

JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)



Analgesia and Sedation Management during Prolonged Field Care

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.

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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 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).
3. Relieve pain. Give medications to treat pain first.
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.
- **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.

- **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.

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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.

	Standard Analgesia (Most Patients)	Difficult Analgesia or Sedation Needed (e.g., Polytrauma/Litter Bound/Mission Demand)	Protected Airway (e.g., Intubated/Cricothyrotomy + Assisted Ventilation)	Shock Present
Goal	Minimize pain and anxiety and maintain normal physiology: • Airway – mental status adequate to protect airway (i.e., coughs, not snoring or obstructing airway) • Breathing – adequate ventilation (RR > 12/min, EtCO ₂ < 50mmHg) and oxygenation (SpO ₂ > 96% ¹ • Perfusion – systolic blood pressure > 90mmHg	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: acetaminophen 1,000mg PO every 6 hours • Give: meloxicam 15mg PO daily • Give: OTFC 800µg per TCCC guidelines • Give: ketamine push ¹ • Give: ondansetron 4mg ODT/IV/IO/IM every 4 hours PRN	• Give: Standard analgesia plus • Give: hydromorphone or alternate opioid ² • Give: ondansetron 4mg ODT/IV/IO/IM every 4 hours PRN	• Give: ketamine push ¹ • Give: hydromorphone or alternate opioid ² • Give: ondansetron 4mg ODT/IV/IO/IM every 4 hours PRN	• Give: ketamine push ¹ • Give: ondansetron 4mg IV/IO every 4 hours PRN
Better	• After initial pain control with OTFC and/or ketamine • Give: acetaminophen/oxycodone (e.g., Percocet; if able to take PO) ²	• Give: Standard analgesia plus • Give: hydromorphone or alternate opioid ² • Give: midazolam ²	• Give: ketamine push ¹ • Give: hydromorphone or alternate opioid ² • Give: midazolam ² • 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)	• Standard analgesia plus • Give: hydromorphone or alternate Opioid ^{2,5} • Give: midazolam ² • Consider: ketamine load, then drip (for sedation) ^{3,4}	• Give: ketamine load, then drip (for sedation) ^{3,4} • Give: hydromorphone or alternate opioid ^{2,5} • Give: midazolam ²	• Give: ketamine push ¹ OR • Consider: ketamine load, then drip (for sedation) ^{3,4} If additional sedation needed AND blood pressure will tolerate: • Consider: hydromorphone or alternate opioid ^{2,5} • Consider: midazolam ²

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EtCO₂, 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; TCCC, Tactical Combat Casualty Care.

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

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

²To 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.

- 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 5mg (range, 2.5–10mg) IV/IO every 1–6 hours PRN (Long acting, more side-effects)
- Midazolam 1mg (range, 0.5–2 mg) IV/IO every 1–6 hours PRN (sedation, amnesia)
- Percocet 1–2 tab PO every 4 hours PRN (slower onset but provides steady pain control for up to 6 hours). Can supplement with effective dose of IV/IO opioids or ketamine for breakthrough pain. *Contains 650mg acetaminophen. Do not exceed 4,000mg acetaminophen per day.*

³**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.**

⁴A 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.

⁵If 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.

Note: Consider using the RASS score as a method to trend the patient’s sedation level. See [Appendix F](#).

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 $\mu\text{g}/\text{kg}/\text{min}$ dose desired. Increase or decrease dose by 5–10 $\mu\text{g}/\text{kg}/\text{min}$ 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)**

Dose		Patient's Weight, kg			
		40	60	80	100
mg/kg/h	$\mu\text{g}/\text{kg}/\text{min}$	Infusion Rate, mL/h			
0.5	8	7*	10	13	17
0.75	13	10	15	20	25
1.0	17	13	20	27	33
1.25	21	17	25	34	42
1.5	25	20	30	40	50
1.75	29	24	35	47	59
2.0	33	27	40	53	67

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

Dose		Infusion Rate, 1 drip/X seconds			
		0.5	8	1/35	1/24
0.75	13	1/27	1/18	1/14	1/8
1.0	17	1/18	1/12	1/9	1/7
1.25	21	1/15	1/10	1/8	1/6
1.5	25	1/12	1/8	1/6	1/5
1.75	29	1/11	1/7	1/6	1/5
2.0	33	1/9	1/6	1/5	1/4

