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TITLE: Development of Predictive Models of Injury for the Lower Extremity, Lumbar, and Thoracic Spine after discharge from Physical Rehabilitation

PRINCIPAL INVESTIGATOR: Dr. Daniel Rhon

CONTRACTING ORGANIZATION: The Geneva Foundation

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14. ABSTRACT The objective and overall hypothesis is that service member performance on a battery of physical performance tests performed upon discharge from physical rehabilitation, will be able to predict 1) the risk of sustaining any injury as well as 2) the risk of reoccurrence of the same injury. A two-pronged injury prevention approach is required to optimize return to duty rates after injury: Screening for known preventable musculoskeletal risk factors and ensuring these risk factors are mitigated prior to discharge from rehabilitation. The current assumption is that a service member discharged from medical care is ready to return to full duty. Because history of prior injury is a well-established risk factor, every service member that is discharged from Physical Rehabilitation is already at a higher risk for future injury. Identifying those at increased risk of recurrence provides the ability for secondary and tertiary prevention programs to optimize return to duty rates. Hypothesis 1: Risk factors shown to be predictive of lower extremity and lumbar/thoracic spine injuries in other populations and in healthy service members will also be predictive of re-occurrence of original injury, future injury, and return to duty rates in service members being discharged from Physical Rehabilitation. Hypothesis 2: The injury prediction models will vary by age and sex. Hypothesis 3: A multi-factorial prediction model that accurately predicts risk of new and recurring injuries, as well as return to duty rates, will consist of multiple variables.						
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1. INTRODUCTION:

Musculoskeletal injuries have a significant deleterious effect on Soldier readiness. Screening algorithms for injury risk have been identified, but have not been evaluated in service members returning to duty after an injury. As past injury and pain with movement are strong risk factors for future injury, the ability to adequately screen service members for injury risk after they have been cleared to return to duty from an injury is of great importance. The purpose of this project is to determine if performance on a battery of functional tests after discharge from medical care, can predict risk for injury after returning to full duty following a spine or lower extremity injury.

2. KEYWORDS: Injury prevention, injury prediction, injury risk, musculoskeletal, lower extremity, spine, return to duty

3. ACCOMPLISHMENTS:

What were the major goals of the project?

	Timeline Months	Site 1 (Partnering PI)	Site 2 (Partnering PI)	Site 3 (Partnering PI)	Site 4 (Initiating PI)
Initial Task IRB submission, personnel hiring, and study-related training					
Subtask IT1: Submission of protocol to primary site IRB	0-2				Dr. R
Subtask IT1: Upon approval of primary site IRB, will submit site-specific addendums for other 3 sites (Institutional Agreements [IAIR] are in place between primary site IRB and all 3 other sites)	15-17	Dr. H	LTC C	MAJ D	Dr. R
Subtask IT2: Hiring of research assistant(s) and physical therapists (months 1-4)	0-4				Dr. R
Subtask IT3: Submit IRB approval and necessary documents for **HRPO review.	3-17				Dr. R
Subtask IT4: Establish administrative support for enrolling subjects. <ul style="list-style-type: none"> - A. Research assistants will create all subject packets - B. Provide the appropriate documentation to all relevant clinicians, - C. Establish databases for data collection and follow-up tracking. - D. Manual of Procedures (MOPs) and training guidelines will be created. 	3-6				Dr. R
<i>Milestone 1: IRB approval and HRPO Approval</i>	6-8	COMPLETE			
Specific Aim 1: To improve prediction of injury-free return to duty following Physical Rehabilitation, we will compare and contrast select physical performance test results in service members that sustain an injury or reoccurrence of previous injury versus those that do not during the 12-month follow-up period.	16-49	COMPLETE			
Task 1a: Enrollment into study for 480 subjects total between 4 sites. Potential subjects include any active duty Soldiers with lower extremity or lumbar/thoracic spine injury discharged from physical rehabilitation and returned to full duty.					

