

Joint Theater Trauma System Clinical Practice Guideline

CENTCOM JTTS CPG DEVELOPMENT, APPROVAL, IMPLEMENTATION AND MONITORING PROCESS

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| Original Release/Approval | 30 Apr 09 | Note: This CPG requires an annual review. | |
| Reviewed: | Feb 2010 | Approved: | 1 Apr 2010 |
| Supersedes: | CENTCOM JTTS CPG Development, Approval, Implementation and Monitoring Process, Apr 09 | | |
| <input checked="" type="checkbox"/> Minor Changes (or) | <input type="checkbox"/> <i>Changes are substantial and require a thorough reading of this CPG (or)</i> | | |
| <input type="checkbox"/> Significant Changes | | | |

1. Goal. To formalize the processes for developing, reviewing, updating, approving, and monitoring CENTCOM JTTS Clinical Practice Guidelines (CPGs).

2. Background. CENTCOM JTTS CPGs are the backbone of the JTTS Performance Improvement system-wide 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 where the need for a CPG is paramount, guidelines are developed based on the best available data and SME consensus. Monitoring of all CPGs is essential to the process, and 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 civilian experts, deployed clinicians, Service trauma/surgical consultants, CENTCOM JTTS Director, CENTCOM JTTS TNCs, JTS Director, Deputy Directors, and Performance Improvement Nurse Coordinator.

3. New CPG Development and Approval:

- Topics for a CPG may be presented by any subject matter expert to the current Joint Theater Trauma System (JTTS) Director, Joint Trauma System Director and/or Joint Trauma System Deputy Director at the JTS.
- The Directors will produce a working draft of the CPG with inputs from theater and other SMEs and circulate it to the prior JTTS Directors and Service Trauma Consultants (designated by each Service SG) for comments, inputs and corrections, resulting in a final draft of the CPG.

Note: 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.

- Final clinical approval will be by consensus of the Directors. On issues where a CPG is indicated, but Director consensus cannot be reached, the JTS Director is the final clinical

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approval authority. At the discretion of the JTS Director, an addendum to the CPG discussing alternate or dissenting opinions will be added.

- d. Final 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 public website: <http://www.usaisr.amedd.army.mil/cpgs.html>. Additionally this link will be placed on the AKO and TMDS websites.

4. Existing CPG Updating and Approval:

- a. Existing CPGs will be updated at least annually, or sooner in response to clinical or operational needs.
- b. Based on the above timeframes, the CENTCOM JTTS Director will initiate the update by first sending out the CPG for inputs from the Level III trauma/surgical chiefs, in-theater and other SMEs, and the JTS Director and Deputy Director
- c. Suspense for submitting updates back to the JTTS Director will be a minimum of 14 calendar days.
- d. The JTTS Director will collate all inputs and discuss these with the JTS Director and Deputy Director.
- e. After approval, the JTTS Director will forward the updated CPG to CENTCOM SG for informational purposes only:

Note: If the updated CPG requires new resources or operational changes (changes in staffing, supplies, equipment, airlift, etc.) final approval authority for the updated CPG will rest with CENTCOM SG.

5. Monitoring. CENTCOM JTTS CPGs are monitored by the in-theater JTTS Director and Trauma Nurse Coordinator (TNC) team. Monitoring specifics (e.g. timing, frequency, compliance criteria, etc.) are determined by the CENTCOM JTTS Director and Program Manager. The JTS Performance Improvement team assists with the CPG monitoring process.

6. References. N/A

Approved by CENTCOM JTTS Director and Deputy
Director and CENTCOM SG

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| Opinions, interpretations, conclusions, and recommendations are those of the authors and are not necessarily endorsed by the Services or DoD. |
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ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGs

A. Purpose.

The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of “off-label” uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

B. Background.

Unapproved (i.e., “off-label”) uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing “investigational new drugs.” These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

C. Additional Information Regarding Off-Label Uses in CPGs.

The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the “standard of care.” Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

D. Additional Procedures.

1. Balanced Discussion. Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

2. Quality Assurance Monitoring. With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

3. Information to Patients. Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.

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