# JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)



# **Cervical and Thoracolumbar Spine Injury Evaluation, Transport and Surgery in the Deployed Setting**

Guidance for providing the best care to patients who suffer a spine or spinal cord injury.

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### GOAL

The *Cervical and Thoracolumbar Spine Injury Evaluation, Transport, and Surgery CPG* delivers updated, accurate guidance to the deployed provider in order to afford the best care to patients who suffer a spinal column or spinal cord injury. This requires constant re-evaluation of the literature, both military and civilian, in addition to reviewing the lessons learned from past and present deployments. Review of these sources drives evidenced-based changes in treatment and triage algorithms, while providing updates on injury classification and current mechanisms of injury.

The authors provide key recommendations for each section.<sup>1</sup> It should be noted that while there may be strong evidence in the civilian literature for managing certain aspects of trauma, not all of these recommendations translate into a combat-trauma setting and so the account for the resource restricted environment of the deployed setting.

### BACKGROUND

Injury to the spinal column or spinal cord occurs in approximately 5.5% of evacuated battle casualties and are among the most disabling conditions wounded service members face.<sup>2,3</sup> Spine injuries in theater occur through a variety of battle-related and nonbattle related mechanisms.<sup>2,4,5</sup> In a review of the Joint Theater Trauma Registry (now the DoD Trauma Registry) from 2001-2009, Blair reported the characteristics of 598 American service members who sustained spine injuries during Operation Iraqi Freedom and Operation Enduring Freedom.<sup>2</sup> In this population, 502 (84%) patients experienced 1,834 battle-related spine injuries. The remaining 96 (16%) service members sustained 267 nonbattle-related injuries.<sup>2</sup> From a mechanistic perspective, most battle injuries occur from explosions (66.7%) or gunshot wounds (17%) while nonbattle injuries most frequently result from motor vehicle accidents (54%) or falls (30.2%).<sup>2</sup> Additionally, patients with battle related spine injuries have significantly higher Injury Severity Scores (ISS), present more frequently with noncontiguous spinal fractures and are more likely to require operative intervention.<sup>2,5</sup> Despite these differences, the rate and severity of underlying spinal cord injury appears similar between groups. Blair reported an 18.1% incidence of spinal cord injury in patients with battle-related injuries compared to a 13.5% incidence in the nonbattle-related group. Of patients with neurologic deficits, approximately 45% from each group presented with a complete deficit.<sup>2</sup> In a separate review of the same 598 records, Blair reported 66% of injuries occurred due to blunt trauma, while 28% resulted from penetrating injuries and 5% experienced a combined blunt and penetrating mechanism.<sup>4</sup> Patients sustaining penetrating injury were more likely to experience spinal cord injury than those with blunt force mechanisms (38% vs. 10% p<.0001).<sup>4</sup>

The timing and location of surgical intervention has also been a point of debate both in civilian and military settings.<sup>6-10</sup> The scarcity of data defining the optimal setting for surgical intervention when the injury occurs in a combat zone adds further challenges. The goal of decompressing and stabilizing the spine/spinal cord injury must be weighed by operational and logistical considerations in addition to the ability of the deployed spine surgeon.

In general, spine trauma patients may be placed into one of 3 clinical categories:

- 1. Patients with complete spinal cord injury.
- 2. Patients with an incomplete spinal cord injury
- 3. Patients with a spine fracture but normal neurological function.

In regards to the timing of surgery, an incomplete injury from a non-penetrating mechanism is often the most challenging in the decision-making process as these patients are the ones most likely to benefit from early surgical intervention in terms of neurological recovery.<sup>5,9</sup>

### CLINICAL & RADIOGRAPHIC EVALUATION

### **KEY RECOMMENDATIONS**

- 1. Document the patient's neurologic status via the American Spinal Injury Association (ASIA) Examination. Alternatively, the Combat Neuro Exam can be used. (Level III)
- 2. Computerized tomography (CT) is the recommended means to radiographically assess for bony spinal injuries. (Level I)
- 3. Plain films can be used to radiographically assess the bony spine if CT is not reasonably available, but caution should be used in removing cervical stabilization without CT imaging. (Level III)
- 4. CT Angiography (CTA) is recommended for any patient with a suspected craniocervical vascular injury. (Level II)
- 5. Given the limited availability of MRI at echelons lower than Role 4, CT myelography may assist in the evaluation and workup of patients with spinal cord injuries in theater if the required resources are available. (Level III)
- 6. Cervical collars should be placed on all patients with symptoms correlating to a cervical spine injury or in accordance with the Canadian C-spine Rule. (Level III)
- Clearance of a C-spine can be done via a clinical exam, radiographic studies, or a combination of the two depending on the neurological status of the patient. Document the clearance of the C-spine (Level II)

### NEUROLOGIC EXAM

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 be degraded by patient's mental status, effort and degree of cooperation, medication effect including sedatives, the presence of an airway adjunct or endotracheal tube, or the presence of other injuries. Failure to perform and document a neurological exam has been the most common source of discrepancy between serial neurological examination findings, especially between levels of care.

A thorough neurologic exam should include:

- Motor exam of the 10 ASIA key motor groups (<u>Appendix A</u>).
- Sensory examination (pin prick and light touch) using ASIA dermatomal standards.
- Digital rectal exam that assesses voluntary anal sphincter contraction strength, pinprick sensation, resting tone and bulbocavernosus reflex (BCR).

 Normal and pathological reflex testing such as biceps, triceps, brachioradialis, knee, and ankle jerk responses as well as presence/absence of Babinski reflex and Hoffman's signs, or evidence of spinal cord injury patterns, including Central Cord Syndrome, Brown-Sequard Syndrome, etc.

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 <u>Appendix A: ASIA Worksheet</u> and attach to the patient's chart.

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. (See <u>Appendix B: Combat Neuro Exam</u>.) This note addresses the minimal elements of a complete neurological exam for a patient with significant spinal column injury. Fill out and attach to the patient's chart.

## RADIOGRAPHIC ASSESSMENT

In the assessment of the patient with possible spinal injury, plain radiography has been superseded by axial CT with sagittal and coronal reconstruction where available.<sup>11</sup> If CT is not available and evacuation to a higher level of care will not occur in a timely fashion, then plain radiographs will suffice for clinical decision.

