

CERVICAL & THORACOLUMBAR SPINE INJURY: SURGICAL MANAGEMENT AND TRANSPORT

Original Release/Approval:	1 Jul 2010	Note: This CPG requires an annual review
Reviewed:	Feb 2012	Approved: 9 Mar 2012
Supersedes:	Spine Injury Surgical Management and Transport 1 Jul 2010	
<input type="checkbox"/> Minor Changes (or)	<input type="checkbox"/> Changes are substantial and require a thorough reading of this CPG (or)	
<input checked="" type="checkbox"/> Significant Changes	PI monitoring plan added	

- 1. Goal.** The goal for the treatment and the movement of US and Coalition patients with spine injuries is to maintain spine stability, to perform decompression when urgently needed, to prevent deterioration of the patient's neurological condition during transport and to avoid secondary injury. Early, thorough and accurate documentation of the patient's neurological examination is crucial to ensure appropriate management decisions are made as the patient transits through the evacuation system.
- 2. Background.**
 - a. The terms "stable" and "unstable" when applied to spinal fractures are markedly subjective and not always of clear significance. Traumatic injury of the spinal cord can occur in the absence of fracture -- particularly in children (Spinal Cord Injury Without Radiologic Abnormality "SCIWORA"), traumatic disc herniation or ligamentous disruption, and middle-aged or elderly patients with cervical spondylosis and hyperextension injuries (most frequently resulting in central cord syndrome presentation).
 - b. The role and timing of operative intervention in spinal traumatized patients with acute spinal cord injury (ACI) is controversial.^{1,2,3,4,5} The paucity of prospective randomized trials defining the operative indications for ACI, results in a disparate approach to these injuries among spine surgeons.
 - c. Spine traumatized patients may be placed into one of four clinical categories: (1) patients with complete spinal cord syndromes; (2) patients with incomplete and progressive spinal cord syndromes; (3) patients with incomplete but nonprogressive spinal cord syndromes; and (4) patients with normal neurological function. The management of these conditions will be discussed in section 6.
- 3. Documentation and neurologic exam.**
 - a. Every effort must be made to document an accurate and thorough neurological examination, especially when surgery or aeromedical transport is planned. The quality of the examination can obviously be influenced by necessary pharmacological manipulations, presence of an airway adjunct or endotracheal tube, cardiovascular and pulmonary performance, and presence of other injuries to the head, torso or extremities. Use of terms such as "intact," "incomplete," or "moves both legs" must be further defined with actual exam findings. Failure to do so is the most common source of

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discrepancy between serial neurological examination findings, especially between levels of care.

- b. Every effort should be made to document as thorough a neurologic exam as possible to include: motor exam using American Spinal Injury Association (ASIA) motor groups; sensory examination (pin prick and light touch) using ASIA dermatomal standards; digital rectal exam assessing both voluntary anal sphincter contraction strength, pinprick sensation, resting tone and bulbocavernosus reflex (BCR). In addition, normal and pathological reflex testing such as biceps, triceps, brachioradialis, knee, and ankle jerk responses as well as presence/absence of Babinski reflex may be recorded. In patients with suspected spinal column injury, with or without neurologic deficit upon presentation, frequent repetition and surveillance of the neurologic examination (focusing upon motor and sensory performance) is imperative (*It is recommended to use Appendix A: ASIA Worksheet and attach to patient's chart*).
- c. Alternatively, the "Combat Neuro Exam" is a simpler documentation tool than the ASIA Worksheet and may be more amenable to non-spine specialists to complete. This note addresses the minimal elements of a complete neurological exam for a patient with significant spinal column injury (*Appendix C: Combat Neuro Exam and attach the patient's chart*).

