JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)

Analgesia and Sedation Management During Prolonged Field Care (CPG ID: 61)
The intent of this guideline is to identify potential issues one must consider when providing analgesia with or without sedation for an extended time. This guideline begins where Tactical Combat Casualty Care (TCCC) guidelines end.

Contributors

LTC Jeremy Pamplin, MD
MAJ Andrew D. Fisher, PA-C
SFC Andrew Penny, 18D
SFC Robert Olufs, 18D
SFC Justin Rapp, 18D

Dr. Katarzyna Hampton, MD
LTC Jamie Riesberg, MD
MAJ Doug Powell, MD
COL Sean Keenan, MD
Col Stacy Shackelford, MD

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This Role 1, prolonged field care (PFC) guideline is intended to be used after Tactical Combat Casualty Care (TCCC) Guidelines, when evacuation to higher level of care is not immediately possible. A provider of PFC first must be an expert in TCCC. The intent of this guideline is to identify potential issues one must consider when providing analgesia with or without sedation for an extended time (i.e. 4–72 hours). As a principle, the guideline attempts to decrease complexity by reducing options for monitoring, medications, and so forth. It prioritizes experience with a limited number of options rather than providing recommendations about many different options that can be used in a more customized way. It does not address induction of anesthesia before airway management (i.e. rapid sequence intubation). The CPG should be used by all clinicians providing analgesia and sedation in a Role 1 (R1) or PFC environment.

**PRIORITIES OF CARE**

Priorities of care as related to analgesia and sedation:

1. Keep the casualty alive. Do not give analgesia and/or sedation if there are other priorities of care (e.g., hemorrhage control).
2. Sustain adequate physiology to maintain perfusion. Do not give medications that lower blood pressure or suppress respiration if the patient is in hemorrhagic shock or respiratory distress (or is at significant risk of developing either condition).
4. Maintain safety. Agitation and anxiety may cause patients to do unwanted things (e.g., remove devices, fight, fall). Sedation may be needed to maintain patient safety.
5. Stop awareness. During painful procedures, and during some mission requirements, amnesia may be desired.

**PRINCIPLES**

- In an R1 or PFC setting, intravenous (IV) or interosseous (IO) medication delivery is preferred over intramuscular (IM) therapies. The IV/IO route is more predictable in terms of dose-response relationship.
- Remember, you can always give more, but it is very difficult to take away. Therefore, it is easier to prevent cardiorespiratory depression by being patient and methodical. **Titrate to effect**.
- Smaller, more frequent doses of medications are preferred to single large doses to achieve a constant level of pain control and sedation over a longer time.
- The lower the blood volume, the less drug and time will be needed to achieve similar affects as compared with a normovolemic patient. **Start low, go slow**.
- Engage telemedicine support early and often if you are inexperienced in delivering analgesia and sedation beyond TCCC or if you are having difficulty.
PRINCIPLES OF MEDICATION USE IN THE PFC SETTING

Comparative effectiveness data for one analgesia/sedation strategy versus another are lacking. The principles of medication use in the PFC setting include:

1. Consider pain in three categories:
   a. **Background**: the pain that is always present because of an injury or wound. This should be managed to keep a patient comfortable at rest but should not impair breathing, circulation, or mental status.
   b. **Breakthrough**: the acute pain induced with movement or manipulation. This should be managed as needed. If breakthrough pain occurs often or while at rest, background pain medication should be increased.
   c. **Procedural**: the acute pain associated with a procedure. This should be anticipated and managed periprocedurally.

2. Analgesia is the alleviation of pain and should be the primary focus of using these medications. In other words, treat pain before considering sedation. Remember, not every patient needs (or should receive) pain medication at first, and unstable patients may require other therapies or resuscitation before the administration of pain or sedation medications.

3. Sedation is used to relieve agitation or anxiety and, in some cases, induce amnesia. The most common causes of agitation are untreated pain or other serious physiologic problems like hypoxia, hypotension, or hypoglycemia. Sedation is used most commonly to ensure patient safety (e.g., when agitation is not controlled by analgesia and there is need for the patient to remain calm to avoid movement that might cause unintentional tube, line, dressing, splint, or other device removal or to allow a procedure to be performed) or to obtain patient amnesia to an event (e.g., forming no memory of a painful procedure or during paralysis for ventilator management).

4. Each patient responds differently to medications, particularly with respect to dose. Some individuals require substantially more opioid, benzodiazepine, or ketamine; some require significantly less. Once you have a “feel” for how much medication a patient requires, you can be more comfortable giving similar amounts during redosing. In general, a single medication will achieve its desired effect if enough is given; however, the higher the dose, the more likely the side effects. Additionally, ketamine, opioids, and benzodiazepines given together have a synergistic effect: the effect of medications given together is much greater than a single medication given alone (i.e. the effect is multiplied, not added. Go with less than what you might normally use if each were given alone).

5. PFC requires a different treatment approach than TCCC. Go slow, use lower doses of medication, titrate to effect, and redose more frequently. This will provide more consistent pain control and sedation. High doses may result in dramatic swings between oversedation with respiratory suppression and hypotension alternating with agitation and emergence phenomenon.

MONITORING

Patients receiving analgesia and sedation require close monitoring for life-threatening side effects of medications.

- **Best**: Portable monitor providing continuous vital signs display and capnography; document vital signs trends frequently.
- **Better**: Capnography (if controlled airway) in addition to minimum requirements.
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- **Minimum:** Blood pressure cuff, stethoscope, pulse oximeter; document vital signs trends.

### MEDICATIONS

**NOTE:** Use the PFC Analgesia and Sedation Guideline table (Appendix A) for recommended treatments.

- Ketamine drip recommendations are detailed in Appendix B.
- A “cheat sheet” of common IV medications is listed in Appendix C.
- Providers using these guidelines should be intimately familiar with the medications in Appendix D, including their pharmacology, and side-effects.

The PFC Analgesia and Sedation Guideline table in Appendix A is arranged according to anticipated clinical conditions, corresponding goals of care, and the capabilities needed to provide effective analgesia and sedation according to (1) the minimum standard, (2) a better option when mission and equipment support is available (all medics should be trained to this standard), and (3) the best option that may only be available in the event a medic has had additional training and experience, and/or equipment is available. The table is intended to be a quick reference guide but is not stand alone: you must also know the information in the rest of the guideline.

