

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

REPORT DATE: Oct 2019

TYPE OF REPORT: Annual

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

**DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited**

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE October 2019		2. REPORT TYPE Annual		3. DATES COVERED 30 Sep 2018-29 Sep 2019	
4. TITLE AND SUBTITLE Enhancing Quality of Orthotic Services with Process and Outcome Information				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-16-1-0788	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Allen Heinemann- Principal Investigator E-Mail: aheinemann@sralab.org				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				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 Stroke, Paralysis, Neurological, Braces, Orthosis, Orthoses, Trauma, Cerebrovascular, Stability, Gait, Balance, Postural					
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	94	19b. TELEPHONE NUMBER (include area code)

TABLE OF CONTENTS

Page

1. Introduction	
2. Keywords	
3. Accomplishments.....	
4. Impact.....	
5. Changes/Problems.....	
6. Products.....	
7. Participants & Other Collaborating Organizations.....	
8. Special Reporting Requirements.....	
Appendices.....	

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) **50% 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)

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)

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 **48** 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 is currently being revised for submission to the *Archives of Physical Medicine and Rehabilitation*.

- 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 submitted a revision to Am J Phys Med & Rehab August 2nd.

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.

How were the results disseminated to communities of interest?

- We presented preliminary study findings at two meetings during the past project year, as described above.

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 previous 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. Currently the project is behind by **12 months**.

Changes that had a significant impact on expenditures

- None.

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

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: None
Nearest person month worked: 2.24
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 Assistant
Research Identifier: None
Nearest person month worked: 3.23
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: 1.61
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: None
Nearest person month worked: 2.01
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: Emily Anderson
Project Role: Project Manager
Research Identifier: None

Nearest person month worked: 3.71
Contribution to Project: Ms. Anderson supervised support staff, assisted with IRB modifications, and assisted with data interpretation.
Funding Support: None

Name: Anna Hindelang
Project Role: Physical Therapist
Research Identifier: None
Nearest person month worked: 1
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: Ontonio Jackson Lucas
Project Role: Research Assistant
Research Identifier: None
Nearest person month worked: 3.64
Contribution to Project: Mr. Jackson- Lucas assisted with recruitment and enrollment of research participants and data collection.
Funding Support: None

Name: Nicholas McCombs
Project Role: Research Assistant
Research Identifier: None
Nearest person month worked: 5.69
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: Nicole Solyts
Project Role: Co-Investigator
Research Identifier: None
Nearest person month worked: 1
Contribution to Project: Ms. Solyts 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: 4.8
Contribution to Project: Mr. Semik works on data and statistical analysis for this project.

Funding Support: None

Name: Jamal Spraggins
Project Role: Research Assistant
Research Identifier: None

Nearest person month worked: 5.52

Contribution to Project: Mr. Spraggins recruited physical therapists for a focus group; coded transcripts; assisted with the development of quality themes; scheduled an advisory board meeting and created a demographics table for the focus group manuscript.

Funding Support: None

Northwestern University

Name: Stefania Fatone
Project Role: Subsite PI
Researcher Identifier: None

Nearest person month worked: 2.37

Contribution to Project: Collaborate with project PI especially in terms of study development, project management, orthotic management expertise, and data interpretation.

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: 1.8

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
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

Previous

Title:	Clinical Adaption of the SCI-QOL Psychosocial Measures
Effort:	.6 CM
Supporting Agency:	Craig H. Neilsen Foundation 367686 (Kisala)
Grants Officer:	Angela Alcaraz University of Delaware 210 Hullihen Hall Newark, DE 19716

Performance Period:	4/30/16-4/30/19
Funding Amount	\$297,000
Project Goals/Aims:	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. Methods

Title:	Texas TBI Model System of TIRR
Effort:	.1 CM
Supporting Agency:	NIDILRR, 90DP0028, Memorial Hermann Health System (Sherer)
Grants Officer:	Jerry Ashworth TIRR Memorial Hermann Research Center 1333 Moursund Street Houston, TX 77030
Performance Period:	9/30/17-3/31/19
Funding Amount	\$7,449
Project Goals/Aims:	Provide statistical analyses as needed for the project

Title:	Midwest Regional Spinal Cord Injury Care System
Effort:	.24 CM
Supporting Agency:	NIDILRR- 90SI5009-02-00 (Chen/Heinemann)
Grants Officer:	Dr. Kenneth Wood 330 C Street SW, 2511B Administration for Community Living Washington, DC 20201
Performance Period:	10/1/11-9/29/17
Funding Amount	\$2,414,304

