

# 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 20, 2017**

# Overview

- Project Summary
- CSP 585 Phase 1:
  - Eligibility, Data Collected, Recruitment Process
  - Enrollment Data
  - Cohort Demographics and Health Conditions
  - CSPEC-Durham Data and Specimen Repository
- CSP 585 Phase 2:
  - Qualitative Research
  - Cohort Maintenance
- Next Steps

# Acknowledgements

## **CSPEC – Durham**

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Lawrence Whitley

## **Organizational Partner**

Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC)



# GWECB Pilot Project Summary

- Phase 1: September 2014 – August 2016
  - Created a cohort of Gulf War Era (GWE) Veterans and a biorepository that can be used for future research
  - Assessed feasibility of and evaluated methods for recruitment, consenting, and blood collection
  - Developed and tested databases for tracking and data storage
  - Established data and specimen repository request process
- Phase 2: June 2016 – Present
  - Conducted qualitative research to better understand GWE Veterans' perspectives related to participation in VA research
  - Conducted cohort maintenance

# CSP 585 PHASE 1

September 2014 – August 2016

# Potential 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

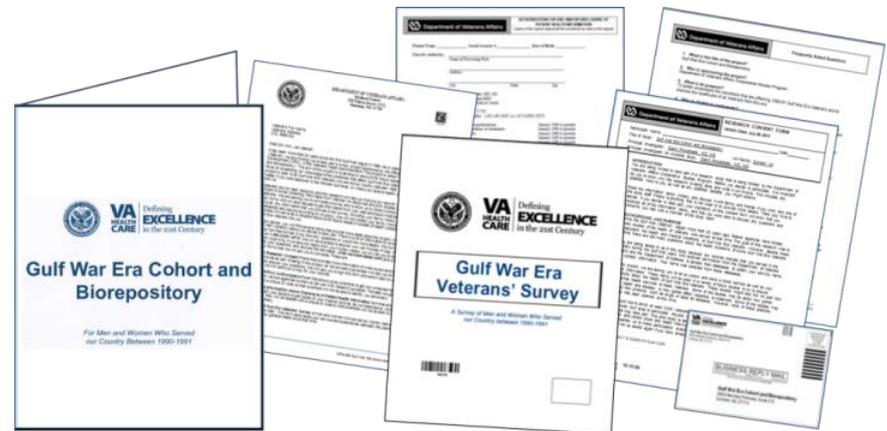
# Data Collected

## September 2014 – May 2016

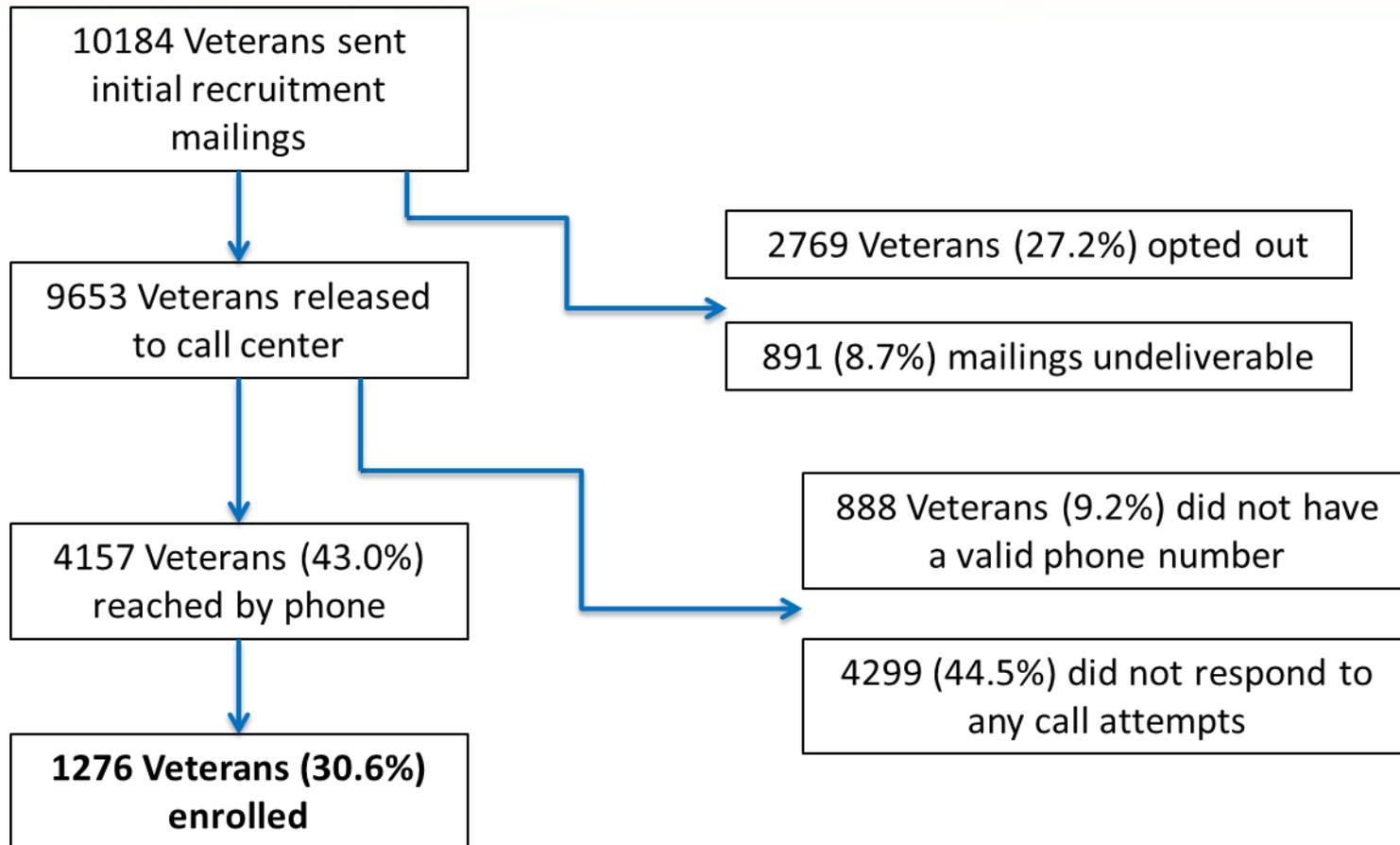
- GWECB paper survey
  - Developed in committee with Gulf War Era study experts and pilot tested; includes full MVP baseline survey
  - Topics: military service and geographic location; lifestyle behaviors; physical/mental health; family and family health
- Blood specimens
  - Trained phlebotomist visited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

- ~10,000 Veterans were contacted by mail, with option to opt-out
- Enrollment Coordinating Center (ECC) followed up by phone, administered informed consent
- Participants mailed ECC consent forms and survey
- Phlebotomists traveled to participants to collect blood sample