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

Dose		Infusion Rate, 1 drip/X seconds			
		0.5	8	1/53	1/36
0.75	13	1/41	1/27	1/21	1/12
1.0	17	1/27	1/18	1/14	1/11
1.25	21	1/23	1/15	1/12	1/9
1.5	25	1/18	1/12	1/9	1/8
1.75	29	1/17	1/11	1/9	1/8
2.0	33	1/14	1/9	1/8	1/6

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):

- 25–100 μg 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

Common IV Meds Cheat Sheet			
	Moderate Pain	Pain Dose Range	Sedation
Ketamine	20mg IV	0.1–0.2mg/kg IV	1mg/kg IV
Midazolam	1mg IV	0.5–2mg IV	1mg every 1–6 hours
Morphine	5mg IV	2.5–10mg IV	
Fentanyl IV	25µg IV	25–100µg IV	
Hydromorphone	0.5–1mg IV	0.25–2mg IV	
OTFC	800µg pop: between cheek and gum		
Opioid overdose	Naloxone: Dilute 0.4mg (1mL) with 9mL normal saline. Give 1ml slowly. Repeat dose PRN		
Benzodiazepine overdose	Flumazenil: <ul style="list-style-type: none"> ▪ Draw 1mL (0.5mg) ▪ Dilute with 4mL sterile water (0.1mg/mL) ▪ Give 3mL/0.3mg over 15 seconds ▪ Additional 1mL/0.1mg every 1 minute PRN Maximum dose, 1mg/h (can cause seizures)		
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

