# JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)



# **Emergency Life-Saving Cranial Procedures by Non-Neurosurgeons in Deployed Setting (CPG ID:68)**

This CPG applies to military non-neurosurgeons in a forward deployed location with surgical capability (Role 2 surgical teams that meet capability requirements) outside of the United States.

## **Contributors**

CDR Randy S. Bell, MC, USN
Col Randall McCafferty, USAF, MC
Col Stacy Shackelford, USAF, MC
CAPT Jeff Tomlin, MC, USN
LTC Michael Dirks, MC, USA
CDR Chris Neal, MC, USN

Col Jeff Bailey, USAF, MC Don Marion, MD COL Kurt Edwards, MC, USA COL Mary Edwards, MC, USA CAPT Zsolt Stockinger, MC, USN

Publication Date: 23 Apr 2018

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## INTRODUCTION

The U.S. Military has deployed combat assets throughout the world. As such, catastrophic injuries can and do occur in austere environments with limited or no resources. It is understood that the standard of care for the treatment of severe traumatic brain injury includes the direct evaluation and treatment by a trained neurological surgeon.<sup>1,2</sup> Because there are not enough neurosurgical assets to support all missions, and because timely critical care air transport of severely brain injured servicemen and women is not always available depending on the location, and because severe and catastrophic brain injury can be rapidly fatal, the U.S. Military has recognized the occasional need for certain non-neurosurgeons (usually general surgeons) to perform cranial procedures far forward.<sup>3</sup> Data from the DoD Trauma Registry demonstrate that craniectomy procedures have been documented at Role 2 surgical facilities in Iraq and Afghanistan 36 times, with indeterminate success. There is some precedent for this practice within the literature, 2,5-6 including reference to the need for this practice as early as World War II.<sup>7</sup> This concept is addressed to a certain extent in the treatise on War Surgery from the International Committee of the Red Cross.<sup>8</sup> In the aforementioned references, there is tacit acknowledgement that neurosurgical procedures are possible in austere locations with appropriate training and resources. With this in mind, it has become the responsibility of the U.S. Military neurosurgical community to ensure that our deployed servicemen and women receive the best care possible from non-neurosurgical colleagues. The purpose of this clinical practice guideline is therefore to provide specific and tailored guidelines for the performance of cranial procedures by non-neurosurgeons. The document has been developed jointly by the neurosurgical departments of all three services to support the non-neurosurgeon faced with this difficult situation.

This CPG was developed by consensus opinion from the Joint Trauma System, neurosurgical members of the American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS), Joint Military Committee and the AANS/CNS Section of Neurotrauma. This document has been reviewed by and is supported by the Defense and Veterans Brain Injury Center.

## **Definitions**

**Craniotomy**: The removal of part of the skull for the purposes of accessing contents of the calvarial vault, and then replacing the bone in its original position using plates and screws.

**Craniectomy**: The removal of portions of the skull for the purposes of accessing the contents of the calvarial vault without replacement of the bone.

**Ventriculostomy**: The placement of a small catheter within the body of the lateral ventricle through a small burr hole drilled approximately 10-11 cm posterior to the glabella and 2.5-3 cm lateral to midline. This catheter can be used to drain cerebrospinal fluid and to measure intracranial pressure.

**Subdural hematoma**: The accumulation of blood within the subdural space, usually as a result of trauma, and best diagnosed with a computerized tomography (CT) scan. Some general indications for surgery include hematomas > 1 cm in maximal thickness especially if associated with > 5 mm midline shift on a non-contrast CT of the head.

**Epidural hematoma**: The accumulation of blood within the epidural space, usually as a result of trauma, and best diagnosed with a CT scan. Common locations include the temporal region (middle cranial fossa) due to laceration of the middle meningeal artery. Some general indications for surgical intervention may include a hematoma > 30 mL in size on non-contrast CT head, especially if associated with evidence of uncal herniation. This can be clinically diagnosed when there is a dilated, unreactive pupil (3rd cranial nerve compression) with contralateral hemiparesis, with or without hemodynamic instability (hypertension, bradycardia, respiratory variation).

**Intracerebral hemorrhage**: The accumulation of blood within the parenchyma of the brain. This can result from trauma, and is best diagnosed with a CT scan.

**Penetrating brain injury**: Injury to the brain resulting from penetration of the skull, dura, and brain parenchyma by a foreign body.

## INDICATIONS TO PERFORM CRANIAL PROCEDURES IN AUSTERE SETTING

The decision to perform a neurosurgical intervention in an austere location is best made with the telemedicine support of a neurosurgeon.