Medications in the table are presented as either Give or Consider.

- **Give:** Strongly recommended.
- **Consider:** Requires a complete assessment of patient condition, environment, risks, benefits, equipment, and provider training.

### Step 1. Identify the clinical condition.

- **Standard analgesia** is for most patients. The therapies used here are the foundation for pain management during PFC. Expertise in dosing oral transmucosal fentanyl citrate (OTFC) and augmenting it with low dose ketamine IV or IO is a must.

- **Difficult analgesia or sedation needed** is for patients in whom standard analgesia does not achieve adequate pain control without suppressing respiratory drive or causing hypotension, OR when mission requirements necessitate sedating a patient to gain control over his/ her actions to achieve patient safety, quietness, or necessary positioning.

- **Protected airway with mechanical ventilation** is for patients who have a protected airway and are receiving mechanical ventilatory support or are receiving full respiratory support via assisted ventilation (i.e., bag valve).

- **Shock present** is for patients who have hypotension and shock.

### Step 2. Read down the column to the row representing your available resources and training.

### Step 3. Provide analgesia/sedation medication accordingly.

### Step 4. Consider using the Richmond Agitation-Sedation Scale (RASS) score (Appendix F) as a method to trend the patient’s sedation level.

For IV/IO drip medications:

- Use normal saline to mix medication drips when possible, but other crystalloids (e.g., lactated Ringer’s, Plasmalyte, and so forth) may be used if normal saline is not available.
• DO NOT mix more than one medication in the same bag of crystalloid because this practice has not been studied and may not be safe. Mixing medications together, even for a relatively short time, may cause changes to the chemical structure of one or both medications and could lead to toxic compounds. There is ongoing research to determine the safety of such practices.

• If a continuous drip is selected, use only a ketamine drip in most situations, augmented by push doses of opioid and/or midazolam if needed. Multiple drips are difficult to manage and are generally not recommended. Multiple drips should only be undertaken with assistance from a telemedicine consultant with critical care experience. Multiple drips are most likely to be helpful in patients who remain difficult to sedate with ketamine drip alone and can “smooth out” the sedation (i.e., fewer peaks and troughs of sedation with corresponding deep sedation mixed with periods of acute agitation).

REGIONAL ANESTHESIA

(Appendix E)
Regional anesthesia (e.g., local anesthetic such as ropivacaine or lidocaine injected adjacent to a large, extremity nerve bundle or on either side of a finger or toe) is a useful technique that can markedly reduce or eliminate limb pain without risk of opioid or benzodiazepine side-effects of respiratory depression, sedation, and hypotension. There are, however, serious potential morbidities (and mortality from proximal injections or injection directly into blood vessels) that may occur.

For these reasons, this guideline has attempted to balance the overall risks and potential benefits of this intervention by recommending optimal procedure technique (e.g., use of ultrasound), a limited number of block sites, and the safest medication and dose combination. It should be noted that even with optimal technique, the risk of systemic toxicity (e.g., seizure or cardiac arrest) is not eliminated. Toxicity occurs either with direct injection of anesthetic into the systemic blood circulation or by absorption over the first 15–20 minutes after injection. Close monitoring MUST be available during this time.

Regional anesthesia should only be used by trained individuals. There should be documentation of competency. Three techniques exist:

1. Ultrasound-guidance: used to visualize targeted nerves, needle placement, and the spread of local anesthetic in real time.

2. Nerve stimulation: requires an assistant, a nerve stimulator, specialized needles, and cannot be reliably applied in cases of partial or complete amputations, given the inability to elicit motor response in severed muscles.

3. Blind or anatomical technique: should be reserved for distal nerve blocks only (i.e. fingers or toes).

ANALGESIA AND SEDATION FOR EXPECTANT CARE (I.E. END-OF-LIFE CARE)

An unfortunate reality of our profession, both military and medical, is that we encounter clinical scenarios that will inevitably end in a patient’s death. In these situations, it is a healthcare provider’s obligation to give palliative therapy to minimize the person’s suffering. In these circumstances, the use of opioid analgesics and sedative medications is therapeutic and indicated, even if these medications worsen a patient’s vital signs (i.e., cause respiratory depression and/or hypotension). If a patient is expectant:

Call a telemedicine consult.
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- **Prepare** to
  - Give opioid (morphine is preferred, but hydromorphone, fentanyl, or other opioid can be given) until the patient’s pain is relieved. If the patient is unable to communicate their pain, give opioid medication until the respiratory rate is less than 20/min.
  - If the patient complains of feeling anxious (i.e. is worrying about the future but not complaining of pain) or he cannot express himself but is agitated despite having a respiratory rate less than 20/min, give a benzodiazepine until the anxiety is relieved or the patient is sedated (i.e. is not feeling anxious or is no longer agitated).
- **Position** the patient as comfortably as possible. Pad pressure points.
- **Provide** anything that gives the patient comfort (e.g., water, food, cigarette).
- **Relief** of suffering, primarily through pain relief, is the goal during expectant care.

Call a telemedicine consult to discuss.

REFERENCES


ABOUT THE AUTHORS

LTC Pamplin, USA, is a board-certified intensivist and is currently the director of Virtual Critical Care at Madigan Army Medical Center, Joint Base Lewis-McChord, Washington. Previously, he was the director of the US Army Burn Intensive Care Unit and chief of Clinical Trials in Burns and Trauma at the US Army Institute of Surgical Research, San Antonio, Texas. He has served as the Simulation and Training Director for the Extracorporeal Membrane Oxygenation Program, San Antonio Military Medical Center, and the director of the Surgical Intensive Care Unit, Brooke Army Medical Center.

MAJ Fisher, USAR, is a first-year medical student at Texas A&M College of Medicine and assigned to the 7249th MSU, Houston, Texas. He was previously assigned to the 75th Ranger Regiment, where he served as a battalion and regimental physician assistant.

SFC Penny, USA, is a senior medic and instructor at the Special Operations Combat Medic Course, US Army John F. Kennedy Special Warfare Center and School.

SFC Olufs, USA, is a Special Forces Medical Sergeant, currently serving as noncommissioned officer in charge of Emergency Medicine at the Joint Special Operations Medical Training Center. He has previously served as a Special Forces Operational Detachment-A Senior Medical Sergeant on four deployments to the Central Command Area of Operations with 5th Special Forces Group.