Often, polytrauma patients will undergo a protocoled study involving a CT angiography of the neck, with follow-through of the chest, abdomen and pelvis, which adequately assesses the entire spinal axis for osseous as well as craniocervical vascular compromise. For less severely injured patients not warranting such a study, clinical suspicion should guide the decision to obtain imaging. A low threshold to obtain a CTA should be maintained, particularly in those with a documented cervical spinal fracture, or positive screening criteria for blunt cerebrovascular injury (BCVI); see <u>Appendix C: Expanded Screening Criteria</u> for Blunt Cerebrovascular Injury).<sup>12</sup>

In instances of spinal injury with incomplete deficits of the spinal cord, conus medullaris or cauda equina, particularly when those deficits are progressive, consideration should be given to performance of CT myelography (See <u>Appendix D: Adaptation from Omnipaque<sup>TM</sup> (iohexol) package insert</u>). This would allow for the most rapid diagnosis and potential opportunity for decompression when faced with an incomplete or progressive deficit.

## WHEN TO USE A RIGID CERVICAL COLLAR

Patients who have sustained injuries through the following mechanisms should have a rigid cervical collar if available, or some other form of cervical stabilization placed in the prehospital environment if the tactical situation allows:

- Trauma resulting in loss of consciousness or even the question of loss of consciousness due to any form of head injury.
- Trauma resulting in temporary amnesia/loss of consciousness.
- Major explosive or blast injury.
- Mechanism that produces a violent impact on the head, neck, torso or pelvis.

- Mechanism that creates sudden acceleration/deceleration or lateral bending forces on the neck or torso.
- Fall from height (vs. fall from standing).
- Ejection or fall from any motorized vehicle.
- Vehicle rollover.

The Canadian C-Spine Rule was developed to reduce unnecessary imaging of the cervical spine in low risk patients.<sup>13</sup> The Rule was subsequently validated and applied to the prehospital setting.<sup>14</sup> The Rule comprises the following three main questions:

- 1. Is there any high-risk factor present that mandates radiography (i.e. age ≥65 years, dangerous mechanism, or paresthesias in extremities)?
- 2. Is there any low-risk factor present that allows safe assessment of range of motion (i.e., simple rear-end motor vehicle collision, sitting position in ED, ambulatory at any time since injury, delayed onset of neck pain, or absence of midline C-spine tenderness)?
- 3. Is the patient able to actively rotate neck 45° to the left and right?

When combined, the Canadian C-Spine Rule has a 100% sensitivity for ruling out clinically important cervical injuries.<sup>13</sup> While combat injury mechanisms generally fall within the definition of a "dangerous mechanism" as listed above, dismounted Improvised Explosive Device (IED) blast injuries without associated head trauma have been found to have a low incidence of cervical spine fractures.<sup>14</sup> Thus, it warrants consideration that injured patients without neurologic symptoms, who are ambulatory, and who have full painless range of motion of the cervical spine may not require prehospital cervical collar placement.<sup>14</sup>

Any patient complaining of neck pain or displaying neurological impairment following a trauma should have a cervical stabilization performed and maintained until the cervical spine has been "cleared" by a qualified provider.<sup>15,16</sup> Removal of the collar may be safely performed without further radiographic imaging if the answers to the Canadian C-Spine Rule are "No" to the first question and "Yes to questions 2 and 3.

In general, patients with penetrating cervical injury from an explosive mechanism should have a cervical collar placed if possible. However, patients with isolated penetrating cervical injury who are conscious and have no neurologic signs should not have a cervical collar placed in the prehospital environment. When a blunt mechanism is combined with a penetrating injury, the cervical collar is an important protection until an unstable spinal injury is ruled out. All providers must be aware that the collar may hide other injuries as well as and developing pathology such as expanding hematoma. Patients with isolated penetrating brain injury do not require a cervical stabilization unless the trajectory suggests cervical spine involvement.<sup>17</sup> On the battlefield, preservation of the life of the casualty and medic are of paramount importance. In these circumstances, evacuation to a more secure area takes precedence over spine immobilization.

If a patient has indications for cervical collar placement, and one had not been placed in the prehospital environment for whatever reason, the collar should be placed at the earliest opportunity. unless cervical clearance has been clearly documented in the record or directly communicated to the receiving treatment team, a rigid cervical collar should be placed at each transition in care from downrange and

maintained until it is officially cleared by the receiving providers. This highlights the need for clear and consistent communication along the echelons of care.

### CERVICAL SPINE CLEARANCE ALGORITHMS

Any patient with a suspected cervical spine injury and a neurologic deficit should have a cervical collar in place, and should be referred immediately for neurosurgical or orthopedic spine consultation and imaging. All other patients who have indications for prehospital cervical collar placement as detailed above with the Canadian C-Spine Rule should undergo cervical spine clearance by the appropriate algorithm. There are separate algorithms for reliable (<u>Appendix E</u>) and unreliable (<u>Appendix F</u>) patients. Unreliable patients are those who cannot adequately communicate, have a decreased level of consciousness (GCS<15), or have a significant distracting injury. However, controversy exists about the clinical importance of distracting injuries.

Significant distracting injury is technically defined as any injury, which is so painful that it may obscure the patient's ability to notice pain in their neck. The treating physician makes the final determination whether a certain injury is distracting enough to render a patient unreliable and require clearance via the unreliable patient algorithm. The rate of missed injury in the presence of a distracting injury is above 12%, but has not been shown to be significantly higher than in patients without distracting injuries.<sup>18,19</sup> However, if uncertain, err on the side of caution and consider the injury distracting and proceed accordingly. Clearing the C-spine in this scenario requires good communication with the next echelon of care (Appendix G: Cervical Spine Clearance Status) or defer to that level of care for clearance.

See <u>Appendix E</u> and <u>Appendix F</u> for protocol diagrams. If possible, the cervical spine should be cleared and the collar removed within 24 hours of collar placement. If the clinical scenario requires that the collar remain in place more than 24 hours, stiff extrication collars should be replaced with collars designed for long-term immobilization that provide greater padding and decubitus ulcer prevention.

