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 Bloomberg School of Public Health

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
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8. PERFORMING ORGANIZATION REPORT

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

U.S. Army Medical Research and Materiel Command
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

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.

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:** *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 an 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
Milestone	*Publish Systematic Review*	*7*	Complete
A3, O1	Develop recommendations and CPG	8-12	Complete
Milestone	*Disseminate CPG*	*12*	Complete
A4, O1	Develop and rate clinical scenarios	13-16	Complete
Milestone	*Disseminate AUC*	*19*	Ongoing, 75% Complete

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	Complete
A2, O1	Conduct systematic review and develop evidence tables	15-18	Complete
Milestone	*Publish Systematic Review*	*18*	Complete
A3, O1	Develop recommendations and CPG	19-21	Complete
A4, O1	Develop and rate clinical scenarios	22-24	Complete
Milestone	*Disseminate CPGs and AUCs*	*27*	Ongoing, 75% Complete

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	Complete
A2, O1	Conduct systematic review and develop evidence tables	15-18	Complete
Milestone	*Publish Systematic Review*	*18*	Complete
A3, O1	Develop recommendations and CPG	19-22	Complete
Milestone	*Disseminate CPG*	*22*	Ongoing, 50% Complete
A4, O1	Develop and rate clinical scenarios	25-30	Ongoing, 50% Complete
Milestone	*Disseminate AUC*	*33*	Ongoing, 75% Complete

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
Milestone	*Patients enrolled through Month 6*		*6*	Complete
Milestone	*All patients (enrolled through Month 6) are followed*		*18*	Complete
A2, O2	Complete analysis and publish results of the clinical trial		13-24	Ongoing, 75% Complete
	ST 1	Develop analysis files	13-18	Ongoing, 75% Complete
	ST 2	Conduct analysis	22	Not yet initiated
	ST 3	Publish 2 results papers	24	Not yet initiated
Milestone	*Analysis Completed*		*22*	Not yet initiated
Milestone	*Manuscripts submitted for publication*		*24*	Not yet initiated
A1, O1	Convene panels to develop criteria for systematic review		25-26	Complete
A2, O1	Conduct systematic review and develop evidence tables		27-30	Complete
Milestone	*Publish Systematic Review*		*30*	Ongoing, 50% Complete
A3, O1	Develop recommendations and CPG		31-33	Ongoing, 50% Complete
A4, O1	Develop and rate clinical scenarios		34-36	Not yet initiated
Milestone	Disseminate CPGs and AUCs		*36*	Not yet initiated

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

Aim/ Milestone	Description		Months	Status
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
Milestone	*Patients enrolled through Month 27*		*27*	Complete
Milestone	*All patients are followed through Month 42*		*42*	Complete
A2, O2	Complete analysis and publish results of the clinical trial		36-45	Not yet initiated
	ST1	Develop analysis files	36-40	Ongoing, 50% Complete
	ST2	Conduct analysis	42-44	Not yet initiated
	ST3	Publish 2 results papers	45	Not yet initiated
Milestone	*Analysis Completed*		*44*	Not yet initiated
Milestone	*Manuscripts submitted for publication*		*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
Milestone	*Publish Systematic Review*		*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
Milestone	Disseminate CPGs and AUCs		*48*	Not yet initiated

Topic 6: Prevention and Treatment of Surgical Site Infection

Aim/ Milestone	Description	Months	Status
A1, O1	Convene panels to develop criteria for Systematic Review	37-38	Complete
A2, O1	Conduct systematic review and develop evidence tables	39-42	Ongoing, 25% Complete
Milestone	*Publish Systematic Review*	*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
Milestone	*Disseminate CPGs and AUCs*	*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.

Major Activities: None to report.

Specific Objectives:

Topic #1: Diagnosis and Treatment of Acute Compartment Syndrome

- The CPG Summary Paper and Case Study paper, and the AUC Summary paper were published in JAAOS. Please see table below for links to these papers. The AUC Case Study was included within the AUC Summary paper as a single publication, as determined by the authors.