SFC Rapp, USA, is assigned to the Office of Special Warfare as the NCOIC for Unconventional Warfare Medicine Research.

Dr Hampton is a board-certified emergency physician with additional fellowship training in emergency ultrasonography. She is an avid medical educator and a volunteer subject matter expert and ultrasound instructor for the military medical community. Dr Hampton is currently practicing at the Landstuhl Regional Medical Center, Germany (US Army Medical Department).

MAJ Powell, USA, is a board-certified intensivist. He is currently the 4th Battalion, 3rd Special Forces Group (Airborne) surgeon and staff intensivist at Womack Army Medical Center, Fort Bragg, North Carolina. He serves on the Prolonged Field Care Working Group as chair of the research subcommittee and a member of the telemedicine subcommittee.

COL Keenan, USA, is a board-certified emergency medicine physician, and is currently serving as Command Surgeon, Special Operations Command, Europe. He has previously served as Battalion Surgeon in both 1st and 3rd SFG(A), and as Group Surgeon, 10th SFG(A). He is the coordinator for the SOMA Prolonged Field Care Working Group.

Col Shackelford, USAF, is a trauma surgeon, currently serving as the chief of Performance Improvement, Joint Trauma System, San Antonio, Texas. She is a member of the Committee on TCCC and has previously deployed as the director of the Joint Theater Trauma System.
**APPENDIX A: PFC ANALGESIA AND SEDATION GUIDELINE**

**Step 1.** Identify the clinical situation on the top row.

**Step 2.** Read down the column to the row representing your available resources and training.

**Step 3.** Provide analgesia/ sedation medication accordingly.

<table>
<thead>
<tr>
<th>Standard Analgesia (Most Patients)</th>
<th>Difficult Analgesia or Sedation Needed (e.g., Polytrauma/Litter Bound/Mission Demand)</th>
<th>Protected Airway (e.g., Intubated/Cricothyrotomy + Assisted Ventilation)</th>
<th>Shock Present</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Goal</strong></td>
<td>In addition to standard analgesia goals: • Control pain unresponsive to standard analgesia • Achieve quiet, calm casualty who can still be aroused</td>
<td>• Maintain airway device (deep sedation) • Achieve patient-ventilator synchrony • Maintain blood pressure</td>
<td>• Initiate treatment for shock before giving analgesia or sedation • Do not worsen shock</td>
</tr>
<tr>
<td><strong>Minimum</strong></td>
<td>Give: acetylsalicyclic 1,000mg PO every 6 hours • Give: meloxicam 15mg PO daily • Give: OTFC 800µg per TCC guidelines • Give: ketamine push (^1) • Give: ondansetron 4mg ODT/IV/IO/IM every 4 hours PRN</td>
<td>Give: ketamine push (^1) • Give: hydromorphone or alternate opioid (^2) • Give: ondansetron 4mg ODT/IV/IO/IM every 4 hours PRN</td>
<td>• Give: ketamine push (^1) • Give: ondansetron 4mg IV/I every 4 hours PRN</td>
</tr>
<tr>
<td><strong>Better</strong></td>
<td>Give: Regional nerve block for limb trauma (See Appendix E)</td>
<td>Give: ketamine push (^1) • Give: hydromorphone or alternate opioid (^2) • Give: midazolam (^2)</td>
<td>• Same as minimum</td>
</tr>
<tr>
<td><strong>Best</strong></td>
<td>Standard analgesia plus • Give: hydromorphone or alternate opioid (^2,5) • Give: midazolam (^2) • Consider: ketamine load, then drip (for sedation) (^1,4)</td>
<td>Give: ketamine load, then drip (for sedation) (^1,4) • Give: hydromorphone or alternate opioid (^2,5) • Give: midazolam (^2)</td>
<td>• Give: ketamine push (^1) OR • Consider: ketamine load, then drip (for sedation) (^1,4) If additional sedation needed AND blood pressure will tolerate: • Consider: hydromorphone or alternate opioid (^2,5) • Consider: midazolam (^2)</td>
</tr>
</tbody>
</table>

*O2CO₂: end-tidal carbon dioxide; IM, intramuscular; IO, intraosseous; IV, intravenous; OTFC, oral transmucosal fentanyl citrate; PO, per os (by mouth); PRN, as needed; RR, respiratory rate; SpO₂, oxygen saturation; TCC, Tactical Combat Casualty Care.

**Note:** Lower doses of pain/sedation medications given more frequently are best for steady control. START LOW, GO SLOW.

\(^1\)If ketamine push (for pain): 20mg (range, 0.1–0.2mg/kg) IV/I every 10–30 minutes PRN. If an IV/I is not available, quadruple the ketamine dose to give 80mg IM (range, 0.4–0.8mg/kg IM).

\(^2\)To identify the effective dose of pain or sedation medication, give the lowest dose every 2–5 minutes until therapeutic target achieved or maximum dose is given. The effective dose is the amount required to achieve the desired effect (i.e., pain control or sedation). If unable to achieve target with maximum-dose opioid, add midazolam.

- Hydroxymorphone 0.5mg (range, 0.25–2mg) IV/I every 1–6 hours PRN (long acting, effective, fewest side-effects)
- ALTERNATIVE opioid:
  - **Fentanyl** 50µg (range, 25–100µg) IV/I every 30 minutes to 2 hours PRN (short acting, extremely fast onset, good for severe pain/procedures, greatest risk of respiratory depression)
  - **Morphine** 5mg (range, 2.5–10mg) IV/I every 1–6 hours PRN (Long acting, more side-effects)
  - **Midalozam** 1mg (range, 0.5–2mg) IV/I every 1–6 hours PRN (sedation, amnesia)
  - **Percocet** 1–2 tab PO every 4–6 hours PRN (slower onset but provides steady pain control for up to 6 hours). Can supplement with effective dose of IV/I opioids or ketamine for breakthrough pain. Contains 650mg acetaminophen. Do not exceed 4,000mg acetaminophen per day.

**Guideline Only/Not a Substitute for Clinical Judgment**

Call telemedicine consult if you are having difficulty managing pain or sedation.
APPENDIX B: KETAMINE DRIP DOSING TABLES

Ketamine drip (for sedation): Sedation loading dose first (1mg/kg IV/IO over 60 seconds).
MIX: 750mg (1.5 vials of 500mg/5mL) in 250mL of normal saline (3mg/mL solution).

