

ADVISORY COMMITTEE MANAGEMENT OFFICE (ACMO)
Annual Assessment of Committee Activities

January 1, 2021 through December 31, 2021

Committee Name: Research Advisory Committee on Gulf War Veterans' Illnesses (RACGWVI)

Calendar Year 2021 Committee Goals: State whether the goals were fully met, partial met or not met and provide measurable results for every goal the committee management identified for calendar year

The Committee fully met the projected 2021 goals.

VA Strategic Goals: The Committee met the projected goals:

1. Parent committee meetings and activities: **Goal: Hold three parent RACGWVI open committee meetings to develop new 2021 recommendations to advise the VA Secretary.**

As the global pandemic continued in FY21, the RACGWVI parent committee successfully held four virtual, open public meetings. Despite the move to virtual meetings, attendance in all committee and subcommittee meetings held or increased from previous meetings due to enhanced efforts by RAC staff to work with VA and Veteran partners to expand outreach.

As part of strategic planning following the first VA:DoD Gulf War Illness (GWI) State of the Science Conference held in August 2020, RACGWVI members worked together to review and present key oral presentations in the conference topic areas of biorepositories, treatments, epidemiology, pathobiology, and definition and diagnostic biomarkers at the first parent committee meeting in FY21. The second parent meeting in March 2021, centered around promising research studies determined closest to implementation. These studies were selected for a deeper dive with the key investigators. Presentations were divided into two areas, biomarkers and therapeutics, and followed by a roundtable discussion with the investigators and committee members. These meetings were highly successful, helping to identify treatments for GWI that were ready for implementation as well as others that are close or show promise, and identifying key areas where VA and non-VA investigators could partner to expand and accelerate GWI research. The third parent meeting held in August 2021 focused on the topic of aging, as this was the 30th anniversary of Operation Desert Shield/Desert Storm and included subject matter experts on non-genetic determinants of aging and the impact of exposures across the lifespan. In addition, the VA WRIISC Director presented a theory of sympathetic nervous system-predominant dysautonomia, common in the dominant symptoms of GWI, as a possibility for the underlying pathogenesis of GWI. Each committee meeting contributed knowledge and content for the Committee's 2021 recommendations to the VA Secretary.

The RACGWVI Committee staff worked throughout the year organizing committee and subcommittee meetings related to understanding and treating health conditions affecting Gulf War Veterans. Quarterly research alerts on GWI were prepared for committee members and posting on the RACGWVI website. Committee staff have stayed in contact with Gulf War Veterans met at subcommittee Veteran Engagement Sessions, building trust and communication within the Gulf War community and enabling 'Own the Moment' experiences. Additional efforts were spent on the logistics of holding these national public meetings virtually and accommodating the discontinuation of the Adobe Connect platform and the VANTS line

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previously used for chat and public comment. RAC staff worked with VA and Veteran partners, including but not limited to, local and national VA Public Affairs, VA Communications, EES, VA Chaplain Service, War Related Illness and Injury Study Centers (WRIISC), Post Deployment Integrative Care Initiative (PDICI), and Health Outcomes Military Exposures (HOME, formerly Post Deployment Health) to share notice of meetings and expand outreach.

2. Subcommittee meetings and activities: Goal: Hold two subcommittee RACGWVI “Veteran Engagement Sessions” to better understand Gulf War Veterans’ current health and quality of life concerns, and increase trust and communication, and enhance customer service with the goal of understanding and treating the health consequences of military service in the Southwest Asia theater of operations during the 1990 - 1991 Gulf War.

The RACGWVI subcommittee was formed January 2019 to support the RACGWVI mission to provide clear information, build trust, and support world class customer service. The diverse subcommittee included the RAC Chair, the DFO, a VA-physician researcher with expertise on chronic multi-symptom illness, a female Vietnam Veteran, and 3 Gulf War Veterans (2 male and 1 female).

