

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

CSP #585 Gulf War Era Cohort and Biorepository
Project Update

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June 23, 2015



Overview

- Purpose and Study Aims
- Participants and Eligibility Criteria
- Data Collected
- Recruitment Process and Current Status
- Challenges and Lessons Learned
- Future Directions
- More Project Information
- Questions for the RAC



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Purpose of the GWECB Project

- To provide valuable tools to examine the prevalence and correlates of medical conditions affecting Gulf War Era Veterans
- To enhance ongoing research and study chronic diseases that affect Veterans with this cohort's demographic profile
- To help target programs to better meet the health care needs of all Veterans



Project Aims

- Establish a research cohort of Gulf War Era Veterans to be used for future research studies
 - Mailed survey
 - Medical/Research records
 - Blood specimen
- Perform a pilot study with two specific aims:
 - Assess feasibility of and evaluate methods for recruitment, consenting, and blood collection to inform a full project and future GW/similar activities
 - Develop, test, and implement databases needed for enrollment tracking, blood specimen tracking, data storage



Participants

- **Eligibility**
 - Member of uniformed services in 1990-1991 Gulf War Era
 - Deployed and not deployed
 - **Users and non-users of VHA care**
 - Reside in 48 contiguous United States
- **Recruited from**
 - Department of Defense Manpower Data Center roster (random sample)
 - Other existing Gulf War Era Veteran studies and registries
 - Self-nominated



Data Collected

- **GWECB paper survey**
 - Developed in committee with Gulf War Era study experts and pilot tested; includes full MVP baseline survey
 - Topics: military service and geographic location; lifestyle behaviors; physical/mental health; family and family health
- **VA and non-VA medical records**
 - Accessed using electronic, administrative and other sources
- **Blood specimens**
 - Trained phlebotomist visits Veteran's home or convenient location to draw blood (~2 tsp); sample is shipped to, processed and stored at MAVERIC

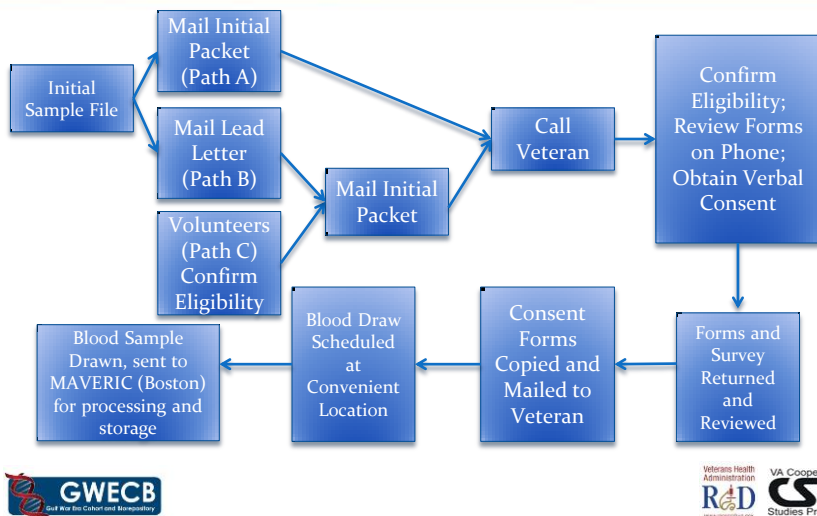


Participation Requirements

- Signing and returning all forms and a completed survey
- Providing a blood sample (about 2 teaspoons) at a time and location convenient for the Veteran
- Consenting to:
 - Review of VA and non-VA medical records
 - Access to data and blood from other VA and non-VA studies in which they participated
 - Possible use of their data and/or blood sample for future research
 - Re-contact to update survey responses (every 3-5 years) and contact information (every year)
 - Re-contact about participation in future research projects



Recruitment Process Overview



Recruitment Locations

- Recruitment began September 2, 2014
- 22 sites were selected according to multiple criteria:
 - Geographic diversity
 - Urban/rural diversity
 - Site phlebotomist readiness (subcontractor “branches”)

North	South	Midwest	West
<i>Boston, MA Philadelphia, PA</i>	<i>Orlando, FL Winter Park, FL Baton Rouge, LA Raleigh, NC Memphis, TN El Paso, TX San Antonio, TX</i>	<i>Des Moines, IA Des Plaines, IL Naperville, IL Detroit, MI Twin Cities, MN St. Louis, MO Oklahoma City, OK</i>	<i>Colton, CA Orange County, CA San Diego, CA Denver, CO Portland, OR Salt Lake City, UT</i>