Telemedicine consult may be obtained from the closest neurosurgeon in the evacuation chain. In addition, worldwide neurosurgery consultation is available at:

- WRNMMC: 301-295-4000 (comm), 312-295-4000 (DSN) or 240-381-2528 (comm).
- SAMMC: 210-539-0817 (comm) or 312-429-2500 (DSN), 210-916-2500 (comm).
- Ask the hospital operator to contact the attending neurosurgeon on call.

In some locations, a CT scan may be available, greatly facilitating the appropriate intervention.

When a CT scan is not available, there is a high risk that procedures may be performed without correct localization of pathology. It is therefore necessary to make an accurate diagnosis, appropriately resuscitate, and exhaust all medical interventions prior to performing a procedure in this environment. Regardless of whether a CT scan is available, the indications for surgical intervention are clinical.

## WHEN TO PERFORM CRANIAL PROCEDURES

- A cranial procedure is recommended after teleconsultation with neurosurgery (when possible), and
- Severe closed supratentorial brain injury with a presenting GCS ≤ 8 AND lateralizing cortical dysfunction such as unilateral dilated pupil or hemiparesis
  - Accompanied by hemodynamic dysfunction: hypertension, bradycardia, and respiratory variation (Cushing's reflex), or
  - Failure of maximal critical care management per the Neurosurgery and Severe Head Injury CPG2 to stabilize the patient. This may manifest by the occurrence of a new lateralizing cortical finding (hemiparesis, rapidly expanding pupil) and/or further decline in GCS off of sedation, and
- Evacuation to a neurosurgeon is not available within approximately 4 hours of injury, and
- Surgeon training and resources are adequate. See Appendix A (Training) and Appendix B (Resources).

## WHEN NOT PERFORM CRANIAL PROCEDURES

- Clinical condition and neurologic status stabilized or improved with aggressive medical management.
- Surgeon and resources are not adequate. See <u>Appendix A</u> (Training) and <u>Appendix B</u> (Resources).
- The patient has a post-resuscitation GCS = 3 with bilateral fixed and dilated pupils. This is non-survivable.

## CHECKLIST/PROCEDURES FOR CRANIECTOMY

- 1. Establish teleconsultation with neurosurgeon. Video consultation is preferred. If unable to communicate with a neurosurgeon, recommend a multi-disciplinary discussion that includes the local command authority prior to proceeding.
- 2. Make every effort to evacuate the patient to a facility where neurosurgery is available within approximately 4 hours.

- 3. Assess indications for craniectomy.
- 4. Assess availability of follow-on care.
- 5. Ensure that maximal medical/critical care management and resuscitation of the patient's intracranial condition has occurred. This should include appropriate blood component resuscitation, 3% saline, anticonvulsant, sedation, etc. in accordance with the JTS Neurosurgery and Severe Head Injury CPG.<sup>2</sup>
- 6. Ensure that the surgeon training and the facility resources are adequate.
- 7. If all of the above indications are met, then, in consultation with a neurosurgeon (when possible), consider intervention as follows: (Note: Review Emergency War Surgery Manual for further details.<sup>3</sup>)

## **CLOSED HEAD INJURY**

If no CT scan is available, an accurate neurological examination must be obtained for the purposes of localizing the lesion. A skull X-ray may improve localization in cases of skull fracture or penetrating brain injury.

Proper positioning of the patient is very important.

- 1. Avoid any compression of the neck to assure unhindered jugular venous outflow.
- 2. The head should be positioned slightly higher than the chest.
- 3. Rotate the head 30-40° off midline such that the side being operated on is highest.
- 4. Mark the midline of the scalp, as well as the location of anticipated burr hole and craniotomy incisions, prior to draping the head.

Once localized, exploratory burr holes will be made over the frontal, temporal and parietal convexities using electric drill for the purposes of identifying a hematoma.

- 1. If necessary, the dura can be opened carefully through the burr hole following cauterization if hemorrhage is subdural.
- 2. If evidence of epidural or subdural bleeding or high intracranial pressure is encountered, a craniectomy should be performed.
- 3. Burr holes alone are unlikely to be helpful in the setting of severe TBI.

Once the decision to proceed with craniectomy is made, the dura must be carefully separated from the inner table of the skull (Penfield 1-3 instruments) and the burr holes connected with the electric drill using either a side cutting bit or a "matchstick" bit.

