Meeting of the Research Advisory Committee on Gulf War Veterans’ Illnesses

CSP #585 Gulf War Era Cohort and Biorepository Project Update

Study Chair: Dawn Provenzale, MD, MS

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
## Acknowledgements

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### CSPEC – Durham (cont.)
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- Becky McNeil
- Dawn Provenzale
- Catherine Thomas
- Corrine Voils
- Lawrence Whitley

### Organizational Partners
- VA Office of Public Health
- Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC)
- Social and Scientific Systems, Inc.
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

1. Mail Initial Packet (Path A)
2. Mail Lead Letter (Path B)
3. Volunteers (Path C) Confirm Eligibility

- Mail Initial Packet
- Call Veteran
- Blood Draw Scheduled at Convenient Location
- Consent Forms Copied and Mailed to Veteran
- Forms and Survey Returned and Reviewed

- Confirm Eligibility; Review Forms on Phone; Obtain Verbal Consent
- Blood Sample Drawn, sent to MAVERIC (Boston) for processing and storage

- Blood Sample
- Volunteers (Path C) Confirm Eligibility
- Initial Sample File
- Mail Lead Letter (Path B)
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”)

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Sources:

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