Project Goals/Aims:	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.
---------------------	---

Title:	Northwestern University Patient-centered intervention and Engagement Training
Effort:	.24 CM
Supporting Agency:	AHRQ 5K12HS023011-01 (Cella)
Grants Officer:	Tylor Carl Office for Sponsored Research Northwestern University 750 N. Lake Shore Dr. 7th Floor Chicago, IL 60611
Performance Period:	9/1/14-7/31/17
Funding Amount	\$25,000
Project Goals/Aims:	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.

Title:	Patient Centered Outcomes Research Institute (PCORI)
Effort:	.6 CM
Supporting Agency:	CD-12-11-4201
Grants Officer:	Scott Solomon Director of Contracts Management and Administration Patient Centered Outcomes Research Institute (PCORI)

	1828 L Street NW. Suite 900 Washington, DC 20036
Performance Period:	9/01/13-7/31/17
Funding Amount	\$1,093,781
Project Goals/Aims:	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.

Title:	RRTC Program: Improving Measurement of Medical Rehabilitation Outcomes
Effort:	1.8 CM
Supporting Agency:	NIDILRR 90RT5008-01-02
Grants Officer:	Dawn Carlson Project Manager One Massachusetts Ave. Administration for Community Living Washington, DC 20201-1401
Performance Period:	10/1/09-9/29/16
Funding Amount	\$4,250,000
Project Goals/Aims:	The goal of this project is to conduct research and training projects related to measurement of rehabilitation outcomes. Specific Aims: 1. Improve measures of cognitive function for use across post-acute settings so that consumers' needs are documented and rehabilitation clinicians can deliver optimally effective services. 2. Evaluate, develop and refine measures of participation barriers and facilitators in a meaningful, reliable and valid manner in order to better capture the long-term outcomes of rehabilitation services. 3. Increase the efficiency of outcome data collection so as to reduce patient burden and measure performance effectively using IRT and CAT methods 4. Utilize the large set of data in validating the CARE Tool and evaluate the extent to which the ICF represents disablement characteristics.

Title:	Development of an extended measure of global function to support clinical trials originating in acute Rehabilitation
--------	--

Effort:	.06 CM
Supporting Agency:	Craig Hospital
Grants Officer:	Cynthia Harrison-Felix Director of Research Craig Hospital 3425 S. Clarkson Street Englewood, Colorado 80113
Performance Period:	11/1/14-9/30/16
Funding Amount	\$10,600
Project Goals/Aims:	Specific Aims: 1. To identify a combination of a small number of outcome measures (or items therefrom) whose items span a range suitable for clinical trials originating in acute rehabilitation (i.e., including patients with disorders of consciousness), and continuing to at least 1-year post-injury (i.e., capable of measuring neuro-cognitive functioning beyond the range of the FIM and with greater precision than the GOS-E or DRS). 2. To gather preliminary data on longitudinal recovery over the first year, using this derived outcome measure, in order to assess its performance and predictive validity. 3. To identify multiple alternative behaviors of comparable difficulty level that mark the boundary between the minimally conscious state (MCS) and higher levels of functioning.

Title:	Improving Psychosocial Outcomes following SCI/D with Measurement Resources
Effort:	.12 CM
Supporting Agency:	Paralyzed Veterans Association PVA/739
Grants Officer:	Marietta Jimmerson Manager, Grants Portfolio Paralyzed Veterans of America Research & Education Department 801 18 th Street, NW Washington, DC 20006
Performance Period:	6/1/14-5/31/15
Funding Amount	\$45,000
Project Goals/Aims:	The goal of this project was to develop instrument measurement summaries for the Rehabilitation Measures Database and provide training to clinicians on outcomes measurement Specific Aims

	1. Develop collaborations with university graduate and undergraduate programs that train health care professionals in six disciplines: Rehabilitation psychology, rehabilitation counseling, recreation therapy, nursing, occupational therapy, and social work and enhance teaching materials on outcomes measurement to apply to psychosocial issues, 2. Enhance the Rehabilitation Measures Database (RMD) by adding instrument summaries that focus on psychosocial, quality of life, and employment issues of persons with spinal cord injury/disease (SCI/D), and 3. Provide online outcome measurement education for clinicians who treat persons with SCI/D, focusing on psychosocial and employment issues.
--	--

Title:	Intergovernmental Personnel Assignment (IPA)
Effort:	.36 CM
Supporting Agency:	Jesse Brown VA Medical Center 537/151
Grants Officer:	Wendy Weinstock Brown, MD, MPH, Chief of Staff Jesse Brown VA Medical Center 820 South Damen Avenue Chicago, IL 60612
Performance Period:	10/1/15-9/30/16
Funding Amount	\$8,737
Project Goals/Aims:	The goal of this project is solely to support Dr. Heinemann's research effort on a project led by Martin Major, PhD.

