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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.

15. SUBJECT TERMS

NONE LISTED

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1. INTRODUCTION:

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

2. KEYWORDS:

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

3. ACCOMPLISHMENTS:

What were the major goals of the project?

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

Task 1.1 Prepare for and convene an Advisory Committee that represents multiple stakeholders to identify important issues in the quality of care for AFO users.
Milestone: Identification of important issues in the quality of care for AFO users (Months 1-6); **100% complete**

Task 1.2 Identify items and instruments that operationalize important quality of care concepts for AFO practice
Milestone: Identification of items and instruments that operationalize important quality of care concepts for AFO practice (Months 1- 6); **100% complete**

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

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

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

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

Task 3.2 Prioritize and select the most compelling quality measures
Milestone: Priority list of quality measures (Months 25-27), **100% complete**

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)
100% complete

Task 3.4 Disseminate findings and promote knowledge translation
Milestone: Broad dissemination of study findings (Months 31-36) **95% complete**

*Prepare and submit quarterly and annual project reports to disseminate project findings.**100% complete**

*Disseminate project findings to Advisory Committee.
95% complete

* Prepare and submit publications and presentations to disseminate project findings. **90% complete**

What was accomplished under these goals?

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

Advisory Meetings held
- March 1, 2017 (in person)
- May 17, 2017 (teleconference call)
- August 30, 2017 (teleconference call)

Task 1.2 Identify items and instruments that operationalize important quality of care concepts for AFO practice. -Task: 100% complete

- We completed a systematic review of literature, using the expertise of a communications coordinator and a 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, *Identifying Instruments to Assess Care Quality for Individuals with Custom Ankle Foot Orthoses: A Scoping Review.* 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. - Task: 100% complete

- -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 Ankle-Foot Orthoses*, 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 - Task: 100% complete

- 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 case mix indicators. On September 24, 2018, we sent a final list of case mix adjusters to obtain 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 - Task: 100% complete

- 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 was built into a secure web application specifically designed for building and managing online surveys and databases (The REDCap survey information is provided in the Appendices section of this 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. - Task: 100% complete

- 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 were used to collect the data of AFO users. The measures were IRB approved on July 2, 2018, and were built into a REDCap survey. In order to assess and analyze the gait pattern of participants, we video recorded performing the GAIT assessment tool and the NHS screening tool to capture this data from the first 30 subjects in the current user group at SRAlab. Research staff at all sites were trained on how to administer the 6-minute walk test, 10-meter walk test and the timed up and go test. Additionally, each site 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 began recruiting and collecting data.
- As of 11/30/2022, there are 111 people enrolled in the study**.**
-

Task 3.1 Review results of Task 2.2 and recommend components of quality measures to the Advisory Committee - Task: 100% complete

Milestone: Quality measure components reported to Advisory Committee (Months 22-24)

An in-person Advisory Committee Meeting was held on March 4, 2020, to share quality measure components. The Advisors provided valuable input to guide the data analysis and dissemination plans for the study results.

Task 3.2 Prioritize and select the most compelling quality measures
Milestone: Priority list of quality measures (Months 25-27) - **Task: 100% complete**

Task: 100% complete

- With input from the advisory committee, clinician survey, focus groups with patients and clinicians, literature reviews and the research team, we have finalized a list of patient reported outcome measures that were used to collect the data of AFO users.
- Across all sites, we invited 210 new custom AFO users and 248 current users to participate in the study. We consented 37 participants receiving a new custom AFO (18%); 34 completed at least one visit (16%). We consented 74 current users (30%), 71 of whom completed at least one visit (29%).
- Results provide evidence of good to excellent test-retest reliability for components of the EQ-5D, OPUS, Rivermead Mobility Index, QUEST 2.0, and PROMIS short forms. Clinicians may consider these PROMs for evaluating the benefits of custom AFOs and PREMs for evaluating patients' experiences with orthotic devices.

Task 3.3 Design the specifications for data collection and obtain usability and feasibility feedback from the Advisory Committee - Task: 100% complete
Milestone: Design specifications for a clinical interface (Months 28-30)

Task: 100% complete

An in-person Advisory Committee Meeting was held on March 4, 2020, to share quality measure components. The Advisors provided valuable input to guide the data analysis and dissemination plans for the study results. We worked with Northwestern University's Statistical Analysis Center for final project data analysis.

Task 3.4 Disseminate findings and promote knowledge translation

*Prepare and submit quarterly and annual project reports to disseminate project findings.

100% complete

Report	Submitted	Report	Submitted
Year 1 Quarter 1	1/14/2017	Year 2 Annual	10/25/2018
Year 1 Quarter 2	4/14/2017	Year 3 Quarter 1	1/14/2019
Year 1 Quarter 3	7/15/2017	Year 3 Quarter 2	4/10/2019
Year 1 Annual	10/27/2017	Year 3 Quarter 3	7/10/2019
Year 2 Quarter 1	1/13/2018	Year 3 Annual	10/29/2019
Year 2 Quarter 2	4/13/2018	Year 4 Quarter 1	1/10/2020
Year 2 Quarter 3	7/14/2018	Year 4 Quarter 2	4/13/2020

Year 4 Quarter 3	7/13/2020	Year 5 Annual	10/29/2021
Year 4 Annual	10/29/2020	Year 6 Quarter 1	1/14/2022
Year 5 Quarter 1	1/14/2021	Year 6 Quarter 2	4/14/2022
Year 5 Quarter 2	4/14/2021	Year 6 Quarter 3	7/15/2022
Year 5 Quarter 3	7/15/2021	Year 6 Final (current)	1/27/2023

*Disseminate project findings to Advisory Committee. **95% complete**
The final project manuscript(s) will be shared with the Advisory Committee upon publication.

* Prepare and submit publications and presentations to disseminate project findings. **90% complete**
Research findings have been disseminated through publications. Three manuscripts have been published and two more manuscripts are in development.

Publications:
Research findings have been disseminated through manuscripts and publications. Three manuscripts have been published and two more manuscripts are in development.

- ❖ Based on the results from the clinician survey, a paper, ***Orthotist and Physical Therapist Perspectives on Quality of Care Indicators for Custom Ankle-Foot Orthoses*** was developed.The manuscript was accepted and published online in the journal Assistive Technology on May 15th, 2019. DOI:10.1080/10400435.2019.1610814.
- A summary of this manuscript is provided here:
  Purpose: To describe the priorities of orthotists and physical therapists about quality measurement themes, and the feasibility and utility of collecting data from persons using custom AFOs that could inform quality measure development.
  Materials and Methods: Online survey assessed respondents' perspectives and experiences. An Advisory Committee representing professional, organizational, and accreditor groups distributed survey invitations.
  Results: 461 orthotists and 153 physical therapists completed part or all of the survey; 60% rated 9 quality themes and 20 quality of care topics as extremely important, and 12 standard instruments as feasible and good to use for quality measurement. Patients were the preferred source of information for ease of scheduling, device weight, ease of donning and doffing, adherence to device use, beneficial effects, activity level and independence, and quality of life. Clinicians were the preferred source for material quality, device modifiability, and joint range of motion. Facility records were the preferred source for timeliness of device delivery and clinician follow-up. Respondents reported that gait speed and walking endurance were best obtained by patient performance.
  Conclusions: Results provide insight on the topics orthotists and physical therapists regard as priorities for defining healthcare quality for persons using custom ankle-foot orthoses and instruments for data collection.

