AWARD NUMBER: W81XWH-20-1-0801

TITLE: Identifying Gaps in Patient-Provider Communication and Improving Care for Veterans with Gulf War Illness

PRINCIPAL INVESTIGATOR: Maxine Krengel, Ph.D.

RECIPIENT: Boston Va Research Institute, Inc., Boston, MA

REPORT DATE: October 2023

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	**2. REPORT TYPE**	**3. DATES COVERED**
October 2023	Annual	30Sep2022-29Sep2023

4. TITLE AND SUBTITLE

Identifying Gaps in Patient-Provider Communication and Improving Care for Veterans with Gulf War Illness

5a. CONTRACT NUMBER
W81XWH-20-1-0801

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Maxine Krengel, Ph.D.

E-Mail: mhk@bu.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Boston VA Research Institute, Inc.
5 Post Office Sq #16-28,
Boston, MA, 02109-3901, United States.

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Research has shown that there are gaps in knowledge that Primary Care Physicians (PCPs) have regarding Gulf War Illness (GWI), etiology, and potential treatments. It is essential to provide awareness of the leading theories of GWI and how etiologic factors have led to biologic markers and specific treatments, so that clinicians can more effectively communicate with their Gulf War veteran (GWV) patients and provide appropriate care. The goals of this project are to identify the gaps in the Department of Veterans Affairs (VA) and community Primary Care Physicians' (PCPs) knowledge about GWI, etiology, and current treatments and address those gaps through a training module.

The specific aims of this proposal are (1) Assess PCPs knowledge of GWI, patient provider communication approaches, and diagnostic strategies. (2) Create the educational training for PCPs based off the gaps identified in Aim 1. (3) Assess PCPs knowledge of GWI, patient provider communication approaches, and diagnostic strategies after having reviewed the training materials provided. (4) Implement sustainment plan. This proposal consists of three phases: Pre-Test, Training, and Post-Test. The Pre-Test Survey will contain 3 structured clinical vignettes, questions pertaining to treating veteran illnesses, and demographics about PCPs training and experiences. Three months after the completion of the Pre-Test Survey, PCPs will receive another survey containing a 25-minute video training module followed by comprehension questions. Three months after the training module has been completed, PCPs will receive the Post-Test survey containing 3 additional structured clinical vignettes and questions pertaining to treating veteran illnesses. We will assess the efficacy of the training module by comparing the PCPs performance on the clinical vignettes before and after training.
There are no results as of yet.

15. SUBJECT TERMS: Gulf War Illness, Health symptoms, Gulf War, Toxicant Exposures, Patient-provider, Primary care physicians.

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRDC
U	U	U	UU	14	**19b. TELEPHONE NUMBER** *(include area code)*

TABLE OF CONTENTS

1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

Research has shown that there are gaps in knowledge that Primary Care Physicians (PCPs) have regarding Gulf War Illness (GWI), etiology, and potential treatments. Recently, researchers have been studying the gaps by interviewing GW veterans (GWVs). This proposal goes one step further by assessing and designing training materials for PCPs to increase their knowledge of GWI. It is essential to provide appropriate training modules, so that clinicians can more effectively communicate with their GWV patients and provide appropriate care. Overarching Challenges: The goals of this project are to identify the gaps in the Department of Veterans Affairs (VA) and community Primary Care Physicians' (PCPs) knowledge about GWI with the use of clinical case examples. PCPs will be asked for their care plan and treatment initiatives. The gaps found will be used to target training materials, which will be sent to these PCPs. Objective/Hypothesis: The main objective is to provide PCPs with a training module aimed at increasing their knowledge of GWI, the etiology, and potential treatments. We will assess the efficacy of the training module by comparing PCPs knowledge pre and post training. Our team at VA Boston are clinicians and researchers who have strong ties to communities who serve GWVs. Through our work with the GW treatment and biorepository consortia and their veteran advisory board, we will strategically include our new training module for use in VA and community wide programs. This proposal will have a major impact on the care given to GWVs by serving as a conduit from the research realm to directly impacting clinical care and improving the quality of life of ailing GWVs.

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

Patient provider, Gulf War Illness, Veterans, Gulf War, Health symptoms, Health status, Chronic Fatigue Syndrome, Patient Provider

3. **ACCOMPLISHMENTS:**

What were the major goals of the project?

- The major goals of the project as stated in the revised SOW is listed in the table below. Specifically, the primary goals were to devise in a Qualtrics format at BUSPH to set up the exposure and clinical vignettes that would be viewed by the clinicians.
- The targeted clinical subgroup was altered after we did not obtain any completed surveys after sending out 400 letters to primary care physicians.
- Milestones/target dates for important activities or phases of these dates are listed in the table and actual completion dates are listed below.