Title:	Improving Psychosocial Outcomes following SCI/D with Measurement Resources
Effort:	.12 CM
Supporting Agency:	Paralyzed Veterans Association PVA 739 (Ehrlich-Jones)
Grants Officer:	Marietta Jimmerson Manager, Grants Portfolio Paralyzed Veterans of America Research & Education Department 801 18 th Street, NW Washington, DC 20006
Performance Period:	6/1/14-5/31/15
Funding Amount	\$45,000

Project Goals/Aims:	The goal of this project was to develop instrument measurement summaries for the Rehabilitation Measures Database and provide training to clinicians on outcomes measurement Specific Aims 1. Develop collaborations with university graduate and undergraduate programs that train health care professionals in six disciplines: Rehabilitation psychology, rehabilitation counseling, recreation therapy, nursing, occupational therapy, and social work and enhance teaching materials on outcomes measurement to apply to psychosocial issues, 2. Enhance the Rehabilitation Measures Database (RMD) by adding instrument summaries that focus on psychosocial, quality of life, and employment issues of persons with spinal cord injury/disease (SCI/D), and 3. Provide online outcome measurement education for clinicians who treat persons with SCI/D, focusing on psychosocial and employment issues.
---------------------	---

Title:	Center for Rehabilitation Research Using Large Dataset
Effort:	.6 CM
Supporting Agency:	NIH R24HD06570 (Deutsch)
Grants Officer:	Karen Myers Office of Sponsored Programs The University of Texas Medical Branch at Galveston 301 University Boulevard Galveston, TX 77555-0156
Performance Period:	7/1/10-5/31/15
Funding Amount	\$281,017
Project Goals/Aims:	The goal of this project is to provide mentoring services to scientists seeking to improve knowledge of how to use large datasets

Title:	The Role of the Built Environment in Quality of Life for Adults with SCI
Effort:	.6 CM
Supporting Agency:	Kessler Foundation -290518 (Botticello)
Grants Officer:	Matthew R. Weiner Manager Grants Administration 1199 Pleasant Valley Way West Orange, New Jersey 07052
Performance Period:	4/1/14-3/31/16

Funding Amount	\$38,995
Project Goals/Aims:	The goal of this project is evaluate the influence of the built environment on quality of life after SCI.

Title:	Developing outcomes data management and reporting capacity for musculoskeletal rehabilitation programs
Effort:	.6 CM
Supporting Agency:	Northwestern University, Foundation for Physical Medicine & Rehabilitation
Grants Officer:	
Performance Period:	10/1/13-9/30/14
Funding Amount	\$30,000
Project Goals/Aims:	This project describes measures that are suitable to measuring outcomes of programs serving patients with lumbar spinal stenosis

Title:	Enhancing Quality of Prosthetic and Orthotic Services with Process and Outcomes information. A research project of the Rehabilitation Engineering Research Center for Prosthetics and Orthotics
Effort:	.36 CM
Supporting Agency:	NIDILRR H133E0800009 (Gard/Fatone)
Grants Officer:	Sally Gale Assistant Grant & Contract Officer Office for Sponsored Research 750 N. Lake Shore Drive Rubloff Building, 7 th Floor Chicago, IL 60611
Performance Period:	10/1/08-9/30/13
Funding Amount	\$188,233
Project Goals/Aims:	The goal of this project is to evaluate the benefits of quality improvement consultation and data management services to prosthetics providers.