- ❖ Stemming from the completion of task 1.2 (Identify items and instruments that operationalize important quality of care concepts for AFO practice), a paper, ***Identifying Instruments to Assess Care Quality for Individuals with Custom Ankle Foot Orthoses: A Scoping Review*****,** was developed. The paper was submitted to the Archives of Physical Medicine and Rehabilitation and was

published in 2020 online and 2021. DOI:10.1016/j.apmr.2020.06.029, Archives of Physical Medicine and Rehabilitation 2021;102:709-34

- A summary of this manuscript is provided here:
  Objectives: We conducted 2 complementary scoping reviews to identify instruments that assess the experience and outcomes of custom ankle-foot orthosis (AFO) care in individuals with neurologic and traumatic conditions and to determine to what extent they might be psychometrically sound for AFO users. A stakeholder advisory committee considered to what extent the identified and psychometrically sound instruments might be feasible for use in developing quality measures for custom AFO users.
  Data Sources: Both scoping reviews were conducted using PubMed, the Cumulative Index to Nursing and Allied Health Literature, Embase, and Cochrane Systematic Reviews. The following were used for the first scoping review only: Cochrane Central Register of Controlled Trials and the Physiotherapy Evidence Database.
  Study Selection: The initial scoping review yielded 79 articles with 82 instruments, 16 of which were used in 4 or more studies. The second scoping review yielded 57 articles reporting psychometric properties.
  Data Extraction: Psychometric properties for populations who use AFOs were summarized for 15 of the 16 instruments. The advisory committee eliminated 2 instruments, noted overlap between 4 instruments in terms of the constructs measured, and suggested 6 potential contemporary substitutes.
  Data Synthesis: Most instruments assessed activity (specifically mobility) and pertained to the National Quality Forum domain of "Health-Related Quality of Life." The 10-meter walk test, 6-minute walk test, Berg Balance Scale, Timed Up and Go, and Rivermead Mobility Index were reported to have adequate reliability and validity and were considered feasible for administration in a clinical setting.
  Conclusions: Complementary scoping reviews demonstrated that some instruments with reasonable psychometric properties are available that are feasible to use in developing quality measures for custom AFO care. However, experience of care instruments suitable for this population were not identified but are needed for a comprehensive evaluation of care quality for AFO users.

❖ 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 published by American Journal of Physical Medicine and Rehabilitation in June 2020; (Am J Phys Med Rehabil 2020;99:540–549). DOI:10.1097/PHM.0000000000001373

- A summary of this manuscript is provided here:
  Objective: As in all healthcare areas, there is a need to improve quality relevant to orthotic practice, but we lack information as to what aspects of healthcare quality are meaningful to measure. Thus, the objective

was to identify issues that are important to the quality-of-care for people who use custom ankle-foot orthoses as identified by ankle-foot orthosis users, orthotists, and physical therapists.
Design: We conducted focus groups with custom ankle-foot orthosis users, orthotists, and physical therapists. A stenographer took verbatim notes and provided transcripts. Research staff members assessed the transcripts using thematic analysis.
Results: Participants included 5 ankle-foot orthosis users (1 focus group), 17 orthotists (2 focus groups), and 7 physical therapists (1 focus group). They discussed domains of quality-of-care relevant for people with ankle-foot orthoses. We identified 28 thematic codes addressing 10 broad themes of quality-of-care. Six of the broad themes (organizational characteristics, patient-clinician communication, care coordination, device fit and comfort, body function, activity, and participation) mapped to the National Quality Forum's person- and family-centered care concepts. Environment of care, clinician competencies, and device characteristics and usage were important to orthotic practice but do not map to any National Quality Forum concept. Participants did not mention the National Quality Forum concept of shared decision-making.
Conclusions: The quality themes provide information as to what aspects of healthcare quality are meaningful to measure with respect to orthotic care, thus providing guidance on how to measure and improve ankle-foot orthosis service delivery.

❖ Final project report data will be used to develop one or two final manuscripts:

- In preparation for the final project manuscript(s), we worked with Northwestern University's Statistical Analysis Center for project data analysis.
- Across all sites, we invited 210 new custom AFO users and 248 current users to participate in the study. We consented 37 participants receiving a new custom AFO (18%); 34 completed at least one visit (16%). We consented 74 current users (30%), 71 of whom completed at least one visit (29%).
- The goal of this project was to identify, select, and evaluate the suitability of performance instruments and PROMs for use with users of custom AFOs. Previously we (1) assessed patient and clinician perspectives on quality-of-care topics that are important to measure for custom AFO users; (2) identified instruments to measure these concepts for individuals using custom AFOs, and (3) assessed orthotists' and physical therapists' perspectives on quality-of-care indicators. The specific aims of this phase of the project were to:
  - Describe score distributions, change over time, and test-retest reliability of performance instruments and PROMs in a sample of current custom AFO users,
  - Describe score distributions, sensitivity to change, and test-retest reliability of performance instruments and PROMs in a sample receiving new custom AFOs,

  - Describe associations between performance instruments and PROMs in a sample of current users and people receiving new custom AFOs,
  - Describe the suitability and feasibility of quality measures based on a modified Consumer Assessment of Healthcare Providers and Services (CAHPS) Patient Experience Survey for custom AFO users.
- Results provide evidence of good to excellent test-retest reliability for components of the EQ-5D, OPUS, Rivermead Mobility Index, QUEST 2.0, and PROMIS short forms. Clinicians may consider these PROMs for evaluating the benefits of custom AFOs and PREMs for evaluating patients' experiences with orthotic devices.
- Findings from this research project fill a knowledge gap regarding the measurement properties of PROMs and PREMs that are suitable for use with custom AFOs users.
- Orthotists and physical therapists may consider using select PROMs and PREMs demonstrating good or excellent test-retest reliability to document patient outcomes and experiences with custom AFOs.
- Table 1 provides descriptive statistics for participants receiving a new device and current users who completed two or more assessments. Males comprised just over half of each group; racial minorities were over-represented in terms of the general population with 45% of participants receiving new AFOs and 34% of the current users being Black or multi-racial. The average age was approximately 60 years. Overall, 23% of the sample was working, with 39% covered by Medicare or Medicaid; 37% were eligible for VA benefits. Time since onset of the condition that required an AFO was 10 years or greater for 59% of the current users, while 47% of the new device group was less than one year since onset. The most common diagnosis was stroke (39% overall) followed by traumatic etiologies (36%), and other neurological conditions (27%).
- Table 2 summarizes device characteristics for the current users and users with new devices. Ninety percent of new device users and 82% of current users wore unilateral AFOs. Reasons for using an AFO included improving function, mobility or gait; promoting safety; correcting alignment; and inhibiting further deformity. Participants reported wearing their custom AFO fewer hours per day and days per week than their clinicians recommended.

Table 1: Demographic characteristics of study participants by user type*

Characteristics	All AFO Users	New Custom AFO Users	Current AFO Users
N	110	31	70
Sex (Male)	60 (55%)	16 (52%)	39 (56%)
Age, years. Mean (SD)	59.4 (14.5)	57.7 (13.5)	61.8 (14.2)
BMI. Mean (SD)	28.4 (6.0)	27.5 (5.9)	28.4 (5.4)
Race White/Caucasian Black/African American Other/Multiracial	 65 (59%) 34 (31%) 11 (10%)	 17 (55%) 11 (32%) 4 (13%)	 46 (66%) 18 (26%) 6 (8%)
Hispanic/Latinx	6 (5%)	2 (6%)	4 (6%)
Veteran	45 (41%)	9 (29%)	32 (46%)
Education			

