

**AWARD NUMBER:** W81XWH-17-2-0032

**TITLE:** Development and Dissemination of Clinical Practice Guidelines and Appropriate Use Criteria for Treatment of Major Extremity Trauma

**PRINCIPAL INVESTIGATOR:** Ellen J. MacKenzie, PhD

**CONTRACTING ORGANIZATION:** Johns Hopkins University  
Baltimore, MD 21205

**REPORT DATE:** September 2018

**TYPE OF REPORT:** Annual

**PREPARED FOR:** U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

**DISTRIBUTION STATEMENT:** Approved for public release; distribution is unlimited.

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

<b>REPORT DOCUMENTATION PAGE</b>			<i>Form Approved</i> <i>OMB No. 0704-0188</i>		
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. <b>PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.</b>					
<b>1. REPORT DATE</b> September 2018		<b>2. REPORT TYPE</b> Annual		<b>3. DATES COVERED</b> 1 Sep 2017 - 31 Aug 2018	
<b>4. TITLE AND SUBTITLE</b>  Development and Dissemination of Clinical Practice Guidelines and Appropriate Use Criteria for Treatment of Major Extremity Trauma			<b>5a. CONTRACT NUMBER</b>		
			<b>5b. GRANT NUMBER</b> W81XWH-17-2-0032		
			<b>5c. PROGRAM ELEMENT NUMBER</b>		
<b>6. AUTHOR(S)</b> Ellen J. MacKenzie, PhD  E-Mail: <a href="mailto:emacken1@jhu.edu">emacken1@jhu.edu</a>			<b>5d. PROJECT NUMBER</b>		
			<b>5e. TASK NUMBER</b>		
			<b>5f. WORK UNIT NUMBER</b>		
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  Johns Hopkins University School of Public Health, 615 N. Wolfe Street Room W1041 Baltimore, MD 21205			<b>8. PERFORMING ORGANIZATION REPORT</b>		
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b>  U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>		
			<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>		
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b>  Approved for Public Release; Distribution Unlimited					
<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b>  See next page.					
<b>15. SUBJECT TERMS</b>  None provided					
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>  Unclassified	<b>18. NUMBER OF PAGES</b>  21	<b>19a. NAME OF RESPONSIBLE PERSON</b> USAMRMC
<b>a. REPORT</b> Unclassified	<b>b. ABSTRACT</b> Unclassified	<b>c. THIS PAGE</b> Unclassified			<b>19b. TELEPHONE NUMBER</b> <i>(include area code)</i>

## ABSTRACT FROM SF-298, SECTION 14

A critical next step for METRC is the integration of its results with other relevant research, multi-disciplinary clinical expertise and patient values to develop Clinical Practice Guidelines (CPGs) and criteria for the appropriate use of the guidelines through development of Appropriate Use Criteria (AUCs). To this end, six clinical topics were identified: 1) Diagnosis and Treatment of Acute Compartment Syndrome; 2) Limb Salvage vs. Amputation Following Major Limb Trauma; 3) Early Screening for Psychosocial Risk and Protective Factors; 4) Use of Multimodal Perioperative Pharmacologic Pain Management; 5) Techniques for Performing Transtibial Amputation- Burgess vs. Ertl; and 6) Prevention and Treatment of Surgical Site Infection. We have made progress on the first 5 topics, as planned. A complete draft guideline document has been produced for topic 1. For topics 2 and 3, a protocol to interview former METRC OUTLET and TCCS study patients has been approved and interviews to help frame PICO questions will commence in the next project year. For topics 4 and 5, enrollment and follow-up into the METRC PAIN and TAOS studies has continued as planned and as necessary to address these topics. We expect to continue work on topics 1-5 as planned with no anticipated major delays or challenges."

