

Management of Pain, Anxiety and Delirium in Injured Warfighters

Original Release/Approval	23 Nov 2010	Note: This CPG requires an annual review.	
Reviewed:	Oct 2010	Approved:	22 Nov 2010
Supersedes:	This is a new CPG and must be reviewed in its entirety.		
<input type="checkbox"/> Minor Changes (or)	<input type="checkbox"/> <i>Changes are substantial and require a thorough reading of this CPG</i> (or)		
<input type="checkbox"/> Significant Changes			

1. **Goal.** To provide an evidenced based framework for the management of pain, anxiety and delirium in injured combat casualties. To provide state of the art pain services to combat casualties and to reduce the incidence of chronic pain syndromes, PTSD and chronic narcotic dependency.
2. **Background.**
 - a. Pain is universally present in combat casualties. Adequate early pain control has been shown to reduce post traumatic stress disorder and ongoing pain control is an obligatory part of trauma care. The stress response involves a well-established sequence of physiologic and molecular events that include fever, tachycardia, tachypnea, hypertension, gastrointestinal ileus, hypercoagulability, protein catabolism, immunosuppression, among other undesirable consequences that delay or prevent a wounded warrior's full rehabilitation and recovery. Effective pain management requires coordination of all medical providers throughout the evacuation system.
 - b. Pain is frequently accompanied by anxiety and delirium in critically injured patients and the medications utilized to treat these conditions may exacerbate them. A multimodal approach to pain control reduces complications associated with narcotics and subsequent narcotic dependence. The use of other modalities such as acetaminophen, ketamine, NSAIDs, continuous peripheral nerve infusions, and continuous epidural infusions greatly increases the effectiveness of narcotics while reducing the incidence of unwanted side effects increasing patient safety. The multimodal approach to pain care requires the establishment of an acute pain service (APS) at all Role 3 (and above) MTFs directed by a physician with extensive experience in pain management.
 - c. Standardized and validated, scoring systems have been created for the assessment of pain - DoD/VA Pain Scale, anxiety - Motor Activity Assessment Scale (MAAS) and delirium - Confusion Assessment Method (CAM). **The DoD/VA Pain Scale and supplemental questions are currently undergoing validation.** Medications utilized to treat these conditions should be specifically directed and dosed to achieve a defined goal; e.g., fentanyl dosed to achieve a Visual Analogue Scale score of 3. Excessive use of analgesics and anxiolytics may result in the inability to assess the evolution of patient injuries by physical exam and prolong the need for mechanical ventilation.
 - d. Assessment of the DoD/VA Pain scale, MAAS and CAM score should be documented in the chart and the effects of treatment should also be documented. (Appendices A-D)

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- e. Intermittent dosing of analgesics and anxiolytics as opposed to continuous dosing has been shown to reduce duration of mechanical ventilation.
- f. Daily interruptions of sedation have been shown to reduce the duration of mechanical ventilation and the incidence of ventilator associated pneumonia. Intermittent dosing and daily sedation holidays both prevent the accumulation of the active metabolites of benzodiazepines which may seriously impede the ability to assess patients and advance their care for a prolonged period of time.
- g. The assessment of pain, anxiety and delirium is complicated by the presence of traumatic brain injury and the treatment of these conditions affects the ability of the practitioner to assess the neurologic examination.

3. Evaluation and Treatment (Critical Care Patients).

- a. An Acute Pain Service (APS) should be developed at Role 3 – 5 facilities. The DOD/VA pain scale should be used to assess pain, the MAAS score should be used to assess anxiety and the CAM should be used to assess the presence of delirium.
- b. Consider potential causes of increased pain and anxiety prior to treating. (Appendix E)
- c. Orders for the treatment of pain and anxiety should include set goals and the minimum amount of medication necessary to achieve the goals should be used. The goals are determined by the need to achieve patient comfort and safety.
- d. The goal for patients with delirium is to achieve a delirium free state as measured by the CAM.
- e. Intermittent dosing of analgesics and anxiolytics should be instituted prior to continuous dosing. Patients who require dosing more frequently than every 2 hours should be placed on continuous dosing titrated to their goal.
- f. Continuous drips should be stopped daily to obtain a reliable physical examination and to perform a spontaneous breathing trial in ventilated patients who are potential candidates for extubation. Intermittent dosing should be attempted following sedation holidays. If continuous drips are still required they should be instituted at one half the prior dose and titrated to achieve the goal. Contraindications to the daily sedation holiday include intractable intracranial hypertension and inability to adequately oxygenate or ventilate mechanically ventilated patients.
- g. Propofol is an option for short term sedation in acutely agitated patients. It has rapid onset and it is also cleared rapidly. Propofol has been associated with hypotension which may be related to intravascular depletion. It is dissolved in a 10% lipid solution which should be considered when calculating calorie requirements. Propofol is an excellent drug for ICU patients scheduled to undergo CCATT missions. When used for transport, propofol should only be administered to intubated patients.
- h. Dexmedetomidine is an option for short term sedation in patients undergoing awake intubation or as a bridge to extubation in patients who are very agitated and do not tolerate spontaneous breathing trials. It may also be used in patients on BIPAP who require sedation. Its use should not exceed 24 hours when spontaneous respiration is desired.

