

Gulf War Veterans' Illnesses (GWVI) Task Force Action Item Update, as of 28 February 2011, compiled by Jeffrey Peters, Department of Veterans Affairs (VA)

PARTNERSHIPS:

Deployment Health Working Group (DHWG):

- During the past 3 months the DHWG has been monitoring new studies related to burn pit exposure and has been briefed by members of a Department of Defense (DoD) sponsored pulmonary research group on the latest research on burn pits and other potential pulmonary exposures.
- The DHWG is continuing work on a robust Data Transfer Agreement that facilitates research and medical surveillance on Veterans exposed to potential environmental hazards during deployment.
- Briefed Health Executive Committee (HEC) on 8 November on Update on Burn Pit Smoke Exposure Concerns. This briefing summarized the most recent report (May 2010) by DoD entitled "Epidemiological Studies of Health Outcomes among Troops Deployed to Burn Pit Sites," May 2010. The briefing also covered the current status of the VA sponsored IOM report "Long-term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan" and summarized the current and planned research by DoD and VA investigators.
- On December 6 the DHWG sponsored a one day seminar for over 50 DoD and VA personnel involved in environmental exposure research and policy. This meeting improved DoD/VA coordination and facilitated information sharing on environmental exposure issues.
- On 5 November the DHWG received an update on Depleted Uranium research and the Embedded Metal Fragment Registry.
- In November the DHWG submitted an issue paper to the HEC concerning specific data transfer concerns.

Congressionally Directed Medical Research Programs (CDMPR): VA staff engaged with DoD staff to collaborate more closely and reduce duplication. Meeting in December 2010

BENEFITS:

Following the initial 1990-1991 Gulf War, Veterans of this conflict began reporting chronic disability patterns that did not fit into commonly diagnosed disease categories. Scientific studies have associated these disability patterns with service in the Gulf War Theater. This led Congress to pass, and later revise, legislation codified at 38 U.S.C. § 1117. The statute identifies "undiagnosed illnesses" and diagnosed "medically unexplained chronic multisymptom illnesses" which qualify for disability compensation. VBA implemented this statute with regulations at 38 CFR § 3.317. The regulations mirrored the statute by identifying specific disability patterns that qualified for service connection when they occurred in Gulf War Veterans. These included chronic fatigue syndrome, irritable bowel syndrome, and fibromyalgia. The authorizing statute used these as examples of qualifying disability patterns. However, there was confusion as to whether the implementing regulations indicated that these were the exclusive and only such disability patterns that qualified for service connection.

- To correct this potential inconsistency, Veterans Benefits Administration (VBA) initiated a technical rulemaking change to § 3.317, which specifically incorporated language stating that these three qualifying disability patterns were only examples and not an exclusive listing. It became effective October 7, 2010, and is intended to open the door for service connecting other disability patterns where medical

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evidence and authoritative opinions indicate an association with Gulf War service. As a means to ensure that all regional office personnel understood this change and to help clarify the regulatory complexity of § 3.317, VBA produced Training Letter 10-01, *Adjudicating Claims Based on Service in the Gulf War and Southwest Asia*, and released it to regional offices on February 4, 2010. As part of a comprehensive initiative associated with this training letter, VBA conducted several nationwide training sessions through Microsoft Live Meeting broadcasts during February and March 2010. The goal was to explain the issues raised in the training letter, promote consistency in adjudicating these claims, and provide a forum for questions from the field. A major component of this training initiative involved instructing field personnel that the threshold for scheduling a Veterans Health Administration (VHA) examination was relatively low and that a Gulf War Veteran's lay statement of symptoms may be sufficient to trigger the examination. The training letter itself contained an attachment for the Veterans Health Administration (VHA) examiners explaining Gulf War disability patterns and the criteria for evaluating them.

- In addition to these initiatives, based on the Secretary of VA's determination that scientific evidence is sufficient to establish certain diseases as presumptively associated with Gulf War service, VBA has added nine new infectious diseases to § 3.317. The final rulemaking for these diseases became effective on September 29, 2010. Also based on scientific evidence and the Secretary's determination, VBA initiated proposed rulemaking in the Federal Register on November 17, 2010, to establish the disability pattern of functional gastrointestinal disorder as a qualifying presumptive associated with Gulf War service.

CLINICAL EDUCATION AND TRAINING:

Status New Veterans Health Initiatives (VHI): Caring for Gulf War Veterans, completed and posted in Learning Management System (LMS) January 2011.

- VHA personnel have given a total of 4 Exposure seminars to VA health care providers in the following locations: Indianapolis Indiana, Charleston, West Virginia, Portland, Oregon and Charleston, SC Carolina. A fifth seminar was conducted the week of February 22, 2011, in Dallas, Texas. The seminar in Dallas was the first to have an additional ½ day seminar to include a workshop on taking an exposure history.
 - In addition, grand rounds presented on Qarmat Ali to the clinical staff at the Indianapolis VAMC. A satellite broadcast also aired in July. More than 300 VA staff personnel have been trained via these programs.
 - These numbers are expected to increase as VA originally concentrated on the 4 states involved in Qarmat Ali. VA will be holding an additional 4 Seminars with a 1/2 day workshop added this fiscal year.

