

AWARD NUMBER: W81XWH-16-1-0788

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

PRINCIPAL INVESTIGATOR: Allen Heinemann, PhD

CONTRACTING ORGANIZATION: Rehabilitation Institute of Chicago dba Shirley Ryan AbilityLab, Chicago, IL

REPORT DATE: October 2020

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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.					
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TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments.....	4
4. Impact.....	9
5. Changes/Problems.....	9
6. Products.....	10
7. Participants & Other Collaborating Organizations.....	12

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, concurrent 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, concurrent 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 **87** 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.

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. For this 2020 annual report, the project is again

behind by **12 months**. A no cost extension was requested and received 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.

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: 1.44
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: Rachel Bond
Project Role: Research Coordinator
Research Identifier: None
Nearest person month worked: 2.88
Contribution to Project: Ms. Bond 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.
Funding Support: None

Name: Wei Ning Chi
Project Role: Research Assistant
Research Identifier: None
Nearest person month worked: 1.80
Contribution to Project: Ms. Chi assisted with recruitment and enrollment of research participants and data collection.
Funding Support: None

Name: Anne Deutsch
Project Role: Co-Investigator
Research Identifier: 0000-0003-2290-7757
Nearest person month worked: 0.96
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: 0.12
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: 0.00
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: 3.48
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.
Funding Support: None

Name: Christian Arenas
Project Role: Research Assistant
Research Identifier: None
Nearest person month worked: 3.00
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: 0.00
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: Patrick Semik
Project Role: Data Analyst

Research Identifier: None
Nearest person month worked: 4.56
Contribution to Project: Mr. Semik works on data and statistical analysis for this project.
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: 0.72
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: 1.2
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: 3.0
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 Support

Allen Heinemann, PhD

Active Research Support

90RTGE0004-01-00 (Heinemann) 09/01/2020-08/31/2025 3.00
calendar months

NIDILRR

Rehabilitation Research Training Center on Home and Community Based Services

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.

90DPKT0007-01-00 (Ehrlich-Jones, Heinemann) 09/01/2020-08/31/2025 0.60
calendar months

NIDILRR

DRRP on KT to Promote Patient-Centered Care through Use of Standardized Assessments

The goal of this project is to promote patient-centered care by developing a comprehensive and coordinated set of KT resources for patients and care partners, students, and clinicians that enhance and sustain the use of standardized assessments as part of evidence-based practice.

90SI5022-01-00 (Heinemann) 09/30/2016-09/29/2021 1.80
calendar months

NIDILRR

The Midwest Regional Spinal Cord Injury Model System (MRSCICS)

The major goals of MRSCICS are to provide state-of-the-art medical and rehabilitative services at all stages of recovery to maximize outcomes for individuals with SCI; to contribute to assessment of long-term outcomes through the national SCI database; and to disseminate research findings to stakeholders. The major goal of the site specific project is to evaluate daily acute intermittent hypoxia as a method of increasing spinal plasticity to improve response to therapy for individuals with upper limb dysfunction due to incomplete SCI. The major goal of the collaborative module project is to evaluate the efficacy, cost, and health economics of wearable exoskeletons as therapeutic tools after SCI.

RRTC (Heinemann) 09/30/2018-09/29/2023 2.52
calendar months

NIDILRR

Rehabilitation Research Training Center on Employment for People with Physical Disabilities

The goal of this Center is to promote job retention by persons with physical disabilities.

W81XWH-16-01-0788 (Heinemann) 09/30/2016-09/29/2021 0.60
calendar months

Department of Defense/CDMRP NCE

Enhancing Quality of Orthotic Services with Process and Outcome Information

The goal of this project is to help the Defense Health Program improve understanding of the benefits of orthotic devices, treatments, and rehabilitation strategies.

90AREM0003 (Heinemann, McHugh) 06/01/2020-05/31/2025 0.60
calendar months

NIDILRR

Northwestern University Advanced Rehabilitation Research Fellowship on Employment

The major goal of the project is to train five individuals who intend to focus their career on employment of people with disabilities during a 2-year fellowship.

90ARHF0003-01-00 (Heinemann) 09/30/2018-09/29/2023 0.60
calendar months

NIDILRR

Northwestern University Advanced Rehabilitation Research Fellowship on Health and Function

The major goal of the project is to train five individuals who intend to focus their career on health and function issues pertaining to disability, independent living, or rehabilitation during a 2-year fellowship.

90ARPO0001-02-00 (Heinemann, McHugh) 09/30/2017-09/29/2022 0.60
calendar months

NIDILRR

Northwestern University Advanced Rehabilitation Research Policy Fellowship

The major goal of the project 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.

90SIMS0001-01-00 (Rymer) 09/30/2017-09/26/2022 0.12
calendar months

NIDILRR

A Multi-Center Clinical Trial to Evaluate the Effectiveness of Intermittent Hypoxia Therapy in Individuals with Spinal Cord Injury

The major goal of this project is to evaluate the effects of daily acute intermittent hypoxia on upper-limb function in persons with incomplete cervical SCI.

R01HS026489-01(Dresden, Heinemann) 09/01/2018-08/31/2023 1.80
calendar months

Agency for Healthcare Research Quality

A Randomized Controlled Trial of Geriatric Emergency Department Innovations

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.

