**AWARD NUMBER:** W81XWH-17-1-0476

**TITLE:** Development of a Biopsychosocial Prospective Surveillance Model of Shoulder Pain in Individuals with Spinal Cord Injury

**PRINCIPAL INVESTIGATOR:** Margaret A. Finley, PT, PhD

**RECIPIENT:** Drexel University
Philadelphia PA 19104-2816

**REPORT DATE:** August 2018

**TYPE OF REPORT:** Annual

**PREPARED FOR:** U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

| REPORT DOCUMENTATION PAGE | | *Form Approved OMB No. 0704-0188* |
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| **1. REPORT DATE *(DD-MM-YYYY)***<br>August 2018 | **2. REPORT TYPE**<br>Annual | **3. DATES COVERED *(From - To)***<br>1 Aug 2017 - 31 Jul 2018 |
| **4. TITLE AND SUBTITLE**<br>Development of a Biopsychosocial Prospective Surveillance Model of Shoulder Pain in Individuals with Spinal Cord Injury | | **5a. CONTRACT NUMBER**<br><br>5b. GRANT NUMBER<br>W81XWH-17-1-0476<br>**5c. PROGRAM ELEMENT NUMBER** |
| **6. AUTHOR(S)**<br>Margaret Finley, PT, PhD; Dave Ebaugh, PT, PhD; Thomas Trojian, MD; Ed Gracely, PhD; Henry York, MD; Paula Geigle, PT, MS, PhD; Sara Kate Frye, OTR/L; Marni Kallins, DPT, PT; Leigh Casey, BS | | **5d. PROJECT NUMBER**<br><br>**5e. TASK NUMBER**<br>**5f. WORK UNIT NUMBER** |
| **7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**<br>Drexel University<br>3141 Chestnut St<br>Philadelphia PA 19104-2816 | | **8. PERFORMING ORGANIZATION REPORT NUMBER** |
| **9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**<br><br>U.S. Army Medical Research and Materiel Command<br><br>Fort Detrick MD 21702-5014 | | **10. SPONSOR/MONITOR'S ACRONYM(S)**<br><br>**11. SPONSOR/MONITOR'S NUMBER(S)** |

**12. DISTRIBUTION / AVAILABILITY STATEMENT**
Approved for Public Release; Distribution Unlimited

**13. SUPPLEMENTARY NOTES**

**14. ABSTRACT:**
The overall purpose of this study is to investigate progression of impairments the first year following injury beginning with inpatient rehabilitation in the acute phase. In the first year of the 3-year award we met nearly all aspects of our proposed SOW. Both sites completed all regulatory requirements, received IRB approvals from local institutions, maintained all modifications and continuing renewal. All contracts between institutions were executed. All necessary equipment and supplies obtained and all investigators completed organized training. Collection of baseline data initiated at both sites (SCI = 8 and control = 5) with 6-month follow-up assessments started as appropriate. Monthly PI meetings and quarterly full team meetings facilitated ongoing communication to include strategies for recruitment and problem solving as needed. All reports (quarterly technical and annual financial) were comprehensive and were submitted on time. We submitted an abstract of the preliminary data for January 2019 presentation at Combined Sections Meeting of the American Physical Therapy Association. As enrollment was below projected, active strategies for improving enrollment are in place (bi-weekly communication, in-service training of in-patient therapists for identification of potential participants, identification of an additional, local site for recruitment).

**15. SUBJECT TERMS**
Spinal cord injury, Shoulder, pain, musculoskeletal

| **16. SECURITY CLASSIFICATION OF:** | | | **17. LIMITATION OF ABSTRACT** | **18. NUMBER OF PAGES** | **19a. NAME OF RESPONSIBLE PERSON** |
|---|---|---|---|---|---|
| **a. REPORT** | **b. ABSTRACT** | **c. THIS PAGE** | UU | 20 | **19b. TELEPHONE NUMBER** ***(include area code)*** |
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## 1. INTRODUCTION:

This study is investigating the progression of musculoskeletal (shoulder muscle flexibility, muscle strength, movement coordination, and rotator cuff health) and psychosocial (fear of movement, pain catastrophizing) impairments for the first year following SCI, starting with inpatient rehabilitation, at 6 months, and at 1 year following SCI. Age- and gender-matched controls will be compared at baseline and at 1 year. Our research is being performed at two facilities: Drexel University (in collaboration with Magee Rehabilitation Hospital) and the University of Maryland Rehabilitation & Orthopaedic Institute.