Table 1: Demographic characteristics of study participants by user type*

Characteristics	All AFO Users	New Custom AFO Users	Current AFO Users
High School/GED	39 (36%)	9 (29%)	23 (33%)
Associates Degree	15 (14%)	3 (10%)	12 (17%)
Bachelors	27 (25%)	11 (35%)	16 (23%)
Masters	18 (16%)	5 (16%)	12 (17%)
Doctorate	9 (8%)	2 (6%)	7 (10%)
Other	2 (2%)	1 (3%)	0 (0%)
Employment			
Working	25 (23%)	11 (35%)	10 (14%)
Unemployed	12 (11%)	4 (13%)	5 (7%)
Retired (disability)	35 (32%)	9 (29%)	25 (36%)
Retired (not disability)	29 (26%)	7 (23%)	22 (31%)
Other	9 (8%)	0 (0%)	8 (12%)
Insurance			
Private	24 (22%)	7 (23%)	15 (22%)
Medicare/Medicaid	43 (39%)	17 (44%)	23 (33%)
Veterans Administration	41 (37%)	7 (23%)	31 (44%)
Other	2 (2%)	0 (0%)	1 (1%)
Time since injury			
1 year or less	22 (21%)	14 (47%)	3 (4%)
2-5 years	22 (21%)	5 (17%)	17 (25%)
6-10 years	13 (12%)	4 (13%)	8(12%)
10+ years	50 (47%)	7 (23%)	40 (59%)
Injury type (may be multiple)			
Stroke	43 (39%)	11 (35%)	29 (41%)
Spinal cord injury	10 (9%)	3 (10%)	6 (9%)
Traumatic brain injury	5 (5%)	1 (3%)	4 (6%)
Parkinson's Disease	1 (1%)	0 (0%)	1 (1%)
Multiple sclerosis	6 (5%)	4 (13%)	2 (3%)
Polytrauma	3 (3%)	2 (6%)	0 (0%)
Other neurological condition	23 (21%)	4 (13%)	18 (26%)
Other traumatic condition	21 (19%)	4 (13%)	15 (21%)
Other	7 (6%)	3 (10%)	3 (4%)

* Includes only participants with measures at 2 or more time points.

Table 2: Device characteristics and goals by user type

Descriptor	New Custom AFO Users (visit 2)	Current AFO Users
N	29	71
Primary AFO Side		
Left	16 (55%)	31 (44%)
Right	10 (34%)	27 (38%)
Bilateral	3 (10%)	13 (18%)
Device Goal (may chose multiple)		
Improve Function/ADLs	21 (68%)	43 (61%)
Inhibit Further Deformity	21 (68%)	36 (51%)
Improve Mobility/Gait	20 (65%)	46 (65%)

Table 2: Device characteristics and goals by user type

Descriptor	New Custom AFO Users (visit 2)	Current AFO Users
N	29	71
Promote Safety	20 (65%)	43 (61%)
Correct Alignment	20 (65%)	37 (52%)
Reduce Pain	0 (0%)	4 (6%)
Prevent or Delay Surgery	0 (0%)	2 (3%)
Improve Appearance	0 (0%)	1 (1%)
Hours instructed to wear custom AFO		
0-6	19 (79%)	24 (39%)
7-12	5 (21%)	24 (39%)
13-18	-	7 (11%)
19-24	-	7 (11%)
Days instructed to wear custom AFO		
0	8 (30%)	12 (19%)
1	1 (4%)	-
3	1 (4%)	-
4	1 (4%)	1 (2%)
5	3 (11%)	2 (3%)
7	13 (48%)	49 (77%)
Hours custom AFO worn		
0-6	17 (59%)	24 (34%)
7-12	9 (31%)	31 (44%)
13-18	3 (10%)	13 (18%)
19-24	-	3 (4%)
Days custom AFO worn		
0	2 (7%)	2 (3%)
1	-	1 (1%)
2	5 (17%)	2 (3%)
3	3 (10%)	4 (6%)
4	3 (10%)	1 (1%)
5	2 (7%)	7 (10%)
6	1 (3%)	2 (3%)
7	13 (45%)	52 (73%)

Presentations:

Research findings have been disseminated through three presentations.

- We presented a symposium at the American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium on March 7, 2019, in Orlando, FL.
- We presented a symposium 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.

- We presented a poster at the AAOP 2022 conference on March 3, 2022, in Atlanta, Georgia. The poster was titled Measurement Properties of Patient-Reported Measures for Custom Ankle-Foot Orthosis (AFO) Users.
  Heinemann AW, Fatone S LaVela, SL Peterson M, Slater T, Deutsch A, Soltys NT, McPherson V, Kale I, McCombs N, Kwasny M. Measurement Properties of Patient-Reported Measures for Custom Ankle-Foot Orthosis (AFO) Users. Poster presented at the 48th Annual Meeting and Scientific Symposium of the American Academy of Orthotists Prosthetists, March 2-5, 2022, Atlanta, GA.

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.
-We presented 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.
- We presented a poster at the AAOP conference on March 3, 2022, in Atlanta, Georgia. The poster was titled Measurement Properties of Patient-Reported Measures for Custom Ankle-Foot Orthosis (AFO) Users.

How were the results disseminated to communities of interest?

We presented the study findings at an Advisory Committee meeting March 4, 2020. We disseminated research findings by presenting two symposia, one poster presentation and completing three manuscripts.

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

We plan to produce 1 or 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.*

4. IMPACT:

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

Orthotists have new information on the reliability, validity, and sensitivity to change of performance tests and PROMs that are suitable and feasible for use in clinical and clinical research settings and the substitutability of PROMs for performance tests.

What was the impact on other disciplines?

Physical therapists and scientists conducting research on orthosis users have new information on the reliability, validity, and sensitivity to change of performance tests and PROMs that are suitable and feasible for use in clinical and clinical research settings, and the substitutability of PROMs for performance tests.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Health service researchers and health quality improvement personnel have new information on the suitability and feasibility of CAHPS for use with orthosis users in ambulatory care settings.

5. CHANGES/ PROBLEMS

Changes in approach and reasons for change

Not applicable

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 was delayed due to staffing issues at the Hines VA IRB office. All sites had difficulties recruiting new users. To remedy this problem, IRB modifications were submitted at SRAlab to recruit from inpatient populations as well as outpatient to reach the proposed sample size. To start the project was behind by 12 months. In March 2020, recruitment for this project was significantly delayed due to the COVID 19 pandemic as was reported in the 2020 annual report. Outpatient orthotic services, the main source of referral at all sites, were closed and then operated at lower capacity during the pandemic which impacted project recruiting. For the 2021 annual report, the project was again behind by 12 months. A no cost extension was requested to complete the recruiting, data collection and dissemination tasks for this project.

Changes that had a significant impact on expenditures

The public health emergency associated with the COVID-19 pandemic put a hold on recruitment. Staff effort on the project was severely reduced to save funds for later recruitment. We requested and received a no cost extension for the period of 9/30/2020 to 9/29/2021. This no cost extension allowed us to continue working towards

recruitment and data collection targets. We received a second no cost extension from 9/30/2021 to 9/29/2022. During the second no cost extension we completed recruitment and data analysis.

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.

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,* 33:4, 206-216, 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* 2021;102:709-34; DOI:10.1016/j.apmr.2020.06.029

Heinemann A, Deutsch A, Fatone S, Soltys N, McPherson V, Peterson M, Slater B, LaVela S,(2020) Patient and clinician perspectives on quality-of-care topics of custom ankle-foot orthoses*. American Journal of Physical Medicine and Rehabilitation* 2020;99:540–549; DOI:10.1097/PHM.0000000000001373

Books or other non-periodical, one-time publications

- Nothing to report

Website (s) or other internet site (s)

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

Technologies or techniques

- Nothing to report

Inventions, patent applications, and/or licenses

- Nothing to report

Other Products

- Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project? What other organizations were involved as partners?

