AWARD NUMBER: W81XWH-20-1-0941

LOG NUMBER: VR190142

TITLE: Epidemiology of Combat Ocular Injury to Guide Prolonged Field Care

PRINCIPAL INVESTIGATOR: Amanda Staudt, MPH, PhD

CONTRACTING ORGANIZATION: The Geneva Foundation at
U.S. Army Institute of Surgical Research (USAISR)
JBSA Fort Sam Houston, TX

REPORT DATE: October 2021

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research Acquisition Activity
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
October 2021	Annual Report	30Sep2020-29Sep2021

4. TITLE AND SUBTITLE

Epidemiology of Combat Ocular Injury to Guide Prolonged Field Care

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-20-1-0941

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Amanda Staudt, MPH, PhD; Jennifer Trevino, MBA;

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
US Army Institute of Surgical Research
3698 Chambers Pass, BLDG 3611
JBSA Fort Sam Houston, TX 78234

8. PERFORMING ORGANIZATION REPORT NUMBER

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

US Army Medical Research Acquisition Activity

820 Chandler St
Fort Detrick, MD 21702-5014

10. SPONSOR/MONITOR'S ACRONYM(S)
USAMRAA

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The key objective of the proposed study is to create an algorithm to inform treatment requirements timeline in a prolonged field care setting to reduce the number of patients with loss of visual acuity. Predicted delays in medical evacuation in future conflicts, will lead to the increased extent of prolonged field care, which could potentially lead to an increase in loss of visual acuity. However, at present, the threshold of allowable maximum time before initiation of primary repair to minimize loss of visual acuity remains unclear. Thus, the identification of the maximum time to treatment in current (shorter) timelines will inform treatment guidelines and expectations during prolonged field care.

In this pursuit, we plan to use a two-part solution to inform new treatment guidelines and expectations during prolonged field care for patients with ocular injury. In the first part, determining the burden of injury for each diagnosis, results will enable prioritization of research initiatives to the ocular injuries determined to cause most disability, which will help identify the most impactful areas in reference to the results from the second part of the project. In the second part, determining the association of time to primary repair with final visual acuity, results will contribute to the development of evidence-based guidelines for care of ocular injuries during prolonged field care.

15. SUBJECT TERMS
Ocular injury, transport timing, prolonged field care, combat

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**	Unclassified	13	**USAMRMC**
Unclassified	Unclassified	Unclassified			**19b. TELEPHONE NUMBER** *(include area code)*

TABLE OF CONTENTS

	Page
1. Introduction	4
2. Keywords	4
3. Accomplishments	4
4. Impact	8
5. Changes/Problems	8
6. Products	9
7. Participants & Other Collaborating Organizations	10
8. Special Reporting Requirements	12
9. Appendices	12

1. INTRODUCTION:

The key objective of the proposed study is to create an algorithm to inform treatment requirements timeline in a prolonged field care setting to reduce the number of patients with loss of visual acuity. Predicted delays in medical evacuation in future conflicts, will lead to the increased extent of prolonged field care, which could potentially lead to an increase in loss of visual acuity. However, at present, the threshold of allowable maximum time before initiation of primary repair to minimize loss of visual acuity remains unclear. Thus, the identification of the maximum time to treatment in current (shorter) timelines will inform treatment guidelines and expectations during prolonged field care.

2. KEYWORDS: Provide a brief list of keywords (limit to 20 words).

DALYs - Disability Adjusted Life Years
DVEIVRTMDS
Ocular injury
Transport timing
Prolonged field care
Combat

ACCOMPLISHMENTS:

What were the major goals of the project?
The goals of this project are to develop knowledge products to answer the study's specific aims.

The project's Specific Aims are as follows:

Specific Aim 1. Determine the burden of ocular injury for each diagnosis.

Aim 1.1 Establish disability weights for each diagnosis. Global Burden of Disease Study unique health states will be cross-walked with patient diagnosis data.

Aim 1.2 Calculate the Disability Adjusted Life Years (DALYs) of ocular injury for each diagnosis. DALYs calculations will determine the years of life lost to disability among all ocular injuries.

Specific Aim 2. Define maximum time from injury to primary repair to reduce loss of visual acuity.

Aim 2.1 Determine the association between time to treatment with loss of final visual acuity. This association will be tested using multivariable logistic regression models stratified by major types of ocular trauma. Covariates will include severity of injury, as measured by the ocular trauma score, and mechanism of injury.

