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EXECUTIVE DIRECTOR

HEARING CENTER OF EXCELLENCE

Presentation to the Recovering Warrior Task Force
14 January 2013



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- 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)

INTRODUCTION



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INTRODUCTION

- **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

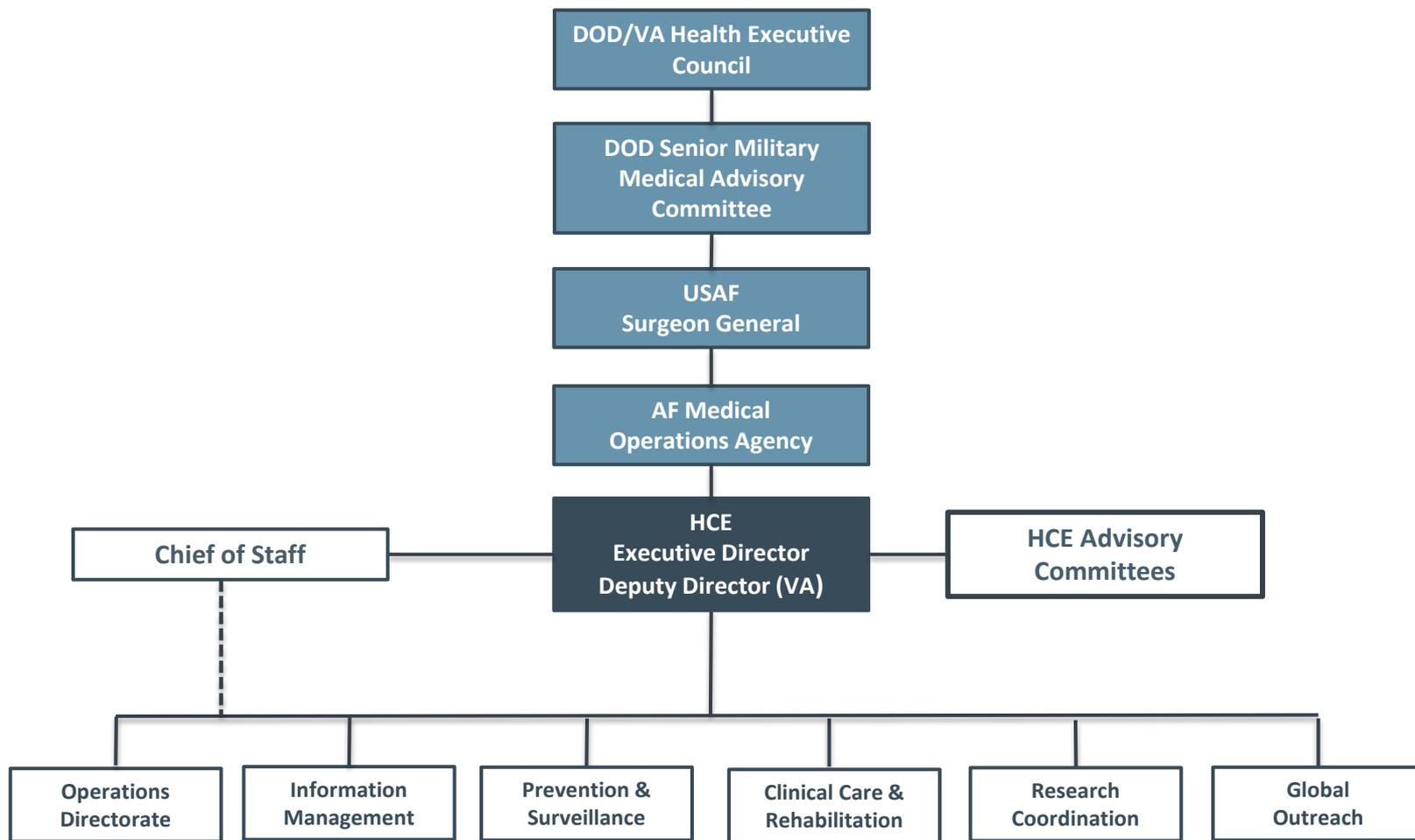


- **Public Law 110-417 Duncan Hunter National Defense Authorization Act (NDAA) 2009 Section 721:**
 - Secretary of Defense shall establish, within the DoD, centers of excellence (CoE) to include a CoE focused on the prevention, diagnosis, mitigation, treatment and rehabilitation of hearing loss and auditory 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