Rehabilitation Institute of Chicago dba Shirley Ryan AbilityLab

Name: Allen Heinemann
Project Role: Principal Investigator
Research Identifier: 0000-0003-2782-7326
Nearest person month worked: 0.48
Contribution to Project: Dr. Heinemann created a focus group guide; moderated focus groups; coded transcripts; generated quality themes/codes; drafted a focus group manuscript; ran advisory board meetings and keep project activities aligned with protocol timeline.
Funding Support: None

Name: Anne Deutsch
Project Role: Co-Investigator
Research Identifier: 0000-0003-2290-7757
Nearest person month worked: 0.01
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: Deborah Crown
Project Role: Project Manager
Research Identifier: 0000-0002-9816-7057
Nearest person month worked: 1,45
Contribution to Project: Ms. Crown supervised support staff, assisted with IRB modifications and project management.
Funding Support: None

Name: Nicholas McCombs
Project Role: Research Coordinator
Research Identifier: None
Nearest person month worked: 1.37
Contribution to Project: Mr. McCombs recorded minutes during the bi-weekly meetings, monitored and reported on the REDCap survey activity, tracked survey, dissemination efforts, assisted with recruitment and enrollment of research participants and data collection and data analysis.
Funding Support: None

Name: Nicole Soltys
Project Role: Co-Investigator
Research Identifier: None

Nearest person month worked: 1.00
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: Kristia Torres
Project Role: Physical Therapist
Research Identifier: None
Nearest person month worked: 0.01
Contribution to Project: Ms. Torres provided assistance with outcome measures for a participant that was seen at one of the SRAlab DayRehab clinics.

Funding Support: None

University of Washington

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: 0.90 (donated)
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: 0.4 (donated)
Contribution to Project: Helps with recruitment of VA staff for focus groups. Provides clinical/content expertise.
Funding Support: VA funds

Name: Ibuola Kale

Project Role:	Research Coordinator
Researcher Identifier:	None
Nearest person month worked:	0.83 (donated)
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:	1.0
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:	1.00
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

PREVIOUS SUPPORT

Title: Perspective and Preferences for Weight Management after Spinal Cord Injury
Supporting Agency: DOD W81XWH-17-1-0678
Address: 5000 South Fifth Ave, Building 1, Room D312, Hines, IL 60141
Performance Period: 09/30/17 - 09/29/20
Total Funding:

Project Goal: The major goals of this project are to examine the perspectives of persons with SCI and their informal caregivers/family members regarding optimal weight management strategies (including preferences, barriers, and facilitators for physical activity and diet/nutrition).
Specific Aims:

1. To develop an informational/educational tool for weight management in individuals with SCI that incorporates the needs and preferences of persons with SCI and their caregivers/family members
2. To assess the feasibility of the educational tool for use with persons with SCI in health settings.

Role: Co-Investigator
Principal Investigator: LaVela

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

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

Role: Principal Investigator
Principal Investigator: Heinemann

Title: Clinical Adaptation of the SCI-QOL Psychosocial Measures
Supporting Agency: Craig H. Neilsen Foundation 367686
Address: 16830 Ventura Boulevard, Suite 352, Encino, CA 91436
Contracting Officer: Gordon R. Kanofsky
Performance Period: 04/30/2016 – 04/30/2019
Total Funding:
Project Goal: Goal of this project is to improve psychosocial outcomes such as emotional well-being and quality of life in individuals with SCI.
Specific Aims:

1. Establish clinically relevant scoring standards (i.e., score cut points) for the SCI-QOL Ability to Participate, Depression, Anxiety, and Resilience item banks;

2. Employ a state of the art quantitative/qualitative mixed methodology technique with extensive consumer participation to enhance the clinical relevance of the scoring standards;
3. Apply these standards to assess statistically significant change using existing SCI-QOL data sets and to develop different profiles of psychosocial adjustment following SCI;
4. Conduct a gold-standard validation study of the Depression and Anxiety cut points.

Role: Co-Investigator
Principal Investigator: Kisala

Title: Evaluating the Utilization and Efficiency of Wearable Exoskeletons for SCI Rehabilitation
Supporting Agency: DOD W81XWH-17-1-0157
Address: USA MED RESEARCH ACQ ACTIVITY, 820 Chandler Street, Fort Detrick MS 21702
Contracting Officer: Jason Kuhns, 301-619-1961
Performance Period: 09/01/17 - 08/31/19
Level of Funding:
Project Goal: The goal of this application is to acquire information that will guide evaluation strategies, training strategies, and clinical decision plans to enable the safe and effective use of robotic exoskeletons to enhance mobility in veterans and civilians with SCI.
Specific Aims:

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

Role: Principal Investigator
Principal Investigator: Heinemann

Title: Evaluating the Utilization and Efficiency of Wearable Exoskeletons for SCI Rehabilitation
Supporting Agency: DOD W81XWH-17-1-0157
Address: USA MED RESEARCH ACQ ACTIVITY, 820 Chandler Street, Fort Detrick MS 21702
Contracting Officer: Jason Kuhns, 301-619-1861
Performance Period: 09/1/17-08/31/19
Total Funding:

Project Goal: The goal of this application is to acquire information that will guide evaluation strategies, training strategies, and clinical decision plans to enable the safe and effective use of robotic exoskeletons to enhance mobility in veterans and civilians with SCI.

Specific Aims:

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

Role: Principal Investigator
Principal Investigator: Heinemann

Title: Disability and Rehabilitation Program: Collaboration on Mobility Training (COMIT)
Supporting Agency: NIDILRR 90DP0025-03-00
Address: 330 C Street, SW, Washington DC 20201
Contracting Officer: Theresa San Agustin, 202-795-7431
Performance Period: 04/01/2015 – 09/29/2018
Total Funding:
Project Goal: Goal of the project is to evaluate effectiveness of training in wheeled mobility at multiple sites

Specific Aims:

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

Role: Co-Principal Investigator
Principal Investigator: Boninger

Title: Midwest Regional Spinal Cord Injury Care System
Supporting Agency: NIDILRR 90SI5009-02-00
Address: 330 C Street SW, 2511B, Administration for Community Living, Washington, DC 20201
Contracting Officer: Kenneth Wood, 202-245-6534

Performance Period: 10/01/2011 – 09/29/2017
Total Funding:
Project Goal: The goals of MRSCICS are to advance the outcomes of our previous Model Systems research, continue to study the effectiveness of innovative treatment strategies; and evaluate the benefits of a well-designed, comprehensive, coordinated, interdisciplinary continuum of care that lead to improved outcomes for persons with SCI.
Specific Aims:

1. Provide a comprehensive continuum of care for persons with SCI.
2. Contribute to assessment of long-term outcomes by enrolling 80 subjects per year into the national SCI database.
3. Conduct one site-specific study
4. Disseminate research findings to various stakeholders in an effective and timely manner.
5. Collaborate effectively with the Model System Knowledge Translation Center.
6. Involve individuals with disabilities in research and dissemination activities.

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

Title: Northwestern University Patient-centered intervention and Engagement Training
Supporting Agency: NIH 5K12HS023011-01
Address: 5600 Fishers Lane, 7th Floor, Rockville, MD 20857
Contracting Officer: Carol Harris, 301-427-1448
Performance Period: 9/1/2014-7/31/2017
Total Funding:
Project Goal: Goal 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.
Role: Faculty Mentor
Principal Investigator: Cella

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

1. Identify issues that are important to the quality of care for rehabilitation patients that are amenable to the collection of patient-reported outcomes.
2. Evaluate the feasibility of collecting PROMs.

3. Specify items required for quality measure development and design data collection modules that that can be used in quality improvement efforts and to demonstrate accountability of health care delivery.

