OVERVIEW

• Introduction and Purpose of the Hearing Center of Excellence (HCE)

• Status since 9 December 2011
  – Staffing vacancies filled in late FY 12/early FY 13
  – Update on Goals and Objectives
  – Joint Strategic Plan 2012 Progress
  – Joint Hearing Loss and Auditory System Injury Registry (JHASIR)
  – DoD Policy for Hearing Aid/Implant Purchase Standardization
  – Centralized Institutional Review Board (IRB)
  – Research Productivity and Dissemination
  – Considerations for Policy Changes

On-track to Full Operating Capability (FOC)
• Combat is extremely chaotic
• The ability to hear and communicate is
  – Critical to the safety of each warrior and their unit
  – Central to effective command and control
  – A vital component for mission accomplishment
  – A key consideration in Force Management
    • Attrition, retrain, replace
• The capability to prevent is available
  – Education & Training
  – Hearing Protection Devices
  – Tactical Communication Devices
• Readiness requires both
  – Performance and Prevention
• Public Law 110-417 Duncan Hunter National Defense Authorization Act (NDAA) 2009 Section 721:
  – Secretary of Defense shall establish, within the DoD, centers of excellence (CoE) to include a CoE focused on the prevention, diagnosis, mitigation, treatment and rehabilitation of hearing loss and auditory system injury
  – The Secretary shall ensure that the center:
    • Collaborates to the maximum extent practicable with the Secretary of Veterans Affairs, institutions of higher education, and other appropriate public and private entities (including international entities)
    • Collaboratively develops a registry with bi-directional data exchange to identify and track incidence and care for hearing loss and auditory injury
    • Utilize registry data to encourage and facilitate the conduct of research, development of best practices and clinical education
• HCE Mission
  – Heighten **readiness**
  – Improve the **health** and **quality of life** of members and veterans
  – Focus on the **prevention, diagnosis, mitigation, treatment, rehabilitation and research** of hearing loss and auditory-vestibular system injuries

• HCE Overview
  – Establish an auditory-vestibular centered collaborative network related to prevention, care and research
  – Provide efficiency and coordination of clinical care and research in areas affecting auditory–vestibular issues
  – Includes academic, industry, and international partners
Attributes for FOC

- JHASIR is activated
- DOD VA bidirectional Data Sharing Agreements in place
- Standardization of Hearing systems acquisition is complete
- DOD HCE is the “one voice” influencing DOD and other federal funding, regulation, and directives for issues regarding prevention, diagnosis, mitigation, treatment, rehabilitation, and research of hearing loss and auditory system injuries
- DOD VA transition of auditory care defined
- DOD HCE prevention plan and education strategy implemented
- Identify process and strategic communications to engage DoD acquisitions and industry communities for the delivery of new systems optimizing noise mitigation and prevention awareness
- DOD auditory Fitness for Duty (FFD) standards are complete
UPDATES SINCE DECEMBER 2011
Staffing Update

• Executive Director formally appointed by ASD (HA)
• FY 13 contracts filled key positions/requirements
  – Registry development now staffed by DOD health data experts and engineers (problematic starts over past years)
  – Execution of prevention campaign now assisted by former Chair of the DOD Hearing Conservation Working Group
  – Clinical/Rehab Directorate led by former senior military neurotologist
  – Research Directorate led by HCE Chief Scientist
  – Research coordinators now facilitating key DOD MTFs/Labs

• Vibrant VA collaboration lays foundation for additional key staff across the HCE
  – Deputy Director
  – Informatics
  – Clinical Directorate
  – Global Outreach

14 January 2013
• Each military Service is staffing HCE with a senior military audiologist – AF Audiologist arrives in 2 weeks
• Civil Service positions finalized, now in classification process, hiring expected by 3rd quarter
  – Chief Operating Officer
  – Neurotologist
  – Logistics Administrator
  – Resource Administrator

• Active AF/SG support thru
  – Air Force Medical Operations Agency (AFMOA)
  – 59 Medical Wing (Wilford Hall Ambulatory Surgical Center)
Goals & Objectives Update
## GOALS & OBJECTIVES

