## CENTCOM JTTS CPG DEVELOPMENT, APPROVAL, IMPLEMENTATION AND MONITORING PROCESS

Original Release/Approval		30 Apr 09	Note: This CPG requires an annual review.		
Reviewed:	Mar 2012	Approved:	2 Apr 2012		
Supersedes:	CENTCOM JTTS CPG Development, Approval, Implementation and Monitoring Process, 1 Apr $2010$				
☐ Minor Changes (or)		Changes are substantial and require a thorough reading of this CPG (or)			
☐ Significant Changes		CPG vetting/approval process updated; PI monitoring plan added			

- **1. Goal.** To formalize the processes for developing, reviewing, updating, approving, and monitoring CENTCOM Joint Theater Trauma System (JTTS) Clinical Practice Guidelines (CPGs).
- 2. Background. CENTCOM JTTS CPGs are the backbone of the theater Performance Improvement (PI) program. Historically, since the early outset of the in-theater trauma system, these guidelines have been developed and implemented by clinical subject matter experts (SME) in response to needs identified in the CENTCOM AOR. More recently, as the trauma system has matured, the process for identifying, developing, vetting, approving, and implementing CPGs has also matured. This CPG describes the most current iteration of the process that helps to standardize and codify the spectrum of CPG development and implementation.

To the greatest extent possible, CENTCOM JTTS CPGs are evidenced-based. Where evidence is lacking or unclear, but a CPG is needed, guidelines are developed based on the best available data and SME consensus. Monitoring of all CPGs is essential to the process, and to this end, each individual CPG will include a system-level PI monitoring plan that will be a written part of the CPG. This system-wide monitoring will be conducted by the Joint Trauma System (JTS) PI division. The PI plan will state the intent and minimal performance measures that will be utilized for monitoring. Trauma chiefs/czars at the MTF level are expected to implement local PI processes to insure compliance with the CPG; the PI monitoring plan will help guide these efforts.

Routine updates of CPGs occur on approximately an annual basis. Additionally, based on new evidence or prevailing SME input, CPGs are updated in whole or part whenever the need arises. SMEs include, but are not limited to, military and DoD-civilian experts, deployed clinicians, Service trauma/surgical consultants, CENTCOM JTTS Director, CENTCOM JTTS Program Manager (PM) and Trauma Nurse Coordinators (TNCs), Joint Trauma System (JTS) Director, JTS Chief, PI Division and JTS PI Nurse Coordinator.

NOTE: CENTCOM JTTS CPGs are applicable ONLY to care delivered within the CENTCOM AOR, from point of injury through strategic evacuation of injured casualties out of theater. Although Level IV and V care is considered in the development of these CPGs, there is no attempt made in them to "guide" the delivery of care at these levels.

Additionally, since these are CENTCOM AOR-specific CPGs, all or parts of these guidelines may NOT be applicable to other COCOM AORs or contingencies.