Recruitment Locations



Map created at batchgeo.com



Current Enrollment Data

As of June 17, 2015

Total consented*: **846**

**Completed survey/consent forms, pending scheduling for blood collection appt.*

Total consented and scheduled for blood collection appointment: **768**

Total fully enrolled, blood specimen at MAVERIC: **657**



Current Enrollment Data

- **Demographics**
 - 76.7% male
 - 75.5% white
 - 85.7% not Hispanic/Latino
 - Average age: 54.9 years
- **VHA user status (self-reported)**
 - 54.7% non-users
- **70.8% deployed to the Gulf**



Current Process Data

Mailings through February 2, 2015 (“closed cycle”)

- Estimates restricted to first 23 mailing weeks
 - Later weeks are still in enrollment processes
- 5678 Veterans were sent initial recruitment mailings
 - 450 (7.9%) were undeliverable
- 5420 who were sent deliverable mailings were released to call center
 - 1778 (32.8%) could never be reached by phone
 - 3642 (67.2%) households were reached by phone
- 804 (22.1%) who were reached by phone provided verbal consent
 - Median time from first mailing: 144 days



Current Process Data (cont.)

Mailings through February 2, 2015 (“closed cycle”)

- 555 (69%) who provided verbal consent returned a completed recruitment packet
 - Median time from verbal consent: 22 days
 - 31% returned incomplete packet or dropped out of process
- 492 (88.6%) who returned a completed packet were scheduled for blood collection
- 452 (91.9%) who were scheduled completed the blood collection appointment
 - Median time since completed packet was received: 40 days
- Overall recruitment rate: 452/5678, 7.96%
 - Approximate recruitment cycle length: 206 days



Opt-Outs and Refusals

As of June 17, 2015

- Total number of Veterans refusing or opting out: 2070/9302= **22.25%**
- Top reasons selected from checklist of options:
 - Not interested
 - Do not have time
 - Confidentiality concerns
 - Do not want to allow access to medical records
- Top “other” reasons:
 - Ineligibility: “Was not in the service 1990-1991”
 - VA-related: “No Faith in the V.A.”
 - Misunderstanding study requirements: “Was never deployed”



Recruitment Challenges and Solutions

Call Operations: Difficult to reach Veterans on phone	Enrollment center calls weighted more heavily in evening <u>Other changes implemented:</u> refined informed consent script; hiring Veterans as call center staff ; regular contact information updates
Mail Operations: Missing or incomplete forms mailed in	Modified forms to address problem areas <u>Other changes implemented:</u> revised follow up mailing packet to improve response rate; regular contact information updates
Field Operations: Various challenges scheduling blood collection appointments	Hired additional schedulers to better respond to Veterans Engaged nation-wide network of phlebotomists to cover for unexpected scheduling conflicts and reduce reschedules
Overall Recruitment: Low response rate; need to better engage Veterans and understand preferences for participation	New qualitative research component; analysis of existing data (opt out cards, participant satisfaction survey, field notes, tracking data, etc.); literature review To explore: engaging with VSOs and other partners

Future Directions

- Qualitative research component
 - Engage GW Veterans now and throughout project
 - Better understand GW Veterans’ perspectives on the project, recruitment materials and project procedures
 - Sessions: focus groups and interviews
 - Recruitment will begin in fall 2015
 - Some sessions are being planned for next RAC meeting
- Connect with Gulf War-related VSOs and networks
- Further analyze process data
- Revise processes and develop outreach plan (2016)



More Information about CSP 585

- Visit the CSP 585 website:
www.research.va.gov/programs/csp/585
- Search for CSP 585 on clinicaltrials.gov
- Call the toll-free CSP 585 hotline :
1-855-493-8387 (10am-7pm all times zones)
- Talk to a CSP 585 project team member today
- Contact Rick Gray, CSP 585 Research Assistant:
Kendrick.Gray@va.gov or 919-286-0411 x4010



Questions for RAC

- How can we more effectively engage Gulf War Veterans in this project?
- What advice do you have on engaging VSOs?
- Which VSOs and other Gulf War Era networks should we connect with?
- What conferences or events might Gulf War Veterans attend?
- What advice do you have for the implementation of the CSP 585 qualitative activity?