## TABLE OF CONTENTS

### Page

1. Introduction	4
2. Keywords	4
3. Accomplishments	4
4. Impact	11
5. Changes/Problems	12
6. Products	14
7. Participants & Other Collaborating Organizations	16
8. Special Reporting Requirements	19
9. Appendices	20

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The Major Extremity Trauma and Rehabilitation Consortium was established in 2009 as a clinical research network with the goal of producing the evidence needed to establish treatment guidelines for the optimal care of the wounded warrior and ultimately to improve the clinical and quality of life outcomes of both service members and civilians who sustain high-energy orthopaedic trauma. METRC has been funded to conduct more than 20 prospective studies in pursuit of this goal. With many studies ending and results being published in the peer-reviewed literature, the critical next step is an integration of METRC results with other relevant research, multi-disciplinary clinical expertise and patient values to develop Clinical Practice Guidelines (CPGs) and criteria for the appropriate use of the guidelines through development of Appropriate Use Criteria (AUCs). The Joint Warfighter Medical Research Program funds are intended to support the development of these CPGs and AUCs and to disseminate the results through the military and civilian trauma communities.

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

Orthopaedic trauma, outcomes, clinical practice guidelines, translation

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official 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.*

**Objective 1 (O1):** For each of the 6 clinical questions/ topics, we will convene a multidisciplinary panel to refine the clinical questions and develop criteria for a systematic review; conduct an extensive and systematic review of the literature and develop evidence tables; develop a range of relevant clinical scenarios and determine the appropriateness of treatment by rating the scenarios; communicate and disseminate the CPGs and AUCs.

**Objective 2 (O2):** Enroll and prospectively follow (for 12 months) an additional 75 patients into the PAIN trial, conduct the analysis and publish results; Enroll and prospectively follow (for 18 months) an additional 135 patients into the TAOS trial, conduct analysis and publish results.

### Topic 1: Diagnosis and Treatment of Acute Compartment Syndrome

Aim/ Milestone	Description	Months	Status
A1, O1	Convene panels to develop criteria for Systematic Review	1-2	Complete
A2, O1	Conduct systematic review and develop evidence tables	3-7	Complete
<i>Milestone</i>	<i>Publish Systematic Review</i>	7	Ongoing, 75% Complete
A3, O1	Develop recommendations and CPG	8-12	Ongoing, 75% Complete
<i>Milestone</i>	<i>Disseminate CPG</i>	12	Not yet initiated
A4, O1	Develop and rate clinical scenarios	13-16	Not yet initiated
<i>Milestone</i>	<i>Disseminate AUC</i>	19	Not yet initiated

### Topic 2: Limb Salvage or Early Limb Amputation Following Major Limb Trauma

Aim/ Milestone	Description	Months	Status
A1, O1	Convene panels to develop criteria for systematic review	13-14	Not yet initiated
A2, O1	Conduct systematic review and develop evidence tables	15-18	Not yet initiated
<i>Milestone</i>	<i>Publish Systematic Review</i>	18	Not yet initiated
A3, O1	Develop recommendations and CPG	19-21	Not yet initiated
A4, O1	Develop and rate clinical scenarios	22-24	Not yet initiated
<i>Milestone</i>	<i>Disseminate CPGs and AUCs</i>	27	Not yet initiated

### Topic 3: Early Screening for Psychosocial Risk and Protective Factors

Aim/ Milestone	Description	Months	Status
A1, O1	Convene panels to develop criteria for Systematic Review	13-14	Not yet initiated
A2, O1	Conduct systematic review and develop evidence tables	15-18	Not yet initiated
<i>Milestone</i>	<i>Publish Systematic Review</i>	18	Not yet initiated
A3, O1	Develop recommendations and CPG	19-22	Not yet initiated
<i>Milestone</i>	<i>Disseminate CPG</i>	22	Not yet initiated
A4, O1	Develop and rate clinical scenarios	25-30	Not yet initiated
<i>Milestone</i>	<i>Disseminate AUC</i>	33	Not yet initiated

