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TITLE: Influence of Rehabilitation After Ankle Injuries in Active Duty Service Members: The Impact of Timing and Dosing on Downstream Healthcare Utilization and Costs

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CONTRACTING ORGANIZATION: The Geneva Foundation
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The overall objective of this project is to 1) organize ankle injuries by severity classifications, 2) understand the role of rehabilitation on outcomes in individuals with ankle injuries and 3) investigate influential comorbidities that bi-directionally influence injury severity classification and outcomes. At present, there is a dearth of information towards understanding ankle injury types, predicting which classifications lead to downstream costs, secondary health deficits, delayed return to duty and function. The role of formalized rehabilitation on outcomes has only been investigated in small trials and the influence of management through physical rehabilitation within a system remains uninvestigated. Lastly, ankle injuries are recognized as multifactorial, suggesting that comorbidities such as sleep disorders, mental health conditions, and additionally diagnosed physical maladies might bi-directionally influence an individual's exposure and recovery to and from an ankle injury. Results from our exploration will be used to better understand the role of rehabilitation, comorbidities and the severity of the condition on outcomes such as downstream costs, secondary health deficits, and utilization. The information will be used to design well-informed prospective trials assessing dose, timing, and impact of rehabilitation on long-term disability and healthcare utilization within the MHS.

15. SUBJECT TERMS
ankle, rehabilitation, healthcare utilization, musculoskeletal injury

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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1. INTRODUCTION:

The overall objective of this project is to 1) organize ankle injuries by severity classifications, 2) understand the role of rehabilitation on outcomes in individuals with ankle injuries and 3) investigate influential comorbidities that bi-directionally influence injury severity classification and outcomes. At present, there is a dearth of information towards understanding ankle injury types, predicting which classifications lead to downstream costs, secondary health deficits, delayed return to duty and function. The role of formalized rehabilitation on outcomes has only been investigated in small trials and the influence of management through physical rehabilitation within a system remains uninvestigated. Lastly, ankle injuries are recognized as multifactorial, suggesting that comorbidities such as sleep disorders, mental health conditions, and additionally diagnosed physical maladies might bi-directionally influence an individual's exposure and recovery to and from an ankle injury. Results from our exploration will be used to better understand the role of rehabilitation, comorbidities and the severity of the condition on outcomes such as downstream costs, secondary health deficits, and utilization. The information will be used to design well-informed prospective trials assessing dose, timing, and impact of rehabilitation on long-term disability and healthcare utilization within the MHS.

2. KEYWORDS:

KEYWORDS: ankle, rehabilitation, healthcare utilization, musculoskeletal injury

3. ACCOMPLISHMENTS:

What were the major goals of the project?

	Timeline Months	Status
Initial Task IRB submission, personnel hiring, Data Sharing Agreement (DSA), and data abstraction/cleaning	**0-9**	
Subtask IT1. Hiring of research assistant (months 2-3)	0-2	Completed Q1Y1
Subtask IT2: Submission of protocol to **IRB (BAMC – months 1-2)	0-2	Completed Q1Y1
Subtask IT3: Submit IRB approval and necessary documents for ***HRPO review.	4	Completed Q1Y1
Subtask IT4: Submit DSA Application to DHA	4-6	Completed Q1Y1
Subtask IT5: CRADA finalized between Duke & BAMC	6-8	Completed Q2Y1
Subtask IT6: Duke IRB approved project to start locally	6-8	Completed Q3Y1
Milestone 1: IRB, HRPO, and DSA Approval	6	Completed Q1Y1 IRB#: C.2016.048n DSA#: 16-1501 HRPO#s: A20656.a (BAMC Site) A20656.b (UN Site) A20656.c (DU Site)
Subtask IT5: Abstract data with analyst to build working dataset for analysis	6-9	Completed Q2Y1
Subtask IT6: Code variables of interest	7-12	Completed Q2Y2

Specific Aim 1: Identify multiple sub-classifications of injury	**12-18**	
Task 1.1: Analyze data for AIM 1	12-18	In progress
Specific Aim 2: Identify the influence of physical rehabilitation on outcomes	12-18	
Task 2.1: Analyze data for AIM 2	12-18	Future
Specific Aim 3: Explore the influence of selected comorbidities (e.g., sleep disorders, mental health disorders) on 1) sub-injury classifications and 2) outcomes.	12-18	
Task 3.1: Analyze data for AIM 3	12-18	Future
Milestone 2: Primary Analyses for all Aims complete	18	Future

What was accomplished under these goals?

For this reporting period – Year 1

1) Major activities:

1. Ensured all necessary agreements were in place between BAMC and Duke.
2. Worked with US Army MEDCOM data analysts to create cohort and abstract all necessary data (fully anonymized) from the MDR to build the working dataset.
3. Inclusion and exclusion variables coded (to determine cohort)

2) Specific objectives:

1. Milestone 1: IRB, HRPO, and DSA Approval
   - Project was approved by the primary site IRB at Regional Health Command - Central (Study Protocol C.2016.048n)
   - The Defense Health Agency approved a Data Sharing Agreement for data extraction from the MDR (DSA #16-1501; renewed June 2018)
   - HRPO provided approval for this protocol on 3 August 2018
   - Project-specific CRADA between BAMC and Duke was approved and executed 05-Nov-2018.
   - Local approval from Duke IRB was granted 12-Dec-18.

