).

Here are the guides to GCP:

1. Keep the patient's best interest in mind
2. Provide excellent documentation
3. Follow the study protocol
4. Follow the rules for research
5. Be sure research follows up for consent from family or patient

Follow Good Clinical Practice (GCP)

EMS REQUIREMENTS

Accurate documentation

Follow the protocols

Keep the patient's best interest in mind

* AND follow the rules for research

RESEARCH REQUIREMENTS

Assures the quality, reliability, and integrity of data collected

Standards and guidelines for conducting clinical research

Protects the rights, safety, and well-being of patients involved in research

Approved consent process

Good Clinical Practice = Good Ethical Standards + Good Data Quality

Principles of **Good Clinical Practice**

How do we ensure GOOD research?

- **Oversight by the Food and Drug Administration (FDA)** – ensures we follow Good Clinical Practice developed by **International Conference on Harmonization (ICH)**.

- **Oversight by the Institutional Review Board (IRB)** –Ensures we are following legal and ethical requirements

- **Oversight by the Data Safety Monitoring Board (DSMB)** – Reviews ALL adverse medical events and makes sure we are doing good medicine

How can **YOU** follow GCP in this study?

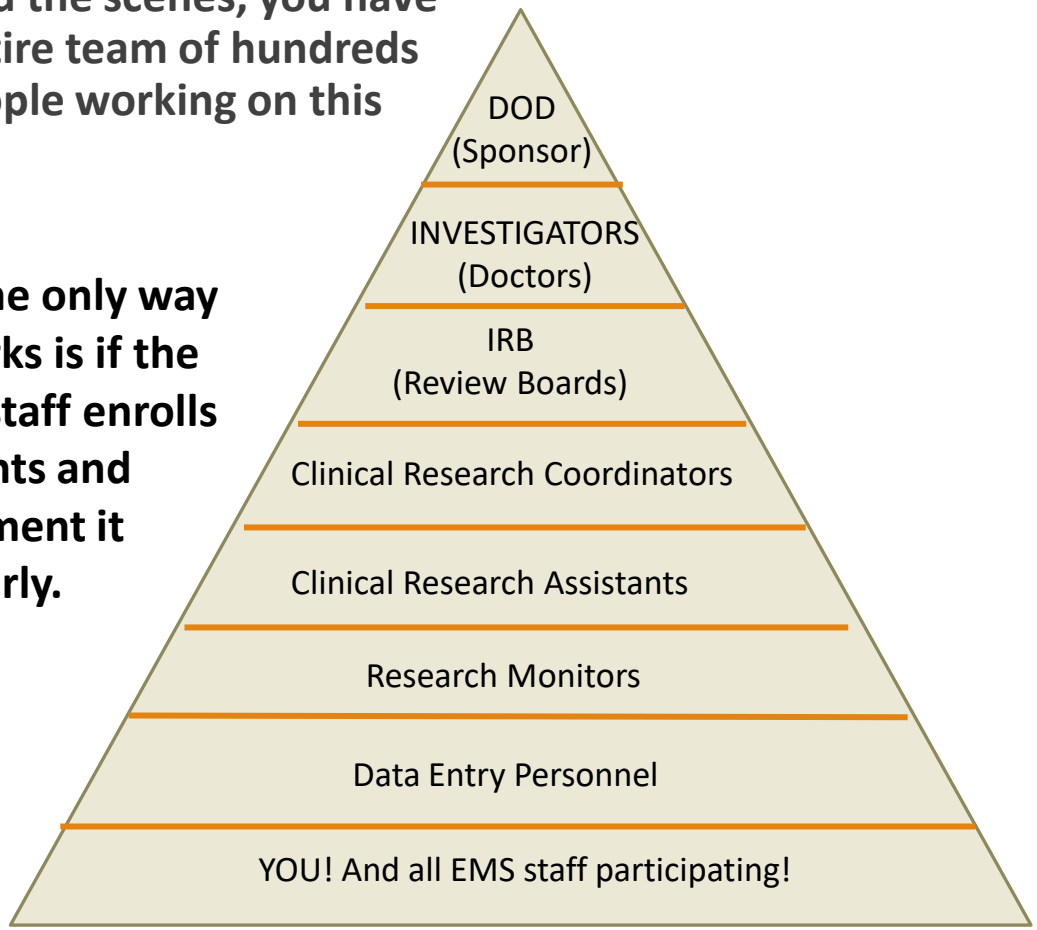
1. **Appropriate evaluation of inclusion/exclusion criteria**
2. **Appropriate administration of drug**
3. **Prompt QR scan to ensure research staff is aware of enrollment (gives kit number as well!)**
4. **Valid data collection/reporting procedures –** Ensure tripsheet is completed quickly so research staff can start to follow patient for follow-up reporting
5. **Document adverse events – report everything you see and do such as:**
   - Need for airway management, any airway interventions, the need for oxygen
   - Hypotension
   - Hypoxia (SPO2 < 90%)
   - Potential allergic reactions to medication
   - Any complications