Title:	Development of Quality Measures for Post-Stroke Rehabilitation
Effort:	2.4 CM
Supporting Agency:	NIDILRR H133G1001825 (Deutsch)
Grants Officer:	Pimjai Sudsawad U.S. Department of Education 400 Maryland Avenue, SW

	Washington, DC 20202
Performance Period:	10/1/10-9/30/13
Funding Amount	\$575,415
Project Goals/Aims:	The goal of this project was to identify quality measures appropriate for rehabilitation patients recovering from a stroke that meet the criteria established by the leading organization that endorses measures, the National Quality Forum. Specific Aims: 1. Identify candidate quality measures for post-stroke rehabilitation that are currently used or endorsed for use; 2. Evaluate the importance, scientific acceptability, usability and feasibility of candidate quality measures using National Quality Forum criteria; 3. Disseminate quality measures to stakeholders including the Centers for Medicare and Medicaid Services, private payers, and consumer organizations.

Title:	Challenging Disparities in Access to Innovation in Spinal Cord Injury Care: Midwest Regional Spinal Cord Injury Care System
Effort:	1.2 CM
Supporting Agency:	NIDILRR H133N060014 (Chen/Heinemann)
Grants Officer:	Kenneth D. Wood U.S. Department of Education 400 Maryland Avenue, SW Washington, DC 20202
Performance Period:	10/1/06-9/30/12
Funding Amount	\$2,401,330
Project Goals/Aims:	The purpose of our Model System Program is to conduct sound, well-designed research on innovative treatment strategies and spinal cord injury (SCI) outcomes of underrepresented populations that will lead to improved outcomes for all persons with SCI, and to provide a multi-disciplinary, coordinated system of care to meet the specialized needs of persons with SCI Specific Aims: Aim 1: Development and assessment of non-motorized (spring-loaded) devices to assist leg swing and forward propulsion during step training in people with iSCI. Aim 2: Assessment of short (2a) - and long (2b)-term adaptations to step training using non-motorized limb swing or propulsive assistance during treadmill walking. Aim 3: Implementation of low cost devices in the clinic to enhance delivery of high intensity.

Title:	Midwest Regional Traumatic Brain Injury Model System: Innovative Approaches to Improve Cognition, Function, and Community Living.
Effort:	.6 CM
Supporting Agency:	NIDILRR H133A080045 (Roth)
Grants Officer:	Kenneth D. Wood U.S. Department of Education 400 Maryland Avenue, SW Washington, DC 20202
Performance Period:	10/1/08-9/30/12
Funding Amount	\$1,673,205
Project Goals/Aims:	The goal of this project was to contribute to the TBI Model Systems Database, conduct site-specific and collaborative research projects

Title:	Functional Needs Assessment in Persons with SCI
Effort:	.6 CM
Supporting Agency:	VA69D-15-0107 (LaVela)
Grants Officer:	Sherri L. LaVela Director, CEPEP Hines VA Hospital 5000 S. Fifth Avenue Hines, IL 60141
Performance Period:	12/1/14-11/30/15
Funding Amount	\$25,000
Project Goals/Aims:	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. Specific Aims: 1. Conduct a functional needs assessment to collect quantitative data using tools validated for use in populations with SCI/D. 2. Utilize photovoice to empower individuals with SCI/D to convey their experiences, perspectives and needs with regard to functional challenges/impacts through visual images and first person narrative.

Current

Title:	Implementing SCI-QOL into Clinical Practice to Enhance Patient Engagement
Effort:	.12 CM
Supporting Agency:	Craig H. Neilson Foundation

Grants Officer:	Kim Cerise Craig H. Neilson Foundation 16830 Ventura Blvd., Suite 352 Encino, CA 81436
Performance Period:	5/1/16-4/30/20
Funding Amount	\$300,000
Project Goals/Aims:	This application adapts and evaluates implementation strategies designed to promote routine use of PROs in SCI 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.

Title:	Enhancing quality of orthotic services with process and outcome information
Effort:	1.8 CM
Supporting Agency:	Department of Defense, W81XWH-16-01-0788
Grants Officer:	Elena G. Howell, Grants Officer USA Med Research ACQ Activity 820 Chandler St. Fort Detrick, MS 21702
Performance Period:	9/30/16-9/29/20
Funding Amount	\$1,590.406
Project Goals/Aims:	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.

Title:	Evaluating the Utilization and Efficiency of Wearable Exoskeletons for SCI Rehabilitation
--------	---

Effort:	1.62 CM
Supporting Agency:	Department of Defense, W81XWH-17-1-0157
Grants Officer:	Amber Stillrich, Grant Officer USA Med Research, ACQ Activity 820 Chandler Street Fort Detrick, MS 21702
Performance Period:	9/1/17-8/31/20
Funding Amount	\$709,197
Project Goals:	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.