Role: Principal Investigator
Principal Investigator: Heinemann

Title: The Midwest Regional Spinal Cord Injury Model System (MRSCICS)
Supporting Agency: NIDILRR 90SI5022-01-00
Address: 330 C Street SW, 2511B, Administration for Community Living, Washington, DC 20201
Contracting Officer: Kenneth Wood, 202-795-7469
Performance Period: 09/30/16 - 09/29/22 (NCE)
Level of Funding:
Project Goal: MRSCICS will continue to provide a comprehensive continuum of care from injury onset to community reintegration for individuals with spinal cord injury (SCI), as it has for over 40 years.
Specific Aims:

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

Principal Investigator: Heinemann/Chen

Title: Personalized Mobility Interventions using Smart Sensor Resources for Lower-limb Prostheses Users
Supporting Agency: DOD W81XWH-18-2-0057
Address: USA Med Research ACQ Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014
Contracting Officer: Jason Kuhns
Performance Period: 09/30/18 - 09/29/22
Level of Funding:
Project Goal: The goal is to assess actual prosthesis use to enable targeted rehabilitation interventions to optimize device use in the home and community.
Specific Aims:

1. To determine whether a participant's prosthesis use matches the assigned K-level and/or self-reported goals and, if not, determine the reason(s) using an

expert panel to evaluate data from performance-related measures, participant-reported measures, and smartphone and prosthesis sensors (clinical toolbox)
2. To quantify effects of targeted physical intervention (prosthesis repair/refit, physical rehabilitation) or psychological intervention (motivational interviewing), or both, on activity levels and patient goals
3. To identify measure(s) that sensitively predict prosthesis use to create a clinically deployable toolkit to evaluate and optimize prosthesis use in the community

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

Title: Enhancing quality of orthotic services with process and outcome information
Supporting Agency: DOD/CDMRP W81XWH-16-01-0788
Address: USA Med Research ACQ Activity, 820 Chandler Street, Fort Detrick MS 21702
Contracting Officer: Jason Kuhns
Performance Period: 09/30/16 - 09/29/22 (NCE)
Level of Funding:
Project Goal: The goal of this project is to help the Defense Health Program improve understanding of the benefits of orthotic devices, treatments, and rehabilitation strategies.
Specific Aims:

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

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

CURRENT SUPPORT

Title: Midwest Regional Spinal Cord Injury Care System
Time Commitment: 0.90 CM (7.5%)
Supporting Agency: NIDILRR 90SIMS0015-01-00
Address: 330 C Street SW, Washington, DC 20201
Contracting Officer: Richard Adrien
Performance Period: 09/01/2021 - 08/31/2026
Level of Funding:
Project Goal: MRSCICS will continue to provide a comprehensive continuum of care from injury onset to community reintegration for individuals with spinal cord injury (SCI), as it has for over 40 years.
Specific Aims:

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

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

Title: Northwestern University Policy Research Fellowship
Time Commitment: 0.60 CM (5%)
Supporting Agency: NIDILRR 90ARPO0001-04-00
NIDILRR, Administration for Community Living, U.S. Department of Health and Human Services, 330 **Address:** C Street SW, Washington, DC 20230
Contracting Officer: Carla Kirksey
Performance Period: 09/30/17 - 09/29/23 (NCE)
Level of Funding:
Project Goal: The overall Goal is to train four individuals who intend to focus their career on policy issues pertaining to disability, independent living, or rehabilitation during a 2-year fellowship.
Specific Aims:

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

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

Title: A Multi-Center Clinical Trial to Evaluate the Effectiveness of Intermittent Hypoxia Therapy in Individuals with Spinal Cord Injury
Time Commitment: 0.24 CM (2%)
Supporting Agency: NIDILRR 90SIMS0001-01-00
Address: NIDILRR, Administration for Community Living, U.S. Department of Health and Human Services, 330 C Street SW, Washington, DC 20230
Contracting Officer: Richard Adrien
Performance Period: 09/30/17 - 09/29/23 (NCE)
Level of Funding:
Project Goal: The goal of this proposal is to evaluate a new strategy called acute intermittent hypoxia (AIH), during which a person is administered brief bouts of low oxygen through a facemask.
Specific Aims:

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

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

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

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

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

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

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

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

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

Address: National Institute on Deafness and Other Communication Disorders (NIDCD), NSC BG RM, 8317 6001 Executive Blvd, Rockville MD 20852
Contracting Officer: Edward Myrbeck
Performance Period: 04/10/19 - 03/31/24
Total Funding:
Project Goal: The goal of this study is to describe the trajectories of linguistic, cognitive-communicative, and health-related quality of life (QoL) outcomes following stroke in persons with aphasia during inpatient and outpatient rehabilitation to 18 months following stroke.
Specific Aims:

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

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

Title: Defining Trajectories of Linguistic, Cognitive-Communicative and Quality of Life Outcomes in Aphasia (Supplement)
Time Commitment: 0.48 CM (4%)
Supporting Agency: NIH R01DC017174-02S1
Address: National Institute on Deafness and Other Communication Disorders (NIDCD), NSC BG RM, 8317 6001 Executive Blvd, Rockville MD 20852
Contracting Officer: Edward Myrbeck
Performance Period: 04/01/2020 - 03/31/2024
Total Funding:
Project Goal: The goal of this study is to describe the trajectories of linguistic, cognitive-communicative, and health-related quality of life (QoL) outcomes following

stroke in persons with aphasia during inpatient and outpatient rehabilitation to 18 months following stroke.

Specific Aims:

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

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

Title: A Randomized Controlled Trial of Geriatric Emergency Department Innovations
Time Commitment: 1.20 CM (10%)
Supporting Agency: NIH AHRQ R01HS026489-02
Address: AHRQ, OMS/Division of Grants Management, 5600 Fishers Lance, Mail Stop 07N13, Rockville, MD 20857
Contracting Officer: Steven Young
Performance Period: 05/01/2019 - 04/30/2024
Level of Funding:
Project Goal: The overall goal of this proposal is to improve patient-oriented outcomes of geriatric patients presenting to an urban emergency departments by conducting a randomized controlled trial of the Geriatric Emergency Department Innovations (GEDI) program.
Specific Aims:
Role: Co-Principal Investigator
Principal Investigator: Heinemann, Dresden
Overlap: No scientific or budgetary overlap with the proposed project.

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

1. To improve patient understanding of standardized assessments by developing patient-centered resources on the Rehabilitation Measures Database

2. To increase student knowledge of the need for and behavioral readiness to administer standardized assessments
3. To promote routine implementation of standardized assessments by rehabilitation clinicians

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

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

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

Role: Principal Investigator
Principal Investigator: Heinemann

Overlap: No scientific or budgetary overlap with the proposed project.

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

Title: Promoting the Psychological Health of Persons with Spinal Cord Injury: A Knowledge Transition Project
Time Commitment: 0.60 CM (5%)
Supporting Agency: Craig H. Neilsen Foundation 724833
Address: 16830 Ventura Boulevard, Suite 352, Encino, CA 91436
Contracting Officer: Constanza Svidler
Performance Period: 04/30/2021 - 04/29/2024
Level of Funding:
Project Goal: This project focuses on research that seeks to better understand the relationship among biological, psychological and social aspects of health and functioning in people living with SCI.
Specific Aims:

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

Role: Principal Investigator
Principal Investigator: Heinemann

Overlap: No scientific or budgetary overlap with the proposed project.

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

1. Establish a process—Connect→Learn, Act, or Share that efficiently and logically delivers C-STAR resources to the rehabilitation research community. After initial connection with C-STAR, researchers can participate in any element at any point.
2. Create four cores of expertise in engineering, clinical, outcomes, and implementation science/community engagement.
3. Create a robust pilot project program that provides outside researchers with funding, mentoring, and expertise to perform sophisticated experiments relevant to the use of technology in rehabilitation.
4. Disseminate our center's resources to the research community via webinars, sabbaticals, and courses, relying heavily on our Rehabilitation Measures Database website (www.rehabmeasures.org), which receives an average of 11,000 hits/day, as well as on our C-STAR website .