STATEMENT OF WORK

Site 1: VA Boston Healthcare System	Site 2: Boston University School of Public Health
150 South Huntington Ave, Boston, MA 02130	715 Albany Street Boston, MA 02118
PI: Dr. Maxine Krengel	PI: Dr. Kimberly Sullivan

Specific Aims: Aim 1: Assess PCPs knowledge of GWI, patient provider communication approaches, and diagnostic strategies. Aim 2: Create the educational training for PCPs based off the gaps identified in Aim 1. Aim 3: Assess PCPs knowledge of GWI, patient provider communication approaches, and diagnostic strategies after having reviewed the training materials provided. Aim 4: Implement sustainment plan.

Tasks Timeline	
Task 1. Obtain necessary authorization prior to initiation of human subjects	Months
1a. Obtain Institutional Review Board (IRB) approval for VA Boston Healthcare System for protocols	1-4
1b. Obtain DOD Human subjects Research Protections Office (HRPO) Approval	5-7
1c. Complete hiring of necessary staff and ensure all mandatory IRB research related trainings are completed by all staff members	1-8
Task 2. Preparations for Study Procedures	Months
2a. Set up Qualtrics platform web page design	7-12
2b. Update and finalize pre-test and post-test vignettes and scoring procedure	1-6
2c. Present vignettes to GWV panel and ask for suggests and edits and update accordingly.	7-10
2d. Pilot the vignettes with physicians who are familiar with assessing and treating GWVs. Update vignettes and scoring procedures with physician feedback.	10-12
Task 3. Recruitment and pre-assessment of Patient Care Providers (PCPs)	Months
3a. Obtain a list of PCPs addresses and emails from American Medical Association	7-12
3b. Assess 50 PCPs and obtain demographics, vignettes responses, and current GWI knowledge responses for Pre-Test Survey.	12-18
Task 4. Creation and Dissemination of Training Materials to PCPs	
4a. Collaboration with Drexel University, WRIISC, and veteran advisory panel to create necessary training program.	8-15
4b. Review the training program with physicians involved in clinical assessment of GWVs. Update as needed with physician feedback.	12-15
4c. Disseminate the training to PCPs	15-24
Task 5. Post-assessment of PCPs	Months
5a. Assess PCPs vignette responses	18-27
5b. Determine GWI knowledge post-training	18-27
Task 6. Perform Interim Data analyses	
6a. Interim statistical analyses of data obtained from vignettes and GWI knowledge scores will be performed periodically.	18-30
6b. Annual reports of progress will be written.	12-24
Task 7. Perform Final Data Analysis, Prepare Manuscripts for Publication	Months
7a. Perform analyses comparing pre-assessment vignette and GWI knowledge to post-assessment vignette and GWI knowledge.	27-36
7b. Write final study report	27-36
7c. Present findings at scientific meetings and prepare manuscripts for submission	27-36

How were the results disseminated to communities of interest?

Nothing to report

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

We sent out the first 200 letters to primary care providers and did not receive any responses. We then sent out 200 more letters to PCPs and did not receive any complete responses. We then moved on to Occupational and environmental health physicians and sent out 200 letters to individuals for whom we were able to obtain addresses. We again did not receive any completed surveys. We have been working with the IRB to determine the efficacy of attending a conference to see if we can recruit in person.

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

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

We have revised the training protocol using guidelines from the WRIISC protocol for VA providers. This has allowed us to use the most up to date research on neurotoxicant exposures and long-term health impacts in order to assist PCPs in their practices.
We will also be adding to the training modules in conjunction with WRIISC providers, the influence of COVID-19 and long COVID on GWI.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Once we have validated our new treatments with PCPs, we will be able to provide this knowledge for use in the VA system as well.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "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
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

We have increased recruitment to include occupational and environmental health physicians who also should have an appreciation for toxicant exposures and healthcare.

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

Given the lack of responses from the PCPs and the environmental health specialists through snail mail, we have been trying to come up with better means of recruitment.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

We had to move the data collection of the project to Boston University School of Public Health because of the IRB concerns of using VA redcap for non-utilizers of the VA system. This did not slow down our process for recruitment.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals.

Significant changes in use of biohazards and/or select agents

N/A

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. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report

Other publications, conference papers, and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to report

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

N/A

- **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.

We are continuing to improve the training module for use in VA and non-VA health systems that is currently being offered through the WRIISC program.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

N/A

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *biospecimen collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*

- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

RedCap has been set up for use with PCPs to determine the initial interest and experience with Gulf War Illness.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."

Example:

Name:	*Mary Smith*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*1234567*
Nearest person month worked:	*5*
Contribution to Project:	*Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support:	*The Ford Foundation (Complete only if the funding support is provided from other than this award).*

Dr. Kimberly Sullivan from Boston University School of Public Health worked on developing the RedCap protocol and is in charge of the oversight of the project.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

n/a

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.
Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*

- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

n/a

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://ebrap.org** 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.