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- i. The typical antipsychotic haloperidol and the atypical antipsychotic quetiapine are commonly used for the treatment of delirium. Both of these drugs may be associated with prolongation of the QT interval potentially resulting in fatal arrhythmias secondary to torsades. If these drugs are used, the QT_c interval should be monitored on a daily basis and they should be discontinued if the QT_c exceeds 500 msec or the interval increases 60 msec from baseline.
- j. Clonidine is an effective drug for patients with hypertension associated with agitation. Clonidine acts as an alpha-2 adrenergic agonist and also has sedative properties that do not result in respiratory suppression. It may also be used for mild sedation and analgesia.
- k. Patients undergoing prolonged air transport are at increased risk of adverse events secondary to the constraints of monitoring and it is the practice of CCATT teams to utilize deep sedation for safety. For this reason, neurologic deterioration in patients with traumatic brain injury cannot be assessed during transport. Patients with evidence of intracranial bleeding on CT scan or those at risk for development of intracranial hypertension who are being transported by CCATT and require deep sedation should have intracranial pressure monitors.
- l. See Appendix E for an algorithm summarizing the management of pain, anxiety and delirium in critically injured patients.
- m. See Appendix F for a sample order set including medication options and dosing.

4. Multi-modality pain therapy for injured warfighters

- a. **Guidelines:** The APS should be available to all patients that are admitted to the Role 3 theater hospital. The primary mission is to give effective pain control for coalition members.
- b. The Physician Pain consultant should round daily on all patients on the acute pain service. An interdisciplinary team of physicians, nurses and pharmacists should be created to provide 24 hour call coverage. This team should be responsible for coordinating pain plans with the evacuation system and the receiving MTF.
- c. Casualties should receive regional anesthesia procedures in a monitored setting where nursing staff is available to help with patient care, and provide appropriate recovery services for the patients.
- d. A tracking system that lists all patients on the acute pain service, their injuries and therapeutic interventions along with comments should be instituted. A cart with all of the needed supplies for regional anesthesia should be stocked in the anesthesia area. A dedicated ultrasound machine should be available for the Acute Pain Service. A pain record to track daily progress should be maintained with the patient record and forwarded to transferring facilities for continuity of care.
- e. The acute pain service should maintain and provide input for standing orders to include:
 - i. Continuous epidural & peripheral nerve catheter infusion and single shot epidural or intrathecal narcotics.