4. Treatment of spinal injuries.

- a. External immobilization options for the cervical spine in theater should include semi-rigid cervical orthosis (e.g., Aspen collar), halo, and Sternal-occipital-mandibular immobilizer (SOMI)-like devices or cervico-thoracic braces (e.g. Aspen CTO). Aspen TLSO and LSO devices may also be available at certain Role III facilities for bracing of thoracolumbar injuries and are primarily suitable for use on patients not being transported out of theater. The actual materials on hand in the deployed setting may be variable. It is imperative that the deployed spine surgeon be intimately familiar with the immediate availability and serviceability of these devices in the assigned expeditionary medical treatment facility in order to proactively guide treatment and logistical decisions. Current traction systems do not work well in the aeromedical evacuation system.
- b. The operative treatment of US and coalition spine fractures in theater is ultimately left to the deployed surgical team. This includes the spine surgeon and the Chief of Trauma. Surgery that can be delayed safely until the patient arrives to the Level IV or V hospital should be delayed. In-theater spine surgery has a number of inherent added concerns to include variations of surgeon expertise, availability of familiar spinal instrumentation systems, and a less controlled operating environment. However, there will be some patients who might benefit from immediate surgery (when available) and these include patients with a progressive and incomplete injury, open CSF leak, an expected prolonged delay in transport (>5 days), or those whose neurologic well being is significantly jeopardized by further transport.
- c. Specific injury patterns and treatment
 - 1) When a spinal cord neurological injury is determined to be a complete injury (i.e., the bulbocavernosus reflex is intact and complete loss of sensorimotor function,

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- including absent proprioception), spinal stabilization may proceed in a less urgent pace. There does not appear to be any evidence in the civilian literature that surgical treatment can alter the prognosis for neurological improvement in patients with complete cord syndromes.⁶ Although this subset of patients may require subsequent stabilization of the spine to facilitate rehabilitation, they do not generally require surgery at in-theater facilities. **One exception may be in the cervical spine, where an urgent reduction may improve the rate of “root sparing” injury.**^{7,8}
- 2) There is broad support for immediate surgery for patients with incomplete but progressive spinal cord syndromes. This syndrome is rare, but may result from progressive spinal cord injury via fracture displacement, bone fragment compression, expanding hematoma, spinal cord edema, or infarction.⁹ Animal studies have demonstrated that immediate decompression of neural elements is associated with a reduction in permanent neurological sequelae.^{10,11}
 - 3) Management of incomplete and nonprogressive spinal cord syndromes involves subacute spinal segment reduction and stabilization to minimize neurological injury. This surgery is typically performed in delayed fashion at the 3-7 days post-injury in civilian centers and therefore, may be performed at a Level IV or V facility if the in-theater spine surgeon feels that the transport will not place the patient at significant risk for further injury. In the cervical spine, management may involve application of skull traction device at Level II (i.e. Forward Surgical Team) or higher facilities although these are difficult devices in which to transport patients. In the thoracolumbar spine, traction is less successful, so if a neutral supine positioning with spine precautions does not restore alignment, definitive correction of the malalignment will be performed typically at the time of definitive stabilizing surgery (Level IV or V).
 - 4) There may not be an indication for stabilization of the injured spinal column when the neurological examination remains normal UNLESS the in-theater spine surgeon feels that the patient is at risk of injury during transport. In 2008, Bellabarba reviewed all spinal traumatized patients evacuated from theater over a 5-year period and reported to the US Army Orthopaedic Surgery Consultant that there were no instances of neurological deterioration in this population of casualties during the evacuation process. However, four cases of potential deterioration were identified by the Landstuhl Regional Medical Center (LRMC) trauma program since 2004. Incomplete and/or inconsistent documentation of the patients' neurological examinations limits definitive review of these cases. Mok completed a performance improvement analysis of 32 spine surgeries (on 31 separate patients) performed in the OEF theater between Feb 2010 to Apr 2011. Only 40% of operations were done for the most commonly accepted indications which are apparent spinal cord injury with a compressive lesion demonstrated on advanced imaging, and cauda equina syndrome. Analysis demonstrated that 38% of these patients had improved neurological findings post-operatively. Patients that had more serious associated injuries were less likely to show improved neurological findings following operation.

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- 5) Reoperation rates (additional stabilization, revision decompression, removing retained drains or repositioning of hardware) as high as 60% have been reported following spinal surgery performed at Level III facilities.
- d. Benefits of early ORIF of spinal fractures in theater may include earlier mobilization (diminishing DVT risk and improving pulmonary toilet), better analgesia during transport and protection of the neural elements. In reality, this benefit will be limited to ORIF one day earlier in-theater than if the patient were evacuated to LRMC.
- e. The risk/benefit analysis of in theater decompression/spinal fixation versus transport to LRMC decision should include both the spinal surgeon, the Trauma Chief and the receiving spine surgeon at LRMC (ICU DSN 314-486-7141). The goal should always be to optimize the patient's neurologic outcome. The decision to proceed with decompression of the neural elements in the setting of a fracture *without* appropriate internal stabilization should be made with great trepidation. Improvements in spinal instrumentation systems available in theater may broaden the surgical options available to the spine surgeon.
- f. Spinal stabilization in theater should use an instrument system that is compatible with the system or equipment used at LRMC and the major Level V locations.
- g. LRMC may be a capable and reasonable location to perform spine surgery given its spinal instrumentation options, MRI availability and consistent staffing. But again, there may be times where prolonging surgery to the next Level V is considered advantages to the patient's long term outcome.
- h. Other patients with spine injuries, such as some non-coalition third country and local nationals will need to be stabilized as best as possible using available methods; these may include external stabilization using bracing.