Title:	Advanced Rehabilitation Research Training in Health Services Research
Effort:	.6 CM
Supporting Agency:	NIDILRR, 90ARP0001-01-00
Grants Officer:	Dr. Sarah Ruiz Switzer Building 310 C Street, SW Washington, DC 20230
Performance Period:	9/30/17-9/29/22
Funding Amount	\$150,000
Project Goals/Aims:	The goal of this project is to provide an integrated, interdisciplinary, collaborative training program for early career scholars focusing on rehabilitation-related health services research. Health services faculty work closely with fellows to provide a rigorous and relevant interdisciplinary curriculum, integrating faculty and programs from diverse departments and centers into a unified health services research training Through this program, six post-doctoral fellows will develop new skills to enhance their previous training in order to pursue a research career in rehabilitation-related health

	services research. Program includes carefully matched mentors, didactic course work, original research, grant writing, and scientific publishing over a two-year period.
--	--

Title:	The Midwest Regional Spinal Cord Injury Model System
Effort:	2.22 CM
Supporting Agency:	NIDILRR, 90SI5022-04-00
Grants Officer:	Dr. Kenneth Wood 330 C Street SW, 2511B Administration for Community Living Washington, DC 20201
Performance Period:	9/30/16-9/29/21
Funding Amount	\$1,917,928
Project Goals/Aims:	The goal of this project is to investigate the effect of dAIH alone and in combination with high-intensity task-specific training on upper extremity function in individual with chronic incomplete cervical SCI. Specific Aims: 1. Quantify the effects of dAIH therapy on hand and arms strength, and hand dexterity in persons with incomplete tetraplegia. 2. Evaluate the benefits of combined dAIH therapy and high-repetition task-specific upper extremity training on arm and hand strength, and hand dexterity in persons with tetraplegia.

Title:	Rehabilitation Research Training Center (RRTC) on employment for people with physical disabilities
Effort:	2.88 CM
Supporting Agency:	NIDILRR, 90RTEM0001-02-01
Grants Officer:	Dr. Amanda Reichard Switzer Building 330 C Street, SW Washington, DC 20201-1401
Performance Period:	9/30/18-9/29/23
Funding Amount	\$3,113,766
Project Goals/Aims:	The goals of this Center are to conduct an 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; assess employer-, client-, job-, and environment-related barriers and facilitators of job retention after VR; evaluate an implementation science approach to employment interventions in people with Parkinson's disease; and 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
--	---

Title:	A Multi-Center Clinical Trial to Evaluate the Effectiveness of Intermittent Hypoxia Therapy in Individuals with Spinal Cord Injury
Effort:	.12 CM
Supporting Agency:	NIDILRR, 90SIM0001-03-01 (Rymer)
Grants Officer:	Dr.Kenneth Wood 355 E Erie St 330 C Street SW, 2511B Chicago. IL 60611-3167 Administration for Community Living Washington, DC 20201
Performance Period:	9/30/17-9/26/22
Funding Amount	\$4,499,458
Project Goals/Aims:	The goal of this project is to conduct an RCT that evaluates the effectiveness of intermittent hypoxia to enhance hand function after SCI.

Title:	A Multi-Center Clinical Trial to Evaluate the Effectiveness of Intermittent Perspective and Preferences for Weight Management After Spinal Cord Injury
Effort:	.3 CM
Supporting Agency:	W81XWH-17-1-0678 (LaVela)
Grants Officer:	
Performance Period:	9/30/17-9/29/20
Funding Amount	\$49,430
Project Goals/Aims:	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); 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; and assess the feasibility of the educational tool for use with persons with SCI in health settings

Title:	Personalized Mobility Interventions using Smart Sensor Resources for Lower-limb Prostheses Users
Effort:	.3 CM
Supporting Agency:	DOD W81XWH-18-2-0057 (Jayaraman)
Grants Officer:	Ebony S. Simmons FORT DETRICK - CDMRP

	1120 FORT DETRICK FREDERICK MD 21702
Performance Period:	9/30/18-9/29/22
Funding Amount	\$2,440,168
Project Goals/Aims:	Loss of the lower limb is the most common major amputation in active duty Service Members as a result of combat-related injury and in civilian and Veteran populations, largely as a consequence of dysvascular disease. Aim: 1 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) Aim 2: Quantify effects of targeted physical intervention (prosthesis repair/refit, physical rehabilitation) or psychological intervention (motivational interviewing), or both, on activity levels and patient goals Aim 3 Identify measure(s) that sensitively predict prosthesis use to create a clinically deployable toolkit to evaluate and optimize prosthesis use in the community.