## CERVICAL SPINE CLEARANCE IN THE OBTUNDED PATIENT

Cervical spine clearance in the obtunded patient is highly controversial and presents additional challenges to the clinician, especially in the combat environment.<sup>15,17,20</sup> Obtunded patients with a concerning mechanism of injury should undergo CT of the spine with fine cuts and multi-planar reconstructed images (3 mm axial, 3 mm coronal and 2 mm sagittal views). If CT is unavailable or unobtainable, full C-Spine plain radiographs (adequate AP, lateral and odontoid) should be performed.<sup>21</sup> Flexion/extension radiography should not be performed in a patient who cannot be simultaneously examined for the development of neurological signs or symptoms. Ultimately, clearance of the cervical spine in the obtunded patient should be left to clinical decision making of the highest level of care the patient is evacuated to who will be providing their longer term care.

For the obtunded patient with negative imaging, the incidence of significant cervical instability is low. It has generally been accepted that occult ligamentous injury is only cleared through a reliable clinical examination with a cooperative, extubated patient or magnetic resonance imaging (MRI). However, recent literature suggests that a high quality negative CT scan may be enough to remove the cervical collar.<sup>22</sup> This protocol has become the new standard to follow in several high-level acute civilian trauma centers and supports the guideline to forego an MRI as a requirement to clear an obtunded patient, per the *Eastern Association for the Surgery of Trauma Practice Management Guideline*.<sup>22</sup>

"[I]n obtunded adult blunt trauma patients, cervical collars should be removed after a negative highquality C-spine CT result alone. This recommendation is based on the finding that there is a worst-case 9% cumulative literature incidence of stable injuries and a 91% negative predictive value of no injury, after coupling a negative high-quality C-spine CT result with 1.5-T MRI, upright x-ray series, flexionextension CT, and/or clinical follow-up. Similarly, there is a best-case 0% cumulative literature incidence of unstable C-spine injuries after negative initial imaging result with a high-quality C-spine CT."

As such, with a high quality CT scan negative for fractures, this method of clearance may be utilized in patients who have arrived at their definitive level of care.

There is risk for significant neck movements in obtunded patients while transiting through the aeromedical evacuation system, so it is recommended that they remain with cervical spine immobilization until arrival at their definitive level of care. The incidence of occipital skin breakdown has decreased with the utilization of collars with greater padding (e.g., Miami-J with Occian back) and increased trauma system awareness of this potential complication.

The clinical decision to definitively clear the cervical spine without exclusion of ligamentous injury by either a reliable clinical examination or a MRI should be left to the level of care providing definitive treatment to the patient. Historically, given the challenges and multiple hand-offs inherent to echeloned care, a "2 out of 3" rule for cervical clearance in the obtunded patient has been Landstuhl Regional Medical Center/Role 4 policy since 2011. This rule requires negative results of 2 of 3 modalities (CT, MRI, clinical exam) prior to removing rigid cervical collars in obtunded patients. Given the low, but non-zero, incidence of significant cervical injury missed on standard 3-plane CT scan, it is recommended that when applying the 2 out of 3 rule, that the obtunded patient be transitioned from the traditional rigid collars to a memory foam enhanced rigid collar if available (i.e. Miami-J with Occian back) until either a reliable clinical examination or MRI can be obtained.<sup>22-25</sup> This method helps to decrease the risk of an occipital decubitus ulcer in those patients with a low likelihood of cervical spine injury who are still in transport and have not yet arrived at their level of definitive care.

Determination of when to image the whole spine (occiput to sacrum) versus selective imaging is based on the mechanism of injury, the physical/neurological exam, as well as the mental status of the patient. Patients who have one identifiable fracture in the spine should have their entire spine imaged. Certain mechanisms of injury, such as a mounted blast, should also warrant imaging of the whole spine.

# CERVICAL SPINE CLEARANCE DOCUMENTATION

It is recommended that the JTS Cervical Spine Clearance Status Sheet (<u>Appendix G</u>) or Trauma Resuscitation Record (DD Form 3019) be used for documenting the cervical spine evaluation and clearance status. This comprehensive worksheet includes indications for clearance, exam, imaging studies, and final clearance status. It is intended to bring together all cervical spine information onto one sheet of paper and was designed to improve both the completeness and ease of documentation.

## PATIENTS UNABLE TO TRANSFER FROM THEATER

The optimal management of host nationals and others unable to transfer is problematic in the austere environment. The availability to obtain CT or transfer the patient to a facility with CT can make spine evaluation and clearance challenging, with reliance on plain radiographs and physical examination. Sound clinical judgment, remote consultation with a spine surgeon (if available), as well as consultation with theater rules of eligibility are of benefit to decision making.

#### TRANSPORTING PATIENTS WITH SPINAL INJURIES

#### **KEY RECOMMENDATIONS**

- 1. Use a cervical spine immobilization for transport of patients with cervical spine injuries that have not been previously cleared. (Level II)
- 2. Consider the use of a vacuum spine board when available for the transport of unstable thoracolumbar fractures. (Level III)

**The recommendations below apply to fixed wing transport of patients**, with the following exception being applicable to all mechanisms of transport: The majority of patients with cervical spine injuries should be transported using semi-rigid orthotic such as an Aspen or Miami-J collar (if available).

Clinical scenarios may arise wherein halo immobilization may be suitable. Halo fixation is the most rigid and stable form of external cervical spine fixation.<sup>26</sup> Prior to approving the patient for transport, the team leader must ensure halo removal tools are secured to vest in case there is a need for emergent removal to obtain airway or perform CPR. Additionally, the sending team should educate the transport team how to properly remove the halo if needed. It is not recommended that patients be transported via air or ground in cervical traction as the risk of excessive traction weight transfer associated with vehicular movement, G-forces during takeoff and landing, as well as turbulence can result in further injury.

If the patient has a thoracolumbar fracture that is unstable, then he/she should be transported by the Critical Care Air Transport Team (CCATT) using either a vacuum spine board (VSB) or a standard NATO litter preferably with a memory foam pad to help mitigate pressure sores from Role 2 to Role 3 and beyond if available. Depending on the injury, either of these options can provide sufficient stability to patients with thoracolumbar fractures.<sup>27-29</sup> One small study suggested that pressure ulcer development might be decreased with use of VSB when compared to traditional long spine board.<sup>30</sup>

A thoracolumbosacral orthosis (TLSO) should not be worn during the transport process. This is unnecessary and increases the risk of pressure sores. Prior to transport, the spine surgeon and transportation team should agree upon suitability of VSB versus standard NATO litter. The VSB protocol requires that the VSB be deflated and re-inflated periodically to reduce the risk of pressure sores during the transport process. Logrolling 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 descent or turbulence is encountered. At a minimum, the VSB pressure should be checked every half hour, smoothed, and repressurized every hour, and every two hours the team should release straps and logroll patient (holding patient in appropriate alignment) and provide adequate time for relief of pressure points as part of their normal turning schedule. If the patient is on "spine precautions" due to an unstable cervical or thoracolumbar fracture, the bed should be placed in 30 degree of reverse Trendelenburg if possible. If not on "spine precautions," then the head of bed should be elevated 30 degrees. During transport, all patients should use the sequential compression devices, which are approved for flight.

