

# JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)



## Radiology: Imaging Trauma Patients in a Deployed Setting (CPG ID: 01)

Provides general imaging guidelines for Radiologist and Emergency Providers when performing trauma patient assessment in a deployed setting.

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## BACKGROUND

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Medical imaging plays a critical role in the rapid diagnosis, effective triage, and management of complex poly-trauma patients. High quality medical imaging can be accomplished successfully in a deployed or wartime setting. Due to advances in aggressive resuscitation techniques and the speed of the latest generation Computed Tomography (CT) scanners (64-detector and beyond), rapid trauma scans utilizing CT and Ultrasound (US) imaging can routinely be performed prior to taking the patient to the operating room potentially providing the trauma team with lifesaving information. This Clinical Practice Guideline (CPG) provides an overview of the imaging modalities available in austere settings, the equipment required, and the role that each plays in triaging and diagnosis of the acutely injured poly-trauma patients.

Given the catastrophic injuries sustained by high-energy mechanisms, including high velocity ballistic trauma and blast injuries often seen during the current conflict, rapid diagnosis and treatment is required to optimally treat these critically injured patients. Advances in aggressive resuscitation techniques and the speed of the latest generation Computed Tomography (CT) scanners (64-detector and beyond), rapid trauma scans utilizing CT and Ultrasound (US) imaging routinely allows for imaging to be performed prior to taking the patient to the operating room potentially providing the trauma team with lifesaving information.

Imaging has become a critical component of the care of any patient in the age of modern medicine. The goal of this CPG is to provide guidelines and recommendations for the optimum integration of high quality diagnostic imaging into the treatment and management of casualties with multiple mechanisms of traumatic injuries and how to facilitate the transfer of this information with the patient across the continuum of care.

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## IMAGING EVALUATION

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### RADIOGRAPHS

The initial radiographic evaluation of a trauma patient begins with supine Anterior-Posterior (AP) chest and pelvis radiographs taken in the trauma bay usually with a portable x-ray machine. The initial focus being major cardiopulmonary injury and fracture dislocations of the pelvis, the latter can be an indicator of life-threatening internal hemorrhage and/or need for pelvic stabilization.

#### Fragments

Radiographs can easily demonstrate metallic fragments common in military specific trauma that can be helpful in determining potential sites of injury and injury tracts.

#### Cervical Spine

Cervical spine radiographic evaluation has been largely replaced by CT and should only be performed when a CT is unavailable. Refer to the JTS CPG, [Cervical and Thoracolumbar Spine Injury Evaluation, Transport, and Surgery in the Deployed Setting](#), for further guidance.<sup>1,2</sup>

## Extremity Injuries

If extremity injury is suspected, radiographs can be obtained; however, these can be time-consuming and should not delay more diagnostic imaging with CT, if available (Role 3 and above). Additionally with CT, extremity osseous and soft tissue injuries can be easily identified with the added benefit of a lower extremity angiogram as well. See [Trauma CT Scan](#) section below.<sup>3</sup>

## Retrograde Urethrogram

When there is a clinical suspicion of possible urethral injury, which can occur with significant pelvic fractures or penetrating perineal injury, a retrograde urethrogram may be helpful to further characterize the injury. One field expedient method uses the portable x-ray machine with a single oblique AP scout image of the pelvis. 10cc of contrast is injected into the tip of the urethra through a Foley catheter. While injecting additional contrast through the catheter an image of the pelvis/urethra is obtained in the same slight AP oblique position. This image is typically obtained at the end of an injection of 17-20 cc of IV contrast but prior to the completion of the injection to insure full luminal distention with contrast.

## Equipment

A variety of portable x-ray units are utilized in theater at Role 2 and Role 3 facilities. Many of the portable units, especially at the Role 2, have limited ability to penetrate (limited range of kVp and mAs) soft tissues. Obtaining lateral views generally requires penetrating a greater thickness of soft tissue, particularly in large patients, and often produces very limited quality images. AP projection images should be adequate on most portable units, but will rely upon the x-ray technician to optimize technique to maximize image quality.