Title:	Sensor Technology Applied to Rehabilitation in Stroke - STARS
Effort:	.36 CM
Supporting Agency:	NIDILRR 90REGE0010-01-00 (Rymer)
Grants Officer:	Mr. Thomas Corfman 330 C St. SW Administration for Community Living Washington, DC 20201-1401
Performance Period:	9/30/19-9/29/24
Funding Amount	\$1,849,479
Project Goals/Aims:	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. Our central hypothesis is that the measures of function currently used to evaluate progress in rehabilitation are insufficiently precise, and do not allow physicians and therapists to characterize and understand the sources of impairment that lead to loss of function. We will test this hypothesis by first designing, developing, and testing sensors suitable for measurement of impairment in stroke survivors, followed by studies to determine the feasibility of implementing these devices in routine clinical practice.

Title:	Defining Trajectories of Linguistic, Cognitive-Communicative and Quality of Life Outcomes in Aphasia
Effort:	.96 CM

Supporting Agency:	NIH 1R01DC017174 (Cherney/Heinemann)
Grants Officer:	Judith Cooper National Institute on Deafness and Other Communication Disorders National Institute of Health Washington, DC
Performance Period:	9/30/19-9/29/24
Funding Amount	\$2,569,372
Project Goals/Aims:	Aim 1: Establish 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. Aim 2: Identify factors that are associated with linguistic, cognitive-communicative, and health-related QoL out-comes from among the following: patient factors including demographic and clinical characteristics related to stroke and aphasia; treatment variables including inpatient and outpatient aphasia therapy characteristics and informal aphasia services; and biomarkers, including genetic and neuroimaging biomarkers. Aim 3: Evaluate the stability of the models of linguistic, cognitive-communicative, and health-related QoL out-comes recovery that are developed from Aims 1 and 2.

Pending

None

Sherri LaVela, PhD

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

CURRENT, PREVIOUS, & PENDING SUPPPORT

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	\$751,910
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 – 06/30/2022
Funding Amount	\$1,046,783
Project Goals:	The goal is to identify risk factors for community-acquired pressure ulcers in persons with SCI and to implement prevention efforts.

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	\$43,994
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:	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 – 09/30/2020
Funding Amount	\$569,840
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 – 09/29/2020
Funding Amount	\$600,000
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:	Engaging Patients and Providers in Identifying and Addressing Modifiable Risk Factors to Prevent Community-Acquired Ulcers in Veterans with SCI (IIR 16-267)
Effort:	1.8 calendar
Supporting Agency:	Department of Veterans Affairs
Grants Officer:	
Performance Period:	07/01/2018 – 06/30/2022
Funding Amount	\$1,046,783
Project Goals:	The major goal of this project is to understand modifiable risk factors for community-acquired pressure ulcers in Veterans with spinal cord injuries.

PREVIOUS

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	\$49,705
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	\$150,000
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	\$200,000
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	\$5,919,826
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	\$324,448

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	\$147,000
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	\$100,000
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	\$100,000
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	\$995,348
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	\$150,000
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	\$102,000
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

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: \$2,099,865

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.

Title: Evaluating outcomes of dysvascular partial foot and transtibial amputation: a systematic review and development of shared decision making resources

Time commitments: 0.6 calendar months (Co-Investigator)

Supporting agency: American Orthotic and Prosthetic Association

Name and address of the Funding Agency's Procuring Contracting/Grants Officer: Thomas F. Fise, Executive Director
330 John Carlyle Street, Suite 200, Alexandria, VA 22314
P: 571-431-0802 F: 571-431-0899
tfise@AOPAnet.org

Performance period: August 1, 2015 to July 31, 2017

Level of funding: \$59,005

Brief description of the project's goals: 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.

Title: Effect of myoelectric custom orthosis on upper limb function

Time commitments: 2.4 calendar months (Principal Investigator)

Supporting agency: Myomo Inc.

