AWARD NUMBER: ***W81XWH-16-1-0788***

TITLE: ***Enhancing Quality of Orthotic Services with Process and Outcome Information***

PRINCIPAL INVESTIGATOR: Allen Heinemann, PhD

CONTRACTING ORGANIZATION: **Shirley Ryan AbilityLab**
Chicago, IL 60611

REPORT DATE: **October 2021**

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

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
OCTOBER 2021	Annual Report	9/30/2020-9/29/2021

4. TITLE AND SUBTITLE

Enhancing Quality of Orthotic Services with Process and Outcome Information

5a. CONTRACT NUMBER
W81XWH-16-1-0788

5b. GRANT NUMBER
n/a

5c. PROGRAM ELEMENT NUMBER
n/a

6. AUTHOR(S)

Allen Heinemann- Principal Investigator

E-Mail: aheinemann@sralab.org

5d. PROJECT NUMBER
n/a

5e. TASK NUMBER
n/a

5f. WORK UNIT NUMBER
n/a

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Rehabilitation Institute of Chicago
dba Shirley Ryan AbilityLab
355 E. Erie ST,
Chicago, IL 60611

8. PERFORMING ORGANIZATION REPORT NUMBER

n/a

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

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

10. SPONSOR/MONITOR'S ACRONYM(S)
n/a

11. SPONSOR/MONITOR'S REPORT NUMBER(S) N/a

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The objective of this proposed project is to develop data collection modules that can be used to improve the quality of services for users of ankle-foot orthoses (AFOs), the largest group of orthosis users. Three specific aims are:
1. Identify issues that are important to the quality of care for AFO users as well as items and instruments that can be used to assess these quality issues.
2. Evaluate and validate patient-reported outcome instruments using performance instruments.
3. Specify items required for quality measure development and design data collection modules that can be used in quality improvement efforts and to demonstrate accountability of health care delivery.

15. SUBJECT TERMS

NONE LISTED

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	44	19b. TELEPHONE NUMBER *(include area code)*

Table of Contents

Page

1. INTRODUCTION:

Orthotic device use by Service members and Veterans is growing, yet outcomes assessment and quality measure development for orthotic services lags far behind other healthcare specialties. Orthotists acknowledge the value of quality measures, but cannot adopt measures used in other healthcare settings because they have not been validated for orthosis users. Thus, the objective of this project is to develop data collection modules that can be used to improve the quality of services for users of ankle-foot orthoses (AFOs), the largest group of orthosis users. This project applies state-of-the-art methods in quality measure development to a large and growing population that has not benefitted from sustained research. An Advisory Committee representing multiple stakeholders will specify criteria for quality measures that are relevant to AFO users. These specifications will guide selection of proposed process and outcome instruments with optimal psychometric properties that are feasible for use in busy clinics. We will assess orthotists' perceptions of barriers and facilitators of quality data with an online survey. Data collection with these instruments is planned at two Veterans Hospitals (Hines, Minneapolis) and the Shirley Ryan AbilityLab. Patient-reported and performance measures will be obtained from 100 patients with trauma etiologies and other neurological disorders. We will examine content, concurrent and discriminant, and known-group validity of the patient-reported instruments; calculate minimal detectable change; examine floor and ceiling effects; compute correlations between patient-reported and performance measures; and evaluate sensitivity to change. We will design specifications for data collection and obtain feedback about usability and feasibility from the Advisory Committee.

2. KEYWORDS:

Stroke, Paralysis, Neurological, Braces, Orthosis, Orthoses, Trauma, Cerebrovascular, Stability, Gait, Balance, Postural

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Preparatory Activities

Milestone: IRB Approval at all sites (Months 1-6); **100% complete**

Task 1.1 Prepare for and convene an Advisory Committee that represents multiple stakeholders to identify important issues in the quality of care for AFO users.

Milestone: Identification of important issues in the quality of care for AFO users (Months 1-6); **100% complete**

Task 1.2 Identify items and instruments that operationalize important quality of care concepts for AFO practice

Milestone: Identification of items and instruments that operationalize important quality of care concepts for AFO practice (Months 1- 6); **100% complete**

Task 1.3 Survey orthotists, physical therapists, and patients to understand their preferences, priorities and barriers to quality measure use.
Milestone: Survey completed and results compiled (Months 7-9); **100% complete**

Task 1.4 Define case-mix indicators – additional critical data elements needed for valid interpretation of quality measures
Milestone: Identification of case mix issues (Months 7-9); **100% complete**

Task 2.1 Select process and outcome items and instruments with optimal properties identified in Task 1.2
Milestone: Selection of process and outcome items and instruments (Months 10-11), **100% complete**

Task 2.2 Collect patient-reported and performance-based data and evaluate test-retest reliability, concur-rent validity, sensitivity to change, and respondent/clinician burden in a sample of 100 AFO users
Milestone: Data set of 50 reliability sample and 50 sensitivity sample cases (Months 13-23)
73% complete

Task 3.1 Review results of Task 2.2 and recommend components of quality measures to the Advisory Committee
Milestone: Quality measure components reported to Advisory Committee (Months 22-24)
100% complete on March 4th, 2020 (in person) Advisory Meeting

Task 3.2 Prioritize and select the most compelling quality measures
Milestone: Priority list of quality measures (Months 25-27)

Task 3.3 Design the specifications for data collection and obtain usability and feasibility feedback from the Advisory Committee
Milestone: Design specifications for a clinical interface (Months 28-30)

Task 3.4 Disseminate findings and promote knowledge translation
Milestone: Broad dissemination of study findings (Months 31-36) **50% complete –** initial findings disseminated to Advisory Committee on March 4, 2020

What was accomplished under these goals?

Task 1.2 Identify items and instruments that operationalize important quality of care concepts for AFO practice.

- As we mentioned on the last annual report, we worked on a systematic review of literature, using the expertise of a communications coordinator and Librarian at Northwestern University. Using the results from the literature review and advisory committee feedback, we developed a systematic literature review paper that discusses quality assessment and measures, called, *A Review of Instruments that Assess Ankle Foot Orthosis Use in Persons with Neurological and Traumatic Etiologies*.
- **See paper details under task 3.4**

Task 1.3 Survey orthotists, physical therapists, and patients to understand their preferences, priorities and barriers to quality measure use.

- As mentioned in the last annual report, with the help of the advisory committee, research team and focus group results, we developed a secure online survey in order to understand orthotists and physical therapists preferences, priorities, and barriers to using quality measures when providing care for AFO users. We received Northwestern IRB approval on **12/4/2017**. When the survey closed on **February 28, 2018**, we received 460 **completed** responses from certified orthotists, physical therapists and other clinicians. Afterwards, the data was analyzed by the research team and the paper, *Orthotist and Physical Therapist Perspectives on Quality of Care Indicators for Custom*, was written based on the analyzed results.
    - **See paper details under task 3.4**

Task 1.4 Define case-mix indicators – additional critical data elements needed for valid interpretation of quality measures

- In order for an outcome measurement to be a valid quality measure, factors other than treatment effectiveness must be taken into account. Case-mix adjustment accounts for differences in the complexity and mix of patients which can vary across clinicians and institutions. Without adjustment, outcomes data may reflect the characteristics of patients treated by a facility rather than treatment effectiveness. With adequate case-mix adjustment, outcomes data can be interpreted in clinically meaningful ways, compared across time and programs, and used to assess program effectiveness. The unique treatment objectives of orthotists, devices prescribed, and patient characteristics require careful consideration of the. As mentioned in the last annual report, on **September 24, 2018** we sent a final list of case mix adjusters to the advisory committee's input. We received feedback from members the following week and finalized the list, based off their input, as well as the research team.

Task 2.1 Select process and outcome items and instruments with optimal properties identified in Task 1.2

- Based off the instruments and measures that were identified in task 1.2 and with the assistance of the research team and the advisory committee, we were able to identify optimal quality instruments and measures that will be used in task 2.2 (**Collect patient-reported and performance-based data and evaluate test-retest reliability, concur-rent validity, sensitivity to change, and respondent/clinician burden in a sample of 100 AFO users**). Some of the instruments include:
    - **10 Meter Walk Test**
    - **6 Minute Walk Test**
    - **2 Minute Walk Test**
    - **Timed Up and Go test**
    - **Rivermead Mobility Index**

The full list of patient survey items were built into a secure web application specifically designed for building and managing online surveys and databases (See appendix in 2018 report)

Task 2.2 Collect patient-reported and performance-based data and evaluate test-retest reliability, concur-rent validity, sensitivity to change, and respondent/clinician burden in a sample of 100 AFO users.

- With input from the advisory committee, clinician survey, literature review paper and research team, we have finalized a list of patient reported outcome measures that will be used to collect the data of AFO users. The measures have been built into a REDCap survey. The measures were IRB approved on **July 2, 2018**. In order to assess and analyze the gait pattern of participants, we will video record them performing the GAIT assessment tool and the NHS screening tool. Previously, we reported that we would do this for both new and current subjects, however, upon further review, we felt it would be more appropriate to capture this data from the first 30 subjects in the current user group at SRAlab. Research staff at all sites have been trained on how to administer the 6 minute walk test, 10 meter walk test and the timed up and go test. Additionally, each site has established interrater reliability. The Secure web application for building and managing online surveys and databases survey was finalized and put into production mode on **9/28/2018** & all sites have begun recruiting and collecting data. As of now, there are **108** people enrolled in the study.