Two subcommittee Veteran Engagement Sessions (VES) were held virtually due to COVID-19 safety precautions and travel restrictions. The intent of the VES is to give Gulf War Veterans a safe environment to share their stories and interact directly with the RACGWVI subcommittee members.

The first VES, held February 2021, allowed Veterans and their family members to describe new and existing health conditions and quality of life concerns. The importance of VA research was extensively discussed, including well known contributions from past VA research (e.g. nicotine patch, kidney transplant, an aspirin/day for heart disease) as well as the importance and benefits of participating in current VA research on GWI. Examples included the Million Veteran Program (MVP) and the MVP sub-study on genomics of GWI, use of nutraceuticals, diet, microflora in the gut, and the need for future research on long-haul COVID-19 with symptoms very similar to GWI. Following the meeting, RACGWVI participated in a virtual tribute for Gulf War Veterans and the 30th Anniversary of Operation Desert Storm which RAC staff helped plan in collaboration with the VA Puget Sound Health Care System. The agenda included tributes from VA leadership, included Director Michael Tadych from VA Puget Sound, the VHA Chief of Staff Mr. Jon Jensen, Former VA Chief of Staff Col. John Gingrich, and President of the Fredericksburg National Guard Association, Sergeant Major Shaun Roach. The National Program Manager for My Life, My Story, Thor Ringler, and a presentation on VA 1991 and VA Now, by past RACGWVI committee member and Director of Post Deployment Integrated Care Initiative. In honor of these Veterans the tribute began with a video presentation of the Presentation of Colors, 3 Volley Rifle Salute and Taps, and ended with a Retreat of Colors.

In May 2021, the VES included discussion of chronic health conditions of the autonomic nervous system. Veterans described the impact of severe memory loss and other cognitive difficulties on quality of life, resulting in stress on family relationships and fear of losing employment. In all public comment, Veterans continue to report a strong need for provider education and a diagnostic code for GWI, training for claims adjudicators on Gulf War

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Veterans and GWI, and most urgently the need to eliminate the presumptive end date coming up in Dec 2021.

3. Goal: Closely follow the status of the VA: National Institutes of Health (NIH) Deep Phenotyping Study on Gulf War Veterans' illnesses, known as Project IN-DEPTH, and discuss progress with the VA Office of Research & Development, Senior Gulf War Project manager.

Project IN-DEPTH continued planning and preparation during the COVID shutdown and 2021, which allowed time to refine the protocol. Problem solving issues related to COVID-19 resulted in ideas for alternate methods of recruitment and data collection that will decrease subject burden once the study begins.

1. Offer guidance on next steps for the Office of Research and Development's Gulf War State of the Science meeting that was held August 2020 with the Department of Defense.

As described above, Committee members reviewed key abstracts and papers from the 2020 GWI State of the Science Conference and presented and discussed these assignments themselves at the November 2020 parent committee meeting. Investigators with promising research or those where Committee members had additional questions were then invited to the March meeting for a deeper dive into these studies. These meetings resulted in information in key areas, including the following:

- a. The need for strategies to expedite implementation.
- b. Leveraging existing research, such as the MVP sub-study with the largest cohort of Gulf War Veterans (N=41,077) with information on GWI, deployment and military exposures.
- c. Integrating future research by establishing and strengthening partnerships with both VA and non-VA investigators to facilitate multi-investigator applications that could more rapidly lead to effective treatments.
- d. Advancing translation of animal to human research, for example, by modeling exposure levels with intentional dosing to mimic environmental conditions experienced by Gulf War Veterans or mining the DoD serum repository for biomarkers for chemical exposures.
- e. Increasing visibility of Gulf War research to increase subject recruitment, attract junior investigators, and enhance provider awareness and knowledge.

All information was assimilated by the RACGWVI to help inform the 2021 recommendations to the VA Secretary.

2. Develop a task force to increase interactions with other government agencies (e.g. FDA, CDC, NIH) to create more explicit communication with these agencies and solidify common goals in Gulf War Veteran research.