### MEDICAL MANAGEMENT OF SPINAL CORD INJURIES

#### **KEY RECOMMENDATIONS**

- 1. Avoid hypoxemia (SaO2 <90%) and hypotension (SBP<90) for all spinal cord injuries. (Level III)
- 2. Maintain MAP >85 for all spinal cord injuries, with an emphasis on avoiding hypotension. (Level III)
- 3. Steroids are not indicated in the management of combat spinal cord injuries. (Level I)
- 4. Gabapentinoid medication should be considered early for the treatment of neuropathic pain in patients with spinal cord injuries. (Level II)
- 5. Early mechanical and chemoprophylactic measures against deep venous thrombosis (DVT) should be taken in patients with spine and spinal cord injuries. (Level II)

Patients who sustain neurologic compromise should have an invasive arterial line for continuous blood pressure monitoring with a goal MAP of 85-90 mmHg for up to seven days following the injury.<sup>15,31</sup> The evidence supporting this goal is mixed, at best, however it is the opinion of the authors that there is a net benefit to maintaining this goal. Regardless, hypotension (SBP < 90 mmHg) and hypoxemia (SaO2 <90%) must be avoided. Acute management of pulmonary dysfunction following traumatic spinal cord injury improves early survival as complications of pulmonary injury are the leading cause of mortality in traumatic spinal cord injury (SCI), specifically in the cervical spine.<sup>32</sup> Vasopressor therapy (in the euvolemic patient) and/or supplemental oxygen are recommended, when necessary, to achieve these goals.<sup>15</sup> Prior to the use of vasopressors, ensure that hypovolemia is addressed through adequate resuscitation and evaluation and control of any bleeding. Vasopressor use in the hypovolemic patient may contribute to additional ischemic loss in other injured tissues.

### GABAPENTINOID & NON-GABAPENTINOID MEDICATIONS

Non-gabapentinoid anticonvulsants (carbamazepine, phenytoin, clonazepam, phenobarbital, valproic acid) are not shown to improve or worsen long-term neurological outcomes from acute spinal cord injury.<sup>33</sup> Early administration of the anticonvulsant gabapentin and pregabalin has been shown to have some improvement of motor recovery, pain intensity, and frequency of autonomic dysreflexia.<sup>34-36</sup> Pregabalin and gabapentin are effective for neuropathic pain, depression, and sleep interference.<sup>36</sup> Early (within 24 hours) administration of enteral gabapentin should be considered for spinal cord injury patients in combat.

#### **OTHER INVESTIGATED THERAPIES**

The use of other pharmacologic agents such as riluzole, dantrolene, baclofen, naloxone, tamoxifen, and interventions such as hyperbaric oxygen and nitrous oxide do not have sufficient evidence to make a recommendation for use in combat-related spinal cord injury.

### HANDLING

While many spinal fractures require the head of bed to be flat prior to surgical correction or external bracing, the bed can usually be placed in 30 degrees reverse Trendelenberg. Logrolling and sacral off-loading can be safely performed in most cases every 2 hours to prevent skin breakdown and to perform

secondary and tertiary assessments. It is incumbent upon the managing provider to better guide positioning management based upon the specific clinical scenario.

### CORTICOSTEROIDS

Although the use of methylprednisolone sodium succinate (MSS) 24-hour infusion remains an option for the treatment of acute spinal cord injury within 8 hours of presentation, its utility in the setting of combat-related blunt or penetrating spinal cord injury is NOT recommended due to the lack of benefit and increased complications.<sup>15,37</sup> The primary reasons are on differences in the mechanism of injury (large caliber high velocity projectiles), geographically different and/or austere environments, and concomitant traumatic injuries sustained in combat. The associated open or contaminated wounds of battle casualties with spine or spinal cord injuries are further complicated with steroid administration. Methylprednisolone administration is NOT recommended for any spinal cord injuries sustained in combat.

### **DVT PROPHYLAXIS REGIMEN**

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) or FIXED, low-dose unfractionated heparin (UFH) should be initiated as soon as possible but definitely within 72 hours of injury or repair to reduce the risk of thromboembolic events in the acute period after SCI. Given the potential for increased bleeding events with ADJUSTED-dose UFH, this is not recommended for prophylaxis.<sup>38</sup> 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 who show clinical signs or symptoms of a DVT should undergo further imaging to confirm the diagnosis. If a DVT is present, treatment should be initiated with therapeutic anticoagulation if approved by the spine surgeon. If full anticoagulation is contraindicated, an IVC filter placement should be considered.

### **OPERATIVE & NONOPERATIVE TREATMENTS**

#### **KEY RECOMMENDATIONS**

In cases of incomplete spinal cord injury, spinal decompression should be undertaken as soon as it is safe and feasible to do so, including at Role 3 installations if appropriate support and resources are available in theater. (Level III)

Taking into account evacuation time, planned staged operations at Role 3 and 4 facilities are an acceptable option in instances where patients present with incomplete injury or worsening neurologic deficit. (Level III)

### NON-OPERATIVE TREATMENT

In order to proactively guide treatment and logistical decisions, it is imperative that the deployed surgeon be intimately familiar with the operative and non-operative options in their theatre of operation. The actual materials on hand for non-operative management in the deployed setting may be variable, but generally include C-collars, other orthotic braces, and occasionally, halo devices.

For cervical fracture-dislocations, especially those associated with incomplete injury, closed reduction downrange is recommended. In patients with cervical dislocation and spinal cord injury, CT myelogram may represent an alternative advanced imaging modality prior to proceeding with closed reduction. In the civilian literature, MRI data obtained prior to reduction have not been shown to affect the outcome of the closed reduction, provided the patient is awake, neurologically intact and able to provide a reliable examination.<sup>39</sup> Thus closed reduction of cervical fracture-dislocations, even in the absence of an MRI, may represent another area of possible intervention while in-theater.

