AWARD NUMBER: W81XWH-16-2-0013

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

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REPORT DATE: July 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
July 2023	Annual	01Jul2022 - 30Jun2023

4. TITLE AND SUBTITLE

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

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-16-2-0013

5c. PROGRAM ELEMENT NUMBER

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

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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

Enter a brief (approximately 200 words) unclassified summary of the most significant finding during the research period.

This past year has concentrated on subject recruitment. An addition one-year no cost extension was recently approved that will extend the project period of performance to June 30, 2024, which will ensure that we maximize accrual and generate analyses of the data as well as prepare materials for dissemination of the study results for the DoD, study participants and other lay audiences, and for peer-reviewed journals.

15. SUBJECT TERMS Key words or phrases identifying major concepts in the report.
Genitourinary injury; epidemiology; rostrum

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
Unclassified	Unclassified	Unclassified	Unclassified	6	USAMRDC

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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)** In accordance with the subcontract between The University of California, Davis (UC Davis) and Susan Davis International (SDI), a strategic communications agency with military community expertise, the study team assisted with implementation of the comprehensive communications plan SDI developed to help publicize the TOUGH study and maximize survey participation. The communications plan included a digital press kit, media outreach, press releases, partner organization outreach, communications toolkit for military/veteran service organizations, and opinion/editorial pieces regarding the TOUGH study prepared by study team members that were distributed to military community publications/platforms. **(2)** The updated TOUGH study website went live in July 2022, followed by the study team and SDI reaching out to various partner organizations/media outlets to discuss the study and the website. **(3)** In July 2022, the study team launched the full-scale data collection phase with the mailing of 900+ participant recruitment letters to potential study participants. The recruitment letter contained a web-based link for the participant to access the study survey housed in The University of Texas Health Science Center at San Antonio (UT Health San Antonio) Research Electronic Data Capture (REDCap) system. **(4)** To date, a total of 56 surveys have been completed. Although the initial response rate was low, it is not atypical for the target study population (post-9/11 injured service members/Veterans). In addition, a portion of the recruitment letters could not be delivered to the recipients due to address validation issues (likely due to out-of-date contact information in the Department of Defense electronic data sources utilized in Phase I of this project). **(5)** Due to the low accrual, the study team developed a plan to validate the mailing addresses of the returned study invitation letters using a protocol-approved search engine. Additionally, the study team continued the recruitment efforts to increase the number of participants. **(6)** The study team coordinated and monitored the electronic gift card requisition process for purposes of disseminating gift cards to eligible study participants who completed the study survey and the separate contact information survey. (In accordance with the study protocol, the purpose of the gift cards is to incentivize survey participation and compensate eligible participants for their time. Participant contact information was collected via a separate IRB-approved survey previously developed by the study team. To maintain participant confidentiality, the participant's contact information is not linked to the study survey.) **(7)** On January 11, 2023, the UC Davis Institutional Review Board (IRB) approved continuation of the study and the U.S. Army Medical Research and Development Command (USAMRDC), Office of Human and Animal Research Oversight (OHARO), Office of Human

Research Oversight (OHRO) acknowledged receipt of the UC Davis IRB continuing review with no further action required. Effective January 2023, Dr. Kuwong Mwamukonda, the Brooke Army Medical Center (BAMC) on-site Principal Investigator (PI), announced her retirement from active duty. Dr. Amanda Reed-Maldonado assumed the role of BAMC On-Site PI. **(8)** Prior to the project period of performance expiring on June 30, 2023, Dr. Brad Pollock (PI), requested a no-cost extension (NCE) to complete the remaining project objectives (data collection, data analysis, and dissemination) extending the project period to June 30, 2024. The NCE request was approved on May 23, 2023.

Opportunities for Training and Professional Development
Nothing to report.

Dissemination to Communities of Interest
Nothing to report.

Plans for the next reporting period

1. The study team will complete the data collection phase and complete distribution of electronic gift cards to eligible participants.
2. The study team will complete the data analysis phase and prepare data presentations/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 lasting morbidity from these injuries has 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 (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