#### Topic 4: Use of Multimodal Perioperative Pharmacologic Pain Management

Aim/ Milestone	Description	Months	Status
A1, O2	Augment recruitment into PAIN	1-24	Complete
	ST 1 Maintain IRB and HRPO regulatory documents of existing sites	1-24	Ongoing
	ST 2 Clinical site RCs will screen and enroll eligible study patients through month 6; RCs will enter data collected on CRFs into REDCap	1-6	Complete
	ST 3 Generate and distribute monthly enrollment and f/up reports; provide ongoing training and support to address problems with enrollment and f/up as they are identified	3-18	Complete
	ST 4 Generate and distribute data quality reports to monitor data completeness, check for errors and inconsistencies	1-18	Complete
<i>Milestone</i>	<i>Patients enrolled through Month 6</i>	<i>6</i>	<i>Complete</i>
<i>Milestone</i>	<i>All patients (enrolled through Month 6) are followed</i>	<i>18</i>	<i>Complete</i>
A2, O2	Complete analysis and publish results of the clinical trial	13-24	Ongoing
	ST 1 Develop analysis files	13-18	Ongoing
	ST 2 Conduct analysis	22	Not yet initiated
	ST 3 Publish 2 results papers	24	Not yet initiated
<i>Milestone</i>	<i>Analysis Completed</i>	<i>22</i>	<i>Not yet initiated</i>
<i>Milestone</i>	<i>Manuscripts submitted for publication</i>	<i>24</i>	<i>Not yet initiated</i>
A1, O1	Convene panels to develop criteria for systematic review	25-26	Not yet initiated
A2, O1	Conduct systematic review and develop evidence tables	27-30	Not yet initiated
<i>Milestone</i>	<i>Publish Systematic Review</i>	<i>30</i>	<i>Not yet initiated</i>
A3, O1	Develop recommendations and CPG	31-33	Not yet initiated
A4, O1	Develop and rate clinical scenarios	34-36	Not yet initiated
<i>Milestone</i>	<i>Disseminate CPGs and AUCs</i>	<i>36</i>	<i>Not yet initiated</i>

**Topic 5: Techniques for Performing Transtibial Amputation: Burgess vs. Ertl**

<b>Aim/ Milestone</b>	<b>Description</b>		<b>Months</b>	<b>Status</b>
A1, O2	Augment recruitment into TAOS		1-48	Ongoing
	ST 1	Maintain IRB and HRPO regulatory documents of existing sites	1-48	Ongoing
	ST2	Clinical site RCs will screen and enroll eligible study patients through month 27; RCs will enter data collected on CRFs into REDCap	1-27	Complete
	ST3	Follow all patients enrolled at 3, 6, 12, and 18 months post discharge	3-42	Ongoing
	ST4	Generate and distribute monthly enrollment and f/up reports; provide ongoing training and support to address problems with enrollment and f/up as they are identified	1-42	Ongoing
	ST5	Generate and distribute data quality reports to monitor data completeness, check for errors and inconsistencies	1-42	Ongoing
<i>Milestone</i>	<i>Patients enrolled through Month 27</i>		27	Complete
<i>Milestone</i>	<i>All patients are followed through Month 42</i>		42	Ongoing
A2, O2	Complete analysis and publish results of the clinical trial		36-45	Not yet initiated
	ST1	Develop analysis files	36-40	Not yet initiated
	ST2	Conduct analysis	42-44	Not yet initiated
	ST3	Publish 2 results papers	45	Not yet initiated
<i>Milestone</i>	<i>Analysis Completed</i>		44	Not yet initiated
<i>Milestone</i>	<i>Manuscripts submitted for publication</i>		45	Not yet initiated
A1, O1	Convene panels to develop criteria for systematic review		37-38	Not yet initiated
A2, O1	Conduct systematic review and develop evidence tables		39-44	Not yet initiated
<i>Milestone</i>	<i>Publish Systematic Review</i>		44	Not yet initiated
A3, O1	Develop recommendations and CPG		43-45	Not yet initiated
A4, O1	Develop and rate clinical scenarios		46-48	Not yet initiated
<i>Milestone</i>	<i>Disseminate CPGs and AUCs</i>		48	Not yet initiated

<b>Topic 6: Prevention and Treatment of Surgical Site Infection</b>			
<b>Aim/ Milestone</b>	<b>Description</b>	<b>Months</b>	<b>Status</b>
A1, O1	Convene panels to develop criteria for Systematic Review	37-38	Not yet initiated
A2, O1	Conduct systematic review and develop evidence tables	39-42	Not yet initiated
<i>Milestone</i>	<i>Publish Systematic Review</i>	42	Not yet initiated
A3, O1	Develop recommendations and CPG	43-45	Not yet initiated
A4, O1	Develop and rate clinical scenarios	46-48	Not yet initiated
<i>Milestone</i>	<i>Disseminate CPGs and AUCs</i>	48	Not yet initiated

