

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

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

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**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:**

**a. REPORT**  
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**b. ABSTRACT**  
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**c. THIS PAGE**  
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## TABLE OF CONTENTS

Page

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

## 1. INTRODUCTION:

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:

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**

<b>Aim/ Milestone</b>	<b>Description</b>	<b>Months</b>	<b>Status</b>
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	Complete
A3, O1	Develop recommendations and CPG	8-12	Complete
<i>Milestone</i>	<i>Disseminate CPG</i>	12	Complete
A4, O1	Develop and rate clinical scenarios	13-16	Complete
<i>Milestone</i>	<i>Disseminate AUC</i>	19	Complete

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

<b>Aim/ Milestone</b>	<b>Description</b>	<b>Months</b>	<b>Status</b>
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
<i>Milestone</i>	<i>Publish Systematic Review</i>	18	Complete
A3, O1	Develop recommendations and CPG	19-21	Complete
A4, O1	Develop and rate clinical scenarios	22-24	N/A
<i>Milestone</i>	<i>Disseminate CPGs and AUCs</i>	27	Complete

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

<b>Aim/ Milestone</b>	<b>Description</b>	<b>Months</b>	<b>Status</b>
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
<i>Milestone</i>	<i>Publish Systematic Review</i>	18	Complete
A3, O1	Develop recommendations and CPG	19-22	Complete
<i>Milestone</i>	<i>Disseminate CPG</i>	22	Complete
A4, O1	Develop and rate clinical scenarios	25-30	Complete
<i>Milestone</i>	<i>Disseminate AUC</i>	33	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	Ongoing	Complete
	ST2   Clinical site RCs will screen and enroll eligible study patients through month 6; RCs will enter data collected on CRFs into REDCap	Complete	Complete
	ST3   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	Complete	Complete
	ST4   Generate and distribute data quality reports to monitor data completeness, check for errors and inconsistencies	Complete	Complete
<i>Milestone</i>	<i>Patients enrolled through Month 6</i>	6	Complete
<i>Milestone</i>	<i>All patients (enrolled through Month 6) are followed</i>	18	Complete
A2, O2	Complete analysis and publish results of the clinical trial	13-24	Complete
	ST1   Develop analysis files	Complete	Complete
	ST2   Conduct analysis	Complete	Complete
	ST3   Publish 2 results papers	Complete	Ongoing
<i>Milestone</i>	<i>Analysis Completed</i>	22	Complete
<i>Milestone</i>	<i>Manuscripts submitted for publication</i>	24	Ongoing
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
<i>Milestone</i>	<i>Publish Systematic Review</i>	30	Complete
A3, O1	Develop recommendations and CPG	31-33	Complete
A4, O1	Develop and rate clinical scenarios	34-36	Complete
<i>Milestone</i>	Disseminate CPGs and AUCs	36	Complete

**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	Complete
	ST 1   Maintain IRB and HRPO regulatory documents of existing sites	Ongoing	Complete
	ST2   Clinical site RCs will screen and enroll eligible study patients through month 27; RCs will enter data collected on CRFs into REDCap	Complete	Complete
	ST3   Follow all patients enrolled at 3, 6, 12, and 18 months post discharge	Ongoing	Complete
	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	Ongoing	Complete
	ST5   Generate and distribute data quality reports to monitor data completeness, check for errors and inconsistencies	Ongoing	Complete
<i>Milestone</i>	<i>Patients enrolled through Month 27</i>	<i>27</i>	<i>Complete</i>
<i>Milestone</i>	<i>All patients are followed through Month 42</i>	<i>42</i>	<i>Complete</i>
A2, O2	Complete analysis and publish results of the clinical trial	36-45	Ongoing
	ST1   Develop analysis files	36-40	Ongoing, 75% Complete
	ST2   Conduct analysis	40-44	Ongoing, 50% complete
	ST3   Publish 2 results papers	44-45	Not yet initiated
<i>Milestone</i>	<i>Analysis Completed</i>	<i>44</i>	<i>Ongoing, 50% Complete</i>
<i>Milestone</i>	<i>Manuscripts submitted for publication</i>	<i>45</i>	<i>Not yet initiated</i>
A1, O1	Convene panels to develop criteria for systematic review	37-38	N/A
A2, O1	Conduct systematic review and develop evidence tables	39-44	N/A
<i>Milestone</i>	<i>Publish Systematic Review</i>	<i>44</i>	<i>N/A</i>
A3, O1	Develop recommendations and CPG	43-45	N/A
A4, O1	Develop and rate clinical scenarios	46-48	N/A
<i>Milestone</i>	<i>Disseminate CPGs and AUCs</i>	<i>48</i>	<i>N/A</i>