Task 3.4 Disseminate findings and promote knowledge translation

- Based on the results from the clinician survey, a paper, *Orthotist and Physical Therapist Perspectives on Quality of Care Indicators for Custom*, was drafted and submitted to the journal, Clinical Rehabilitation, on **6/22/18**. The editor determined that the paper was not a good fit for the publication**.** The team made

edits to the paper and resubmitted *to Disability and Rehabilitation* on **7/24/18**. In December of 2018 the editor sent feedback and co-authors submitted a revision on **1/24/2019**. The manuscript was accepted and published online in the journal Assistive Technology on **May 15th, 2019.** doi: 10.1080/10400435.2019.1610814.

- Stemming from the completion of task 1.2 (Identify items and instruments that operationalize important quality of care concepts for AFO practice) , a paper, *A Review of Instruments used to Assess Ankle Foot Orthosis Use in Persons with Traumatic and Neurological Conditions*, was developed. The paper was submitted Prosthetics *and Orthotics International* on **8/13/18** and it was rejected. A re-write was submitted in August of 2019 to *Disability and Rehabilitation*, and it was rejected at the end of September. The paper was revised and resubmitted to the *Archives of Physical Medicine and Rehabilitation* on 12/1/19 and was sent back on 3/16/20 with only minor revisions needed before acceptance. It was resubmitted on 4/20/20 and accepted on 6/25/2020.

- We conducted four separate, cross-sectional focus groups with patients and clinicians in order to gain a thorough understanding of underlying or nonobvious issues related to quality-of-care for custom AFO users, and drafted a manuscript based on these results, *Patient and Clinician Perspectives on Quality-of-Care Topics for Users of Custom Ankle-Foot Orthoses.* The manuscript was first submitted for publication 3/3/18 and the editor requested revisions. A revised version of the manuscript was submitted 6/22/18. The publisher sent the paper to reviewers in early December and revisions were requested. Revisions were submitted January 11th, 2019. The paper was rejected by Prosthetics & Orthotics International on 2/22/19. Investigators revised and submitted to American Journal of Physical Medicine and Rehabilitation on 8/2/19 and again on 11/25/19. The manuscript was accepted for publication on 12/13/19.

Based on findings from this project, we presented two Symposia, one at the American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium on March 7, 2019 in Orlando, FL and a second at the International Society for Prosthetics and Orthotics World Congress on October 5-8, 2019 in Kobe, Japan. These symposia described issues important to the quality-of-care for custom AFO users, instruments that could measure these issues, and the measurement priorities of orthotists and physical therapists.

Stemming from the completion of task 1.2 (Identify items and instruments that operationalize important quality of care concepts for AFO practice) , a paper, *A Review of Instruments used to Assess Ankle Foot Orthosis Use in Persons with Traumatic and Neurological Conditions*, was developed. The paper was submitted to Prosthetics and Orthotics International on 8/13/18 and was rejected. The manuscript was revised and submitted to *Archives of Physical Medicine and Rehabilitation* on 12/1/19 and was sent back on 3/16/20 with only minor revisions

needed before acceptance .It was resubmitted on 4/20/20 and accepted on 6/25/20.

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

- We provided training to orthotists and physical therapists who attended our presentations at the American Academy of Orthotics Prosthetics Annual Meeting and Scientific Symposium on March 7, 2019 in Orlando, FL and a second at the International Society for Prosthetics and Orthotics World Congress on October 5-8, 2019 in Kobe, Japan. These symposia described issues important to the quality-of-care for custom AFO users, instruments that could measure these issues, and the measurement priorities of orthotists and physical therapists.
- Allen Heinemann, PhD was scheduled to present on "Exploring Quality-of-Care Topics for Users of Custom Ankle-Foot Orthoses" at an Orthotics and Prosthetics Conference in Canada in November 2019 but the conference was cancelled.

How were the results disseminated to communities of interest?

- We presented preliminary study findings at an Advisory Committee meeting in March 2020

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

- During the next reporting period, we plan to finish recruiting and collecting patient reported and performance measure data, using the secure online survey that we built (see appendix in 2018 report). Then, we will then organize and analyze the data. Next, we will summarize and recommend components of quality measures to the Advisory Committee for feedback. We plan to produce 2 papers based on primary data collection from patients. The papers will focus on (1) *Sensitivity to change with the TUG, 10 meter and 6 minute walk test, and (2) Primary outcome manuscript: PRO correlation & measures. We decided not to pursue the analysis of gait videos discussed in the last annual report because of the excessive time demands of this task. We did not propose this analysis in the application.*

4. IMPACT:

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

- When data collection is complete, we will share the data collection modules that can be used to improve the quality of services for users of ankle-foot orthoses (AFOs), the largest group of orthosis users.

What was the impact on other disciplines?

- Nothing to report yet

What was the impact on technology transfer?

- Nothing to report yet

What was the impact on society beyond science and technology?

- Nothing to report

5. CHANGES/ PROBLEMS

Changes in approach and reasons for change

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

- In the 2018 annual report, we explained that the project was 6 months behind schedule. A pending IRB modification kept Hines VA from recruiting from ***1/18/2019 to 5/7/2019.*** The modification took this long to approve due to staffing issues at the Hines VA IRB office. All sites have had difficulties recruiting New Users. In an effort to remedy this problem, IRB modifications have been submitted at SRAlab to recruit from inpatient populations as well as outpatient in order to reach the proposed sample size. In the 2019 annual report, the project was behind by ***12*** **months.** In March 2020, recruitment for this project was significantly delayed due to the COVID 19 pandemic which was reported in the 2020 annual report. For this 2021 annual report, the project is again behind by ***12 months***. A no cost extension was requested in order to complete the recruiting, data collection and dissemination tasks for this project.

Changes that had a significant impact on expenditures

- COVID-19 put a hold on recruitment. Staff effort on the project was severely reduced in order to save those funds for future recruitment. We requested and received a second no cost extension for the period of 9/30/2020 to 9/29/2021 to continue reaching recruitment and data collection targets. We also received a no cost extension for the 9/30/2021 to 9/29/2022 period. During the no cost extension we will focus on completing recruitment and project tasks.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

- Nothing to report yet

Significant changes in use or care of vertebrate animals

- Not applicable

- **Significant changes in use of biohazards and/or select agents**

- Not applicable

Significant changes in use of biohazards and/or select agents

- Not applicable

6. PRODUCTS

Publications, conference papers, and presentations

Journal publications:

Heinemann A, Fatone S, LaVela S, Slater B, Deutsch A, Peterson M, Soltys N, McPherson V (2019) Orthotists' and physical therapists' perspectives on quality of care indicators for persons with custom ankle-foot orthoses, Assistive Technology, DOI: 10.1080/10400435.2019.1610814

Fatone, S., Jerousek, S., Slater, B. C. S., Deutsch, A., LaVela, S. L., Peterson, M., Heinemann, A. W. (2020). Identifying instruments to assess care quality for individuals with custom ankle foot orthoses: A scoping review. *Archives of Physical Medicine and Rehabilitation,* doi:10.1016/j.apmr.2020.06.029

Books or other non-periodical, one-time publications

- Nothing to report yet

Website (s) or other internet site (s)

https://www.sralab.org/node/86384

Technologies or techniques

- Nothing to report yet

Inventions, patent applications, and/or licenses

- Nothing to report yet

Other Products

- Nothing to report yet

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Rehabilitation Institute of Chicago dba Shirley Ryan AbilityLab

Name: Allen Heinemann
Project Role: Principal Investigator
Research Identifier: 0000-0003-2782-7326
Nearest person month worked: 0.00
Contribution to Project: Dr. Heinemann created a focus group guide; moderated focus groups; coded transcripts; generated quality themes/codes; drafted a focus group manuscript; ran advisory board meetings and keep project activities aligned with protocol timeline.
Funding Support: None

Name: Anne Deutsch
Project Role: Co-Investigator
Research Identifier: 0000-0003-2290-7757
Nearest person month worked: 0.00
Contribution to Project: Ms. Deutsch brings expertise in quality measure development from her National Quality Forum service to the project; she also assists with data interpretations and dissemination activities.
Funding Support: None

Name: Deborah Crown
Project Role: Project Manager
Research Identifier: 0000-0002-9816-7057
Nearest person month worked: 0.51
Contribution to Project: Ms. Crown supervised support staff, assisted with IRB modifications and project management.
Funding Support: None

Name: Anna Hindelang
Project Role: Physical Therapist
Research Identifier: None
Nearest person month worked: 0.01
Contribution to Project: Ms. Hindelang provided assistance with outcome measures for participants that had a greater than usual fall risk. Only recruited to help when extra safety is needed.
Funding Support: None

Name: Nicholas McCombs
Project Role: Research Coordinator
Research Identifier: None
Nearest person month worked: 2.24
Contribution to Project: Mr. McCombs recorded minutes during the bi-weekly meetings, monitored and reported on the REDCap survey activity, tracked survey, dissemination efforts, assisted with recruitment and enrollment of research participants and data collection and data analysis.
Funding Support: None

Name: Christian Arenas
Project Role: Research Assistant
Research Identifier: None
Nearest person month worked: 1.53
Contribution to Project: Mr. Arenas assisted with recruitment and enrollment of research participants and data collection.
Funding Support: None

Name: Nicole Soltys
Project Role: Co-Investigator
Research Identifier: None
Nearest person month worked: 0.01
Contribution to Project: Ms. Soltys serves as a clinical liaison with orthotic expertise that assists in recruitment efforts, interpreting data, and paper writing
Funding Support: None

Name: Kristia Torres
Project Role: Physical Therapist
Research Identifier: None
Nearest person month worked: 0.01
Contribution to Project: Ms. Torres provided assistance with outcome measures for a participant that was seen at one of the SRAlab DayRehab clinics.

