

Title: The Longitudinal Effects of the Gulf War: Veterans' Reproductive And Children's Health Survey (LEGACY) Study Protocol

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Abstract

Since their deployment to the 1990-1991 Gulf War Gulf War veterans (GWVs) have experienced several adverse health outcomes, including the multisymptom illness known as Gulf War Illness (GWI). According to current literature, GWI is more prevalent among women veterans compared to male veterans. Studies also have consistently linked chemical exposures during deployment to adverse health outcomes in GWVs, but few studies have examined reproductive health outcomes in these veterans or health, developmental and reproductive outcomes in their offspring. Though prior data support the potential of transgenerational effects, questions still remain about how deployment may have affected the development and overall health of GWV's children. The Longitudinal Effects of the Gulf War: Veteran Reproductive and Children's Health Survey (LEGACY) Study aims to: 1) characterize the reproductive health of a newly created, national cohort of GWVs, 2) examine the association of veterans' reproductive outcomes with GWI and GW exposures, and 3) investigate the development and overall health of children of GWVs in relation to GWI and GW exposures. To achieve these objectives, data collection will occur via self-administered surveys that were informed by GWV input, GW expert perspectives, and previous literature on the reproductive health of GWVs.

Introduction

After returning from the 1990-1991 Gulf War (GW), military personnel have reported a broad range of persistent adverse health effects.¹⁻⁴ Compared to veterans who were in the military during the same time as the GW but did not deploy to the Persian Gulf region (i.e., GW-era veterans), Gulf War Veterans (GWVs) have experienced a greater prevalence of musculoskeletal, neurological, pulmonary, gastrointestinal, and dermatological symptoms.⁴⁻⁸ Veterans experiencing a myriad of these symptoms have a chronic multi-symptomatic illness called Gulf War Illness (GWI).^{3,9,10}

In our 2022 preliminary report on women veterans who served in the military during 1990-1991 by Friedman et al.,¹¹ the prevalence of adverse pregnancy and children's developmental health outcomes were higher among GWVs compared to GW-era veterans and general population rates in the United States. For example, 12% of GWVs reported having pre-eclampsia, which is more than double that of the general U.S population according to the CDC (approximately 5-7% in recent years).^{11,12} The prevalence of Attention-Deficit Hyperactivity Disorder (ADHD) among children of deployed GWVs (31%) was roughly three times that of the U.S general population (9%) and the rate of behavioral problems in GWVs' offspring (15%) was about double the prevalence in the U.S. (7%).¹¹ Notably, the rates for these outcomes were higher among GWVs with GWI compared to GWVs without GWI, though the sample size was small.¹¹

There are only a handful of studies that have examined rates of poor reproductive outcomes, all of which reported an increased rate of birth defects among children of GWVs. However, previous studies were generally small in size, could not examine potential associations with GWI, and/or did not examine the relationship between deployment exposures and health outcomes. Further, only one study has examined the overall health of the children of GWVs.^{13–17} The authors of that study reported that children of GWVs experienced worse dentition, greater obesity, and more behavioral problems compared to children of non-deployed GW-era veterans.¹³ Given preliminary findings, examining these questions in larger cohorts is vital to confirm findings and be able to recommend early public health interventions.

The Longitudinal Effects of the Gulf War: Veterans' Reproductive And Children's Health (LEGACY) Study aims to assess reproductive and developmental outcomes in a large sample of GWVs and their offspring. To achieve these objectives, survey data are collected from GWVs and their family members across the U.S. The project developed detailed questionnaires based on information provided by GWVs and their families, GWV clinical and research experts, neurotoxicological literature, and findings from previous GWV studies.

2. Materials and Methods

2.1 Study Design

Data are collected from GWVs and their adult children (i.e., 18 years or older) using self-administered surveys. The LEGACY survey obtains systematic, detailed information on the general health and medical, behavioral, and reproductive health histories of GWVs, their

spouses, as well as Gulf War deployment and post-deployment exposure histories. Open-ended questions are included to allow respondents to report additional information about health conditions, experiences, or concerns not specifically queried by the survey.