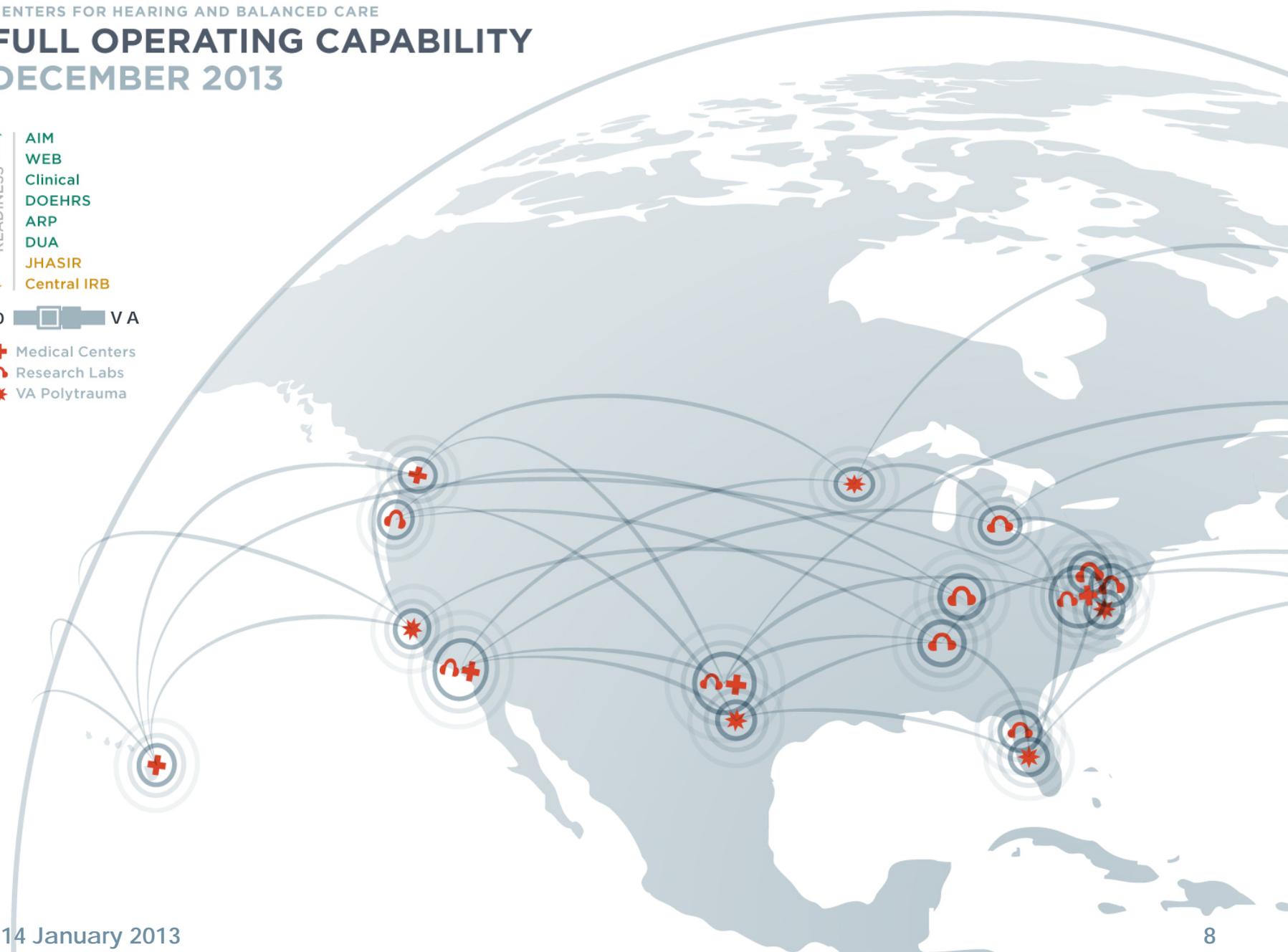
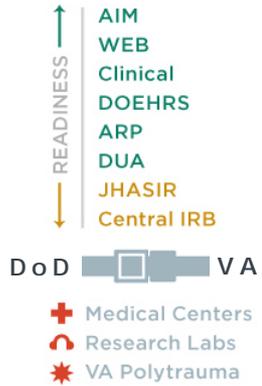