Who is responsible for compliance?

EVERYONE!

Behind the scenes, you have an entire team of hundreds of people working on this study.

But the only way it works is if the field staff enrolls patients and document it properly.



EFIC AND COMMUNITY CONSULTATION

4 SLIDES

Consent in Research

What is the consent process?

- Most research requires that patients give permission (consent) before being in a research study
- This doesn't work in EMS when there is a life-threatening condition. The FDA allows us to use Exception From Informed Consent (EFIC) to study patients who can't consent
- EFIC requires the research staff to consent the patient as soon as possible AFTER the intervention is done. Typically done at the hospital with the patient or the Legally Authorized Representative
- Before the study began, we had to 'inform' the public using Community Consultation and Public Disclosure
- The FDA reviews the protocol and must agree that it meets EFIC criteria
- Finally, a few rules MUST be met to get EFIC….

EFIC: Federal regulations permit research for emergency medical situations in which patients or family members cannot give informed consent before treatment.

To qualify for an exception from informed consent, research must involve:

- **Life-threatening disease/injury;** standard of care associated with high mortality rate.
- **Evidence that the research has the potential to benefit the patient**.
- **Multiple independent rigorous reviews** to meet ethical standards.
- **Communities are consulted** about participation.
- **Surviving patients and/or authorized representatives are informed about the trial as soon as feasible** after the intervention has been given.

What is **Community Consultation?**

Reaching out to the community to make them aware of the study

- Talk to key stakeholders (elected officials, community leaders)
- Media (radio, internet, random digit dialing of individuals, bus ads)
- Solicit public comment

Reaching out to vulnerable populations

- For example: for blood administration studies we would reach out to religious groups that do not approve of blood administration

https://www.litesnetwork.org/pain/

How we explain this study to the public…

"We are conducting a research study looking at prehospital pain medication administration in patients with traumatic injuries before arriving to the hospital".

"Participants will be enrolled by participating EMS services under Exception from Informed Consent".

If you have questions, please ask us at https://www.litesnetwork.org/pain/
We want everyone to be comfortable and transparent with the consent process.

4 SLIDES

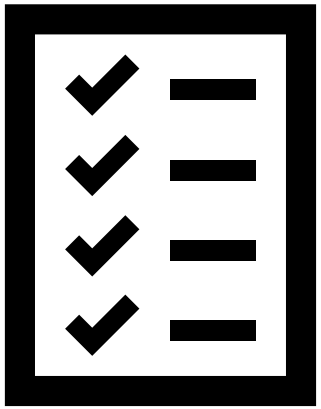
Documentation

Documentation by EMS

EMS run sheets should contain the following:

- Pain scores (which score was used)
- Study drug – dosage(s) administered
- Vitals (shock index is an inclusion criteria)
- Any other medications given
- All airway attempts
- Any complications / adverse events
- Any hand-off information provided by other providers on the scene.
- Document **KIT number** in run sheet.

Documentation by EMS
Important items to note



- Vital signs, especially those that show subject met shock index, need to be stated on your run sheet (even if they were a verbal report by mutual aid)
- The weight of the patient needs documented so we can make sure of proper dosing
- When you provide a pain score, research team will default to NRS if scale used (NRS or CPOT) is not indicated. Please state which scale you used.
- When giving a second dose, please remember to provide pain score indicating the need for pain medication.