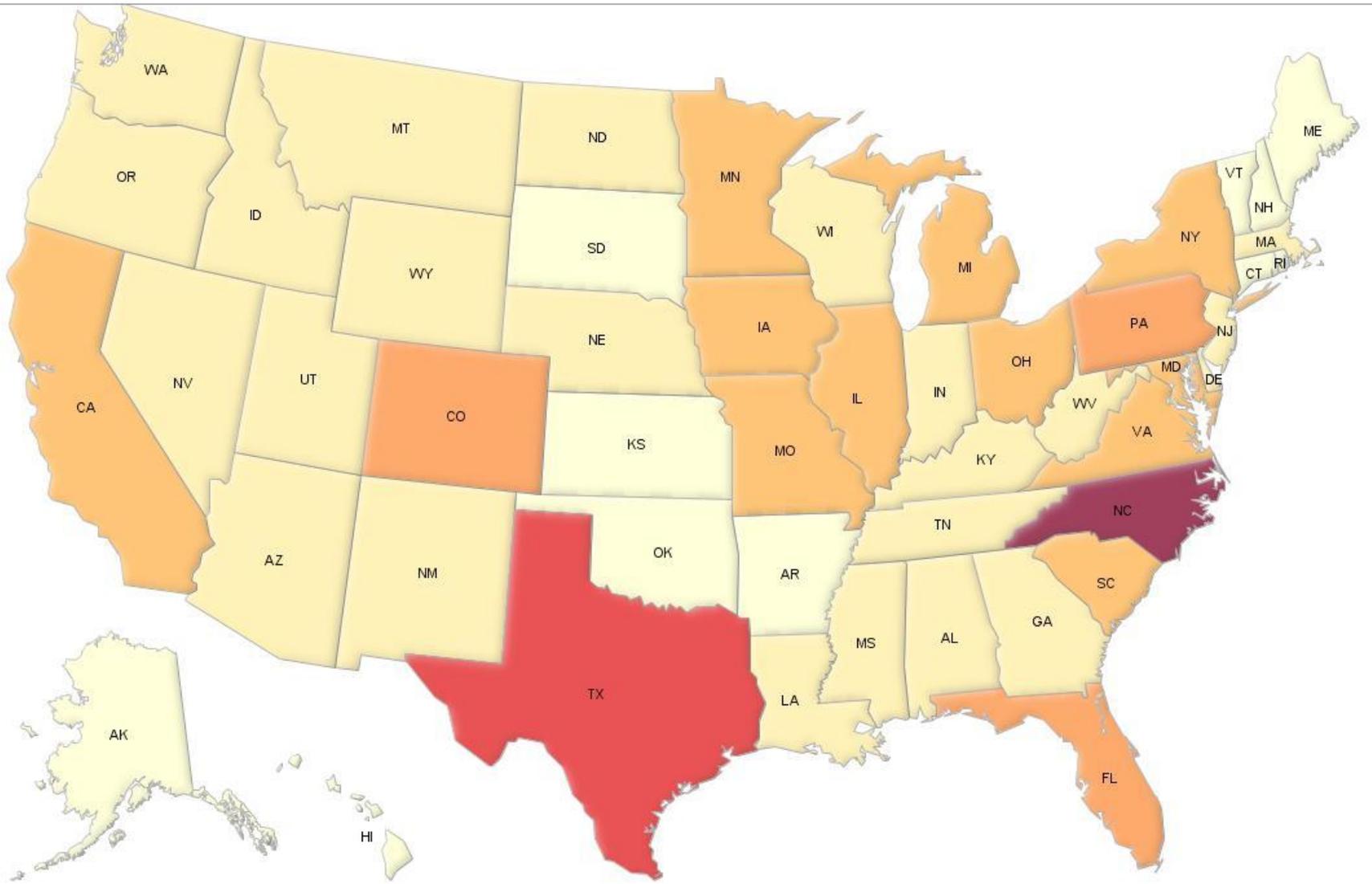
# Process Data (as of 05/22/16)



# Enrollment Information

Enrollment category	Total
“Fully enrolled”: all 3 consent forms, survey, and blood collected	1276
“Consented plus survey”: ICF and survey only	68
“Consented”: ICF only	80
Enrollment rate for fully enrolled Veterans	12.5%

Cohort Members by State (N = 1276)



Number in Cohort:  None  25 and under  26 - 50  51 - 75  101 - 300  Over 301

# Characteristics of Cohort

	All (n=1276)	VHA non-users (n=680)	VHA users (n=584)
<b>Age (median years)</b>	52.8	52.5	53.7
<b>Male</b>	967 (75.8%)	517 (76.0%)	443 (75.9%)
<b>African American</b>	270 (21.2%)	95 (14.0%)	174 (29.8%)
<b>White</b>	923 (72.3)	552 (81.2%)	364 (62.3%)
<b>American Indian</b>	56 (4.4%)	17 (2.5%)	38 (6.5%)
<b>Asian/Pacific Islander</b>	17 (1.3%)	10 (1.5%)	7 (1.2%)
<b>Other</b>	5 (0.4%)	3 (0.4%)	2 (0.3%)
<b>Deployed to the Gulf</b>	900 (70.5%)	473 (69.6%)	418 (71.6%)
<b>Deployed elsewhere</b>	95 (7.5%)	47 (6.9%)	48 (8.2%)
<b>Did not deploy</b>	277 (21.7%)	152 (22.4%)	123 (21.1%)