- 1. An appropriately sized craniectomy is usually at least 15cm long in the sagittal plane and 12cm in height in the coronal plane, however a smaller craniectomy may be advisable in the far-forward setting.
- 2. Take care to stay off midline in order to avoid injury to the superior sagittal sinus.
- 3. If the hematoma is epidural, it must be evacuated and the bleeding source cauterized.
- 4. If subdural, the dura must be opened, the hematoma evacuated, and if visible, the bleeding source cauterized.
- 5. Do not replace the bone.
- 6. If not visible, do not search for a bleeding source.
- 7. If subdural hematoma, do not close the dura.

In all circumstances, the scalp must be closed.

If the brain herniates rapidly out after dural opening, close the scalp immediately.

## PENETRATING HEAD INJURY

Penetrating brain injury is one of the most challenging indications for cranial procedures performed by neurosurgeons.

- 1. Exploration without teleconsultation from a neurosurgeon is not recommended.
- 2. There is often deep and uncontrollable bleeding that may not be evident on the cortical surface.
- 3. Surgical exploration below the surface of the brain is NOT recommended.
- 4. Surgical intervention should be limited to removing bone, opening the dura, controlling bleeding, and closing the skin rapidly.

If cranial contents are herniated from either the entry or exit wound, allow this to continue. Do not close the wound.

Adequately resuscitate as necessary, and transport at the soonest opportunity.

If evacuation to a higher level of care is not possible, recognize that intervention in this case may be futile.

#### PERFORMANCE IMPROVEMENT MONITORING

## POPULATION OF INTEREST

All patients at a Role 2 surgical capability with an initial GCS ≤ 8 AND diagnosis of traumatic brain injury.

## INTENT (EXPECTED OUTCOMES)

- 1. Cranial procedures will be performed by non-neurosurgeons only when a neurosurgeon is not available within approximately 4 hours.
- 2. Only patients with following criteria undergo decompressive craniectomy by a non-neurosurgeon:
  - a. Traumatic brain injury with post-resuscitation GCS 4-8 AND
  - b. Lateralizing neurologic signs AND
  - c. Hemodynamic dysfunction (hypertension, bradycardia, and respiratory variation: i.e. Cushings reflex) OR failure of maximal critical care management (new lateralizing cortical finding such as hemiparesis or rapidly expanding pupil, and/or further decline in GCS off of sedation).
- 3. Non-neurosurgeons will perform emergency life-saving cranial procedures only after teleconsultation with a neurosurgeon.
- 4. Non-neurosurgeons will perform emergency life-saving cranial procedures using an electric drill and saw.

## PERFORMANCE/ADHERENCE METRICS

- 1. Number and percentage of patients in the population of interest with documentation of anticipated length of time > 4 hours to arrive at a facility with a neurosurgeon.
- 2. Number and percentage of patients in the population of interest who have the following indications documented:
  - a. Traumatic brain injury with post-resuscitation GCS 4-8 AND
  - b. Lateralizing neurologic signs AND
  - c. Hemodynamic dysfunction (hypertension, bradycardia, and respiratory variation: i.e. Cushing's reflex) OR failure of maximal critical care management (new lateralizing cortical finding such as hemiparesis or rapidly expanding pupil, and/or further decline in GCS off of sedation).
- 3. Number and percentage of patients in the population of interest who have documentation of teleconsultation with a neurosurgeon.
- 4. Number and percentage of patients in the population of interest who have documentation of the use of an electric drill and saw for the procedure.

#### DATA SOURCE

- Patient Record
- Department of Defense Trauma Registry (DoDTR)
- ICU flow sheet

## 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.

#### REFERENCES

- 1. Wester K. Decompressive surgery for "pure" epidural hematomas: Does neurosurgical expertise improve outcome? Neurosurgery. 1999;44(3);495-500.
- 2. Joint Trauma System, Neurosurgery and Severe head Injury Clinical Practice Guideline. <a href="https://jts.health.mil/index.cfm/PI\_CPGs/cpgs">https://jts.health.mil/index.cfm/PI\_CPGs/cpgs</a>
- 3. Wester K. Decompressive surgery for "pure" epidural hematomas: Does neurosurgical expertise improve outcome? Neurosurgery. 1999;44(3);495-500.
- 4. Emergency War Surgery Manual, 4th United States Revision. Office of the Surgeon General, United States Army. Borden Institute. Pp. 20, 233.

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- 6. Springer MF, Baker FJ. Cranial burr hole decompression in the emergency department. Am J Emerg Med. 1988:6(6);640-6.
- 7. Gilligan J, Reilly P, Pearce A, Taylor D. Management of acute traumatic intracranial haematoma in rural and remote areas of Australia. ANZ J Surg. 2017:87(1-2);80-85.
- 8. Luck T, Treacy PJ, Mathieson M, Sandilands J, Weidlich S, Read D. Emergency neurosurgery in Darwin: still the generalist surgeons' responsibility. ANZ J Surg. 2015;85(9):610-4.