<table>
<thead>
<tr>
<th>PROGRAM</th>
<th>2011</th>
<th>Now</th>
</tr>
</thead>
<tbody>
<tr>
<td>PREVENTION &amp; SURVEILLANCE</td>
<td></td>
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<tr>
<td>Develop a Strategic Communications and Prevention Plan</td>
<td>[completed]</td>
<td>[completed]</td>
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<tr>
<td>Interval screening and questionnaire sampling of military population</td>
<td>[in progress]</td>
<td>[in progress]</td>
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<tr>
<td>Develop interactive web-based educational tools</td>
<td>[in progress]</td>
<td>[in progress]</td>
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<tr>
<td>Determine scope of FFD standards for appropriate Military Occupational Specialties (MOS)/AFSCs/Ratings</td>
<td>[not started]</td>
<td>[completed]</td>
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<tr>
<td>Publish qualified-products standards for hearing protection and communication systems</td>
<td>[in progress]</td>
<td>[in progress]</td>
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</tbody>
</table>

- **Completed**: Green
- **In Progress**: Yellow
- **Not Started**: Red

14 January 2013
## GOALS & OBJECTIVES

<table>
<thead>
<tr>
<th>PROGRAM</th>
<th>2011</th>
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<tbody>
<tr>
<td>CLINICAL CARE &amp; REHAB</td>
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<tr>
<td>Establish DOD Information Assurance Certifications and Accreditation Process (DIACAP) to interface Clinical audiometric data with Electronic Health Record (EHR) and JHASIR</td>
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<tr>
<td>Complete ongoing Clinical Practice Guidelines (CPGs) and clinical tools for providers</td>
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<tr>
<td>Sponsor clinical conferences and workshops</td>
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<tr>
<td>Determine scope of fitness-for-duty (FFD) standards for appropriate MOS/AFSCs/Ratings</td>
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<tr>
<td>Baseline &amp; identify compliance gaps across existing regulations and policies—begin remediation actions</td>
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<tr>
<td>Acoustic Trauma/FFD/acquisition standards/Military Vestibular Assessment Rehabilitation (MVAR)/Blast tinnitus conferences</td>
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<tr>
<td>Develop and institute emerging technologies for rehabilitation</td>
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<tr>
<td>Establish plan for transitional care sharing with VA</td>
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</tbody>
</table>

- **Completed**
- **In Progress**
- **Not Started**

14 January 2013
# GOALS & OBJECTIVES

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<tr>
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<tbody>
<tr>
<td><strong>Global Outreach</strong></td>
<td></td>
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<tr>
<td>Hearing Aid Purchasing Standardization – draft regulation</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Partner with hearing health advocacy groups</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Develop Hearing Health Caucus</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Promote FFD, CPGs and clinical tools to appropriate clinical and line communities</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Lead NATO effort addressing auditory injury and troop reintegration</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Develop rehabilitation and restoration technologies with international partners</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Establish advisory boards</td>
<td>✓</td>
<td>✓</td>
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</table>

- **Green** - Completed
- **Yellow** - In Progress
- **Red** - Not Started
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<tbody>
<tr>
<td>INFORMATICS</td>
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<tr>
<td>Launch website</td>
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<tr>
<td>Develop requirements to interface Defense Occupational Environmental Health Readiness System- Hearing Conservation (DOEHRS-HC) data with authoritative personnel databases</td>
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<tr>
<td>Develop JHASIR architecture to interface DOEHRSHC data, clinical audiometric data, Joint Theater Trauma Registry (JTTR) data</td>
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<tr>
<td>Pilot the Joint Hearing Loss and Auditory System Injury Registry (JHASIR)</td>
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<tr>
<td>Publish Inter-Agency business rules for data capture and sharing – including signed MOAs</td>
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<tr>
<td>Provide VA DOEHRSHC data for baseline documentation</td>
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<thead>
<tr>
<th></th>
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<tr>
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</thead>
<tbody>
<tr>
<td><strong>RESEARCH</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Develop Auditory Research Program and charter Inter-Agency Auditory Research Working Group (ARWG)</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Partner with grant-sponsoring agencies (provide prioritization, scientific review, steering, programmatic review, and reporting)</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Coordinate auditory research portfolios between sponsoring agencies</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Consolidate auditory-vestibular scientific interests, resources and opportunities on interactive web-based platform. Target 2QFY13</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Host third collaborative research conference</td>
<td></td>
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<tr>
<td>Formal approval of MOU for HCE-Centralized IRB</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Lead multisite DOD investigation of implantable hearing aids</td>
<td></td>
<td>✔</td>
</tr>
</tbody>
</table>