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

- The CPG Summary Paper and Case Study Paper are still under review at JAAOS. Summary is completed and linked below.
- The authors are still finalizing the AUC Summary Paper and the AUC Case Study Paper.

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

- The authors are still finalizing the CPG Summary Paper and Case Study Paper. The papers have been submitted to JAAOS and are pending publication
- The AUC Summary Paper and Case Study Paper are completed and published (linked in table below).

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

- Regarding the PAIN Study: Adjudication of nonunion and the lost to follow-up and healing adjudication are complete. Main analyses are underway.
- The PAIN CPG and AUC have both been completed. Both were approved and are linked in table below.

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

- Regarding the TAOS Study: Adjudication is nearly complete; adjudicators are expected to complete their review of all cases by early October of the next project year. Main analyses will commence as soon as the adjudication is complete.
- The CPG and AUC development will continue to be on hold until the TAOS study results are published.

Topic #6: Prevention and Treatment of Surgical Site Infection

- The CPG literature review is in progress. The final meeting was held on August 27, 2021 with a follow-up call held September 15th. We are currently finalizing the draft.
- The AUC voting panel completed its first round of voting. We are finalizing Round 2 voting.

Please see the table on the next page which summarizes the status of each key output for the 6 topics. The outputs that are complete and published are also linked within the table.

Significant Results or Key Outcomes: None to report

Other Achievements: None to report

Clinical Topic	Clinical Practice Guideline			Appropriate Use Criteria		
	Online CPG	**Summary Paper**	**Case Study Paper**	**Online AUC**	**Summary Paper**	**Case Study Paper**
Topic 1: Diagnosis and Treatment of Acute Compartment Syndrome	CPG 2018	Summary 2020	Case Studies 2021	AUC 2019	Summary 2021	Included within the Summary Paper
Topic 2: Limb Salvage or Early Limb Amputation	CPG 2019	Summary 2021	N/A	AUC	N/A	N/A
Topic 3: Early Screening for Psychosocial Risk Factors	CPG 2019	Pending Publication with JAAOS	Pending Publication with JAAOS	AUC 2020	Summary 2021	Case Studies 2021
Topic 4: Use of Multimodal Perioperative Pharmacologic Pain Management	CPG 2021	--	--	AUC 2021	--	--
Topic 5: Techniques for Performing Transtibial Amputation	--	--	--	--	--	--
Topic 6: Prevention and Treatment of Surgical Site Infection	Finalizing draft for Review Period.	--	--	AUC Voting is in Progress	--	--

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.

Completed CPGs and AUCs are published to the AAOS's OrthoGuidelines platform at: http://www.orthoguidelines.org/. METRC also disseminates completed CPGs consortium-wide through listservs, during regular Consortium Committee meetings, as well as during our in-person Annual Meeting. The CPG and AUC Summary papers and the Case Study papers are also submitted for publication to the Journal of the American Academy of Orthopaedic Surgeons.

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

- We expect that the AUC Case Study Paper will be published.

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

- JAAOS publication pursuit pending confirmation of grant requirement.

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

- The CPG Summary and Case Study paper will be published in JAAOS.

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

- CPG and AUC summary and case study papers to be submitted to JAAOS in Q4 2021-Q1 2022

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

- We will complete the adjudication process (by beginning of October) and continue to prepare the main analysis files.

Topic #6: Prevention and Treatment of Surgical Site Infection

- We will complete the Review Period and finalize the CPG draft. Expected AAOS Board approval in December 2021.
- Second round voting for the AUC will be finalized. Expected AAOS Board approval in December 2021.

4. **IMPACT:** D*escribe 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).

The CPGs and AUCs that have been published have been disseminated to the Orthopaedic Trauma community where they impact care and treatment for patients who sustain major orthopaedic injuries.

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.

We do not expect problems or delays during the upcoming 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

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).*

No additional journal publications aside from those noted above in the accomplishments section/ summary table.

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).*

The CPGs, AUCs, and Case Study Papers are linked in the summary table within the accomplishments section above.