- ii. IV patient controlled analgesia (PCA) Orders. Fentanyl, hydromorphone, and morphine are the narcotic agents of choice. Meperidine (Demerol) is not an approved compound for repeated PCA dosing as the metabolite normeperidine reduces the seizure threshold.
 - iii. Low dose ketamine infusions have profound analgesic effects with very minimal side effects. Ketamine binds the NMDA receptor and decreases the total dose of narcotics that is needed to treat a patient. Ketamine infusions should be made as follows: 250mg of Ketamine in 250 ml of normal saline. For patients that are 70kg or greater and less than 60 years old, start infusions at 10mg per hour in the setting of acute and neuropathic pain. Patients that fall out of these guide lines should receive 100 micrograms per hour of ketamine in the setting of acute or neuropathic pain. Custom orders may be titrated by the attending anesthesiologist or critical care physician.
- f. **Epidural Catheters:**
- i. In light of the fact that warfighters injured in theater are transported through a spectrum of care, the implementation of regional anesthesia must be integrated throughout the trauma system to be safe and effective.
 - ii. All catheters should receive a 3 ml test dose of 1.5% lidocaine with epinephrine.
 - iii. Enoxaparin use in patients undergoing epidural anesthesia increases the risk of spinal or epidural hematoma, which may cause long term or permanent paralysis.
Note: Recommend advising not using Enoxaparin in AE patients given the increased propensity for spinal & epidural hematoma formation and the inevitable increased motion of delivery catheters during patient transport in the DOD AE System.
 - iv. Prophylactic low molecular weight heparin dosing should be held for 12 hours prior to placement of an epidural catheter. Therapeutic dosing should be held for 24 hours prior to placement of epidural catheters. Administration of LMWH should be delayed for 2 hours after catheter removal. The maximum recommended prophylactic dose of low molecular weight heparin with an epidural catheter in place is 40mg sq daily. This is consistent with the most recent ASRA guidelines for the prevention of epidural hematoma.
- g. **Peripheral Nerve Catheters:**
- i. All catheters should receive a test dose of lidocaine with epinephrine.
 - ii. Low molecular weight heparin should be held for 12 hours prior to placement of peripheral nerve catheters. Administration of LMWH should be delayed for 2 hours after catheter removal.
 - iii. For femoral, sciatic, popliteal, and supraclavicular catheters, the patient may receive 30mg of low molecular weight heparin twice daily as long as the placement of the catheter was not traumatic. If the catheter placement was traumatic the patient

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- should receive 40mg of low molecular weight heparin for the first 24 hours and then convert to 30mg twice daily.
- iv. Each patient should have no more than two catheters and the total dose of 0.2% Ropivacaine should not exceed 20 ml per hour.
 - h. **Compartment Syndrome:** Compartment Syndrome is a well described complication of severe traumatic injury. Definitive treatment is complete surgical release of the compartments. Patients who are at high risk for compartment syndrome should be discussed in detail between the trauma surgeon, and the acute pain anesthesiologist as pain control may mask symptoms of compartment syndrome.
 - i. **Air Evacuation:** The PMR must state the type of regional anesthesia being utilized. All individuals participating in the care of the patient should have up-to-date training and experience with regional anesthesia and the equipment. All equipment associated with the use of regional anesthesia must be approved for flight. The current infusion pump system that has been approved by the United States Air Force for air evacuation is the small portable Ambit pump. Ambit pumps should be used for epidural, peripheral nerve catheters, ketamine infusions, narcotic infusions, and patient controlled anesthesia. **For all patients receiving regional anesthesia/analgesia, coordinate with the Trauma Chief, Theater Validating Flight Surgeon and Theater CCATT Director prior to any planned fixed-wing tactical (Intratheater) or strategic (Intertheater) transport to ensure patient safety during flight operations.**
 - j. **Nursing Care:** Regional anesthesia patients should be recovered by standard post anesthesia care unit (PACU) criteria. Patients with epidurals, and peripheral nerve blocks should be held in recovery until they meet standard discharge criteria from PACU and ICU. Patients with peripheral nerve blocks and epidural catheters that have met discharge criteria from ICU and PACU may be managed on the floor.
 - k. **Pharmacy support:** Standard preservative free local anesthetics include 0.5% ropivacaine and 1% lidocaine with epinephrine. The standard drip for air transfer out of country should be a 250cc bag of 0.2% ropivacaine. No narcotics will be added to the peripheral nerve block or epidural infusions as they change the validation for air transport by the United States Air Force.
 - l. 1000 ml of 20% intralipid should be maintained for use in patients with local anesthetic toxicity (to include availability in air evacuation of patients). 1000ml of 20% Intralipid must accompany patients receiving local anesthetic infusions during transport in the AE System. Patients with signs of local anesthetic toxicity should immediately receive 1.5 ml per kilogram of 20% intralipid. In a 70 kilogram adult give a 100ml bolus and 100 ml per hour for four hours. If the patient has arrested, they will require chest compressions to circulate the intralipid. This is an uncommon side effect but one that all caregivers should be aware of.

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- m. The Military Advanced Regional Anesthesia and Analgesia handbook is an excellent APS reference text for pain care standards and issues (www.bordeninstitute.army.mil or www.DVPMI.org).
- n. Tri-service policies for pain management can be found at www.DVPMI.org. Strategic issues on evacuation pain management should be referred by the health care facility APS physician to the Defense and Veterans Pain Management Initiative organization (www.DVPMI.org).

