AWARD NUMBER: W81XWH-16-2-0005

TITLE: Economic Impact of Combat-Related Injuries from the Wars in Iraq and Afghanistan

PRINCIPAL INVESTIGATOR: Ted R Miller, PhD

RECIPIENT: Pacific Institute for Research and Evaluation Beltsville, MD 20705

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PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

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PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)	8. PERFORMING ORGANIZATION REPORT
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12. DISTRIBUTION / AVAILABILITY STATEMENT

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13. SUPPLEMENTARY NOTES

14. ABSTRACT Background: In the wars in Iraq and Afghanistan more than 59,000 US military have been wounded, with 6,800+ dying. The economic impact of these injuries is not well quantified. Hypothesis: Innovations in combat casualty care during these wars increased survival. We hypothesize that they also reduced care costs and improved outcomes for survivors. Aims: The proposed study aims to (1) quantify economic impacts of combat-related injuries to US service members incurred in these conflicts, (2) evaluate outcomes of and return on investment in selected combat casualty care innovations from military, Federal government, and societal perspectives, and (3) study the effects of alterative field and transport treatment protocols on the course and outcomes of moderate to severe traumatic brain injury. Study Design: We will build incidence, cost, and Disability-Adjusted Life Year (DALY) estimates from DoD, Department of Veterans' Affairs, and Social Security Administration earnings databases, plus diagnosis-specific civilian data on missing cost factors. We will use case-control studies to better understand impacts of trauma and of combat casualty care innovations on mortality, medical costs, and earnings losses. We will compute cost/DALY and cost-benefit estimates for a variety of trauma prevention and treatment innovations. Relevance: This study will provide information military leaders can use to inform policymakers and the public about the savings resulting from advanced trauma care techniques and the research that developed them and to support the need for an ongoing program of innovative research after the wars end and provide information that hastens diffusion of those innovations into the civilian sector.

15. SUBJECT TERMS

Cost, combat injury, cost-effectiveness, cost-benefit, TBI, transexamic acid, tourniquets, MACE

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a. REPORT	b. ABSTRACT	c. THIS PAGE	Unclassified	16	19b. TELEPHONE NUMBER (include area code)
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1. INTRODUCTION: Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

This project's purpose is to (1) estimate the economic impact of combat-related injuries to US service members in the ongoing conflicts in Iraq and Afghanistan and (2) evaluate outcomes of/return on investment in combat casualty care innovations including tourniquets, damage control resuscitation and improved blood component use, tranexamic acid, improved hemostatic bandages and dressings, undergarments to prevent genitourinary injury, and field and transport treatment protocols for traumatic brain injury. We will build incidence, cost, and Disability-Adjusted Life Year estimates from DoD, Department of Veterans' Affairs, and Social Security Administration earnings databases.

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

Cost, combat injury, cost-effectiveness, cost-benefit, TBI, tranexamic acid, tourniquets, MACE

3. ACCOMPLISHMENTS: The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

- (1) quantify the full range of economic impact of combat-related injuries to US service members incurred in the current conflicts in Iraq and Afghanistan
- (2) evaluate the outcomes of and return on investment in selected combat casualty care innovations from military, Federal government, and societal perspectives
- (3)) study the effects of alterative field and transport treatment protocols on the course and outcomes of moderate to severe traumatic brain injury

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Not enough. We still do not have the data approvals required. Injury epidemiologist Spicer, who was leading preparation for the paperwork, never developed a sufficient grasp of the DoD approval processes and data sets. We tried bringing Eileen Taylor, a senior project manager with extensive IRB package experience on to move things forward faster, but that did not resolve the problem. Finally, in March 2017, we hired Dr. David Swedler, an injury epidemiologist with experience as a civilian employee of the Department of Defense. He replaced Dr. Spicer on the project and has been working full-time on the approval packages.

We spent two months exploring a potential collaboration with Maj. Ian Stewart, an investigator identified by Dr. Orman. That collaboration would have grounded our study in a linked DoD-VA data set that he had already gotten approved, but we eventually determined that this approach was not workable because all his data resided at the VA and they could only provide finished tables. We subsequently located and tentatively agreed to collaborate with a VA collaborator suggested by Dr. Orman -- Dr. Mary Jo Pugh. In year 2, we will seek permission to subcontract some of PIRE's funds to Dr. Pugh to lead efforts to add VA data to the study. ISR also may subcontract some of its project funds to Dr. Pugh, but cannot do so until MRMC approves the study protocol,

We completed one book chapter during this period that compared civilian and military TBI issues.