### **OPERATIVE TREATMENT**

The decision for operative treatment of U.S. and coalition spine fractures in theater is ultimately left to the deployed surgical team, including the spine surgeon (if available) and the Chief of Trauma. Good clinical judgment is a priority in the care of patients with spine and spinal cord injuries in a deployed setting. Surgery that can be delayed safely until the patient arrives to the Role 4 military treatment facility should be delayed. However, there may be some conditions which may benefit from immediate surgery in-theater, including but not limited to:

- incomplete spinal cord injuries
- open cerebrospinal fluid (CSF) leaks
- expected prolonged delay in transport, or
- where an urgent reduction may improve the degree of "root sparing" in a cervical spinal cord injury.

### **INCOMPLETE INJURIES**

The management of incomplete spinal cord injuries in theater remains controversial due to the potential for higher rates of neurologic improvement with early operative intervention weighed against obvious challenges posed by an austere environment. Initial spinal cord injury or subsequent progression can occur via fracture displacement, bone fragment compression, expanding hematoma, spinal cord edema or infarction. In civilian literature, animal studies have demonstrated that immediate decompression of neural elements is associated with a reduction in neurological sequela.<sup>40-44</sup> Several large investigations have demonstrated significant improvement in neurologic outcomes with early surgical intervention in incomplete spinal cord injuries.<sup>6,10,45,46</sup> This information has led many major U.S. trauma centers to adopt a goal of early surgical decompression in cases of incomplete spinal cord injury. There are some data to suggest that it is not the timing of surgery alone that is the key factor, but the extent of decompression.<sup>47</sup> However, these data must be carefully applied to the deployed setting as forward medicine presents unique challenges not experienced in high volume modern trauma centers. In one investigation examining the outcomes of 50 cases of spinal cord injury treated surgically in theater versus those undergoing delayed care at Landstuhl Regional Medical Center, Schoenfeld demonstrated no differences in neurologic recovery between groups.<sup>9</sup> Patients who were treated with surgery in theater had significantly higher rates of postoperative complications (40% vs. 20%) and had higher rates of additional surgical procedures. Though limited by its relatively low case numbers and retrospective nature, this study may challenge the extrapolation of civilian literature to a deployed setting. Given this conflict in civilian and military literature, deployed spine surgeons should carefully weigh the potential for neurologic recovery with available forward resources in cases of incomplete spinal cord injury. Instances of incomplete neurologic deficit with easily addressed compressive pathology, neurologic progression, delayed evacuation or injuries in coalition partners not eligible for evacuation represent times when operative intervention in theater may provide clear benefit to the patient. In these cases,

implants used in theater should be compatible with systems at higher levels of care in case revision surgery is required.

### SPINAL INSTRUMENTATION

The decision to perform spinal stabilization in a deployed setting depends, in part, on the presence and sterility of appropriate implants, comfort level of the operative team and availability of sufficient diagnostic imaging modalities. Advocates for early instrumentation argue that stabilizing these injuries minimizes the need for spinal immobilization, improves pulmonary toilet, lowers the risk of venous thromboembolism and may improve analgesia. Yet, these advantages may not fully translate to the deployed population as over half have concomitant extremity or pelvis fracture and/or significant hemodynamic distress.<sup>48</sup> Deployed surgeons may also consider non-instrumented decompressive procedures in cases with incomplete or progressive neurologic deficit and ongoing canal compromise. These simpler cases often place less strain on the deployed operative team and medical logistical system while requiring less operative time and exposure. This decision for early decompressive surgery with delayed stabilization requires careful direct coordination between spine surgeons at Role 3 and 4 facilities. In Schoenfeld's retrospective review of patients who sustained operative spinal injuries in theater this approach resulted in neurologic improvement in 2 of 3 cases.<sup>9</sup>

### PENETRATING SPINE INJURIES

### **KEY RECOMMENDATIONS**

- 1. Consider early surgery in penetrating spinal cord injury for progressive or incomplete neurological deficits in the setting of continued mass effect upon the spinal cord if surgeon and treatment facility capabilities allow.
- 2. Patients with concomitant hollow-viscus injuries and penetrating spinal cord injuries should be treated with broad-spectrum anti-microbial coverage for 48 hours to 10 days, depending upon the level of contamination of the injury and control of associated any cerebrospinal fluid leak.

### SURGICAL INTERVENTION

Spinal cord injuries from penetrating mechanisms are more likely to produce complete neurologic deficit than those sustained through blunt force.<sup>4,49</sup> With penetrating mechanisms, spinal cord injury can occur through direct damage in the projectile tract or via cavitation injury, whereby shock waves imparted on the tissue surrounding the path of the projectile and rapid changes in pressure damage tissue.<sup>50</sup> The two latter forces can produce severe irrecoverable spinal cord injuries, even in cases where the projectile does not penetrate the spinal canal. In these injuries staged debridement of the wound may be required given the cavitary injury to soft tissue. Surgical indications may include progressive neurological deterioration, 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 with an attempt at "water tight" repair. Anterior and oblique entry to the lumbar and lower thoracic spine are at increased risk of infectious complications due to traversal of hollow viscus organs.<sup>51</sup> In these cases the patient's infectious risk and neurological status are key factors in determining the need for and timing of surgical intervention. There is no evidence from the current conflict to support the concept that a complete SCI from a penetrating mechanism has a significant chance of clinical improvement with surgical intervention.

### TREATMENT

In 2010, Klimo et al., led a tri-service literature review of articles on penetrating spinal injury sustained in combat and provided treatment recommendations.<sup>52</sup> Based on this review of both military and civilian literature, they concluded that the role of decompression in promoting neurologic recovery remains ambiguous.<sup>52</sup> For an incomplete injury with continued canal compromise, decompression, if attempted, should ideally occur within 24-48 hours. Additionally, persistent and high-flow CSF-cutaneous and pleural fistulae should be surgically treated. The authors recommended consideration of spinal stabilization at the time of initial surgery in cases with associated instability.<sup>52</sup> Because the unique natural histories of these may render typical blunt injury classification systems less applicable, the treatment of these injuries relies largely on clinical decision making of the operative physician.<sup>5,53</sup> In these situations, surgeons should consider: available resources, expertise of the operative team, infectious risks and the patient's neurological status when determining the need for and timing of operative intervention in theater.

