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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PURPOSE

This Role 1, prolonged field care (PFC) guideline is intended to be used after Tactical Combat Casualty Care (TCCC) Guidelines, when evacuation to a 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. **Titrated 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.

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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.
• 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 ANDSEDATION 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.
• **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/Cricothyotomy + Assisted Ventilation)</th>
<th>Shock Present</th>
</tr>
</thead>
</table>
| **Goal**                          | In addition to standard analgesia goals:  
  • Control pain unresponsive to standard analgesia  
  • Achieve quiet, calm casualty who can still be aroused | • Maintain airway device (deep sedation)  
  • Achieve patient-ventilator synchrony  
  • Maintain blood pressure | • Initiate treatment for shock before giving analgesia or sedation  
  • Do not worsen shock |
| **Minimum**                       | • Give: acetylmorphine 1,000mg PO every 6 hours  
  • Give: meloxicam 15mg PO daily  
  • Give: OTFC 800μg per TCCC guidelines  
  • Give: ketamine push  
  • Give: ondansetron 4mg ODT/IV/IO/IM every 4 hours PRN | • Give: ketamine push  
  • Give: hydromorphone or alternate opioid  
  • Give: ondansetron 4mg ODT/IV/IO/IM every 4 hours PRN | • Give: ketamine push  
  • Give: ondansetron 4mg IV/IO every 4 hours PRN |
| **Better**                        | • After initial pain control with OTFC and/or ketamine  
  • Give: acetylmorphine/oxycodone (e.g., Percocet; if able to take PO)  
  • Give: ketamine push  
  • Give: ondansetron 4mg ODT/IV/IO/IM every 4 hours PRN | • Give: ketamine push  
  • Give: hydromorphone or alternate opioid  
  • Give: midazolam  
  • Give: ondansetron 4mg ODT/IV/IO/IM every 4 hours PRN | • Same as minimum |
| **Best**                          | • Give: Regional nerve block for limb trauma (See Appendix E)  
  • Give: ketamine push  
  • Give: ondansetron 4mg ODT/IV/IO/IM every 4 hours PRN  
  • Give: hydromorphone or alternate opioid  
  • Give: midazolam  
  • Consider: ketamine load, then drip (for sedation) | • Give: ketamine load, then drip (for sedation)  
  • Give: hydromorphone or alternate opioid  
  • Give: midazolam  
  • Consider: ketamine load, then drip (for sedation)  
  • Give: hydromorphone or alternate opioid  
  • Give: midazolam 2 | • Give: ketamine push  
  • Consider: ketamine load, then drip (for sedation)  
  • If additional sedation needed AND blood pressure will tolerate:  
  • Consider: ketamine load, then drip (for sedation)  
  • Consider: midazolam 2 |

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

Ketamine loading dose (for sedation): 1mg/kg IV push over 60 seconds, then drip for continuous sedation. See mixture and dosing tables in Appendix B.

Ketamine may be used for either pain control or sedation, depending on the dose.

- Hydromorphone 0.5mg (range, 0.25–2mg) IV/IO every 1–6 hours PRN (long acting, effective, fewest side-effects)
- ALTERNATIVE opioid:  
  - Fentanyl 50μg (range, 25–100μg) IV/IO every 30 minutes to 2 hours PRN (short acting, extremely fast onset, good for severe pain/procedures, greatest risk of respiratory depression)  
  - Morphine 1mg (range, 0.5–1mg) IV/IO every 1–6 hours PRN (Long acting, more side-effects)
- Midazolam 1mg (range, 0.5–2mg) IV/IO every 1–6 hours PRN (sedation, amnesia)
- Ketamine may be used for either pain control or sedation, depending on the dose.

+ Ketamine loading dose (for sedation): 1mg/kg IV push over 60 seconds, then drip for continuous sedation. See mixture and dosing tables in Appendix B.

A continuous ketamine drip may take an hour to take full effect or wear off. Always start with a loading dose and augment with an effective dose of opioid and/or midazolam if additional sedation is needed. Increase or decrease drip gradually.

