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TITLE: Gulf War Women's Health Cohort

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14. ABSTRACT The objectives of this study are: 1) To establish the Gulf War Women's Cohort (GWWC), a large sample of women veterans who served in the 1990-1991 Gulf War and a comparison group of women who served in other locations during that period; and 2) To provide current, comprehensive data on the health status of women who served during the 1990-1991 Gulf War, and identify any specific conditions that affect GW women veterans at excess rates. The specific aims are: 1) To assemble the GWWC from data collected from women veterans who participated in previous and ongoing population studies of GW era veterans; 2) To conduct a multimodal health survey to provide data on the current health status of women who served during the 1991 GW era and comparisons between GW deployed veterans and non-deployed GW era veterans; 3) To provide comprehensive data on veteran-reported pregnancy and birth outcomes among GW and GW era women veterans; 4) To evaluate GWI and other high interest health outcomes in women veteran subgroups, including subgroups identified by (i) deployment characteristics.					
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1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

This epidemiologic study utilizes both existing datasets and newly collected survey data to examine the prevalence and patterns of GWI symptoms, diagnosed medical conditions, reproductive health, birth outcomes, and other health issues among women who served during the Gulf War. The study will utilize data from multiple studies in order to establish a Gulf War Women's Health Cohort. In new data collection, the projected number of completed surveys is 450.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Birth defects; Gulf War veterans; reproductive outcomes; women's health

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

Coordinate with sites for IRB protocol submission; coordinate with sites for Augusta University IRB review; coordinate with sites for military 2nd level IRB review (ORP/HRPO).
 Hire and train staff.
 Assemble the GWWC from previous study data; develop and finalize data use agreements.
 Conduct a pilot of survey questionnaire.
 Implement quality assurance measures for data collection and data management.

What was accomplished under these goals?

Year two activities have carefully followed the Statement of Work. These activities have included submission of human subject's protocol and related documents at subsites and submission of IRB protocol and related documents to ORP/HRPO.

Dr. Maxine Krengel submitted the human subject's protocol and related documents to the VA Boston Healthcare System IRB. The VA Boston Healthcare IRB required that letters be sent to Ft. Devons Study participants informing them that longitudinal data from the study was being placed in a VA data repository and asking them for their consent to have their study information placed in the repository.

A data use agreement is in place between CDC and Augusta University for the CDC Air Force dataset. The CDC did not consider the CDC Air Force study dataset to be human subjects as there are no personal identifiers. The data use agreement between VA CSP and Augusta University has essentially been completed was executed, allowing the VA ERIC program in Durham, NC to send CSP 585 Gulf War Survey and Biorepository survey data to the Boston University Data Coordinating Center via a secure server.

A major accomplishment in year two was the analysis of data from the CDC Air Force Study, Ft. Devens Study, and CSP 585 Gulf War Survey and Biorepository survey data in support of collaborative manuscripts.

Boston University Data Coordinating Center Staff (Emily Sisson and others) and Vahe Heboyan and Steve Coughlin at Augusta University have continued the process of quality assurance of data management and data collection. This includes documenting data files and verifying n's of key variables included in existing datasets.

Another major accomplishment in year two was publication of journal articles. These publications are included in the Appendices.

The second annual study group meeting of the Gulf War Women's Health Cohort Study was held in Baltimore in June. Drs. Steven Coughlin, Benjamin Ansa, and Nancy Klimas were in attendance. Ongoing data analyses and draft manuscripts were discussed.

What opportunities for training and professional development has the project provided?

Nothing to report

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?

Obtain all IRB approvals; hire and train additional staff at subsites; continue to assemble GWWC from previous study data; continue quality assurance measures; undertake postal survey and telephone interviews; code postal survey questionnaire/telephone interview responses; continue to prepare manuscripts and present finding at professional and scientific meetings.

- 4. IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?

The Gulf War Women's Health Cohort Study will provide a comprehensive picture of the health of women GW veterans. This includes assessment of current health status, changes in health symptoms and conditions over time, and possible differences in health outcomes associated with specific experiences and exposures during the war. It will allow for an assessment of GWI symptom patterns that may be specific to women veterans and a determination of diagnosed medical conditions. The study will generate data that will improve our understanding of GWI in

women veterans who served in the Gulf War, women GW veteran's health, and adverse reproductive outcomes.

What was the impact on other disciplines?

Nothing to report

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

- 5. CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change

Nothing to report

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

There has been a delay in obtaining IRB approval from VA Boston Healthcare and Balor College of Medicine. We are working to resolve this problem. An unanticipated event that occurred during year one is that Penny Pierce of the Uniformed Services University Graduate School of Nursing notified Steve Coughlin that she had determined that the data from her survey of Air Force women no longer exist. This dataset did not include any personally identifying information and was never a part of new data collection or longitudinal analyses for the Gulf War Women's Health Cohort.

Changes that had a significant impact on expenditures

Nothing to report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals.

Not applicable

Significant changes in use of biohazards and/or select agents

Not applicable

- 6. PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**

Report only the major publication(s) resulting from the work under this award.

Journal publications.

Coughlin SS. Physical Activity among Gulf War Veterans (Editorial). *Annals of Translational Medicine and Epidemiology* 2016;3
 Coughlin SS, Krengel M, Sullivan K, Pierce P, Heboyan V, Wilson C. A Review of Epidemiologic Studies of the Health of Gulf War Women Veterans. *Journal of Environment and Health Science* 2017, in press
 Coughlin SS. Need for Gulf War women's health research (Letter to the Editor). *Military Medicine* 2016;181:198.

Nothing to report

Other publications, conference papers, and presentations.