CT scans remain the study of choice for penetrating spinal injuries as MRI is typically not as helpful or available in the deployed setting. Additionally, they can be contraindicated given the ferromagnetic activity of the fragment and bullet material.<sup>54</sup> CT myelogram can be considered in patients with occult or persistent CSF leaks that are not easily localized based on exam or plain CT.

Appropriate antibiotic coverage and duration may often prove controversial. In 2011 the Infectious Disease Society and Surgical Infection Society released a joint guideline for the prevention of infection associated with combat-related injuries.<sup>55</sup> This combined statement recommended Cefazolin 2 gm IV q8hrs for 24-72hrs for penetrating spine injuries without evidence of contamination. Fragments passing through contaminated viscus structures such as the esophagus or colon require extended spectrum intravenous anti-microbial coverage of enteric organisms for longer periods of time. Potential antibiotic regimens include Ancef 2g IV q6-8hrs and Metronidzole 500mg IV q8-12hrs; Cetriaxone 2 g IV q24hrs and Metronidazole 500 mg IV q 8-12hrs. Patients with penicillin or cephalosporin allergies may be treated with Vancomycin 1g IV q12hrs + Ciprofloxacin 400 mg IV q8-12hrs. This working group recommended a minimum antibiotic duration of 5 days or until any CSF leak is closed. Steroids should not be considered as therapy for patients with penetrating spinal cord injuries.<sup>56</sup>

### PERFORMANCE IMPROVEMENT (PI) MONITORING

### **POPULATION OF INTEREST**

All patients at risk of or diagnosed with cervical or thoracic spine injury defined as:

- mechanism of injury explosion, fall, or motor vehicle crash;
- head or neck injury with AIS head or neck > 1;
- diagnosis of fracture of vertebral column with spinal cord injury (806), or spinal cord injury without evidence of spinal bone injury (952); and
- less than 1 day between time of injury and arrival at initial medical treatment facility (MTF).

### INTENT (EXPECTED OUTCOMES)

- 1. Patients in population of interest have documented application of cervical collar or any other method for cervical spine stabilization in the prehospital setting or on MTF arrival.
- 2. Patients with diagnosis of fracture of vertebral column with spinal cord injury (806), or spinal cord injury without evidence of spinal bone injury (952) have a documented neurologic exam to include GCS and completed *ASIA or Combat Neuro Exam worksheet*.
- 3. Patients in population of interest have the C-spine clearance status documented on the JTS C-spine Clearance Status sheet and Resuscitation Record (DD Form 3019).
- 4. Patients with spinal cord injury and abnormal neurologic exam have an arterial line placed within 24 hours of injury or documentation that not indicated.
- 5. Patient in population of interest who have an unreliable exam due to decreased level of consciousness (GCS < 14) do not have C-spine cleared prior to arrival at definitive level of care.

### **PERFORMANCE/ADHERENCE METRICS**

- 1. Number and percentage of patients in population of interest with documented application of cervical collar or any other method for cervical spine stabilization in the prehospital setting or on MTF arrival.
- 2. Number and percentage of patients with diagnosis of fracture of vertebral column with spinal cord injury (806), or spinal cord injury without evidence of spinal bone injury (952) with documented neurologic exam to include GCS completed *ASIA or Combat Neuro Exam worksheet*.
- 3. Number and percentage of patients in population of interest with C-spine clearance status documented on the *C-spine Clearance Status sheet* and *Resuscitation Record (DD Form 3019).*
- 4. Number and percentage of patients with spinal cord injury and abnormal neurologic exam who have an arterial line placed within 24 hours of injury or documentation that not indicated.
- 5. Number and percentage of patients in population of interest with Role 2 and/or Role 3 discharge GCS < 14 who have a C-collar in place on arrival to Role 3 for host nation patients or Role 4 for coalition patients.

### DATA SOURCE

- Patient Record and the ASIA or Combat Neuro Exam worksheet
- Department of Defense Trauma Registry (DoDTR)

### SYSTEM REPORTING & FREQUENCY

The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed annually; additional PI monitoring and system reporting may be performed as needed. The system review and data analysis will be performed by the JTS Chief and the PI Branch.

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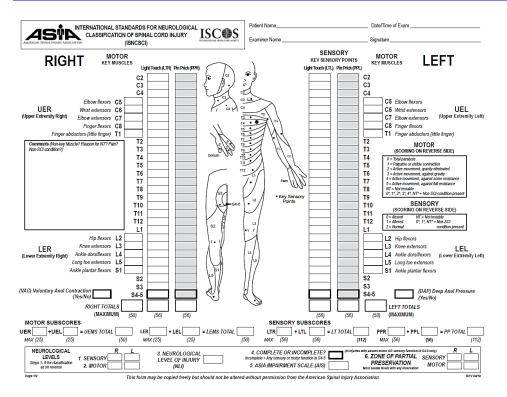
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### APPENDIX A: AMERICAN SPINAL INJURY ASSOCIATION (ASIA) WORKSHEET

#### Download form here:

https://jts.health.mil/assets/docs/forms/ASIA International Stds Diagram Worksheet.pdf



#### Muscle Function Grading

#### 0 = Total paralysis

- 1 = Palpable or visible contraction
- 2 = Active movement, full range of motion (ROM) with gravity eliminated 3 = Active movement, full ROM against gravity
- 4 = Active movement, full ROM against gravity and moderate resistance in a muscle specific position
- $\pmb{5}$  = (Normal) active movement, full ROM against gravity and full resistance in a functional muscle position expected from an otherwise unimpaired person
- $\pmb{NT}$  = Not testable (i.e. due to immobilization, severe pain such that the patient cannot be graded, amputation of limb, or contracture of > 50% of the normal ROM) 0\*, 1\*, 2\*, 3\*, 4\*, NT\* = Non-SCI condition present \*

#### Sensory Grading

- 0 = Absent 1 = Altered, either decreased/impaired sensation or hypersensitivity 2 = Normal NT = Not testable
- 0\*, 1\*, NT\* = Non-SCI condition present \*
- Note: Abnormal motor and sensory scores should be tagged with a "" to indicate an impairment due to a non-SCI condition. The non-SCI condition should be explained in the comments box together with information about how the score is rated for classification purposes (at least normal / not normal for classification).