5. Responsibilities.

- a. All healthcare providers will:
 - i. Become familiar with the guidelines for the management of pain, anxiety and delirium in critically injured patients.
 - ii. Appropriately manage patients with pain, anxiety and delirium.
 - iii. Provide feedback on these guidelines and suggestions for changes to the CPG to the JTTS Director.
- b. The Trauma Chief, Pain Director and Intensivist at each level III facility will:
 - i. Implement care that is consistent with the intent of this CPG.
 - ii. Monitor adherence with the CPG.

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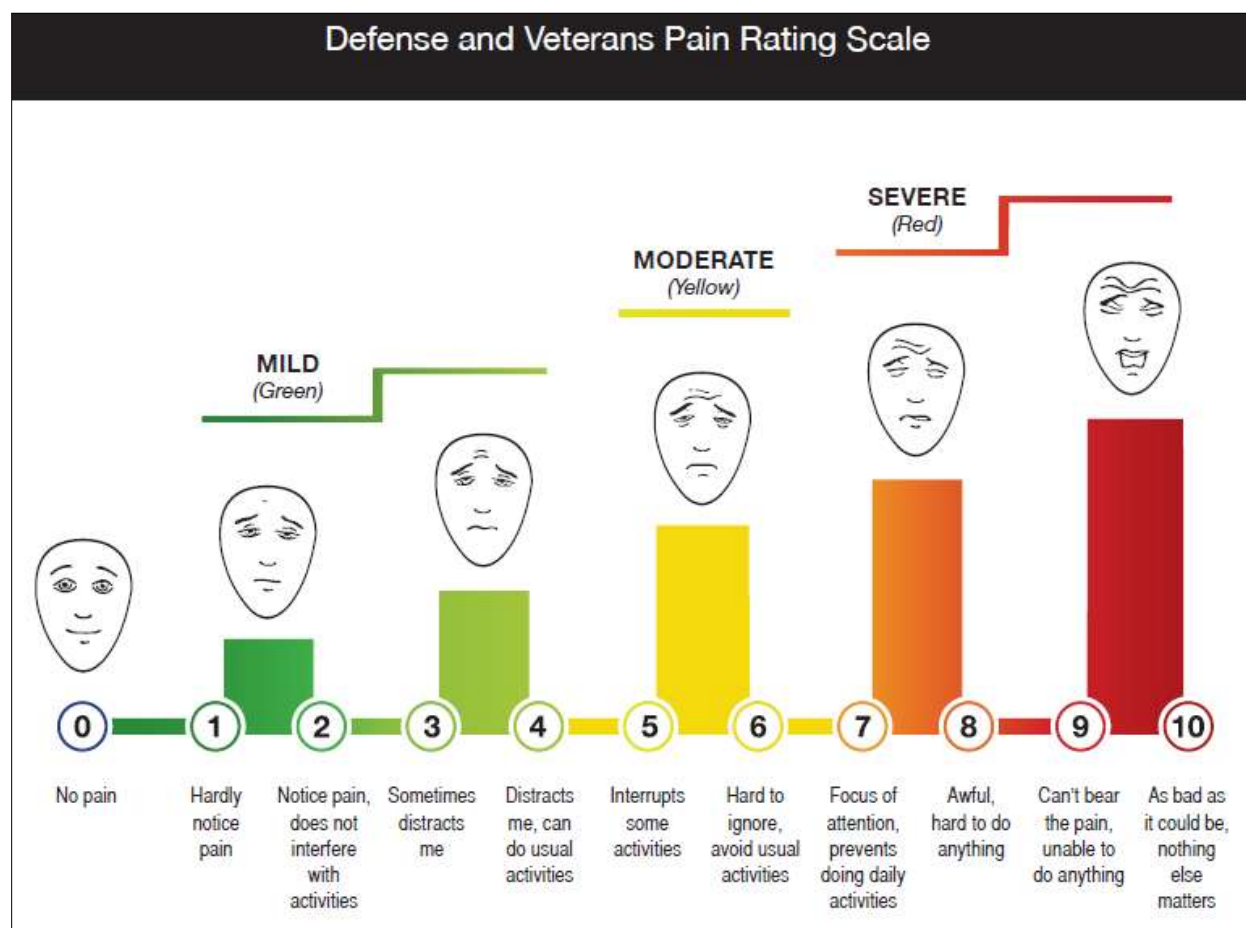
Approved by CENTCOM JTTS Director and Deputy
Director and CENTCOM SG

Opinions, interpretations, conclusions, and recommendations are those of the authors and are not necessarily endorsed by the Services or DoD.
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APPENDIX A

DOD/VA PAIN SCALE.