2.2 Study Participants and Inclusion Criteria

The LEGACY Study recruits all GWVs and, if applicable, their adult children. GWVs without children are also eligible to participate in the LEGACY study and will serve as a comparison group in some analyses. The eligibility and inclusion/exclusion criteria for GWVs and their children are listed below:

GW Veterans. To be eligible for the study, veterans must have deployed to the Persian Gulf region for any period between August 1990 and July 1991. Initial recruitment of GWVs into the study will be conducted through already existing research sites at Boston University (BU), NOVA Southeastern University, San Francisco Veterans Affairs (VA) Medical Center, and Baylor College of Medicine. The existing cohorts include:

- ***Gulf War Illness Consortium (GWIC) cohort:***¹⁸ *GWIC* was developed as a multi-site, multidisciplinary research program capable of integrating and building on GWI findings in multiple fields. The largest *GWIC* clinical project was a three-site case-control study, which conducted in-depth evaluations of GWVs at BU, Miami VA, and Baylor College of Medicine in Houston between 2015 and 2020 and includes data for roughly 300 veterans.

- ***The Boston Biorepository, Recruitment, and Integrated Network (BBRAIN) cohort:***¹⁹

The BBRAIN collaboration brings together leading investigators from 15 institutions to support participant recruitment, administrative activities, data management and biostatistics, and biorepository and biomarker evaluation. Recruitment is ongoing for this cohort, but currently includes about 250 Gulf War Veterans from both the past GWIC cohort and recent BBRAIN recruitment activities.

- ***Gulf War Women's Cohort (GWWC):***²⁰ The GWWC was designed to specifically address questions on women's health following GW deployment. The study sites include Augusta University, Boston VA and BU. The study population consists of approximately 150 GWV women.

- ***University of California, San Francisco VA GW Cohorts:***^{21–24} Includes three studies funded by the VA and DOD aimed at examining the effects of GW deployment and deployment-related exposures on brain structure and brain function. Combined across the three cohorts approximately 600 GWVs are eligible to be contacted for this reproductive and developmental health study.

GWVs are invited to participate regardless of their original GWI case status or if they have since developed any condition originally identified as exclusionary by one of the previous studies.

Duplicate participants who may have existed in multiple cohorts will only be included once.

Recruitment is not limited to participation of GWVs in the aforementioned cohorts. Other GWVs who verify that they were deployed to the Persian Gulf region between August 1990 and July 1991 are eligible to participate.

GWV Adult Children. For children of GWVs to be eligible to participate, they must be at least 18 years of age at the time of the study and the biological child of a GWV who completed the adult survey.

2.3 Procedures

Gulf War Veterans

This study utilizes a two-pronged approach to recruit GWV participants:

- (1) Recruitment from existing study cohorts. BU, NOVA Southeastern University, San Francisco VA, and Baylor College of Medicine were established research sites. GWVs who previously participated in GWIC, BBRAIN, GWWC, or any one of the three UCSF GW studies – and agreed to future contact – will be contacted by site leaders and invited to participate in the LEGACY study.
- (2) Recruitment of new GWV participants. Extensive outreach efforts, such as sharing information publicly on the LEGACY and BBRAIN Studies' websites, the BBRAIN Consortia BU Facebook page, hosting information tables at GWVs events, and distributing recruitment flyers, will be taken to recruit GWVs who had not participated in the aforementioned studies.