ONGOING SCIENTIFIC REVIEWS & POPULATION BASED SURVEILLANCE:

- Recommendation 4B: Improve collaboration with the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS) to ensure Veteran-specific identifying questions and analyses are included in two major longitudinal health-related national surveys: the National Health and Nutrition Examination Survey (NHANES); and the National Health Interview Survey (NHIS).

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- **Status:** The NHANES and NHIS will include in 2011 detailed questions regarding Veteran status to ascertain better enumeration of participants who have served in the military. These questions have been agreed upon by both NHANES and NHIS. NCHS has proposed a plan to develop a report on previously collected data that will provide preliminary information about NHANES participants who had reported past military service.
- **Recommendation 4C:** Improve collaboration between DoD and the VA Office of Research and Development (ORD) to ensure Veteran-specific data collection and analyses are included in the Millennium cohort Study (MCS).
- **Status:** Representatives from VHA Offices including Office of Public Health and Environmental Hazards (OPHEH) and ORD have been meeting regularly with MCS investigators, and planning analyses and a manuscript on the development of respiratory symptoms among study participants who have separated from active duty military status. This collaboration is proceeding well and results should be available during the third quarter of FY 2011.
- **Recommendation 4D:** Conduct a *National Health Study for a New Generation of U.S. Veterans* on the health status of 60,000 Veterans who have separated from active duty, National Guard, or Reserves, half of whom served in either Iraq or Afghanistan and half who did not; and oversample women Veterans to permit appropriate comparisons.
- **Status:** Data collection is complete and results are projected to be available in 2011. Planning for a clinical follow-up study with a physical examination component is underway. Regulatory requirements are being satisfied; staffing and procurement efforts are ongoing. The clinical follow-up study implementation is expected in the 2nd quarter FY11.
- **Recommendation 4E:** Explore with DoD the feasibility of using health records of Military Working Dogs (MWD) deployed and non-deployed to the 1991 Gulf War and to the current conflicts in Iraq and Afghanistan to determine if there are clinical conditions or post mortem diagnoses related to environmental exposures.
- **Status:** VHA has had negotiations with MWD Center at Lackland AFB and with AFIP to create a research database. There has been one presentation at an epidemiology research meeting, and preparations have begun for a special issue in 2011 of a peer-reviewed environmental health journal. VHA staff met with staff from the MWD Center during the first week in January 2011 and proposed a project to review MWD health records. That proposal is now under consideration.
- **Recommendation 4F:** Continue to fund the study of Post War Mortality from Neurological Disease in Gulf War Veterans at least through 2013.
- **Status:** The original study of Post War Mortality from Neurological Disease in Gulf War Veterans is complete. VA will conduct an additional study, with results expected in 2013. Study documents have been submitted and approved by the VAMC DC IRB. The acquisition package has been submitted to a VHA contracting officer and a solicitation is being prepared.
- **Recommendation 4G:** Conduct a follow-up study of an established permanent panel of 30,000 deployed and non-deployed Veterans from the 1990 – 1991 Gulf War period. Baseline and follow-up data have been previously collected. This study will

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provide health trends over time and the current status of the health of 1990 – 1991 Gulf War Veterans.

- **Status:** A study proposal has been prepared and approved by the VAMC DC Internal Review Board (IRB). An Office of Management and Budget (OMB) justification package has been submitted to OMB through the VHA OMB liaison and the 60 day Federal Register Notice "Comment Request" was published September 7, 2010. VA received several comments and responded to all questions. We are awaiting OMB approval to proceed with the survey. Completion of data collection is planned for 2013, and results should be available for publication in late 2013 or 2014.

ENHANCED MEDICAL SURVEILLANCE OF POTENTIAL HAZARDOUS EXPOSURES

The Qarmat Ali Medical Surveillance Program:

- Officially launched on 27 July 2010 when VA began contacting Veterans by phone and offering enrollment in the medical surveillance program.
- A letter has been signed by both Secretary Shinseki and Secretary Gates. This letter is being mailed beginning the week of February 21, 2011, as certified mail with a return receipt, to remain cognizant of whom VA has not reached.
- To date, VA has contacted 390 Veterans directly by phone. Of these, 278 have asked to be enrolled in the program and 9 had already had an exam prior to our contact. This is an enrollment rate of 74% of those contacted. This is well above the 50% rate of Operation Enduring Freedom (OEF) / Operation Iraqi Freedom (OIF) Veterans using VA health care services.
- VA staff is working with DoD and the National Guard to get updated contact information for those we cannot reach.
- VA has not yet evaluated any information from the examinations. VA will wait until the majority of those involved have been contacted and had time to have an appointment for the examination.