Upon request of the PIRE team, ISR has been assisting with protocol development including reviewing and editing protocol drafts, has supplied example protocols and data request forms, provided information/documentation and contact names for data sources, and worked hard to identify VA and DOD partnership opportunities; however, because the funds allocated for the ISR were primarily to support a biostatistician and study data are not yet accessible, ISR has not used the funds other than overhead allocated to it for Year 1.

The table below shows the status of the data approval paperwork at the end of year 1. (Please note: major progress has been made since this table was completed. Of particular note, following up on a verbal discussion with the PI in year 1, PIRE's IRB now has worked with DoD to complete a DoD Institutional Agreement for Institutional Review Board Review MOU with the MRMC IRB that means that the PIRE IRB will defer to the MRMC IRB. As MRMC is the IRB of record for the ISR, this should allow for one protocol to be submitted on behalf of both PIRE and ISR.

Table 1. Progress made by the study team on each proposed dataset, 3/2017

Database	Progress	Data elements to be requested	Point of Contact
DODTR	Obtained data dictionary; identified data elements to be obtained; agreement in principal	Trauma data; medical transport; injury details (mechanism, severity, diagnosis, mortality); pre-existing conditions	Susan West
MDR/DHA	Obtained MDR data dictionary; initiated the Data System Access Application	Diagnosis; battle injury; Pharmaceutical data; In patient visits; Ambulatory data; PTSD; ER data; Discharge data; Sick/light duty; Pre-existing conditions; Alcohol/tobacco use	Gary Baker/ Philip Keller
DMSS	Reviewing data dictionary	TBI data; blast-involvement	Alicia Cost
AHLTA	Spoke with contact	TBI data; MTF data	Jean Orman
PEB/MEB	No progress	Disability due to injury	Lance Kent, LtCol Mark Eramo, Aruro Ybarra
AFMES	No progress	Autopsy data; toxicology	Lt Col Edward Mazuchowski
DSPO	No progress	Cause of death Follow-up treatment;	Chistopher Dorr
VA	Coordinating with Mary_Jo Pugh; identified necessary VHA data	Pharmaceutical costs; Retraining costs	Mary_Jo Pugh
SSA	Vender data request will be generated in the last year of the project.	Life-time earning <u>s</u>	ORDP.Data.Excyhange@ssa.gov

What opportunities for training and professional development has the project provided? If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops,

Nothing to report.		

conferences, seminars, study groups, and individual study. Include participation in conferences,

How were the results disseminated to communities of interest?

workshops, and seminars not listed under major activities.

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

We wrote a book chapter related to traumatic brain injury.

B Lawrence, J Orman, T Miller, R Spicer, D Hendrie The Cost of Traumatic Brain Injuries and the Return on Helmet Investment in the United States. In J Jallo, C Loftus (ed.), Neurotrauma and Critical Care of the Brain, Second Edition, in editing by publisher.

If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

During the next quarter, we will talk to the data owners, obtaining data dictionaries that we have not yet located and obtaining their guidance on our preliminary data item selections, The IRB package and most associated data set applications will start into review in July. As soon as data access is approved, we are prepared to commit substantial resources to data processing in the hopes of catching up to schedule.

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? *If there is nothing significant to report during this reporting period, state "Nothing to Report."*

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge,

If there is nothing significant to report during this reporting period, state "Nothing to Report." Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including: transfer of results to entities in government or industry; instances where the research has led to the initiation of a start-up company; or adoption of new practices.	Nothing to report	
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If there is nothing significant to report during this reporting period, state "Nothing to Report."

What was the impact on society beyond science and technology?

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- improving public knowledge, attitudes, skills, and abilities;
- changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or
- improving social, economic, civic, or environmental conditions.

	Nothing to Report
	CHANGES/PROBLEMS: The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to
	Report," if applicable: Changes in approach and reasons for change Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.
•	Nothing to Report
_	Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

The approval package for data access was not coming together properly or in a timely enough fashion. We hired someone with experience that qualified him to develop a responsive package and its assembly is now moving forward quickly.