### 3. New CPG Development and Approval.

- a. Topics for a CPG may be presented by any subject matter expert to the current CENTCOM JTTS Director or JTS Director at the United States Army Institute of Surgical Research (USAISR), Ft Sam Houston, TX.
- b. The Directors will produce a working draft of the CPG which the CENTCOM JTTS Director will vet through the JTTS PM, the Role III trauma chiefs and other in-theater SMEs as deemed applicable, seeking inputs into the draft CPG. Once these inputs have been received, the draft document will be sent to the Chief, PI division at JTS. The Chief will then send the document for additional vetting and inputs through a second level of experts which includes, but may not be limited to: prior CENTCOM JTTS directors who are still on active duty or are still associated with the DoD in an official capacity; trauma chiefs/directors at Level IV and Level V facilities that receive critically ill trauma victims directly from the CENTCOM AOR or directly from Level IV facilities; the Serviceidentified trauma consultant from each Service; the Chairman, Tactical Combat Casualty Care and the incoming CENTCOM JTTS Director (if already identified). NOTE: It is the responsibility of the Service trauma consultants to seek inputs into the draft CPGs from identified physician and nurse SMEs within their respective Services prior to returning the draft document to the Chief, PI at JTS. Lack of response/input from the above named entities within 14 calendar days of dissemination of the draft CPG will constitute concurrence with the draft. Exceptions or extensions to the above may be granted by the CENTCOM JTTS Director, JTS Director, or the Chief, PI division, JTS.
- c. Final clinical approval will be by consensus of the CENTCOM JTTS and JTS Directors and the Chief, PI division based upon the best existing clinical evidence and/or experience. On issues where a CPG is indicated, but director consensus cannot be reached, the JTS Director is the final clinical approval authority. At the discretion of the JTS Director, an addendum to the CPG discussing alternate or dissenting opinions may be added. Additionally, the JTS Director, at his discretion, may convene a specific discussion by telecon and/or video teleconference on CPGs or aspects of CPGs, especially if significant differences of opinion exist. Key participants in the discussion will be notified by invitation from the JTS Director. Following discussions, if consensus is not reached, final clinical approval for the CPG rests with the JTS Director.
- d. Final <u>overall</u> approval authority for implementation of the CPG rests with CENTCOM SG to insure the CPG is in line with theater needs, objectives, resources, etc.
- e. Once approved by CENTCOM SG, the CPG will undergo OPSEC/PAO review and then be placed on the USAISR public website, JTS CPG webpage: <a href="http://www.usaisr.amedd.army.mil/cpgs.html">http://www.usaisr.amedd.army.mil/cpgs.html</a>. Additionally this link will be placed on the AKO and TMDS websites.

#### 4. Existing CPG Updating and Approval.

- a. Existing CPGs will be updated generally on an annual basis, or sooner in response to clinical or operational needs.
- b. Based on the above timeframes, the Chief, PI division, JTS will send the CPGs to the CENTCOM JTTS Director who, in turn, will initiate the update by first sending the CPG for inputs from the JTTS PM, Role/Level III trauma/surgical chiefs, and in-theater SMEs.
- c. Suspense for submitting updates back to the JTTS Director will be a minimum of 14 calendar days. Limited extensions may be granted by the JTTS Director.
- d. The JTTS Director will collate all inputs from theater and discuss these with the Chief, PI division.
- e. The Chief, PI division will then send the CPGs for vetting and inputs through the second tier as described in 3a above.
- f. After all inputs have been received, consensus reached and clinical approval granted by the JTS Director, the Chief, PI division will forward the updated CPG to CENTCOM SG for final overall approval.
- g. Once CENTCOM SG approval has been granted, the CPGs will undergo OPSEC/PAO review prior to posting on the JTS CPG webpage: http://www.usaisr.amedd.army.mil/cpgs.html
- 5. Monitoring. CENTCOM JTTS CPG adherence is monitored at the theater level by the JTTS Director, PM and TNC team. System level monitoring of the CPGs is conducted by the JTS PI division. Monitoring specifics (e.g. timing, frequency, performance measures, etc.) are written in the PI Monitoring Plan contained in and individualized to each CPG.

#### 6. Performance Improvement (PI) Monitoring.

- a. Intent (Expected Outcomes).
  - 1) Existing CENTCOM JTTS CPGs will be updated at least annually
- b. Performance/Adherence Measures.
  - 1) All existing CENTCOM JTTS CPGs were updated and posted no later than 60 days after the annual review date.
- c. Data Source.
  - 1) JTS CPG webpage
  - 2) Joint Theater Trauma Registry (JTTR)
- d. System Reporting & Frequency.

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

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

- **7. Responsibilities.** It is the responsibility of the Chief, JTS PI division to ensure system-level compliance with this CPG. It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.
- 8. References. N/A

# Approved by CENTCOM JTTS Director, JTS Director and CENTCOM SG

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

#### APPENDIX A

#### ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGs

- **1. Purpose**. The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of "off-label" uses of U.S. Food and Drug Administration (FDA)—approved products. This applies to off-label uses with patients who are armed forces members.
- 2. Background. Unapproved (i.e., "off-label") uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing "investigational new drugs." These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.
- 3. Additional Information Regarding Off-Label Uses in CPGs. The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the "standard of care." Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

#### 4. Additional Procedures.

- a. Balanced Discussion. Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDAissued warnings.
- b. Quality Assurance Monitoring. With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.
- c. Information to Patients. Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.