## Radiation Safety

Members of the trauma team should have lead aprons and thyroid shields available near the trauma bay. In ideal situations, trauma team members will don the lead shielding beneath other personal protective equipment prior to patient arrival. Distance is also protective from radiation exposure. If feasible based on the patient's condition, any personnel without lead shielding should move a short distance (recommended minimal distance 6 feet) away from the x-ray unit. Cross table lateral images produce a much higher level of radiation exposure to personnel in the trauma bay and nearby areas and should only be obtained when absolutely necessary.

Radiation certainly remains a concern during the performance of all imaging particularly with CT. The radiologist should carefully monitor mAs and kVp settings such that dose is minimized while achieving sufficient diagnostic image quality.

## FOCUSED ABDOMINAL SONOGRAPHIC ASSESSMENT FOR TRAUMA (FAST) EXAMINATION

While the FAST scan has been validated only in hemodynamically unstable blunt trauma patients, it has become a standard tool in the trauma bay and Emergency Department (ED) in most trauma patients.<sup>4</sup> It is now considered an adjunct to the primary survey in Advanced Trauma Life Support (ATLS) guidelines, ninth edition.<sup>5</sup> It has also come into use for hemodynamically stable patients and penetrating trauma in the deployed setting where CT scans are not readily available. If positive, these scans provide quick information that can aid trauma surgeons in triaging patients, either to the Operating Room (OR) or to further imaging. FAST in combat trauma

has a sensitivity of only 56% and specificity of 98%.<sup>6</sup> Routine use of the FAST in trauma patients allows for a consistent evaluation strategy while maintaining the skills of providers. A negative FAST cannot be relied upon to rule out injury, especially in penetrating trauma.

### **Diagnostic Peritoneal Lavage (DPL)**

In the absence of a CT scanner, DPL should be considered in determining need for laparotomy in trauma patients. It has largely been supplanted by the FAST exam (and is considered an optional skill in the current edition of ATLS). DPL remains the most sensitive test for hollow viscus injury and mesenteric injury, and retains its usefulness in the unstable patient with a negative or equivocal FAST exam. DPL is 100% accurate for intrabdominal injury in these patients.<sup>7</sup> One must consider the additional time that this diagnostic test may require, and should not delay immediate surgical intervention in patients that have mechanisms concerning for intra-abdominal trauma and remain unstable despite resuscitative measures.<sup>8</sup>

### **Role of the Radiologist**

At the Role 3, properly trained providers including radiologists, surgeons and emergency physicians, can perform and interpret FAST scans in the ED on a hand held portable US device. The utility of radiologists performing the exams would be to free up emergency providers and surgeons to either perform other assessments or interventions, or care for additional patients in the trauma bays. While in the trauma bay, the radiologist would also be available to provide preliminary interpretations of the portable chest x-ray/pelvis exams on the digital portable machines. However, once CT scans begin to be obtained on the trauma patients, the emergency physicians and surgeons would primarily perform the FAST scans and interpret plain radiographs at the bedside.

### **Equipment**

The examination is performed with a portable hand-held machine most commonly using a standard 3-7 MHz curved array US probe. A phased array probe is also acceptable, and occasionally is preferred if cardiac or pulmonary imaging is necessary. Real-time imaging is performed without the necessity of saving static images.

### **Standard Examination**

The standard FAST examination is focused on evaluating for the presence of free intraperitoneal fluid in:

1. The right upper quadrant between the liver and kidney,
2. The left upper quadrant between the spleen and kidney, and;
3. The pelvis at the level of the bladder.
4. An evaluation for cardiac activity and hemopericardium/tamponade should also be performed by placing the probe in the subxiphoid location and aiming towards the patients left shoulder.<sup>4</sup>

### **Additional Examinations**

The cardiac portion of the exam can rapidly identify cardiac injury, evaluate cardiac function and give information about the success of resuscitation.<sup>9</sup> In the case of massive exsanguination; the examination should be rechecked for free fluid after blood is given. A clot identified within a ventricle indicates prolonged asystole and may aid in the decision to terminate efforts. Pneumothorax or hemothorax may also be identified by placing the probe along the chest wall and looking for the presence of lung sliding. Loss of sliding implies the possible presence of a pneumothorax.<sup>10</sup>