## 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	Complete
<i>Milestone</i>	<i>Publish Systematic Review</i>	42	Complete
A3, O1	Develop recommendations and CPG	43-45	Complete
A4, O1	Develop and rate clinical scenarios	46-48	Complete
<i>Milestone</i>	<i>Disseminate CPGs and AUCs</i>	48	Complete

### 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:**

The table on the next page summarizes the status of each key deliverable for **Clinical Topics 1-4, and Topic 6.**

Deliverables for **Topic 5, Techniques for Performing Transtibial Amputation: Burgess vs. Ertl**, were awaiting completion of the METRC TAOS Study. This decision was made with the guidance of the Steering Committee and in partnership with our colleagues at AAOS, in recognition of the dearth of existing literature on the topic. The intent was to wait for the publication of the TAOS main results so that the results could be included in the evidence base generated by the Systematic Review.

As the end of the past project year was approaching, in preparation for submitting our final NCE request, we worked with our Program Officer, Dr. Miriam Redington, to develop an appropriate and realistic plan to move forward. We shared our projected timeline for publishing the TAOS main results in the context of new resource constraints among our collaborators at AAOS. Given the unpredictability of peer review timelines, and recognizing that the body of literature, even with the TAOS results included, would still provide a weak evidence base, it was determined that the only remaining deliverable would be the TAOS publication itself.

**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	<a href="#">CPG 2018</a>	<a href="#">Summary 2020</a>	<a href="#">Case Studies 2021</a>	<a href="#">AUC 2019</a>	<a href="#">Summary 2021</a>	Included within the Summary Paper
Topic 2: Limb Salvage or Early Limb Amputation	<a href="#">CPG 2019</a>	<a href="#">Summary 2021</a>	N/A	<a href="#">AUC</a>	N/A	N/A
Topic 3: Early Screening for Psychosocial Risk Factors	<a href="#">CPG 2019</a>	<a href="#">Summary 2021</a>	Pending Publication with JAAOS	<a href="#">AUC 2020</a>	<a href="#">Summary 2021</a>	<a href="#">Case Studies 2021</a>
Topic 4: Use of Multimodal Perioperative Pharmacologic Pain Management	<a href="#">CPG 2021</a>	<a href="#">Summary 2022</a>	<a href="#">Case Studies 2022</a>	<a href="#">AUC 2021</a>	<a href="#">Summary 2023</a>	<a href="#">Case Studies 2022</a>
Topic 5: Techniques for Performing Transtibial Amputation	N/A	N/A	N/A	N/A	N/A	N/A
Topic 6: Prevention and Treatment of Surgical Site Infection	<a href="#">CPG 2022</a>	<a href="#">Summary 2023</a>	--	<a href="#">AUC 2022</a>	<a href="#">Summary 2023</a>	<a href="#">Case Studies 2023</a>

**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.*

During the next reporting period, we expect to complete the TAOS main results analysis and for the writing group to produce a complete draft of the main results manuscript.

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).*

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

*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?**

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?**

Nothing to report

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

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; 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:** *N/A*

## **9. QUAD CHARTS:** *N/A*

## **10. APPENDICES:** *N/A*