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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 validating the DoDTR database records that identified service members who sustained GU injury. The validation included comparison with medical records in the Armed Forces Health Longitudinal Technology Application (AHLTA) system; this phase is almost completed. Our preliminary findings are that <9% of DoDTR records with an indication of GU injury actually presented with no verified injury; a lower percent than originally anticipated.

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

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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 development of more effective long-term care strategies.

KEY WORDS

Genitourinary injury; epidemiology; urotrauma

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 an annual health survey; and 3) Investigate the physiologic impairments and associated adverse outcomes based on an in-person physical examination (for a local subset of the study population).

Progress:

During the current reporting period, several key milestones have been achieved: **1)** On July 11, 2018, the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) Human Research Protection Office (HRPO) approved the revised protocol and completed the Component Level Administrative Review (CLAR) for Brooke Army Medical Center (BAMC) Institutional Review Board's (IRB's) reliance on a non-Department of Defense (DoD) IRB (i.e., UT Health San Antonio IRB). On July 19, 2018, the BAMC IRB provided final authorization for the TOUGH study to proceed at BAMC; **2)** On August 24, 2018, the Clinical & Translational Research Program Office (CTRPO) approved and executed the medical records abstraction/validation Statement of Work (SOW) under UT Health San Antonio's existing master Cooperative Research and Development Agreement (CRADA). The approved SOW authorized the medical records abstractor to obtain the BAMC security clearance required to review medical records in the Armed Forces Health Longitudinal Technology Application (AHLTA) system in order to validate the cases of genitourinary (GU) injury identified in the DoD Trauma Registry (DoDTR) in Part I of the study. To date, a total of 1,354 of the 1,398 records identified in Phase I have been reviewed in AHLTA (96.8% completed); **3)** On January 30, 2019, the Defense Health Agency (DHA) Privacy and Civil Liberties Office finished its review of the Data Sharing Agreement (DSA) Application the study team submitted last year. The DHA approved and executed the DSA on March 22, 2019. The approved DSA permits BAMC to transmit patient contact information to UT Health San Antonio for the purpose of deploying the study survey; **4)** The study team finalized the Phase II data transmission plan and performed tests of the data transfer links prior to BAMC transferring patient contact information to UT Health San Antonio; **5)** The study team secured the *TOUGH Study* website domain name and began building the website, including developing site content. The website is in the final phase of construction; **6)** On May 21, 2019, UC Davis and UT Health San Antonio executed an amendment to the UT Health San Antonio subaward to add Year 4 to the subaward period of performance; **7)** On May 24, 2019, the UT Health San Antonio IRB approved continuation of the study. On May 30, 2019, BAMC HRPO acknowledged the continuing review and required no further action.

Opportunities for Training and Professional Development

Nothing to report.

Dissemination to Communities of Interest

As part of the public website development for the *TOUGH Study*, the study team began preparing blog content for publication on the website and various social media platforms.

Plans for the next reporting period

1. Data collection, primarily via survey deployment, will begin during the next reporting period. For any records that contain an overseas address and/or military installation address, the study team will validate patient contact information prior to deploying the survey in accordance with the protocol.
2. Once the data transfer from BAMC to UT Health San Antonio is complete, the study team will configure the UT Health San Antonio IT systems to receive the incoming project REDCap data, which will be linked to the study electronic case report forms (eCRFs) and associated hard copy documentation.
3. The medical records abstractor will complete the records review/validation in AHLTA and utilize Essentris (a comprehensive clinical documentation system for use in Military Health System acute care hospitals) to validate GU injuries in any records flagged for additional review during the initial AHLTA records sweep.

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

While we anticipated some delay due to a higher proportion of DoDTR records not being concordance with the AHLTA records (verification source), we observed a relative small number of records with discordant information.

The following changes occurred during the current reporting period: **(1)** On April 12, 2019, the UT Health San Antonio IRB approved a protocol amendment changing the BAMC on-site PI from Dr. Steven Hudak to Dr. Kuwong Mwamukonda, BAMC Chief of Urology. Dr. Hudak retired from active duty but will continue his involvement with the study as an Associate Investigator. **(2)** Since the revised study protocol has been approved and the BAMC IRB deferral to UT Health San Antonio is complete, the study team worked with Dr. Hudak to

prepare a closure report for the original BAMC protocol. On April 19, 2019, the Regional Health Command-Central Institutional Review Board acknowledged the closure report and required no further action for the original protocol.

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