If breakthrough pain occurs on ketamine drip, give an effective dose of opioid. If effective dose is needed twice in 1 hour, increase drip rate to next higher level. If no breakthrough pain in past 2 hours, decrease drip rate to next lower level.

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>
</tr>
<tr>
<td>0.5</td>
<td>8</td>
<td>7*</td>
</tr>
<tr>
<td>0.75</td>
<td>13</td>
<td>10</td>
</tr>
<tr>
<td>1.0</td>
<td>17</td>
<td>13</td>
</tr>
<tr>
<td>1.25</td>
<td>21</td>
<td>17</td>
</tr>
<tr>
<td>1.5</td>
<td>25</td>
<td>20</td>
</tr>
<tr>
<td>1.75</td>
<td>29</td>
<td>24</td>
</tr>
<tr>
<td>2.0</td>
<td>33</td>
<td>27</td>
</tr>
</tbody>
</table>

#### Ketamine drip count for 15 drips/mL tubing (starting dose highlighted)

<table>
<thead>
<tr>
<th>Dose (mg/kg/h)</th>
<th>Infusion Rate, 1 drip/X seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5</td>
<td>1/35</td>
</tr>
<tr>
<td>0.75</td>
<td>1/27</td>
</tr>
<tr>
<td>1.0</td>
<td>1/18</td>
</tr>
<tr>
<td>1.25</td>
<td>1/12</td>
</tr>
<tr>
<td>1.5</td>
<td>1/8</td>
</tr>
<tr>
<td>1.75</td>
<td>1/6</td>
</tr>
<tr>
<td>2.0</td>
<td>1/5</td>
</tr>
</tbody>
</table>

#### Ketamine drip count for 10 drips/mL tubing (starting dose highlighted)

<table>
<thead>
<tr>
<th>Dose (mg/kg/h)</th>
<th>Infusion Rate, 1 drip/X seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5</td>
<td>1/53</td>
</tr>
<tr>
<td>0.75</td>
<td>1/41</td>
</tr>
<tr>
<td>1.0</td>
<td>1/27</td>
</tr>
<tr>
<td>1.25</td>
<td>1/23</td>
</tr>
<tr>
<td>1.5</td>
<td>1/18</td>
</tr>
<tr>
<td>1.75</td>
<td>1/17</td>
</tr>
<tr>
<td>2.0</td>
<td>1/14</td>
</tr>
</tbody>
</table>