**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.*

<p><b>Major Activities:</b> None to report.</p> <p><b>Specific Objectives:</b></p> <p><b>Topic #1: Diagnosis and Treatment of Acute Compartment Syndrome</b></p> <ul style="list-style-type: none"> <li>• A conference call to discuss the draft recommendations was held on 07 Jun 2018</li> <li>• A guideline document has been drafted for review</li> </ul> <p><b>Topic #2: Limb Salvage or Early Limb Amputation Following Major Limb Trauma</b></p> <ul style="list-style-type: none"> <li>• The systematic review is expected to start in October 2018. Prior to starting the systematic review, we plan to solicit patient input on their most important questions and outcomes on this topic. The patient interviews will be used to help frame the PICO questions and to ensure that the guideline meets the needs of patients.</li> <li>• We have drafted an IRB protocol for interviewing patients. The IRB protocol has been approved by the Johns Hopkins School of Medicine IRB and by the Office of Research Protections Human Research Protection Office. Two of the individual sites that will be recruiting patients for the interviews have received IRB approval. Both of these site are awaiting approval from the Office of Research Protections Human Research Protection Office (DoD HRPO).</li> <li>• The Guideline Development Committee met on 03 Oct 2018.</li> </ul>
--

**Topic #3: Early Screening for Psychosocial Risk and Protective Factor**

- The systematic review is not scheduled to start until late October 2018 or November 2018. Prior to starting the systematic review, we plan to solicit patient input on their most important questions and outcomes on this topic. The patient interviews will be used to help frame the PICO questions and to ensure that the guideline meets the needs of patients. We have drafted an IRB protocol for interviewing patients. The IRB protocol has been approved by the Johns Hopkins School of Medicine IRB and is currently under review by the Office of Research Protections Human Research Protection Office (DoD HRPO). One of the sites (University of Maryland) has received a Not Human Subject Research approval because they will not be conducting any of the recruiting or screening. The other site (Carolinas Medical Center) has received IRB approval. Both of these sites are waiting to submit their applications to the Office of Research Protections Human Research Protection Office
- The Guideline Development Committee is expected to meet in October or November 2018.

**Topic #4: Use of Multi-Modal Perioperative Pain Management**

- Enrollment and follow-up in the PAIN Study (METRC 2) are complete as of the end of the reporting period. Data cleaning in preparation for analyses is well underway.
- The systematic review is expected to start in October 2019.

**Topic #5: Techniques for Performing Transtibial Amputation: Burgess vs. Ertl**

- Enrollment into the TAOS Study (METRC 2) is complete as of the end of the reporting period. Patient follow-up will be ongoing for another 18 months. Data cleaning activities will occur in an ongoing fashion for the duration of the study with the goal of being able to complete the main analysis shortly after the final follow-up visits are completed.
- The systematic review is expected to start in October 2020.

**Topic #6: Prevention and Treatment of Surgical Site Infection**

- The systematic review is expected to start in October 2020.

***Significant Results or Key Outcomes:*** None to report

***Other Achievements:*** None to report

**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, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.*

Nothing to report

**How were the results disseminated to communities of interest?**

*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.*

Nothing to report

**What do you plan to do during the next reporting period to accomplish the goals?**

*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.*

**Topic #1: Diagnosis and Treatment of Acute Compartment Syndrome**

- Final recommendations and a draft guideline document will be reviewed by the Guideline Steering Committee.

**Topic #2: Limb Salvage or Early Limb Amputation Following Major Limb Trauma**

- We expect to receive the remaining regulatory approvals necessary to initiate the patient interviews. The interviews will be used to help frame the PICO questions and to ensure that the guideline meets the needs of patients.

**Topic #3: Early Screening for Psychosocial Risk and Protective Factor**

We expect to receive the remaining regulatory approvals necessary to initiate the patient interviews. The interviews will be used to help frame the PICO questions and to ensure that the guideline meets the needs of patients

**Topic #4: Use of Multi-Modal Perioperative Pain Management**

- We will continue to clean the data in the PAIN Study in preparation for the main analyses.

**Topic #5: Techniques for Performing Transtibial Amputation: Burgess vs. Ertl**

- We will continue to complete follow-up on all patients enrolled into the TAOS Study. We will also complete data cleaning prospectively.