Recommended Pain and Sedation Medication			
Name	Purpose/Dose	Side Effects and Notes	Pharmacology
Ketamine (Ketalar)	<p>Background pain:</p> <ul style="list-style-type: none"> Use low dose 10–20mg (0.1–0.2mg/kg) OV/IO PRN. Avoid oversedation <p>Breakthrough pain in hemodynamically stable or unstable patient: IV/IO push: dose every 5 minutes until goal achieved or nystagmus occurs or RR < 10/min.</p> <ul style="list-style-type: none"> 10–20mg (or 0.1–0.2mg/kg) slow push <p>IM/IN: every 15 minutes until goal achieved or nystagmus occurs</p> <ul style="list-style-type: none"> 40–60mg (or 0.5–0.75mg/kg) <p>Sedation: IM sedation dose:</p> <ul style="list-style-type: none"> 250–400mg (or 4–5mg/kg) <p>IV/IO sedation loading dose:</p> <ul style="list-style-type: none"> 1mg/kg IV push over 60 seconds <p>Then IV/IO drip for ongoing sedation (load above dose, then drip):</p> <ul style="list-style-type: none"> Nonintubated: 1mg/kg/h Intubated 1–2mg/kg/h 	<ul style="list-style-type: none"> Cataleptic-like state (dissociated from the surrounding environment) Respiratory depression at higher doses (>1mg/kg), especially with fast administration IV/IO 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/IO) Consider glycopyrrolate if significant sialorrhea Consider antiemetic (e.g., ondansetron) empirically (may vomit when recovering from sedation) To avoid rapid respiratory depression, IV/IO 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. 	<ul style="list-style-type: none"> 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/IO) 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)*	<p>Breakthrough pain in hemodynamically stable patient: IV/IO/ IN: dose every 5 minutes until goal achieved or RR < 10/min.</p> <ul style="list-style-type: none"> Nonintubated: 0.25–2mg Intubated: 1–4mg <p>IM: not recommended</p>	<ul style="list-style-type: none"> Respiratory/cardiac/mental status depression Nausea/vomiting Pruritus (itching) Constipation 	<ul style="list-style-type: none"> 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			
Name	Purpose/Dose	Side Effects and Notes	Pharmacology
Fentanyl*** (Actiq)	<p>Background pain: Oral: only in NONINTUBATED, awake patients, per TCCC guidelines</p> <ul style="list-style-type: none"> OTFC 800µg <ul style="list-style-type: none"> Place lozenge between the cheek and the gum Do not chew the lozenge <p>Breakthrough pain in hemodynamically stable patient: IV/IO/ IN: dose every 5 minutes until goal achieved or RR < 10/min.</p> <ul style="list-style-type: none"> Nonintubated: 25–50µg Intubated: 50–200µg <p>**IV push should be over 30–60 seconds, monitor for difficulty breathing (e.g., rigid chest syndrome) IM: not recommended</p>	<ul style="list-style-type: none"> Respiratory/cardiac/mental status depression Nausea/vomiting Pruritus (itching) Constipation <p>Unique concerns:</p> <ul style="list-style-type: none"> Chest-wall muscle rigidity with rapid IV infusion (rare) Bradycardia (rare) QT-interval prolongation (rare) Highly lipophilic 	<ul style="list-style-type: none"> 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**	<p>Breakthrough pain in hemodynamically stable patient: IV/IO/ IN: dose every 5 minutes until goal achieved or RR < 10/min.</p> <ul style="list-style-type: none"> Nonintubated: 2.5–10mg Intubated: 5–10mg <p>IM: not preferred; can give 5–10mg IM if necessary</p>	<ul style="list-style-type: none"> Respiratory/cardiac/mental status depression Nausea/vomiting Pruritus (itching) Constipation Anticholinergic like effects, particularly urinary retention 	<ul style="list-style-type: none"> 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	<p>Background pain Contains oxycodone (5mg) AND acetaminophen (325mg) PO/enteral (may be crushed): 1–2 tabs every 4–6 hours.</p> <ul style="list-style-type: none"> DO NOT exceed 4,000mg total acetaminophen per day. 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Oxycodone Hepatic metabolism Active metabolites Urinary excretion Duration of effect: 4–6 hours <p>Acetaminophen (see below)</p>
Midazolam (Versed)	<p>Sedation (includes anxiety or agitation): IV/IO: dose every 5 minutes until goal achieved or RR < 10/min.</p> <ul style="list-style-type: none"> Nonintubated: 0.5–2mg Intubated: 1–4mg <p>IM: not recommended</p>	<ul style="list-style-type: none"> Respiratory/cardiac/mental status depression Amnestic Nausea/vomiting Hypotension Constipation Personnel and equipment needed for standard respiratory resuscitation should be available during midazolam administration. 	<ul style="list-style-type: none"> Onset: 1–5 minutes Duration of effect: 1–4 hours Hepatic metabolism (active metabolites) Renal excretion
Glycopyrrolate (Robinul)	<p>Antisialagogue (i.e., to stop hypersalivation from ketamine) SC/IM/IV/IO:</p> <ul style="list-style-type: none"> 0.1–0.2mg every 4 hours 	<ul style="list-style-type: none"> Tachycardia/palpitations Nausea/vomiting Flushing Urinary retention Not to exceed 4 doses/d 	<ul style="list-style-type: none"> Anticholinergic Rapid onset Duration of effect: 2–6 hours Renal excretion (85%, 80% unchanged)

