

Research Advisory Committee on Gulf War Veterans' Illnesses

**Committee Meeting Minutes
June 25–26, 2018**

**U.S. Department of Veterans Affairs
Washington, DC**

Research Advisory Committee on Gulf War Veterans' Illnesses
Committee Meeting Minutes

I hereby certify the following minutes as being an accurate record of what transpired at the June 25–26, 2018, meeting of the Research Advisory Committee on Gulf War Veterans' Illnesses.



Stephen L. Hauser, M.D.
Chair, Research Advisory Committee on Gulf War Veterans' Illnesses

Attendance Record

Members of the Committee:

Dr. Stephen Hauser, Chair
Ms. Kimberly Adams (telephone)
Mr. James Bunker
Dr. Fiona Crawford
Ms. Marilyn Harris (telephone)
Dr. Stephen Hunt
Dr. Nancy Klimas
Dr. Katherine McGlynn
Mr. Jeffrey Nast
Dr. Stephen Ondra (telephone)
Ms. Frances Perez-Wilhite
Dr. Scott Rauch (telephone)
Dr. Caroline Tanner
Dr. Mitchell Wallin
Dr. Scott Young (telephone)

Committee Staff:

Mr. Stanley Corpus
Mr. John Rukkila
Dr. Jon Van Leeuwen

Designated Federal Officer:

Dr. Karen Block

Invited Speakers:

Dr. Wes Ashford, VA Palo Alto
Dr. Peter Bayley, VA Palo Alto
Dr. Howard Fields, University of California, San Francisco
Dr. Karunesh Ganguly, San Francisco VA Medical Center
Mr. Jeff Gracianette, retired U.S. Army (1988 to 1995) Gulf War Desert Shield/Desert Storm Veteran
Dr. Drew Helmer, VA East Orange, NJ
Dr. Steve Hunt, VA Puget Sound
Dr. Lawrence Steinman, Stanford University
Dr. Michael Wilson, University of California, San Francisco

VA Personnel

Mr. Jeffrey Moragne, Director and Management Officer, VA Advisory Committee Management Office
Dr. Matthew Reinhard, WRIISC, Washington, DC VAMC
Ms. Marsha Turner, VA Office of Research and Development, Cooperative Studies Program

Veterans:

Ms. Angie McLamb (telephone)
Ms. Denise Nichols
Ms. Marsha Young (telephone)

**Meeting of the Research Advisory Committee on Gulf War Veterans' Illnesses
Department of Veterans Affairs**

**LOCATION: Intercontinental Mark Hopkins in the California & Powell Room
(999 California Street, San Francisco, CA 94108)**

Call-in: (800) 767-1750; access code 56978#

Watch Online: <http://va-eerc-ees.adobeconnect.com/racgwvi-june2018/>

**Agenda
Monday, June 25th, 2018**

9:00 – 9:15	Introductory Remarks	Dr. Stephen Hauser, Chairman Res Adv Cmte on GW Veterans' Illnesses
9:15 – 9:45	Neurological Health in Gulf War Veterans	Dr. Lawrence Steinman Stanford University
9:45 – 11:00	GWI Patient Case Series	Dr. Wes Ashford and Dr. Steve Hunt VA Palo Alto and VA Puget Sound
11:00 – 11:15	Break	
11:15 – 12:30	Roundtable Discussion on Treatments for Gulf War Veterans	Dr. Stephen Hauser, Chairman Res Adv Cmte on GW Veterans' Illnesses and Invited Speakers
12:30 – 1:30	Lunch	
1:30 – 2:15	Placebo Analgesia: Understanding How Expectations Become Self-Fulfilling	Dr. Howard Fields UCSF
2:15 – 3:00	Emerging Technology in Rehabilitative Medicine	Dr. Karunesh Ganguly San Francisco VA Medical Center
3:00 – 3:15	Break	
3:15 – 4:00	VA Updates on GW Program and RAC-GWVI Recommendations	Dr. Karen Block VA Office of Research and Development
4:00 – 4:30	Committee Discussion	Dr. Stephen Hauser, Chairman Res Adv Cmte on GW Veterans' Illnesses
4:30 – 5:00	Public Comment	
5:00	Adjourn	

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**Agenda
Tuesday, June 26th, 2018**