5. Penetrating spine injuries.

- a. The need for surgical intervention of penetrating spine injuries is sometimes unclear and staged debridement of the wound may be required given the cavitary injury to soft tissues. Indications for surgery may include cauda equina injury, progressive neurologic deficit, incomplete deficit (particularly if a missile or fragment is still within the canal) or the presence of a CSF leak. If surgery is undertaken, good dural closure is paramount. Anterior and oblique entry to the lumbar and lower thoracic spine are at increased risk of infectious complications. If instability is present, infectious risks and neurologic status are key factors to determining the timing of stabilization and a staged procedure may be considered. Steroids should not be used.^{12, 13}
- b. Cefazolin 2 gm IV q 8 hrs for 24 hours is sufficient for penetrating spine injuries without evidence of contamination. Fragments passing through enteric contents require extended spectrum anti-microbial coverage for enteric organisms for a longer period of time because of increased risk of osteomyelitis.

6. Patient medical management.

- a. Patients who sustain neurologic compromise should have an invasive arterial line for continuous blood pressure monitoring with a goal MAP of 80-90 mm Hg for up to seven

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days following the injury. Hypotension (SBP < 90 mm Hg) and hypoxemia (SaO₂ <92%) must be avoided. Vasopressor therapy (in the euvoletic patient) and/or supplemental oxygen is recommended, when necessary, to achieve these goals.¹⁴ Vasopressor use in the hypovolemic patient may contribute to additional ischemic loss in other injured tissues.

- b. While many spinal fractures require flat bed rest prior to surgical correction or external bracing, the bed can usually be placed in 30 degrees reverse Trendelenberg. Log-rolling the patient can be safely performed in most cases every 2 hours to prevent skin breakdown. It is incumbent upon the spine surgeon to alter these assumptions based upon the specific clinical scenario.
- c. The use of corticosteroids in the setting of acute blunt spinal cord injury is no longer recommended due to no proven benefit and increased complications. The frequent associated open or contaminated wounds of battle casualties further complicate steroid administration. Methylprednisolone administration is NOT recommended for any blunt spinal cord injuries.
- d. An aggressive DVT prophylaxis regimen should be established early and maintained beyond the evacuation process. Pneumatic compression devices in conjunction with chemoprophylaxis are established treatment standards. Prophylactic dosing of a subcutaneous low molecular weight heparin (LMWH -- e.g. enoxaparin) is preferred and can usually be initiated within 72 hours of injury or repair. Early active or passive mobilization of the patient helps to reduce DVT formation and is frequently cited in support of early surgical fixation, when appropriate. Patients should be regularly screened for DVT with duplex Doppler ultrasound and, if a DVT is present, fully anticoagulated if approved by the spine surgeon. If full anticoagulation is contraindicated (i.e. < 14 days from surgery), IVC filter placement should be considered.

7. Transport of patients with spinal injuries.

- a. The majority of patients with cervical spine injuries will be transported using semi-rigid orthosis such as an Aspen collar. Clinical scenarios may arise wherein halo immobilization may be suitable. Transporting patients in traction is not a good option given the dynamics of air transport, particularly G-Forces during aircraft takeoff and landing, and the multiple transfers required from hospital-vehicle-aircraft-vehicle-hospital.
- b. If the patient has a thoracolumbar fracture that is unstable (3 column instability), then he should be transported by CCATT using a vacuum spine board (VSB). Use of a VSB is preferable to supine transport in a TLSO or other external brace. Prior to transport the theater spine surgeon and CCATT leader should agree upon suitability of VSB 'release of vacuum' and log-roll to reduce stress on pressure points. Log-rolling in a VSB without 'release of vacuum' does not significantly reduce skin pressure. Additionally, pre-transported skin integrity should be documented and care must be given to padding and pressure reduction maneuvers of the occiput and heels. Once cruising in smooth flight is accomplished, it would be reasonable to release the vacuum until either decent or turbulence is encountered. At a minimum, every two (2) hours the team should open the valve, release straps, +/- log-roll patient (holding patient in appropriate alignment) and

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provide adequate time for relief of pressure points as part of their normal turning schedule. The head of the bed should be elevated 30 degrees unless specifically told otherwise by the spine surgeon.