The COVID-19 pandemic drew many key personnel, both VA and non-VA, away from their normal responsibilities to focus on COVID-19 clinical and research responsibilities, and/or to care for their own families during the pandemic. Existing research studies and laboratories that had closed in 2020 had investigators rushing in 2021 to look for virtual and other options to continue their recruitment and resume study progress.

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Committee Activities:

The activities of the Committee in FY21 fully supported accomplishing its mission and aligned with VA Strategic Goals:

Goal 1: Veterans choose VA for easy access, greater choices, and clear information to make informed decisions.

RACGWVI enhanced efforts for outreach to Gulf War Veterans by engaging relevant VA partners and past VES attendees who have enlisted their social networks. Meeting participation increased five-fold and has allowed the committee to understand the Veteran's needs by direct communication during public comment and VES meetings. Information shared by Veterans has provided crucial information to the Committee to guide the direction of research. Equally important, these sessions have allowed an opportunity to pass on clear information to the Gulf War Veterans, such as the importance of research in providing strength of evidence to impact their treatment options, quality of life and benefits. Past VA research success stories were shared, such as development of the nicotine patch, low dose aspirin for heart health, and liver transplants just to name a few. This information has increased interest in VA research studies and subject recruitment. Information from Gulf War Veterans during the VES have also informed VA partners responsible for clinical care decisions and training for providers and benefits adjudicators, such as Health Outcomes Military Exposures (HOME, formerly Post Deployment Health) and work on the Clinical Practice Guidelines for Chronic Multisymptom Illness. These meetings have developed into a committee/veteran partnership to communicate clear and understandable information in both directions.

Goal 2: Veterans receive timely and integrated care and support that emphasizes their well-being and independence throughout their life journey.

As described above, information gained from parent committee meetings and VES have informed 1) 2021 committee recommendations to the VA Secretary on research close to or ready for implementation and key focus areas that will expedite diagnosis and treatments for GWI, and 2) clinical and operations partners and other resources working directly with Gulf War Veterans. The importance of evidence based research combined with clinical operations will ensure integrated care and support for these Veterans with GWI and comorbid conditions of aging. Vaccinations, COVID-19 and long-haul COVID-19 are now a significant concern. These meetings have also addressed other issues that affect their well-being. VA benefits are a frequent topic. Clinician researchers on the committee as well as knowledgeable Veterans attending the meetings have passed helpful information to other Gulf War Veterans navigating this process. Although out of the committee purview, issues like these affect the overall quality of life of the Veteran and their families. The Committee's flexibility discussing these issues have enhanced trust and customer satisfaction within the VA, and the RACGWVI's understanding of the Gulf War Veteran's experiences and life journey.

Goal 3: Veterans trust VA to be consistently accountable and transparent.

In support of the VA transparency and trust mission, the RACGWVI Chair invited subject matter experts to provide information on the following issues relevant to GWV:

- A deeper understanding of current VA and non-VA GWI research presented at the 2020 VA:DoD GWI State of the Science Conference and its relevance to GWV.
- A deeper dive into candidate biomarkers and potential therapies for GWI.
- Plans for a VA Military Exposure Research Program and Gulf War Program updates.

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- The effects of toxic exposures on aging: 1) the exposome, a measure of all exposures over an individual's lifetime, and 2) ageotypes, looking at individual differences in aging and the influence of health risk factors.

In addition, RACGWVI invited Dr. Carolyn Clancy, VHA Deputy Under Secretary for Health for the Office of Discovery, Education and Affiliate Networks to speak at its August parent committee meeting to discuss priorities of the new Biden and VA administrations related to toxic exposures and research initiatives aimed at improving the health and quality of life of Gulf War Veterans.

Goal 4: VA will transform business operations by modernizing systems and focusing resources more efficiently to be competitive and to provide World Class customer service to Veterans and its employees

In support of this mission, RACGWVI activities have included enhanced efforts to provide excellent customer service to Gulf War Veterans, employees and committee members.