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APPENDIX B

DOD/VA PAIN SUPPLEMENTAL QUESTIONS

DEFENSE AND VETERANS PAIN SUPPLEMENTAL QUESTIONS
For clinicians to evaluate the biopsychosocial impact of pain

1. Circle the one number that describes how, during the past 24 hours, pain has interfered with your General Activity:

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

2. Circle the one number that describes how, during the past 24 hours, pain has affected your Mood:

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

3. What is your Level Of Stress related to pain in the past 24 hours?

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

4. Circle the one number that describes how, during the past 24 hours, pain has affected your Sleep:

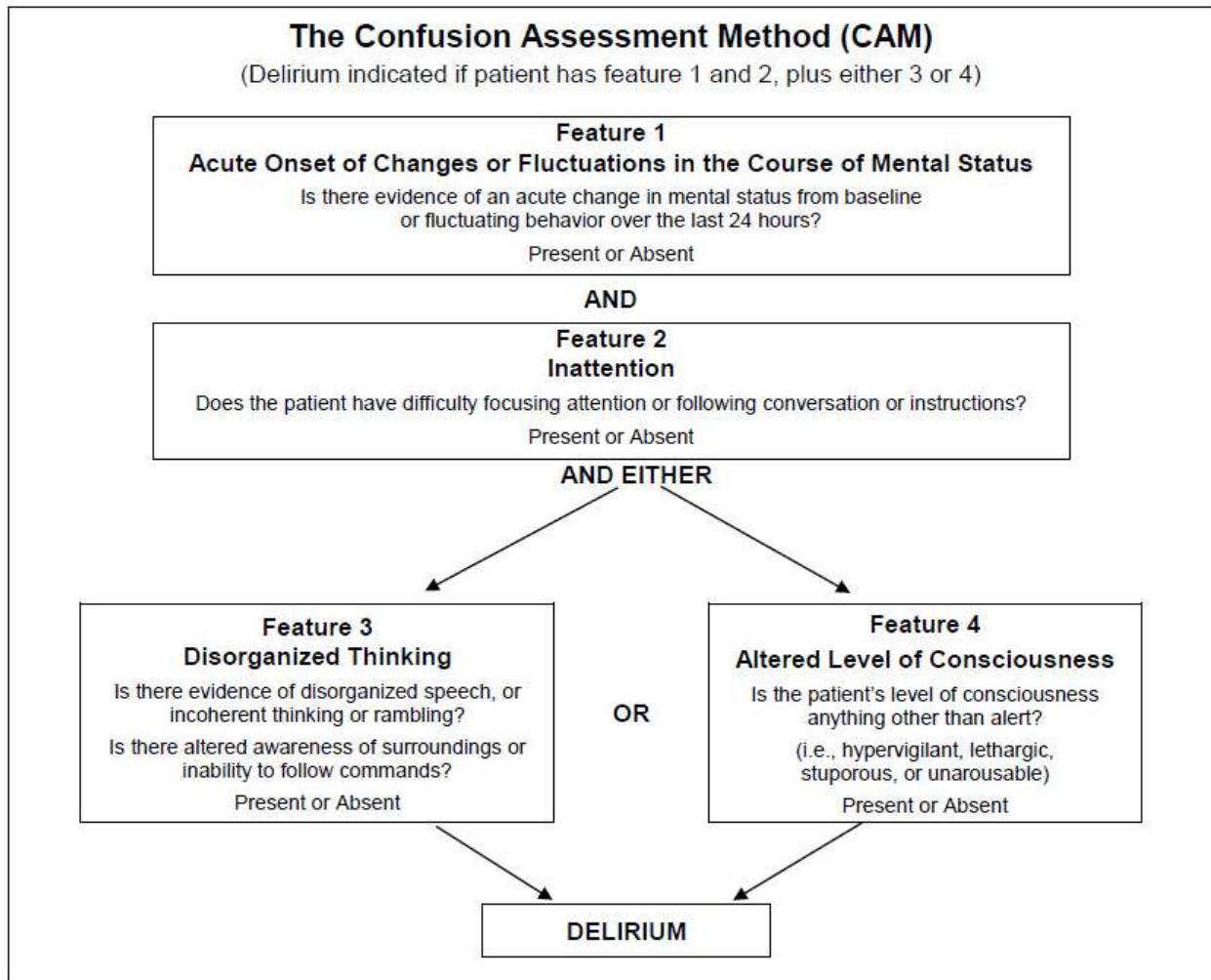
0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