## TRAUMA CT SCAN

If at all possible given the patient's clinical stability, a trauma CT can be performed before going to OR. Often indications for surgical intervention are already present; however the CT scan can provide additional information to the surgeon, identifying unsuspected and potentially clinically significant injuries. Given the relatively small footprint of most Role 3 facilities the patient can be taken to the OR immediately following the acquisition of the CT scan, with the radiologist providing the pertinent findings to surgeons while in the OR. For clinically unstable patients, this trauma CT can be obtained after continued resuscitation and surgical intervention in the OR.<sup>11</sup>

### CT Protocol (Adult)

. Initial acquisition includes non-contrast CT through head and face (to include the entire mandible), at 1 mm axial slice thickness which allows for isotropic sagittal and coronal reformatted images. This scan is followed by a contrast enhanced CT from the level of the circle of Willis through the bottom of the pelvis. Alternatively in the setting of significant lower extremity trauma such as dismounted complex blast injury, the scan can be performed through the lower extremities (default through the feet) allowing evaluation of skeletal and vascular injury of the lower extremities. A discussion with the trauma team should be performed prior to the scan to establish the inferior extent of the scan coverage. Of course, additional information including long bone fractures and metallic fragments can be seen on the scout image, which may alter the scan coverage to include those areas. Some difficulties may arise if the patient is tall and the CT gantry movement does not allow coverage through the lower extremities, however this can be ameliorated by scanning from the head to as low as possible, then either physically sliding the patient up on the gantry or rotating them 180 degrees on the gantry table and scanning through the remainder of the legs.<sup>11-13</sup> See [Appendix A](#) for more information.

### CT Review

3D workstations are a required resource in any civilian trauma center and are a required resource for any Role 3 where major casualties are expected. These workstations allow the radiologist a rapid overview of injuries and ability to zoom into abnormalities. Additionally these powerful workstations allow for rapid creation of detailed 3D shaded surface and multiplanar reconstructions that facilitate a broad overview of numerous soft tissue and osseous injuries at different locations and accentuate the location of fragments. Utilizing these shaded bone or skin surface and Multiplanar Reconstruction (MPR) images can be very helpful for injury tract analysis. The workstation also enables focused arterial vascular analysis, thus supporting early identification of more subtle vascular injuries that can have a significant clinical impact on patient morbidity and mortality.<sup>13</sup> In mass casualty situations, a modified workflow may be necessary. The performance of preliminary readings or "wet reads" may be required, especially when there is a sole radiologist present.

## IV Access for CT

18g antecubital IV is typically desired – if placed on a medical evacuation platform prior to arrival, the cannula must be thoroughly rechecked/flushed to ensure function and avoid contrast extravasation. More distal upper extremity IVs should typically not be used due to the risk of extravasation and compartment syndrome. A central line can be used for contrast power injection. A large lumen resuscitation catheter such as those utilized for the rapid infusion device (normally rated up to 9cc/sec) can usually handle contrast injection.<sup>14</sup> Ensure that the correct size catheter lumen is utilized for the power injection as the catheter will often have various sized lumens. The largest lumen of catheter would be the best to handle the power injection. Of course, should the rapid infusion device be used to infuse fluid/blood products at the same time, it should be turned off during the injection to avoid dilution of the contrast with the instillate. Current intraosseous needles should not be used for contrast administration. Though a few case reports of individual patients undergoing CT examination with contrast injection through IO needles have been published, larger studies in trauma patients are needed to establish efficacy, adverse effects, and bolus timing modifications.

**CT Contrast Injection**

The goal of the injection is to provide concurrent solid organ enhancement, arterial enhancement, and pulmonary arterial. Typical doses are approximately 150 cc of Iovue 300 or 340 contrasts utilizing a dual phase injection – 80cc at 1.4 cc/sec, followed immediately by 70cc at 3.5 cc/sec for the pan scan. The scan is started 2-3 seconds before the completion of the contrast injection to maximize pulmonary arterial filling. For pediatric injection volume and rates by weight, see [Appendix B](#).