## 2. KEYWORDS:

Spinal cord injury; pain, shoulder, musculoskeletal, psychosocial

## 3. ACCOMPLISHMENTS:

**What were the major goals of the project?**

Statement of Work (SOW) Major Tasks and Milestones during this reporting period (Year 1) are listed below, with target completion dates and status towards completion

| **Required for all AIMS:** | **Target Completion (YearQuarter)** | **Status** |
|---|---|---|
| **Major Task 1: Complete start-up protocols, regulatory reviews, data management and training** | Completed Y1Q1 | |
| • *Milestone(s) Achieved: Sites prepared to conduct research project* | Y1Q1 | Completed Y1Q1 |
| • *Milestone Achieved: Site specific & DoD/HRPO Approval* | Y1Q2 | Completed Y1Q1 |
| • *Milestone Achieved: Database Management established* | Y1Q2 | Completed Y1Q1 |
| | | |
| **Major Task 2: Recruitment, enrollment, data collection** | Ongoing | |
| • *Milestone(s) Achieved: Baseline data collected* | Y2Q2 | Ongoing (45%) |
| • *Milestone(s) Achieved: 6-month assessments completed* | Y2Q4 | Initiated and ongoing |
| | | |
| **Major Task 3: Data Analysis, reporting and dissemination** | Ongoing | |
| • *Milestones Achieved: Data analysis completed* | Y3Q2 | Analysis of initial data for abstract |
| • *Milestones Achieved: Required reporting completed* | Ongoing | Ongoing-all reports were comprehensive and submitted on time |

**What was accomplished under these goals?**
Below are the subtasks scheduled during this reporting period (Year 1) and status towards completion

| **Required for all AIMS:** | | |
|---|---|---|
| **Major Task 1: Complete start-up protocols, regulatory reviews, data management and training** | | |
| **Subtask 1: Develop structure for collaboration** | **Target Timeframe (Year/Quarter)** | **Status** |
| Prepare contract between DU and UMROI & maintain annually | Y1Q1 | Contracts completed 10/4/17 |
| Establish accounts and payments process between sites | Y1Q1 | Both sites established financial accounts. Sept 13, 2017 at Drexel on-site meeting the invoicing procedures, documentation requirements were established. |
| Establish meeting schedules | Y1Q1 | Monthly and quarterly meetings scheduled—all monthly PI and quarterly full team meetings completed |
| Finalize protocol with screening protocol and data collection forms | Y1Q1 | All screening, SOP and data collection forms finalized by the sites and approved by IRB as necessary |
| Establish data safety and monitoring board (DSMB) | Y1Q1 | Per HRPO a DSMB is not necessary, due to investigation determined to be minimal risk study |
| Investigator and clinical staff training (musculoskeletal, biopsychosocial measures) | Y1Q1 | Training occurred on Sept 13-14, 2017 at Drexel with both sites present. Drexel and UM Rehab each performed follow-up site-specific investigator training |
| Purchase equipment and supplies | Y1Q1 | Each site obtained supplies necessary to initiate data collection |

| **Subtask 2: Obtain Regulatory Approval** | **Target Timeframe (Year/Quarter)** | **Status** |
|---|---|---|
| Submit site specific IRB applications | Y1Q2 | Completed |
| Submit DoD HRPO/IRB application | Y1Q2 | Completed |
| Obtain approval from UM Rehab Medical Executive Committee | Y1Q2 | Completed |
| IRB Modifications (as indicated) and Continuing Reviews | As needed/ CR annually | Completed<br><br>Modifications (data forms, inclusion wording, OSPRO, personnel changes) at both sites submitted and approved.<br><br>Continuing review acquired both sites through IRB and HRPO (approval through UM 4/9/19, Drexel 4/17/19) |
| | | |
| **Subtask 3: Create Database/Data Management Protocol & Train personnel** | **Target Timeframe (Year/Quarter)** | **Status** |
| Create electronic data reports for RedCap | Y1Q2 | One Drive determined to be the better option for data capture and sharing. Al databases and data dictionaries created and reviewed by biostatistician One Drive access verified for investigators. |
| Train personnel on use of RedCap | Y1Q2 | Access to encrypted One Drive folder and documents established. |