Recommended Pain and Sedation Medication			
Name	Purpose/Dose	Side Effects and Notes	Pharmacology
Acetaminophen (Tylenol)	For mild to moderate pain: IV/PO: 500–1000mg every 6 hours	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Onset: <1 hour PO, 5–10 minutes IV Duration of effect: 4–6 hours Hepatic metabolism Renal excretion
Odansatron (Zofran)	For nausea and vomiting: <ul style="list-style-type: none"> 4mg ODT/IV/IO/IM, every 4–8 hours PRN Can repeat once at 15 minutes if nausea and vomiting are not improved 	<ul style="list-style-type: none"> Maximum 8mg in any 8-hour interval QT-interval prolongation (rare) Constipation Dizziness/headache 	<ul style="list-style-type: none"> Selective serotonin 5-HT₃ receptor antagonist Hepatic metabolism Excreted in the urine and feces
Flumazenil (Romazicon)	For reversal of benzodiazepine overdose (e.g., midazolam) <ul style="list-style-type: none"> 0.2mg IV over 15 seconds 	<ul style="list-style-type: none"> DO NOT USE IN CHRONIC BENZODIAZEPINE USERS! (May cause seizures) Use only to reverse benzodiazepines YOU have given the patient. 	<ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 0.4–2mg IV/IM/SC/IN; repeat every 2–3 minutes PRN; not to exceed 10mg (0.01mg/kg) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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) <ul style="list-style-type: none"> 25–50mg IV/IO/PO every 4–6 hours PRN (maximum: 400mg daily) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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	HOW TO MINIMIZE RISK:
<ul style="list-style-type: none"> ● 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. 	<ul style="list-style-type: none"> <input type="checkbox"/> Know the drugs you have available and ensure you have easy access to procedural references prior to deployment. <input type="checkbox"/> Establish baseline neurological function of a given extremity prior to block. <input type="checkbox"/> Calculate the maximum total dose of local anesthetic for your patient and never exceed it when performing multiple blocks. <input type="checkbox"/> Use local anesthetics with epinephrine for all blocks to facilitate immediate recognition of intravascular injection. <input type="checkbox"/> Use blunt-tip needles to minimize nerve injury. <input type="checkbox"/> Monitor your patient during the injection & for 15-20 minutes after the procedure. <input type="checkbox"/> Use pulse oximetry with audible signal as the minimum monitoring device when performing regional nerve blocks. <input type="checkbox"/> Mark & date all the block sites with a permanent marker on the skin. <input type="checkbox"/> Pad all the pressure points <input type="checkbox"/> Know how to manage LAST syndrome (see checklist).
RISK	
<ul style="list-style-type: none"> ■ 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:	RECOMMENDED LOCAL ANESTHETIC
<ul style="list-style-type: none"> ■ NERVOUS SYSTEM: <ul style="list-style-type: none"> ● perioral numbness, tingling, metallic taste, tinnitus, muscle twitching, visual disturbance, extreme anxiety, screaming, impending death feeling, SEIZURE, COMA ■ CARDIOVASCULAR SYSTEM: <ul style="list-style-type: none"> ● chest pain, shortness of breath, diaphoresis, ARRHYTHMIA, HYPOTENSION, CARDIOVASCULAR COLLAPSE 	<p>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.</p> <p>MAXIMUM CUMULATIVE DOSE: 3 mg/kg (all blocks at multiple sites combined)</p> <ul style="list-style-type: none"> <input type="checkbox"/> 0.2% solution: 1.5mL/kg <input type="checkbox"/> 0.5% solution: 0.6mL/kg <p>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.</p>
RECOMMENDED MODALITIES:	
<ul style="list-style-type: none"> <input type="checkbox"/> Ultrasound-guidance for real-time visualization of targeted nerves, needle & anesthetic spread. It is recommended for any block performed (except digital blocks). <input type="checkbox"/> Paresthesia/anatomical technique may be used for distal nerve blocks if no ultrasound available. 	

Regional Anesthesia – Recommendations (Continued)