Name and address of the
Funding Agency's
Procuring
Contracting/Grants Officer: Steve Kelly
President & COO
Myomo, Inc
One Broadway, 14th floor
Cambridge MA 02142
617.444.9661

Performance period: January 20, 2013 to January 20, 2016

Level of funding: \$144,000

Brief description of the
project's goals: The purpose of this project is to evaluate the functional benefits of a myoelectric custom orthosis for persons with upper limb impairments using a cross-sectional repeated measures study that combines both patient-reported and quantitative outcome measures.

Title: Rehabilitation Engineering Research Center for Prosthetics & Orthotics
H133E080009

Time commitments: 4.2 calendar months (Co-Principal Investigator)

Supporting agency: National Institute on Disability and Rehabilitation Research

Name and address of the
Funding Agency's
Procuring
Contracting/Grants Officer: Thomas Corfman
Rehabilitation Engineer
Rehabilitation Program Specialist
U.S. Department of Education
National Institute on Disability and Rehabilitation Research (NIDRR)
550 12th Street, SW
Washington, DC 20202-2700
Phone: (202) 245-7306
Fax: (202) 245-7643
Email: Thomas.Corfman@ed.gov

Performance period: October 1, 2008 to September 30, 2014

Level of funding: \$4,749,995

Brief description of the
project's goals: This program is the NIDRR Rehabilitation Engineering Research Center for prosthetics and orthotics. We proposed five development projects and seven research projects, with emphasis on the training and education of graduate students.

Title: Pilot Study: Effect of Two Orthotic Approaches to Ankle Motion Restriction on Activity Level, Balance and Patient Satisfaction in Children with Cerebral Palsy

Time commitments: 0.12 calendar months (Co-Investigator)

Supporting agency: Ultraflex Systems Inc.

Name and address of the Funding Agency's Procuring Contracting/Grants Officer: Mark DeHarde
Ultraflex Systems, Inc.
237 South Street, Suite 200
Pottstown PA 19464
Phone: (610) 906-1410
Fax: (610) 906-1420
Email: mdeharde@ultraflexsystems.com

Performance period: January 8, 2012 to August 31, 2014

Level of funding: \$35,000

Brief description of the project's goals: The purpose of this project is to evaluate whether the approach to orthotic management and degree of ankle motion restriction affect activity level, balance and satisfaction in children with CP.

Title: iGRAB: Innovative Glove for Rehabilitation and Assistance using Biomimicry (Phase II SBIR)

Time commitments: 1.08 calendar months (Subcontract PI)

Supporting agency: Defense Health Program

Name and address of the Funding Agency's Procuring Contracting/Grants Officer: Stephanie P. Davis
SBIR Admin Coordinator
USAMRAA
Phone: 301-619-2797
stephanie.p.davis12.civ@mail.mil

Performance period: January 1, 2016 to March 31, 2019

Level of funding: \$198,097 (NU subcontract)

Brief description of the project's goals: 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.

Title: Functional Assistance provided by Myoelectric Elbow-wrist-hand orthoses (FAME)

Time commitments: 0.60 calendar months (Co-Principal Investigator)

Supporting agency: Myomo Inc.

Name and address of the Funding Agency's Procuring Contracting/Grants Officer: Sam Kesner, PhD
Dir. of Research and Advanced Development
Myomo, Inc.
One Broadway, 14th Floor
Cambridge, MA, 02142
617-564-1334

Performance period: June 1, 2017 to Dec 31, 2018

Level of funding: \$112,407

Brief description of the project's goals: 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 extremity dysfunction.

Title: Interface Monitoring System to Promote Residual Limb Health R01EB019337

Time commitments: 1.2 calendar months (Co-Principal Investigator)

Supporting agency: NIH

Name and address of the Funding Agency's Procuring Contracting/Grants Officer: Grace C.Y. Peng, Ph.D.
Director, NIBIB Modeling, Simulation and Analysis Programs
Director, NIBIB Next Generation Engineering Systems Program
Chair, Interagency Modeling and Analysis Group (IMAG)
6707 Democracy Blvd, Ste 200,
Bethesda, MD 20892
301-451-4778
penggr@mail.nih.gov

Performance period: September 22, 2014 to May 31, 2019

Level of funding: \$1,480,303

Brief description of the project's goals:	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.
---	--

Current Support

Title:	Functional Performance Evaluation of the Northwestern University Flexible Subischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation
Time commitments:	1.86 calendar months (Principal Investigator)
Supporting agency:	Department of Defense Peer Reviewed Orthopaedic Research Program
Name and address of the Funding Agency's Procuring Contracting/Grants Officer:	Elvera M. Messina Grants Officer US Army Medical Research Acquisition Activity 820 Chandler Street Fort Detrick MD 21702-5014
Performance period:	September 30, 2015 to September 29, 2020
Level of funding:	\$1,326,755
Brief description of the project's goals:	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.

