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

Gulf War Era Cohort and Biorepository Study Update
CSP #585

Study Chair: Dawn Provenzale, MD, MS

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GWECB
Gulf War Era Cohort and Biorepository

Background

- Many important questions remain to be answered about the health of Gulf War Era Veterans

Study 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
- Pilot study has two specific aims:
  - Assess feasibility of recruitment, consenting, and blood drawing and shipping processes
  - Develop, test, and implement databases needed for enrollment tracking, blood sample tracking, and data storage

Inclusion Criteria

- Members of Uniformed Services during the 1990-1991 Gulf War era
- Eligibility not dependent on deployment or combat status
- Includes users and non-users of Veterans Health Administration (VHA) care

Sampling Frame

Participants will be recruited from:

- Stratified random sample from Department of Defense Manpower Data Center roster (n=90k)
- Participants in VA Office of Public Health longitudinal survey
- Self-nominated

Pilot Study Recruitment

- Pilot study aims to reach 10,000 Veterans with the goal of enrolling 3,000
- An Enrollment Coordinating Center (ECC), SRA International, will recruit and enroll Veterans
- ECC will mail the Invitation Packet:
  - Consent documents (informed consent and HIPAA)
  - Opt-out card
  - Survey
- ECC will call Veterans who did not return the opt-out card
- ECC will administer informed consent by phone
- Veterans will mail in completed forms and survey

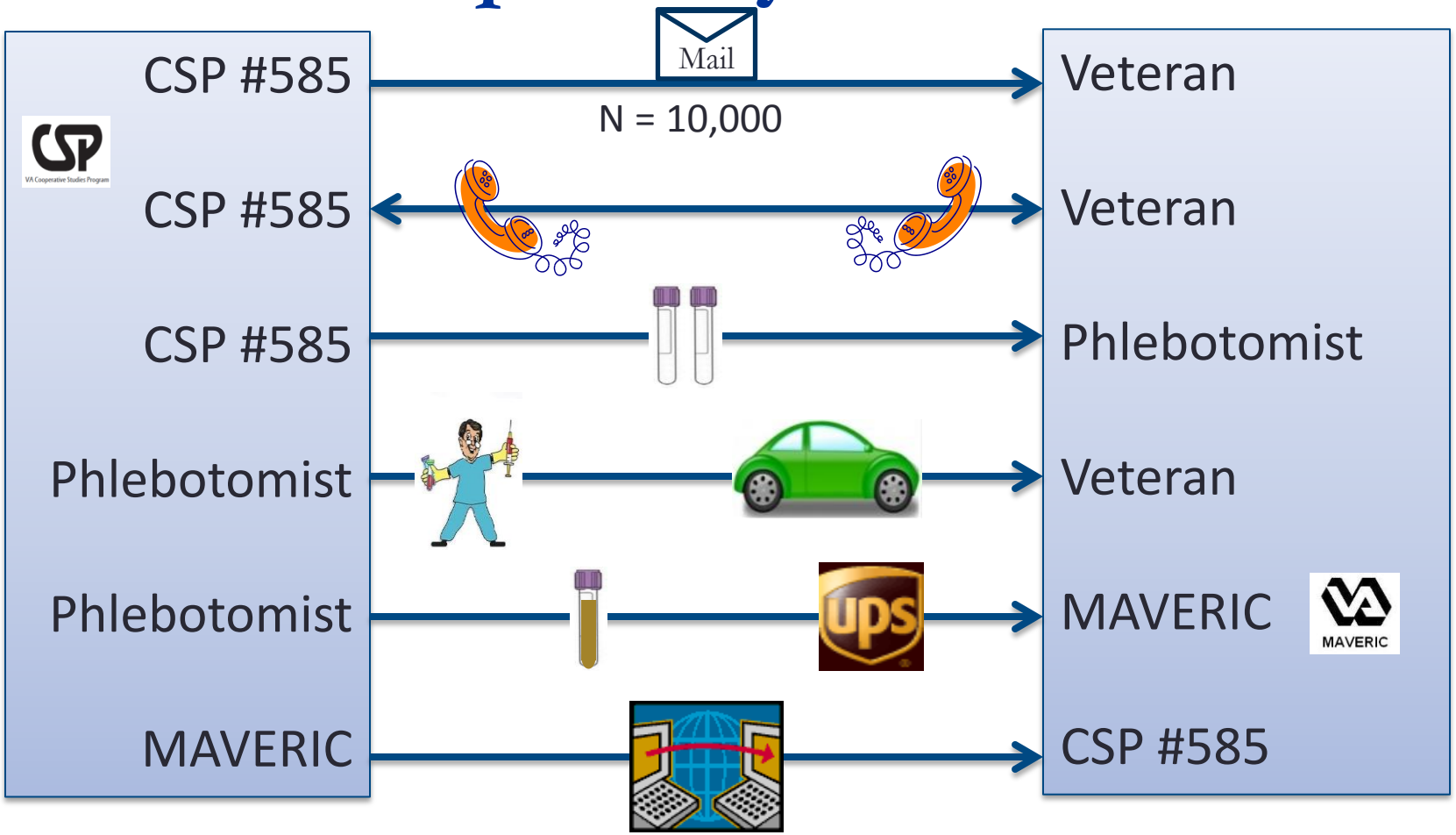
Pilot Study Blood Collection

- The ECC will arrange with Veterans for blood collection at their home or other convenient place
- The ECC will send blood samples to the Boston VA (MAVERIC) biorepository storage center