Initial drip dose:
- **Best:** Using an IV pump, set to μg/kg/min dose desired. Increase or decrease dose by 5–10μg/kg/min increments.
- **Better:** Using a dial flow adaptor, initial drip rate in mL/h equals the casualty’s weight in kg divided by 2 (see mL/h table).
- **Minimum:** Count drip rate. Increase or decrease rate by 1–2 drips/min (very slowly) to achieve goal.

Drip adjustments: Increase or decrease drip by 0.25mg/kg/h (1 row).

### Ketamine Drip Dosing Tables

**Ketamine drip rate for dial flow or IV pump (starting dose highlighted)**

<table>
<thead>
<tr>
<th>Dose (mg/kg/h)</th>
<th>Patient’s Weight, kg</th>
<th>Infusion Rate, mL/h</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>40</td>
<td>60</td>
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<td>μg/kg/min</td>
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<td>0.5</td>
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<td>2.0</td>
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**Ketamine drip count for 15 drips/mL tubing (starting dose highlighted)**

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<tr>
<th>Infusion Rate, 1 drip/X seconds</th>
<th>0.5</th>
<th>0.75</th>
<th>1.0</th>
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**Ketamine drip count for 10 drips/mL tubing (starting dose highlighted)**

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<td>1/46</td>
<td>13</td>
<td>1/27</td>
<td>1/18</td>
<td>1/15</td>
<td>1/12</td>
<td>1/11</td>
<td>1/9</td>
</tr>
<tr>
<td>1/45</td>
<td>8</td>
<td>1/27</td>
<td>1/18</td>
<td>1/15</td>
<td>1/12</td>
<td>1/11</td>
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<td>1/44</td>
<td>13</td>
<td>1/27</td>
<td>1/18</td>
<td>1/15</td>
<td>1/12</td>
<td>1/11</td>
<td>1/9</td>
</tr>
</tbody>
</table>

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**Procedural Sedation**

**Step 1:** Bolus (1.0–2.0mg/kg) 80–160mg ketamine IV/IO over 60 seconds (250–400mg IM if necessary).

**Step 2:** Consider adding (start low, give more):
- 25–100μg fentanyl IV/IO
- 1–4mg midazolam IV/IO

**Step 3:** May need to repeat doses as below if procedure lasts longer than 10–15 minutes.
- Ketamine every 10–15 minutes
- Fentanyl every 15–30 minutes
- Midazolam every 30–60 minutes

*dial flow adaptor not accurate for rate < 10mL/h; use drip count*
## APPENDIX C: COMMON IV MEDS CHEAT SHEET

<table>
<thead>
<tr>
<th>Common IV Meds Cheat Sheet</th>
<th>Moderate Pain</th>
<th>Pain Dose Range</th>
<th>Sedation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketamine</td>
<td>20mg IV</td>
<td>0.1–0.2mg/kg IV</td>
<td>1mg/kg IV</td>
</tr>
<tr>
<td>Midazolam</td>
<td>1mg IV</td>
<td>0.5–2mg IV</td>
<td>1mg every 1–6 hours</td>
</tr>
<tr>
<td>Morphine</td>
<td>5mg IV</td>
<td>2.5–10mg IV</td>
<td></td>
</tr>
<tr>
<td>Fentanyl IV</td>
<td>25μg IV</td>
<td>25–100μg IV</td>
<td></td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>0.5–1mg IV</td>
<td>0.25–2mg IV</td>
<td></td>
</tr>
<tr>
<td>OTFC</td>
<td>800μg pop: between cheek and gum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opioid overdose</td>
<td>Naloxone: Dilute 0.4mg (1mL) with 9mL normal saline. Give 1ml slowly. Repeat dose PRN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzodiazepine overdose</td>
<td>Flumazenil:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Draw 1mL (0.5mg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Dilute with 4mL sterile water (0.1mg/mL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Give 3mL/0.3mg over 15 seconds</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Additional 1mL/0.1mg every 1 minute PRN</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maximum dose, 1mg/h (can cause seizures)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The moderate-pain category follows this clinical practice guideline philosophy: Prolonged field care analgesia/sedation should begin with smaller amounts of a drug first: START LOW, GO SLOW. The doses are not all inclusive; therefore, the dose by weight or a safe range is also included.

IV, intravenous; OTFC, oral transmucosal fentanyl citrate; PRN, as needed.
## Recommended Pain and Sedation Medication