Title:	Longitudinal Observation of Myoelectric Upper Limb Orthosis Use among Veterans with Upper Limb Impairment
Time commitments:	1.15 calendar months (Principal Investigator)
Supporting agency:	Orthotics and Prosthetics Outcomes Research Program (OPORP) Orthotics Outcomes Research Award (OORA)
Name and address of the Funding Agency's Procuring Contracting/Grants Officer:	Elena G. Howell Tel: 301-619-6871 Email: elena.g.howell.civ@mail.mil

Performance period:	September 30, 2016 to September 29, 2020
Level of funding:	\$500,000
Brief description of the project's goals:	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.
Title:	Enhancing Quality of Orthotic Services with Process and Outcome Information
Time commitments:	2.38 calendar months (Co-Investigator)
Supporting agency:	Orthotics and Prosthetics Outcomes Research Program (OPORP) Orthotics Outcomes Research Award (OORA)
Name and address of the Funding Agency's Procuring Contracting/Grants Officer:	Elena G. Howell Grants Officer Department of the Army US Army Medical Research Acquisition Activity 820 Chandler Street Fort Detrick MD 21702-5014
Performance period:	September 30, 2016 to September 29, 2019 (NCE Requested)
Level of funding:	\$99,167 (NU Subcontract)
Brief description of the project's goals:	The objective of this application is to develop data modules that can be used to improve the quality of services for AFO users.
Title:	No longer smooth: introducing striations into prosthetic socket construction to improve suspension, rotation, fit and comfort
Time commitments:	1.75 calendar months (Principal Investigator)
Supporting agency:	CDMRP NMSIRA
Name and address of the Funding Agency's Procuring Contracting/Grants 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 Email: sandra.rosario2.civ@mail.mil.
Performance period:	September 30, 2016 to September 29, 2019 (NCE Requested)

Level of funding:	\$674,666
Brief description of the project's goals:	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.
Title:	Effect of Ankle-Foot Orthoses (AFOs) on Continuous Walking in Persons with Post- Stroke Hemiplegia
Time commitments:	0.6 calendar months (Principal Investigator)
Supporting agency:	American Orthotic and Prosthetic Association
Performance period:	2/1/2019 – 1/31/2020
Level of funding:	\$74,966
Brief description of the project's goals:	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.
Title:	Biomechanics and Walking in Cerebral Palsy: Ankle Foot Orthoses – Footwear Combinations
Time commitments:	0.18 calendar months (Consultant)
Supporting agency:	NIH
Performance period:	9/1/18 – 8/31/20
Level of funding:	\$8,221 (NU Subaward)
Brief description of the project's goals:	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.

Pending Support

Title:	Hybrid Electrical-Mechanical Pump for Vacuum Suspension of Prosthetic Sockets
Time commitments:	0.72 calendar months (Co-Investigator)
Supporting agency:	VA
Performance period:	11/1/18 – 10/31/21
Level of funding:	\$734,710
Brief description of the project's goals:	The purpose of this project is to further design and evaluate the HIPPI system and enhance commercial-viability to attract industry partners to then generate a market-ready device through future collaborative efforts.
Title:	The influence of 3D printed prostheses on neural activation patterns of the primary motor cortex in children with unilateral congenital upper-limb reductions
Time commitments:	2.88 calendar months (Co-Investigator)
Supporting agency:	NIH
Performance period:	4/1/19 – 3/31/24
Level of funding:	\$35,830
Brief description of the project's goals:	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.
Title:	A Pilot Clinical Trial to Assess the Effect of Transfemoral Socket Design on Hip Muscle Function
Time commitments:	0.6 calendar months (Co-I)
Supporting agency:	DOD OPORP
Performance period:	9/1/2019 – 8/31/2021
Level of funding:	\$68,536
Brief description of the project's goals:	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.

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: 10/1/2016-9/30/20 (extended 1 year)

Level of Funding: \$ 183,679.42

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

Name and address of funding agency's Contracting/Grants Officer: Robin Millard

Pending Support – None