Other Data Sources

- VA electronic medical records
- Non-VA health records
- Death records
- Research records from other studies

Gulf War Era Cohort and Biorepository Workflow



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Survey Development

Survey Development: Survey Measures Review

McNeil *et al. Environmental Health* 2013, **12**:4
http://www.ehjournal.net/content/12/1/4

ENVIRONMENTAL HEALTH

REVIEW **Open Access**

An assessment of survey measures used across key epidemiologic studies of United States Gulf War I Era Veterans

Rebecca B McNeil[1*], Catherine M Thomas[1], Steven S Coughlin[2], Elizabeth Hauser[1,3], Grant D Huang[4], Karen M Goldstein[5], Marcus R Johnson[6], Tyra Dunn-Thomas[7] and Dawn T Provenzale[1,5,3]

- Review of survey measures and research tools used by 12 epidemiologic studies and 2 government registries
- Many studies used similar instruments, but this varied by domain
- Future surveys should consider issues of comparability with past data
- Biospecimen/genomic analyses will add to informative power of surveys

Survey Development

- Susan Proctor, PhD
- Lea Steele, PhD
- Dan Clauw, MD
- Steve Coughlin, PhD
- Durham Research Team

Survey Development

- We collaborated with experts in conducting studies with Gulf War Era Veterans
- Survey goals:
  1. Include the entire Million Veterans Program (MVP) short baseline survey
  2. Provide researchers with enough info to use the biorepository and determine subsets of the Gulf War cohort
  3. Avoid overburdening Veterans, keep survey short (up to 1 hour)

Survey Development

- Topics included: military service, lifestyle behaviors, physical and mental health, and family (including family health)
- All questions were from previously developed instruments
- If available, validated instruments from prior Gulf War research were chosen in order to compare data between studies

Survey Instruments	
Survey	**Number of Questions** (does not include subparts)
National Survey of Veterans	6
Exposure Questions developed for Kansas study	5
Physical Activities Questions based off of the CDC's BRFSS	4
SNAC	3
VR-12	9
PHQ-8	1
PCL-C	1
Cancer Prevention Study III	1
AUDIT-C	3
US Census 2010	2
Atlantic PATH Main Questionnaire	1
UK Biobank Version 4.6	9
Physician's Health Study I Enrollment Questionnaire	1
Finbalt Questionaire	2
PROMIS Sleep Disturbance Short Form	1

Cognitive Testing

- In-person testing of survey items with Veterans
- Goal is to ensure that survey is easy to understand
- Results will be used to revise survey prior to kick-off

Cognitive Testing Recruitment and Interviewing

Recruitment/Interview Process	Number of Veterans
Letters sent	202
Letters returned to sender	11
Ineligible based on phone call	5
Deceased	1
Served during different time period	4
Agreed to interview	14
Completed interviews	11*
No-shows	3

*Interviews conducted from May 15, 2013, through June 3, 2013

Veteran Demographics by VHA Health Services Utilization

Demographics	
Gender	**Number of Veterans**
Male	8
Users	3
Non-Users	5
Female	3
Users	0
Non-Users	3
Age	**Average Age (in Years)**
Users	68
Non-users	49

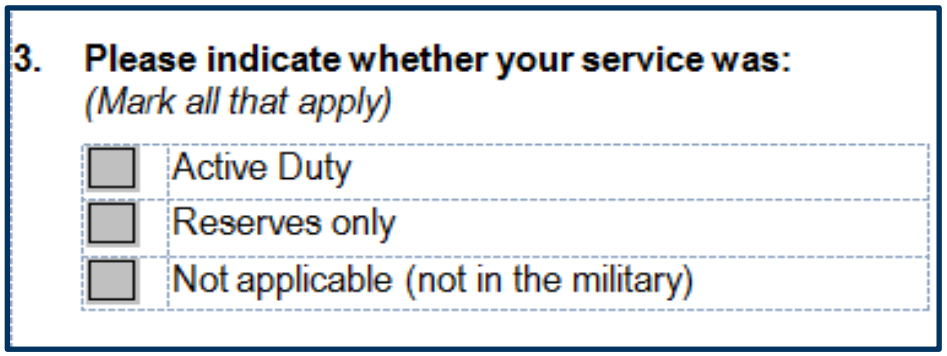
VHA Health Services Utilization of Interview Participants