Changes that had a significant impact on expenditures Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.	
None	
Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents	
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.	
Significant changes in use or care of human subjects	
No change; no human subjects are involved.	
Significant changes in use or care of vertebrate animals.	
No change; no animals are involved.	

Significant changes in use of biohazards and/or select agents

N	o change; no biohazards are involved.
6.	PRODUCTS: List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."
•	Publications, conference papers, and presentations
	Report only the major publication(s) resulting from the work under this award.

Journal publications. List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

None.			

Books or other non-periodical, one-time publications. Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

(ed.), N publish	rence, J Orman, T Miller, R Spicer, D Hendrie The Cost of Traumatic Brain s and the Return on Helmet Investment in the United States. In J Jallo, C Loftus Neurotrauma and Critical Care of the Brain, Second Edition, in editing by ner.
publicati status of	ublications, conference papers, and presentations. Identify any other ions, conference papers and/or presentations not reported above. Specify the the publication as noted above. List presentations made during the last year
•	tional, national, local societies, military meetings, etc.). Use an asterisk (*) if tion produced a manuscript.
None.	
List the U activities	U(s) or other Internet site(s) URL for any Internet site(s) that disseminates the results of the research s. A short description of each site should be provided. It is not necessary to the publications already specified above in this section.
None.	
Technol	ogies or techniques
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•	Inventions, patent applications, and/or licenses Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.
	None.
,	Other Products Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include: • data or databases; • biospecimen collections; • audio or video products; • software; • models; • educational aids or curricula; • instruments or equipment; • research material (e.g., Germplasm; cell lines, DNA probes, animal models); • clinical interventions; • new business creation; and • other.
Non	ne.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."

Name: Ted Miller
Project Role: Principal Investigator

Researcher Identifier ORCID ID 0000-0002-0958-2639

Nearest person month worked: 2

Contribution to Project: Principal Investigator

Name: Jean Orman Project Role: Co-investigator

Researcher Identifier ORCID ID 0000 0001 8085 1654

Nearest person month worked:

Contribution to Project: co-Principal Investigator

Name: Bruce Lawrence

Project Role: Economist/Senior Analyst

Researcher Identifier

Nearest person month worked: 1

Contribution to Project: Provided data runs and contributed to writing for the book chapter

described above

Name: Rebecca Spicer

Project Role: Injury Epidemiologist

Researcher Identifier

Nearest person month worked:

Contribution to Project: Responsible for drafting the IRB package and data access

applications. No longer on project.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported

previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Dr. Miller had two projects end and two (in aggregate smaller) projects start. Two more projects will end by July. Here is his current other support beyond the DoD project:

1R01MH095767-01A1 (Dawn Johnson) 07/18/2012 – 06/30/2017 0.6 CM

NIH/NIMH (University of Akron)

Treatment of PTSD in Residents of Battered Women's Shelters

AN:3421751 (Bernstein)

07/01/2012-07/31/2017 0.48 CM

NIH/NHLBI

Implementation of HIT-Enhanced Tobacco Treatment for Hospitalized Smokers

4R44DA040318 - 02 (Xiaoyan Zhang) 02/15/2016-01/31/2018 3.6 CM

NIH/NIDA (Mosaix Software)

Prevention Economic Impact Model, Phase 2

U01 MH106660 (Johnson and Weinstock) 10/1/15-9/30/19

0.36CM

NIH (NIMH, OBSSR) and NIJ (Michigan State University)

Suicide Risk Reduction in the Year Following Jail Release: the SPIRIT Trial (Suicide Prevention Intervention for at-Risk Individuals in Transition)

U54 MD011227 (Furr-Holden) 7/1/16-6/30/21

1.8 CM

NIH/National Institute on Minority Health Disparities (Michigan State University)

The Flint Center for Health Equity Solutions

1R01CA201873 (Bernstein)

07/01/16 - 06/30/20 0.22 CM

NIH/NCI (Yale University)

Optimizing Tobacco Dependence Treatment in the Emergency Department

<u>Partner's contribution to the project</u> (identify one or more)

- Financial support;
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- Facilities (e.g., project staff use the partner's facilities for project activities);
- Collaboration (e.g., partner's staff work with project staff on the project);
- Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and
- Other.

We are bringing in a VA collaborator to access the required VA data. We expect Dr. Mary Jo Pugh in San Antonio to fill that role, are negotiating her compensation.

ISR is funded directly by USAMRMC.