# Characteristics of Cohort (cont.)

	All (n=1276)	VHA non-users (n=680)	VHA users (n=584)
<b>Army</b>	669 (52.4%)	308 (45.3%)	355 (60.8%)
<b>Navy</b>	232 (18.2%)	140 (20.6%)	91 (15.6%)
<b>Air Force</b>	202 (15.8%)	121 (17.8%)	78 (13.4%)
<b>Marine Corps</b>	182 (14.3%)	110 (16.2%)	70 (12%)
<b>Coast Guard</b>	12 (0.9%)	10 (1.5%)	2 (0.3%)
<b>National Guard</b>	149 (11.7%)	79 (11.6%)	68 (11.6%)
<b>Merchant Marines</b>	2 (0.2%)	1 (0.1%)	1 (0.2%)
<b>Some college or greater</b>	1111 (87.1%)	603 (88.7%)	501 (85.8%)
<b>Working full-time</b>	742 (58.2%)	462 (67.9%)	274 (46.9%)
<b>Working part-time</b>	94 (7.4%)	54 (7.9%)	40 (6.9%)

# Participant Health Conditions

Self-reported diagnoses	VHA non-users	VHA users
Circulatory system problems	62.9%	78.3%
Skeletal/muscular problems	42.9%	69.5%
Mental health disorders	29.7%	57.2%
Vision/hearing problems	40.0%	58.2%
Infectious diseases	4.1%	4.6%
Kidney disease	2.8%	3.6%
Digestive system problems	44.1%	57.7%
Cancer	12.2%	11.0%
Nervous system problems	34.0%	60.6%

# Participant Health History

Health issue	All (n=1276)	VHA non-user	VHA user
<b>Fatigue</b>	784 (61.4%)	371 (54.6%)	407 (69.7%)
<b>Other sleep disturbances</b>	969 (75.9%)	476 (70.0%)	485 (83.0%)
<b>Joint pain/stiffness</b>	1051 (82.4%)	523 (76.9%)	518 (88.7%)
<b>Headache</b>	629 (49.3%)	272 (40.0%)	351 (60.1%)
<b>Difficulty concentrating</b>	655 (51.3%)	284 (41.8%)	365 (62.5%)
<b>Numbness/tingling in extremities</b>	733 (57.5%)	321 (47.2%)	405 (69.4%)
<b>Pain in muscles</b>	769 (60.3%)	335 (49.3%)	428 (73.3%)

# 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
Established protocol for data and specimen repository	

# CSPEC-Durham Data and Specimen Repository

- Data and specimen request process is developed, approved
- Data and specimens available include:
  - Participant survey data
  - Data dictionary
  - Blood specimen – serum, buffy coat, DNA
  - Release form for access to VA and non-VA medical records
- Veterans also consented to being re-contacted about new studies

For more information about requesting CSP 585 data:

[www.research.va.gov/programs/csp/585/repository.cfm](http://www.research.va.gov/programs/csp/585/repository.cfm)



# CSP 585 PHASE 2

## June 2016 – Present

# CSP 585 Qualitative Research

- Aim: To better understand barriers/motivators affecting GWE Veterans' participation in VA research; and to identify strategies for improving recruitment and study processes for future research projects
- Total of 55 participants
- Semi-structured interviews w/ subject matter experts (n=9)
  - Researchers, clinicians, and Veteran advocates
  - Recruited nationally; interviews conducted via phone