- HCE Mission
 - Heighten **readiness**
 - Improve the **health** and **quality of life** of members and veterans
 - Focus on the **prevention, diagnosis, mitigation, treatment, rehabilitation and research** of hearing loss and auditory-vestibular system injuries
- HCE Overview
 - Establish an auditory-vestibular 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





FULL OPERATING CAPABILITY DECEMBER 2013



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



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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



- 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



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GOALS & OBJECTIVES

PROGRAM		2011	Now
PREVENTION & SURVEILLANCE	Develop a Strategic Communications and Prevention Plan		
	Interval screening and questionnaire sampling of military population		
	Develop interactive web-based educational tools		
	Determine scope of FFD standards for appropriate Military Occupational Specialties (MOS)/AFSCs/Ratings		
	Publish qualified-products standards for hearing protection and communication systems		

Completed
 In Progress
 Not Started



GOALS & OBJECTIVES

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

Completed
 In Progress
 Not Started



GOALS & OBJECTIVES

PROGRAM		2011	Now
Global Outreach	Hearing Aid Purchasing Standardization – draft regulation		
	Partner with hearing health advocacy groups		
	Develop Hearing Health Caucus		
	Promote FFD, CPGs and clinical tools to appropriate clinical and line communities		
	Lead NATO effort addressing auditory injury and troop reintegration		
	Develop rehabilitation and restoration technologies with international partners		
	Establish advisory boards		

Completed
 In Progress
 Not Started



GOALS & OBJECTIVES

PROGRAM		2011	Now
INFORMATICS	Launch website		
	Develop requirements to interface Defense Occupational Environmental Health Readiness System- Hearing Conservation (DOEHRS-HC) data with authoritative personnel databases		
	Develop JHASIR architecture to interface DOEHRS-HC data, clinical audiometric data, Joint Theater Trauma Registry (JTTR) data		
	Pilot the Joint Hearing Loss and Auditory System Injury Registry (JHASIR)		
	Publish Inter-Agency business rules for data capture and sharing – including signed MOAs		
	Provide VA DOEHRS data for baseline documentation		

Completed
 In Progress
 Not Started



GOALS & OBJECTIVES

PROGRAM		2011	Now
RESEARCH	Develop Auditory Research Program and charter Inter-Agency Auditory Research Working Group (ARWG)		
	Partner with grant-sponsoring agencies (provide prioritization, scientific review, steering, programmatic review, and reporting)		
	Coordinate auditory research portfolios between sponsoring agencies		
	Consolidate auditory-vestibular scientific interests, resources and opportunities on interactive web-based platform. Target 2QFY13		
	Host third collaborative research conference		
	Formal approval of MOU for HCE-Centralized IRB		
	Lead multisite DOD investigation of implantable hearing aids		

Completed
 In Progress
 Not Started



JOINT STRATEGIC PLAN PROGRESS



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HCE JOINT STRATEGIC PLAN - 2012 PROGRESS

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

(Table continued on next slide)



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



Data Registry



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Joint Hearing Loss & Auditory System Injury Registry (JHASIR)

- **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

14 January
2013



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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

Centralized Institutional Review Board and Coordination Efforts



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- **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 (Nov2011) 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

Number of Active Studies in FY2012 (Coordination Efforts)				Number articles in of Peer-Reviewed Publications	Number of Poster/Podium Presentations
Number Under Development	Number in IRB Review	Number in Data Collection	Number Completed		
30	7	3	0	0	85