- Green: Completed
- Yellow: In Progress
- Red: Not Started
JOINT STRATEGIC PLAN PROGRESS
**FY 2011 JSP MILESTONES**

<table>
<thead>
<tr>
<th>Date</th>
<th>Milestone</th>
<th>Status</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 Nov 11</td>
<td>Obtain approval of CONOPS, implementation plan, and resource requirements</td>
<td>Completed</td>
<td>Approved by DOD, 10 January 2012</td>
</tr>
<tr>
<td>30 Nov 11</td>
<td>Implementation plan activated with Initial Operating Capability (IOC) established</td>
<td>Completed</td>
<td>Staff on-board; Hearing.Health.Mil web site launched</td>
</tr>
<tr>
<td>30 Jun 11</td>
<td>Select location for Center Headquarters</td>
<td>Completed</td>
<td>59th Medical Wing (Wilford Hall Ambulatory Surgical Center), Lackland AFB, TX is the HCE “hub”</td>
</tr>
<tr>
<td>1 Dec 11</td>
<td>Select Director and Deputy Director</td>
<td>Completed</td>
<td>Executive Director appointed by ASD (HA). Discussions in final stages with VA to appoint Deputy</td>
</tr>
<tr>
<td>31 May 11</td>
<td>Develop CONOPS for the JHASIR</td>
<td>Completed</td>
<td>CPMB approved by Mar 2011</td>
</tr>
<tr>
<td>31 Aug 11</td>
<td>Develop a comprehensive plan and strategy to address prevention of noise-induced hearing loss</td>
<td>Completed</td>
<td>Plan finalized 31 Aug 11, robust implementation now underway with key DOD expert on staff</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>FY 2011 JSP MILESTONES</th>
<th>STATUS</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>31 Dec 11: Develop a comprehensive internal and external communication plan and launch</td>
<td>Completed</td>
<td>Plan finalized 31 Aug 2011, implementation began Oct 2011</td>
</tr>
<tr>
<td>outreach campaign</td>
<td></td>
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</tr>
<tr>
<td>30 Jun 12: Develop a comprehensive plan for collaboration with the VA, Govt. agencies</td>
<td>Pending</td>
<td>Relationships across federal and private sector entities well underway – need for formalization as an advisory board in consideration</td>
</tr>
<tr>
<td>and industry partners via the first meeting of the HCE Advisory Board</td>
<td>Completed</td>
<td></td>
</tr>
<tr>
<td>30 Jun 12: Develop a comprehensive plan for JHASIR utilization to encourage/facilitate</td>
<td>Pending</td>
<td>JHASIR architecture and reports feature under development – Courses of Action selected in January 2013</td>
</tr>
<tr>
<td>research, development of best practices and clinical education</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Joint Hearing Loss & Auditory System Injury Registry (J HASIR)

• NDAA Requirement
  – Develop a registry with bi-directional data exchange to identify and track incidence and care for hearing loss and auditory injury, and utilize registry data to encourage and facilitate the conduct of research, development of best practices and clinical education

• Key Accomplishments
  – Information security processes well underway
  – Collaborating with the Vision Center of Excellence is a focus; however, pursuing immediate solution to collect and house data within the Health Systems Data Warehouse (HSDW)
  – Collaborating with VA’s Hearing Loss Repository developers in Denver, CO

• Next Steps
  – Prototype hearing data collection at Wilford Hall by October 2013
  – If successful, implement at Army, Navy site (then, prepare for deployment across DOD – with VA accessibility)
  – Immediately, ensure VA has access to DOEHRS data – awaiting Data Use Agreement approval
VA/DOD Hearing Aids Purchasing
HEARING AID/ IMPLANT PURCHASE STANDARDIZATION

• Background
  – DOD standardization of hearing device purchasing through VA’s secure web-based system will improve efficiency and reduces DOD costs

• Key Accomplishments
  – February 2012 members from VA, Defense Logistics Agency-Troop Support (DLA-TS), HCE and Health Affairs Force Health Protection and Readiness (FHP&R) began planning
  – To use the VA as an acquisition source, DOD must approve a waiver from restrictions of NDAA FY 2008
    • Waiver under review by Acquisition Technology & Logistics (AT&L) / Defense Procurement Acquisition Policy (DPAP)