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.

http://www.orthoguidelines.org/

- **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

- *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:
<u>Organization Name:</u>
<u>Location of Organization: (if foreign location list country)</u>
<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.*

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 $1,146,545
- 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.*

Appendix A - JWP Study Personnel (Yr5 - Annual)

Personnel	Role	Calendar Months	
Ellen Mackenzie	Principal Investigator, Director	0.45	*Effort reduced to 3.75%*
Renan Castillo	Deputy Director	1.68	
Daniel Scharfstein	Principal Statistician	0.84	*Sub to Utah for effort support*
Stephen Wegener	Co-Investigator	1.20	
Lisa Reider	Study Director	1.20	
Katherine Frey	Study Director	0.60	
Lauren Allen	Project Manager	2.40	*Effort reduced to 20%*
Jiawei Bai	Data Analyst (TAOS)	1.80	
Linda Gai	Data Analyst (TAOS)	1.50	
Reshmi Nair	Data Analyst (TAOS)	1.50	*Linda Gai left JHU in February*
Jack Dagg	Data Analyst (PAIN)	3.00	
Tara Taylor	Study Manager	1.20	
Dana Alkhoury	Study Manager	1.80	
Paige Sullivan	Programmer	1.80	
Elias Weston Farber	Programmer	2.40	*Replaced Alina*
Anthony Carlini	Director Informatics	0.60	
Chris Witczak	Financial Analyst	2.40	
Rebecca Pickard/ Danielle Drye	Editorial Coordinator	1.20	*Rebecca replaced by Danielle Drye*
Aiden McDermot	Biostatistician	1.20	
Hope Woolf	Research Assistant	1.20	

Notes:

- Effort for Dr. Scharfstein ended 07/31/20 as he moved to Utah and his effort is supported via sub to Utah.

Appendix B: Enrollment by METRC Sites into PAIN and TAOS Studies

Code	Site Name	PAIN	TAOS
BMC	Boston Medical Center	17	
CMC	Carolinas Medical Center	77	28
HCM	Hennepin County Medical Center	9	2
HOU	University of Texas Health Science Center, Houston	14	12
MET	MetroHealth Medical Center	37	8
PIT	University of Pittsburgh Medical Center	9	10
PSU	Penn State M.S. Hershey Medical Center	2	9
RYD	University of Miami Ryder Trauma Center	17	4
STL	St. Louis University Hospital		4
TGH	Tampa General Hospital		5
UIA	University of Iowa Hospitals and Clinics	4	6
UMD	University of Maryland R Adams Cowley Shock Trauma Center	126	9
UMS	University of Mississippi Medical Center		6
UOK	University of Oklahoma/OU Medical Center		15
USF	University of California at San Francisco		8
UTX	University of Texas Southwestern Medical Center	22	
UWA	University of Washington/ Harborview Medical Center		2
VMC	Vanderbilt Medical Center	22	23
WFU	Wake Forest University Baptist Medical Center		2
BAM	San Antonio Military Medical Center		15
NPM	Naval Medical Center Portsmouth	7	0
WRD	Walter Reed National Military Medical Center		5

BJH	Barnes-Jewish Hospital/ Washington University		1
COR	Center for Orthopaedic Research and Education	3	
EMU	Emory University School of Medicine		3
ESK	Eskenazi Health	19	0
GRT	Grant Medical Center		1
RIH	Rhode Island Hospital/ Brown University		4
SHV	Louisiana State University Health Sciences Center	55	
STM	St. Mary's Medical Center	10	

Table 2. Participation in Patient Input for CPG Development Protocols

Code	Site Name	Limb Salvage vs. Amputation Patient Input Protocol Status	Psychosocial Risk Factors Patient Input Protocol Status
CMC	Carolinas Medical Center	Approved by local IRB and by DoD HRPO	Approved by local IRB and DoD HRPO
UMD	University of Maryland R Adams Cowley Shock Trauma Center	Approved by local IRB and by DoD HRPO	Local IRB determined site personnel were not engaged in research and so protocol is exempt from UMD IRB oversight; HRPO issued a concurrence memo