Funding Support: None

Northwestern University

Name: Stefania Fatone
Project Role: Subsite PI
Researcher Identifier: None
Nearest person month worked: 1.00
Contribution to Project: Collaborate with project PI especially in terms of study development, project management, orthotic management expertise, and data

interpretation. Dissemination efforts include contributing to project publications and presentations.
Funding Support: None

Chicago Association for Research & Education in Science (CARES)

Name: Sherri LaVela, PhD
Project Role: Subcontract PI
Researcher Identifier: None
Nearest person month worked: 0.6
Contribution to Project: Participates in weekly team meetings. Helps plan methods and study strategies. Recruitment site activities, helps recruit participants and helps develop data collection tools. Dissemination efforts -- helps author manuscripts.
Funding Support: None

Name: Rodney Stuck, MD
Project Role: Co-Investigator
Researcher Identifier: None
Nearest person month worked: 0.6
Contribution to Project: Helps with recruitment of VA staff for focus groups. Provides clinical/content expertise.
Funding Support: VA funds

Name: Ibuola Kale
Project Role: Research Coordinator
Researcher Identifier: None
Nearest person month worked: 0.6
Contribution to Project: Helps with recruitment efforts. Primary contact for IRB efforts at Hines VA. Participates in team meetings and discussion.
Funding Support: None

Department of Veterans Affairs- Minneapolis VA Health Care System

Name: Michelle D. Peterson, DPT
Project Role: Site PI
Researcher Identifier: None
Nearest person month worked: 2.4
Contribution to Project: Preparation of regulatory documents (initial IRB, R&D, resubmission IRB), participation in advisory committee (assist in developing committee nominees, conference call attendance, review of committee findings) participation in bi-weekly conference calls, manuscript review, survey development.
Funding Support: None

Name: Billie C.S. Slater, MA
Project Role: Study Coordinator
Researcher Identifier: None

Nearest person month worked: 2.52
Contribution to Project: Preparation of regulatory Documents including Initial IRB Application, participated in bi-weekly conference calls, participated in coding of focus group transcripts.
Funding Support: None

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Allen Heinemann, PhD
There have been many changes in other support for Dr. Heinemann. We are attaching his current support document for review.

PREVIOUS, CURRENT & PENDING SUPPPORT

PREVIOUS SUPPORT

Title: Perspective and Preferences for Weight Management after Spinal Cord Injury
Time Commitment: 0.30 CM (2.5%)
Supporting Agency: DOD W81XWH-17-1-0678
Address: 5000 South Fifth Ave, Building 1, Room D312, Hines, IL 60141
Performance Period: 09/30/17 - 09/29/20
Total Funding:
Project Goal: The major goals of this project are examine the perspectives of persons with SCI and their informal caregivers/family members regarding optimal weight management strategies (including preferences, barriers, and facilitators for physical activity and diet/nutrition).
Specific Aims:
1. To develop an informational/educational tool for weight management in individuals with SCI that incorporates the needs and preferences of persons with SCI and their caregivers/family members
2. To assess the feasibility of the educational tool for use with persons with SCI in health settings.

Role: Co-Investigator
Principal Investigator: LaVela

Title: Implementing SCI-QOL into Clinical Practice to Enhance Patient Engagement
Time Commitment: 0.12 CM (1%)
Supporting Agency: Craig H. Neilsen Foundation, 323994
Address: 16830 Ventura Boulevard, Suite 352, Encino, CA 91436
Performance Period: 05/01/16 – 04/30/20
Level of Funding:
Project Goal: This project adapts and evaluates implementation strategies designed to promote routine use of Patient Reported Outcomes in Spinal Cord Injury rehabilitation.

Specific Aims:

1. Identify barriers and supports to the use of SCI-QOL measures and identify strategies to reduce them during inpatient rehabilitation,
2. Develop an implementation strategy designed to facilitate the adoption and sustained use of SCI-QOL measures during inpatient rehabilitation, and
3. Implement an intervention to support routine collection of SCI-QOL measures, evaluate their effects on patient activation and team communication, assess sustainability, and determine generalizability of the intervention to other SCI rehabilitation providers.

Role: Principal Investigator
Principal Investigator: Heinemann

Title: Clinical Adaptation of the SCI-QOL Psychosocial Measures

Time Commitment: 0.60 CM (5%)

Supporting Agency: Craig H. Neilsen Foundation 367686

Address: 16830 Ventura Boulevard, Suite 352, Encino, CA 91436

Performance Period: 04/30/2016 – 04/30/2019

Total Funding:

Project Goal: Goal of this project is to improve psychosocial outcomes such as emotional well-being and quality of life in individuals with SCI.

Specific Aims:

1. Establish clinically relevant scoring standards (i.e., score cut points) for the SCI-QOL Ability to Participate, Depression, Anxiety, and Resilience item banks;
2. Employ a state of the art quantitative/qualitative mixed methodology technique with extensive consumer participation to enhance the clinical relevance of the scoring standards;
3. Apply these standards to assess statistically significant change using existing SCI-QOL data sets and to develop different profiles of psychosocial adjustment following SCI;
4. Conduct a gold-standard validation study of the Depression and Anxiety cut points.

Role: Co-Investigator

Principal Investigator: Kisala

Title: Evaluating the Utilization and Efficiency of Wearable Exoskeletons for SCI Rehabilitation
Time Commitment: 1.62 CM (13.5%)
Supporting Agency: DOD W81XWH-17-1-0157

Address: USA MED RESEARCH ACQ ACTIVITY, 820 Chandler Street, Fort Detrick MS 21702
Performance Period: 09/01/17 - 08/31/19
Level of Funding:
Project Goal: The goal of this application is to acquire information that will guide evaluation strategies, training strategies, and clinical decision plans to enable the safe and effective use of robotic exoskeletons to enhance mobility in veterans and civilians with SCI.
Specific Aims:

1. Describe the interest in, perceived need for, and expected outcomes of exoskeletons among persons with SCI who have not received robotic therapy with exoskeletons.
2. Describe the perceived benefits, limitations, and costs of exoskeletons among persons with SCI who received exoskeleton therapy during SCI rehabilitation or in the community, and compare their perspectives with persons who have no exoskeleton experience.
3. Describe physical therapists', physicians', other stake holders' experiences, clinical evaluation and training strategies using exoskeleton therapy in rehabilitation and community settings.

Role: Principal Investigator
Principal Investigator: Heinemann

Title: Evaluating the Utilization and Efficiency of Wearable Exoskeletons for SCI Rehabilitation
Time Commitment: 1.62 CM (13.5%)
Supporting Agency: DOD W81XWH-17-1-0157
Address: USA MED RESEARCH ACQ ACTIVITY, 820 Chandler Street, Fort Detrick MS 21702
Performance Period: 09/1/17-08/31/19
Total Funding:
Project Goal: The goal of this application is to acquire information that will guide evaluation strategies, training strategies, and clinical decision plans to enable the safe and effective use of robotic exoskeletons to enhance mobility in veterans and civilians with SCI.
Specific Aims:

1. Describe the interest in, perceived need for, and expected outcomes of exoskeletons among persons with SCI who have not received robotic therapy with exoskeletons.
2. Describe the perceived benefits, limitations, and costs of exoskeletons among persons with SCI who received exoskeleton therapy during SCI rehabilitation or in the community, and compare their perspectives with persons who have no exoskeleton experience.
3. Describe physical therapists', physicians', other stake holders' experiences, clinical evaluation and training strategies using exoskeleton therapy in rehabilitation and community settings.

Role: Principal Investigator

Principal Investigator: Heinemann

Title: Disability and Rehabilitation Program: Collaboration on Mobility Training (COMIT)

Time Commitment: 0.60 CM (5%)

Supporting Agency: NIDILRR 90DP0025-03-00

Address: 330 C Street, SW, Washington DC 20201

Performance Period: 04/01/2015 – 09/29/2018

Total Funding:

Project Goal: Goal of the project is to evaluate effectiveness of training in wheeled mobility at multiple sites

Specific Aims:

1. Test a readily translatable intervention to improve manual wheelchair (WC) skills in individuals with paraplegia or tetraplegia.
2. Create training and testing materials for maintenance of manual and power WC users based on the current draft developed by the World Health Organization.
3. Test a readily translatable intervention to improve maintenance of manual and power WCs.
4. Identify the relative benefits of the combination of WST and WMT training on the quality of life of the WC users.
5. Develop readily accessible web-based training programs for clinicians to learn the MST and WMT.

