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TITLE: Development of a PTSD Population Registry

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14. ABSTRACT:
The purpose of this project is to develop the first longitudinal registry of combat-exposed men and women with posttraumatic stress disorder (PTSD). This registry will provide essential data on the natural history and outcomes associated with PTSD in military service men and women who have utilized the Department of Veterans Affairs (VA) health care system. An additional goal of this project is to evaluate risk factors for PTSD among combat-exposed service men and women. Since September of 2010, data were collected on 265 men and 324 women. Of these participants, 75% met criteria for PTSD. To date, 765 phase 2 participants have completed.

15. SUBJECT TERMS: Risk factors for PTSD. PTSD symptom development and VA healthcare utilization.

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INTRODUCTION

The purpose of this project is to develop the first longitudinal registry of combat-exposed men and women with PTSD. This registry will provide essential data on the natural history and outcomes associated with PTSD in military service men and women who have utilized the Department of Veterans Affairs (VA) health care system. An additional goal of this project is to determine risk factors for PTSD among combat-exposed service men and women (by incorporating a combat-exposed non-PTSD group of veterans into analyses). Thus, the registry will allow an evaluation of current theoretical models of symptom development in a large sample of service men and women who utilize the VA medical system.

BODY

Research technicians attempted to make contact with the remaining potential participants from the level 1 roster. After 2 opt out letters were sent to all 3,000 participants from the level 1 roster, 1,232 non-responders from the roster remained. Research technicians then contacted all remaining non-responders by phone, as outlined in the project protocol. In month 25 of the project, a new level 1 roster of 6,000 potential participants was received. In months 25 through 34 initial opt out letters were sent to all 6,000 participants on the roster. Of the 6,000 letters mailed, 1,959 were returned. Currently, a second round of opt-out letters is being sent to the 4,041 participants who did not respond to the initial mailing. Of the 6000 participants who have been contacted, 1,372 returned letters agreeing to be contacted about the study, and 222 returned letters declining to be contacted further. Five hundred and fifty-eight (558) recruitment letters have been returned for bad addresses. A second opt-out letter was sent to these participants using the secondary address that was provided with the second level 1 roster. At present, 765 phase 2 participants have completed the project.

To date, no problems have impeded performance of the project.

Personnel receiving salary from this research effort are Raymond C. Rosen, Ph.D. (Partnering PI), Margaret A. Gates, Sc.D. (Project Manager and Co-I), Lin Guey, Ph.D. (hired to replace Lynn Sleeper as Project Statistician and Co-I), and Blandyna Williams (Research Assistant).

KEY RESEARCH ACCOMPLISHMENTS

- Phase 2 recruitment is ongoing

REPORTABLE OUTCOMES


CONCLUSION

The PTSD registry will provide information to assist researchers, military leaders, and treatment providers to better understand the etiology and course of PTSD, how it can be identified at early stages, and the responsiveness of recent returnees to various treatment options. This knowledge will be of benefit to policy makers and current service members as well as victims of trauma in the broader community. It will include:

• Evaluation of the natural history and long-term outcomes of PTSD across treatments, treatment settings, and practitioners, using cost-efficient methods and economies of scale;

• A more accurate assessment of current theoretical models of symptom development, and

• Documentation of health resource utilization and development of a database that is an ideal resource for health services planning and policy.

Furthermore, this study will contribute:

• The formation of a potential cohort of subjects for ancillary studies, ranging from genomic influences to quality of life and psychosocial outcomes, as well as future clinical trials;
• The creation of a representative sample of PTSD OEF/OIF Veterans who use the VA medical system, available for use in epidemiologic studies, particularly for comparisons with active duty and other Veteran or civilian populations;
• Utility to clinicians, patient advocacy groups, and health policy planners;
• Publications and dissemination of the registry results to provide a representative perspective of what is achieved in actual current care settings, thereby augmenting outcomes data from clinical trials.
This project requires human subject participation.

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<th>Major Task (Milestone)</th>
<th>Timeline (Months)</th>
<th>BVARI</th>
<th>NERI</th>
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<td><strong>PHASE I – STUDY INITIATION</strong></td>
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<td>IRB Approvals/Finalize Protocol</td>
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<tr>
<td>Finalize Protocol; NERI/VHA IRB approvals and USAMRMC HRPO human subject protocol approval</td>
<td>Completed</td>
<td>TK/BM</td>
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<td><strong>Program and Test De-Identification</strong></td>
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<td>Programs to de-identify VA in/outpatient electronic records database will be created</td>
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<td>De-identification programs will be tested on sample data</td>
<td>33-36</td>
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<td>Design statistical analysis programs</td>
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<td>Data on potential participants will be merged from electronic databases</td>
<td>Completed</td>
<td>TK/BM</td>
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<tr>
<td>Data will be de-identified</td>
<td>Completed</td>
<td>TK/BM</td>
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<td>Transfer data to NERI</td>
<td>33-45</td>
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<td>Generate query reports that relate to the quality of the database based on pre-determined values</td>
<td>33-45</td>
<td>RR</td>
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<td>Data cleaning and tracking</td>
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<td>Pretest telephone Interview Instrument</td>
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<td>The interview will be tested in a sample of 20 veterans who will not be enrolled in the study to assess burden, ease of comprehension and time to completion</td>
<td>Completed</td>
<td>TK/BM</td>
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<tr>
<td>Make modifications based on pre-testing</td>
<td>Completed</td>
<td>TK/BM</td>
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<tr>
<td>Final interview tested to allow completion in a 40-50 minute telephone call</td>
<td>Completed</td>
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<tr>
<td>Develop manual of operations</td>
<td>Completed</td>
<td>TK/BM</td>
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<tr>
<td>Identification</td>
<td>Task Description</td>
<td>Timeframe</td>
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<tr>
<td>Identify Target Sample for Interview</td>
<td>Identify 1,200 OIF/OEF veterans with diagnosis of PTSD and 400 OIF/OEF veterans without diagnosis of PTSD and one or more visits during post-deployment years in the VA medical records database</td>
<td>Completed</td>
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<tr>
<td>Conduct Interim Analyses</td>
<td>Conduct interim analyses using existing PTSD Registry data</td>
<td>33-39</td>
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<tr>
<td>Conduct Interviews</td>
<td>Interviewers will be extensively trained and monitored for quality assurance</td>
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<td>Patients will be contacted by telephone and informed consent will be obtained verbally</td>
<td>21-45</td>
<td>TK/BM</td>
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<td>Patients provide verbal consent and interviews are scheduled</td>
<td>21-45</td>
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<td>Interview Data Entry De-Identification and Transfer</td>
<td>Data entry and quality control measures will be ongoing at the VA</td>
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<td>Analyses will be conducted to address the Specific Aims of the Registry Reports and Publication</td>
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<td>Continued Abstraction of Medical Records</td>
<td>Perform abstraction periodically of VA in/outpatient electronic medical records for PTSD registrants who have return in/outpatient visits to VA medical centers</td>
<td>24-48</td>
<td>TK/BM</td>
</tr>
<tr>
<td>Prepare PTSD Database for Future Use</td>
<td>PTSD Registry database of 1,200 OIF/OEF veterans will be prepared for potential sharing as a public dataset</td>
<td>46-48</td>
<td>TK/BM</td>
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