- c. During transport, all patients should use the sequential compression devices which are approved for flight. These must be obtained from the AE system.

8. Performance Improvement (PI) Monitoring.

a. Intent (Expected Outcomes).

- 1) A complete and thorough neurologic exam is performed on all patients with known or suspected spinal injuries and it is documented in the patient's medical record.
- 2) There is no proven benefit to the use of steroids in penetrating or blunt spinal cord injury so steroids are not used in these patients.
- 3) In patients with unstable TLS spine injuries, the vacuum spine board is used for transfer out of theater.

b. Performance/Adherence Measures.

- 1) In patients with known or suspected spine injuries, the ASIA or Combat Neuro Exam worksheet was utilized to document adequately the patients neurologic status and the documentation was placed in the patient's medical record.
- 2) Steroids were not used in the management of patients with penetrating or blunt spinal cord injuries
- 3) In patients with known or suspected unstable spine fractures (3 column instability) being evacuated out of theater, the vacuum spine board was used for transport.

c. Data Source.

- 1) Patient Record and the ASIA or Combat Neuro Exam worksheet
- 2) Joint Theater Trauma Registry (JTTR)

d. System Reporting & Frequency.

The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed biannually; additional PI monitoring and system reporting may be performed as needed.

The system review and data analysis will be performed by the Joint Theater Trauma System (JTTS) Director, JTTS Program Manager, and the Joint Trauma System (JTS) Performance Improvement Branch.

9. **Responsibilities.** It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.

10. References.

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4. Tator CH, Duncan EG, Edmonds VE, et al. Comparison of surgical and conservative management in 208 patients with acute spinal cord injury. *Can J Neurol Sci* 1987;14(1):60-69.
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14. Guidelines for the management of acute cervical spine and spinal cord injuries. © 2001 The Section on Disorders of the Spine and Peripheral Nerves of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons.

11. Appendices

[APPENDIX A](#), , ASIA Standard Neurological Classification of Spinal Cord Injury Worksheet. (American Spinal Injury Association (ASIA)). <http://www.asia-spinalinjury.org/>

[APPENDIX B](#), Combat Neuro Exam Worksheet

[APPENDIX C](#), Additional Information Regarding Off-Label Uses In CPGs

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Approved by CENTCOM JTTS Director,
JTS Director and CENTCOM SG

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and are not necessarily endorsed by the Services or DoD.

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APPENDIX A, ASIA WORKSHEET

Use to document neurologic injury

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Patient Name _____
 Examiner Name _____ Date/Time of Exam _____

ASIA AMERICAN SPINAL INJURY ASSOCIATION **STANDARD NEUROLOGICAL CLASSIFICATION OF SPINAL CORD INJURY** **ISCOS**

MOTOR
 KEY MUSCLES (scoring on rawenna side)

	R	L	
C5	<input type="checkbox"/>	<input type="checkbox"/>	Elbow flexors
C6	<input type="checkbox"/>	<input type="checkbox"/>	Wrist extensors
C7	<input type="checkbox"/>	<input type="checkbox"/>	Elbow extensors
C8	<input type="checkbox"/>	<input type="checkbox"/>	Finger flexors (distal phalanx of middle finger)
T1	<input type="checkbox"/>	<input type="checkbox"/>	Finger abductors (little finger)
UPPER LIMB TOTAL (MAXIMUM)	<input type="checkbox"/> + <input type="checkbox"/>	= <input type="checkbox"/>	(25) (25) (50)

Comments: _____

SENSORY
 KEY SENSORY POINTS

0 = absent
 1 = impaired
 2 = normal
 NT = not testable

	LIGHT TOUCH		PIN PRICK	
	R	L	R	L
C2				
C3				
C4				
C5				
C6				
C7				
C8				
T1				
T2				
T3				
T4				
T5				
T6				
T7				
T8				
T9				
T10				
T11				
T12				
L1				
L2				
L3				
L4				
L5				
S1				
S2				
S3				
S4-5				