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

Title: Advanced Rehabilitation Research Training (ARRT) Program – Employment
Time Commitment: 0.60 CM (5%)
Supporting Agency: NIDILRR 90AREM0003-01-00
Address: 330 C Street SW, Washington, DC 20201
Contracting Officer: Marlene Spencer
Performance Period: 06/01/2020 - 05/31/2025
Level of Funding:
Project Goal: Researchers with specific training focused on rehabilitation and disability are needed to conduct critical and innovative studies to address the health and function, employment, and participation needs of persons with disabilities. Production of sophisticated research requires intensive and targeted post-doctoral training.
Role: Principal Investigator

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

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

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

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

Title: Meaningful changes in fitness, functional independence, and transfer independence as defined by individuals living with spinal cord injury
Time Commitment: 0.30 CM (2.5%)
Supporting Agency: DOD W81XWH2110813
Address: USA Med Research ACQ Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014
Contracting Officer: Christopher Meinberg
Performance Period: 09/30/2021 – 9/29/2024
Level of Funding:
Project Goal: This project seeks to define meaningful changes in fitness, functional independence, and transfer independence as defined by individuals living with spinal cord injury.
Specific Aims:

1. Identify ‘meaningful changes’ in self-care, mobility, and transfer independence that can be measured with existing measurement tools and are associated with fitness level or changes.

2. Assess the external validity and clinical utility of the model predicting if fitness is below the amount required to independently complete bed transfers.
3. Plan an exercise intervention clinical trial to test if improved fitness can achieve meaningful self-care, mobility, and/or transfer independence gains.

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

Title: Midwest Regional Spinal Cord Injury Care System (Supplement)
Time Commitment: 0 CM (0%)
Supporting Agency: NIDILRR, 90SIMS0015-02-01
Address: Switzer Building, 330 C Street SW, Washington, DC 20201
Contracting Officer: Carla Kirksey
Performance Period: 09/01/2022 – 08/31/2023
Level of Funding:
Project Goal: MRSCICS will continue to provide a comprehensive continuum of care from injury onset to community reintegration for individuals with spinal cord injury (SCI), as it has for over 40 years.
Specific Aims:

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

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

PENDING SUPPORT

Title: Development and Validation of a Nutrition Knowledge Questionnaire for Individuals with Spinal Cord Injuries and Disorders
Time Commitment: 0.60 CM (5%)
Supporting Agency: DOD
Contracting Officer: Nick Heroux
Performance Period: 09/01/2022 – 08/31/2025
Level of Funding:
Specific Aims:

1. To develop the initial nutrition knowledge questionnaire content. We will define the measurement construct (trait) and properties, develop a test plan, and generate the item pool using the expertise within our research team, two comprehensive literature reviews, and a focus group with a SCI Nutrition Expert Panel.

2. To conduct a preliminary review and a pre-test of the nutrition knowledge questionnaire to continue iterative refinement.
3. Field the questionnaire with a larger sample of individuals with SCI/D to statistically evaluate measurement properties and make necessary edits.
4. To field a final questionnaire and use Rasch analysis to fully evaluate psychometric properties, temporal stability, concurrent validity, and construct validity.

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

Title: Advanced Rehabilitation Research Training (ARRT) Program: Northwestern University Advanced Rehabilitation Research Training Application
Time Commitment: 0.60 CM (5%)
Supporting Agency: NIDILRR
Address: Switzer Building, 330 C Street SW, Washington, DC 20201
Contracting Officer: Carla Kirksey
Performance Period: 06/01/2023 – 05/31/2028
Level of Funding:
Project Goal: Researchers with specific training focused on rehabilitation and disability are needed to conduct critical and innovative studies to address the health and function, employment, and participation needs of persons with disabilities. Production of sophisticated research requires intensive and targeted post-doctoral training.
Role: Principal Investigator
Principal Investigator: Heinemann
Overlap: Effort will replace 90ARHF0003 ending in 2023.

Title: Moss TBI Model System Collaborative Module
Time Commitment: 0.60 CM (5%) beginning in 2025
Supporting Agency: NIDILRR 90DPTB0004
Address: Switzer Building, 330 C Street SW, Washington, DC 20201
Contracting Officer: Carla Kirksey
Performance Period: 09/01/2022 – 08/31/2027
Level of Funding:
Principal Investigator: Rabinowitz
Project Goal: Create and disseminate new knowledge to improve health, function, and quality of life for people with Traumatic Brain Injury.
Role: Co-Investigator
Overlap: No scientific or budgetary overlap with the proposed project.

Sherri LaVela, PhD. MPH, MBA

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

CURRENT, PREVIOUS, & PENDING SUPPORT

CURRENT

Agency: Department of Defense
ID# SC210189
Title: Development and Validation of a Nutrition Knowledge Questionnaire for Individuals with Spinal Cord Injuries and Disorders
Principal Investigator(s): Sherri L. LaVela, PhD, MPH, MBA
Role on project: PI
Percent effort: 60%
Direct costs:
Project period: 9/30/2022-9/30/2025

Agency: Department of Veterans Affairs
ID#: SWC 22-xxx
Title: Nutrition needs to optimize health and reduce chronic and secondary complications in Veterans with spinal cord injuries and disorders (SCI/D)
Principal Investigator(s): Sherri L. LaVela, PhD, MPH, MBA; Lorena Reyes, RD, MS, LDN
Role on project: Co-PI
Percent effort: 10%
Direct costs:
Project period: 01/01/2023-12/31/2024

Agency: Paralyzed Veterans of America
ID# 876
Title: Social Isolation and Loneliness in Persons with SCI/D: Developing an Educational Curriculum for Health Care Professionals
Principal Investigator(s): Sherri L. LaVela, PhD, MPH, MBA
Role on project: PI
Percent effort: 20%
Direct costs:
Project period: 09/01/2022-8/31/2023

Agency: Craig H. Neilsen Foundation
ID# 864046
Title: Caring Connections: A program to alleviate social isolation and loneliness in individuals living with spinal cord injury
Principal Investigator(s): Sherri L. LaVela, PhD, MPH, MBA
Role on project: PI
Percent effort: 20%
Direct costs:
Project period: 04/30/2022-04/30/2025

Agency: Department of Veterans Affairs
ID#: SWC 21-002

Title: Understanding Social Isolation, Loneliness, and Treatment Preferences in Veterans with Spinal Cord Injuries and Disorders: A Qualitative Evaluation Principal Investigator(s): Sherri L. LaVela, PhD, MPH, MBA Role on project: PI Percent effort: 12% Direct costs: Project period: 01/01/2022-12/31/2022

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

Title:	Engaging Patients and Providers in Identifying and Addressing Modifiable Risk Factors to Prevent Community-Acquired Ulcers in Veterans with SCI; IIR 16-267; (PI: Burkhart)
Effort:	1.2 calendar
Supporting Agency:	Department of Veterans Affairs, HSR&D
Grants Officer:	Cathie Plouzek Office of Research and Development Veterans Health Administration Washington DC 20420
Performance Period:	07/01/2018 – 12/31/2022
Funding Amount	
Project Goals:	The goal is to identify risk factors for community-acquired pressure ulcers in persons with SCI and to implement prevention efforts.