Role: Co-Principal Investigator

Principal Investigator: Boninger

Title: Midwest Regional Spinal Cord Injury Care System
Time Commitment: 0.24 CM (2%)
Supporting Agency: NIDILRR 90SI5009-02-00
Address: 330 C Street SW, 2511B, Administration for Community Living, Washington, DC 20201
Performance Period: 10/01/2011 – 09/29/2017
Total Funding:
Project Goal: The goals of MRSCICS are to advance the outcomes of our previous Model Systems research, continue to study the effectiveness of innovative treatment strategies; and evaluate the benefits of a well-designed, comprehensive, coordinated, interdisciplinary continuum of care that lead to improved outcomes for persons with SCI.
Specific Aims:

1. Provide a comprehensive continuum of care for persons with SCI.
2. Contribute to assessment of long-term outcomes by enrolling 80 subjects per year into the national SCI database.

3. Conduct one site-specific study
4. Disseminate research findings to various stakeholders in an effective and timely manner.
5. Collaborate effectively with the Model System Knowledge Translation Center.
6. Involve individuals with disabilities in research and dissemination activities.

Role: Co-Principal Investigator
Principal Investigator: Chen/Heinemann

Title: Northwestern University Patient-centered intervention and Engagement Training
Time Commitment: 0.24 CM (2%)
Supporting Agency: NIH 5K12HS023011-01
Address: 5600 Fishers Lane, 7th Floor, Rockville, MD 20857
Performance Period: 9/1/2014-7/31/2017
Total Funding:
Project Goal: Goal of Dr. Daniel Pinto's project is to provide a clear path to independence beginning with an innovative idea, that is, to identify the global problem of adherence to the attributes that are associated with adherence, apply preference weights tot the relative importance of these attributes using choice modeling, and build patient-centered physical activity recommendations based on an individual's preferred attributes.
Specific Aims:
Role: Faculty Mentor
Principal Investigator: Cella

Title: Patient Centered Outcomes Research Institute (PCORI)
Time Commitment: 0.60 CM (5%)
Supporting Agency: PCORI CD-12-11-4201
Address: 1828 L Street NW. Suite 900, Washington, DC 20036
Performance Period: 09/01/2013 – 07/31/2017
Total Funding:
Project Goal: The goal of this project is evaluate the feasibility of developing quality measures from patient-reported outcome measures.
Specific Aims:

1. Identify issues that are important to the quality of care for rehabilitation patients that are amenable to the collection of patient-reported outcomes.
2. Evaluate the feasibility of collecting PROMs.
3. Specify items required for quality measure development and design data collection modules that that can be used in quality improvement efforts and to demonstrate accountability of health care delivery.

Role: Principal Investigator
Principal Investigator: Heinemann

CURRENT SUPPORT

Title: Midwest Regional Spinal Cord Injury Care System
Time Commitment: 0.90 CM (7.5%)

Supporting Agency: NIDILRR 90SIMS0015-01-00
Address: 330 C Street SW, Washington, DC 20201
Performance Period: 09/01/2021 - 08/31/2026
Level of Funding:
Specific Aims:

1. With input from consumers and clinicians, we will develop and modify two apps (Pt Pal and MyCap).
2. Determine the relationship between spasticity, neurologic and functional recovery during inpatient SCI rehabilitation
3. Determine the relationship between serum BDNF levels, spasticity, and neurologic and functional recovery during inpatient SCI rehabilitation.

Role: Principal Investigator
Principal Investigator: Heinemann
Overlap: No scientific or budgetary overlap with the proposed project.

Title: The Midwest Regional Spinal Cord Injury Model System (MRSCICS)
Time Commitment: 0.00
Supporting Agency: NIDILRR 90SI5022-01-00
Address: 330 C Street SW, 2511B, Administration for Community Living, Washington, DC 20201
Performance Period: 09/30/16 - 09/29/22 (NCE)
Level of Funding:
Project Goal: MRSCICS will continue to provide a comprehensive continuum of care from injury onset to community reintegration for individuals with spinal cord injury (SCI), as it has for over 40 years
Specific Aims:

1. To provide state-of-the-art medical and rehabilitative services at all stages of recovery to maximize outcomes for individuals with SCI;
2. To contribute to assessment of long-term outcomes by enrolling 80 subjects per year into the national SCI database and following up on the 1,100 individuals enrolled from 1973-2000 and 2005-2016;
3. To disseminate research findings to various stakeholders in an effective and timely manner through various channels including the Model System Knowledge Translation Center;
4. To complete a site-specific research project evaluating daily Acute Intermittent Hypoxia and a method of increasing spinal plasticity to improve response to therapy for individuals with upper limb dysfunction due to incomplete SCI;
5. To participate in collaborative module projects
6. Role: Co-Principal Investigator

Principal Investigator: Heinemann/Chen
Overlap: No scientific or budgetary overlap with the proposed project.

Title: Enhancing quality of orthotic services with process and outcome information
Time Commitment: 0
Supporting Agency: DOD/CDMRP W81XWH-16-01-0788

Address: USA Med Research ACQ Activity, 820 Chandler Street, Fort Detrick MS 21702
Performance Period: 09/30/16 - 09/29/22 (NCE)
Level of Funding:
Project Goal: The goal of this project is to help the Defense Health Program improve understanding of the benefits of orthotic devices, treatments, and rehabilitation strategies.
Specific Aims:

1. Identify issues that are important to the quality of care for AFO users as well as instruments that can be used to assess these quality issues.
2. Evaluate and validate patient-reported outcome instruments using performance instruments.
3. Specify items required for quality measure development and design data collection modules that can be used in quality improvement efforts and to demonstrate accountability of health care delivery.

Role: Principal Investigator
Principal Investigator: Heinemann
Overlap: No scientific or budgetary overlap with the proposed project.

Title: Northwestern University Policy Research Fellowship
Time Commitment: 0.60 CM (5%)
Supporting Agency: NIDILRR 90ARPO0001-04-00
NIDILRR, Administration for Community Living, U.S. Department of Health and Human Services, 330 **Address:** C Street SW, Washington, DC 20230
Performance Period: 09/30/17 - 09/29/22
Level of Funding:
Project Goal: The overall Goal is to train four individuals who intend to focus their career on policy issues pertaining to disability, independent living, or rehabilitation during a 2-year fellowship.
Specific Aims:

1. Recruit and train highly qualified trainees in advanced policy research methods, focused on disability, independent living, or rehabilitation policy;
2. Provide trainees with an immersive, residential experience in the application of disability policy research;
3. Provide trainees with robust mentorship for a disability policy research project; and
4. Continuously monitor and improve the effectiveness of the ARRT DPRF-NU.

Role: Principal Investigator
Principal Investigator: Heinemann
Overlap: No scientific or budgetary overlap with the proposed project.

Title: A Multi-Center Clinical Trial to Evaluate the Effectiveness of Intermittent Hypoxia Therapy in Individuals with Spinal Cord Injury
Time Commitment: 0.24 CM (2%)
Supporting Agency: NIDILRR 90SIMS0001-01-00

Address: NIDILRR, Administration for Community Living, U.S. Department of Health and Human Services, 330 C Street SW, Washington, DC 20230
Performance Period: 09/30/17 - 09/26/22
Level of Funding:
Project Goal: The goal of this proposal is to evaluate a new strategy called acute intermittent hypoxia (AIH), during which a person is administered brief bouts of low oxygen through a facemask.
Specific Aims:

1. To test whether daily AIH improves upper-limb function in persons with incomplete cervical SCI;
2. To evaluate training when AIH is used alone, in combination with task-specific traditional training, or using a sensorized robotic device (RAPAEL Smart Glove).

Role: Co-Investigator
Principal Investigator: Rymer
Overlap: No scientific or budgetary overlap with the proposed project.

Title: Rehabilitation Research Training Center (RRTC) on employment for people with physical disabilities
Time Commitment: 1.2 CM (10%)
Supporting Agency: NIDILRR 90RTEM0001-04-00
Address: Switzer Building, 330 C Street SW, Washington, DC 20201
Performance Period: 09/30/18 - 09/29/23
Level of Funding:
Project Goal: The major goals of this Center are to conduct a RCT comparing an evidence-based, telehealth pain self-management intervention, adapted to address risk and protective factors for employment disability, to a waitlist control in adults who are employed;
Specific Aims:

1. To assess employer-, client-, job-, and environment-related barriers and facilitators of job retention after Vocational Rehabilitation;
2. To evaluate an implementation science approach to employment interventions in people with Parkinson's disease;
3. To evaluate job accommodation strategies and assistive technology resources for rural and low re-source environments, in order to promote job retention by persons with physical disabilities.

Role: Principal Investigator
Principal Investigator: Heinemann
Overlap: No scientific or budgetary overlap with the proposed project.

Title: Personalized Mobility Interventions using Smart Sensor Resources for Lower-limb Prostheses Users
Time Commitment: 0.36 CM (3%)
Supporting Agency: DOD W81XWH-18-2-0057
Address: USA Med Research ACQ Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014
Performance Period: 09/30/18 - 09/29/22

Level of Funding:
Project Goal: The goal is to assess actual prosthesis use to enable targeted rehabilitation interventions to optimize device use in the home and community.
Specific Aims:

1. To determine whether a participant's prosthesis use matches the assigned K-level and/or self-reported goals and, if not, determine the reason(s) using an expert panel to evaluate data from performance-related measures, participant-reported measures, and smartphone and prosthesis sensors (clinical toolbox)
2. To quantify effects of targeted physical intervention (prosthesis repair/refit, physical rehabilitation) or psychological intervention (motivational interviewing), or both, on activity levels and patient goals
3. To identify measure(s) that sensitively predict prosthesis use to create a clinically deployable toolkit to evaluate and optimize prosthesis use in the community

Role: Co-Investigator
Principal Investigator: Jayaraman
Overlap: No scientific or budgetary overlap with the proposed project.