RESEARCH & DEVELOPMENT:

New Office Research and Development (ORD) Gulf War (GW) position

- The position description for the GW position in ORD has been sent to Human Resources and a posted job announcement is expected imminently
- Dr. Robert Jaeger has been named as the acting Director of Deployment Health Research
- A separate job announcement for a permanent Director has been posted

Annual GW Research and Development funding

- From the previous Request for Applications (RFAs): 2 new clinical trials and a new animal study to identify therapeutic targets will begin funding in FY 2011
- ORD will reissue the three RFA as promised in the Task Force report (RAC members had the opportunity to review at the November meeting). Additionally, they will issue two new RFAs for pilot projects.
- All five RFAs will be on the street in March or April 2011
- VA ORD continues in its support for state-of-the-art neuroimaging studies

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Cooperative Studies Program (CSP) GW Cohort Study:

- On January 6, 2011 VA-ORD approved funding for a 2-year pilot study to determine the best methods for creating and managing a cohort and biorepository of blood samples from Gulf War Era Veterans
- The longitudinal research database and biorepository will be used to enhance ongoing research, facilitate new research on GWVI, and study other chronic diseases that may these Veterans
 1. Assess the feasibility and efficacy of recruiting, consenting, and blood collection and management processes for a geographically diverse sample of Gulf War Era Veterans
 2. Develop, test, and implement the technical and administrative aspects for maintaining the cohort
 3. Initially, the research database will be populated with data from participating veterans using 2 survey instruments; the Genomic Medicine Short Form Survey and the Follow-up Study of a National Cohort of Gulf War and Gulf Era Veterans Survey (see Recommendation 4G above).
 4. These surveys will be supplemented by data collected from medical records, national VA resources and from prior studies of Gulf War era veterans

Gulf War Biorepository

- On February 25, 2011 VA-ORD approved funding for a 2-year pilot study to expand the Amyotrophic Lateral Sclerosis (ALS) Brain Bank to develop a GWVI Biorepository
- The GWVI Biorepository will accept postmortem donations of CNS (brain and spinal cord) and non-CNS tissue from 1990-91 Gulf War Veteran who wish to donate

Research Advisory Committee on Gulf War Veterans' Illnesses (RAGWVI)

- RACGWVI will meet on February 28-March 1
- The meeting will include a discussion panel of 10 VA Gulf War investigators plus representatives from the new GW Cohort Study and the GW Biorepository.
 1. These investigators have been funded by VA and/or the CDMRP Gulf War Illnesses Research Program
 2. Their research includes clinical trials of new therapies, identification of new biomarkers, and animal studies to identify new therapeutic targets.

Interactions with CDMRP Gulf War Research program

- Dr. Goldberg participated in the FY 2011 Vision Setting meeting on Dec 2, 2010
- The VA Gulf War research portfolio was discussed
- VA plans for new and revised RFAs were discussed
- Ways in which the 2 programs could and could not directly interact were discussed

Gulf War Steering Committee

- The Gulf War Steering Committee has met twice (June and October 2010)
- A 3rd meeting is being scheduled for March or April 2011
 1. Review recommendations from the Feb-Mar RAC meeting
 2. Meet with representatives from the CDMRP Gulf War Illness Research Program to discuss ways to better interact
 3. Meet with VA Gulf War researchers
 4. Discuss ways to improve outreach efforts to promote the VA Gulf War research program

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OUTREACH:

- Gulf War Review and Gulf War related Web sites:
 - Published an edition of Gulf War Review commemorating the 20th anniversary of the Gulf War and commemorative poster.
 - Editorial process and review have been streamlined. Next issue is underway and due to be published by summer 2011.
 - Plan to engage stakeholders by sponsoring focus groups to solicit feedback from Gulf War Review readers. Project due to be completed by fall 2011.
 - Continued to review all VA sponsored web sites related to the Gulf War to ensure information is up to date and accessible. In the 2nd quarter FY11 plan to review structure and navigation of web sites to ensure ease of use.
- Published new brochure on health registry programs, including the Gulf War Registry. Brochure was promoted and distributed to VAMCs, Vet Centers, VA Regional Offices, VSOs and Veterans, and VA program offices.
- Recent Key Dates GW Outreach Highlights:
 - 17 January 2011 – AIR WAR ANNIVERSARY, Blog post by Brandon Friedman on VAntage Point that marked the transition from Operation Desert Shield to Operation Desert Storm, the event that inspired his own military service year later. <http://www.blogs.va.gov/VAntage/?p=1197>
 - 23 February 2011- GROUND WAR ANNIVERSARY, Blog post by CoS John Gingrich: Personal story and VA's progress in supporting Gulf War Veterans, and ask for era photos from Gulf War Veterans. 28 February 2011

MISCELLANEOUS ACTION ITEMS:

Institute of Medicine (IOM) Update:

- Statement of Work for, "Best Treatments for Multi-Symptom Illness" in Gulf War Veterans has been reviewed by VHA. IOM has forwarded a formal proposal to VA. The study is now awaiting action by contracting.
- IOM study "Long-term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan" is currently in process and due to be reported out in late 2011.

Southwest Asia Veterans System (SWAVETS) Reports Update:

- Draft Gulf War Era Veterans Report: Pre 9/11: due 1 October 10, Completed January 2011
- Final product released to public 23 February 2011, may be found this link: http://www.va.gov/vetdata/docs/SpecialReports/GW_Pre911_report.pdf