Voluntary anal contraction (Yes/No)

Any anal sensation (Yes/No)

LOWER LIMB TOTAL (MAXIMUM) + = (25) (25) (50)

TOTALS { (56) + (56) = (112) }
 PIN PRICK SCORE (max: 112)
 LIGHT TOUCH SCORE (max: 112)

NEUROLOGICAL LEVEL
 The most caudal segment with normal function

SENSORY: R L
 MOTOR: R L

COMPLETE OR INCOMPLETE?
 Incomplete - Any sensory or motor function in S4-S5

ASIA IMPAIRMENT SCALE

ZONE OF PARTIAL PRESERVATION
 Caudal extent of partially innervated segments: R L

SENSORY: R L
 MOTOR: R L

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MUSCLE GRADING

- 0 total paralysis
 - 1 palpable or visible contraction
 - 2 active movement, full range of motion, gravity eliminated
 - 3 active movement, full range of motion, against gravity
 - 4 active movement, full range of motion, against gravity and provides some resistance
 - 5 active movement, full range of motion, against gravity and provides normal resistance
 - 5* muscle able to exert, in examiner's judgement, sufficient resistance to be considered normal if identifiable inhibiting factors were not present
- NT not testable. Patient unable to reliably exert effort or muscle unavailable for testing due to factors such as immobilization, pain on effort or contracture.

ASIA IMPAIRMENT SCALE

- A = Complete:** No motor or sensory function is preserved in the sacral segments S4-S5.
- B = Incomplete:** Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-S5.
- C = Incomplete:** Motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade less than 3.
- D = Incomplete:** Motor function is preserved below the neurological level, and at least half of key muscles below the neurological level have a muscle grade of 3 or more.
- E = Normal:** Motor and sensory function are normal.

CLINICAL SYNDROMES (OPTIONAL)

- Central Cord
- Brown-Sequard
- Anterior Cord
- Conus Medullaris
- Cauda Equina

STEPS IN CLASSIFICATION

The following order is recommended in determining the classification of individuals with SCI.

1. Determine sensory levels for right and left sides.
2. Determine motor levels for right and left sides.
Note: in regions where there is no myotome to test, the motor level is presumed to be the same as the sensory level.
3. Determine the single neurological level.
This is the lowest segment where motor and sensory function is normal on both sides, and is the most cephalad of the sensory and motor levels determined in steps 1 and 2.
4. Determine whether the injury is Complete or Incomplete (sacral sparing).
If voluntary anal contraction = No AND all S4-5 sensory scores = 0 AND any anal sensation = No, then injury is COMPLETE. Otherwise injury is incomplete.
5. Determine ASIA Impairment Scale (AIS) Grade:

Is injury Complete? If YES, AIS=A Record ZPP (For ZPP record lowest dermatome or myotome on each side with some (non-zero score) preservation)

NO ↓

Is injury motor incomplete? If NO, AIS=B (Yes=voluntary anal contraction OR motor function more than three levels below the motor level on a given side.)

YES ↓

Are at least half of the key muscles below the (single) neurological level graded 3 or better?

NO ↓

AIS=C

YES ↓

AIS=D

If sensation and motor function is normal in all segments, AIS=E
Note: AIS E is used in follow up testing when an individual with a documented SCI has recovered normal function. If at initial testing no deficits are found, the individual is neurologically intact; the ASIA Impairment Scale does not apply.

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APPENDIX B, COMBAT NEURO EXAM WORKSHEET

- ❖ Need Safety Pin or Needle
- ❖ Perform all elements for all patients with a fracture of the vertebral body (excludes stable isolated transverse or spinous process fractures) noted on CT scan.