Pierce P, Wilson C. Gulf War Women's Health Cohort Study, poster presentation, AMSUS Annual Continuing Education meeting, National Harbor, MD, November 29th-December 2nd, 2016

- **Website(s) or other Internet site(s)**

Nothing to report

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

Nothing to report

- **Inventions, patent applications, and/or licenses**

Nothing to report

- **Other Products**

Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Steven Coughlin, PI, 2.4 person months, overseeing all aspects of the study
 Vahe Heboyan, Co-I and study biostatistician, 2.4 person months, analysis of data and assisting with manuscripts
 Maxine Krengel, Co-I, contributing to all aspects of the study, surveying GW women included in Ft. Devons Study
 Kimberly Sullivan, Co-I, contributing to all aspects of the study
 Emily Sisson, overseeing Boston University Data Coordinating Center activities
 Stacy Iobst, Co-I, contributing to all aspects of the study
 Candy Wilson, Co-I, contributing to all aspects of the study

period?

Nothing to report

What other organizations were involved as partners?

Nothing to report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

9. **APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

Appendix: Gulf War Women's Cohort Study Publications and Presentations

Title	Research Questions/Aims	Hypothesis	Data	Assignments	Timeline
1. Gulf War Women's Health Cohort Study, poster presentation, AMSUS Annual Continuing Education meeting, National Harbor, MD, November 29 th -December 2 nd , 2016		N/A	N/A	PIERCE AND WILSON	Presented
2. Need for Gulf War women's health research (letter to the Editor)		N/A	N/A	COUGHLIN	Published in <i>Military Medicine</i> 2016;181:198.
3. A Review of Epidemiologic Studies of the Health of Gulf War Women Veterans, journal article		N/A		COUGHLIN, KRENGEL, SULLIVAN, PIERCE, HEBOYAN, WILSON	Published in <i>Environment and Health Science</i> 2017
4. Gulf War Women's Health Cohort Study, presentation to Augusta University College of Medicine Ob-Gyn residents				COUGHLIN	August 3, 2016
5. Physical Activity among Gulf War Veterans (Editorial)		N/A	N/A	COUGHLIN	Published in <i>Annals of Translational Medicine and Epidemiology</i> 2016
6. Reproducibility and Transparency of Epidemiologic Research (commentary)				COUGHLIN	Published in <i>American Journal of Epidemiology</i> 2017

Title	Research Questions/Aims	Hypothesis	Data	Assignments	Timeline
7. (untitled)	The specific research questions of interest are: 1) what is the crude and age-adjusted prevalence of GWI among female and male GW veterans, defined by both the CDC and Kansas criteria? 2) How do results compare across the two surveys?	It is hypothesized that the prevalence of GWI will be somewhat greater among female GW veterans than their male counterparts.	Ft. Devens Co-hort Study, and CSP 585 Pilot Study	KRENGEL, SULLIVAN, et al.	The analysis is underway
8. Gender Differences in Gulf War Illness: A Re-analysis of Data from the CDC Air Force Study	The specific research questions of interest are: 1) what is the crude and age-adjusted prevalence of GWI among female and male GW veterans, defined by both the CDC and Kansas criteria?	It is hypothesized that the prevalence of GWI will be somewhat greater among female GW veterans than their male counterparts.	CDC Air Force Study	Heboyan, Kregel, Sullivan, et al.	Journal of Occupational and Environmental Medicine, in press/
9. Deployment and pre-term birth among US Army soldiers (letter to the Editor)				Coughlin	Published in the <i>American Journal of Epidemiology</i>
10. A neuroimmune model of Gulf War Illness				Coughlin	Published in <i>Environment and Health Science</i> 2017
11. On the need for epidemiologic studies of Gulf War Illness among African American veterans (Editorial)				Coughlin and Heboyan	Published in <i>Environment and Health Science</i> 2018
12. study protocol: Gulf War Women's Health Cohort Study				Ansa et al.	In preparation
13. Scoping review of epidemiologic studies of birth defects and adverse birth outcomes among veterans	Scoping review of epidemiologic studies of birth defects and adverse birth outcomes among veterans			Ansa et al.	In preparation

Title	Research Questions/Aims	Hypothesis	Data	Assignments	Timeline
14. Frequency of Symptoms among Female Veterans of the 1991 Gulf War Era: Results from the Cooperative Studies Program 585 Gulf War Era Cohort and Biorepository,	Comparison of frequency of symptoms among deployed and non-deployed women veterans		CSP 585	Coughlin, Heboyan, Sullivan, et al.	Submitted for publication
15. Frequency of Symptoms among Female Veterans of the 1991 Gulf War Era: Results from the Cooperative Studies Program 585 Gulf War Era Cohort and Biorepository,	Comparison of frequency of symptoms among deployed and non-deployed women veterans		CSP 585	Coughlin, Heboyan, Sullivan, et al.	Submitted for presentation to American Society of Epidemiology annual meeting
16. Gender Differences in Gulf War Illness: A Re-analysis of Data from the CDC Air Force Study	The specific research questions of interest are: 1) what is the crude and age-adjusted prevalence of GWI among female and male GW veterans, defined by both the CDC and Kansas criteria?	It is hypothesized that the prevalence of GWI will be somewhat greater among female GW veterans than their male counterparts.	CDC Air Force Study	Heboyan, Kregel, Sullivan, et al.	Submitted for presentation to American Society of Epidemiology annual meeting
17. Cardiovascular Disease among Women Gulf War Veterans (letter to-the-Editor)	Comparison of CVD among deployed and non-deployed women veterans		CSP 585	Coughlin, Heboyan, Sullivan, et al.	Submitted for publication
18. Deployment-related exposures associated with Gulf War Illness among women veterans	Examination of deployment-related exposures in relation to Gulf War Illness		CSP 585	Sullivan, Kregel, et al.	In preparation