Title: Advanced Rehabilitation Research Training (ARRT) Program: Northwestern University Advanced Rehabilitation Research Training Application
Time Commitment: 0.60 CM (5%)
Supporting Agency: NIDILRR 90ARHF0003-02-00
Address: Switzer Building, 330 C Street SW, Washington, DC 20201
Performance Period: 09/30/2018 - 09/29/2023
Level of Funding:
Principal Investigator: Heinemann
Project Goal: The goal of this project is to provide an integrated, interdisciplinary, collaborative training program for early career scholars focusing on health and function research.
Specific Aims:

1. To assist post-doctoral fellows in developing new skills to enhance their previous training in order to pursue a research career.
2. To provide carefully matched mentors, didactic course work, original research, grant writing, and scientific publishing over a two-year period.

Role: Principal Investigator
Principal Investigator: Heinemann
Overlap: No scientific or budgetary overlap with the proposed project.

Title: Defining Trajectories of Linguistic, Cognitive-Communicative and Quality of Life Outcomes in Aphasia
Time Commitment: 0.72 CM (6%)
Supporting Agency: NIH 1R01DC017174-03

Address: National Institute on Deafness and Other Communication Disorders (NIDCD), NSC BG RM, 8317 6001 Executive Blvd, Rockville MD 20852
Performance Period: 04/10/19 - 03/31/24
Total Funding:

Project Goal: The goal of this study is to describe the trajectories of linguistic, cognitive-communicative, and health-related quality of life (QoL) outcomes following stroke in persons with aphasia during inpatient and outpatient rehabilitation to 18 months following stroke.
Specific Aims:

1. To model the trajectories of linguistic, cognitive-communicative, and health-related QoL outcomes during inpatient and outpatient rehabilitation to 18 months following stroke;
2. To validate models to predict recovery of linguistic, cognitive-communicative, and health-related QoL outcomes with trajectories derived from characteristics listed in Aim 1b, 1c, and 1d.
3. To evaluate the validity and responsiveness of Neuro-QoL in adults recovering from aphasia.

Role: Co-Principal Investigator
Principal Investigator: Heinemann, Cherney
Overlap: No scientific or budgetary overlap with the proposed project.

Title: Defining Trajectories of Linguistic, Cognitive-Communicative and Quality of Life Outcomes in Aphasia (Supplement)
Time Commitment: 0.48 CM (4%)
Supporting Agency: NIH R01DC017174-02S1
Address: National Institute on Deafness and Other Communication Disorders (NIDCD), NSC BG RM, 8317 6001 Executive Blvd, Rockville MD 20852
Performance Period: 04/01/2020 - 03/31/2022
Total Funding:
Project Goal: The goal of this study is to describe the trajectories of linguistic, cognitive-communicative, and health-related quality of life (QoL) outcomes following stroke in persons with aphasia during inpatient and outpatient rehabilitation to 18 months following stroke.
Specific Aims:

1. To model the trajectories of linguistic, cognitive-communicative, and health-related QoL outcomes during inpatient and outpatient rehabilitation to 18 months following stroke;
2. To validate models to predict recovery of linguistic, cognitive-communicative, and health-related QoL outcomes with trajectories derived from characteristics listed in Aim 1b, 1c, and 1d.
3. To evaluate the validity and responsiveness of Neuro-QoL in adults recovering from aphasia.

Role: Co-Principal Investigator
Principal Investigator: Heinemann, Cherney
Overlap: No scientific or budgetary overlap with the proposed project.

Title: A Randomized Controlled Trial of Geriatric Emergency Department Innovations
Time Commitment: 1.20 CM (10%)
Supporting Agency: NIH AHRQ R01HS026489-02

Address: AHRQ, OMS/Division of Grants Management, 5600 Fishers Lance, Mail Stop 07N13, Rockville, MD 20857
Performance Period: 05/01/2019 - 04/30/2024
Level of Funding:
Project Goal: The overall goal of this proposal is to improve patient-oriented outcomes of geriatric patients presenting to an urban emergency departments by conducting a randomized controlled trial of the Geriatric Emergency Department Innovations (GEDI) program.
Role: Co-Principal Investigator
Principal Investigator: Heinemann, Dresden
Overlap: No scientific or budgetary overlap with the proposed project.

Title: DRRP on KT to Promote Patient-Centered Care through Use of Standardized Assessments
Time Commitment: 0.60 CM (5%)
Supporting Agency: NIDILRR 90DPKT0007-02-00
Address: 330 C Street SW, Washington, DC 20201
Performance Period: 09/01/2020 - 08/31/2025
Level of Funding:
Project Goal: The goal of this project is to apply knowledge translation (KT) principles to enhance evidence-based practice by reducing barriers that limit use of standard assessments.
Specific Aims:

1. To improve patient understanding of standardized assessments by developing patient-centered resources on the Rehabilitation Measures Database
2. To increase student knowledge of the need for and behavioral readiness to administer standardized assessments
3. To promote routine implementation of standardized assessments by rehabilitation clinicians

Role: Co-Principal Investigator
Principal Investigator: Ehrlich-Jones, Heinemann
Overlap: No scientific or budgetary overlap with the proposed project.

Title: Home and Community Based Services Person Centered Outcomes and Measurements
Time Commitment: 1.80 CM (15%)
Supporting Agency: NIDILLR 90RTGE0000-02-00
Address: 330 C Street SW, Washington, DC 20201
Performance Period: 09/01/2020 - 08/31/2025
Level of Funding:
Project Goal: The goal of this 5-year project is to accelerate the development and application of non-medical, person-centered outcome measures that inform the design, implementation, and continuous improvement of Federal and State home and community-based programs, policies, and interventions.
Specific Aims:

1. Review current quality measures and quality measure sets that address the personal experiences of people with disabilities who are receiving HCBS
2. conduct the necessary testing, in order to identify outcomes measures and measure sets that may be used in support of other priorities addressed under this RRTC
3. Define the scope of HCBS practices and specific service-delivery competencies.
4. Identify promising HCBS practices and requisite service-delivery competencies.
5. Describe how HCBS providers deliver best HCBS practices and assure that staff demonstrate service-delivery competencies.
6. Identify care managers', facilitators', and direct service providers' training needs and strategies regarding the promising HCBS practices and competencies identified in response to Priority A and B along with feedback from the Advisory Committee.
7. Develop manualized training materials for care managers and facilitators focused on the promising HCBS practices, and competencies identified in response to Priority B.
8. Beta test the training materials that are designed to support person-centered care delivery and coordination, using the promising HCBS practices, and competencies identified in response to Priority A and B
9. Evaluate the feasibility of scaling up the manualized intervention.

Role: Principal Investigator
Principal Investigator: Heinemann
Overlap: No scientific or budgetary overlap with the proposed project.

Title: The Claude D. Pepper Older Americans Independence Center (OAIC) at Northwestern University
Time Commitment: 1.02 CM (8.5%)
Supporting Agency: NIH P30AG059988-01A1
Address: Building 31, Room 5C27, 31 Center Drive, MSC 2292, Bethesda, MD 20892
Performance Period: 08/01/2020 - 06/30/2025
Level of Funding:
Project Goal: The proposed Northwestern Older Adults Independence Center (OAIC) will generate innovative research that will enhance primary care for medically complex, older adults with multiple chronic conditions to achieve optimal health, function, independence and quality of life.
Role: Co-Investigator
Principal Investigator: Linder, Wolf
Overlap: No scientific or budgetary overlap with the proposed project.

Title: Promoting the Psychological Health of Persons with Spinal Cord Injury: A Knowledge Transition Project
Time Commitment: 0.60 CM (5%)
Supporting Agency: Craig H. Neilsen Foundation 724833

Address: 16830 Ventura Boulevard, Suite 352, Encino, CA 91436
Performance Period: 04/30/2021 - 04/29/2024
Level of Funding:
Project Goal: This project focuses on research that seeks to better understand the relationship among biological, psychological and social aspects of health and functioning in people living with SCI.
Specific Aims:

1. Identify mental health topics that are important to consumers with SCI, their care partners, and mental health professionals,
2. Develop systematic reviews of identified mental health topics in collaboration with the Model Systems Knowledge Translation Center, the Center on Knowledge Translation for Disability and Rehabilitation Research, and Cochrane Rehabilitation,
3. Disseminate systematic reviews to primary care and mental health professionals with annotation highlighting clinical utility and evaluate their utility, and
4. Develop, disseminate, and evaluate consumer-friendly information and guidance on how to access relevant resources.

Role: Principal Investigator
Principal Investigator: Heinemann
Overlap: No scientific or budgetary overlap with the proposed project.