- 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

Veterans

Performance
Service Members

Prevention

Acute Care

Rehabilitation

INJURY

brain
psyche
vision
hearing
pain
extremity

MOM

CCC

CRM

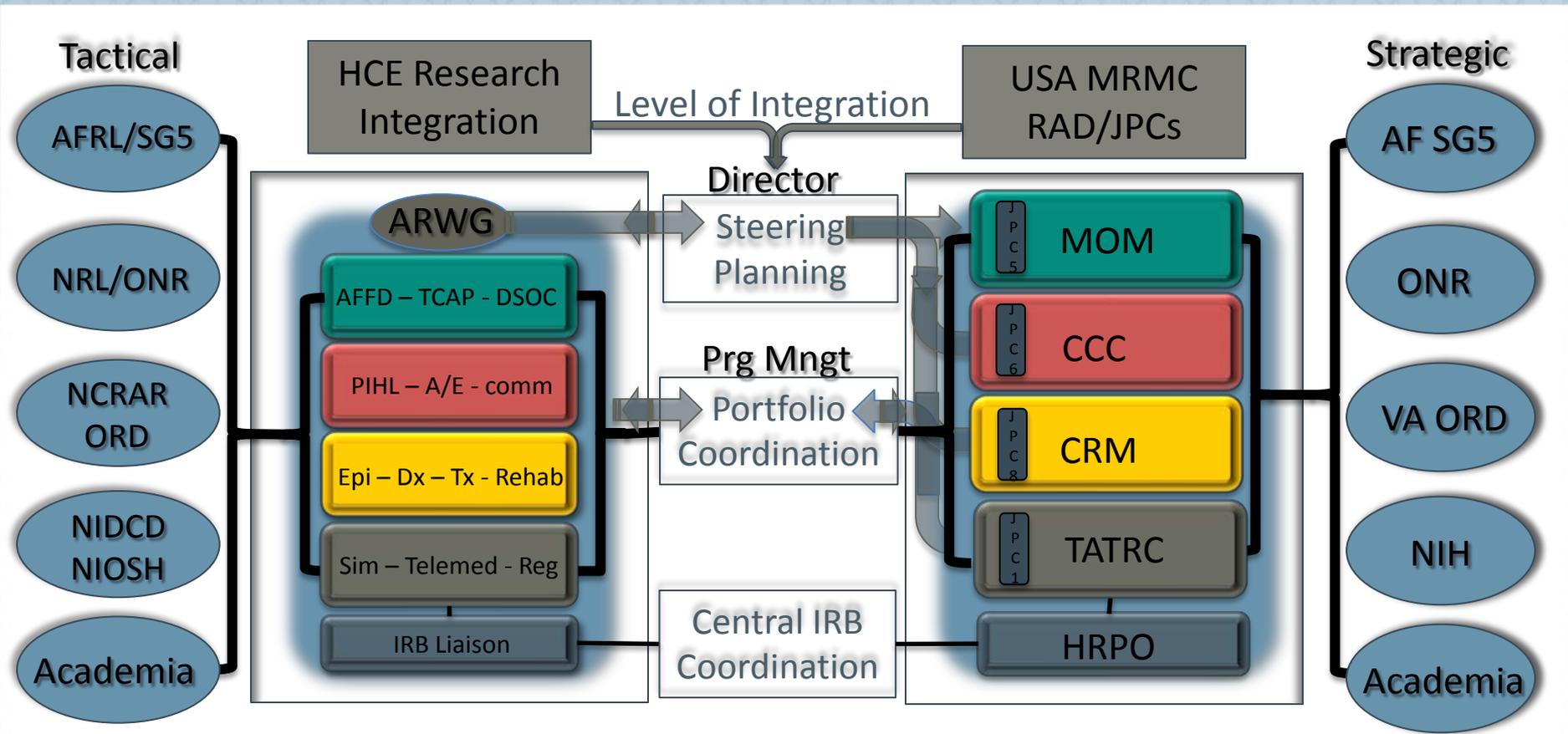
ONR

ORD

NIH



Programmatic Translational Research



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



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- **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

- 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

- 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



- **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



Hearing.Health.Mil