- RACGWI meetings in 2021 were not cancelled due to COVID-19, but rather RACGWVI staff quickly navigated to a completely virtual platform and enabling the committee to hold four parent meetings and two VES. When Adobe and VANTS were discontinued, RAC staff researched the best virtual platform that would allow toll-free calling for all, the ability to hear and view subject matter experts and their presentations, the ability to hear and view the Committee members, and a platform for public comment by both chat and phone.
- VES were cancelled locally due to COVID-19 but instead held virtually allowing nationwide attendance.
- RACGWVI staff increased efforts to enlist VA partners to increase attendance to inform committee efforts and hear more Gulf War Veteran voices.
- The Chair invited experts in cutting edge areas of research to address Gulf War Veteran concerns 30 years after the 1990-91 Gulf War.
- A request for new Committee members was posted in the Federal Register to enlist a broad range of expertise, community leaders and Veterans, including Gulf War Veterans, family members and caregivers. RACGWVI aims for a membership that parallels the Veterans it serves: 1990-91 Gulf War Veterans that accounts for gender, race, geographical reach, branch of service, service occupation, deployed vs non-deployed and subject matter expertise in the health spectrum.
- RACGWVI staff partnered with the Director of the VA Post Deployment Integrated Care Initiative to hold a 1990-91 Gulf War tribute in honor of the 30th Anniversary of Operation Desert Storm following the February 2021 VES.
- VA Senior Leadership provided updates on the new Biden and VA administration related to improvements in direction patient care and current modernization of the electronic health record.

Reports and Recommendations: 2021 recommendations to the VA Secretary are currently under review. They include the following four recommendations:

1. Fund research into key focus areas to support the diagnosis and treatment of GWI.
2. Establish one or more Gulf War-Military Exposure Research Innovation Center(s)
3. Initiate research on the relationship between COVID-19, long-haul COVID-19, and their impact on GWI.
4. Continue the RACGWVI subcommittee, Veteran Engagement Sessions (VES).

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Senior VA leadership Participation:

- Although participation was limited due to extended travel restrictions and shortened virtual meetings, the Committee viewed VA Secretary McDonough's prepared message sent in 2021.
- Dr. Carolyn Clancy attended the August 2021 meeting, originally invited in the role of Acting DEPSECVA but back in her role as VHA Deputy Under Secretary for Health for the Office of Discovery, Education and Affiliate Networks (DEAN) by the meeting date. Dr. Clancy complimented RACGWVI on their resourcefulness and continued support of Gulf War Veterans during the challenges of the pandemic, noted that VA and ORD leadership recognize that the VES have provided key insight into new directions in research and SECVA recommendations, reaffirmed VHAs commitment to GWI related research, and stated RACGWVI is essential to guiding GWI research going forward, noting this is also recognized by VA Secretary McDonough who she states is dedicated to improving the health and care of veterans suffering with GWI.
- The SECVA or other VA Senior Leadership from the new administration will be invited to participate in the planned in-person meeting in Washington DC in September 2022.

Program Office Assessment: Strategic planning for research presented at the VA:DoD GWI State of the Science Conference and subsequent RACGWVI meetings has informed future funding for GWI research and new directions. Planning for the 2022 GWI State of the Science Conference is already in progress. The VA ORD Military Exposures Research Program will be a key mechanism to support future funding of a Gulf War Military Exposure Research Innovation Center(s) (recommendation 2), if approved by the SECVA.

General Comments: RACGWVI will continue using a virtual platform for its parent and subcommittee meetings to allow nationwide attendance even when travel restrictions are lifted and in-person meetings resume.

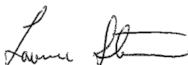
Signatures:

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DFO's Signature

Date



November 14, 2021

Chair's Signature

Date

Program Office Signature (SES or SES Equivalent)

Date