### 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.
## APPENDIX D: 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>
| **Ketamine (Ketalar)**| **Background pain:**  
- Use low dose 10–20mg (0.1–0.2mg/kg) OV/O PRN.  
- Avoid oversedation  
  **Breakthrough pain** in hemodynamically stable or unstable patient:  
  - IV/O push: dose every 5 minutes until goal achieved or nystagmus occurs or RR < 10/min.  
  - 10–20mg (or 0.1–0.2mg/kg) slow push  
  - IM/IN: every 15 minutes until goal achieved or nystagmus occurs  
    - 40–60mg (or 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  
| - Cataleptic-like state (dissociated from the surrounding environment)  
- Respiratory depression at higher doses (>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 (>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 >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.  
| - 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 (“regular”) 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 |
| **Hydromorphone (Dilaudid)** | **Breakthrough pain** in hemodynamically stable patient:  
  - IV/O/IN: dose every 5 minutes until goal achieved or RR < 10/min.  
  - Nonintubated: 0.25–2mg  
  - Intubated: 1–4mg  
  IM: not recommended  
| - Respiratory/cardiac/mental status depression  
- Nausea/vomiting  
- Pruritus (itching)  
- Constipation  
| - Onset <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 |
### 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>
| Fentanyl™ (Actiq) | **Background pain:** Oral only in NONINTUBATED, awake patients, per TCCC guidelines  
• OTFC 800μg  
• Place lozenge between the cheek and the gum  
• Do not chew the lozenge  
**Breakthrough pain** in hemodynamically stable patient: IV/IO: 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 (rare)  
• Liver toxicity (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>
<tbody>
<tr>
<td><strong>Acetaminophen (Tylenol)</strong></td>
<td>For mild to moderate pain: IV/PO: 500–1000mg every 6 hours</td>
<td>• Hypersensitivity (rare)</td>
<td>• Onset: &lt;1 hour PO, 5–10 minutes IV</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Increased serum transaminases</td>
<td>• Duration of effect: 4–6 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Nausea/vomiting (IV)</td>
<td>• Hepatic metabolism</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Acute liver failure: limit daily dose of acetaminophen and acetaminophen-containing</td>
<td>• Renal excretion</td>
</tr>
<tr>
<td></td>
<td></td>
<td>products (e.g., Percocet) to 4,000mg</td>
<td></td>
</tr>
<tr>
<td><strong>Odansatron (Zofran)</strong></td>
<td>For nausea and vomiting: • 4mg ODT/IV/IO/IM, every 4–8 hours PRN</td>
<td>• Maximum 8mg in any 8-hour interval</td>
<td>• Selective serotonin 5-HT3 receptor antagonist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can repeat once at 15 minutes if nausea and vomiting are not improved</td>
<td>• Hepatic metabolism</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Excreted in the urine and feces</td>
</tr>
<tr>
<td><strong>Flumazenil (Romazicon)</strong></td>
<td>For reversal of benzodiazepine overdose (e.g., midazolam) • 0.2mg IV over 15 seconds</td>
<td>• Use only to reverse benzodiazepines YOU have given the patient.</td>
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<tr>
<td><strong>Naloxone (Narcan)</strong></td>
<td>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)</td>
<td>• Withdrawal reaction precipitated</td>
<td>• Specific benzodiazepine receptor antagonist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Abrupt reversal of opioid depression may result in nausea, vomiting, sweating, tachycardia, increased blood pressure, and tremulousness</td>
<td>• Resedation may occur 20–60 minutes after initial dose, may require redosing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Short duration of action relative to longer-acting opioids (e.g., morphine); may need to redose before opioid effect has worn off</td>
<td>• Hepatic metabolism</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Renal excretion</td>
</tr>
<tr>
<td><strong>Diphenhydramine (Benadryl)</strong></td>
<td>For itching or allergic reaction (may also cause drowsiness) • 25–50mg IV/IO/PO every 4–6 hours PRN (maximum: 400mg daily)</td>
<td>• May potentiate the effect of other sedative agents</td>
<td>• Histamine receptor (H1) antagonist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• May reduce seizure threshold</td>
<td>• Hepatic metabolism</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• May cause paradoxical CNS stimulation (e.g., agitation or anxiety) and/or psychosis</td>
<td>• Renal excretion</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Mild anticholinergic and may cause dry secretions (dry mouth, constipation, urinary retention), blurred vision, flushing, fever, tachycardia</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• May reduce nausea</td>
<td></td>
</tr>
</tbody>
</table>

CNS, central nervous system; IM, intramuscular; IN, intranasal; IO, intravenous; 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. Greater 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

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

**CPG ID: 61**
APPENDIX E: REGIONAL ANESTHESIA – RECOMMENDATIONS

<table>
<thead>
<tr>
<th>REGIONAL ANESTHESIA - RECOMMENDATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WORKING DEFINITION</strong></td>
</tr>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>BENEFITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superior pain control in patients with limb injuries.</td>
</tr>
<tr>
<td>Successful block decreases your patient’s need for systemic analgesia. May need less or none at all.</td>
</tr>
<tr>
<td>It is logistically easier to take care of a patient who doesn’t need heavy sedation or systemic analgesia.</td>
</tr>
</tbody>
</table>

**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:
  - Perioral 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).
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)
☐ SAPHENOUS 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

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)

GENERAL POINTERS ON TECHNIQUE:
- In cross-section on ultrasound nerves, look like honeycomb cells;
- Find blood vessels and use color Doppler to locate associated nerves;
- Best find the nerve in cross-section & approach with needle in-plane, some blocks can be done out-of-plane to see the needle well, avoid steep needle angles in-plane;
- Pop the fascial plane - tight needle-tip-to-nerve proximity is not as important, if you are within the right fascial plane;
- Deposit a small amount of local anesthetic to hydro-dissect the nerve from its surrounding tissues - this hydrolocalization technique will help you see it better;
- Push 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.