**Topic #6: Prevention and Treatment of Surgical Site Infection**

- Per the statement of work, we do not expect to do anything during the next reporting period to further this particular topic. Work on this topic will be initiated in 2020.

**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, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).*

Nothing to report

**What was the impact on other disciplines?**

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

*Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.*

Nothing to report

**What was the impact on technology transfer?**

*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

**What was the impact on society beyond science and technology?**

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

*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

- 5. CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official 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.*

It has taken longer than expected to obtain all necessary regulatory approvals for the patient interviews that are planned to inform the guidelines for Topics 2 and 3. We have followed up on the status of these reviews as appropriate and expect to receive them within the next reporting period.

**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.*

Nothing to report

**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**

Nothing to report

**Significant changes in use or care of vertebrate animals**

Nothing to report

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

Nothing to report

**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).*

Nothing to report

**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).*

Nothing to report

**Other publications, conference papers and presentations.** *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (\*) if presentation produced a manuscript.*

Nothing to report

- **Website(s) or other Internet site(s)**

*List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.*

Nothing to report

- **Technologies or techniques**

*Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.*

Nothing to report

- **Inventions, patent applications, and/or licenses**

*Identify inventions, patent applications with date, and/or licenses that have resulted from the research. 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.*

Nothing to report

- **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;*
- *physical 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.*

Nothing to report

## **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”.*

*Example:*

*Name: Mary Smith*  
*Project Role: Graduate Student*  
*Researcher Identifier (e.g. ORCID ID): 1234567*  
*Nearest person month worked: 5*

*Contribution to Project:*

*Ms. Smith has performed work in the area of combined error-control and constrained coding.*

*Funding Support:*

*The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

See Attachment A

**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.*

Nothing to report

**What other organizations were involved as partners?**

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

*Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.*

*Provide the following information for each partnership:*

*Organization Name:*

*Location of Organization: (if foreign location list country)*

*Partner’s contribution to the project (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.*

Organization Name: American Academy of Orthopaedic Surgeons

Location of Organization: (if foreign location list country) Rosemont, IL 60018-4976

Partner's contribution to the project (identify one or more):

- AAOS will partner with JHU to conduct systematic reviews (SRs) and develop CPGs and AUCs relevant to the treatment of severe extremity trauma in both the civilian and military settings.
- AAOS will help integrate the results of METRC studies with their existing development infrastructure including other relevant research, multi-disciplinary clinical expertise and patient values to develop guidelines and AUCs to ensure quality care and good patient outcomes.
- Financial support; Yr1: \$226,712; Overall estimate \$1,507,047
- In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff); AAOS will help integrate the results of METRC studies with their existing development infrastructure including other relevant research, multi-disciplinary clinical expertise and patient values to develop guidelines and AUCs.
- Facilities (e.g., project staff use the partner's facilities for project activities); See above
- Collaboration (e.g., partner's staff work with project staff on the project); Site PI: Deborah Cummins; Site Co-PI: David Jevsevar collaborate with METRC PI: Dr. Ellen Mackenzie
- Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and Other. Project Director, Analyst, Medical Librarian and Statistician at AAOS are working on this project.

## 8. SPECIAL REPORTING REQUIREMENTS

**COLLABORATIVE AWARDS:** *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.*

**QUAD CHARTS:** *If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.*

9. **APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

Attachment A: Personnel

**JWP study**

<b><u>Personnel</u></b>	<b><u>Role</u></b>	<b><u>Calendar Months</u></b>
Ellen Mackenzie	Principal Investigator, Director	1.20
Renan Castillo	Deputy Director	0.36
Daniel Scharfstein	Principal Statistician	0.60
Eric Bass/ Karen Robinson	Co-Investigator	2.40
Stephen Wegener	Co-Investigator	0.60
Lisa Reider	Study Director	1.2
Katherine Frey	Study Director	1.35
Lisa Wilson	Project Manager	3
Jason Luly	Biostatistician/ Data Analyst	1.2
Tara Taylor	Study Manager	1.8
Dana Alkhoury	Study Manager	1.8
Datla Raju	Programmer	0.9
Anthony Carlini	Programmer	0.3
Manisha Anand	Financial Manager	0.6