Subtask 1: Subjects are consented and study measures, that include self-report and physical performance tests, are taken	16-37	Dr. H (N = 80)	LTC C (N = 125)	MAJ D (N = 125)	Dr. R (N =50)
<i>Milestone 2: Target recruitment met</i>					
Task 1b: Injury surveillance occurs monthly for the 12-month period following each subjects enrollment.	16-49				Dr. R
Subtask 1: Monthly injury surveillance surveys sent Subtask 2: Track compliance with surveys	16-49				Dr. R
<i>Milestone 3: 1-year injury surveillance complete</i>	COMPLETE				
Specific Aim 2: Develop predictive models from collected variables in order to derive a multi-factorial injury risk prediction algorithm to identify high risk Soldiers in the return to duty process.	40-68				
Task 2a: Regulatory Steps to Receive MDR data	42-48				Dr. R
Subtask 2: Data request submitted to MEDCOM PA&E. DATA RECEIVED	49				Dr. R
Task 2b: Consolidate and organize healthcare utilization data . (This is a data-analysis task and requires no additional subject testing beyond Aim 1.)	52-60				Dr. R
Subtask 1: Match MDR data with appropriate subject ID numbers	52				Dr. R
Subtask 2: Identify, group, and develop syntax for identification of relevant diagnosis and procedure codes related to MSK Injury (both ICD9 and ICD10)	48-60				Dr. R
Subtask 3: Identify limited duty days from e-profile (type, length, total unique profiles, etc)	52-55				Dr. R
Subtask 4: Manual records review using AHLTA/CHCS	54-62	Dr. H			Dr. R
Subtask 4: Consolidate data from both sources, along with surveys, and organize by individual subject ID to obtain master spreadsheet for analysis	62				Dr. R
Task 2c: Develop injury prediction models (This is a data-analysis task and requires no additional subject testing beyond Aim 1.)	62-68				Dr. R
Subtask 1: Perform stepwise logistic regression based on injury surveillance reports, physical performance tests results, and self-report measures	62-65				Dr. R
Subtask 2: Perform sensitivity analysis, and account for specific populations (females)	65-68				Dr. R
Specific Aim 3: Develop an optimal physical performance standard that should be met prior to discharge from physical rehabilitation with the aim of decreasing future injury risk and facilitating successful injury-free return to duty.	68-72				Dr. R
Subtask 1: The injury prediction algorithms should provide decision guidance based on a combination of physical performance standards and self-report measures that includes sleep and psychosocial factors. These will be evaluated by the research team for pragmatic implementation as part of a standard clinic discharge criteria. This is a data-analysis task and requires no additional subject testing beyond Aim 1.	68-72				Dr. R

What was accomplished under these goals?

For this reporting period – Year 5

1) **Major activities:** The primary focus this past year was on appropriately flagging and identifying the healthcare utilization data from the MDR.

2) **Specific objectives:**

The past year focused on cleaning data and preparing ICD code lists for flagging of relevant diagnoses from the healthcare utilization data. The delays with IRB Approval due to IRBNet going away and adoption of eIRB at the beginning of the study put us about 10-12 months behind schedule. We also cleaned the 1-year follow-up surveillance data, a task that longer than expected due to the format that data was received from the third-party company.

3) **Significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative):**

Selective Functional Movement Assessment in soldiers cleared for unrestricted full duty after musculoskeletal injury

Results: Demographics were similar in both groups. Between group comparisons (thoracolumbar spine vs. lower extremity) identified a significantly higher percentage of those with thoracolumbar spine injuries presented with pain on the movement patterns for back bending (41% vs. 23%; $p<.001$), forward bending (9% vs. 2%; $p=0.002$), cervical extension (14% vs. 8%; $p=0.04$), and trunk rotation (10% vs. 4%; $p=0.015$) than those returning from lower extremity injuries. More soldiers with prior thoracolumbar injuries reached the threshold for classification of a dysfunction with back bending (87% vs. 77%; $p=0.015$), while significantly more soldiers with lower extremity injuries presented with dysfunction classification during the overhead squat (96% vs. 90%; $p=0.006$).