REGIONAL ANESTHESIA - WORKSHEET	
PATIENT'S WEIGHT [kg]:	MAXIMUM CUMULATIVE DOSE:
<p>RECOMMENDED UPPER EXTREMITY BLOCKS:</p> <p>SEE REGIONAL ANESTHESIA REFERENCE - ULTRASOUND-GUIDED NERVE BLOCKS</p> <p><input type="checkbox"/> SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK (must be performed under ultrasound guidance; inject 20-25mL of local anesthetic)</p> <p><input type="checkbox"/> AXILLARY BRACHIAL PLEXUS BLOCK (preferably under ultrasound guidance; inject 15-20mL of local anesthetic)</p> <p><input type="checkbox"/> WRIST BLOCK: radial, median & ulnar nerves (ultrasound use is optional; inject a total of 10mL of local anesthetic for all 3 nerves)</p> <p><input type="checkbox"/> DIGITAL BLOCK (inject < 5mL of local anesthetic)</p> <p>RECOMMENDED LOWER EXTREMITY BLOCKS:</p> <p>SEE REGIONAL ANESTHESIA (3) ULTRASOUND-GUIDED NERVE BLOCKS REFERENCE</p> <p><input type="checkbox"/> FEMORAL NERVE BLOCK (use ultrasound guidance; inject 10-20mL of local anesthetic)</p> <p><input type="checkbox"/> PROXIMAL SCIATIC NERVE BLOCK (subgluteal approach; use ultrasound guidance; inject 15-20mL of local anesthetic)</p> <p><input type="checkbox"/> DISTAL SCIATIC NERVE BLOCK (popliteal approach; use ultrasound guidance; inject 20mL of local anesthetic)</p> <p><input type="checkbox"/> SAPHENOUS BLOCK (ultrasound use is optional: proximal approach at tibial tuberosity; inject 10mL of local anesthetic)</p> <p><input type="checkbox"/> 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)</p> <p><input type="checkbox"/> DIGITAL BLOCK (inject < 5mL of local anesthetic)</p> <p>CONTRAINDICATIONS:</p> <ul style="list-style-type: none"> ■ 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 	<p>TECHNIQUE:</p> <ul style="list-style-type: none"> ● Identify target nerve according to training ● Gather equipment and place the patient on monitor: <ul style="list-style-type: none"> <input type="checkbox"/> MINIMUM: pulse oximetry with audible signal <input type="checkbox"/> BETTER: add blood pressure monitoring <input type="checkbox"/> 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 1 mL of anesthetic, and if no resistance, then aspirate again & slowly inject 3-5mL, and wait 60 seconds to monitor for toxicity. STOP IF 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 5-mL increments given over 10-15 sec each, and always aspirate for blood between each 5-mL increment ● Mark and date each block site <p>Local Anesthetic Systemic Toxicity (LAST) checklist:</p> <ul style="list-style-type: none"> ■ 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: <ul style="list-style-type: none"> <input type="checkbox"/> 1 mL/kg every 3-5 minutes IV, up to 3mL/kg IV during ACLS <input type="checkbox"/> Follow with continuous infusion 0.25mL/kg/min <input type="checkbox"/> Double the infusion rate to 0.5mL/kg/min if blood pressure remains low <input type="checkbox"/> Continue infusion for at least 10 minutes once hemodynamically stable <input type="checkbox"/> Upper limit: approx. 10mL/kg IV over 30 minutes

Regional Anesthesia – Recommendations (Continued)

REGIONAL ANESTHESIA REFERENCE - ULTRASOUND-GUIDED NERVE BLOCKS

<p>SUPRACLAVICULAR BRACHIAL PLEXUS</p>	<ul style="list-style-type: none"> • TIPS: identify subclavian artery lying on the first rib; the plexus 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 	<p>LATERAL</p>	<p>SBP SCA FIRST RIB LUNG</p> <p>SBP = SUPRACLAVICULAR BRACHIAL PLEXUS SCA = SUBCLAVIAN ARTERY</p> <p>LATERAL MEDIAL</p>
<p>AXILLARY BRACHIAL PLEXUS</p>	<ul style="list-style-type: none"> • 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 	<p>SUPERIOR</p>	<p>BP AA MCN BP AA MCN</p> <p>AA = AXILLARY ARTERY BP = BRACHIAL PLEXUS MCN = MUSCULOCUTANEOUS NERVE</p> <p>SUPERIOR INFERIOR</p>
<p>FEMORAL NERVE</p>	<ul style="list-style-type: none"> • 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 	<p>LATERAL</p>	<p>FN FA FV</p> <p>FN = FEMORAL NERVE FA = FEMORAL ARTERY FV = FEMORAL VEIN</p> <p>LATERAL MEDIAL</p>
<p>PROXIMAL SCIATIC NERVE</p>	<ul style="list-style-type: none"> • TIPS: identify greater trochanter and ischial tuberosity; sciatic nerve can be seen between them. • PITFALLS: may need to inject more distally or in long axis of the nerve. • INJECTION VOLUME: 15-20mL 	<p>LATERAL</p>	<p>GREATER TROCHANTER ISCHIAL TUBEROSITY PROXIMAL SCIATIC NERVE</p> <p>LATERAL MEDIAL</p>
<p>DISTAL SCIATIC NERVE</p>	<ul style="list-style-type: none"> • TIPS: identify popliteal vessels; inject at confluence of CPN & TN; scan after injection to ensure spread. • INJECTION VOLUME: 20mL 	<p>LATERAL</p>	<p>DISTAL SCIATIC NERVE CPN TN FA PV TN CPN</p> <p>FA = POPLITEAL ARTERY PV = POPLITEAL VEIN TN = TIBIAL NERVE CPN = COMMON PERONEAL NERVE</p> <p>LATERAL MEDIAL</p>

GENERAL POINTERS ON TECHNIQUE:

- In cross-section on ultrasound nerves look like honey-comb cereal;
- Find blood vessels and use color Doppler to localize 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;
- Flush 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.

