

AWARD NUMBER: W81XWH-14-2-0141

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

PRINCIPAL INVESTIGATOR: MAJ Daniel Rhon

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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 increase 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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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 a 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 physical rehabilitation, can predict risk for injury after returning to full duty following a spine or lower extremity injury.

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

ACCOMPLISHMENTS:

What were the major goals of the project?

Milestone 1: IRB approval and HRPO Approval (Initial Target – 6-8 months)

- *STATUS – Pending IRB approval at 3 of the main sub-sites (sites 2-4)*

Milestone 2: Target recruitment met (Initial Target – 24 months)

- *STATUS (not started)*

Milestone 3: 1-year injury surveillance complete (Initial Target – 36 months)

- *STATUS (not started)*

Milestone 4: Analysis for Primary Aims complete (42 months)

- *STATUS (not started)*

What was accomplished under these goals?

1) Major activities

The focus has been on getting approval by the IRB. That has been our #1 priority, and we cannot continue with any other projects or objectives until that has been accomplished. Unfortunately, the Defense Health Agency chose to terminate the contract with IRBNet. The primary IRB where this project was to be approved received a 2-week notice of this and had to create a new local tracking system from scratch. The following is our timeline and processes leading up to this point related to regulatory approval:

- We submitted the core protocol to the IRB at Madigan Army Medical Center in November 2014.
- We received approval by the Madigan IRB for the project on 26 February, 2015.
- The Site Specific Addendums (SSA) for the other 3 sites (WBAMC, Womack, and BAMC) were submitted in March, 2015. Because the core protocol is usually the biggest hurdle, and other multi-site projects that our team been involved in have usually received sub-site approval within 2-3 months at most, we went ahead and hired research personnel to begin 1 June 2015.
- We planned and executed training trips and sessions for all research staff
- Now, we are at the end of November and we still have not received approval for the other sites. We have had monthly communication, and even Dr. Rhon had a face-to-face meeting in person at the IRB at Madigan. We have sent many emails to various DCI chiefs and IRB chairs indicating the impact that this has on our ability to complete our study, but have been told again and again that the closure or IRBNet has resulted in some “disastrous” consequences. As of right now, we are hoping that the protocols at the other sites will be approved by the end of 2015.

2) Specific objectives: N/A at this time

3) Significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or
N/A at this time

4) Other achievements. N/A at this time

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

Training was provided to all the physical therapy staff at 2 of the large hospitals (William Beaumont Army Medical Center and Womack Army Medical Center). The consultants (Dr. Plisky, Dr. Kiesel, and Dr. Butler) traveled to these sites to provide training for research staff, but also allowed other hospital staff to attend the training.

MAJ Rhon met with Dr. Gerard Brennan at Intermountain Healthcare, Salt Lake City, Utah and with Dr. Lori Michener, University of Southern California. Both are involved with establishing an orthopaedic national outcomes database for musculoskeletal care under the American Physical Therapy Association. The relevance to this particular project lies in the ability to scale a very similar injury risk registry throughout the MHS. The meetings were very valuable in helping provide insight to lessons learned, challenges, and similar obstacles to be expected when rolling out a tool across many clinics and various settings.

The key investigators of this team presented a 2-hour educational breakout session on injury prediction/prevention titled "Prediction, Prevention, and Preemption: Screening for sports and training injuries. What are the possibilities?" The talk was presented to a national audience at the American Physical Therapy Association annual Combined Sections Meeting, February, 2015.

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?

We are in weekly communication with the IRB regarding approval. We have had our hired research physical therapists practice putting patients through the screening protocol on a weekly basis, in order to keep their skills sharp. We will continue to do this until we receive approval.

We anticipate having approval by the start of 2016, and then being able to kick into full gear with recruitment at that time. As soon as we have approval for those 3 sites, we will send them off for HRPO approval prior to enrolling subjects.

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

CHANGES/PROBLEMS:

Changes in approach and reasons for change

No changes in approach to report

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

Although the Madigan site has received IRB approval, that site had been changed to an alternate site that would not be supported with research personnel. We could only provide full support at 2 of the 4 locations. The other 2 had lower recruitment targets and were willing to try and enroll subjects if we provided the resources and training. The decision was made after MAJ Rhon's PCS to BAMC, and because the site PI at Madigan there had some pregnancy complications and then was on maternity leave at the beginning of the study. This led us to postpone training and shift the focus of recruitment away from Madigan, to the other 3 sites. But it also meant that we cannot begin recruitment at all until full approval is acquired. Even with the delay, we did not anticipate that the delay would take this long.

We have been in bi-weekly communication with the IRB at Madigan. We have sent emails to the DCI Chief and the PI (Dr. Rhon) even took a trip to discuss in person these issues and its significance in delaying our project. Everyone is reluctant to give hard deadlines, and has blamed everything on the closure of IRBNet. Dr. Rhon has emailed representatives at MRMC, MEDCOM, and the Office of the Surgeon General. We realize that this delay is not unique to only our study.

Changes that had a significant impact on expenditures

The delay in starting the project related to IRB approval means that we have had 2 FTE research physical therapists working and on payroll for the last 6 months (equivalent of 1 full year), without even enrolling a single subject. This may have a significant impact our on the tail end of our project depending on how our enrollment numbers pan out.