| Major Task 2: Recruitment, enrollment, data collection | | |
|---|---|---|
| **Subtask 1: Initial assessments (baseline)** | **Target Timeframe (Year/Quarter)** | **Status** |
| Recruitment, screening and enrollment (consenting) of participants with acute SCI (n=34, 17 per site) and age-matched controls (n=34, 17 per site) | Y1Q3 through Y2Q2 | Recruitment, screening and enrollment are ongoing.<br><br>Drexel screened 19 individuals with SCI -6 eligible but only 3 consented; 1 withdrew; 1 declined; 14 ineligible; 1 matched control enrolled. Additional matched controls will be identified and enrolled in August 2018 (Y2Q1). SCI #4 identified and begins 8/7/18.<br><br>UM Rehab enrolled 6 with SCI and 4 matched controls.<br><br>(see Actual Problems and Actions to Resolve below) |
| Baseline musculoskeletal (MPS, WUSPI, PM, MSK, strength, and psychosocial (TSK, PCS, FOP, CPCI, SQoL) measures (n=68, 34 per site) | Y1Q3 through Y2Q2 | Baseline data has been collected on eight with SCI (33.3%) and five control participants (21%). Below targeted enrollment – however, scheduling for August 2018 (Y2Q2) is increasing at both sites. Matched control participants being identified as well.<br><br>(see Actual Problems and Actions to Resolve below).<br><br>Drexel: Two with SCI and one control completed (two scheduled for 8/2018-Y2Q1); one withdrew during initial data collection. 17% completed; one control completed (9% of target)<br><br>UM Rehab: Six with SCI (50%) and four control participants (33.3%) completed, two other age and sex matched controls identified and will be enrolled next quarter. |

| | | |
|---|---|---|
| Baseline musculoskeletal (SMC) assessment (n=34, all Drexel) | Y1Q3 through Y2Q2 | Baseline motion analysis on two participants completed (9%) |
| | | |
| **Subtask 2: 6-month assessments** | **Target Timeframe (Year/Quarter)** | **Status** |
| 6-month musculoskeletal (MPS, WUSPI, PM, MSK, strength, and psychosocial (TSK, PCS, FOP, CPCI, SQoL) measures (n=34, 17 per site) | Y2Q1-Y2Q4 | 6-month data collection is ahead of schedule<br><br>UM Rehab completed two 6-month follow-up sessions and Drexel scheduled one 6-month follow-up. This subtask is on-schedule based on timeframes for follow-up. |
| Subtask 2: 6-month musculoskeletal (SMC) assessment (n=17, all Drexel) | Y2Q1-Y2Q4 | One SCI scheduled for 6-month follow-up in Y2Q1. |
| | | |
| **Major Task 3: Data Analysis, reporting and dissemination** | | |
| **Subtask 1: Data analysis** | **Target Timeframe (Year/Quarter)** | **Status** |
| Verify accuracy of data | Y1Q2-Y3Q2 | Ongoing review of data entry for a consistency and accuracy |
| Analysis of primary measures | Y2Q2- Y3Q2 | Initial analysis of the first six SCI performed |
| | | |
| **Subtask 2: Prepare and Submit Ongoing Regulatory Reports** | **Target Timeframe (Year/Quarter)** | **Status** |
| Provide quarterly reports to DoD | Quarterly | All quarterly reports comprehensive and submitted on time, as required |

| | | |
|---|---|---|
| Provide annual reports to DoD and respond to queries | Annually | Annual financial report submitted 1/12/18<br>Current report is Year 1 annual report |
| Provide annual reports to site IRB and DSMB (not required) | Annually | Annual report to Drexel and UM IRB April 2018 with approvals received 4/5/18 (Drexel) and 4/11/18 (UM) |
| | | |
| **Subtask 3: Dissemination** | **Target Timeframe (Year/Quarter)** | **Status** |
| Prepare abstracts, presentations and manuscripts | Y2Q2-Y3Q2 | Abstract for presentation at the 2019 Combined Section Meeting of the APTA submitted 6/14/18—this is ahead of planned dissemination schedule |

**Participant enrollment**

- As July 31, 2018 Drexel enrolled four total with one withdrawal; UM Rehab enrolled 10 participants (several identified to be enrolled in early August, 2018 -Y2Q1)
- Total enrolled to date is 14—with several identified to be enrolled in early August, 2018 (Y2Q1)
- Total anticipated enrollment at this time was 48
- **Explanation of efforts and strategies to promote enrollment described in Actual Problems and Actions to Resolve**

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

**How were the results disseminated to communities of interest?**
Preliminary data submitted as an abstract for presentation at the 2019 Combined Sections Meeting of American Physical Therapy Association.