Conclusions: The proportion of individuals in this cohort that was cleared for unrestricted duty is higher than what has been previously reported for currently injured cohorts in similar settings. 99.8% of soldiers regardless of injury type presented with at least one dysfunctional movement pattern and 44.4% still had pain during at least one of the movements. Depending on the movement, 18-47% presented with appreciable asymmetry. These findings suggest that back bending and squatting continue to be challenging movements following a complete course of treatment and may need to be more adequately addressed before returning soldiers to unrestricted full duty. The results merit cautious interpretation as the validity of the SFMA to determine physical performance, function, and risk for future injury has not been determined.

Clinical Relevance: Soldiers who have been cleared to return to full unrestricted duty are still experiencing pain and dysfunction with functional movement. It is unclear what criteria is being used to determine if Soldiers are ready to return to full unrestricted duty and what this residual dysfunction and pain may have on future injury. Established return to unrestricted duty criteria that account for these findings are needed to improve return to work determinations.

Does recency of musculoskeletal injury strengthen the association between past injury history and future injury risk?

Results: We found a significant relationship between recency of injury and the percent of individuals found with sufficient risk factors (5+) to place them in the high-risk for future injury category. In group 1, 70.3% ($n=306$) presented with 5+ risk variables placing them in the high-risk category for future injury (OR = 29.9; 95CI 21.4, 41.8). In group 2, it was 43.7%, ($n=244$; OR =9.8; 95CI 7.2, 13.4) and in group 3 only 7.3% ($n=60$; reference standard) that reached a similar threshold for high-risk. Physical performance measures followed this same trend with

the best performance on most measures seen in those with no prior injury, and the worst scores on most measures seen by those most recently cleared for unrestricted full duty after a preceding injury.

Conclusions: Among soldiers with no current duty restrictions, there were significant differences in physical performance and the number of risk factors associated with future injury between all three groups, with a much higher proportion of individuals in the highest risk group and overall worst performance in those just recently cleared for unrestricted duty. Those with no prior injury in the last 5 years had the lowest proportion of individuals in the high-risk group.

Clinical Relevance: Individuals most recently cleared to return to unrestricted duty after an injury presented with a large number of residual risk factors for future injury, and are likely being prematurely cleared for unrestricted duty.

4) Other achievements:

We had two abstracts accepted for presentation at the American Physical Therapy Association (APTA) annual conference.

What opportunities for training and professional development has the project provided?

Although our project was not intended to provide training and professional development, there have been several opportunities to do so. The MEDCOM Executive Health program implemented at BAMC utilized some of the screening components from this study, and our team provided the relevant training to healthcare providers on these injury screening procedures. Dr. Rhon and COL Teyhen were able to lead a session on injury prevention at the 4th International Congress on Soldier Physical Performance which was well received. Due to the delays associated with the format of 1-year follow-up surveillance data, we worked with the company to develop a report format that is more user-friendly and streamlined (which saves a lot of time) and will benefit our own future studies, and likely those of other consumers.

How were the results disseminated to communities of interest?

Abstract submissions to scientific conferences.

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

In the coming year, we will finish cleaning all follow-up data, prepare ICD code lists and finalize flagging syntax, flag all relevant injury diagnoses from the MDR healthcare utilization data, and analyze our primary aims. At that point, we will be able to finalize the prediction algorithms.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report

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

As the focus was on predicting return to duty after injury, we expanded our recruitment footprint to include musculoskeletal injuries in primary care.

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

Actual: 1-year follow-up surveillance data cleaning took much longer than expected due to the format that data was received from the third-party company. We were able to accomplish this task and developed a streamlined system for receiving the data in the future, but with 1 year's worth of data from 480 participants, manually organizing and cleaning took longer than anticipated.