#### When to Test Non-Key Muscles:

In a patient with an apparent AIS B classification, non-key muscle functions more than 3 levels below the motor level on each side should be tested to most accurately classify the injury (differentiate between AIS B and C).

Movement	Root level
Shoulder: Flexion, extension, adbuction, adduction, internal and external rotation Elbow: Supination	C5
Elbow: Pronation Wrist: Flexion	C6
Finger: Flexion at proximal joint, extension Thumb: Flexion, extension and abduction in plane of thum	ь С7
Finger: Flexion at MCP joint Thumb: Opposition, adduction and abduction perpendicular to palm	C8
Finger: Abduction of the index finger	T1
Hip: Adduction	L2
Hip: External rotation	L3
Hip: Extension, abduction, internal rotation Knee: Flexion Ankle: Inversion and eversion Toe: MP and IP extension	L4
Hallux and Toe: DIP and PIP flexion and abduction	L5
Hallux: Adduction	S1

#### ASIA Impairment Scale (AIS)

### A = Complete. No sensory or motor function is preserved in the sacral segments S4-5

B = Sensory Incomplete. Sensory but not motor function is preserved below the neurological level and includes the saral segments 54-5 (light touch or pin prick at 54-5 or deep anal pressure) AND no motor function is preserved more than three levels below the motor level on either side of the body.

C = Motor Incomplete. Motor function is preserved at the C = Motor Incomplex. Motor function is preserved at the most caudal scenaria segments for volunary and contraction (VAC) OR the patient meets the criteria for sensory incomplex status (sensory function preserved at the most caudal sacral segments \$4.5 by LT, PP or DAP), and has some sparing of motor function more than three levels below the ipsilateral motor level on either side of the body. This includes key or non-key muscle functions to determine motor incomplete status.) For AIS C – less than half of key muscle functions below the single NLI have a muscle grade  $\geq 3$ .

D = Motor Incomplete, Motor incomplete status as defined above, with at least half (half or more) of key muscle functions below the single NLI having a muscle grade ≥ 3.

E = Normal. If sensation and motor function as tested with the ISNCSCI are graded as normal in all segments, and the patient had prior deficits, then the AIS grade is E. Someone without an initial SCI does not receive an AIS grade.

Using ND: To document the sensory, motor and NLI levels, the ASIA Impairment Scale grade, and/or the zone of partial preservation (ZPP) when they are unable to be determined based on the examination results.



CLASSIFICATION OF SPINAL CORD INJURY



Page 2

#### Steps in Classification

The following order is re individuals with SCI. 1. Determine sensory levels for right and left sides The sensory level is the most caudal, intact dermatome for both pin prick and light touch sensation.

2. Determine motor levels for right and left sides above that level is also normal

3. Determine the neurological level of injury (NLI). unemme the neutrological level of injury (NLI). This refers to the most caudal segment of the cord with intact sensation and anigravity (3 or more) muscle function stength, provided that there is normal (intact) sensory and motor function restraily respectively. The NLI is the most caphalad of the sensory and motor levels determined in steps 1 and 2.

4. Determine whether the injury is Complete or Incomplete. (i.e. absence or presence of sacral sparing) If voluntary anal contraction = No AND all 34-5 sensory scores = 0 AND deep anal pressure = No, then injury is Complete. Otherwise, injury is Incomplete.

5. Determine ASIA Impairment Scale (AIS) Grade Is injury <u>Complete</u>? If YES, AIS=A

#### NO 🗜

Is injury Motor Complete? If YES, AIS=B NO (No=voluntary anal contraction OR motor function more than three levels below the <u>motor</u> <u>level</u> on a given side, if the patient has sensory incomplete classification)

### Are <u>at least</u> half (half or more) of the key musel <u>neurological level of injury</u> graded 3 or better? NO VESV cles below the

If sensation and motor function is normal in all segments, AIS=E Note: AIS E is used in follow-up lesting when an individual with a documented SCI has recovered normal function. If all initial lesting on defacts are found, the individual is neurologically intact and the ASIA Impairment Scale does not appl

8. Determine the zone of partial preservation (ZPP). The ZPP is used only in liquies with absent motir (no VAC) CR servery function (no DAP, no L1 and no PP searching) in the lowest acroal segment S4-5, and refers to those dematomes and myctomes caudat to the senso and motiv levels that remain partially inventeau. With scaral segment sensory linution, the sensory ZPP is not applicable and therether TWA' is sensory linution. recorded in the block of the worksheet. Accordingly, if VAC is present, the motor ZPP is not applicable and is noted as "NA".

#### APPENDIX B: COMBAT NEURO EXAM WORKSHEET

Need Safety Pin or Needle

DATE:\_\_\_\_\_ TIME:\_\_\_\_

 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.

#### 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	
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)	
Great Toe Extension (L5) LEFT: []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	
Great Toe Extension (L5) LEFT: []No Motion []Motion against gravity []Normal [][*] []NT RIGHT: []No Motion []Motion against gravity []Normal [][*] []NT Ankle Plantarflexion (S1)	
Great Toe Extension (L5) LEFT: []No Motion []Motion against gravity []Normal [][*] []NT RIGHT: []No Motion []Motion against gravity []Normal [][*] []NT Ankle Plantarflexion (S1) LEFT: []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 Ankle Plantarflexion (S1)	

### **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:**

Bulbocavern	osis []Abs	ent []Presen	t []Indete	erminate	[ ]NT
Patella	LEFT: [ ]Abs	ent []Present	RIGHT:	[]Absent	[]Present
Clonus	LEFT: [ ]Abs	ent []Present	RIGHT:	[]Absent	[]Present
Foley: [ ]Pre	esent []Void	ing spontaneou	Isly without cat	heter.	

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] <1/2 the muscles below level of injury have motion against gravity
- [D] >1/2 the muscles below level of injury have motion against gravity
- [E] Normal

NEURO LEVEL: \_\_\_\_\_\_ (Lowest level with normal sense and at least antigravity strength)1

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

### APPENDIX C: SCREENING FOR BLUNT CEREBROVASCULAR INJURY

# Expanded Screening Criteria for Blunt Cerebrovascular Injury (BCVI)<sup>12</sup>

### Signs and Symptoms of BCVI

- > Arterial hemorrhage from neck, nose, or mouth.
- Cervical bruit in patient <50 years of age.</p>
- Cervical hematoma.
- > Focal neurologic deficit inconsistent with head CT.
- Ischemic change on head CT.