<table>
<thead>
<tr>
<th>Name</th>
<th>Purpose/Dose</th>
<th>Side Effects and Notes</th>
<th>Pharmacology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ketamine (Ketalar)</strong></td>
<td><strong>Background pain</strong>: Use low dose 10–20mg (0.1–0.2mg/kg) IV/IO PRN. Avoid oversedation Breakthrough pain in hemodynamically stable or unstable patient: IV/IO push: dose every 5 minutes until goal achieved or nystagmus occurs or RR &lt; 10/min. • 10–20mg (0.1–0.2mg/kg) slow push IM/IN: every 15 minutes until goal achieved or nystagmus occurs • 40–60mg (0.5–0.75mg/kg) Sedation: IM sedation dose: • 250–400mg (or 4–5mg/kg) IV/O sedation loading dose: • 1mg/kg IV push over 60 seconds Then IV/O drip for ongoing sedation (load above dose, then drip): • Nonintubated: 1mg/kg/h • Intubated 1–2mg/kg/h</td>
<td>• Cataleptic-like state (dissociated from the surrounding environment) • Respiratory depression at higher doses (&gt;1mg/kg), especially with fast administration IV/O • Sialorrhea (hypersalivation) (can be problematic in an austere setting) • Releases endogenous catecholamines (epinephrine, norepinephrine), which maintain (or increase) blood pressure and heart rate. • Consider adding midazolam to avoid emergence phenomenon (e.g., delusions, agitation, irrational/violent behavior) in adults with higher doses (&gt;0.3mg/kg IV/O) • Consider glycopyrrolate if significant sialorrhea • Consider antiemetic (e.g., odansatron) empirically (may vomit when recovering from sedation) • To avoid rapid respiratory depression, IV/O administration should be slow: Push no faster than over 60 seconds • No additional sedation or analgesic effects with doses &gt;1.5mg/kg—only longer duration of effects. • There are no absolute contraindications for the use of ketamine; ketamine is safe for use in TBI and/or eye injury.</td>
<td>• NMDA antagonist • Time to onset: 30 seconds IV or 1–5 minutes IM • Duration of action: 10–15 minutes IV or 20–30 minutes IM • S(+) ketamine has four times the affinity of R(−) ketamine for the NMDA receptor (S ketamine is common in non-US pharmacies) • In practice, S(+) ketamine (e.g., Esketamin, Ketanest) is twice as potent; use half the recommended dose in mg as racemic (&quot;regular&quot;) ketamine • Mid-range dose (0.3–0.8mg/kg IV/O) has the highest incidence of emergence reactions and dysphoria. AVOID THIS DOSE WHENEVER POSSIBLE. Treat with midazolam or other benzodiazepine (or rebolus ketamine with sedation dose) • Metabolized in the liver to an active metabolite, norketamine, which has a potency one-third that of ketamine • Renal excretion</td>
</tr>
<tr>
<td><strong>Hydromorphone (Dilaudid)</strong></td>
<td>Breakthrough pain in hemodynamically stable patient: IV/O/ IN: dose every 5 minutes until goal achieved or RR &lt; 10/min. • Nonintubated: 0.25–2mg • Intubated: 1–4mg IM: not recommended</td>
<td>• Respiratory/cardiac/mental status depression • Nausea/vomiting • Pruritus (itching) • Constipation</td>
<td>• Onset &lt;5 minutes • Duration of action 1–4 hours • Hepatic metabolism • Renal clearance (~10% as unchanged drug) • Caution in hepatic/renal impairment (reduce dose by 25%) • IM dose variable and delayed</td>
</tr>
<tr>
<td>Name</td>
<td>Purpose/Dose</td>
<td>Side Effects and Notes</td>
<td>Pharmacology</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| **Fentanyl*** (Actiq) | **Background pain:** Oral: only in NONINTUBATED, awake patients, per TCCC guidelines  
• OTFC 800ug  
• Place lozenge between the cheek and the gum  
• Do not chew the lozenge  
**Breakthrough pain** in hemodynamically stable patient:  
IV/IO/IN: dose every 5 minutes until goal achieved or RR < 10/min.  
• Nonintubated: 25–50μg  
• Intubated: 50–200μg  
**IV push should be over 30–60 seconds, monitor for difficulty breathing (e.g., rigid chest syndrome)**  
IM: not recommended | • Respiratory/cardiac/mental status depression  
• Nausea/vomiting  
• Pruritus (itching)  
• Constipation  
Unique concerns:  
• Chest-wall muscle rigidity with rapid IV infusion (rare)  
• Bradycardia (rare)  
• QT-interval prolongation (rare)  
• Highly lipophilic | • Rapid IV onset (<2 minutes)  
• Duration of action: 30–60 minutes  
• Hepatic metabolism  
• Renal clearance (~10% as unchanged drug)  
• Caution in hepatic/renal impairment (reduce dose by 25%) |
| **Morphine**** | **Breakthrough pain** in hemodynamically stable patient:  
IV/IO/IN: dose every 5 minutes until goal achieved or RR < 10/min.  
• Nonintubated: 2.5–10mg  
• Intubated: 5–10mg  
IM: not preferred; can give 5–10mg IM if necessary | • Respiratory/cardiac/mental status depression  
• Nausea/vomiting  
• Pruritus (itching)  
• Constipation  
• Anticholinergic like effects, particularly urinary retention | • Onset <5 minutes.  
• Active metabolites.  
• **Duration of action:** 1–4 hours  
• 85% renal clearance; 7%–10% bile/stool clearance  
• Significantly reduced clearance in renal failure  
• IM dose variable and delayed |
| **Percocet** | **Background pain**  
Contains oxycodone (5mg) AND acetaminophen (325mg)  
PO/enteral (may be crushed): 1–2 tabs every 4–6 hours.  
DO NOT exceed 4,000mg total acetaminophen per day. | • Respiratory/cardiac/mental status depression  
• Nausea/vomiting  
• Pruritus (itching)  
• Constipation  
• Hypersensitivity (acetaminophen) at high doses or if compromised liver function at baseline | • Oxycodone  
• Hepatic metabolism  
• Active metabolites  
• Urinary excretion  
• **Duration of effect:** 4–6 hours  
Acetaminophen (see below) |
| **Midazolam (Versed)** | **Sedation** (includes anxiety or agitation):  
IV/IO: dose every 5 minutes until goal achieved or RR < 10/min.  
• Nonintubated: 0.5–2mg  
• Intubated: 1–4mg  
IM: not recommended | • Respiratory/cardiac/mental status depression  
• Amnestic  
• Nausea/vomiting  
• Hypotension  
• Constipation  
• Personnel and equipment needed for standard respiratory resuscitation should be available during midazolam administration. | • Onset: 1–5 minutes  
• **Duration of effect:** 1–4 hours  
• Hepatic metabolism (active metabolites)  
• Renal excretion |
| **Glycopyrrolate (Robinul)** | **Antisialogogue** (i.e., to stop hypersalivation from ketamine)  
SC/IM/IV/IO:  
0.1–0.2mg every 4 hours | • Tachycardia/palpitations  
• Nausea/vomiting  
• Flushing  
• Urinary retention  
• Not to exceed 4 doses/d | • Anticholinergic  
• Rapid onset  
• **Duration of effect:** 2–6 hours  
• Renal excretion (85%, 80% unchanged) |
## Recommended Pain and Sedation Medication