Veterans who indicate their interest in the study are provided a unique REDCap survey link shared via email. This link directs interested veterans to an information sheet for their review. Veterans who, after reviewing the information, choose to participate in the study are invited to complete an online survey in which the individual reports on sociodemographic characteristics, GW service, deployment exposure history, information on symptoms and medical conditions,

academic performance as well as reproductive, birth, and child health outcomes. The participant will also report this information as it pertains to the other biological parent of the reported child(ren). Participants who have difficulty accessing or using digital devices have the option to complete the study over the phone with study research staff. The self-administered survey takes roughly 60 minutes to complete. We predict that use of the electronically delivered surveys will decrease the time burden for participants as well as the number of response errors due to the use of branching logic. Participants can resume survey completion if they choose to stop the survey and return at a later time. Once the survey is completed participants receive an email containing a \$20 gift card in appreciation of their contributions to the study.

Adult Children of Gulf War Veterans

When GWVs complete the survey online or by telephone, they are informed that the project will be establishing a Gulf War Adult Child Cohort (GWACC). The goal of the GWACC is to collect and evaluate health information reported by adult children of GWVs. Veterans who complete the study and indicate that they have biological children aged 18 or older are asked to share information about the study with their adult children. GWVs who indicate they are willing to share information with their adult children are provided a GWACC study summary and recruitment flyer for this purpose. Additionally, GWVs receive a unique REDCap link to share with each of their adult children that provides study information and the GWACC survey link. GWV adult children who receive electronic study information from their GWV parent are also encouraged to contact the study research team with any questions they have.

Interested adult children of GWVs use the sub-survey REDCap link provided by their parent to access and review the GWACC information sheet. They are asked if they want to participate, and if so, are directed to the survey. If either the GWV parent or adult child participant has difficulty accessing the unique REDCap survey link, it can be retrieved and provided by LEGACY research staff at BU's Biostatistics and Epidemiology Data Analytics Center (BEDAC). Adult children are offered the option to complete a phone survey if they prefer. Once a survey is completed by a veteran or their child, the participant has the choice to receive a \$20 Amazon electronic card code, sent via email in appreciation for their time and study contributions.

2.4 Survey Questionnaire Design

The survey questionnaires for this study were developed from prior GW studies including BBRAIN, GWIC, and the previous GW Women's studies. The LEGACY Study surveys include the Structured Neurotoxicant Assessment Checklist (SNAC)²⁵ and Gulf War and Health Questionnaire.^{26,27} Additionally, the survey utilizes the Kansas case definition and the DePaul Symptom Questionnaire, both of which were listed as core and highly recommended supplementary elements in the VA/DOD GWI Common Data Elements Project, respectively.²⁸ Additionally, the inquiries regarding birth defects in the survey were informed by findings from the National Birth Defect Registry,²⁹ which is sponsored by the non-profit Birth Defect Research for Children and includes a special section on military exposures for Gulf War veterans.³⁰ The LEGACY Study survey will improve upon previous survey designs, specifically in the realm of child health outcomes, as they were informed by testimonies from GWVs. The survey for GWVs consists of eight sections: 1) Sociodemographic, 2) Military History, 3) General Health Status, 4)

Obstetric and Reproductive History, 5) Pregnancy Outcomes, 6) Children's Health Outcomes, 7) Other Biological Parent History, and 8) Exposure History (**Table 1**). The survey for GWVs' adult children is a modified version of the GWVs survey.

The main outcomes of interest include self-reported health status, with a particular focus on reproductive and children's health outcomes. For each health outcome, respondents are asked to report the year of diagnosis or onset, as well as respond to questions aimed to determine the severity of the outcome (e.g., symptoms reported as mild, moderate or severe; use of prescription medications to alleviate symptoms).