Documentation by EMS

Adverse events and Complications

Please document all patient care events in your runsheet. Items of particular interest are as follows:

- √ Nausea
- √ Vomiting
- √ Headache
- √ Allergic reaction
- √ Pruritus (itching)
- √ Laryngospasm
- √ Emergence (agitation)
- √ Administration of opioid antagonist (ex. Narcan/naloxone)
- √ Hypotension (SBP < 90 mmHg)
- √ Hypoxia (SpO2 <90%)
- √ Received supplemental oxygen for SpO2 ≥90%
- √ Received an advanced airway
- √ Received bag mask ventilation

Treatment of adverse events potentially associated with study pain medications

Always follow your local protocols & procedures to treat events such as:

- ✓ Hypoxia
  - Ensure an open airway
  - Provide supplemental oxygen
- ✓ Hypotension
  - Fluid boluses
  - Epinephrine if indicated
  - Other interventions per agency protocol if indicated
- ✓ Hypoventilations
  - Support with BVM
  - Naloxone if necessary
- ✓ Need for Airway Management
  - BVM, basic airway maneuvers
  - Advanced airway support per agency protocols

What happens after I transfer care?

- Notify the Trauma research staff when you enroll (by scanning QR)
- Research Staff will get consent from the patient or family as able
- Research Staff will collect data from the EMS and hospital medical records
- The data will be reviewed for accuracy and analyzed

3 SLIDES

‘What if’ scenarios

Frequently asked questions…

-Q1. What if I open and don't use it?

A: Still enroll that subject. Scan QR code. Waste medication and document wastage appropriately. Still give drug packaging to study staff. Research staff will handle the paperwork on the back end

- Q2. What if I drop the kit on the ground into a pool of blood, can I just grab a different kit?

A: No, if a study drug syringe is dropped or unusable, a second kit may not be opened for that subject. However, if you drop one of the syringes, the second syringe is still available for use. You just won't have a second dose for re-dosing and will need to use standard care pain management for subsequent treatments

-Q3. What if the patient is larger than 100kg?

A: Treat patient as 100kg, by giving 10ml. Reassess in 15 minutes to see if you need to give second syringe

Frequently asked questions…

- Q4. What if we don't use the second syringe?

A: Waste the entire syringe according to your waste protocols and document appropriately

- Q5. What if we divert to a different hospital/hand off to flight crew?

A: This is still an enrollment. Just make sure to answer the QR code questions "Did not give medication according to protocol" if subject is taken to another hospital. If handing off to another EMS service, be sure to scan the QR code and waste any unused medication. Do not give study medication to the next agency.

- Q6. What if the QR code doesn't work?

A: Take a picture of the content bag. Try again with better reception. If still no luck, contact your training coordinator/Medical Director to have the relay the information to the research staff

Frequently asked questions…

- Q7. What if the patient has an allergic reaction?

A: Follow your local protocol on treating the patient and then be sure to tell hospital staff the potential reaction. Especially important to hand-off the drug packaging so the research/hospital staff have the kit number and unblinding instructions from the label

- Q8. What if the patient doesn't have pain controlled with the study drug?

A: Clinical care always come above research work. The medic can use rescue medication at any point and does not need to wait 15 minutes between study drug administration if the patient is suffering with pain.

- Q9. What if the patient cannot verbalize answers for the exclusion criteria?

A: For patients who are unable to verbalize, consider using nonverbal cues such as a thumbs-up if the female patient is over 50 years of age.

- Q10. Who's my first line for questions if something weird happens that's not on this list?

A: Contact your training coordinator/EMS medical director who can submit & collaborate with the research team and submit an urgent help ticket to LITES

Thank you for helping us to learn what is the best way to manage pain in the trauma patient!

1. Consider inclusion / exclusion criteria:

- Adult trauma patients with SI ≥ 0.9 who need pain management

2. Apply the principles of Good Clinical Practice for Research

3. This is EFIC, we will get consent from the patient or family later, so you must make sure to notify the research staff of your enrollment by scanning that QR code.

4. Document well in your run sheets!

Let’s practice using a QR code

Please scan training code:

1. Using a cell phone or tablet, please open your camera
2. Point the camera at the QR code here
3. Answer the questions listed
4. You have officially been registered as participating in this training!

www.chrissanders.org

We want to hear from you!

1. Using a cell phone or tablet, please open your camera
2. Point the camera at the QR code here
3. Let us know your thoughts!

All responses are anonymous

If you'd prefer to use a link to complete the survey, please click:

https://pitt.co1.qualtrics.com/jfe/form/SV_5ccWzkWHgJavK4K