Title: Center for Smart Use of Technology to Assess Real-World Outcomes
Time Commitment: 0.60 CM (5%)
Supporting Agency: NIH P2CHD101899-01
Address: P.O. Box 3006, Rockville, MD 20847
Performance Period: 5/1/2020 - 4/30/2025
Level of Funding:
Project Goal: The proposed Center for Smart use of Technologies to Assess Real-world Outcomes (C-STAR) will serve as a national resource to help investigators employ technologies correctly to measure and interpret data relevant to sensorimotor and cognitive function in the lab, clinic, and real world.
Specific Aims:

1. Establish a process—Connect→Learn, Act, or Share that efficiently and logically delivers C-STAR resources to the rehabilitation research community. After initial connection with C-STAR, researchers can participate in any element at any point.
2. Create four cores of expertise in engineering, clinical, outcomes, and implementation science/community engagement.
3. Create a robust pilot project program that provides outside researchers with funding, mentoring, and expertise to perform sophisticated experiments relevant to the use of technology in rehabilitation.
4. Disseminate our center's resources to the research community via webinars, sabbaticals, and courses, relying heavily on our Rehabilitation Measures

Database website (www.rehabmeasures.org), which receives an average of 11,000 hits/day, as well as on our C-STAR website.
Role: Co-Investigator
Principal Investigator: Lieber
Overlap: No scientific or budgetary overlap with the proposed project.

Title: Advanced Rehabilitation Research Training (ARRT) Program – Employment
Time Commitment: 0.60 CM (5%)
Supporting Agency: NIDILRR 90AREM0003-01-00
Address: 330 C Street SW, Washington, DC 20201
Performance Period: 06/01/2020 - 05/31/2025
Level of Funding:
Project Goal: Researchers with specific training focused on rehabilitation and disability are needed to conduct critical and innovative studies to address the health and function, employment, and participation needs of persons with disabilities. Production of sophisticated research requires intensive and targeted post-doctoral training.
Role: Principal Investigator
Principal Investigator: Heinemann
Overlap: No scientific or budgetary overlap with the proposed project.

Title: Sensor Technology Applied to Rehabilitation in Stroke – STARS
Time Commitment: 0.36 CM (3%)
Supporting Agency: NIDILRR 90REGE0010-03-00
Address: 330 C Street SW, Washington, DC 20201
Performance Period: 09/30/2019 - 09/29/2024
Level of Funding:
Project Goal: Our primary objective is to enhance the capacity of clinicians to measure impairment by developing and testing a range of sensors suitable for clinical use.
Specific Aims:

1. Design, build & test a new sensor glove for spasticity measurement in hemispheric stroke.
2. Validate the accuracy of glove-based estimates using a precision DC motor to assess torque angle relations in chronic stroke survivors at the elbow and knee joint.
3. Test the use of the glove by clinicians for spasticity assessment in a monitored setting.
4. Perform large scale evaluation of translation of sensor glove output parameters in a routine setting on clinical floors, to map the output of the sensor glove to the MAS and Tardieu scales.

Role: Co-Investigator
Principal Investigator: Rymer
Overlap: No scientific or budgetary overlap with the proposed project.

PENDING SUPPORT

None.

Sherri LaVela, PhD. MPH, MBA

There have been many changes is other support for Dr. LaVela. We are attaching his current support document for review.

CURRENT, PREVIOUS, & PENDING SUPPPORT

CURRENT

Title:	Body mass index (BMI) risk zones, and variations in obesity detection and management in veterans with spinal cord injury (SCI), HX002432-01A1 (PI: Eisenberg)
Effort:	3.6 calendar
Supporting Agency:	Department of Veterans Affairs, HSR&D
Grants Officer:	Cathie Plouzek Office of Research and Development Veterans Health Administration Washington DC 20420
Performance Period:	10/1/2019-9/30/2022
Funding Amount	
Project Goals:	The goal is to understand the burden of obesity in patients with SCI and to identify individuals at risk for obesity-related morbidity.

Title:	Engaging Patients and Providers in Identifying and Addressing Modifiable Risk Factors to Prevent Community-Acquired Ulcers in Veterans with SCI; IIR 16-267; (PI: Burkhart)
Effort:	1.2 calendar
Supporting Agency:	Department of Veterans Affairs, HSR&D
Grants Officer:	Cathie Plouzek Office of Research and Development Veterans Health Administration Washington DC 20420
Performance Period:	07/01/2018 – 12/31/2022
Funding Amount	

Project Goals:	The goal is to identify risk factors for community-acquired pressure ulcers in persons with SCI and to implement prevention efforts.

PREVIOUS

Title:	Perspectives and Preferences for Weight Management after Spinal Cord Injury; W81XWH-16-SCIRP-QRA SC160051; LaVela (PI)
Effort:	3.6 calendar
Supporting Agency:	Department of Defense
Grants Officer:	Mark Wilkison 301-619-9883; mark.d.wilkison.civ@mail.mil
Performance Period:	10/01/2017 – 09/30/2021
Funding Amount	
Project Goals:	The goals of this study are to understand the experiences, barriers, and facilitators encountered by persons with SCI, their informal caregivers, and their health care providers, and to assess their expectations of and preferences for weight management strategies using in-depth qualitative interviews and focus groups will be used.

Title:	Enhancing Quality of Orthotic Services with Process and Outcome Information; W81XWH-16-1-0788 OP150034, LaVela (site PI & co-I, Heinemann (lead PI)
Effort:	0.6 calendar
Supporting Agency:	Department of Defense
Grants Officer:	Elena G. Howell, Grants Officer USA MED RESEARCH ACQ ACTIVITY 820 Chandler St. Fort Detrick MS 21702
Performance Period:	09/30/2016 – 09/29/2021
Funding Amount	
Project Goals:	The major goal of this project is to identify quality measures and develop data collection modules that can be used to improve the quality of services for users of ankle-foot orthoses (AFOs).

Title:	Evaluating the Use of Acute Intermittent Hypoxia to Enhance Motor Function in Persons with Multiple Sclerosis; PP-1706-27896: LaVela (PI)
Effort:	2.4 calendar
Supporting Agency:	National Multiple Sclerosis Society
Grants Officer:	Kathleen Zackowski, PhD, OTR; 212-476-0442; Kathleen.zackowski@nmss.org
Performance Period:	11/01/2017-10/31/2019
Funding Amount	
Project Goals:	The goals of this study are to evaluate if acute intermittent hypoxia will facilitate lower limb motor function in a cohort of persons with Multiple Sclerosis.

Title:	Developing a Curriculum on Grief/Loss due to SCI for Health Providers; PVA821; LaVela (PI)
Effort:	2.4 calendar
Supporting Agency:	Paralyzed Veterans of America Education Foundation
Grants Officer:	Paralyzed Veterans of America 801 Eighteenth Street, NW Washington, DC 20006 Rita Obi, Grant Portfolio Manager ritao@pva.org; 202-416-7611
Performance Period:	06/01/2017 – 11/30/2018
Funding Amount	
Project Goals:	The goal of this study is to develop a curriculum to educate health providers and persons with SCI about potential consequences of feelings of grief/loss due to injury, how to prevent their occurrence, and if they do occur, how to deal with and overcome these feelings.

Title:	Development of a Comprehensive Screening Protocol for Depressive Symptoms in People Living with SCI; CHNF324723; LaVela (Co-PI)
Effort:	2.0 calendar
Supporting Agency:	Craig H. Neilsen Foundation. Psychosocial Research Grants

Grants Officer:	Craig H. Neilsen Foundation 16830 Ventura Bl Ste Encino, CA 91436 Joy B. Guihama, MPH, Program Officer (818) 925-1246; joy@chnfoundation.org
Performance Period:	11/30/2015 – 10/31/2017
Funding Amount	
Project Goals:	The goal of this study is to develop a depression screening tool for individuals with SCI that can be used across settings and for individuals with varying levels and severity of injury.

Title:	Burden and Outcomes of Resistant Gram Negative Organisms in Veterans with SCI/D; B1583-P VA RR&D SPIRE; LaVela (Co-I); Evans (PI)
Effort:	2.0 calendar
Supporting Agency:	Department of Veterans Affairs, RR&D
Grants Officer:	Rehabilitation Research and Development (RR&D) Department of Veterans Affairs Veterans Affairs (10P9R) 810 Vermont Avenue, NW Washington, DC 20420 Patricia A. Dorn 202.443.5756
Performance Period:	11/01/2014-10/31/2016
Funding Amount	
Project Goals:	The objective of this study is to use national clinical microbiology data and other medical encounter datasets to describe the national burden, risk factors and impact of multidrug-resistant gram-negative organisms (MDRGNOs) in Veterans with SCI/D.

Title:	Quality Enhancement Research Initiative (QUERI), Spinal Cord Injury; SCI 98-000 (Evans); LaVela (Co-I); Weaver (PI) 1999-2012 /Evans (PI) 2013-2016
Effort:	3.0 calendar
Supporting Agency:	Department of Veterans Affairs
Grants Officer:	Amy Kilbourne, PhD, MPH, Director Quality Enhancement Research Initiative (QUERI) Department of Veterans Affairs

	810 Vermont Ave NW (10P9H) Washington, DC 20420 amy.kilbourne@va.gov
Performance Period:	10/01/1999-09/30/2016
Funding Amount	
Project Goals:	The major goal is to improve outcomes of Veterans with SCI by implementing evidence-based care.