• Next Steps
  – Disseminate interim implementation policy to the DOD
  – Develop on site and web based training for audiologists
  – Develop ordering/payment interface between DoD/VA

14 January 2013
Centralized Institutional Review Board and Coordination Efforts
CENTRALIZED: IRB BACKGROUND

• **Background**
  – Joint collaborative research requires IRB approval from every engaged research facility
  – Army, Navy, Air Force and VA have varying review processes and policies
  – Process requires duplication of time and effort decreasing overall efficiency
  – DODI 3216.02 (Nov 2011) recommends single IRB review for multi-site research
  – Drafted MOA process for participating regional institutions, June 2010
  – Estimated Completion of Centralized IRB process: Dec 2013

• **Progress since May 2011**
  – Centralized IRB meeting with Health Affairs and Medical Research and Materiel Command (MRMC) decision to proceed with MRMC C-IRB plan, August 2011
  – Memorandum of Agreement (MOA) drafted to establish working relationship between HCE and MRMC, November 2011
  – MOA fully executed September 2012
  – Kickoff meeting between HCE and MRMC administrators took place December 2012
  – FOC reached December 2012
Research Productivity & Dissemination

- Coordination for Auditory Research (ARWG), Pharmaceutical Interventions for Hearing Loss (PIHL), Auditory Fitness for Duty (AFFD), and DOD Otology Working Groups
- Cross-COE efforts
  - ANSW2R/Polytrauma
  - CENC Consortium
  - Gaps Analysis
- NATO RTO 229 Efforts
Coordination

Performance | Prevention | Acute Care | Rehabilitation

Service Members | Veterans

INJURY

brain, psyche, vision, hearing, pain, extremity

MOM, CCC, CRM, ONR, ORD, NIH

14 January 2013
ARWG - Auditory research Working Group – Practice Based Research Network: 7 DoD Acoustic Research Labs, 6 MTFs, 5 VA sites

- Fitness for Duty, Total Comm and Protection, Job Task Analysis
- Pharm Intervention in Hearing loss, POI care, Air evacuation comm
- Clinical / translational investigations
Policy Changes
Considerations for Policy Changes

• Create a rapid process to develop data sharing agreements between DVA and DOD
  – Clinical and Claims data between agencies is highly relevant to effect change, yet very difficult to obtain data for improving outcomes of HCE programs

• Authorization for access to survey Service Members:
  – DTM 12-004 requires high-level coordination and approval
  – DD Form 2936-1, “Request for Sponsorship Transfer of DOD Internal Information Collection“ – cumbersome process

• Hearing acuity needs to be a readiness issue
  – Policy needed to conduct baseline audiograms for all new Service Members
  – Post-deployment hearing issues need immediate evaluation by qualified hearing specialist
Considerations for Policy Changes

• CRADA/T2 issues currently cannot be addressed on a DOD wide level and service specific routes are duplicative and time exhaustive
• Program 6 HCE funding does not support workstreams which require Program 8/RDT&E funding lines
• Strategic MOU for MTF Resource Sharing with the VA could champion value and experience of care
• Inter-agency IRB reliance between DOD and VA to promote longitudinal multisite study of transition outcomes and to improve Inter-agency partnering
Pending Decisions/ Approvals

- Next POM cycle to support necessary resources for FOC
- Focus group process to assess efficacy of HCE programs
- DALC/DLA
- CPG roadmap
- DIACAP AUDBASE/NOAH
- Clinical Portfolio Management Board (CPMB) to Theater Functional Working Group (TFWG) transition
- IRB Agreement for Institutional Review approvals
FACILITIES

• Background
  – Location – Hub and Regional Centers
    • Pre-BRAC
      – Wilford Hall Medical Center (WHMC), Lackland AFB
    • Post-BRAC
      – Wilford Hall Ambulatory Surgical Center (WHASC), Lackland AFB
    • DOD and VA Regional Centers

• Progress since May 2011
  – Transitioned to WHASC (Wing 6B)

• Resolution
  – Transition to be completed in phase IV MILCON construction of WHASC
    • HCE designed at 8,226 SF