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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. The pilot phase of this project was completed in January 2010. Pilot data were collected on 13 men and 14 women. 73% met criteria for PTSD. Data collection for the full sample began in May 2010. To date, 169 phase 2 participants have completed.

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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

Initial study approval was received from OHRP in month 12 of year 1. In months 1 and 2 of year 2 sites submitted all continuing review approval materials to OHRP. Approval to begin the pilot phase was received from OHRP in month 2 of year 2. Pilot testing took place over the course of months 3 through 5. The level 1 roster of potential participants was obtained from the DC VA Medical Center in month 3. During months 3 and 4 the initial opt-out letter was mailed to the 3,000 participants on the level 1 roster. In month 5 the second opt-out letter was mailed to the 2,169 potential participants on the level 1 roster who did not respond to the initial opt-out letter. Approximately 900 letters were returned because of a bad addresses or forwarding address. A third cycle of opt-out letters was mailed to these participants after a correct address was located in CPRS. In total, 772 positive responses and 160 refusals were received. Of the original level 1 roster there were a total of 1,232 non-responders.

Pilot participants were 13 men and 14 women (n=27) who returned the initial opt-out letter. The mean age of the pilot sample was 41. Seventy-three percent of pilot participants met criteria for PTSD. Pilot testing was completed in month 5 concluding phase 1 of the project. Materials for approval to begin phase 2 were submitted to OHRP at the beginning of month 6. Additional supporting materials as well as documentation of local continuing review were submitted to OHRP in month 7. Approval to begin phase 2 was received on April 30th 2010 (month 8). Full sample data collection began in early in month 9 and is ongoing. By the end of month 11 research technicians had made at least initial contact with most of the 772 potential participants. Research technicians began making calls to the level 1 roster non-responders in month 12. To date 169 phase 2 participants have completed the project.

The study’s Scientific Advisory Board met in month 10 to review changes made during pilot testing. One new research technician was research credentialed and trained in the same month. To date there have not been any problems that have impeded performance of the project.

Personnel receiving salary from this research effort are Darren Holowka, Ph.D. (project coordinator and clinical interviewer) and Elise Ratchford (research technician). Kate Glossner
(research technician) was hired to replace Joseph Gonzalez (research technician). Daniella Halperin M.A. (clinical interviewer) also receives salary.

**KEY RESEARCH ACCOMPLISHMENTS**

- Study measures and procedures were finalized and the manual of operations was completed.
- Pilot testing was completed.
- Phase 1 of the project is completed.
- Phase 2 recruitment is under way.

**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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<td>Make modifications based on pre-testing</td>
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### Identify Target Sample for Interview
Identify 1200 OIF/OEF veterans with diagnosis of PTSD, 400 OIF/OEF veterans without diagnosis of PTSD and a mental health evaluation/assessment conducted post-deployment years in the VA medical records database

| 11-12 | TK/BM |

### Conduct Interim Analyses
Conduct interim analyses using existing PTSD Registry data

| 14-15 | RR |

### Conduct Interviews
Interviewers will be extensively trained and monitored for quality assurance
Patients will be contacted by telephone to conduct informed consent.
Patients who provide their consent will complete the interview

| 10-26 | TK/BM | RR |
| 12-26 | TK/BM |
| 13-26 | TK/BM |

### Interview Data Entry De-Identification and Transfer
Data entry and quality control measures will be ongoing at the VA
Data will be de-identified
Data will be transferred to NERI

| 12-27 | TK/BM |
| 13-27 | TK/BM |
| 26-27 | RR |

### PHASE III – DATA ANALYSIS & REPORTS

#### Conduct Data Analysis
Analyses will be conducted to address the Specific Aims of the Registry
Reports and Publication

| 24-36 | RR |
| 24-36 | TK/BM |

#### Continued Abstraction of Medical Records
Perform abstraction periodically of VA in/outpatient electronic medical records for PTSD registrants who have return in/outpatient visits to VA medical centers

| 24-36 | TK/BM | RR |

#### Prepare PTSD Database for Future Use
PTSD Registry database of 1200 OIF/OEF veterans will be prepared for potential sharing as a public dataset

| 34-36 | TK/BM | RR |