LINEAR **LINEAR PROBE IS PREFERRED**

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APPENDIX F: THE RICHMOND AGITATION-SEDATION SCALE (RASS)¹²

+4	Combative	Combative, violent, immediate danger to staff
+3	Very agitated	Pulls to remove tubes or catheters; aggressive
+2	Agitated	Frequent non purposeful movement; fights ventilator
+1	Restless	Anxious, apprehensive, movements not aggressive
0	Alert and calm	Spontaneously pays attention to caregiver
-1	Drowsy	Not fully alert but has sustained awakening to voice (eye opening and contact >10 seconds)
-2	Light sedation	Briefly awakens to voice (eyes open and contact <10 seconds)
-3	Moderate sedation	Movement of eye opening to voice (no eye contact)
-4	Deep sedation	No response to voice but movement or eye opening to physical stimulation
-5	Unarousable	No response to voice or physical stimulation
Procedure for RASS assessment		Score
1. Observe patient. • Patient is alert, restless, or agitated.		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.		-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.		-4 -5

APPENDIX G: PLANNING CONSIDERATIONS

Best:	Better:	Minimum:
<ul style="list-style-type: none"> • Fluids: fluid for medication administration/drip (normal saline [NS]: 100mL/250mL bags and 5mL/10mL prefilled syringes) • 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 • Macro/microdrip intravenous (IV) administration tubing; • infusion pump • Analgesic medications: Ketamine, hydromorphone, fentanyl, morphine (for IV use), oral transmucosal fentanyl citrate (OTFC), Percocet tabs for oral (PO) use • Mild pain: meloxicam, acetaminophen • Sedation/Anxiety: midazolam for IV use (diazepam tabs for PO) • Mild pain: meloxicam, acetaminophen • Antisialagogue: glycopyrrolate • Antiemetic: ondansatron • Antihistamine and reversals: diphenhydramine, flumazenil, naloxone • Local/regional anesthesia: 2% lidocaine/ropivacaine • 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 • Communications: real-time video telemedicine consultation • Push-pack capability: prepackaged additional 24-hour supplies of fluids, and medications for scenarios >24 hours. 	<ul style="list-style-type: none"> • Fluid for medication administration/ drip (NS: 250mL bags and 10mL prefilled syringes) • 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 • Graduated container to monitor urine output • Analgesic medications: ketamine, hydromorphone for IV • Percocet tabs for PO • Mild pain: meloxicam, acetaminophen • Sedation/Anxiety: midazolam • Antiemetic: ondansatron • Antihistamine and reversals: diphenhydramine, flumazenil, naloxone • Nonsteroidal anti-inflammatory drug (NSAID): acetminophen • Local/regional anesthesia: 2% lidocaine/ropivacaine • Monitoring: frequent vital signs, examination, fluid input/urine output • Communications: telephone; e-mail digital photos 	<ul style="list-style-type: none"> • Fluids: NS: 250mL bags • Equipment: blood pressure cuff, stethoscope, pulse oximeter, bag-valve mask with positive end-expiratory pressure valve, airway management kit • Macrodrip tubing and counting drops per second to get infusion rate • Analgesic medications: ketamine, hydromorphone for IV, Percocet tabs for PO • Mild pain: meloxicam, acetaminophen • Sedation/Anxiety: midazolam • Antiemetic: ondansatron • Antihistamine and reversals: diphenhydramine, flumazenil, naloxone • Local/regional anesthesia: 2% lidocaine/ropivacaine • Monitoring: frequent vital signs, examination, fluid input documented on preprinted or improvised flowsheet. • Communications: telephone

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.