USE OF ELECTRONIC CLINICAL DOCUMENTATION IN THE CENTCOM AOR				
Original Release/Approval		1 Jun 2008	Note: This CPG requires an annual review.	
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Supersedes:	Use of Electronic Clinical Documentation in the CENTCOM AOR, 7 Nov 2008			
Minor Changes (or) X		X Changes are substantial and require a thorough reading of this CPG (or)		
Significant Changes				

1. Goal. To outline the process by which medical information – particularly as it pertains to combat casualty care – is transmitted along the continuum of care. The Theater Medical Information Program (TMIP) suite of programs will be utilized for clinical documentation at all levels of care.

2. Background. Information entered electronically into TMIP is visible throughout the continuum of care in the Theater Medical Data Store (TMDS), (formerly the Joint Patient Tracking Application - JPTA). TMDS is accessible from any .mil computer at the following link: https://tmds.tmip.osd.mil/

- a. TC2 is the inpatient documentation system approved for use in CENTCOM AOR. It should be used at all inpatient facilities. AHLTA-T is outpatient documentation system approved for use in the CENTCOM AOR. AHLTA-T should be used at all levels of facilities to document outpatient care.
- b. TMDS is the preferred module for Level IV and Level V facilities to enter documentation on trauma patients originating in the CENTCOM AOR. Information entered into TMDS also allows medical providers down range real time feedback on care provided in the combat theater. In some cases, downrange providers may enter patient notes directly into TMDS if TC2 or AHLTA-T are not available and upon approval of CENTCOM Surgeon.
- c. If the primary system is not available or operational, use one of the remaining two modules, if available. For example, if TC2 is not available to document an inpatient encounter, use AHLTA-T or TMDS.
- d. If no electronic means exist for transmitting medical information, then it is incumbent upon the physician responsible for that patient to ensure that detailed paper records are provided to the next echelon of care to facilitate an orderly hand-off to the next set of providers.

3. Responsibilities.

- a. At a minimum, the following information shall be entered:
 - 1) Detailed admission note (not to be done in lieu of completing the Trauma form)
 - 2) Operative note(s)
 - 3) Radiology dictation(s)
 - 4) Physician note(s)
 - 5) Detailed discharge summary

Note: Additional electronic documentation is highly encouraged, including but not limited to nursing documentation, pharmacy entries, and laboratory results.

- b. It is the trauma team leader's responsibility to ensure familiarity and appropriate compliance with this CPG.
- 4. References. None

Approved by CENTCOM JTTS Director and Deputy 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

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. <u>Balanced Discussion</u>. 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. <u>**Quality Assurance Monitoring.**</u> 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. <u>Information to Patients</u>. 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.