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TITLE: Trauma Outcomes and UroGenital Health in OEF/OIF (TOUGH) - A Retrospective Cohort Study with Long-Term Follow-up

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14. ABSTRACT This past year has focused on finalizing (including adding items on the impact of the COVID-19) and pilot testing the TOUGH Survey. A one-year no cost extension was approved that extends the project period of performance to June 30, 2022. Subcontracting is in progress with Susan Davis International (SDI), a PR/Marketing Firm with significant military and Veteran community experience. SDI will assist in the recruitment process as well as develop dissemination materials for study participants and other lay audiences.						
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INTRODUCTION

The goal of this study is to identify the characteristics of Service Members (SMs), their genitourinary injuries (GU), the care received for these injuries, and other factors that predict long-term outcomes. The knowledge gained will help optimize acute injury treatment planning as well as help inform the development of more effective long-term care strategies.

KEY WORDS

Genitourinary injury; epidemiology; urotrauma; Veterans

ACCOMPLISHMENTS

Goals:

The major goals of this project are: 1) Using a cohort design, estimate the incidence of adverse outcomes and identify prognostic factors including comorbid injuries that predict poor long-term outcomes; 2) Using a patient-centered approach, describe the natural history of recovery from GU injuries based on patient-reported outcome measures obtained via a health survey; and 3) Investigate the physiologic impairments and associated adverse outcomes.

Progress:

During the current reporting period, the following key milestones were achieved: **(1)** On September 24, 2021, the U.S. Army Medical Research and Development Command (USAMRDC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) approved the two-step consent process protocol amendments previously approved and acknowledged by the Institutional Review Boards (IRBs) at The University of Texas Health Science Center at San Antonio (UT Health San Antonio) and Brooke Army Medical Center (BAMC) IRB. **(2)** As noted in the study protocol, low participation rates have been traditionally associated with this target participant population (post-9/11 injured service members/Veterans). Therefore, in December 2021, the University of California, Davis (UC Davis) finalized an agreement with Susan Davis International (SDI), a marketing/communications firm with military community experience/expertise, to develop a communications initiative to help maximize study recruitment/participation rates. Working with SDI, the study team developed various communications materials, including an Organizational Partners Resource Toolkit, designed study team members as *TOUGH Study Spokespersons*, developed a social media campaign that leverages existing social media platforms to publicize the study, developed a digital press kit as well as enhancements to the existing TOUGH study website and a study logo. **(3)** Prior to mailing the 900⁺ study recruitment letters and launching the full-scale data collection phase scheduled for August 2022, the study team utilized an address validation software program to help verify the contact information for potential participants is valid/complete and complies with the United States Postal Service's (USPS) standardized address requirements. The study team performed the address validation to help minimize data quality issues that could exist due to the time lapse between when the participant contact information was first obtained during Phase I of the study and the actual survey deployment. **(4)** The study team utilized the Research Electronic Data Capture (REDCap) system at The University of Texas Health Science Center San Antonio (UT Health San Antonio) to establish an external link in the study survey for participants to enter their contact information if they elect to receive the designated participant incentive (monetary debit card) when they complete the survey. The external link allows the study team to separate the survey data from the participant's identifying information, which helps safeguard the anonymity of the participant's survey responses. **(5)** On June 12, 2022, the UT Health San Antonio IRB approved continuation of the study. On June 28, 2022, the USAMRDC ORP HRPO acknowledged the UT Health San Antonio IRB's continuing review with no further action required. **(6)** Due to the continued impact of delays that occurred early in the project for obtaining the necessary IRB/other regulatory approvals and COVID-19 restrictions, the study could not be completed prior to

the June 30, 2022, expiration of the first no-cost extension (NCE) period. As a result, on April 13, 2022, the study team requested an additional one-year NCE to complete the remaining project objectives (participant recruitment/data collection, data analysis, and dissemination.) The NCE request was approval extending the project to June 30, 2023.

Opportunities for Training and Professional Development

Nothing to report.

Dissemination to Communities of Interest

Part of the rationale for engagement of Susan Davis International is to facilitate the dissemination of study results to the study participants who comprise the target community. At present, there is nothing to report.

Plans for the next reporting period

1. Susan Davis International (SDI) is initiating partner outreach to further publicize the study and continue to oversee administration of the communications plan aimed at enhancing outreach/engagement of the participant population.
2. The study team will launch the full-scale data collection phase with the mailing of the 900⁺ participant recruitment letters.
3. Once data collection/data stratification is complete, the study team will perform the data analysis phase that will include the in-depth review of participant electronic medical records at BAMC to further characterize the GU injuries (extent of injury, injury type, mechanism of injury) and identification of adverse health outcomes.
4. The study team will prepare applicable study reports, data presentations, and manuscripts for dissemination of study findings.

IMPACT

The incidence and characteristics of GU injuries treated in Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF) have been described in recent literature. However, the information about care received and needed, and the lasting morbidities from these injuries have yet to be described. The information obtained from this study will ensure that wounded warriors have and are receiving the care required for their injuries. The information will be used to guide military leadership to ensure programs are in place to better serve SMs with GU injuries.

Care for returning SMs is and will be a lasting duty that is entrusted to all healthcare providers in the DoD and the Department of Veterans Affairs. Ensuring that those who have served receive all necessary care is paramount to this duty. The initial treatment in theatre may have been temporizing or definitive. However, the lasting impact is unknown and patterns of healthcare utilization and unmet needs for care for the outcomes of GU injury are also unknown. Identifying the group of SMs with lower/external GU injuries and asking them about their health status and healthcare needs will allow us to ensure that they have received and are receiving proper care as well as identify changes over time. Because some of the SMs in our study will have been injured more than 10 years ago during the early years of the war, we will have very long-term outcome data (i.e., 20 years or more) on a subset of the participants in this study.

CHANGES/PROBLEMS

(1) No-cost extension (NCE): The NCE is necessary to complete the remaining project objectives (recruitment/data collection, data analysis, and dissemination). There is no change in the project's originally approved scope of work and the study team anticipates completing the project objectives during the extension period. In addition, sufficient funds remain to support the study team's effort during the NCE period, and the project maintains all applicable IRB approvals for continuation.

There are no significant changes in use of care of human subjects, vertebrate animals, biohazards, and/or select agents.

PARTICIPANTS AND OTHER COLLABORATING ORGANIZATIONS DURING THE REPORTING PERIOD

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SPECIAL REPORTING REQUIREMENTS

None

APPENDICES

None