8:45 – 9:00	Introductory Remarks	Dr. Stephen Hauser, Chairman Res Adv Cmte on GW Veterans' Illnesses
9:00 – 9:45	TBD	TBD
9:45 – 10:30	Autoimmune Diseases and Diagnostics	Dr. Michael Wilson UCSF
10:30 – 10:45	Break	
10:45 – 11:30	Preliminary Report of Post-deployment Health Services Needs Assessment	Dr. Drew. Helmer VA East Orange, NJ
11:30 – 12:00	Committee Discussion	Dr. Stephen Hauser, Chairman Res Adv Cmte on GW Veterans' Illnesses
12:00 – 12:30	Public Comment	
12:30	Adjourn	

**Meeting of the Research Advisory Committee on Gulf War Veterans' Illnesses
U.S. Department of Veterans Affairs**

June 25th, 2018

Minutes

Introductory Remarks:

—Dr. Stephen Hauser, Chair, Research Advisory Committee on Gulf War Veterans' Illnesses

Dr. Hauser welcomed committee members, presenters, and attendees to the meeting. He reiterated that 2018 RAC-GWVI priorities are to focus on the two 2017 recommendations: Continue partnership with the National Institutes of Health for a deep phenotyping study of Gulf War illness and chronic fatigue syndrome; and continue conceptualization of the Coordinated Centers concept. He introduced Dr. Karen Block, who as Designated Federal Officer (DFO), offered notes on meeting proceedings to open the meeting. Dr. Hauser announced an agenda change that the Acting Secretary for the VA would no longer be able to join the meeting. He also noted ongoing transitions in VA leadership, including a confirmation hearing on June 27th for Mr. Robert Wilkie, the nominee for VA Secretary.

Session 1: Neurological Health in Gulf War Veterans

—Dr. Lawrence Steinman, Stanford University

Dr. Steinman, a Stanford University neurologist and immunologist, reviewed past studies on neurologic health in Gulf War Veterans and presented conclusions from a National Academy of Medicine (NAM) report that he served on. Dr. Steinman was a Committee member for the NAM (formerly the Institute of Medicine) report on *Considerations for Designing an Epidemiologic Study for Multiple Sclerosis and Other Neurologic Disorders in Pre and Post 9/11 Gulf War Veterans*. Dr. Steinman highlighted past studies investigating neurological conditions, such as multiple sclerosis, in Gulf War Veterans. He reviewed the charge to the NAM committee to design and manage an epidemiologic study of the incidence and prevalence of neurologic disorders associated with Gulf War Veterans and that the committee conclusion had been not to proceed with the study because of major limitations with the data. The Committee had concluded a rigorous study could not be conducted relying solely on VA data and there were challenges in constructing a suitable comparison group. Follow-up discussion for the presentation included connecting large data sets to investigate Veteran health issues, including neurological conditions, with Gulf War service.

Session 2-A: The Evolution of VA Approaches to the Management of Chronic Multi-Symptom Illness in Gulf War Veterans

—Dr. Steve Hunt, VA Puget Sound

Dr. Hunt, National Director for the Post-Deployment Integrated Care Initiative (PDICI), provided insight about how Veterans are affected by unexplained chronic multi-symptom illness (CMI) and about the nature of medical care for Veterans within the VA. Dr. Hunt gave an overview and history of CMI care for Gulf War Veterans at the VA. He presented what is and is not known about CMI and stressed that the related health issues are complex and that recognizing this complexity can help to effectively manage unexplained symptoms. He described that Gulf War Veterans suffer from multiple exposures and conditions not conducive to good health, are chronically ill and need healthcare for ongoing health issues, particularly following deployment. He noted that it is not necessary to know the specific cause of a symptom or problem in order to provide treatment and there is much that can be done to help Veterans

suffering from unexplained symptoms. Dr. Hunt presented approaches to VA management of CMI in Gulf War Veterans, their pathway to entry into care, and post-deployment integrated care. He described a stepped-care approach to post-deployment care starting at the primary care level with local expertise to help out as needed and the WRIISCs as tertiary care.

Session 2-B: Caring for ODS/S Veterans at the WRIISC: Focus on Symptoms: Chronic Pain, Chronic fatigue, Irritable Bowel Syndrome, etc.

—Dr. Wes Ashford, VA Palo Alto

Dr. Ashford, Director of the California War Related Illness and Injury Center (WRIISC), presented next focusing on case studies of providing care to Gulf War Veterans and treatment of their symptoms at the WRIISC. He began with an overview and history of the WRIISCs, Gulf War exposures and living conditions, exposure concerns, and case definitions for Gulf War illness. He reviewed the constellation of symptoms and problems reported by Gulf War Veterans seen at the WRIISCs and discussed how care is provided that encompasses these issues in a coordinated way through integrated care platforms and teams. Dr. Ashford presented cases of three Veterans with a variety of symptoms and diagnoses, particularly chronic pain syndromes, characteristic of Gulf War illness. He discussed care and management for Gulf War illness unexplained symptoms with a patient-centered approach to reduce pain, fatigue, and bowel instability and a focus on fitness and healthy diet plus inclusion of complementary and alternative medicine therapies.

