AURAL BLAST INJURY / ACOUSTIC TRAUMA AND HEARING LOSS				
Original Release/Approval:		21 Jul 2007	Note: This CPG requires an annual review	
Reviewed:	Feb 2012	Approved for PACOM:	DEC 2014	
Supersedes:	Acoustic Trauma and Hearing Loss, 16 Feb 2010			
$\square \text{ Minor Changes } (or) \qquad \boxtimes \mathbf{C}$		Changes	Changes are substantial and require a thorough reading of this CPG (or)	
Significant Changes System		System PI mor	monitoring plan added; evaluation and treatment of TM injury updated	

- 1. Goal. Patients exposed to hazardous noise (for the purposes of this clinical practice guideline (CPG) hazardous noise is impact noise or noise greater than 140dB) are at high risk of acoustic trauma and subsequent hearing loss (HL). Patients exposed to blasts are at risk for both aural and acoustic trauma. This CPG is designed to quickly identify and treat aural trauma and hearing loss, to prevent morbidity and to preserve as much function as possible, while in the combat theater.
- 2. Background. Hazardous noise causes acoustic trauma by injuring the hearing mechanism in the inner ear. The symptoms of acoustic trauma are sensorineural hearing loss (SNHL), tinnitus (ringing in the ear), aural fullness, recruitment (ear pain with loud noise), difficulty localizing sounds, and difficulty hearing in a noisy background. Acoustic trauma may result in SNHL that is either temporary (temporary threshold shift, TTS) or permanent (permanent threshold shift, PTS). A TTS will resolve with time, while the time frame for hearing recovery is unique in every case, any SNHL that persists beyond 8 weeks after injury is most likely permanent and should be considered a PTS. There are no clinical predictors for which patients with a TTS will persist to develop PTS.

The ear, specifically the tympanic membrane (TM), is the most sensitive organ to primary blast injury (PBI). Blast exposure often results in perforation of the TM. The signs and symptoms of a TM perforation are ear pain, bloody ear discharge, and conductive hearing loss (decreased ability to transmit sound through the middle ear to the inner ear,). TM perforations resolve spontaneously in 80 to 90% of cases. The smaller the size of the TM perforation the greater the likelihood is of spontaneous closure. The majority of TM perforations that close spontaneously do so within the first 8 weeks after injury.

The ossicular chain may also rarely be injured as a result of PBI, with fracture of the ossicles or disruption of the chain both of which result in CHL.

The temporal bone may also be fractured as a result of higher order blast injury. Patients with temporal bone fractures may have lacerations in the canal or along the TM resulting in either bloody otorrhea or hemotypanum (blood behind the TM). They may also have either SNHL or CHL, depending on the orientation of the fracture. A small number of these fractures (15%) will have an associated cerebral spinal fluid (CSF) leaks either CSF otorrhea (a leak from the auditory canal) or CSF rhinorrhea (a leak from the nose). The risk of meningitis for the first 7 days post injury is very small, 3% or less; therefore antibiotic prophylaxis is controversial. It is almost impossible without beta2-transferrin (a protein

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unique to CSF) testing to distinguish between patients with bloody drainage containing CSF from those who have bloody drainage without CSF.

Dizziness expressed as unsteadiness or vertigo (spinning sensation) following blast injury is usually a result of traumatic brain injury but may be caused by injury to the inner ear, specifically either a perilymphatic fistula or benign paroxysmal positional vertigo (BPPV).

3. Evaluation and Treatment. All patients exposed to hazardous noise occurring from exposure to battle (improvised explosive devices (IED's), rockets, and small arms fire), airplane or shipboard noise, and all patients exposed to a blast should be asked specifically about hearing loss during their initial trauma evaluation. If there is debris in the external auditory canal (EAC) or in the middle ear (as seen through a TM perforation), treat the patient with a fluoroquinolone- steroid containing topical antibiotic, e.g., four (4) drops of Ciprodex in the affected ear TID for seven (7) days. Do NOT irrigate the ear as it will provoke pain and vertigo. Patients should observe strict dry ear precautions and keep ALL water out of their EAC until the TM perforation is healed. Removal of debris should only be done by an ENT surgeon to avoid injury to the EAC or middle ear. Hearing loss that persists 72 hours after acoustic trauma warrants a hearing test or audiogram. When hearing loss is present, individuals should be restricted from hazardous noise environments and kept on base if possible. This is important to allow time for healing. A service member with hearing loss is less effective during missions and can negatively impact mission accomplishment. All patients with vertigo should undergo a Dix-Hallpike test and if positive an Epley or canolith repositioning maneuver (see Appendix A and B).

## 4. Absolute Indications for Screening Audiogram (Hearing Test)

Hearing loss that persists for more than 72 hours after an acoustic trauma or blast injury warrants a screening hearing test or audiogram.

Patients with TTS greater than 60 dB on three consecutive frequencies and ten or more days after noise exposure should be considered for evacuation out of theater (without Role III evaluation).