<table>
<thead>
<tr>
<th>Name</th>
<th>Purpose/Dose</th>
<th>Side Effects and Notes</th>
<th>Pharmacology</th>
</tr>
</thead>
</table>
| Acetaminophen (Tylenol) | For mild to moderate pain: IV/PO: 500–1000mg every 6 hours | • Hypersensitivity (rare)  
• Increased serum transaminases  
• Nausea/vomiting (IV)  
• Acute liver failure: limit daily dose of acetaminophen and acetaminophen-containing products (e.g., Percocet) to 4,000mg | • Onset: <1 hour PO, 5–10 minutes IV  
• Duration of effect: 4–6 hours  
• Hepatic metabolism  
• Renal excretion |
| Odansatron (Zofran)     | For nausea and vomiting:  
• 4mg ODT/IV/IO/IM, every 4–8 hours PRN  
• Can repeat once at 15 minutes if nausea and vomiting are not improved | • Maximum 8mg in any 8-hour interval  
• QT-interval prolongation (rare)  
• Constipation  
• Dizziness/headache | • Selective serotonin 5-HT3 receptor antagonist  
• Hepatic metabolism  
• Excreted in the urine and feces |
| Flumazenil (Romazicon)  | For reversal of benzodiazepine overdose (e.g., midazolam)  
• 0.2mg IV over 15 seconds | • DO NOT USE IN CHRONIC BENZODIAZEPINE USERS! (May cause seizures)  
• Use only to reverse benzodiazepines YOU have given the patient. | • Specific benzodiazepine receptor antagonist  
• Resedation may occur 20–60 minutes after initial dose, may require redosing  
• Hepatic metabolism  
• Renal excretion |
| Naloxone (Narcan)      | For reversal of opioid overdose  
• 0.4–2mg IV/IM/SC/IN, repeat every 2–3 minutes PRN; not to exceed 10mg (0.01mg/kg) | • Withdrawal reaction precipitated  
• Abrupt reversal of opioid depression may result in nausea, vomiting, sweating, tachycardia, increased blood pressure, and tremulousness  
• Short duration of action relative to longer-acting opioids (e.g., morphine); may need to redose before opioid effect has worn off | • Competitive opioid antagonist  
• Onset: 2 minutes IV; 2–5 minutes IM/SC  
• Duration of effect: 30–60 minutes, may require redosing  
• Hepatic metabolism  
• Renal excretion |
| Diphenhydramine (Benadryl) | For itching or allergic reaction (may also cause drowsiness)  
• 25–50mg IV/IO/PO every 4–6 hours PRN (maximum: 400mg daily) | • May potentiate the effect of other sedative agents  
• May reduce seizure threshold  
• May cause paradoxical CNS stimulation (e.g., agitation or anxiety) and/or psychosis  
• Mild anticholinergic and may cause dry secretions (dry mouth, constipation, urinary retention), blurred vision, flushing, fever, tachycardia  
• May reduce nausea | • Histamine receptor (H1) antagonist  
• Hepatic metabolism  
• Renal excretion |

CNS, central nervous system; IM, intramuscular; IN, intranasal; IO, interosseous; IV, intravenous; NMDA, N-methyl-D-aspartate; ODT, oral disintegrating tablet; OTFC, oral transmucosal fentanyl citrate; PO, per os (by mouth); PRN, as needed; RR, respiratory rate; SC, subcutaneous; TBI, traumatic brain injury; TCCC, Tactical Combat Casualty Care.

*Hydromorphone is selected as the opioid medication of choice in the PFC setting for the following reasons:*

1. Long acting
2. Lower likelihood of accumulating in the setting of organ dysfunction (particularly renal injury/insufficiency) and, therefore, less likely to cause respiratory depression or hypotension
3. Smaller doses produce greater effect; thus, less medication needs to be carried for longer duration of treatment
4. Less histamine activation, less pruritus, better tolerated

**Morphine**

1. Long acting
2. Can give IM if necessary, but not preferred
3. More side-effects compared with hydromorphone (e.g., higher rate of respiratory depression, hypotension, and pruritus)

**Fentanyl**

1. Short acting
2. Faster onset
3. Greatest risk of respiratory depression; highly recommend monitoring SpO2 (oxygen saturation)
4. Be prepared to support breathing if necessary
5. Reserved for severe pain or procedures
## APPENDIX E: REGIONAL ANESTHESIA – RECOMMENDATIONS

### REGIONAL ANESTHESIA - RECOMMENDATIONS

**WORKING DEFINITION**
It is a useful technique of local anesthetic agent injection adjacent to a single nerve or a nerve bundle, that can markedly reduce or eliminate limb-related pain without negative systemic effects such as respiratory depression, sedation or hypotension.

**BEFORE ATTEMPTING - COMPETENCY IN ANY BLOCK PERFORMED MUST BE DOCUMENTED**
**ULTRASOUND GUIDANCE IS THE PREFERRED MODALITY FOR BLOCKS**

### BENEFITS
- Superior pain control in patients with limb injuries.
- Successful block decreases your patient’s need for systemic analgesia. May need less or none at all.
- It is logistically easier to take care of a patients who doesn’t need heavy sedation or systemic analgesia.

### RISK
- LAST (local anesthetic systemic toxicity) - serious cardiovascular & CNS toxicity from accidental injection into the blood vessels or from absorption into systemic circulation - know signs & symptoms; stay out of blood vessels when injecting local anesthetics!
- Accidental nerve damage from needle or injection into the nerve - don’t inject against resistance!
- Increased risk of unrecognized compartment syndrome or local pressure wounds given patient cannot provide feedback due to lack of sensory (+/motor) function in a blocked extremity.
- Risk from injury to surrounding structures such as blood vessel injury or a pneumothorax.

### SYMPTOMS & SIGNS OF LAST:
- NERVOUS SYSTEM: perceived numbness, tingling, metallic taste, tinnitus, muscle twitching, visual disturbance, extreme anxiety, screaming, impending death feeling. **SEIZURE, COMA**
- CARDIOVASCULAR SYSTEM: chest pain, shortness of breath, diaphoresis, **ARRHYTHMIA, HYPOTENSION, CARDIOVASCULAR COLLAPSE**

### RECOMMENDED MODALITIES:
- **Ultrasound-guidance** for real-time visualization of targeted nerves, needle & anesthetic spread. It is recommended for any block performed (except digital blocks).
- **Paresthesia/anatomical technique** may be used for distal nerve blocks if no ultrasound available.

### HOW TO MINIMIZE RISK:
- Know the drugs you have available and ensure you have easy access to procedural references prior to deployment.
- Establish baseline neurological function of a given extremity prior to block.
- Calculate the maximum total dose of local anesthetic for your patient and never exceed it when performing multiple blocks.
- Use local anesthetics with epinephrine for all blocks to facilitate immediate recognition of intravascular injection.
- Use blunt-tip needles to minimize nerve injury.
- Monitor your patient during the injection & for 15-20 minutes after the procedure.
- Use pulse oximetry with audible signal as the minimum monitoring device when performing regional nerve blocks.
- Mark & date all the block sites with a permanent marker on the skin.
- Pad all the pressure points
- Know how to manage LAST syndrome (see checklist).