Aim 2.2 Extrapolate the regression model equation to predict odds of loss of visual acuity with time to treatment extended to 24, 48, and 72 hours. For each diagnosis, using the intercept and regression coefficients calculated in Aim 2.1, the odds of loss of final visual acuity will be calculated using the log (odds) model equation at 24, 48, and 72 hours.

What was accomplished under these goals?

1) **Major Activities: The research team continued to work towards accomplishing the SOW deliverables (below):**

The approved SOW was broken down by specific aim and includes several subtasks for each aim. During the reporting year, we achieved Specific Aim 1, Major Task 1, Subtask 1-5, which are as follows:

Major Task 1

Subtask 1: Hire research staff. Prepare cooperative research and development agreements (CRADAs), MOUs, and MOAs. Prepare research protocol and regulatory documents.

Subtask 2: Prepare Defense Health Agency (DHA) Data Sharing Agreement (DSA) to include: Walter Reed Ocular Trauma Database (WROTD), Defense and Veterans Eye Injury and Vision Registry (DVEIVR), and Theater Medical Data Store (TMDS).

Subtask 3: Request identifiable datasets directly from WROTD, DVEIVR, and access to TMDS in accordance with approved protocol and DSAA.

Subtasks 4 Create Health Insurance Portability and Accountability Act (HIPAA) compliant database. For this deliverable, the research team received access to the platform and training for REDCap (Research Electronic Data Capture) for the HIPAA compliant database. REDCap will be the secure web application for building and managing the online surveys and databases. Ongoing process.

Subtask 5: Identify patients meeting inclusion criteria using the WROTD and DVEIVR. The research team received the DVEIVR data, and started cleaning the data to determine which patients meet the protocol inclusion criteria. Ongoing process.

During this reporting year, we worked towards accomplishing Major Task 2, Subtask 1-1b:

Major Task 2

Subtask 1: Continued to identify the best way to establish disability weights for each diagnosis, which includes implementing a new protocol that uses a web-based survey to establish disability weights. Establish disability weights for each diagnosis. The Global Burden of Disease network is the most prominent developer of disability weights in the world.

The PI/team are members of the Global Burden of Disease collaborator network and plan to gain further insight into the disability weight development process. The new protocol (awaiting regulatory approval) will involve a web-based survey. The team reached out to Information Management Collections Officer (IMCO), Office of People Analytics (OPA),

and DHA DSA team for further guidance on survey approvals (Tri-Service, active/reservists, and combat-related roles), and anticipates using REDCap or similar for the survey platform as well. Ongoing process.

Subtask 1a: Pending protocol approval, a web-based survey was created as part of the protocol submission review and approval process.

Subtask 1b: Initiated approval to launch survey. Initiated IMCO, DHA DSA and OPA process if the protocol is approved by USAISR, however, the research team may transition over to Uniformed Services University of the Health Sciences (USUHS) for this specific protocol, and may qualify under the current 2-year survey approval waiver.

2) Specific objectives: Completed/initiated SOW deliverables (Major Task 1, Subtask 1-5, Major Task 2, Subtask 1-1b)

3) Significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative):

- Accepted to present at the 2021 Military Health System Research Symposium (MHSRS) Conference. Abstract MHSRS-21-02939 “Epidemiology of Combat Ocular Injury to Guide Prolonged Field Care”. Although conference was cancelled, website published abstract.
- Accepted to present at the 2021 Military City USA Trauma Collaborative Research Conference scheduled for October 20-21, 2021. Abstract “Epidemiology of Combat Ocular Injury to Guide Prolonged Field Care”.
- Initiated Web-based Survey protocol approval process during the previous reporting period (The USAISR regulatory and business office put this project on hold per their internal policy). The following documents were submitted during the previous reporting period:
    - IRB Protocol and required documents (drafted/under review)
    - US MBD Recruitment plan
    - US MBD Questionnaire
    - Recruitment Material – Meme
    - Note, drafts were submitted to IMCO, OPA, DHA DSA for review and approved by OPA (pending protocol/IRB approval)
    - Explored survey instrument platforms approved for use on DoD-network
        - max.gov, REDCap, intelink, MilSurvey, MS Teams, etc.
    - Explored using Tricare online patient portal - TOLPP Secure Messaging
    - Explored incentives for this population (i.e., gift cards, donation, sweepstake)
- Identified alternate site for survey protocol review and approval process.
    - Initiated via USUHS EIRB process
    - Protocol number is 21-13952
    - Note, protocol may qualify for a waiver of survey review/approval
- Received access to DVEIVR and TMDS. The team may need ocular specific tabs for TMDS.
- Submitted original request for DVEIVR dataset (requested December 2, 2020).
    - Received access to DVEIVR data dictionary via CarePoint.