Session 3-A: Comparative Efficacy of Yoga vs. Cognitive Behavioral Therapy for Treating Chronic Pain in Gulf War Illness: Preliminary Findings

—Dr. Peter Bayley, VA Palo Alto

Dr. Bayley, a principal investigator at the WRIISC, reviewed his clinical trial evaluating yoga for treating chronic pain in patients with Gulf War illness. He reviewed previous research indicating yoga may be effective for treating symptoms of fatigue, gastro-intestinal problems, and musculoskeletal pain. He described how the WRIISC success with yoga as clinical treatment inspired their clinical trial to assess the efficacy of yoga vs. cognitive behavioral therapy in reducing chronic pain in patients with Gulf War illness. Dr. Bayley reviewed the preliminary results of the clinical trial that showed yoga was effective at reducing pain at the end of a 10-week treatment trial and at 6-month follow-up. He discussed plans for follow-up analyses and publication in a scientific journal.

Session 3-B: Gulf War Veteran Discussion on Treatments

—Invited Speaker Jeff Gracianette, Gulf War Desert Shield/Desert Storm Veteran.

Mr. Gracianette reviewed his military service in the Gulf War and deployments to other military conflicts and military duty stations. He described his various symptoms and diagnoses, particularly chronic pain and cognitive dysfunction, characteristic of Gulf War illness. He detailed his difficulties with VA health care in being medically diagnosed, the complications and confusions in getting an accurate diagnosis, and problems he experienced in getting appropriate care from the VA. Mr. Gracianette reviewed varied treatments and medications he received and their past and present effectiveness in management of his daily symptoms.

Session 3-C: Follow-up Roundtable Discussion on Treatments

—Dr. Stephen Hauser, Chair, Research Advisory Committee on Gulf War Veterans' Illnesses, Invited Speaker Jeff Gracianette, RAC-GWVI Committee Members, and Presenters.

Dr. Hauser asked the Committee to consider how to make VA research more impactful for the health of Veterans. A range of topics were covered including: Dr. Stephen Hunt compared the effectiveness of the

military Comprehensive Clinical Evaluation Program (CCEP) and Gulf War registry program and their use in getting a comprehensive evaluation on Veterans to start their care. Dr. Howard Fields reviewed that hypothesis-based research has allowed physician researchers to further scientific discovery through in-depth review with patients and by keeping focus on what is really going on in the patient. Dr. Steinman noted that inflammation when treated with medications may also result in resolution of pain and Dr. Hauser stated that increased funding for pain research at all levels in the VA could have a significant impact.

Session 4: What is Placebo Analgesia: And How Does It Happen?

—**Dr. Howard Fields, University of California, San Francisco**

Dr. Fields, a professor of neurology and physiology who has made major contributions to understanding and treating pain, gave an overview of placebo analgesia, what it is, and its biological underpinnings. He noted chronic pain is a major problem for 30% of the U.S. population and 50% of the Veteran population suffers from chronic pain. Dr. Fields reviewed that a beneficial placebo effect may be produced by a placebo drug or treatment, cannot be attributed to the biochemical properties of the placebo itself, and therefore the patient's expectations play a role in influencing the treatment effect. He stated that negative outcomes are common in placebo controlled clinical trials for analgesics and the question is whether the treatment is ineffective or is the placebo too effective. He reviewed the biological circuits underlying pain transmission and modulation as well as that these pathways can be influenced not only by medications but also by a patient's expectations. Dr. Fields stated that all treatments include a bidirectional expectation component and that expectations can facilitate or inhibit pain via a modulatory circuit. He concluded by discussing the clinical implications of the placebo effect phenomenon, such as patient expectations may influence clinical outcomes and how repeated failure "stacks the deck" against even otherwise effective treatments.

Session 5: Neural Engineering Approaches to Neurorehabilitation

—**Dr. Karunesh Ganguly, San Francisco VA Medical Center**

Dr. Ganguly, a clinical neurologist and research scientist focusing on using advanced technology in the neurological rehabilitation of patients with stroke and brain injury, provided an overview of brain-computer interface for functional restoration and neural interfaces to enhance motor function after stroke/brain injury. He reviewed technology used to record and decode neural signals that actuate movement and feedback into the system, creating closed-loop interfaces for rehabilitation. He outlined neural interfaces for functional restoration and development of neural interfaces for the injured brain that augment and enhance motor function. He described a distributed motor network with quasi-oscillatory pulse activity that can deliver precisely targeted stimulation and facilitate prosthetic limb control to enhance motor function for skilled reaching. Dr. Ganguly stated that to improve clinical research in this area at the VA, it is important to foster collaboration with commercial entities and to have clear guidance from the Office of General Counsel on how VA investigators can properly navigate these partnerships.

