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

April 29, 2016
Overview

- Purpose and Study Aims
- Participants
- Data Collected
- Recruitment and Enrollment Data
- Participant Information
- Current Status
- Successes and Challenges
- Future Directions
- Additional Project Information
- Input from the RAC
Acknowledgements

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Organizational Partners
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

• 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 non-deployed
  – Users and non-users of VHA care
  – Reside in 48 contiguous United States

• Recruited from
  – Department of Defense Manpower Data Center roster (representative sample)
  – 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

• Blood specimens
  – Trained phlebotomist visited Veteran’s home or convenient location to draw blood (~2 tsp); sample was shipped to, processed and stored at MAVERIC

• VA and non-VA medical records
  – Accessed using electronic, administrative and other sources
Recruitment and Enrollment

- During the pilot 10,000 Veterans were contacted, with the goal of enrolling 3,000

- Enrollment Coordinating Center (ECC) mailed an invitation packet containing consent documents, a request for medical records release, a survey, and an opt-out card

- The ECC called Veterans who did not return the opt-out card, and administered informed consent by phone
Process Data (as of 04/03/16)

10184 Veterans sent initial recruitment mailings

9653 Veterans released to call center

4466 Veterans (46.3%) reached by phone

1267 Veterans (28.4%) enrolled

2769 Veterans (27.2%) opted out

891 (8.7%) mailings undeliverable

888 Veterans (9.2%) did not have a valid phone number

4299 (44.5%) did not respond to any call attempts
## Characteristics of Cohort (n=1267)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>All</th>
<th>VHA non-users (676)</th>
<th>VHA users (577)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years, median)</strong></td>
<td>52.8</td>
<td>52.5</td>
<td>53.7</td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td>75.7%</td>
<td>513 (75.9%)</td>
<td>436 (75.6%)</td>
</tr>
<tr>
<td><strong>White</strong></td>
<td>920 (72.6%)</td>
<td>550 (81.4%)</td>
<td>360 (62.4%)</td>
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<tr>
<td><strong>African-American</strong></td>
<td>266 (21.0%)</td>
<td>92 (13.6%)</td>
<td>173 (30.0%)</td>
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<tr>
<td><strong>Army</strong></td>
<td>661 (52.2%)</td>
<td>303 (44.8%)</td>
<td>349 (60.5%)</td>
</tr>
<tr>
<td><strong>Navy</strong></td>
<td>231 (18.2%)</td>
<td>139 (20.6%)</td>
<td>91 (15.8%)</td>
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<tr>
<td><strong>Air Force</strong></td>
<td>202 (15.9%)</td>
<td>121 (17.9%)</td>
<td>78 (13.5%)</td>
</tr>
<tr>
<td><strong>Marines</strong></td>
<td>180 (14.2%)</td>
<td>110 (16.3%)</td>
<td>69 (12.0%)</td>
</tr>
<tr>
<td><strong>Deployed to Gulf</strong></td>
<td>890 (70.2%)</td>
<td>469 (69.4%)</td>
<td>413 (71.6%)</td>
</tr>
<tr>
<td><strong>Deployed elsewhere</strong></td>
<td>95 (7.5%)</td>
<td>48 (7.1%)</td>
<td>46 (8.0%)</td>
</tr>
<tr>
<td><strong>Not deployed</strong></td>
<td>276 (21.8%)</td>
<td>152 (22.5%)</td>
<td>121 (21.0%)</td>
</tr>
<tr>
<td><strong>Some college or greater</strong></td>
<td>1102 (87.0%)</td>
<td>598 (88.5%)</td>
<td>495 (85.8%)</td>
</tr>
<tr>
<td><strong>Working full-time</strong></td>
<td>736 (58.1%)</td>
<td>459 (67.9%)</td>
<td>271 (47.0%)</td>
</tr>
<tr>
<td><strong>Working part-time</strong></td>
<td>94 (7.4%)</td>
<td>54 (8.0%)</td>
<td>40 (6.9%)</td>
</tr>
</tbody>
</table>
Participant Health Conditions

VA non-user self-reported diagnoses

Mental health disorders: 29.4%
Circulatory: 62.6%
Digestive: 45.1%
Musculoskeletal: 42.8%
Nervous system: 33.7%

VA user self-reported diagnoses

Mental health disorders: 57.2%
Circulatory: 78.3%
Digestive: 59.1%
Musculoskeletal: 69.7%
Nervous system: 60.5%
Current Status

• The pilot project is ending in May 2016
• Recruitment into the biorepository has ended
• Additional data analyses are planned
• The GWECB project is transitioning into a new phase that will focus more on the Veteran voice
## Successes and Challenges

<table>
<thead>
<tr>
<th>Successes</th>
<th>Challenges</th>
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<tbody>
<tr>
<td>Recruited non-users of VHA</td>
<td>Identifying correct contact information</td>
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<tr>
<td>Established cohort of Gulf War Era Veterans</td>
<td>Reaching Veterans during call center hours of operation</td>
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<td>Collected blood specimens and survey data that can be useful for future research</td>
<td>Lower than expected response rate</td>
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<td>Learned important lessons about recruiting into a project like this</td>
<td>Outreach to potential self-nominated participants</td>
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Data Use

• Creating a process for reviewing requests from researchers who want to use the information and blood samples in additional research

• When the process is approved, researchers can submit requests to access the information collected through CSP 585 for additional research
CSP 585 Phase 2

- This phase will begin in summer 2016 and will include:
  - Up to 12 focus groups, with 8-10 Veterans per group
  - Approximately 30 phone interviews with Veterans
  - Up to 20 interviews with subject matter experts

- CSP 585 project team will partner with VSOs and other community organizations to recruit for focus group discussions
Cohort Maintenance

- Enrollment into the cohort and biorepository involved consenting to be re-contacted

- The CSP 585 project team will be contacting participants this summer to collect updated information and to send a project newsletter
Additional Information about CSP 585

• Visit the CSP 585 website: www.research.va.gov/programs/csp/585

• Search for CSP 585 on clinicaltrials.gov

• Contact Kristina Felder, CSP 585 Project Manager: kristina.felder@va.gov or 919-286-0411 x7379
Input from the RAC

- Guidance about which VSOs and other Gulf War Era networks to engage for focus groups and interviews
- Conferences or events focusing on Gulf War Era Veterans
- Identification of Gulf War Era experts, inside and outside of VHA, to interview as subject matter experts
- Additional strategies for engagement of Gulf War Era Veterans