


**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

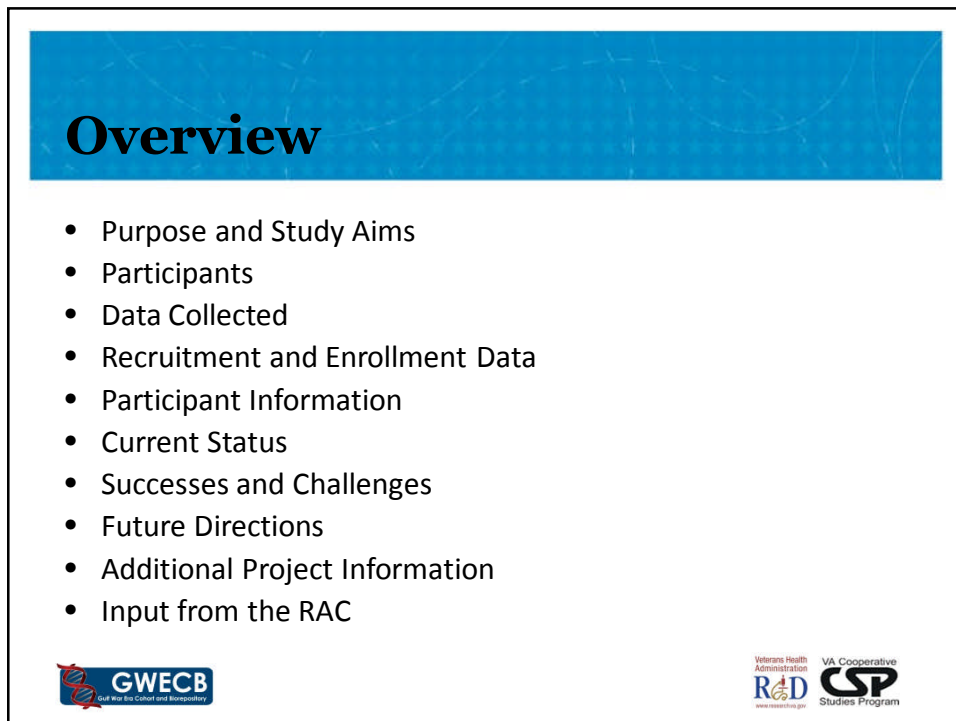
April 29, 2016

 Defining **EXCELLENCE**
in the 21st Century

 **GWECB**
Gulf War Era Cohort and Biorepository


 Veterans Health Administration
Research & Development
Improving Veterans' Lives - www.research.va.gov


 **Veterans Health
Administration**




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

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 Veterans Health
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 **VA Cooperative
Studies Program**

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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



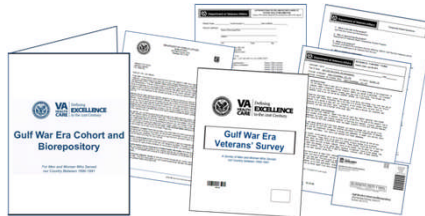
Data Collected

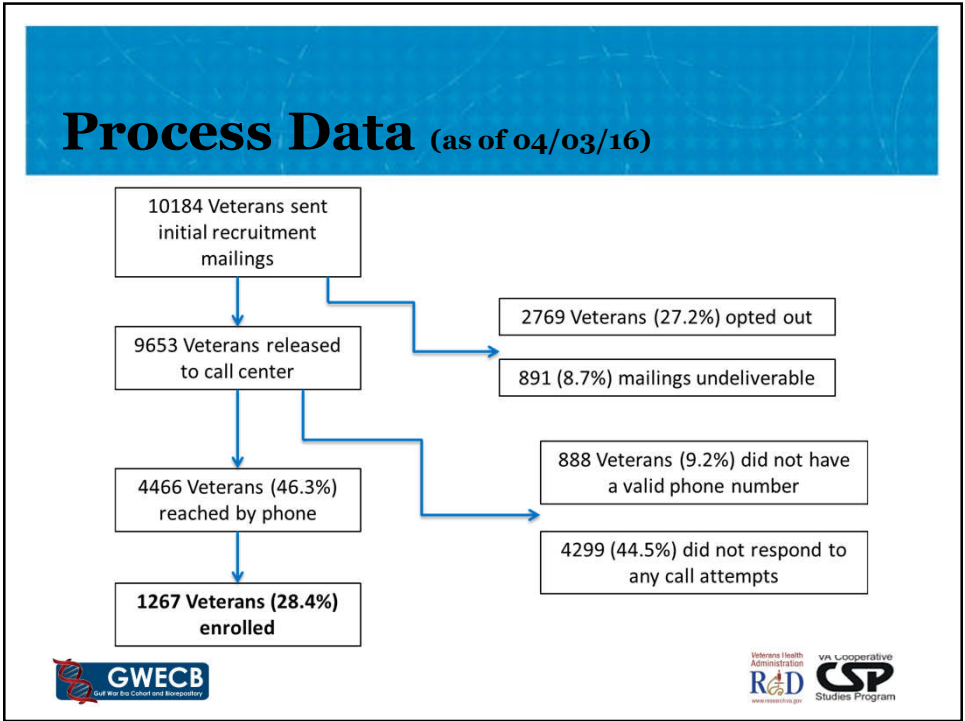
- GWECB paper survey
 - Developed in committee with Gulf War Era study experts and pilot tested; includes full MVP baseline survey
 - Topics: military service and geographic location; lifestyle behaviors; physical/mental health; family and family health
- Blood specimens
 - Trained phlebotomist visited 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





Characteristics of Cohort (n=1267)

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

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

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



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