Title:	Enhancing Quality of Orthotic Services with Process and Outcome Information; W81XWH-16-1-0788 OP150034, LaVela (site PI & co-I, Heinemann (lead PI)

Effort:	0.6 calendar
Supporting Agency:	Department of Defense
Grants Officer:	Elena G. Howell, Grants Officer USA MED RESEARCH ACQ ACTIVITY 820 Chandler St. Fort Detrick MS 21702
Performance Period:	09/30/2016 – 09/29/2022
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:	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
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:	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

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
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
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
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
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
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
Performance Period:	06/1/2014 – 05/31/2016
Funding Amount	
Project Goals:	To objective of this work was to develop a tool to accurately assess functional self-efficacy in people with SCI.

Title:	Functional Needs Assessment in Persons with Spinal Cord Injuries and Disorders; RRP 13-248; LaVela (PI)
Effort:	2.4 calendar
Supporting Agency:	Department of Veterans Affairs, HSR&D
Grants Officer:	Department of Veterans Affairs Veterans Health Administration

	Washington DC 20420 Linda McIvor, MHS, MS, Program Manager, QUERI (10P9H)
Performance Period:	10/01/2014-09/30/2015
Funding Amount	
Project Goals:	The overall objective of this study is to conduct a systematic comprehensive needs assessment using mixed methods and triangulated data to understand functional challenges that are most important to Veterans with SCI/D, mediating factors that may affect function, and how these variables and relationships impact participation, life satisfaction, and quality of life (QOL) in Veterans with SCI/D. The long-term goal is to use the factors we identify as unmet needs to develop a lifestyle intervention to implement within this population.

Title:	Use of Declination Forms to Improve Influenza Vaccination in Health Care Workers; RRP 12-515; LaVela (PI)
Effort:	2.4 calendar
Supporting Agency:	Department of Veterans Affairs, HSR&D
Grants Officer:	Department of Veterans Affairs Veterans Health Administration Washington DC 20420 Linda McIvor, MHS, MS, Program Manager, QUERI (10P9H)
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

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
Performance Period:	10/01/2012-09/30/2013
Funding Amount	
Project Goals:	The main objective was to measure comfort and tolerability among healthcare workers when wearing face-piece respirators; using a newly developed validated survey instrument.

Title:	Current weight management practices for Veterans with SCI/D across the VA system of care; RRP 12-213; LaVela (PI)
Effort:	3.6 calendar
Supporting Agency:	Department of Veterans Affairs, HSR&D
Grants Officer:	Department of Veterans Affairs Veterans Health Administration Washington DC 20420 Linda McIvor, MHS, MS, Program Manager, QUERI (10P9H)

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

Agency: Department of Veterans Affairs, HSR&D
ID: HX-21-001
Title: Developing a Risk Calculator for the Development of Metabolic Disease Including Type 2 Diabetes, Hypertension, Dyslipidemia, and Nonalcoholic Fatty Liver Disease in Persons with Spinal Cord Injuries and Disorders
Principal Investigator: Daniel Eisenberg, MD
Role on project: Co-Investigator
Percent effort: 20%
Direct costs for project period:
Performance period: 12/01/2023 - 11/31/2027

Agency: Department of Defense
ID: Department of Defense (DOD) Chronic Pain Management Research Program (CPMRP) Translational
Research Award
Title: Effectiveness and Implementation of Osteopathic Manipulative Treatment in the Multimodal Management of Veterans and Service Members with Chronic Low Back Pain
Principal Investigator: Clarence L. Nicodemus, DO, PhD
Role on project: Consultant
Percent effort: 150 hours
Direct costs for project period:
Performance period: 1/01/2024 - 1/01/2028

Agency: Department of Defense
ID: SCIRP W81XWH-22-SCIRP-HRA
Title: Ecological Momentary Assessment Measures Micro-Level Trends of Social Isolation and Loneliness and Develops Caring Messages Intervention for Persons with SCI
Principal Investigator: Wing (Alex) Wong, PhD
Role on project: Co-Investigator
Percent effort: 15%
Direct costs for project period:
Performance period: 6/01/2024 - 5/31/2027

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

Stefania Fatone, PhD

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

CURRENT, PREVIOUS, & PENDING SUPPORT

UNIVERSITY OF WASHINGTON

CURRENT

VA RR&D (PI: Stine)
10/01/2022-09/30/2024 0.66 calendar
SPIRE
Jesse Brown VA Medical Center/VA IPA
Does Transfemoral Prosthetic Socket Design and Alignment Influence Low Back Pain? Comparison Between Ischial-Containment and Sub-Ischial Sockets
The purpose of this study is to investigate and compare the effects of the standard ischial containment socket to a newer sub-ischial socket design on the spinal segmental and pelvic motions of transfemoral prosthesis users.
Project Officer: Kristy Benton-Grover, BFA, CAE
Office of Research and Development
Rehabilitation Research & Development Service
Washington, DC 20420

DOD (PI: Fatone)
09/01/2022 – 08/31/2025 0.6 calendar
OPORP W81XWH2210362
University of Washington
Evaluation of the Northwestern University Sub-Ischial Socket for Persons with Transfemoral Amputation and Lower Mobility Levels
The objective of this project is to assess use and benefits of the sub-ischial socket for persons with TFA and lower mobility levels.
Project Officer: Amanda Coldren

VA RR&D (PI: Pundik)
04/01/2022 – 03/30/2026 0.48 calendar
Merit Review 1 I01 RX003674

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

VA RR&D (PI: Major)
4/01/2020 – 03/31/2023 0.72 calendar
Merit Award RX003090
Jesse Brown VA Medical Center/VA IPA
Hybrid Electrical-Mechanical pump for Vacuum Suspension of Prosthetic Sockets
The purpose of this research and development project is to further design and evaluate a hybrid vacuum pump device that integrates electrical and mechanical systems to produce vacuum-assisted suspension of lower limb prosthetic sockets.
Project Officer: Brian W. Schulz
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

DOD (PI: Fatone/Gard)
09/30/2019 – 09/29/2023 2.0 calendar
OPORP W81XWH1910835
Northwestern University/SubK
Comparative Effectiveness of Socket Casting Methods: Improving Form and Fit
The overall objective of this project is to compare hand casting to standing hydrostatic pressure casting using a water cylinder in persons with lower limb amputation. Our overall hypothesis is that standing hydrostatic pressure casting with a water cylinder will lead to more consistent and efficient residual limb shape capture and improved initial socket fit and comfort compared to hand casting.
Project Officer: Lucinda F. Keeney

NIH (PI: Zuniga)

2/01/2019 – 11/23/2023 0.24 calendar
1R01NS114282-01
University of Nebraska Omaha/SubK
The influence of 3D printed prostheses on neural activation patterns of the primary motor cortex in children with unilateral congenital upper-limb reductions
The objective of this project is to determine the influence of using a prosthesis on the neural activation patterns of the primary motor cortex in children with unilateral congenital upper-limb reductions to inform the development of rehabilitation programs aimed at reducing prosthesis rejection and abandonment.
Project Officer: Sahana Nalini Kukke

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

PENDING

NIH (PI: Bjornson)
07/01/2023-06/30/2028 1.2 calendar
NIH R01
Seattle Children's Research Institute/SubK
Multimodal Gait training (MGAIT): Walking Attainment in Young Children with Cerebral Palsy
The premise of this proposal is that a combined orthotic and treadmill training multi-modal approach will enhance timing of acquisition of independent walking and static standing in pre-ambulatory toddlers with CP. Within a randomized clinical trial, we will examine the effectiveness of an integrated multi-modal gait training (MGAIT) comprised of the AFO-FC approach and an intensive, 8-week home-based treadmill training protocol compared to the same treadmill protocol with standard of practice prefabricated AFO with uniform alignment (AFO-SP) in emerging walkers with bilateral spastic CP.
Project Officer: TBD