Title:	Developing a Patient Inventory to Facilitate Patient-centered Care Delivery; SDR 12-280; LaVela (Co-I); Weaver (PI)
Effort:	1.6 calendar
Supporting Agency:	Department of Veterans Affairs, HSR&D
Grants Officer:	Miho Tanaka PhD, Scientific Portfolio Manager Department of Veterans Affairs HSR&D Office 810 Vermont Ave, NW Washington DC 20420 202-443-5759
Performance Period:	10/01/2013-09/31/2016
Funding Amount	
Project Goals:	The goal of this study is to assess factors that influence the delivery of technology-based patient-centered care to Veterans.

Title:	Instrument development to measure function self-efficacy in people with SCI ; CHNF 290435; LaVela (Co-PI)
Effort:	1.6 calendar
Supporting Agency:	Craig H. Neilsen Foundation. Psychosocial Research Grants
Grants Officer:	Craig H. Neilsen Foundation 16830 Ventura Bl Ste Encino, CA 91436 Joy B. Guihama, MPH, Program Officer (818) 925-1246; joy@chnfoundation.org
Performance Period:	06/1/2014 – 05/31/2016
Funding Amount	
Project Goals:	To objective of this work was to develop a tool to accurately assess functional self-efficacy in people with SCI.

Title:	Functional Needs Assessment in Persons with Spinal Cord Injuries and Disorders; RRP 13-248; LaVela (PI)
Effort:	2.4 calendar
Supporting Agency:	Department of Veterans Affairs, HSR&D
Grants Officer:	Department of Veterans Affairs Veterans Health Administration Washington DC 20420 Linda McIvor, MHS, MS, Program Manager, QUERI (10P9H) (202) 443-5740; Linda.McIvor@va.gov
Performance Period:	10/01/2014-09/30/2015
Funding Amount	
Project Goals:	The overall objective of this study is to conduct a systematic comprehensive needs assessment using mixed methods and triangulated data to understand functional challenges that are most important to Veterans with SCI/D, mediating factors that may affect function, and how these variables and relationships impact participation, life satisfaction, and quality of life (QOL) in Veterans with SCI/D. The long-term goal is to use the factors we identify as unmet needs to develop a lifestyle intervention to implement within this population.

Title:	Use of Declination Forms to Improve Influenza Vaccination in Health Care Workers; RRP 12-515; LaVela (PI)
Effort:	2.4 calendar
Supporting Agency:	Department of Veterans Affairs, HSR&D
Grants Officer:	Department of Veterans Affairs Veterans Health Administration Washington DC 20420 Linda McIvor, MHS, MS, Program Manager, QUERI (10P9H) (202) 443-5740; Linda.McIvor@va.gov
Performance Period:	10/01/2013 – 09/30/2014
Funding Amount	
Project Goals:	The overall objective of this study is to pilot test a declination form program intended to improve influenza vaccination uptake in HCWs providing care to Veterans with SCI/D.

Title:	Center for Evaluation of Practices and Experiences of Patient-centered Care (CEPEP); PEC 13-002; LaVela (PI)
Effort:	4.2 calendar
Supporting Agency:	Department of Veterans Affairs, Office of Patient-Centered Care and Cultural Transformation (OPCC&CT)
Grants Officer:	VA Research and Development, QUERI program John Midolo Program Coordinator (202) 443-5630; John.Midolo@va.gov
Performance Period:	11/01/2012-10/31/2014
Funding Amount	
Project Goals:	The main goal of this center grant, CEPEP, was to evaluate the processes and outcomes of approaches to implementing patient-centered care (PCC) and cultural transformation at the patient, family/caregiver, provider/employee, and system levels within and across the Veterans Health Administration Centers of Innovation to identify the most effective ways to change (improve) culture throughout the organization.

Title:	Outcome Assessment of Respirator Comfort and Tolerability using a Validated Instrument; VA-OPR-001-12; LaVela (PI)
Effort:	3.0 calendar
Supporting Agency:	Department of Veterans Affairs, Office of Public Health, National Center for Occupational Health and Infection Control
Grants Officer:	Megan Gosch, MPH Program Specialist, National Center for Occupational Health and Infection Control Public Health Veterans Health Administration 1601 SW Archer Road (151E) Gainesville, FL 32608 (352) 376-1611 Ext. 4990; Megan.Gosch@va.gov
Performance Period:	10/01/2012-09/30/2013
Funding Amount	
Project Goals:	The main objective was to measure comfort and tolerability among healthcare workers when wearing face-piece respirators; using a newly developed validated survey instrument.

Title:	Current weight management practices for Veterans with SCI/D across the VA system of care; RRP 12-213; LaVela (PI)

Effort:	3.6 calendar
Supporting Agency:	Department of Veterans Affairs, HSR&D
Grants Officer:	Department of Veterans Affairs Veterans Health Administration Washington DC 20420 Linda McIvor, MHS, MS, Program Manager, QUERI (10P9H) (202) 443-5740; Linda.McIvor@va.gov
Performance Period:	07/01/2012 – 06/30/2013
Funding Amount	
Project Goals:	The goal of this study was to evaluate current weight management practices used to address obesity/overweight in Veterans with chronic spinal cord injuries and disorders.

PENDING

Title:	Caring Connections: An initiative to improve feelings of social isolation and loneliness in Veterans with chronic spinal cord injury; LaVela (PI)
Effort:	2.4 calendar
Supporting Agency:	Department of Veterans Affairs, HSR&D
Grants Officer:	Cathie Plouzek Office of Research and Development Veterans Health Administration Washington DC 20420
Performance Period:	12/01/2021-91130/2025
Funding Amount	
Project Goals:	To learn about the experiences of social isolation and loneliness of individuals with SCI in general and in the wake of the COVID-19 pandemic, describing at risk subgroups and associations of social isolation and loneliness with health outcomes. Also, to implement and evaluate a program to reduce feelings of social isolation and loneliness in persons with SCI.

Title:	Development and Validation of a Nutrition Knowledge Questionnaire for Individuals with Spinal Cord Injuries and Disorders
Effort:	6.6 calendar
Supporting Agency:	Department of Defense
Grants Officer:	Mark Wilkison

Performance Period:	09/01/2022 - 08/31/2026
Funding Amount	
Project Goals:	The study objective is to develop and validate a questionnaire that measures nutrition knowledge, including assessment of SCI-specific knowledge that are relevant to nutrition in individuals with chronic SCI.

OVERLAP
There are no scientific or budgetary overlaps on any of the funded or pending projects listed above.

Stefania Fatone, PhD

Dr. Fatone has an appointment with Northwestern University (NU) as a Professor and is a Without Compensation Employee with the Veterans Administration (VA).

CURRENT, PREVIOUS, & PENDING SUPPPORT

NORTHWESTERN UNIVERSITY

CURRENT

DOD (PI: Heinemann)
9/30/2016- 09/29/2022 0.44 calendar
OORA W81XWH-16-1-0788 (SubK)
Shirley Ryan Ability Lab/Department of Defense
Enhancing Quality of Orthotic Services with Process and Outcome Information
The objective of this application is to develop data modules that can be used to improve the quality of services for AFO users.
Project Officer: Elena G. Howell
Grants Officer
Department of the Army
US Army Medical Research Acquisition Activity
820 Chandler Street
Fort Detrick MD 21702-5014

AOPA (PI: Fatone)
02/01/2019-01/31/2022 0.6 calendar

Effect of Ankle-Foot Orthoses (AFOs) on Continuous Walking in Persons with Post-Stroke Hemiplegia
We propose a prospective, randomized cross-over, comparative assessment trial with the following specific aims:
(1) to investigate how continuous walking affects the gait of persons with hemiplegia following stroke when walking without AFOs;

(2) to evaluate how well a clinically prescribed AFO addresses impairments that occur during continuous walking; and
(3) to evaluate if a 'tuned' AFO-FC is more effective than the clinically prescribed AFO at diminishing walking impairments during continuous walking.
Project Officer: Ashlie White
Director of Strategic Alliances
American Orthotic and Prosthetic Association (AOPA)
330 John Carlyle Street, Suite 200
Alexandria, VA 22314
Direct: 571.431.0812

DOD (PI: Sawers)
9/23/2019-09/22/2021 0.6 calendar
OPORP W81XWH-19-1-0507 (SubK)
University of Illinois at Chicago/Department of Defense
A Pilot Clinical Trial to Assess the Effect of Transfemoral Socket Design on Hip Muscle Function
The objective of the proposed prospective pilot clinical trial is to assess the effect of socket design on residual limb hip muscle strength and endurance in Service members, Veterans, and civilian transfemoral prosthesis users transitioning from an ischial-containment to a sub-ischial socket. Our central hypothesis is that walking with a sub-ischial socket will increase residual limb hip muscle strength and endurance in persons with transfemoral amputation who are long-term ischial-containment users.