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

PRODUCTS: Nothing to Report

Publications, conference papers, and presentations

None

Journal publications. None

Books or other non-periodical, one-time publications. None

Other publications, conference papers, and presentations. None

Website(s) or other Internet site(s)

None

Technologies or techniques

None

Inventions, patent applications, and/or licenses

None

Other Products

None

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	<i>MAJ 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>2</i>
Contribution to Project:	<i>Writing IRB protocols for all 4 sites; Coordinating training at 2 main sites. Traveling to all 3 sites for site visits, coordinate with local IRBs, and help deliver training to research team.</i>
Funding Support:	<i>N/A</i>

Name:	<i>Dr. Matt Hartshorne</i>
Project Role:	<i>Research Physical Therapist</i>
Researcher Identifier (e.g. ORCID ID):	<i>N/A</i>
Nearest person month worked:	<i>2</i>
Contribution to Project:	<i>Local assistance with IRB at Womack site. Assistance with setting up and planning local training meeting. Putting together study material for local site.</i>
Funding Support:	<i>N/A</i>

Name:	<i>Dr. Danielle Langness</i>
Project Role:	<i>Research Physical Therapist</i>
Researcher Identifier (e.g. ORCID ID):	<i>N/A</i>
Nearest person month worked:	<i>2</i>
Contribution to Project:	<i>Local assistance with IRB at WBAMC site. Assistance with setting up and planning local training meeting. Putting together study material for local site.</i>
Funding Support:	<i>N/A</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?

Nothing to report

SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: Attached

APPENDICES: None

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PI: MAJ Daniel Rhon

Org: The Geneva Foundation

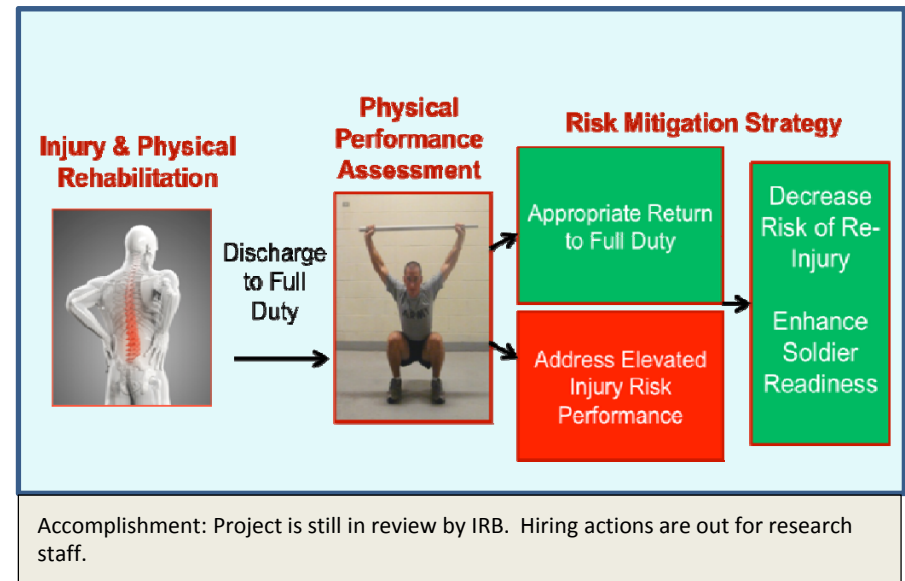
Award \$1,084,186

Study/Product Aim(s)

- **Aim 1:** To improve prediction of injury-free, we will compare and contrast select performance test results in service members that sustain an injury versus those that do not during the 12-month follow-up period.
- **Aim 2:** Develop predictive models from collected variables in order to derive a multi-factorial injury risk prediction algorithm.
- **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.

Approach

- Screen 480 Soldiers being discharged from physical rehabilitation
- Prospectively follow them for one year to identify injuries.
- Screening process includes movement and balance screens, measures of power, demographic data and biopsychosocial measures.
- Injury data will be collected through self-report, profile data, and healthcare utilization data. Clinical prediction rules will be used for algorithm development.



Activities	FY	14	15	16	17
IRB Approval, hiring and training of support personnel			■		
Subject enrollment and data collection and 1-year follow-up.			■	■	
Healthcare utilization pull from DoD database & medical records					■
Data analysis, interpretation, prediction model derivation, and reporting of results					■
Estimated Budget (\$1084K)		\$407K	\$380K	\$237K	\$60K

Updated: 24 Nov 2015

Goals/Milestones

CY14 Goal – System Development/Demonstration

- Optimal testing pathways established & tested

CY15 Goals – Data Collection

- IRB protocol submission/approval
- HRPO Approval
- Initiate subject recruitment late Summer 2015
- Collect follow up data regarding Injuries incurred

CY16 Goal – Data Collection

CY17 Goal – Data Collection/Analysis

- Analyze data to determine greatest predictors of injury risk
- Develop prediction algorithms based on findings
- TMA approval for healthcare utilization data pull from PASBA

CY18 Goal

- Risk mitigation strategies developed and linked to predictor variables

Comments/Challenges/Issues/Concerns

We were behind schedule to begin data collection in early 2015 due to delays in receiving USAMRAA approval to change sites. This has been resolved.

Budget Expenditure to date

Projected Expenditure: \$407K Actual Expenditure: \$140K