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

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CONTRACTING ORGANIZATION: The Geneva Foundation, Tacoma, WA

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5d. PROJECT NUMBER

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

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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

None listed.

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
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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
DVEIVR
TMDS
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. Daly's 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 times 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 aims and subtasks. During the current reporting period, we achieved Specific Aim 1, Major Task 1, Subtask 4-5, and Major Task 2, Subtasks 1-1b which are as follows:

Major Task 1

Subtasks 4 Create Health Insurance Portability and Accountability Act (HIPAA) compliant database. For this deliverable, the research team created the survey in REDCap (Research Electronic Data Capture) for the HIPAA compliant database and will begin inputting survey logic now that survey approval was awarded.

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. DSA renewal was also approved (expiration 30 Sep 2023). Ongoing process.

Major Task 2

Subtask 1: Determined the best way to establish disability weights for each diagnosis, which includes the new protocol that uses a web-based survey to establish disability weights.

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

Subtask 1b: During this reporting period, we received final survey approval. Report Control Symbol (RCS) DD-USA-2712, "Elicitation of disability weights among combat casualties using a web-based survey," is now active. The expiration date of this RCS is October 31, 2027.

During the previous reporting year, we fully achieved Major Task 1 (subtasks 1-3)

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.

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):

- DALY's calculations are pending efforts to map patient data to disability weights
- In-person collaboration and disseminations efforts at the 2022 Military Health System Research Symposium (September 2022). Presentations included:
    - Abstract # MHSRS-22-07288 for Improving Warfighter Readiness and Performance through Health Services Research "Design to develop disability weights using a web-based survey among combat casualties: Experience from the US Military Burden of Disease Study"
    - Abstract # MHSRS-22-07264 for Expeditionary Eye Care "Preliminary analysis of disability-adjusted life years due to ocular injury among combat casualties, 2001-2020"
- The Web-based Survey protocol (H-21-023) was approved (26 May 2022)
    - IRB Protocol and required documents
    - US MBD Recruitment plan
    - US MBD Questionnaire
    - Recruitment Material – Meme
- Received survey approval and the Report Control Symbol (DD-USA-2712) for "Elicitation of disability weights among combat casualties using a web-based survey". It is now active with an expiration date October 31, 2027.
- The survey was created in REDCap pending survey logic.
- The research team requested survey respondent email addresses from DMDCRS Request # 144017, Combat MOS, and plan to finalize and launch the survey during the next reporting period.
- Final WHS approval was provided (05 October 2022):
    - Report Control Symbol (RCS) DD-USA-2712, "Elicitation of disability weights among combat casualties using a web-based survey," is now active. The expiration date of this RCS is October 31, 2027.
- The following four papers are already in progress: (1. Analysis of disability-adjusted life years due to ocular injury among combat casualties, 2001-2020; 2. Time to treatment of ocular injury among combat casualties, 2001-2020; 3. Elicitation of disability weights among combat casualties using a web-based survey; 4. Comparison of disability-adjusted

life years using Global Burden of Disease versus US Military Burden of Disease military specific disability weights).

What opportunities for training and professional development has the project provided?
Ongoing 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?
Results were disseminated at the Military Health Systems Research Symposium September 12-15, 2022 including the following presentations:

Abstract # MHSRS-22-07288 for Improving Warfighter Readiness and Performance through Health Services Research "Design to develop disability weights using a web-based survey among combat casualties: Experience from the US Military Burden of Disease Study"

Abstract # MHSRS-22-07264 for Expeditionary Eye Care "Preliminary analysis of disability-adjusted life years due to ocular injury among combat casualties, 2001-2020"

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. (initiated/ongoing)

Subtask 1c: Identify contact information for survey study population (initiated/ongoing)

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:

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:

Reviewers delayed IRB and survey approvals by ~1.5 years (initially submitted 5/6/2021).

Changes in approach and reasons for change
No change.

Actual or anticipated problems or delays and actions or plans to resolve them
A no cost extension was requested due to the delayed approvals with the CRADA, protocol, and survey.

Changes that had a significant impact on expenditures
A no cost extension was requested to complete the project deliverables.

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

Abstract # MHSRS-22-07288 for Improving Warfighter Readiness and Performance through Health Services Research "Design to develop disability weights using a web-based survey among combat casualties: Experience from the US Military Burden of Disease Study"

Abstract # MHSRS-22-07264 for Expeditionary Eye Care "Preliminary analysis of disability-adjusted life years due to ocular injury among combat casualties, 2001-2020"

Journal publications.
The following 4 papers are in progress:
1. Analysis of disability-adjusted life years due to ocular injury among combat casualties, 2001-2020
2. Time to treatment of ocular injury among combat casualties, 2001-2020
3. Elicitation of disability weights among combat casualties using a web-based survey
4. Comparison of disability-adjusted life years using Global Burden of Disease versus US Military Burden of Disease disability weights

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/ (ongoing)

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:	8
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:	8
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:	3
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:	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:	6

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:	Akash S. Halagur
Project Role:	Collaborator/student
Researcher Identifier:	NA
Nearest person month worked:	3
Contribution to Project:	Mr. Halagur has performed work in the area of providing support in the area of disability weights.
Funding Support:	NA
Name:	Boonkit Purt, MD
Project Role:	Collaborator
Researcher Identifier:	NA
Nearest person month worked:	3
Contribution to Project:	Dr. Purt has performed work in the area of providing SME support in the area of Ophthalmology and ocular trauma.
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:

1. Abstract # MHSRS-22-07288 for Improving Warfighter Readiness and Performance through Health Services Research “Design to develop disability weights using a web-based survey among combat casualties: Experience from the US Military Burden of Disease Study”
2. Abstract # MHSRS-22-07264 for Expeditionary Eye Care “Preliminary analysis of disability-adjusted life years due to ocular injury among combat casualties, 2001-2020”
3. RCS approval email and DD-USA-2712 Form (05 OCT 2022)
4. Data Sharing Agreement Approvals for DSA #20-2470B “Epidemiology of combat ocular injury to guide prolonged field care“ (20 OCT 2022)