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: 15-30mL

- 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 adductor tubercle, sartorius 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; impact at confluence of CPN & TN; can after injection to ensure spread.
- INJECTION VOLUME: 20mL

Guideline Only/Not a Substitute for Clinical Judgment
### APPENDIX F: THE RICHMOND AGITATION-SEDATION SCALE (RASS)\(^{12}\)

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>+4</td>
<td>Combative, violent, immediate danger to staff</td>
</tr>
<tr>
<td>+3</td>
<td>Pulls to remove tubes or catheters; aggressive</td>
</tr>
<tr>
<td>+2</td>
<td>Frequent non purposeful movement; fights ventilator</td>
</tr>
<tr>
<td>+1</td>
<td>Anxious, apprehensive, movements not aggressive</td>
</tr>
<tr>
<td>0</td>
<td>Spontaneously pays attention to caregiver</td>
</tr>
<tr>
<td>-1</td>
<td>Not fully alert but has sustained awakening to voice (eye opening and contact &gt;10 seconds)</td>
</tr>
<tr>
<td>-2</td>
<td>Briefly awakens to voice (eyes open and contact &lt;10 seconds)</td>
</tr>
<tr>
<td>-3</td>
<td>Movement of eye opening to voice (no eye contact)</td>
</tr>
<tr>
<td>-4</td>
<td>No response to voice but movement or eye opening to physical stimulation</td>
</tr>
<tr>
<td>-5</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;</td>
<td>• Graduated container to monitor urine output</td>
<td>• Macrodrip tubing and counting drops per second to get infusion rate</td>
</tr>
<tr>
<td>• infusion pump</td>
<td>• Analgesic medications: ketamine, hydromorphone for IV, Percocet tabs for PO</td>
<td>• Analgesic medications: ketamine, hydromorphone for IV, Percocet tabs for PO</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>• Mild pain: meloxicam, acetaminophen</td>
<td>• Mild pain: meloxicam, acetaminophen</td>
</tr>
<tr>
<td>• Mild pain: meloxicam, acetaminophen</td>
<td>• Sedation/Anxiety: midazolam</td>
<td>• Sedation/Anxiety: midazolam</td>
</tr>
<tr>
<td>• Sedation/Anxiety: midazolam for IV use (diazepam tabs for PO)</td>
<td>• Antiemetic: ondansatron</td>
<td>• Antiemetic: ondansatron</td>
</tr>
<tr>
<td>• Mild pain: meloxicam, acetaminophen</td>
<td>• Antihistamine and reversals: diphenhydramine, flumazenil, naloxone</td>
<td>• Antihistamine and reversals: diphenhydramine, flumazenil, naloxone</td>
</tr>
<tr>
<td>• Antisialogogue: glycopyrrolate</td>
<td>• Nonsteroidal anti-inflammatory drug (NSAID): acetaminophen</td>
<td>• Local/regional anesthesia: 2% lidocaine/ropivacaine</td>
</tr>
<tr>
<td>• Antihistamine and reversals: diphenhydramine, flumazenil, naloxone</td>
<td>• Local/regional anesthesia: 2% lidocaine/ropivacaine</td>
<td>• Monitoring: frequent vital signs, examination, fluid input documented on preprinted or improvised flowsheet.</td>
</tr>
<tr>
<td>• Local/regional anesthesia: 2% lidocaine/ropivacaine</td>
<td>• Monitoring: frequent vital signs, examination, fluid input documented on preprinted or improvised flowsheet.</td>
<td>• Communications: telephone</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>• Communications: telephone; e-mail digital photos</td>
<td>• Communications: telephone</td>
</tr>
<tr>
<td>• Communications: real-time video telemedicine consultation</td>
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<td></td>
</tr>
<tr>
<td>• Push-pack capability: prepackaged additional 24-hour supplies of fluids, and medications for scenarios &gt;24 hours.</td>
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</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.