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

During the next reporting cycle (Year 2, 8/1/2018-7/31/19) we will continue recruitment, enrollment, and data collection to complete all 34 SCI baseline assessments, identify, and enroll all 34 matched controls. Communication with enrolled participants maintained to facilitate retention for the 6-month and one-year data collection in those with SCI and the control group.

To insure fidelity of data collection, on-site investigator training will occur on August 15, 2018 with continued communication regarding procedures. Monthly meeting with the site PIs and investigators as well as quarterly full team meeting are scheduled and will continue appearing on the group calendar to foster open communication and early identification of any issues as well as strategies to enhance enrollment and retention.

To facilitate accuracy, all data entry is reviewed at least one per monthly by investigators not involved in initial entry to address any data concerns that arise or identified data entry errors. All data is spot checked for accurate entry. Once 10 participants with SCI and matched control baseline data are collected initial analysis will be performed with intent of potential initial finding dissemination.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior occurring as a result of the project relative to:

**What was the impact on the development of the principal discipline(s) of the project?**
Although at the date of this report, no formal analysis of data has been performed comparing the groups, a preliminary report was generated for the CSM abstract. Upper extremity pain was reported in 3 of 6 participants with SCI. Mean strength of shoulder flexor, extensor and abductor was below age-specific norms. Pectoralis minor extensibility was reduced to 13.7% in non-dominant limb with greatest reduction in older participants (> 50 years age) and those reporting pain. Range of motion was symmetrical and within normal limits. Ultrasound Pathology Shoulder Rating Scale scores indicated minimal structural impairment. Pain Catastrophizing Scale and Tampa Kinesiophobia Scale-11 scored higher than other populations such as low back pain. Subjective Quality of Life Questionnaire (SQoL) was reported to be 4.3/7 was lower than other groups with SCI. The most common pain coping strategy was seeking social support. This preliminary data analyses indicate individuals with new SCI demonstrate physical impairments of pain, reduced shoulder muscle strength with older individuals demonstrating reduced pectoralis minor muscle extensibility. Minimal structural changes in tissue integrity are noted. Maladaptive psychosocial pain factors were elevated and present in all six participants, with 50% reporting pain with reduced SQoL. Management of shoulder pain in the SCI population is reactive rather than proactive. Interventions focusing on impairments occur after the onset of pain as opposed to providing regular screens to identify and treat pain-related factors prior to the development of pain and dysfunction. Early identification of pain-related factors may ameliorate pain related reduction of activity and participation for individuals with SCI.

**What was the impact on other disciplines?**
The findings that individuals with new SCI demonstrate physical impairments of pain, reduced shoulder muscle strength with older individuals demonstrating reduced pectoralis minor muscle extensibility. Elevated maladaptive psychosocial pain factors with all six participants, with 50% reporting pain reduced SQoL may indicate need for clinical psychological management early following SCI. Management of shoulder pain in the SCI population is reactive rather than proactive. Interventions focusing on impairments occur after the onset of pain as opposed to providing regular screens to identify and treat pain-related factors prior to the development of pain and dysfunction. Early identification of pain-related factors, physical and psychosocial, may ameliorate associated reduction of activity and participation for individuals with SCI.

**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:** 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.*

Our enrollment is lower than we originally projected. We projected to enroll 12 with SCI at each site during the final 2 quarters of year 1. Based on hospital admissions, both Magee and UM Rehab, we now realize this was over ambitious. We identified barriers/limitations to our enrollment of participants with SC (controls not a concern) and initiated numerous strategies to facilitate enrollment during the next two quarters. The primary obstacle was communication—wording of recruitment documents and interpretation of eligibility by referring clinicians. Below are the factors we determined to be enrollment obstacles and our actions and plans to resolve:

1) Eligible individuals becoming ambulatory during initial rehabilitation were not being referred.

- These individuals were ambulating within their initial rehabilitation phase using upper extremity weight bearing assistive devices to ambulate in conjunction with a manual wheelchair. We will continue to enroll eligible individuals (neurological capacity to use a manual wheelchair) and if they progress to ambulation, we will continue the collect data on their physical and psychosocial characteristics with intent to determine factors associated with their mobility progression and pain. This is relevant as ambulatory individuals with AIS level C-D have similar rates of shoulder pain as manual wheelchair users who are AIS A-B. (Jain NB, Higgins LD, Katz JN, Garshick E.PM R. 2010 Oct;2(10):896-900. doi: 10.1016/j.pmrj.2010.05.004.)