**Rectal Contrast**

This can be helpful when evaluating penetrating flank injuries or possible rectal involvement below the peritoneal reflection from pelvic injuries. One may utilize 1L of saline/water with the addition of 1 bottle (50ml) of IV contrast. A Foley catheter is used to cannulate the rectum and the balloon is instilled with saline. In the setting of significant rectal or perineal trauma the surgeon may need to place the Foley catheter in the rectum.<sup>16</sup>

**Delayed Images**

Routinely performed for further evaluation of identified solid organ injury, identify active extravasation or pseudoaneurysm formation, which can aid surgeons in grading the solid organ injury. Additionally, contrast excretion within the ureters and subsequently into the bladder can also aid in diagnosis of injuries to these structures.

**CT Cystogram**

50 cc of IV contrast diluted into 500 cc of saline is infused through the indwelling urinary catheter. A minimum of 300 cc and up to 500 cc of this dilute contrast material should be infused to provide adequate evaluation of the integrity of the bladder wall. The catheter is then clamped for the CT examination. This type of exam is performed following the routine trauma CT with 1mm thick images acquired through the pelvis with the bladder filled. If necessary, additional axial imaging of the bladder can be performed following the drainage of the contrast to detect more subtle extraperitoneal bladder injuries which may be obscured by the distended bladder.<sup>17</sup>

**CT Language Settings**

Become familiar with the languages available/preloaded on the scanner for breathing instructions, which often include: English, French, Spanish, Japanese, and Chinese. Using interpreters available in your facility, record the same instructions in commonly encountered languages of coalition partners and host-nation patients (e.g., Arabic, Pashtun, Dari, Farsi, Georgian, Italian, Danish, Estonian, etc.). Ensure to select the correct language at the time of scan setup for each patient. Using these instructions will improve image quality for conscious patients.

**MILITARY WORKING DOGS (MWD)**

Given the nature of military operations in the current conflict, MWDs have sustained similar injuries to dismounted soldiers and will need CT trauma scans as well.<sup>18</sup> These examinations will typically be performed in consultation with veterinarians who will sedate the dog as necessary for the scan. However in an emergency situation, it may be necessary for the radiologist to perform the scan. Given this eventuality, prior coordination between the radiologist and veterinarian is essential. Utilize a scanning protocol based on the pediatric settings to include the doses of and rates of contrast administration. Refer to the JTS CPG, [Clinical Management of Military Working Dog](#)<sup>18</sup> and [Appendix B](#) for further details.

## IMAGE TRANSFER

All patients evacuated through casualty evacuation should have images sent electronically ahead of time as well as have a CD created to send with the patient as a backup. Although at times trauma patient's true name may not be known during the initial evaluation, it should be stressed that usually it becomes known sometime soon thereafter. Ensuring the patient's information is updated with the real name rather than a local hospital's trauma name will ensure those studies are available for review through the health care evacuation system.

## MRI

While MRI has been deployed to theater in the past, its utility in the acute management of combat trauma has not been established. Refer to the JTS CPG [Use of MRI in Management of mTBI in the Deployed Setting](#).<sup>19</sup>

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## PERFORMANCE IMPROVEMENT (PI) MONITORING

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### INTENT (EXPECTED OUTCOMES)

All trauma patients arriving at a Role 3 hospital will receive proper and expeditious radiologic screening of injuries.

### PERFORMANCE/ADHERENCE MEASURES

Identify missed injuries with appropriate radiographic imaging and/or reading.

### DATA SOURCE

- Patient Record
- Department of Defense Trauma Registry (DoDTR)
- Theater Image Repository

### 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 JTS PI Branch.

### RESPONSIBILITIES

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

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## REFERENCES

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1. Como JJ, Diaz JJ, Dunham CM, et al. Practice management guidelines for identification of cervical spine injuries following trauma: Update from the Eastern Association for the Surgery of Trauma Practice Management Guidelines Committee. J Trauma. 2009;67:651-659.