### RECOMMENDED LOCAL ANESTHETIC

**ROPIVACAINE** (0.2% - 2mg/mL or 0.5% - 5mg/mL) is the local anesthetic of choice due to its excellent efficacy and improved cardiovascular safety profile.

**MAXIMUM CUMULATIVE DOSE**: 3 mg/kg (all blocks at multiple sites combined)
- 0.2% solution: 1.5mL/kg
- 0.5% solution: 0.6mL/kg

**ONSET & DURATION**: approximately 20 minutes from injection to onset of block. An effective dose provides 4-8 hours of anesthesia. The analgesic effect lasts for 5-12 hours.
Analgesia and Sedation Management During Prolonged Field Care

Regional Anesthesia – Recommendations (Continued)

REGIONAL ANESTHESIA - WORKSHEET

PATIENT'S WEIGHT [kg]:  
MAXIMUM CUMULATIVE DOSE:  

RECOMMENDED UPPER EXTREMITY BLOCKS:

SEE REGIONAL ANESTHESIA REFERENCE - ULTRASOUND-GUIDED NERVE BLOCKS

☐ SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK (must be performed under ultrasound guidance; inject 20-25mL of local anesthetic)

☐ AXILLARY BRACHIAL PLEXUS BLOCK (preferably under ultrasound guidance; inject 15-20mL of local anesthetic)

☐ WRIST BLOCK: radial, median & ulnar nerves (ultrasound use is optional; inject a total of 10mL of local anesthetic for all 3 nerves)

☐ DIGITAL BLOCK (inject < 5mL of local anesthetic)

RECOMMENDED LOWER EXTREMITY BLOCKS:

SEE REGIONAL ANESTHESIA (3) ULTRASOUND-GUIDED NERVE BLOCKS REFERENCE

☐ FEMORAL NERVE BLOCK (use ultrasound guidance; inject 10-20mL of local anesthetic)

☐ PROXIMAL SCIATIC NERVE BLOCK (subgluteal approach; use ultrasound guidance; inject 15-20mL of local anesthetic)

☐ DISTAL SCIATIC NERVE BLOCK (popliteal approach; use ultrasound guidance; inject 20mL of local anesthetic)

☐ SAPHEOUS BLOCK (ultrasound use is optional; proximal approach at tibial tuberosity; inject 10mL of local anesthetic)

☐ ANKLE BLOCK: saphenous, sural, posterior tibial, superficial & deep peroneal nerves; ultrasound use is optional; inject a total of 20mL of local anesthetic for all 5 nerves)

☐ DIGITAL BLOCK (inject < 5mL of local anesthetic)

CONTRAINDICATIONS:

- UNTRAINED PROVIDER
- Refusal & inability to communicate with patient
- Infants, children, elderly
- Infection at the injection site
- Trauma or history of trauma at the injection site
- Systemic anticoagulation/coagulopathy
- Pre-existing neurological disease

TECHNIQUE:

- Identify target nerve according to training
- Gather equipment and place the patient on monitor:
  - MINIMUM: pulse oximetry with audible signal
  - BETTER: add blood pressure monitoring
  - BEST: full monitor with EKG leads
- Prepare & label the syringes with local ANESTHETIC
- Clean (preferably sterile) procedure: cleanse injection site with chlorhexidine (preferred), betadine or alcohol, & use gloves (best sterile)
- Ensure good verbal and visual communication with the patient prior to injection
- Introduce needle and aspirate for blood; then inject 1mL of anesthetic, and if no resistance, then aspirate again & slowly inject 3-5mL, and wait 60 seconds to monitor for toxicity. STOP IF any signs or symptoms of toxicity or other adverse events occur
- Continue injection if no changes occur
- Always aspirate before any injection
- Slowly inject your target dose for a given block in 5mL increments given over 10-15 sec each, and always aspirate for blood between each 5mL increment
- Mark and date each block site

Local Anesthetic Systemic Toxicity (LAST) checklist:

- STOP injection at first sign or symptom!
- Airway management: use 100% oxygen
- Seizure management: benzodiazepines are preferred; can give propofol (25-50mg) if hemodynamically stable
- Use ACLS protocols for cardiovascular collapse
- 20% LIPID EMULSION is the antidote:
  - 1 mL/kg every 3-5 minutes IV, up to 3mL/kg IV during ACLS
  - Follow with continuous infusion 0.25mL/kg/min
  - Double the infusion rate to 0.5mL/kg/min if blood pressure remains low
  - Continue infusion for at least 10 minutes once hemodynamically stable
  - Upper limit: approx. 10mL/kg IV over 30 minutes
Regional Anesthesia – Recommendations (Continued)

Regional Anesthesia Reference - Ultrasound-Guided Nerve Blocks

- **TIPS:** Identify subclavian artery lying on the first rib, the pleura is immediately lateral and superficial to it.
- **PITFALLS:** Keep needle tip always in sight to avoid pneumothorax, and don’t point below the first rib.
- **INJECTION VOLUME:** 20-25mL

- **TIPS:** Identify axillary artery; musculocutaneous nerve is distant from the plexus bundles.
- **PITFALLS:** There are multiple vessels in this area – avoid intravascular injection.
- **INJECTION VOLUME:** 15-20mL

- **TIPS:** Identify femoral artery; femoral nerve is lateral to it; pop the iliac fascia, target the nerve prior to bifurcation of the femoral artery.
- **PITFALLS:** Beware of motor weakness of quadriceps - fall risk!
- **INJECTION VOLUME:** 10-20mL

- **TIPS:** Identify greater trochanter and inguinal ligament; obturator nerve can be seen between them.
- **PITFALLS:** May need to inject more distally or in long axis of the nerve.
- **INJECTION VOLUME:** 15-20mL

- **TIPS:** Identify posterior vessels; test at confluence of CPN & TN; see after injection to ensure spread.
- **INJECTION VOLUME:** 20mL

- **Deposit a small amount of local anesthetic to hydrodissect the nerve from its surrounding tissues - this hydrodissection technique will help you see it better.**
- **Punt the needle with local anesthetic prior to injection, in order to avoid injecting air and resultant poor image quality from artifacts caused by air.**
- **Local anesthetics are lipophilic - do not simply deposit into surrounding fat tissue.**
# APPENDIX F: THE RICHMOND AGITATION-SEDATION SCALE (RASS)\(^{12}\)