W81XWH-18-2-0057 (Jayaraman) 9/30/2018-9/29/2022 0.30
calendar months

Department of Defense

Personalized Mobility Interventions using Smart Sensor Resources for Lower-limb
Prostheses Users

The goal of this project is to determine, quantify and identify whether a prosthesis' use matches a patient's K-level and self-reported goals and, if not, determine the reasons using an expert panel to evaluate data from performance-related measures, participant-reported measures, and smartphone and prosthesis sensors.

90REGE0010-01-00 (Rymer) 9/30/2019-9/29/2024 0.36
calendar months

NIDILRR

Sensor Technology Applied to Rehabilitation in Stroke – STARS

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.

R01DC017174 (Cherney, Heinemann) 9/30/2019-9/29/2024 0.96
calendar months

NIH

Defining Trajectories of Linguistic, Cognitive-Communicative and Quality of Life
Outcomes in Aphasia

The goals are to establish, identify, and evaluate a prospective cohort of stroke patients with aphasia, and define their typical trajectory of linguistic, cognitive-communicative, and health-related QoL recovery at admission to and discharge from the IRF, and at 6, 12, and 18 months post onset.

Recently Completed Research

W81XWH-17-1-0157 (Heinemann, Jayaraman) 09/01/2017-08/31/2020 0.60
calendar months

Department of Defense

NCE

Evaluating the Utilization and Efficiency of Wearable Exoskeletons for SCI
Rehabilitation

The major goal of this project 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.

323994 (Heinemann) 04/30/2016 – 04/30/2020 0.12
calendar months

Craig H. Neilsen Foundation NCE

Implementing SCI-QOL into Clinical Practice to Enhance Patient Engagement

The major goals of this project are to adapt and evaluate implementation strategies designed to promote routine use of patient reported outcomes (PROs) in SCI rehabilitation.

W81XWH-17-1-0678 (LaVela) 09/30/2017 – 09/29/2020 0.30
calendar months

Department of Defense

A Multi-Center Clinical Trial to Evaluate the Effectiveness of Intermittent Perspective and Preferences for Weight Management after Spinal Cord Injury

The goals of this project are to examine the perspectives of persons with SCI and their informal caregivers/family members regarding optimal weight management strategies; develop an informational/educational tool for weight management; and assess the feasibility of the educational tool.

Sherri LaVela, PhD

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

CURRENT, PREVIOUS, & PENDING SUPPORT

Sherri L. LaVela, PhD, MPH, MBA

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:	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:	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.

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:	2.4 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).

PREVIOUS

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 Mclvor, MHS, MS, Program Manager, QUERI (10P9H) (202) 443-5740; Linda.Mclvor@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.
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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 Mclvor, MHS, MS, Program Manager, QUERI (10P9H) (202) 443-5740; Linda.Mclvor@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 Mclvor, MHS, MS, Program Manager, QUERI (10P9H) (202) 443-5740; Linda.Mclvor@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:	Development of a Person-Centered Web-Based Weight Management Informational Resource for Persons with SCI based on Patient and Provider Feedback; W81XWH-20-SCIRP-EA SC200208; LaVela (PI)
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Effort:	3.6 calendar
Supporting Agency:	Department of Defense
Grants Officer:	Mark Wilkison 301-619-9883; mark.d.wilkison.civ@mail.mil
Performance Period:	09/01/2021 – 09/30/2024
Funding Amount	
Project Goals:	The goal of this project is to develop and evaluate a person-based, user-centered website to facilitate weight management in people with SCI.

Title:	Addressing Social Isolation through Online, Enjoyable, Adaptive Physical Activity; LaVela (PI)
Effort:	1.2 calendar
Supporting Agency:	Christopher & Dana Reeve Foundation
Grants Officer:	Not Assigned
Performance Period:	01/01/2021-12/31/2021
Funding Amount	
Project Goals:	To create a professionally produced high quality series of online adaptive physical activity videos for individuals with SCI and caregivers/family to both encourage physical activity and reduce social isolation through creative, fun, group and dyad physical activity participation during the pandemic and beyond.

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:	10/01/2021-9/30/2025
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.

OVERLAP

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

Stefania Fatone, PhD

Fatone Previous/Current/Pending Support

There is no overlap between current/pending support and the requested support.

Previous Support (last 5 years) Title:	Development of Sub-Ischial Prosthetic Sockets with Assisted-Vacuum Suspension for Highly Active Persons with Transfemoral Amputations W81XWH-10-1-0744
Time commitments:	3.6 calendar months (Principal Investigator)
Supporting agency:	Department of Defense Peer Reviewed Orthopedic Research Program (PRORP) Technology Development Award
Name and address of the Funding Agency's Procuring Contracting/Grants Officer:	Vera Pollard USA Med Research ACQ Activity Fort Detrick MD 21702 Phone: (301) 619-7264 Email: vera.pollard@amedd.army.mil
Performance period:	September 15, 2010 to September 14, 2015
Level of funding:	
Brief description of the project's goals:	The objective of this proposal is to develop prosthetic socket technology that will maintain residual limb volume; improve active range of motion of the hip; and increase comfort during sitting, standing, walking, and running in highly active transfemoral prosthesis users, allowing users to be more active.

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: Sam Mombou

Pending Support – None