DATE: _____ TIME: _____

Fractured Vertebrae: (circle all that apply)

C1 C2 C3 C4 C5 C6 C7

T1 T2 T3 T4 T5 T6 T7 T8 T9 T10 T11 T12

L1 L2 L3 L4 L5 Sacrum

MOI: [Vehicle vs. IED] [Dismounted IED] [Fall from Ht] [Aircraft Crash] [GSW] [OTHER]

Alertness at time of exam: [Intubated/Sedated] [Intubated/Alert/Compliant] [Extubated]

External Fixation: [RUE] [LUE] [RLE] [LLE] Splint: [RUE] [LUE] [RLE] [LLE]

Motor Strength:

Elbow Flexion (C5)

LEFT: []No Motion []Motion against gravity []Normal [][*] []NT

RIGHT: []No Motion []Motion against gravity []Normal [][*] []NT

Wrist Extension (C6)

LEFT: []No Motion []Motion against gravity []Normal [][*] []NT

RIGHT: []No Motion []Motion against gravity []Normal [][*] []NT

Elbow Extension (C7)

LEFT: []No Motion []Motion against gravity []Normal [][*] []NT

RIGHT: []No Motion []Motion against gravity []Normal [][*] []NT

MF DIP Flex (C8)

LEFT: []No Motion []Motion against gravity []Normal [][*] []NT

RIGHT: []No Motion []Motion against gravity []Normal [][*] []NT

SF Abduction (T1)

LEFT: []No Motion []Motion against gravity []Normal [][*] []NT

RIGHT: []No Motion []Motion against gravity []Normal [][*] []NT

Hip Flexion (L2)

LEFT: []No Motion []Motion against gravity []Normal [][*] []NT

RIGHT: []No Motion []Motion against gravity []Normal [][*] []NT

Knee Extension (L3)

LEFT: []No Motion []Motion against gravity []Normal [][*] []NT

RIGHT: []No Motion []Motion against gravity []Normal [][*] []NT

Ankle Dorsiflexion (L4)

LEFT: []No Motion []Motion against gravity []Normal [][*] []NT

RIGHT: []No Motion []Motion against gravity []Normal [][*] []NT

Great Toe Extension (L5)

LEFT: []No Motion []Motion against gravity []Normal [][*] []NT

RIGHT: []No Motion []Motion against gravity []Normal [][*] []NT

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Ankle Plantarflexion (S1)

LEFT: []No Motion []Motion against gravity []Normal [][*] []NT]

RIGHT: []No Motion []Motion against gravity []Normal [][*] []NT]

Rectal Exam:

Voluntary Anal Contraction []None []Weak []Normal

Tone []None []Weak []Normal

Pinprick Anal Sensation (S4/5) []Absent []Impaired []Normal

Anal Wink []Absent []Present

Sensation:

Start at Clavicle and progress inferiorly until light touch sensation is abnormal. Then, test pin prick at this level and prick with sharp and then with dull surface at each dermatome. Check the LOWEST level where the patient had reliable detection of sharp and dull sensation. Indicate if levels are different on Left or Right side.

[]Clavicle (C3/4)

[]Umbilicus (T10)

[]Lateral Elbow (C5)

[]Mid-Inguinal Crease (T12)

[]Dorsal Thumb (C6)

[]Medial Thigh (Prox 1/3) (L1)

[]Dorsal MF (C7)

[]Medial Thigh (Mid Point) (L2)

[]Dorsal SF (C8)

[]Medial Knee (L3)

[]Medial Elbow(T1)

[]Medial Ankle (L4)

[]Nipple Level (T4)

[]Dorsum Middle Toe (L5)

[]Xiphoid Level (T6)

Reflexes:

Bulbocavernosus []Absent []Present []Indeterminate []NT]

Patella LEFT: []Absent []Present RIGHT: []Absent []Present

Clonus LEFT: []Absent []Present RIGHT: []Absent []Present

Foley: []Present []Voiding spontaneously without catheter]

ASIA Score: (circle score)

[A] COMPLETE (no motor/sensory function below level of injury)

[B] Pinprick sensation PRESENT at anus (S4/5) – NO Motor

[C] <½ the muscles below level of injury have motion against gravity

[D] >½ the muscles below level of injury have motion against gravity

[E] Normal

NEURO LEVEL: _____ (Lowest level with normal sense and at least antigravity strength)

Incomplete Syndrome: (SCI – Occ-T11 Fx) (Conus – T12-L2 Fx) (CES – L3-Sacrum)

MF = middle finger; SF = small finger; * Suspect NORMAL strength, but limited due to pain; NT = Not Tested

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APPENDIX C, ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGs

1. 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.

2. 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.

3. 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.

4. Additional Procedures.

- a. 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.
- b. 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.
- c. 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.

Guideline Only/Not a Substitute for Clinical Judgment
Month 2012