Session 6: Gulf War Research Program and 2017 RAC Recommendations

—**Dr. Karen Block, VA Office of Research and Development**

Dr. Block as the new Designated Federal Officer (DFO) for the RAC-GWVI and senior program manager for the Gulf War program of the VA's Office of Research and Development (ORD) reviewed the ORD Gulf War Research Program and provided an update on the 2017 Committee recommendations. She described the organizational structure of ORD and its mission. She provided an overview of funding for the ORD GW Research Program and how its funding policies for investigator-initiated projects compares to other VA ORD programs and to Department of Defense funded projects. Dr. Block noted updates on the two 2017 RAC-GWVI recommendations recently signed-off by the Acting Secretary of VA. The VA

response to the recommendations were: (1) concur with conducting a study in partnership with the NIH on deep phenotyping of Gulf War illness and chronic fatigue syndrome, which is now called Project IN-DEPTH; (2) concur-in-principle with piloting and establishing a coordinated system of centers and expertise focused on complex chronic conditions of post-deployment, which will have to be coordinated with VA's modernization plan, but VA has identified short- and long-term action items.

Public Comment

Denise Nichols, Gulf War Veteran, provided comments on a range of topics including: suggesting future RAC-GWVI meetings be held in other cities; making scientific information reviewed more accessible to Veterans; concerns about the health of Veterans' offspring; accuracy of Veteran death and cancer rates; using medications and laboratory tests for improving blood oxygen and health of Veterans.

Marsha Young, Gulf War Veteran on the phone line from Kansas City, suggested: have meeting in locations more economical for Veterans to attend, such as Kansas for example; summarize in layman terms the scientific content of meeting and post online; have a virologist review of Gulf War illness; follow-up on combat Gulf War female Veterans who are noting in social media correspondence that they are experiencing seizure disorders.

Angie McLamb, Gulf War Veteran on the phone line from Indiana, commented on: deployment records not always accurate for locations and dates because units frequently moved; experiencing pain, trouble breathing, and intolerance to chlorine in swimming in pools after she returned from deployment; hair loss after deployment and wondering if it could be a biomarker; her experience with memory problems and treatment considerations; VA doctors need more time to be thorough and effective in their medical workups that should include obstetric and gynecological review; previous research on Veteran spouses that was lost and recovered should be reviewed.

Kimberly Adams, Committee member on the phone line from central northeast Ohio, commented: she is in contact with a group of 15 female Army Veterans deployed during Desert Storm and 7 have either breast or ovarian cancer, which she suggested for further discussion by the Committee; suggesting meetings routinely include case study reviews to better inform Veterans; holistic care as necessary for interdisciplinary treatment of Veterans and their families.

Adjourn

Dr. Hauser, RAC-GWVI Chair, adjourned the Committee meeting and noted continuation of the meeting on Tuesday, June 26th.

**Meeting of the Research Advisory Committee on Gulf War Veterans' Illnesses
U.S. Department of Veterans Affairs**

June 26th, 2018

Minutes

Introductory Remarks:

—**Dr. Stephen Hauser, Chair, Research Advisory Committee on Gulf War Veterans' Illnesses**

Dr. Hauser welcomed committee members, presenters, and attendees to the continuation of the meeting. He introduced the speaker for the first presentation.

Session 7: Autoimmune and Immune Repertoires in Neuroinflammatory Disease

—**Dr. Michael Wilson, University of California, San Francisco**

Dr. Wilson, a neurologist at UCSF whose research focuses on infectious and autoimmune syndromes of the central nervous system and the development of genomic technologies to identify causes of autoimmune disease, presented a newly developed and state-of-the-art technique for detecting autoantibodies. He described the novel protocol, clinical applications and their significance, and presented three case reviews of patients with viral infections and autoimmune and neuroinflammatory disease. Dr. Wilson also presented research that identified clonally-related B cell subsets that persisted in cerebrospinal fluid over time in a cohort of 10 multiple sclerosis patients. To close, he discussed current limitations and future directions for using a phage-based approach to autoantibody detection in neuroinflammatory disease.

