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

PRINCIPAL INVESTIGATOR: Bradley H. Pollock, PhD MPH

CONTRACTING ORGANIZATION: University of California, Davis

REPORT DATE: July 2021

TYPE OF REPORT: ANNUAL

PREPARED FOR: U.S. Army Medical Research and Materiel 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 2021	ANNUAL	01-JUL-2020 - 30-JUN-2021

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

6. AUTHOR(S)

POLLOCK, BRADLEY H.

E-Mail: BPOLLOCK@UCDAVIS.EDU

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

UNIVERSITY OF CALIFORNIA, DAVIS
1850 RESEARCH PARK DR, STE 300
DAVIS CA 95618-6134

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel 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

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.

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	USAMRMC

TABLE OF CONTENTS

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 cumulative 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)** The study team completed the two-step consent process protocol regulatory amendments, these will allow the research team to link patient data to their electronic medical record to better characterize the injuries/treatment received. The study team also incorporated additional survey questions to assess the potential impact of the SARS-CoV-2-related COVID-19 pandemic on study participants. The study team then alpha-tested the survey internally to confirm the respondent burden was reasonable in terms of time commitment, survey length, and survey question invasiveness. The study team also beta-tested the survey with a small group of non-study stakeholders and based on the feedback, incorporated a select cluster of additional questions regarding post-injury hobbies/recreational activities as well as refined a few additional survey items. The study team updated the final revised survey in the Research Electronic Data Capture (REDCap) system. **(2)** On November 19, 2020, the study team submitted the revised survey and two-step consent process protocol regulatory amendments to The University of Texas Health at San Antonio (UT Health San Antonio) Institutional Review Board (IRB). The IRB approved the revised survey/protocol amendments on December 7, 2020 and forwarded the amendment package to the Brooke Army Medical Center (BAMC) IRB for approval. On February 12, 2021, the BAMC IRB reviewed and acknowledged the revised survey and protocol amendments. **(3)** Due to the delayed IRB submission/approval for the revised survey and additional delays based on multi-step/multi-organizational (UT Health San Antonio IRB, BAMC IRB, DHA) regulatory approvals that could not run concurrently, the study could not be completed prior to the original project expiration date. As a result, the study team requested a one-year no-cost extension (NCE) to complete the remaining project objectives: participant recruitment/data collection, data analysis, and dissemination. The NCE request was approved and extends the project period of performance to June 30, 2022. **(4)** The medical records abstractor completed verifying patient contact information for the 999 records at Brooke Army Medical Center (BAMC) that were validated as a genitourinary (GU) injury during Part II of the study. A total of 964 of the 999 records were confirmed as containing updated contact information for mailing the study recruitment letter. **(5)** In May 2021, the study team began pilot testing the survey by mailing the study recruitment letter and accompanying information sheet to a small cohort of 25 potential participants. The recruitment letter contained a web-based link for the participant to access the study survey. **(6)** On June 3, 2021, the UT Health San Antonio IRB approved continuation of the study. On June 24, 2021, the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) Human Research Protection Office (HRPO) acknowledged

receiving the UT Health San Antonio IRB's continuing review with no further action required. **(7)** The study team held several planning meetings with Susan Davis International (SDI), a PR/Marketing Firm with significant military and Veteran community experience. Contracting with SDI is nearly complete with work expected to commence in August 2021.

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 will complete the TOUGH Study outreach materials to enhance outreach to and engagement of the population of interest.
2. Full-scale data collection via survey deployment will begin.
3. Once data collection is complete, comprehensive data analysis will commence. This include an 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 identify both participant-reported and medical record documented adverse health outcomes.
4. No medical records data can be transferred from BAMC to UT Health San Antonio until the existing BAMC/UT Health San Antonio Data Sharing Agreement (DSA) is revised to reflect all data that will be collected. The study team will prepare and submit the revised DSA to the Defense Health Agency (DHA) for approval.
5. The study team will prepare applicable study reports, data presentations, and manuscripts for dissemination of study findings. Results dissemination will also be done to the study participants.

IMPACT

The incidence and characteristics of GU injuries treated in Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF) have been described in the literature. However, the information about care received and needed and lasting morbidity from these injuries has yet to be described. The information obtained from TOUGH 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 determining 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. This subset of participants will be especially informative in defining the trajectories of SMs who sustained more recent injuries.

CHANGES/PROBLEMS

(1) Delayed Survey Deployment/Data Collection: As discussed in the Progress section of this report, the survey revisions/consent process protocol amendments delayed the IRB submission and (non-concurrent) regulatory approval processes, which in turn delayed survey deployment and data collection. The survey changes did not substantially modify the research or increase risk to participants. The study team believes the benefits associated with the additional data collected and potential improved data quality outweighs the delay and any minimal risks associated with the survey revisions.

(2) 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

University of California, Davis
Brad H. Pollock, PhD, MPH (PI)

UT Health San Antonio
Roxana E. Delgado, PhD (Site PI)
Bill Sanns (Project Operations Director)
Kimberly S. Peacock, EdD (Co-Investigator)

BAMC
Dr. Kuwong Mwamukonda, LTC, MC, USA (Site PI)

UT SOUTHWESTERN MEDICAL CENTER
Steven J. Hudak, MD, GU Injury and Reconstructive Surgery (Associate Investigator)

SPECIAL REPORTING REQUIREMENTS

None

APPENDICES

None