    - Received DVEIVR dataset on March 15, 2021.
    - Requested DVEIVR additional variables including “Current Disability Rating (percentage) and “Disability Rating Date” on October 18, 2021
        - DVEIVR identified patients that meet criteria (n=52 patients), and will discuss with their team and notify the PI
- The study team continues to identify additional datasets and collaborators, specifically, TSGLI and Psychological Health Center of Excellence.
    - TSGLI request is for disability rating for our patient population. This would be used to link our current patient population to patients that made a claim with TSGLI.
    - Psychological Health Center of Excellence request is to validate a mental health diagnoses in our DVEIVR patient population.
- In order to collaborate with the Psychological Health Center of Excellent, the study team submitted a protocol amendment adding MDR data to the protocol (currently pending IRB review/approval). Once approved, the team will submit a modification request for the DHA DSA.

What opportunities for training and professional development has the project provided?
Professional development activities included collaboration with the Global Burden of Disease network. The Global Burden of Disease network is the most prominent developer of disability weights in the world. The PI joined the Global Burden of Disease collaborator network so the team can gain further insight into the disability weight development process. Additionally, the team conducted a literature review to uncover all publically available ocular disability weights and learn more about commonly used disability weight development methodology.

How were the results disseminated to communities of interest?
The PI participated in a summer internship program at the US Army Institute of Surgical Research, mentored a student, and disseminated the research to the community of interest.

The PI plans to present the abstract entitled “Epidemiology of Combat Ocular Injury to Guide Prolonged Field Care” at the 2021 Military City USA Trauma Collaborative Research Conference scheduled for October 20-21, 2021.

What do you plan to do during the next reporting period to accomplish the goals?
During the next reporting period, the research team will continue working towards accomplishing the following SOW goals and objectives.

Major Task 2:

Subtask 1: Establish disability weights for each diagnosis.

Subtask 1a: Create a web-based survey (using platform, i.e., REDCap)

Subtask 1b: Obtain approval to launch survey (IRB and as required by the organization)

Subtask 1c: Identify contact information for survey study population

Subtask 1d: Execute the survey

Subtask 1e: Analyze results of the survey

Subtask 2: Calculate the Disability Adjusted Life Years (DALYs) of ocular injury for each diagnosis.

Milestone Achieved: Prepare and present preliminary findings.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?
Nothing to Report.

What was the impact on other disciplines?
Nothing to Report.

What was the impact on technology transfer?
Nothing to Report.

What was the impact on society beyond science and technology?
Nothing to Report.

5. **CHANGES/PROBLEMS:**
During this reporting year, the performance site implemented a new statement of work (SOW) specific CRADA requirements that impacted and delayed the IRB/regulatory review and approval process of a critical protocol necessary for accomplishing the SOW deliverables. Currently, the performance site is still waiting for the finalized SOW specific CRADA for this project.

Please note, the contract organization and primary site did have a Master CRADA in place, as well as letters of support from the primary site, however, when the newly implemented SOW specific CRADA requirements were implemented the research team was notified only upon protocol submission with a denial to review the project and aforementioned rational.

Changes in approach and reasons for change
Due to the delays with the SOW specific CRADA at the primary site, the primary USAISR PI and sub-award PI discussed the possibility of utilizing the sub-award site and IRB for the survey protocol's regulatory submission process.

Changes in approach have not yet been implemented, only investigated as a feasible and practicable option. Note, these changes will not impact the study or funding, and will only utilize the originally budgeted funds and resources.

Actual or anticipated problems or delays and actions or plans to resolve them
Primary site and contract organization are in the final stages of submitting and approving the SOW specific CRADA. The research protocol is pending final review and approval.

If further delays continue, the contract organization and research team will plan to utilize the sub-awardees IRB and site for the survey protocol.

Changes that had a significant impact on expenditures
These unanticipated changes will not impacted the expenditures but delayed the team's ability to implement and initiate the project by 9-12 months.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
NA

Significant changes in use or care of human subjects
NA

Significant changes in use or care of vertebrate animals
NA

Significant changes in use of biohazards and/or select agents
NA

6. PRODUCTS:

- **Publications, conference papers, and presentations**
  Accepted to present at the 2021 Military Health System Research Symposium (MHSRS) Conference. Abstract MHSRS-21-02939 "Epidemiology of Combat Ocular Injury to Guide Prolonged Field Care".