Update: Common Data Elements Development

—**Dr. Nancy Klimas, Nova Southeastern University and Miami VA Medical Center**

Dr. Klimas, a clinical immunologist and a RAC-GWVI member who is also leading on the VA effort to develop Common Data Elements (CDE) for Gulf War illness, updated progress on development of the core CDEs for Gulf War illness. She described supplemental highly recommended CDEs and discussed their relevance. Dr. Klimas reported that the process is on schedule to meet a goal of completing a final document to be presented to the RAC-GWVI at the September 2018 meeting, following which there will be a public comment period of 30 days and the finalized document will be posted online on VA and NIH websites. She announced another ORD-funded field-based meeting that will focus on establishing a Gulf War illness research case definition that will complement the effort led by VA Central Office to establish a clinical case definition for Gulf War illness.

Session 8: Preliminary Report of VHA Post-Deployment Health Services Needs Assessment

—**Dr. Drew Helmer, VA East Orange, NJ**

Dr. Helmer, Director of the New Jersey WRIISC who has extensive experience in deployment health issues, presented his findings from a preliminary report of a Veterans Health Administration (VHA) post-deployment health services needs assessment. He stated that PDHS/WRIISC was named a core and foundational service of the VA and it focuses on delivering health care to Veterans who have concerns about occupational and environmental exposures, unexplained conditions, suspected adverse reactions to prophylaxis, or sequelae of deployment-related injury and trauma. He presented data depicting where veterans receive care and how many receive care at the VA, noting that active VHA users may be close to

32% of living veterans. He noted PDHS provides integrated stepped care according to intensity of need and provided estimates for what percentage of VHA users need PDHS-related services at each level. Dr. Helmer presented ideas and a vision for PDHS/WRIISC and discussed beneficial implications for research if such a system were implemented with specialty stepped care and training. The presentation and ensuing discussion were very pertinent to the recommendation made by the RAC-GWVI for the VA to establish a coordinated system of centers focused on post-deployment health issues. During discussion with the Committee, Dr. Helmer indicated that PDHS and ORD could work together more closely to address research considerations as the vision for PDHS/WRIISC comes into focus. There was also discussion of recent high-level policy issues relevant to VA (e.g., VA Mission Act and ongoing VA modernization efforts).

Committee Discussion

A separate session was not commenced for Committee discussion; however, Committee discussion essentially merged with extended discussion after Dr. Helmer's talk. Committee members, presenters, and attendees also had discussions during an extended break before Dr. Helmer's presentation.

Public Comment

Denise Nichols, Gulf War Veteran, made comments addressing: alternative locations for holding RAC-GWVI meetings; engaging private sector medical societies; transfer of medical data from military service to VA; encourage doctors to write-up Gulf War-related cases; making information available on family caregivers; interest in VA facilitating its doctors ability to communicate with specialists electronically to request guidance in treating Veterans; regularly including veteran outreach sessions as part of Committee meetings; ensure follow-up review education of VA adjudicators; noted the development of the Gulf War memorial will begin and encouraged people to donate to support its construction.

Jeffrey Moragne, Director and Management Officer, VA Advisory Committee Management Office presented congratulations on a meeting that he described as very productive, very well focused, and very well executed. He noted that a separate VA Family Care Giver and Survivor Advisory Committee focuses on families, care-givers, and survivor issues to provide advice and recommendations to the Secretary. He cautioned the RAC-GWVI to focus on operating within the boundaries of their charter, which does not permit advertising or promoting third parties even if focused on a good cause, such as development of memorials.

Marsha Young, Gulf War Veteran on the phone line from Kansas City, gave comments on: expressing thanks to Dr. Hauser for his promotion of and continued work in the field of genetics and translational medicine practices and processes that are essential to Veterans; thanks to the advocacy by Denise Nichols to facilitate and increase Veteran referrals to the WRIISCs; doctors outside of the VA not being educated about Gulf War illness but also only 10% of VA doctors are educated on Gulf War illness and VA facilities continue to be understaffed.

Committee members discussed possibilities for better engaging Veterans; it was discussed that often Veterans want information on issues related to claims and compensation benefits processes, which are beyond the scope of the Committee's charter and engaging on those issues would need be led by the VA rather than the RAC-GWVI; however, it was noted that it would be informative for the Committee to hear about current barriers the Gulf War Veterans face and to determine how implementation of novel scientific technologies and clinical trials could assist in better quality of life.

Adjourn

Dr. Hauser, RAC-GWVI Chair, thanked the Committee for a productive meeting, adjourned the meeting, and announced the Committee will meet again in September of 2018.