Table 1. Categories of information collected by the LEGACY study, by survey sections

Sociodemographic Factors	Age, sex, race, ethnicity, Marital status Educational attainment Employment status and occupation
Military History	Current military status and past military history Gulf War service details Parents and grandparents' military history
General Health Status	Questions about health status Symptoms persisting 6 months or longer Diagnosed medical and psychiatric conditions Academic difficulties
Reproductive Health	Measures of fecundability and fertility Diagnosis of reproductive related conditions
Pregnancy Characteristics and Outcomes	Pregnancy history Exposures during pregnancy Pregnancy complications Status of infant at delivery

Children's Health Outcomes	Birth defects Diagnosed medical and psychiatric conditions Academic performance Reproductive history
Other Biological Parent's History	Sociodemographic information Diagnosed medical and psychiatric conditions Exposure history prior to conception and during pregnancy
Veterans' Exposure History*	Exposures that occurred during deployment to the Persian Gulf region during 1990-91

*Only applies to veterans survey and not the adult children survey

2.5 Quality Assurance, Confidentiality and Data Security

Prior to the study start, the surveys were piloted by collaborators to improve the usability of the survey. To further ensure data quality, the research team will carefully monitor surveys for completeness and will conduct the range for appropriate values. Study data provided by individual participants will be identified by a unique study ID number which is linked to a master-code list that contains all study ID numbers and direct subject identifiers (such as names or addresses). The master-code list is stored and maintained separately from study files, and its access is restricted. To further mitigate the potential loss of confidentiality, research data is stored on password-protected encrypted devices.

2.6 Summary of research goals/objectives

The overall research goal of the LEGACY study is to investigate the relationship between characteristics of GW deployment and adverse health outcomes in GWVs and their children. The study will also establish the first cohort of GWV adult children. Our specific research objectives are listed below:

Gulf War Veterans. The primary objectives of this study are (1) to determine the occurrence of various health outcomes among GWVs, specifically focusing on veterans' reproductive health and pregnancy outcomes, and medical, behavioral, and developmental outcomes among their minor children, and (2) to determine the associations of these health outcomes with GWI and with exposures (e.g., sarin gas, oil fire smoke, pyridostigmine bromide, pesticides) during 1990-1991 Gulf War deployment.

GWV Adult Children. Primary study objectives are (1) to characterize the health of adult children of GWVs and (2) to evaluate whether general health indicators or a range of specific health outcomes are associated with parental GWI or with specific parental deployment exposures.. We will also explore modification or mediation by parent GWI case status will be considered, along with other potential effect measure modifier/mediators of these associations.

For both GWVs and GWV adult children, additional exploratory analyses will be considered to 1) identify effect measure modifiers and mediators of identified associations between deployment characteristics and adverse health outcomes and 2) evaluate possible effects of combinations of exposures (i.e., chemical mixtures) in relation to health outcomes in veterans and their children.

2.7 Ethical Considerations/Discussion

Prior to study involvement, interested subjects are provided with detailed information about the study purpose, procedure, confidentiality measures, potential risks and benefits, and their right to withdraw at any point. The potential risks of participating in this study include minor discomfort in answering the survey questions and the risk of breaches of confidentiality.

For any questions that cause participants discomfort, the research team is prepared to promptly provide support and more detailed information as to the rationale behind the question being posed. Participants have the option to pause and return to any questions that cause them discomfort. Additionally, participants can skip any questions that they do not feel comfortable answering (aside from those required to assess study eligibility).

There are no direct benefits to participants in this study. However, there are potential indirect benefits including increasing the understanding of GWI case status and/or deployment-related exposures associated with reproductive, birth, and children's health outcomes across the life course.

3. Conclusions

There is a significant research gap and need for information regarding reproductive and developmental health outcomes among GWVs and their offspring. The LEGACY study is designed to thoroughly investigate Gulf War deployment-related and subsequent exposures in relation to veterans' reproductive health, birth outcomes, and the health of their children, and to determine if these associations differ by GWI case status. The LEGACY Study also establishes the first cohort of GWV adult children in order to address GWVs' pressing questions concerning possible intergenerational effects of GW service. Data collected for the LEGACY study hold promise for providing improved understanding of long-term effects of GW service on the health of GWVs and their children, as well as teratogenic effects of chemicals similar to those used in the Gulf War theater in other populations.

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