VA Health Services Utilization	Number of Veterans
User	3
Non-User	8

Average Time to Complete Survey

VA Health Services Utilization	Average Time (in minutes)
User	39
Non-User	32

Veteran Survey Feedback

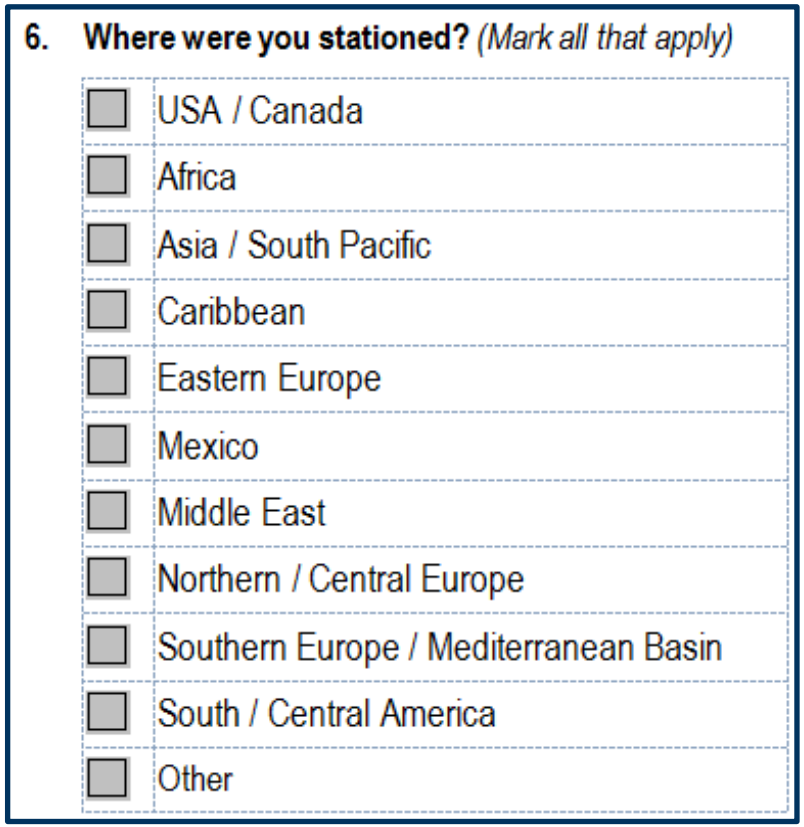


3. Please indicate whether your service was:
(Mark all that apply)

- ☐ Active Duty
- ☐ Reserves only
- ☐ Not applicable (not in the military)

- Veterans noted that the question indicated that all applicable response options should be selected, but the options indicate "active duty" and "reserves only."
- Veterans selected both, but noted they did not only serve in the reserves.

Veteran Survey Feedback



6. Where were you stationed? *(Mark all that apply)*

- ☐ USA / Canada
- ☐ Africa
- ☐ Asia / South Pacific
- ☐ Caribbean
- ☐ Eastern Europe
- ☐ Mexico
- ☐ Middle East
- ☐ Northern / Central Europe
- ☐ Southern Europe / Mediterranean Basin
- ☐ South / Central America
- ☐ Other

- Veteran served in the Navy and was displeased that a "ship" option was not offered
- Veteran stated that the military typically does not refer to the "Middle East," but instead uses the phrase "***Southwest Asia***." Veteran not used to thinking about Iraq in terms of the Middle East

Upcoming Events

- ECC data and phone system testing
- Kick-off meeting and training: August 29-30, 2013
- Estimated first mailing: September 2013
- ECC operational the day after first mailing occurs
- Estimated first blood draw: October 2013

What Is Involved in Participation?

- Signing and returning the informed consent form, HIPAA authorization form, and the document permitting release of your medical records
- Completing and returning the survey
- Providing a blood sample (about 2 teaspoons) at a time and location convenient for you
- Permitting access to your VA and non-VA medical records
- Providing access to your data and blood from other VA and non-VA research studies
- Allowing the use of your blood sample and study data in future research studies
- Being contacted by study staff for updated survey, provider, and contact information
- Being contacted about new studies that you might wish to join

Obtaining Access to CSP 585 Data and Specimens

- CSP stores all study data
- Data may be released to other investigators after study completion
- Must make written request specifying data needed and intended use
- Must gain approval from Study Chair, Executive Committee, and Director, CSR&D Service
- Need a Data Use Agreement (DUA)
- Limited, de-identified dataset will then be released

For More Information

Go to clinicaltrials.gov and read about CSP 585:

http://clinicaltrials.gov/ct2/show/NCT01803854?term=NCT01803854&rank=1