2) Wording within protocol and consent documents regarding past upper extremity medical impairment history and/or availability for return visits has led investigator screening to deem individuals as ineligible and limited clinician referral.

- By the middle of Y1Q3 six potential participants were screened: one was enrolled while the remaining five were classified as ineligible. Three were due to report of self-report medical history of upper extremity trauma (history of possible shoulder dislocation in high school, gunshot wound, greater tuberosity fracture). Each of these three demonstrated normal upper extremity range or motion and function and were at the time already using manual wheelchair. In response to this occurrence, we modified the wording of the inclusion criteria to reflect current upper extremity function and mobility.
- Another two individuals were not enrolled due to discharge placement to skilled nursing facility (SNF) with concern by the screening investigator follow-up visits would be a challenge. Our research team determined we can and will provide continued contact and provide transportation for follow-up session to individuals placed in local and regional SNF. We will maintain contact with the facility and the participant to foster enrollment as well as retention of these potential participants. Additionally, we are providing training on our inclusion criteria to therapists who are referring potential participants.

- Research clinician and referring clinicians being more thoroughly informed on our specific eligibility criteria and advised to contact the PI if they have questions regarding potential eligibility.

3) Individuals with neurological capacity for using a manual wheelchair being discharged in power wheelchairs and therefore were not being considered as eligible.

- We understand third party payer guidelines created the propensity to send individual home in a power wheelchair over a manual wheelchair, even if they demonstrate the capacity for manual wheelchair use. We worked with referring clinicians to educate them our criteria is neurological capacity for a manual wheelchair and many of those who are discharged in a power wheelchair will transition to the manual wheelchair. We will enroll these individuals and based on 6-month and one-year follow-up be able to identify characteristics that facilitated transfer to the manual wheelchair.

**We diligently worked on our recruitment efforts, providing in-services to the referring clinician and the Research Clinician who is consenting individuals at Magee with a minimum of twice per weekly communication. Furthermore, we have identified additional, local rehabilitation hospitals as sites for enrolling in-patient participants. Meetings are scheduled with personnel at two facilities for the week of 8/7/18 to discuss collaboration. With the combined approaches of clarifying our inclusion criteria and recruiting at additional sites, we are confident that we can increase enrollment rate to achieve our goal.**

**Changes producing a significant impact on expenditures**
Nothing to Report.

**Significant changes in use or care of human subjects**

No significant changes in use or care of human subjects occurred. Below is the log of all IRB/HRPO tasks/approvals

| Organization | Task | Reason | approval date | expiration date |
|---|---|---|---|---|
| Drexel | initial approval | initial | 4/21/2017 | 4/18/2018 |
| UM | initial approval | initial | 5/5/2017 | 5/5/2018 |
| HRPO-Drexel | initial approval | initial | 5/24/2017 | 4/17/2018 |
| HRPO-UM | initial approval | initial | 5/24/2017 | 5/4/2018 |
| Drexel | modification | data collection form change | 10/3/2017 | 4/18/2018 |
| UM | modification | data collection form change | 10/2/2017 | 5/5/2018 |
| Drexel | modification | personnel addition | 12/1/2017 | 4/18/2018 |
| Drexel | modification | recruitment flyer wording change | 12/4/2017 | 4/18/2018 |
| Drexel | cont review | continuing review | 4/5/2018 | 4/17/2019 |
| UM | cont review | continuing review | 4/11/2018 | 4/9/2019 |

| | | | | |
|---|---|---|---|---|
| Drexel | modification | addition of OSPRO outcome measure | 5/15/2018 | 4/17/2019 |
| UM | modification | addition of OSPRO outcome measure | 6/19/2018 | 4/9/2019 |
| Drexel | modification | rewording of inclusion/exclusion on consent documents | 6/11/2018 | 4/17/2019 |
| UM | modification | rewording of inclusion/exclusion on consent documents | 7/11/2018 | 4/9/2019 |
| Drexel | modification | personnel changes due to completion/initiation of fellowship of fellowship | pending | |

**Significant changes in use or care of vertebrate animals.**
Not applicable

**Significant changes in use of biohazards and/or select agents**
Not applicable

**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.**
    Nothing to Report

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

  **Other publications, conference papers, and presentations**.

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

  - **Technologies or techniques**
    Not applicable

  - **Inventions, patent applications, and/or licenses**
    Not applicable

- **Other Products**
  Not applicable

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

**What individuals have worked on the project?**

Drexel:

Name: Margaret Finley, PT, PhD
Project Role: PI
Researcher Identifier (e.g. ORCID ID): N//A
Nearest person month worked: 0.6 calendar months
Contribution to Project: Dr. Finley directed all aspects of the project to date. She completed quarterly reporting and annual financial reporting as required. She is responsible for the financial management of the project. She submitted IRB continuing review materials and acquired approval. Dr. Finley oversees the monitoring of the shared databases, ongoing recruitment with Magee Rehab Hospital including in-services and bi-weekly communication with clinical research personnel, supply acquisition, organization and leading of monthly and quarterly meetings. She participates in all data collection sessions. Maintained monthly meetings with UMRehab team as well as led quarterly full-team meeting.

Name: Dave Ebaugh PT, PhD
Project Role: Co-I
Researcher Identifier (e.g. ORCID ID): N//A
Nearest person month worked: 0.15 calendar months
Contribution to Project: Dr. Ebaugh reviewed screening eligibility criteria as well as assisted with supply acquisition.

Name: Thomas Trojian, MD
Project Role: Co-I
Researcher Identifier (e.g. ORCID ID): N//A
Nearest person month worked: 0.15 calendar months
Contribution to Project: Dr. Trojian participated in the ongoing training on ultrasound, establishing US standard operating procedures and performing baseline US on participant(s).

Name: Elizabeth Euiler, MS
Project Role: Research Assistant (graduate Student)
Researcher Identifier (e.g. ORCID ID): N//A
Nearest person month worked: 0.3 calendar months (paid through Drexel University Fellowship)

Contribution to Project: Ms Euiler participated in control participant data collection as well as data entry and data checking for the shared database.

UM Rehab:
Name: Paula Geigle, PT, MS, PhD
Project Role: Co-I
Nearest person month worked: 0.45 calendar months
Contribution to Project: Dr. Geigle provided oversight of all UM Rehab project aspects since initiation to date. Dr. Geigle continues oversight of all aspects of the UM Rehab site including: developing recruitment strategies and planning flow of assessment activity, consulted with Dr. York for medical oversight and ultrasound procedures, supported sponsor reporting, co-led monthly conference call meetings and quarterly full team meetings.

Name: Henry York, MD
Project Role: Site PI
Nearest person month worked: 0.3 calendar months
Contribution to Project: Dr. York performed ultrasound assessments for all participants, consulted with Drs. Geigle and Finley on ultrasound procedures based upon observations, and entered data to one-drive database.

Name: Sara Kate Frye, MS OTR/L ATP
Project Role: Investigator – OT lead Assessor
Nearest person month worked: 0.15 calendar months
Contribution to Project: Ms. Frye performed clinical evaluations as well as QOL and PR measures with SCI participants

Name: Marni Kallins, PT DPT OCS
Project Role: Investigator – PT lead Assessor
Nearest person month worked: 0.15 calendar months
Contribution to Project: Dr. Kallins performed clinical evaluations as well as QOL and PR measures on control participants

Name: Leigh Casey, BA
Project Role: Research Coordinator
Nearest person month worked: 0.15 calendar months
Contribution to Project: Ms. Casey recorded financial reporting requirements with Drexel finance administrator. Ms. Casey facilitated recruitment of control participant and supported consent process and administration of some QOL and PR measures. Ms. Casey entered data in shared database.

**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 Maryland Rehabilitation and Orthopedic Institute
Location of Organization: 2200 Kernan Dr, Baltimore, MD 21207

Partner's contribution to the project:

- UMROI is our collaborating site. Investigators are recruiting, screening, consenting and collecting data on both individuals with SCI and age-matched controls.
- Facilities – we are collecting data in the facility
- Collaboration- Henry York, MD, Paula Geigle, PT, MS, PhD, Leigh Casey, BA, Sara Kate Frye MS OTR/L ATP and Marni Kallins DPT are investigators with roles for recruiting, screening and consenting participants.

Organization Name: Magee Rehabilitation Hospital
Location of Organization: 513 Race St, Philadelphia, PA 19102
Partner's contribution to the project:

- Facilities – we are collecting baseline data in the facility
- Collaboration- Mary Schmidt, DPT and Director of Research is on the research team with a role for recruiting, screening and consenting participants.