APPENDIX C

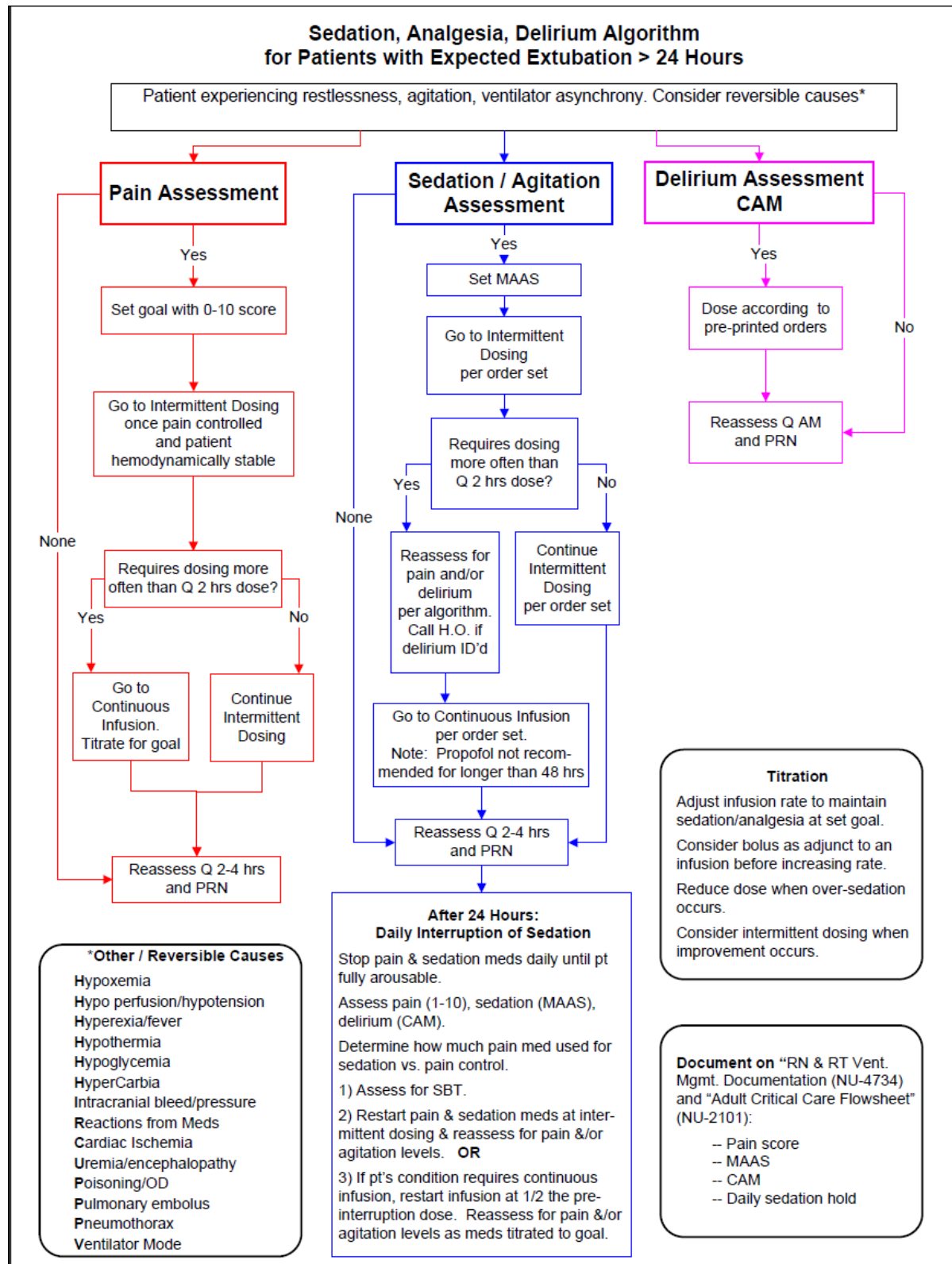
MOTOR ACTIVITY ASSESSMENT SCALE (MAAS) SEDATION SCORING SYSTEM

	Definition
0 Unresponsive	Does not move with noxious stimuli (i.e., suctioning or 5 seconds of vigorous sternal or nail bed pressure)
1 Responsive only to noxious stimuli	Opens eyes, raises eyebrows, turns head towards stimulus or moves limbs with noxious stimuli
2 Responsive to touch or name	Opens eyes, raises eyebrows, turns head towards stimulus or moves limbs when name is spoken loudly
3 Calm and cooperative	No external stimulus required to elicit response, movements purposeful, follows commands
4 Restless and cooperative	No external stimulus required to elicit response AND patient is picking at sheets or tubes OR uncovering self and follows commands
5 Agitated	No external stimuli required to elicit response AND attempting to sit up OR move limbs out of bed AND does not consistently follow commands
6 Dangerously agitated, uncooperative	No external stimuli required to elicit response AND patient is pulling at tubes or catheters OR thrashing side to side OR striking at others OR trying to climb out of bed AND does not calm down when asked

APPENDIX D



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APPENDIX F
SEDATION ORDERS

Allergies: _____ **Weight:** _____ kg

Diagnosis: _____

Service: _____ **Attending:** _____

SEDATION ANALGESIA DELIRIUM

See ICU Sedation Analgesia Delirium Algorithm

Nursing Orders

- ☐ Daily sedation Hold
 1. Hold sedation/analgesia daily.
 2. Assess pt for SBT if on ventilator.
 3. Restart sedation/analgesia at intermittent dosing;
OR if pt's condition requires continuous infusion, restart infusion at ½ pre-interruption dose.
- ☐ Sedate to MAAS goal of 2-3.
See MAAS scale.
- ☐ ICU Sedation Analgesia Delirium Protocol
See CAM scale.
See Treatment Algorithm
- ☐ Notify MD
For delirium prior to initiating pharmacologic treatment
For patient on Clonidine - If SBP falls > 30 mmHg or DBP fall > 20 mmHg

ANALGESIA