## APPENDIX A: TRAINING FOR CRANIAL PROCEDURES IN AUSTERE SETTING

The training and experience of individual surgeons is a factor that must be considered on a case-by-case basis when deciding whether to perform a neurosurgical intervention in an austere environment. In some cases a prolonged evacuation may be preferred over intervention by an untrained surgeon, while in other cases, such as with host national casualties, evacuation is not an option and the deployed care available is the only option.

Since neurosurgical training is not standard training for the majority of general surgeons, the following recommendations have been established to allow general surgeons to better prepare for austere surgical missions. The main purpose is to establish a guideline that, per expert opinion, optimizes the benefit: risk ratio for injured patients cared for in the forward deployed, resource limited environment.

Recommendations for non-neurosurgeons to perform cranial procedures for specific clinical indications in austere environments include:

- Board certified/eligible general or head and neck surgeon
- Participation in at least 10 cranial procedures supervised by a neurosurgeon. At least 1 of these procedures should occur within 1 year of scheduled deployment.
- Completed a cranial simulator course within 1 year of deployment run by a board certified/board eligible neurosurgeon (i.e. Emergency War Surgery Course or ASSET+).

Training recommendations do not constitute a credentialing requirement. Individual surgeons may perform cranial procedures when the clinical situation, available resources, and analysis of the risks and benefits of both surgical and medical management favor surgical intervention.

In cases where a surgeon has not completed the recommended training, the risk of neurosurgical intervention may outweigh the benefit and medical management may be preferred.

For context and perspective, the minimum number of trauma craniotomies required to graduate a neurosurgical resident trainee is 40. The committee of subject matter experts arrived at the number 10 in an effort to balance forward requirements with what was thought to be the necessary competency given the current training environment.

\*Recommendations based on Consensus opinion American Association of Neurological Surgeons/Congress of Neurological Surgeons Joint Committee of Military Neurosurgeons, meeting 24 Apr 2017.

## APPENDIX B: RESOURCES FOR CRANIAL PROCEDURES IN AUSTERE SETTING

Neurosurgical intervention is greatly facilitated by obtaining the recommended supplies and equipment. The risk of neurosurgical intervention is higher when proper equipment is not available. Every effort should be made to obtain the necessary supplies and equipment if neurosurgical procedures are within the scope of a surgical team's mission. If only a Gigli saw and Hudson brace are available to an inexperienced provider, the risk of neurosurgical intervention may outweigh the benefit, and medical management may be preferred.

Recommended resources necessary to support non-neurosurgeons who may have to perform cranial procedures in an austere environment should include all of the following:

- 1. Tele-conference capability (video-teleconference capability preferred).
- 2. Emergency cranial pack that includes an electric drill with cranial perforator bit and matchstick or cutting ball, a Leksell Rongeur, Penfield instruments, bipolar cautery, Dural substitutes, and hemostatic agents (i.e. gel foam, surgicel, etc.). A Gigli saw and Hudson drill may be included as back up should the electric drill fail during the procedure.
- 3. Critical care capabilities.

NOTE: Non-invasive measures of intracranial injury are an emerging technology that may be utilized to improve localization of injury or superficial hematoma.

#### **Non-invasive Measurement Resources**

- 1. Quantitative pupillometry: This is a small hand-held device that initiates a miotic pupillary response, records the speed of the response, and supplies a normative pupillary index (NPI).<sup>1</sup>
  - As intracranial pressure increases, the NPI decreases.
  - Asymmetric injury can result in asymmetric NPI and can aide with determining the hemisphere injured.
- 2. A handheld infrared scanner is another emerging technology for non-invasive brain imaging that may be considered to localize superficial intracranial hematomas.<sup>2</sup>

<sup>&</sup>lt;sup>1.</sup> Taylor WR, Chen JW, Meltzer H, Gennarelli TA, et al. Quantitative Pupillometry, a new technology: normative data and preliminary observations in patients with acute head injury. Technical note. J Neurosurg. 2003:98(1);205-13.

<sup>&</sup>lt;sup>2.</sup> Sen AN, Gopinath SP, Robertson CS. Clinical application of near-infrared spectroscopy in patients with traumatic brain injury: a review of the progress of the field. Neurophoton. 2016:3(3); 031409.

## APPENDIX C: ADDITIONAL 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.