#### **Risk Factors for BCVI**

- ➢ High-energy mechanism.
- > LeFort II or III facial fracture, or mandible fracture.
- Skull or skull-base fracture.
- Severe TBI, as defined by GCS < 6.
- Cervical fracture, subluxation, or ligamentous injury.
- "Clothesline," "seat-belt," or "hanging"-type mechanism of injury.
- > TBI with associated thoracic injuries.
- Thoracic vascular injuries or upper rib fractures.
- Scalp de-gloving injury.
- Blunt cardiac injuries.

### APPENDIX D: SUMMARY OF PERFORMANCE OF MYELOGRAPHY

(Adapted from Omnipaquetm package insert)

### **BACKGROUND:**

Iohexol is a non-ionic, water-soluble contrast agent with 46.36% iodine content. It is excreted renally.

Available concentrations include: 140, 180, 240, 300 and 350 milligrams of iodine per milliliter.

Omnipaque 180, 240 and 300 are indicated for intrathecal use in adults. DO NOT ADMINISTER OMNIPAQUE 140 OR 350 INTRATHECALLY.

**Contraindications:** known hypersensitivity to iohexol; active local/systemic infection; co-administration of intra-thecal corticosteroids; overdose; significant intra-cranial entry; use in patient with epilepsy; grossly bloody CSF; co-administration with: phenothiazines, MAOI, TCA, CNS stimulants, antipsychotics.

**Adverse occurrences**: headache, meningismus, nausea, seizure, anaphylaxis. With inadvertent administration of Omnipaque not indicated for intrathecal use: death, seizure, cerebral hemorrhage, arachnoiditis, renal failure, rhabdomyolysis, hyperthermia, cerebral edema.

### **TECHNIQUE:**

A total of 3,060 milligrams of iodine should not be exceeded in one study in an adult patient.

For total columnar myelography, instill 6-12.5 mL of Omnipaque 240, or 6-10 mL of Omnipaque 300, via standard lumbar puncture over 1-2 minutes. To allow time for complete opacification of the subarachnoid space, obtain CT roughly 15-30 minutes, but not more than 1 hour, after contrast injection.

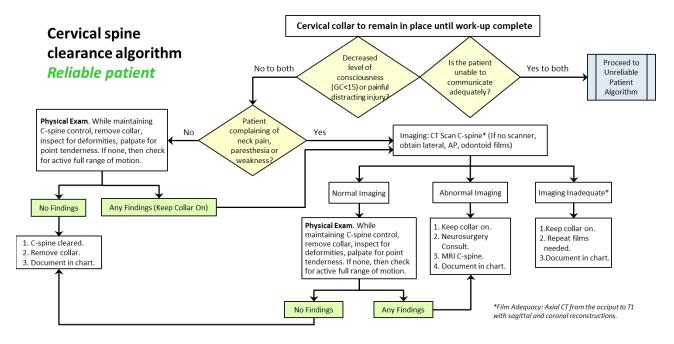
The patient should remain hydrated and observed for at least 12 hours post myelogram. Avoid excessive entry of contrast intracranially and maintain elevated head-of-bed once the study is complete.

Full details can be viewed in the OmnipaqueTM (iohexol) package insert, freely available at:

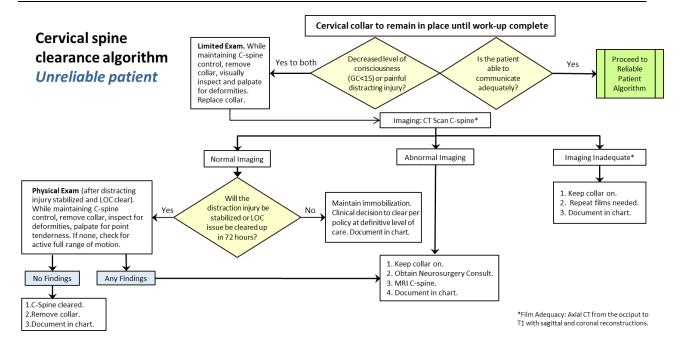
https://www.accessdata.fda.gov/drugsatfda\_docs/label/2017/018956s099lbl.pdf

#### APPENDIX E: CERVICAL SPINE CLEARANCE ALGORITHM RELIABLE PATIENT

### Patient is without neurologic deficit.



#### APPENDIX F: CERVICAL SPINE CLEARANCE ALGORITHM UNRELIABLE PATIENT



## APPENDIX G: CERVICAL SPINE CLEARANCE STATUS

### Download form here:

https://jts.health.mil/assets/docs/forms/Cervical\_Spine\_Clearance\_Status\_Notes.pdf

Cervical Spine Clearance Status Notes Joint Trauma System		
Mechanism: Explosive M/C Fall Other		
Notes:		
Collar placed:  Prehospital Hospital No collar		
Patient reliable? 🗌 Yes 🗌 No Reason unreliable? 🗌 Altered Mental Status (GCS<15) 📄 Significant Distracting Injury		
Notes:		
Patient complaints None Neck pain (specify location:)		
Notes:		
Physical Findings		
Inspection: Normal Deformity		
Palpation: Normal Point tendemess Deformity		
Notes:		
Active range of motion: Full Limited specify:		
Notes:		
Imaging Studies (CT is standard. Films acceptable only when CT is unavailable.)		
CT scan: Normal Abnormal specify:		
Notes:		
Lateral: 🗌 Normal 🗌 Abnormal specify:		
AP: Normal Abnormal specify:		
Odontoid: 🗌 Normal 📄 Abnormal specify:		
Cervical spine is: Cervical spine is: CILEAR of significant injury and instability on the basis of the following: Normal exam in completely reliable patient with no need for imaging Normal exam in completely reliable patient with no need for imaging Normal exam in completely reliable patient with no need for imaging		
Normal imaging of full C-Spine and normal exam.  Normal imaging Unreliable patient at time of evacuation/final disposition		
Physician name Physician signature Date		
MTF Medical Record (Rev. May 2018)		

### APPENDIX H: 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.