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TITLE:
Project VALOR: Trajectories of Change in PTSD in Combat-Exposed Veterans

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The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.
This goal of this project is to develop a large-scale, longitudinal registry of PTSD in combat-exposed OIF/OEF/OND male and female veterans. The objective of the current study is to systematically expand the longitudinal assessment by collecting follow-up data at additional time points for multiple domains of interest. Patterns of longitudinal change in the VALOR cohort will be empirically classified into trajectory subtypes by means of latent growth mixture modeling. The availability of comprehensive data on PTSD symptoms and related exposures and outcomes at multiple time points in a cohort of VA users with and without PTSD provide a unique opportunity to examine a number of hypotheses regarding longitudinal trajectories in combat-exposed veterans. In addition, the large proportion of women in our sample will allow us to examine variation in the associations by gender.
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1. **INTRODUCTION:**
Project VALOR is a large-scale, longitudinal registry of PTSD in combat-exposed OIF/OEF/OND male and female veterans. The objective of the current study is to systematically expand the longitudinal assessment by collecting follow-up data at additional time points for multiple domains of interest. Patterns of longitudinal change in the VALOR cohort will be empirically classified into trajectory subtypes by means of latent growth mixture modeling. The availability of comprehensive data on PTSD symptoms and related exposures and outcomes at multiple time points in a cohort of VA users with and without PTSD provide a unique opportunity to examine a number of hypotheses regarding longitudinal trajectories in combat-exposed veterans. In addition, the large proportion of women in our sample will allow us to examine variation in the associations by gender.

Using baseline and follow-up data from participants in Project VALOR, we will evaluate the following specific aims:

1. Examine trajectories of PTSD symptomatology and diagnosis by chart and diagnostic interview assessments in combat-exposed men and women.
2. Examine the nature and extent of military sexual trauma (MST) in combat-exposed men and women who have utilized the VA Healthcare System, including the contribution of MST to PTSD symptoms and diagnosis.
3. Examine associations of PTSD, mTBI, major depressive disorder (MDD), and treatment utilization in relation to changes in suicidal ideation.

2. **KEYWORDS:**
   Post-traumatic stress disorder (PTSD), military sexual trauma (MST), suicide, combat-exposed veterans, PTSD trajectory, longitudinal, VA utilization

3. **OVERALL PROJECT SUMMARY:**
In quarter one of this year the protocol and the manual of operations were finalized in accordance with the recommendations of our Scientific Advisory Board in preparation for submission to the local IRBs. In addition, candidates were identified to fill vacant positions. In quarter two, our protocol and manual of operation were submitted to the IRB and vacant positions were filled. In addition, training of personnel in anticipation of recruitment in the fourth quarter began. Final approval from the VA Boston Healthcare System IRB was received in the first month of quarter three and our application for initial review was submitted to HRPO in the third month of the quarter. Additional vacant positions were filled and training of personnel in anticipation of recruitment in the fourth quarter continued. In the first month of the fourth quarter final approval was received from HRPO. In addition, subject recruitment and data collection began in the fourth quarter. At this point, 72 participants have completed the study and 156 participants have been consented. Throughout the year, we have continued to analyze data from Phase I of the project for multiple manuscripts and presentations in preparation

4. **KEY RESEARCH ACCOMPLISHMENTS:**
• Study measures and procedures were finalized and approved.
• Recruitment, consenting participants, and data collection are under way.

5. CONCLUSION:

The PTSD registry will provide information to assist researchers, military leaders, and treatment providers to better understand PTSD and related problems, with specific focus on the course of the disease, suicidal ideation, and military sexual trauma. This knowledge will be of benefit to healthcare providers, policy makers and current service members as well as victims of trauma in the broader community. It will include:
• Evaluation of long-term outcomes of PTSD;
• A more accurate assessment of current theoretical models of symptom development, and;
• Documentation of health resource utilization and development of a database that would serve as a 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.

6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

PUBLICATIONS


PRESENTATIONS


7. INVENTIONS, PATENTS AND LICENSES:

Nothing to report

8. REPORTABLE OUTCOMES:

Nothing to report

9. OTHER ACHIEVEMENTS:

Nothing to report
Project VALOR: Trajectories of Change in PTSD in Combat-Exposed Veterans
Annual Report
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PI: Terence M. Keane, PhD  Org: VA Boston Healthcare System  Award Amount: $3,295,994

**Study/Product Aim(s)**

- Examine trajectories of PTSD symptomatology and diagnosis by medical chart abstractions and diagnostic interview assessments in combat-exposed men and women.
- Examine the nature and extent of military sexual trauma (MST) in combat-exposed men and women who have utilized the VA Healthcare System, including the contribution of MST to PTSD symptoms and diagnosis.
- Examine associations of PTSD, mTBI, major depressive disorder (MDD), and treatment utilization in relation to changes in suicidal ideation.

**Approach**

To develop the first longitudinal registry of combat-exposed men and women with post-traumatic stress disorder (PTSD), 1649 participants from across the country will complete a second follow-up round of online questionnaires, and telephone interviews. We will also have access to our participants’ electronic VA medical charts.

**Timeline and Cost**

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<thead>
<tr>
<th>Activities</th>
<th>CY 12</th>
<th>CY 13</th>
<th>CY 14</th>
<th>CY 15</th>
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<tr>
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<td>$875.5</td>
<td>$808.2</td>
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**Goals/Milestones**

**CY12 Goal** – Start Data Collection
☑ Training of study stuff
☑ Continue analysis of data from Valor 1

**CY13 Goals** – Continue Data Collection
☐ Collection of Round 1 data
☐ Continue analysis of data from Valor 1 and 2

**CY14 Goal** – Continue Data Collection
☐ Finish collection of Round 2 data
☐ Start Round 3 data collection

**CY15 Goal** – Complete Data Collection and Analyze Data
☐ Finish collection of Round 3 data
☐ Continue data analysis and prepare database for future use

**Budget Expenditure to Date**
Projected Expenditure: $759,832.00
Actual Expenditure: $423,563.00

Data collection began in 09/2013 and we are currently meeting our recruitment goals. Analysis of Phase 1 data is ongoing.

Updated: 10/15/13