<table>
<thead>
<tr>
<th>Score</th>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>+4</td>
<td>Combative</td>
<td>Combative, violent, immediate danger to staff</td>
</tr>
<tr>
<td>+3</td>
<td>Very agitated</td>
<td>Pulls to remove tubes or catheters; aggressive</td>
</tr>
<tr>
<td>+2</td>
<td>Agitated</td>
<td>Frequent non purposeful movement; fights ventilator</td>
</tr>
<tr>
<td>+1</td>
<td>Restless</td>
<td>Anxious, apprehensive, movements not aggressive</td>
</tr>
<tr>
<td>0</td>
<td>Alert and calm</td>
<td>Spontaneously pays attention to caregiver</td>
</tr>
<tr>
<td>-1</td>
<td>Drowsy</td>
<td>Not fully alert but has sustained awakening to voice (eye opening &gt;10 seconds)</td>
</tr>
<tr>
<td>-2</td>
<td>Light sedation</td>
<td>Briefly awakens to voice (eyes open and contact &lt;10 seconds)</td>
</tr>
<tr>
<td>-3</td>
<td>Moderate sedation</td>
<td>Movement of eye opening to voice (no eye contact)</td>
</tr>
<tr>
<td>-4</td>
<td>Deep sedation</td>
<td>No response to voice but movement or eye opening to physical stimulation</td>
</tr>
<tr>
<td>-5</td>
<td>Unarousable</td>
<td>No response to voice or physical stimulation</td>
</tr>
</tbody>
</table>

## Procedure for RASS assessment

1. Observe patient.
   - Patient is alert, restless, or agitated.

   Score: 0 to +4

2. If not alert, state patient’s name and tell patient to open eyes and look at speaker.
   - Patient awakens with sustained eye opening and eye contact.
   - Patient awakens with eye opening and eye contact, but not sustained.
   - Patient has any movement in response to voice but no eye contact.

   Score: −1, −2, −3

3. When no response to verbal stimulation, physically stimulate patient by shaking shoulder and/or rubbing sternum.
   - Patient has any movement to physical stimulation.
   - Patient has no response to any stimulation.

   Score: −4, −5
**APPENDIX G: PLANNING CONSIDERATIONS**

<table>
<thead>
<tr>
<th>Best:</th>
<th>Better:</th>
<th>Minimum:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluids: fluid for medication administration/drip (normal saline [NS]: 100mL/250mL bags and 5mL/10mL prefilled syringes)</td>
<td>Fluid for medication administration/ drip (NS: 250mL bags and 10mL prefilled syringes)</td>
<td>Fluids: NS: 250mL bags</td>
</tr>
<tr>
<td>Equipment: portable monitor with capnography, laboratory capability for serum electrolytes, arterial blood gases, lactate, Foley catheter with graduated collection system, portable ventilator, portable suction, portable sonography, airway management kit to include endotracheal suction catheter</td>
<td>Equipment: blood pressure cuff, stethoscope, pulse oximeter, capnometer, portable ventilator, Stimuplex (peripheral nerve stimulation), airway management kit to include endotracheal suction catheter, Micro/macrodrip tubing with dial-a-flow adaptor</td>
<td>Equipment: blood pressure cuff, stethoscope, pulse oximeter, bag-valve mask with positive end-expiratory pressure valve, airway management kit</td>
</tr>
<tr>
<td>Macro/microdrip intravenous (IV) administration tubing; infusion pump</td>
<td>Graduated container to monitor urine output</td>
<td>Macro/microdrip tubing and counting drops per second to get infusion rate</td>
</tr>
<tr>
<td>Analgesic medications: Ketamine, hydromorphone, fentanyl, morphine (for IV use), oral transmucosal fentanyl citrate (OTFC), Percocet tabs for oral (PO) use</td>
<td>Analgesic medications: ketamine, hydromorphone for IV</td>
<td>Analgesic medications: ketamine, hydromorphone for IV, Percocet tabs for PO</td>
</tr>
<tr>
<td>Mild pain: meloxicam, acetaminophen</td>
<td>Mild pain: meloxicam, acetaminophen</td>
<td>Mild pain: meloxicam, acetaminophen</td>
</tr>
<tr>
<td>Sedation/Anxiety: midazolam for IV use (diazepam tabs for PO)</td>
<td>Sedation/Anxiety: midazolam</td>
<td>Sedation/Anxiety: midazolam</td>
</tr>
<tr>
<td>Mild pain: meloxicam, acetaminophen</td>
<td>Antihistamine and reversals: dihydramine, flumazenil, naloxone</td>
<td>Antihistamine and reversals: dihydramine, flumazenil, naloxone</td>
</tr>
<tr>
<td>Antidiuretic: glycopyrrolate</td>
<td>Assisted ventilation: bag-valve mask with positive end-expiratory pressure valve, airway management kit</td>
<td>Local/regional anesthesia: 2% lidocaine/ropivacaine</td>
</tr>
<tr>
<td>Local/regional anesthesia: 2% lidocaine/ropivacaine</td>
<td>Local/regional anesthesia: 2% lidocaine/ropivacaine</td>
<td>Local/regional anesthesia: 2% lidocaine/ropivacaine</td>
</tr>
<tr>
<td>Monitoring: portable monitor providing continuous vital sign display; capnography if intubated; document vital signs trends, intake and output, GCS, and pain level every 5 minutes until goal achieved, every 15 minutes thereafter; pain assessment sheet</td>
<td>Monitoring: frequent vital signs, examination, fluid input/urine output</td>
<td>Monitoring: frequent vital signs, examination, fluid input documented on preprinted or improvised flowsheet</td>
</tr>
<tr>
<td>Communications: real-time video telemedicine consultation</td>
<td>Communications: telephone; e-mail digital photos</td>
<td>Communications: telephone</td>
</tr>
<tr>
<td>Push-pack capability: prepackaged additional 24-hour supplies of fluids, and medications for scenarios &gt;24 hours.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX H: ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

PURPOSE

The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of “off-label” uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

BACKGROUND

Unapproved (i.e., “off-label”) uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing “investigational new drugs.” These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the “standard of care.” Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

ADDITIONAL PROCEDURES

Balanced Discussion

Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

Quality Assurance Monitoring

With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

Information to Patients

Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.