# CSP 585 Qualitative Research

- Semi-structured “process evaluation” interviews w/GWEVs Veterans (n=12)
  - Recruited nationally; interviews conducted via phone
  - 3 GWECEB participants, 7 opt outs, and 2 non-responders
  - 6 deployed to the Gulf, 3 deployed elsewhere, 3 did not deploy
  - 5 women, 7 men; 9 VA non-users
- Four focus groups with GWE Veterans (n=34)
  - Locations: CA (1), FL (1), and NC (2)
  - Two of the focus groups were women’s groups
  - 21 deployed to the Gulf, 7 deployed elsewhere, 7 did not deploy
  - 21 women, 13 men; 11 non VA-users

# CSP 585 Qualitative Research

- Topics addressed in interviews and focus groups included:
  - Concerns/motivators affecting GWE Veterans' participation in research
  - Strategies researchers can use to address GWE Veterans' concerns
  - GWE Veterans' preferences related to various study procedures (e.g., survey mode, blood draw location)
  - Effective recruitment methods for reaching GWE Veterans
- Process evaluation interviews also solicited Veterans' feedback about the GWECEB

# Preview of Qualitative Findings

## Concerns influencing Veteran participation in VA research

- Veteran distrust and dissatisfaction with VA/federal government
  - “It’s just a distrust of the government and I wouldn’t want them using my information against me at some point in time... it’s always scary when you think the government’s collecting information on you.”
- Concerns about privacy, confidentiality, and use of research data
  - “My biggest concern now would be with all the stuff that’s been going on, the hacking and all that, is information being compromised.”
- Previous lack of follow-through
  - “Most researchers live in a different world and they offer up their results and never follow through and make sure that it’s actually implemented.”
  - “I mean, I’ve filled out surveys and I’ve done health questionnaires and who knows where that stuff’s gone? I don’t know any of the results of that.”

# Preview of Qualitative Findings

## Factors motivating Veterans to participate in VA research

- Seeking answers about exposures and health conditions
  - “I don’t know of anybody that I’ve served with that would turn down the opportunity to help find an answer. “
- Helping oneself
  - “I want information that tells me how it pertains to me and if it’s anything that could help lessen what I’m going through to get me back to being as normal as possible.”
- Helping other Veterans and service members
  - “Well, if not [helping] me personally, just by analyzing my data and... If they narrow it down to something that happened that seems to be causing this... they could adjust the way they deal with soldiers on the ground now.”

# Preview of Qualitative Findings

- In addition to concerns/motivators affecting GWE Veterans' participation in research, findings highlight:
  - Veterans' preferences related to study procedures (e.g. blood draw, survey mode)
  - Strategies for researchers to help address barriers/concerns
  - Effective recruitment methods

# Qualitative Research Next Steps

- Analyses to be finalized in May 2017
- Researchers will be able to use findings to improve recruitment and more effectively address the needs and priorities of GWE Veterans, including VA non-users
- Developing reports and other products for multiple audiences, including researchers and Veterans

We would welcome the opportunity to present our findings at August RAC meeting

# Cohort Maintenance Activities 2017

- Mailed project newsletter and contact information update form to all Veterans who signed an Informed Consent Form
- Project team will utilize LexisNexis to obtain accurate contact information for participants whose addresses had changed since enrollment ended



# CSP 585 Next Steps

- Integration with other Gulf War Research activities in ORD/CSP:
  - CSP 2006 – first activity will be to create a standardized phenotype for Gulf War Illness using the CDC and Kansas definitions
- Finalize qualitative analyses to identify themes that can be addressed to improve recruitment for future research
- Disseminate qualitative findings to stakeholders
- Implementation of lessons learned for Gulf War and other research

# Additional Information about CSP 585

- Visit the CSP 585 website:  
[www.research.va.gov/programs/csp/585](http://www.research.va.gov/programs/csp/585)
- Search for CSP 585 on [clinicaltrials.gov](http://clinicaltrials.gov)
- Contact Kristina Felder, CSP 585 Project Manager:  
[kristina.felder@va.gov](mailto:kristina.felder@va.gov) or 919-286-0411 x7379

# Questions?