2. Joint Trauma System, Cervical and Thoracolumbar Spine Injury Evaluation, Transport, and Surgery in the Deployed Setting CPG, 05 Aug 2016.
3. Watchorn J, Miles R, Moore N. The role of CT angiography in military trauma. *Clinical Radiology*. 2013;68:39-46.
4. Scalea T, Rodriguez A, Chiu W, et al. Focused Assessment with Sonography for Trauma (FAST): Results of an International Consensus Conference. *J Trauma*. 1999;46:466-472.
5. ATLS 9th Edition, American College of Surgeons, 2012.
6. Smith, I. M., Naumann, D. N., Marsden, M. E., Ballard, M., & Bowley, D. M. Scanning and war: Utility of FAST and CT in the assessment of battlefield abdominal trauma. *Ann Surg*. 2015 Jan 29 [epub].
7. Cha JY, Kashuk JL, Sarin EL, et al. Diagnostic peritoneal lavage remains a valuable adjunct to modern imaging techniques. *J Trauma*. Aug 2009;67(2):330-4; discussion 334-6.
8. Kumar S, Kumar A, Joshi MK, Rathi V. Comparison of diagnostic peritoneal lavage and focused assessment by sonography in trauma as an adjunct to primary survey in torso trauma: A prospective randomized clinical trial. *Ulus Travma Acil Cerrahi Derg*. 2014 Mar;20(2):101-6.
9. Ferrada P, Evans D, Wolfe L, Anand RJ, Vanguri P, Mayglothling J, Whelan J, Malhotra A, Goldberg S, Duane T, Aboutanos M, Ivatury RR. Findings of a randomized controlled trial using limited transthoracic echocardiogram (LTTE) as a hemodynamic monitoring tool in the trauma bay. *J Trauma Acute Care Surg*. 2014 Jan;76(1):31,7; discussion 37-8.
10. Kirkpatrick AW, Sirois M, Laupland KB, Liu D, Rowan K, Ball CG, Hameed SM, Brown R, Simons R, Dulchavsky SA, Hamilton DR, Nicolaou S. Hand-held thoracic sonography for detecting post-traumatic pneumothoraces: The extended focused assessment with sonography for trauma (EFAST). *J Trauma*. 2004 Aug;57(2):288-95.
11. The Royal College of Radiologists. Standards of practice and guidance for trauma radiology in severely injured patients. London: The Royal College of Radiologists, 2011.
12. Gibb, I., Denton, E. Guidelines for imaging the injured blast/ballistic patient in a mass casualty scenario. (NHS Improvement System)NHS, London; June 2011.
13. Graham R. Battlefield Radiology. *British Journal of Radiology*. 2012 (85); 1556-1565.
14. Macha D, Nelson R, Howle L, et al. Central Venous Catheter Integrity during Mechanical Power Injection of Iodinated Contrast Medium. *Radiology*. 2009;253:870-8.
15. Nguyen D, Platon A, Shanmuganathan K, et al. Evaluation of a Single-Pass Continuous Whole-Body 16-MDCT Protocol for Patients with Polytrauma. *AJR*. 2009;192:3-10.
16. Shanmuganathan K, Mirvis S, Chiu W et al. Penetrating Torso Trauma: Triple-Contrast Helical CT in Peritoneal Violation and Organ Injury-A Prospective Study in 200 Patients. *Radiology*. 2004;231:775-784.
17. Morgan DE, Nallamala LK, Kenney PJ, Mayo MS, Rue LW,3rd. CT cystography: Radiographic and clinical predictors of bladder rupture. *AJR*. 2000;174:89-95.
18. Joint Trauma System, Clinical Management of Military Working Dog CPG, 19 Mar 2012.
19. Joint Trauma System, Use of MRI in Management of mTBI in the Deployed Setting CPG, 11 Jun 2012.