Intermittent Dosing Start with Intermittent Dosing. If required more than Q 2 Hours, go to Continuous Infusion.

- ☐ fentanyl IV _____ mcg (25-100 mcg). Intravenous, EVERY 1 HOUR AS NEEDED for mild to moderate pain.
Titrate pain medications to achieve a level 3 or _____ (pain scale 1-10).
Start with Intermittent Dosing. If required more than Q 2 hours, go to Continuous infusion.
Administer via slow IV.

Continuous Dosing Stop intermittent dosing if continuous infusion initiated and notify Pharmacy.

- ☐ fentanyl IV _____ mcg (25-250 mcg/hr), Intravenous, CONTINUOUS
Titrate pain medication to achieve a level 3 or _____ (pain scale 0-10).
Stop intermittent dosing if continuous infusion initiated and notify Pharmacy Services.
High-Risk Medication
- ☐ fentanyl IV bolus _____ mcg (25-100 mcg), Intravenous, EVERY 10 MINUTES AS NEEDED for breakthrough pain.
Titrate pain medication to achieve a level 3 or _____ (pain scale 0-10).
Administer via slow IV.

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SEDATION See MAAS scale

Intermittent Dosing Start with Intermittent Dosing. If required more than Q 2 hours, go to Continuous Infusion.

- ☐ lorazepam (aka ATIVAN) IV _____ mg (1-4 mg), Intravenous, EVERY 1 HOUR AS NEEDED for anxiety/agitation.

Start with Intermittent Dosing. If required more than Q 2 hours, go to Continuous Infusion.

Titrate sedation to MAAS score of 2-3

Continuous Infusion Stop intermittent dosing if continuous infusion initiated and notify Pharmacy.

- ☐ lorazepam (aka ATIVAN) IV infusion _____mg/hr (1-5 mg/hr), Intravenous, CONTINUOUS

Stop intermittent dosing if continuous infusion initiated and notify Pharmacy.

Titrate sedation to MAAS score of 2-3

- ☐ lorazepam (aka ATIVAN) IV bolus _____ mg (1-2 mg), Intravenous, EVERY 20 MINUTES AS NEEDED for breakthrough agitation/anxiety.

Titrate sedation to MAAS score of 2-3

- ☐ midazolam (aka VERSED) IV infusion (avoid in renal/liver dysfunction) _____ mg/hr (1-6 mg/hr), Intravenous, CONTINUOUS.

Stop intermittent dosing if continuous infusion initiated and notify Pharmacy.