Anticipated: No further anticipated problems.

Changes that had a significant impact on expenditures

Nothing that has not been reported previously.

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

Presentation at 4th International Congress on Soldier Physical Performance

Are we trying to prevent injuries or prevent disability? Why it matters.

<https://doi.org/10.1016/j.jsams.2017.09.085>

Predicting injuries in the military: What works, what doesn't, and does it even matter?

<https://doi.org/10.1016/j.jsams.2017.09.080>

Journal publications.

Rhon DI, Teyhen DS, Shaffer SW, Goffar SL, Kiesel K, Plisky PP. *Developing predictive models for return to work using the Military Power, Performance and Prevention (MP3) musculoskeletal injury risk algorithm: a study protocol for an injury risk assessment programme.* Injury Prevention. 2016 Nov 24. pii: injuryprev-2016-042234. doi: 10.1136/injuryprev-2016-042234

Acknowledgement of federal support: YES

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:	<i>Dr. Dan Rhon</i>
Project Role:	<i>Primary Investigator</i>
Researcher Identifier (e.g. ORCID ID):	<i>0000-0002-4320-990X</i>
Nearest person month worked:	<i>3</i>
Contribution to Project:	<i>Writing IRB protocols for all 4 sites; Coordinating training at 2 main sites. Traveled to all 4 sites for site visits, coordinate with local IRBs, and help deliver training to research team. Continued oversight of all sites. Data analysis, interpretation and reporting of results.</i>
Funding Support:	<i>N/A</i>
Name:	<i>Dr. Tina Greenlee</i>
Project Role:	<i>Research Associate</i>
Researcher Identifier (e.g. ORCID ID):	<i>N/A</i>
Nearest person month worked:	<i>6</i>
Contribution to Project:	<i>Local assistance with IRB at BAMC site. Assistance with setting up and planning local training meeting. Putting together study material for local site. Help with enrollment/recruitment at local site. Updating protocols and other IRB documents as necessary. Data cleaning, analysis, interpretation and reporting of results.</i>
Funding Support:	<i>100%</i>
Name:	<i>Dr. Rachel Mayhew</i>
Project Role:	<i>Research Physical Therapist</i>
Researcher Identifier (e.g. ORCID ID):	<i>N/A</i>
Nearest person month worked:	<i>3</i>
Contribution to Project:	<i>Local assistance with IRB at BAMC site. Assistance with setting up and planning local training meeting. Putting together study material for local site. In charge of enrollment/recruitment at local site. Updating protocols and other IRB documents as necessary.</i>
Funding Support:	<i>100%</i>

Name:	<i>COL Deydre Teyhen</i>
Project Role:	<i>Associate Investigator</i>
Researcher Identifier (e.g. ORCID ID):	<i>N/A</i>
Nearest person month worked:	<i>1</i>
Contribution to Project:	<i>Consultation and input for planning, data collection, and follow-on steps after study.</i>
Funding Support:	<i>100%</i>
Name:	<i>Dr. Phil Plisky</i>
Project Role:	<i>Associate Investigator</i>
Researcher Identifier (e.g. ORCID ID):	<i>N/A</i>
Nearest person month worked:	<i>2</i>
Contribution to Project:	<i>Consultation and input for planning, data collection, and follow-on steps after study.</i>
Funding Support:	<i>100%</i>

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: University of Evansville

Location of Organization: Evansville, IN

Partner's contribution to the project

In-kind support: Contributed to the study design and provide consultation throughout the study enrollment process. Dr. Phil Plisky and Dr. Kyle Kiesel have an extensive history of this line of work with professional athletes. They will be more active in this final year as we work on the predictive statistical models. Some of the grant funds also went to help adapt the MP3 software for data collection pertinent to this particular study.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: See attached

9. APPENDICES: None