NSF (PI: Erenstone)
01/01/2023-12/31/2023 0.24 calendar
SBIR

Mountain Orthotics and Prosthetics Services/SubK
Additive Manufactured Reciprocal Textured Prosthetic Liner and Socket
To improve prosthetic suspension and function, the innovation we propose is a method of digitally designing liners with an embossed texture, which is reciprocated and mirrored to debossed textures on the prosthetic socket.
Project Officer: TBD

VA RR&D (PI: Major)
12/01/2022 – 11/30/2024 0.36 calendar
SPIRE
Jesse Brown VA Medical Center/VA IPA
Mapping ankle-foot stiffness to socket comfort and pressure using a robotic emulator platform to personalize prosthesis function via human-in-the-loop optimization
The aim of this research project is to map relationships between prosthetic ankle-foot stiffness, user-reported comfort, and residuum-socket interface pressure and use this correlation map to drive prosthesis optimization.
Project Officer: Kristy Benton-Grover, BFA, CAE
Office of Research and Development
Rehabilitation Research & Development Service
Washington, DC 20420

PREVIOUS (5 YEARS)

DOD (PI: Sawers)
9/23/2019-09/22/2022 0.6 calendar
OPORP W81XWH-19-1-0507 (SubK)
University of Illinois at Chicago/SubK
A Pilot Clinical Trial to Assess the Effect of Transfemoral Socket Design on Hip Muscle Function
The objective of the proposed prospective pilot clinical trial is to assess the effect of socket design on residual limb hip muscle strength and endurance in Service members, Veterans, and civilian transfemoral prosthesis users transitioning from an ischial-containment to a sub-ischial socket. Our central hypothesis is that walking with a sub-ischial socket will increase residual limb hip muscle strength and endurance in persons with transfemoral amputation who are long-term ischial-containment users.

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

Northwestern University
Effect of Ankle-Foot Orthoses (AFOs) on Continuous Walking in Persons with Post-Stroke Hemiplegia
We propose a prospective, randomized cross-over, comparative assessment trial with the following specific aims:
(1) to investigate how continuous walking affects the gait of persons with hemiplegia

following stroke when walking without AFOs;
(2) to evaluate how well a clinically prescribed AFO addresses impairments that occur during continuous walking; and
(3) to evaluate if a 'tuned' AFO-FC is more effective than the clinically prescribed AFO at diminishing walking impairments during continuous walking.
Project Officer: Ashlie White
Director of Strategic Alliances
American Orthotic and Prosthetic Association (AOPA)
330 John Carlyle Street, Suite 200 Alexandria, VA 22314

NIH (PI: Bjornson)
09/01/2018 – 07/31/2020 0.18 calendar
5R21HD094823 (SubK)
Seattle Children's Research Institute/SubK
Biomechanics and Walking in Cerebral Palsy: Ankle Foot Orthoses – Footwear Combinations
The goal of this proposal is to assess the feasibility of using a randomized waitlist study to acquire pilot data on a targeted clinical cohort of children with CP. Aim 1: Examine the effect of AFO-FC on overall gait deviations and walking speed as compared to current AFO in children with CP. Aim 2: Examine the effect of AFO-FC on daily walking activity, balance and satisfaction as compared to current AFO in children with CP.
Project Officer: Louis Quatrano

Defense Health Program (PI: Sharma)
6/18/2017- 05/31/2019 1.08 calendar
SBIR Phase II W81XWH-16-C-0012 (SubK)
Lynntech Inc./SubK
iGRAB: Innovative Glove for Rehabilitation and Assistance using Biomimicry
The aim of the iGrab is to provide assistance for hand function resulting from hand injury during rehabilitation and every day activities. As part of Phase II, efficacy of the device in terms of assisting grasping activities in persons with impaired hand function must be demonstrated. Therefore, quantitative clinical evaluation of hand function with and without the iGrab will be evaluated in persons with impaired hand function due to both stroke and hand trauma.
Project Officer: Stephanie P. Davis
SBIR Admin Coordinator
USAMRAA

Myomo Inc. (PI: Page)
06/01/2017-12/31/2018 0.6 calendar
(SubK)

The Oklahoma State University/SubK
Functional Assistance provided by Myoelectric Elbow-wrist-hand orthoses (FAME)
The primary study objective is to compare upper extremity movement while wearing 1) the MyoPro 2 Motion-G; 2) a resting hand splint; and 3) no device among stroke survivors with moderate upper
Project Officer: N/A

DOD (PI: Fatone)
09/30/2016 – 09/29/2020 0.36 calendar
OORA W81XWH-16-1-0733
Northwestern University
Longitudinal Observation of Myoelectric Upper Limb Orthosis Use among Veterans with Upper Limb Impairment
The objective of this observational study is to document longitudinal outcomes in Veterans using the myoelectric upper limb orthosis with powered elbow and grasp using both patient-centric performance and patient-reported outcome measures. Longitudinal observation will allow us to document both therapeutic effects as well as functional outcomes of orthosis use.
Project Officer: Elena G. Howell

DOD (PI: Fatone)
09/30/2016 – 09/29/2021 1.2 calendar
NMSIRA W81XWH-16-1-0485
Northwestern University
No longer smooth: introducing striations into prosthetic socket construction to improve suspension, rotation, fit and comfort
The objective of this pre-clinical research project is to investigate the effect of different types of inner surface texturing on the suspension, rotation, fit, and comfort of prosthetic sockets.
Contracting Officer: Ms. Sandra Rosario
Assistance Agreement Branch 1
US Army Medical Research Acquisition Activity
820 Chandler Street
Fort Detrick, MD 21702-5014

DOD (PI: Fatone)
09/30/2015 –09/29/2020 2.4 calendar
PRORP W81XWH-15-1-0708
Northwestern University
Functional Performance Evaluation of the Northwestern University Flexible Subischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation
This proposal aims to provide evidence to support the use of the NU-FlexSIV Socket for persons with transfemoral amputation. This will be accomplished by undertaking a

prospective, assessor-blinded randomized cross-over trial comparing comfort and functional performance with the NU-FlexSIV Socket to the standard-of-care ischial containment socket in persons with unilateral transfemoral amputation.
Project Officer: Elvera M. Messina
Grants Officer
US Army Medical Research Acquisition Activity
820 Chandler Street
Fort Detrick MD 21702-5014

NIH (PI: Fatone, Rogers, Huang, Coleman)
09/22/2014 – 05/31/2019 1.2 calendar
R01 R01EB019337
Northwestern University
Interface Monitoring System to Promote Residual Limb Health
This proposal aims to develop a stretchable and flexible sensor technology capable of transforming healthcare from reactive and hospital-centered to preventive, proactive, evidence-based, and person-centered.
Project Officer: Michael Wolf, Ph.D.
6707 Democracy Blvd, Ste 200,
Bethesda, MD 20892

Overlap
None.

Michelle Peterson, PT

Other Support – Michelle Peterson, PT, DPT, NCS

Current Support –

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

Role in Project: Site Principal Investigator

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

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

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

Pending Support – None

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: Not Applicable

QUAD CHART: See Attached

APPENDICES

a. **REDCap Survey:** See Attached
b. **Manuscript:** See Attached
    i. 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,* 33:4, 206-216, DOI: 10.1080/10400435.2019.1610814
c. **Manuscript:** See Attached
    i. 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* 2021;102:709-34; DOI:10.1016/j.apmr.2020.06.029
d. **Manuscript:** See Attached
    i. Heinemann A, Deutsch A, Fatone S, Soltys N, McPherson V, Peterson M, Slater B, LaVela S,(2020) Patient and clinician perspectives on quality-of-care topics of custom ankle-foot orthoses*. American Journal of Physical Medicine and Rehabilitation* 2020;99:540–549; DOI:10.1097/PHM.0000000000001373