## 8. SPECIAL REPORTING REQUIREMENTS

**COLLABORATIVE AWARDS:** Not applicable

**QUAD CHARTS:** If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

- Quad Chart included

## 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.

- Copy of abstract submitted to the Combined Section Meeting of the American Physical Therapy Association for dissemination at Annual meeting, January 23-26, 2019, Washington, DC. Acceptance decisions expected in September 2018.

**Development of a Biopsychosocial Prospective Surveillance Model of Shoulder Pain in Individuals with Spinal Cord Injury**
Log No. SC160041
Award W81XWH-17-1-0476

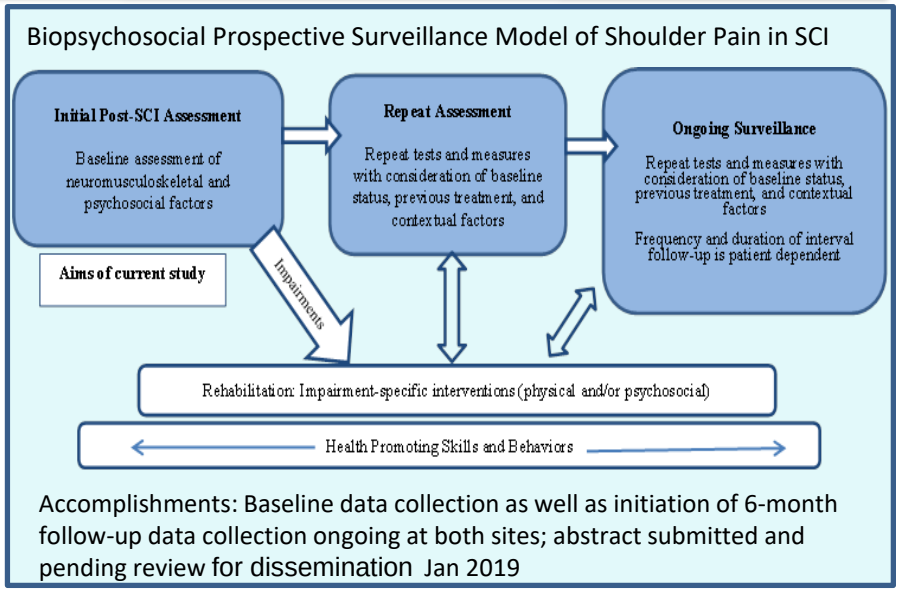
**PI:** Finley, Margaret **Org: Drexel University** **Award Amount:** $664,270

### Study Aim

**Aim 1***:* Determine musculoskeletal and psychosocial factors associated with shoulder pain in individuals with acute SCI. **Aim 2**: Establish the changes in musculoskeletal and psychosocial factors in individuals with SCI between the acute phase of rehabilitation, 6 months and one year post–SCI. **Aim 3**: Determine the relationship between shoulder pain, musculoskeletal factors, psychosocial factors, and QoL, during the first year following SCI.

### Approach

A multi-site repeated-measures investigation of individuals with SCI across the first year of injury will be compared with an age-gender matched control group. Primary measures of physical impairment (shoulder and general musculoskeletal pain, muscle extensibility, shoulder muscle strength ratios, rotator cuff integrity via musculoskeletal ultrasound) and psychosocial measures (Tampa Kinesiophobia Scale, Pain Catastrophizing Scale, Fear of Pain Questionnaire, QoL) will be obtained from all participants. Three dimensional kinematic data that will be used to derive intersegmental coordination measures during a functional reaching task will be obtained from the Drexel cohort.




Accomplishments: Baseline data collection as well as initiation of 6-month follow-up data collection ongoing at both sites; abstract submitted and pending review for dissemination Jan 2019

### Timeline and Cost

| Activities | CY 17 | 18 | 19 | 20 |
|---|---|---|---|---|
| Regulatory approval & collaboration structure | | | | |
| Participant data collection | | | | |
| Data Analysis and interpretation | | | | |
| Dissemination | | | | |
| **Estimated Budget ($664K)** | $226,237 | $224,332 | $213,701 | |

**Updated:** (Philadelphia, PA July 31, 2018)

### Goals/Milestones

**CY17 Goal** – Regulatory approvals
- ✓ Complete site and HRPO regulatory approval
- ✓ Collaboration structure developed
- ✓ Initiated participant enrollment and baseline data collection

**CY18 Goals** – Data Collection
- ✓ Baseline and 6-month follow-up data collection initiated and ongoing
- ☐ Participant enrollment and data collection all baseline and 6-month completed

**CY19 Goal** – Final data collection, analysis & interpretation
- ☐ Complete one-year data collection sessions
- ☐ Complete data analysis and interpretation

**CY20 Goal** – Dissemination
- ☐ Abstracts, presentations, publications
- ✓ Abstract submitted to CSM of APTA for January 2019 dissemination – decision pending.