Titrate sedation to MAAS score of 2-3

- ☐ midazolam (aka VERSED) IV bolus _____ mg/hr (1-2 mg/hr), Intravenous, EVERY 2 MINUTES AS NEEDED for breakthrough agitation/anxiety.

Titrate sedation to MAAS score of 2-3

Dexmedetomidine Continuous Infusion

- ☐ dexmedetomidine IV _____mcg/kg/hr (0.3-0.7 mcg/kg/hr), Intravenous, CONTINUOUS for 24 hours

1. Is rapid extubation expected (24-48 hrs)? ☐ Yes ☐ No

2. Ordered by IC fellow or ICU staff? _____

3. Please select the indication (must meet one of the following):

☐ Awake intubation

☐ BIPAP use requiring sedation

☐ Bridge to extubation

☐ Desired light to moderate sedation

Titrate in increments of 0.1 mcg/kg/hr Q 10 minutes to achieve a sedation score of 2-3 and pain score < 4/10.

Do not exceed maximum dose of 0.7 mcg/kg/hr.

Keep heart rate greater than _____ beats per minute and systolic blood pressure greater than _____ mmHg and mean arterial pressure greater than _____mmHg.

Discontinue for heart rate < 45 beats per minute or if patient develops 2nd or 3rd degree Atrioventricular block.

For persistent hypotension unresponsive to fluid challenge, decrease the rate by 50%.

Discontinue if systolic blood pressure and mean arterial pressure do not return to parameters specified above in 10 minutes. Call House Officer for further instructions.

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DELIRIUM See CAM scale

Initiating Therapy

- ☐ haloperidol (aka HALDOL) IV x 1 ____mg (2-10 mg), Intravenous, ONCE For 1 Dose
Administer over 1 minute. See CAM scale.
- ☐ haloperidol (aka HALDOL) IV PRN ____mg (2-5 mg), Intravenous, EVERY 15 MINUTES AS
NEEDED for agitation. Recommend not to exceed 20 mg over one hour.
Slow administration over 5-10 minutes preferred to minimize hypotension. See CAM scale.

Maintenance Dosing QTc monitoring required for patients receiving more than 10 mg haloperidol
per day

- ☐ haloperidol (aka HALDOL) IV ____ mg (2-5 mg), Intravenous, EVERY 1 HOUR AS NEEDED
for delirium.
 - Not to exceed dose 80 mg IV in 24 hours.
 - Slow administration over 5-10 minutes preferred to minimize hypotension. See CAM scale.
- ☐ quetiapine (aka SEROQUEL) PO tablet (Day 1) 25 mg, Oral, TWICE DAILY. See CAM scale.
- ☐ quetiapine (aka SEROQUEL) PFT tablet (Day 1) 25 mg, Feeding tube, TWICE DAILY. See
CAM scale.
- ☐ quetiapine (aka SEROQUEL) PO tablet (Day 2) 50 mg, Oral THREE TIMES DAILY.
If patient responds to initial dose and PO/PFT available. See CAM Scale.
- ☐ quetiapine (aka SEROQUEL) PFT tablet (Day 2) 50 mg Feeding tube, THREE TIMES DAILY.
If patient responds to initial dose and PO/PFT available. See CAM scale.
- ☐ clonidine (aka CATAPRES) tablet PRN 0.1-0.2 mg, Oral EVERY 1 HOUR AS NEEDED for
hypertension due to agitation.
May repeat x 3 doses as needed, until SBP \leq 140 mmHg (160 mmHg if over 65 years of age).
If blood pressure goal is not achieved with clonidine 0.1 mg, give clonidine 0.2 mg every 1 hour as
needed to achieve SBP \leq 140 mmHg (160 mmHg if over 65 years of age).
Once BP goal is met, move to maintenance and/or PRN dose.
Hold clonidine if systolic blood pressure falls more than 30 mmHg of diastolic blood pressure falls
more than 20 mmHg and notify physician.
- ☐ clonidine (aka CATAPRES) tablet scheduled 0.1-.02 mg, Oral, EVERY 8 HOURS
Administer until SBP < 140 mmHg then change to maintenance/PRN dose.
Hold clonidine if systolic blood pressure falls more than 30 mmHg or diastolic blood pressure
falls more than 20 mmHg and notify physician.

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APPENDIX G

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGs

A. 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.

B. 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.

C. 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.

D. Additional Procedures.

1. 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.

2. 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.

3. 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.