  Accepted to present at the 2021 Military City USA Trauma Collaborative Research Conference scheduled for October 20-21, 2021. Abstract "Epidemiology of Combat Ocular Injury to Guide Prolonged Field Care".

  Journal publications. Nothing to Report.

  Books or other non-periodical, one-time publications. Nothing to Report.

Other publications, conference papers and presentations. Nothing to Report.

- **Website(s) or other Internet site(s)**
  The Geneva Foundation highlighted the Eye Epi grant and grant PI (Dr. Amanda Staudt) as a "Researcher to watch". Platforms included twitter and LinkedIn:
  https://genevausa.org/news/story/epidemiology-of-combat-ocular-injury/

- **Technologies or techniques**
  Nothing to Report.

- **Inventions, patent applications, and/or licenses**
  Nothing to Report.

- **Other Products**
  Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Amanda Staudt, PhD, MPH
Project Role:	Geneva/USAISR Principal Investigator (PI)/Epidemiologist
Researcher Identifier:	NA
Nearest person month worked:	12
Contribution to Project:	Dr. Staudt has performed work in the area of regulatory compliance and submissions, and data access.
Funding Support:	NA

Name:	Jennifer Trevino, MBA
Project Role:	Geneva/USAISR Program Manager/Co-Investigator
Researcher Identifier:	NA
Nearest person month worked:	12
Contribution to Project:	Ms. Trevino has performed work in the area of regulatory compliance and submissions, program/project management, and data access.
Funding Support:	NA

Name:	LTC Marcus Colyer, MD
Project Role:	USUHS Site PI
Researcher Identifier:	NA
Nearest person month worked:	12
Contribution to Project:	LTC Colyer has performed work in the area of providing SME support in the area of Ophthalmology and ocular trauma.
Funding Support:	US Army

Name:	Denise Ryan
Project Role:	USUHS Regulatory support
Researcher Identifier:	NA
Nearest person month worked:	1
Contribution to Project:	Ms. Ryan has performed work in the area of providing regulatory support for LTC Colyer.
Funding Support:	NA

Name:	Ebony Carter
Project Role:	USUHS regulatory support and helped provide dataset
Researcher Identifier:	NA
Nearest person month worked:	1
Contribution to Project:	Ms. Carter has performed regulatory support at USUHS
Funding Support:	NA

Name:	CPT Grant Justin
Project Role:	Co-Investigator
Researcher Identifier:	NA
Nearest person month worked:	3
Contribution to Project:	CPT Justin has performed work in the area of providing SME support in the area of Ophthalmology and ocular trauma.
Funding Support:	US Army

Name:	William Gensheimer
Project Role:	Co-Investigator
Researcher Identifier:	NA
Nearest person month worked:	3
Contribution to Project:	Mr. Gensheimer has performed work in the area of providing SME support in the area of Ophthalmology and ocular trauma.
Funding Support:	US Army

Name:	Helen White
Project Role:	Collaborator
Researcher Identifier:	NA
Nearest person month worked:	1
Contribution to Project:	Ms. White has performed work in the area of providing SME support for DVEIVR.
Funding Support:	NA

Name:	Patty Morris
Project Role:	Collaborator
Researcher Identifier:	NA
Nearest person month worked:	1
Contribution to Project:	Ms. Morris has performed work in the area of providing SME support for DVEIVR.
Funding Support:	NA

Name:	Alex Odou
Project Role:	Collaborator
Researcher Identifier:	NA
Nearest person month worked:	1
Contribution to Project:	Mr. Odou has performed work in the area of providing SME support for DVEIVR.
Funding Support:	NA

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
Nothing to Report.

What other organizations were involved as partners?
Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHARTS: Attached

9. APPENDICES:

- DHA DSA Renewal and approval
- USAISR Continuing Review Annual Report (H-20-023)
- Map Injury to Disability Weights meeting
- 2021 MHSRS abstract (MHSRS-21-02939)
- 2021 Military City USA poster plus invitation
- OPA Recommended Approval for Survey Protocol
- USUHS Survey Protocol - EIRB Template
- USAISR Survey Protocol (H-21-023) - USAMRDC IRB Template
    - US MBD Questionnaire Appendix
    - US MBD Recruitment text Appendix
    - Meme
    - US MBD Health States Appendix
    - Scientific Review
    - CITI training – Trevino
    - CITI training – Staudt