**Comments/Challenges/Issues/Concerns:** On task for achieving goals. Challenges with baseline enrollment being addressed with clarification of inclusions criteria and contact of additional referral sources.

**Budget Expenditure to Date**
Projected Expenditure: $664,270
Actual Expenditure: $178,574 (07/31/18 report)

**CONTROL ID:** 3037590

**TITLE:** BIOPSYCHOSOCIAL CHARACTERISTICS OF INDIVIDUALS WITH NEW SCI: PRELIMINARY DATA FROM A LONGITUDINAL STU

**PRESENTATION TYPE:** Platform

**CURRENT SECTION:** Neurology

**Author Details**

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**SPONSOR NAME:** None

**Student Category - Research Report:** Not a Student

**Abstract**

**ABSTRACT BODY:**

**Purpose/Hypothesis :** Knowledge of biopsychosocial determinants of shoulder pain is directly applicable to a prospective surveillance model [1] of clinical management promoting early detection, intervention, and prevention of secondary disability. The interdependence among psychosocial factors, biological factors and musculoskeletal pain is unknown in individuals with spinal cord injury (SCI) from onset of rehabilitation through the first year following injury. This, longitudinal study is investigating biopsychosocial factors associated with shoulder pain in individuals with acute SCI(N=34) compared with age and gender-matched controls. The purpose is to determine the relationship and temporal characteristics of shoulder pain, musculoskeletal factors, psychosocial factors, and QoL during the first year following SCI. The current data provide a preliminary investigation of these factors.

**Number of Subjects :** Six individuals participating in inpatient SCI rehabilitation

**Materials/Methods :** Demographics, Musculoskeletal Pain Survey upper extremity (MPS), muscle strength, pectoralis minor extensibility, shoulder range of motion (ROM), musculoskeletal ultrasound (Ultrasound Pathology Shoulder Rating Scale (USPRS).[2] Psychosocial measures were Tampa Kinesiophobia Scale-11 (TSK), Pain Catastrophizing Scale (PCS), Fear of Pain Questionnaire (FPQ), Subjective Quality of Life Questionnaire (SQoL), Chronic Pain Coping Inventory (CPCI-42).

**Results :** Upper extremity pain was reported in 3 of 6 participants. Mean strength of shoulder flexor, extensor and abductor was below age-specific norms.[3] Pectoralis minor extensibility was reduced[4,5] to 13.7% in non-dominant limb with greatest reduction in older participants (> 50 years age) and those reporting pain. ROM was symmetrical and within normal limits with USPRS scores indicating minimal structural impairment. PCS and TSK scores higher than other populations.[6] SQoL=4.3/7 was lower than other groups with SCI .[7,8] The most common pain coping strategy was seeking social support.

**Conclusions :** Preliminary data indicate individuals with new SCI demonstrate physical impairments of pain, reduced shoulder muscle strength with older individuals demonstrating reduced pectoralis minor muscle extensibility. Minimal structural changes in tissue integrity are noted. Maladaptive psychosocial pain factors were elevated and present in all 6 participants with 50% reporting pain with reduced SQoL.

**Clinical Relevance :** Management of shoulder pain in the SCI population is reactive rather than proactive. Interventions focusing on impairments occur after the onset of pain as opposed to providing regular screens to identify and treat pain-related factors prior to the development of pain and dysfunction. Early identification of pain-related factors may ameliorate pain related reduction of activity and participation for individuals with SCI. To facilitate this goal, this longitudinal study aims to identify these biopsychosocial determinants of shoulder pain in the initial year following SCI.

**KEYWORDS:** SCI, Pain, Biopsychosocial.

**References: Limit to only those materials that ensure that the content is evidence-based; minimum 5 references, no more than 10 years old (2009 and forward):**

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7. Gutierrez DD, Thompson L, Kemp B, et al. The relationship of shoulder pain intensity to quality of life, physical activity, and community participation in persons with paraplegia. The journal of spinal cord medicine. 2007;30(3):251-255.
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