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**APPENDIX A: DETECTOR TRAUMA CT PROTOCOL**

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**TRAUMA CT PROTOCOL**

1. Unenhanced spiral brain 1.25mm (bone and soft tissue algorithm); 5mm reconstructions immediately available for review.
2. Circle of Willis to symphysis (bone and soft tissue algorithms).
  - 150ml biphasic contrast injection – initial 65ml at 2ml/sec then 85 ml at 3.5ml/sec Scan starts at 60 sec
  - This gives both portal venous enhancement with good arterial contrast at the same time and the scan can be carried on down to the legs/feet is necessary. The cervical contrast has been very useful both for penetrating injury and for spinal injury/vertebral artery injury.
3. The use of delayed scans limited to specific cases at the request of the radiologist.

**64 DETECTOR TRAUMA CT PROTOCOL**

1. Unenhanced helical brain 1.25mm (bone and soft tissue algorithm); 3mm reconstructions immediately available for review.
2. Circle of Willis to symphysis 1.25mm (bone and soft tissue algorithms); 3 to 5mm reconstructions immediately available for review.
  - 150mL biphasic contrast injection – initial 80cc at 1.4 cc/sec then 70cc at 3.5 cc/sec
  - Scan starts 3 sec before the completion of the contrast injection.
3. This gives both portal venous enhancement with good arterial contrast at the same time and the scan can be carried on down to the legs/feet is necessary. The cervical contrast has been very useful both for penetrating injury and for spinal injury/vertebral artery injury.
4. The use of delayed scans limited to specific cases at the request of the radiologist.

**16 DETECTOR TRAUMA CT PROTOCOL**

1. Unenhanced helical brain 1.5mm (bone and soft tissue algorithm); 3mm reconstructions immediately available for review.
2. Circle of Willis to symphysis 1.5mm (bone and soft tissue algorithms); 5mm reconstructions immediately available for review.
  - Arterial phase imaging – 150mL single arterial phase contrast injection at 3.5 cc/sec.
  - Automatically triggered with a threshold of 100 HU at the level of the aortic arch.
3. The arterial phase imaging alone is preferred due to the technical limitations of the scanner.
4. The use of delayed scans limited to specific cases at the request of the radiologist.

**APPENDIX B: 64 DETECTOR PEDIATRIC (MWD) IV CONTRAST INJECTION PROTOCOLS**

CHILD WEIGHT (kg)	VENOUS PHASE RATE/VOLUME	ARTERIAL PHASE RATE/VOLUME	TOTAL CONTRAST DELIVERED
5	0.2sec/7mls	0.4sec/3mls	10
10	0.3sec/14mls	0.6sec/6mls	20
15	0.4sec/20mls	0.8sec/10mls	30
20	0.5sec/26mls	1.0sec/14mls	40
25	0.6sec/33mls	1.3sec/17mls	50
30	0.7sec/40mls	1.6sec/20mls	60
35	0.8sec/47mls	1.8sec/23mls	70
40	0.9sec/53mls	2.1sec/26mls	80
45	1.0sec/60mls	2.2/30mls	90
50	1.2sec/66mls	2.4sec/34mls	100
55	1.3sec/73mls	2.6sec/37mls	110
60	1.4sec/80mls	2.8sec/40mls	120
70	1.6sec/94mls	3.3/46mls	140
<b>COLOR CODED PEDIATRIC DOSE SETTINGS (mA/kV)</b>			
Pink	6.0 - 7.5 kg	59.5 - 66.5 cm	
Red	7.5 - 9.5kg	66.5 - 74 cm	
Purple	9.5 - 11.5kg	74 - 84 cm	
Yellow	11.5 - 14.5kg	84.5 - 97.5 cm	
White	14.5 - 18.5kg	97.5 - 110cm	
Blue	18.5 - 22.5kg	110 - 122cm	
Orange	22.5 - 31.5kg	122 - 137cm	
Green	31.5 - 40.5kg	137 - 150cm	
Black	40.5 - 55 kg	< 150 cm	

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**APPENDIX C: ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS**

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**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.