DOD (PI: Fatone)
09/30/2019 – 09/29/2022 2.8 calendar
W81XWH1910835
Comparative Effectiveness of Socket Casting Methods: Improving Form and Fit
The overall objective of this project is to compare hand casting to standing hydrostatic pressure casting using a water cylinder in persons with lower limb amputation. Our overall hypothesis is that standing hydrostatic pressure casting with a water cylinder will lead to more consistent and efficient residual limb shape capture and improved initial socket fit and comfort compared to hand casting.
Project Officer: Lucinda F. Keeney
Phone: 301-619-3325
Email: lucinda.f.keeney.civ@mail.mil

NIH (PI: Zuniga) 1
2/01/2019 – 11/23/2023 0.24 calendar
R01 (SubK)
University of Nebraska Omaha/NIH
The influence of 3D printed prostheses on neural activation patterns of the primary motor cortex in children with unilateral congenital upper-limb reductions
The objective of this project is to determine the influence of using a prosthesis on the neural activation patterns of the primary motor cortex in children with unilateral

congenital upper-limb reductions to inform the development of rehabilitation programs aimed at reducing prosthesis rejection and abandonment.

VA RR&D (PI: Major)
4/01/2020 – 03/31/2023 0.72 calendar
Merit Award
Hybrid Electrical-Mechanical pump for Vacuum Suspension of Prosthetic Sockets
The purpose of this research and development project is to further design and evaluate a hybrid vacuum pump device that integrates electrical and mechanical systems to produce vacuum-assisted suspension of lower limb prosthetic sockets.
Project Officer: Brian W. Schulz
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420
Phone: 202-443-5769

PENDING

VA (PI: Pundik)
06/01/2022 – 05/30/2025 0.6 calendar
Merit Review (SubK)
Louis Stokes Cleveland VA Medical Center/VA IPA
Exoskeleton Research: Myoelectric orthosis for rehab of severe chronic arm motor deficits
The purpose of this randomized controlled trial is to investigate the efficacy of combining MyoPro with motor learning-based therapy for individuals with chronic severe upper limb motor deficits (>6 months post; FM≤30) compared with a similar dose of motor learning-based rehabilitation alone. We propose to explore four aims:
Aim 1: Determine if use of MyoPro in motor learning-based therapy results in a greater treatment response than motor learning alone in individuals with chronic severe upper limb motor deficits.
Aim 2: Characterize structural and functional brain changes for both treatment groups,
Aim 3: Evaluate factors associated with greater functional improvement.
Aim 4: Evaluate cost-effectiveness of motor learning-based therapy with MyoPro versus motor learning-based therapy alone.

NIH (PI: Pundik)
04/01/2022 – 03/31/2027 0.6 calendar
R01 (SubK)
Louis Stokes Cleveland VA Medical Center/NIH
Myoelectrically controlled orthotic device in rehabilitation of chronic severe arm motor deficits after stroke
The purpose of this randomized controlled trial is to investigate the efficacy of combining MyoPro with motor learning-based therapy for individuals with chronic severe upper limb motor deficits (>6 months post; FM≤30) compared with a similar dose of motor learning-based rehabilitation alone. We propose to explore four aims:

Aim 1: Determine if use of MyoPro in motor learning-based therapy results in a greater treatment response than motor learning alone in individuals with chronic severe upper limb motor deficits.
Aim 2: Characterize structural and functional brain changes for both treatment groups,
Aim 3: Evaluate factors associated with greater functional improvement.
Aim 4: Evaluate cost-effectiveness of motor learning-based therapy with MyoPro versus motor learning-based therapy alone.

DOD (PI: Fatone)
04/01/2022 – 03/31/2025 0.6 calendar
OPORP
Evaluation of the Northwestern University Sub-Ischial Socket for Persons with Transfemoral Amputation and Lower Mobility Levels
The objective of this project is to assess use and benefits of the sub-ischial socket for persons with TFA and lower mobility levels.

VARR&D (PI: Major)
12/01/2021 – 11/30/2023 (this request) 0.6 calendar
SPiRE
Mapping ankle-foot stiffness to socket comfort and pressure using a robotic emulator platform to personalize prosthesis function via human-in-the-loop optimization
The aim of this research project is to map relationships between prosthetic ankle-foot stiffness, user-reported comfort, and residuum-socket interface pressure and use this correlation map to drive prosthesis optimization.
Project Officer: TBD

PREVIOUS (5 YEARS)

AOPA (PI: Fatone)
08/01/2015 – 07/31/2017 0.6 calendar

Evaluating outcomes of dysvascular partial foot and transtibial amputation: a systematic review and development of shared decision making resources
The aim of this project will be to compare the outcomes of people with partial foot and transtibial amputation secondary to peripheral vascular disease and/or diabetes as well as translate what we learn from this research to help clinicians and patients make well-informed decisions about amputation surgery.
Project Officer: Thomas F. Fise, Executive Director
330 John Carlyle Street, Suite 200, Alexandria, VA 22314
P: 571-431-0802 F: 571-431-0899

Defense Health Program (PI: Sharma)
6/18/2017- 05/31/2019 1.08 calendar
SBIR Phase II (SubK)
iGRAB: Innovative Glove for Rehabilitation and Assistance using Biomimicry

The aim of the iGrab is to provide assistance to hand function resulting from hand injury during rehabilitation and every day activities. As part of Phase II, efficacy of the device in terms of assisting grasping activities in persons with impaired hand function must be demonstrated. Therefore, quantitative clinical evaluation of hand function with and without the iGrab will be evaluated in persons with impaired hand function due to both stroke and hand trauma.

Project Officer: Stephanie P. Davis
SBIR Admin Coordinator
USAMRAA
Phone: 301-619-2797

Myomo Inc. (PI: Page)
06/01/2017-12/31/2018 0.6 calendar
(SubK)
The Oklahoma State University
Functional Assistance provided by Myoelectric Elbow-wrist-hand orthoses (FAME)
The primary study objective is to compare upper extremity movement while wearing 1) the MyoPro 2 Motion-G; 2) a resting hand splint; and 3) no device among stroke survivors with moderate upper

Project Officer: N/A

NIH (PI: Fatone, Rogers, Huang, Coleman)
09/22/2014 – 05/31/2019 1.2 calendar
R01
Interface Monitoring System to Promote Residual Limb Health
This proposal aims to develop a stretchable and flexible sensor technology capable of transforming healthcare from reactive and hospital-centered to preventive, proactive, evidence-based, and person-centered.

Project Officer: Michael Wolf, Ph.D.
6707 Democracy Blvd, Ste 200,
Bethesda, MD 20892

DOD (PI: Fatone)
09/30/2015 –09/29/2020 2.4 calendar
PRORP
Functional Performance Evaluation of the Northwestern University Flexible Subischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation
This proposal aims to provide evidence to support the use of the NU-FlexSIV Socket for persons with transfemoral amputation. This will be accomplished by undertaking a prospective, assessor-blinded randomized cross-over trial comparing comfort and functional performance with the NU-FlexSIV Socket to the standard-of-care ischial containment socket (Figure 5) in persons with unilateral transfemoral amputation.

Project Officer: Elvera M. Messina
Grants Officer
US Army Medical Research Acquisition Activity
820 Chandler Street

Fort Detrick MD 21702-5014

DOD (PI: Fatone)
09/30/2016 – 09/29/2020 0.36 calendar
OORA
Longitudinal Observation of Myoelectric Upper Limb Orthosis Use among Veterans with Upper Limb Impairment
The objective of this observational study is to document longitudinal outcomes in Veterans using the myoelectric upper limb orthosis with powered elbow and grasp using both patient-centric performance and patient-reported outcome measures. Longitudinal observation will allow us to document both therapeutic effects as well as functional outcomes of orthosis use.
Project Officer: Elena G. Howell
Tel: 301-619-6871
Email: elena.g.howell.civ@mail.mil

DOD (PI: Fatone)
09/30/2016 – 09/29/2020 1.2 calendar
NMSIRA
No longer smooth: introducing striations into prosthetic socket construction to improve suspension, rotation, fit and comfort
The objective of this pre-clinical research project is to investigate the effect of different types of inner surface texturing on the suspension, rotation, fit, and comfort of prosthetic sockets.
Contracting Officer: Ms. Sandra Rosario
Assistance Agreement Branch 1
US Army Medical Research Acquisition Activity
820 Chandler Street
Fort Detrick, MD 21702-5014
Phone: 301-619-9656

NIH (PI: Bjornson)
09/01/2018 – 07/31/2020 0.18 calendar
R21 (SubK)
Seattle Children's Research Institute/NIH
Biomechanics and Walking in Cerebral Palsy: Ankle Foot Orthoses – Footwear Combinations
The goal of this proposal is to assess the feasibility of using a randomized waitlist study to acquire pilot data on a targeted clinical cohort of children with CP. Aim 1: Examine the effect of AFO-FC on overall gait deviations and walking speed as compared to current AFO in children with CP. Aim 2: Examine the effect of AFO-FC on daily walking activity, balance and satisfaction as compared to current AFO in children with CP.

Overlap

None.

Michelle Peterson, PT

Other Support – Michelle Peterson, PT, DPT, NCS

Current Support –

Title: Enhancing Quality of Orthotic Services with Process and Outcome Information

Role in Project: Site Principal Investigator

Time Commitment: 20%
Performance Period: 10/1/2016-9/29/20(extended 1 year) 9/30/20-9/29/21 (extended 1 year)

Level of Funding:

Supporting Agency: DOD grant W81XWH-16-1-0788

Name and address of funding agency's Contracting/Grants Officer: Amy Witherspoon

Pending Support – None