## 5. Absolute Indications for Otolaryngology (ENT) Referral

- Temporal bone fracture with or without ear drainage
- Persistent HL occurring 72 hours after acoustic trauma, or <u>inability to perform duties due</u> to perceived HL.
- TM perforation that has not resolved 8 wks after injury
- Vertigo that does not resolve within 7 days of injury even if episodic
- Clear ear drainage
- Persistent discolored ear drainage that does not resolve after 3 days of topical antibioticsteroid combination drop therapy
- On screening audiogram :
  - Average hearing threshold greater than 30 dB at 500, 1000, and 2000 Hz

- Or any hearing threshold greater than 35 dB at 500, 1000, and 2000 Hz
- $\circ~$  Or any hearing threshold greater than 45 dB at 3000 Hz or 55dB at 4000 Hz.

Interpretation of the post-traumatic audiogram is facilitated by review of a baseline audiogram, if available.

• This referral should be delayed until 8 weeks after injury to allow for healing.

## 6. Relative Indications for Otolaryngology (ENT) Referral

- Debris in the external ear (EAC) that does not clear with topical ear drops
- Inability to visualize the TM despite treatment with topical ear drops
- Persistent dizziness, even if not true vertigo
- Significant communication problems regardless of the hearing test results. Tinnitus that interferes with the patient's duty performance or lifestyle, regardless of hearing test results.

## 7. Performance Improvement (PI) Monitoring.

- a. Intent (Expected Outcomes).
  - 1) All patients at risk for TM injury are assessed when initially evaluated at each MTF in the continuum
- b. Performance/Adherence Measures.
  - 1) The patient was assessed for TM injury during the initial evaluation at each MTF
- c. Data Source.
  - 1) Patient Record
  - 2) Dept of Defense Trauma Registry (DoDTR)
- 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.

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

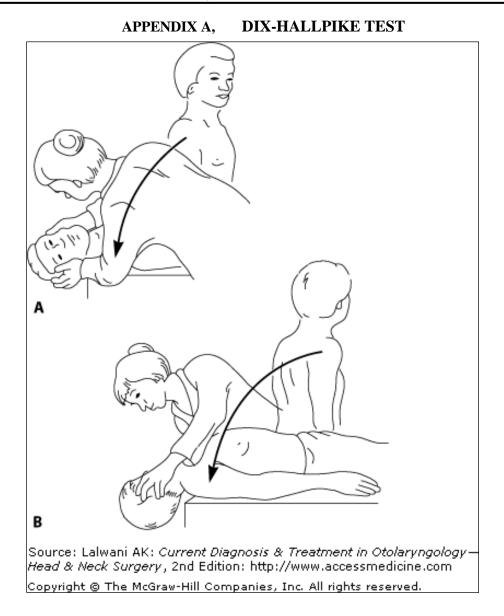
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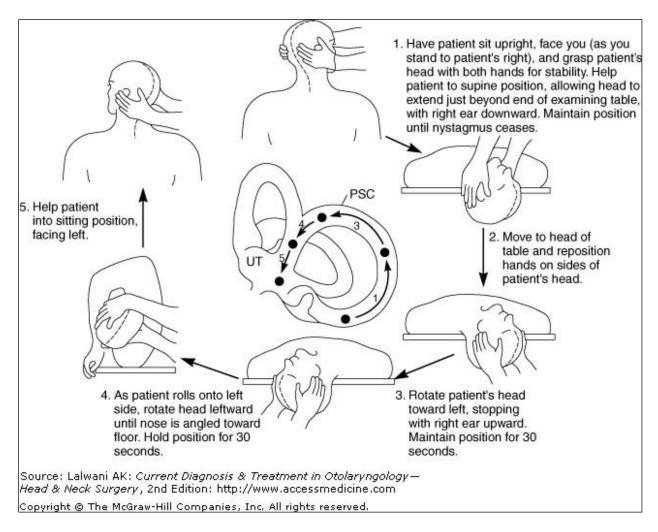
# Approved by PACOM JTTS Director, JTS Director and PACOM SG

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



#### Dix-Hallpike Test

- **A.** For testing the right posterior semicircular canal, the patient sits on the exam table and turns his or her head to the right 45 degrees. This places the posterior semicircular canal in the sagittal plane. The examiner stands facing the patient on the patient's right side or behind the patient.
- **B.** The patient is then moved by the examiner from the seated to the supine position with the head slightly hanging over the edge of the table. The right ear is down and the chin is pointing slightly up. The eyes are observed for the characteristic nystagmus.



#### APPENDIX B, EPLEY MANEUVER

#### Epley Maneuver

The patient is taken through four moves, starting in the sitting position with the head turned at a  $45^{\circ}$  angle toward the affected side.

- **1.** The patient is placed into the Dix-Hallpike position (supine with the affected ear down) until the vertigo and nystagmus subside.
- **3.** The patient's head is then turned to the opposite side, causing the affected ear to be up and the unaffected ear to be down.
- **4.** The whole body and head are then turned away from the affected side to a lateral decubitus position, with the head in a face-down position.
- **5.** The last step is to bring the patient back to a sitting position with the head turned toward the unaffected shoulder.

#### APPENDIX C, 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. <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.
- b. <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.
- c. <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.