2. The initial raw data (fully anonymized) was extracted from MDR in Quarter 2 (2019) and was successfully transferred to the Predictive Analytics team at Duke Clinical Research Institute.

3. Operational definitions of acute and overuse injuries were categorized based upon existing taxonomies created by USACHPPM and Army Public Health Command. Relevant ICD and CPT codes were organized into lists for each variable of interest (ankle injuries, physical rehabilitation, comorbidities). Syntax/codes was created for all conditions of interest in preparation to flag the raw datasets.

3) Significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative):
Nothing to report

4) Other achievements:
Nothing to report

What opportunities for training and professional development has the project provided?
Nothing to report

How were the results disseminated to communities of interest?
Nothing to report

What do you plan to do during the next reporting period to accomplish the goals?
Reclassify the data to analyze for the aims.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?
The creating of syntax to be used by statistical software to rapidly flag (rather than manually) pre-specified codes that define our variables of interest will reduce chances for human error, serve as a record of documentation of our operational definitions for each variable of interest, and be a tool that can be used in future studies of musculoskeletal injury.

What was the impact on other disciplines?
Nothing to report

What was the impact on technology transfer?
Nothing to report

What was the impact on society beyond science and technology?
Nothing to report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change
Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them

Actual: There was a delay in finalizing the contracts between BAMC and Duke, due to some unforeseen policy changes associated with the process. This mean that all of the regulatory hurdles were not completely finalized across all sites until the end of 2018, 7 months into the period of performance. The data transfer then happened over January – March, over a course of several conference calls and an in-person meeting by Dr. Rhon to meet with the team at Duke the end of March. In addition, the initial analyst at Duke assigned to our project Duke was no longer able to work on our project (for local internal reasons) and a new statistician was assigned, which required additional time to review and catch her up to current progress (still in the middle of that process). By the end of this 1-year period, we had not received the initial draft of the statistical analysis plan (SAP) for the first aim. The large bulk of the effort will occur in the remaining months of the current period of performance.

The primary delay was due to miscommunication with the Duke Statistical section. After analyzing the data, their cost to complete the analyses was much higher than we had anticipated, and not a

cost that was budgeted for. This unexpected delay resulted reassessment of priorities and plans, and the internal DoD/Geneva team is now cleaning up the data and will conduct the analysis. Dr. Rhon has finished a similar project for the knee, with very successful outcomes and output and will use that same approach to finalize the ankle data.

For the reason stated above, a no-cost extension was requested and approved with an effective date of 29 November 2019. The purpose of this modification was to extend the Period of Performance by 12 months (through 30 November 2020) at no additional cost to the government. Adjusted period of performance is: 01 Jun 2018 – 30 Nov 2020.

Anticipated: No further anticipated problems.

Changes that had a significant impact on expenditures
The challenges related to data delays and change of plan for cleaning and analyzing data pushed the deadline back.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
None

Significant changes in use or care of human subjects
None

Significant changes in use or care of vertebrate animals
N/A

Significant changes in use of biohazards and/or select agents
N/A

6. PRODUCTS:

- **Publications, conference papers, and presentations**

  Journal publications.
  Nothing to report

  Books or other non-periodical, one-time publications.
  Nothing to report

  Other publications, conference papers and presentations.
  Nothing to report

- **Website(s) or other Internet site(s)**
  Nothing to report

- **Technologies or techniques**
  Nothing to report

- **Inventions, patent applications, and/or licenses**
  Nothing to report

- **Other Products**
  Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Dr. Dan Rhon
Project Role:	Primary Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-4320-990X
Nearest person month worked:	2.4
Contribution to Project:	Writing and approval oversight of protocols, CRADAS, and data sharing agreements; coordinated data extraction from MDR and transfer of data to Duke. Data cleaning
Funding Support:	N/A
Name:	Dr. Tina Greenlee
Project Role:	Research Associate
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3.0
Contribution to Project:	Local assistance with IRB at BAMC site. Creating syntax code for flagging relevant healthcare utilization and diagnosis variables. Data cleaning
Funding Support:	
Name:	Dr. Chad Cook
Project Role:	Associate Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0001-8622-8361
Nearest person month worked:	1.0
Contribution to Project:	Consultation and planning of study; Management of project at Duke consultant on manuscripts and interpretation of results.
Funding Support:	

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
The grant PI remains as Dr. Rhon, but for IRB purposes, the site PI of the study protocol was transferred to MAJ Christopher Allen, switching Dr. Rhon to Associate Investigator. This Amendment was acknowledged by the BAMC Human Research Protections Office on June 29, 2018

What other organizations were involved as partners?

Organization name: Duke University
Location of Organization: Durham, North Carolina
Partner's contribution to the project:

Collaboration: The Predictive Analytics team at Duke will work with the BAMC team to analyze and interpret findings. Dr. Chad Cook is an investigator and will assist in finalizing the data plans, synthesizing the results, and disseminating the final reports.
Facilities: The Predictive Analytics team at the Duke Clinical Research Institute is sharing their resources to complete the data analysis for this project (statisticians,

Organization name: University of Newcastle
Location of Organization: Callaghan, New South Wales, Australia
Partner's contribution to the project:

Collaboration: Dr. Snodgrass and Dr. Young are consultant and will assist with interpretation, synthesis, and reporting of results.
Facilities: N/A

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: See attached.

9. APPENDICES: None