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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

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.

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

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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

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)** To address the protocol aims, the study team revised the survey and informed consent process to collect medical record information from participants with linkage of the subject's data extracted from the Department of Defense Trauma Registry (DoDTR) in Part I of the study to their medical record. The study team convened a face-to-face meeting on February 20, 2020, at Brooke Army Medical Center (BAMC) in San Antonio, TX, to conduct a thorough review of the survey, incorporate feedback from internal/external subject-matter experts, and address additional data points specific to the study population. In March 2020, the study team further revised the survey to include questions regarding the potential impact of Corona Virus 2019 (COVID-19); **(2)** The study team entered the revised survey into the UT Health San Antonio Research Electronic Data Capture (REDCap) system to identify and mitigate all technical/coding issues and alpha-tested the survey (internally) to confirm the reasonableness of the respondent burden (e.g., time commitment, invasiveness of survey questions) based on the study population; **(3)** The study team completed the review/validation of 1,183 records in the BAMC Armed Forces Health Longitudinal Technology Application (AHLTA) and Essentris system. (These records were part of the 1,398 total records identified as potential GU injury cases in the DoDTR during Part I of the study.) Of the 1,183 records, 76 required second-level thorough review by Dr. Mwamukonda, BAMC Site PI, to confirm the GU injury status. To date, the study team has validated 1,001 GU injury cases and excluded 182 from the potential participant population due to no GU injury or deceased status. The remaining 215 records will require validation at Walter Reed Army Medical Centre (WRAMC) to confirm the GU injury status. The study team has identified a Site Principal Investigator (PI) at WRAMC who has the medical expertise and WRAMC credentials necessary for the WRAMC records review/validation; **(4)** The UT Health San Antonio medical records abstractor continued verifying patient contact information for records that contained an overseas address and/or military installation address. To date, patient contact information has been verified for 860 of the 1,001 records with a validated GU injury. However, the patient contact information verification process was temporarily halted in March 2020 due to COVID-19 worksite restrictions implemented at BAMC, which prevented the records abstractor from accessing applicable government databases. Although the worksite/access restrictions currently remain in place, the study team has coordinated with BAMC personnel for the provision of a CAC-enabled laptop, which will allow the UT Health San Antonio medical records abstractor to continue verifying patient contact information; **(5)** The study team completed construction of the project study website that will be used for registration and

survey administration, coordinated a comprehensive website security scan, obtained an SSL certificate (which establishes a secure internet connection for the transmission/receipt of sensitive data), and registered the study website domain name; **(6)** On May 27, 2020, the UT Health San Antonio Institutional Review Board (IRB) approved the continuation of the study. On June 11, 2020, the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) Human Research Protection Office (HRPO) acknowledged the UT Health San Antonio IRB's continuing review with no further action required.

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 submit the final revised survey and revised consent process protocol amendments to the UT Health San Antonio IRB for approval. Following IRB approval, the study team will beta pilot-test the survey with a small cohort of participants before launching the study website, making it available for study participants and general public viewing.
2. Once the UT Health San Antonio IRB approves the revised survey and consent process, data collection via survey deployment will begin. However, 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 via the revised survey/consent process. The study team will then submit the revised DSA to the Defense Health Agency (DHA) for approval.
3. The UT Health San Antonio medical records abstractor will resume and complete the patient contact verification for the 1,001 records with a validated GU injury.
4. The study team will coordinate with the WRAMC Site PI to facilitate the WRAMC IRB and DSA approval processes for validating GU injuries in the 215 WRAMC medical records.

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

As noted in Section 1 of this report: **(1)** The study team delayed deploying the survey due to the important survey/consent process revisions, which will link patient data to their medical record. The study team determined the changes did not substantially modify the research or substantially increase risk to participants. Although data collection was delayed, the study team believes the benefit of the additional data that will be collected outweighs the delay and any minimal risks associated with the survey revisions; **(2)** Due to BAMC COVID-19 worksite/access restrictions, the study team temporarily halted the patient verification process. Although the restrictions remain in place, the study team has already coordinated pre-return logistics with BAMC personnel, including access to a CAC-enabled laptop that will allow the UT Health San Antonio medical records abstractor to resume and complete the patient contact verification.

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