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

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

PRINCIPAL INVESTIGATOR: Allen Heinemann, PhD

CONTRACTING ORGANIZATION: **Rehabilitation Institute of Chicago**
Chicago, IL 60611

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

Rehabilitation Institute of
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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

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

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TABLE OF CONTENTS

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 and 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) **40% complete**

Task 3.1 Review results of Task 2.2 and recommend components of quality measures to the Advisory Committee
Milestone: Quality measure components reported to Advisory Committee (Months 22-24)

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

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

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

What was accomplished under these goals?

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

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

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

- 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 28th, 2018**, we received 460 **completed** responses from certified orthotists, physical therapists and other clinicians. Afterwards, the data was analyzed by the research team and the paper, *Orthotist and Physical Therapist Perspectives on Quality of Care Indicators for Custom*, was written based on the analyzed results.
    - **See paper details under task 3.4**

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

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

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

- Based off the instruments and measures that were identified in task 1.2 and with the assistance of the research team and the advisory committee, we were able to identify optimal quality instruments and measures that will be used in task 2.2 (**Collect patient-reported and performance-based data and evaluate test-retest reliability, concur-**

rent validity, sensitivity to change, and respondent/clinician burden in a sample of 100 AFO users). Some of the instruments include:

- **10 Meter Walk Test**
- **6 Minute Walk Test**
- **2 Minute Walk Test**
- **Timed Up and Go test**
- **Rivermead Mobility Index**

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

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

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

Task 3.4 Disseminate findings and promote knowledge translation

- Based on the results from the clinician survey, a paper, *Orthotist and Physical Therapist Perspectives on Quality of Care Indicators for Custom*, was drafted and submitted to the journal, Clinical Rehabilitation, on **6/22/18**. The editor determined that the paper was not a good fit for the publication**.** The team made edits to the paper and resubmitted *to Disability and Rehabilitation* on **7/24/18**. **The paper is currently under review.**
- Stemming from the completion of task 1.2 (Identify items and instruments that operationalize important quality of care concepts for AFO practice) , a paper, *A Review of Instruments used to Assess Ankle Foot Orthosis Use in Persons with Traumatic and Neurological Conditions*, was developed. The paper was submitted Prosthetics *and Orthotics International* on **8/13/18***.* **The paper is currently under review**.

- We conducted four separate, cross-sectional focus groups with patients and clinicians in order to gain a thorough understanding of underlying or nonobvious issues related to quality-of-care for custom AFO users, and drafted a manuscript based on these results,

Patient and Clinician Perspectives on Quality-of-Care Topics for Users of Custom Ankle-Foot Orthoses. **The manuscript was first submitted for publication 3/3/18 and the editor requested revisions. A revised version of the manuscript was submitted 6/22/18 and is currently under review** at *Prosthetics and Orthotics International.*

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

- Nothing to report

How were the results disseminated to communities of interest?

- Dr. Heinemann shared results of the focus group and the literature review during the Midwest Chapter of the American Academy of Orthotists Prosthetists during its Fall One Day Education Symposium on Saturday, November 11, 2017.

- Dr. Heinemann shared results of the focus group and the literature review to the Rehabilitation Outcomes Conference organized by the Fujian University of Traditional Chinese Medicine in Fuzhou, China on November 16, 2017.

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

- During the next reporting period, we plan to continue recruiting and collecting patient reported and performance measure data, using the secure online survey that we built (see appendix). Once we have collected data from 25-30 current AFO user and 25 new AFO users (SRALab), for a total of 100 subject across all study sites, we will then organize and analyze the data. From there we will summarize and recommended components of quality measures to the Advisory Committee for feedback. Additionally, we are looking to produce 3 more papers based off the survey data. The papers will focus on (1) *Sensitivity to change with the TUG, 10 meter and 6 minute walk test, (2) Primary outcome manuscript: PRO correlation & measures and (3) AFO screening tool & video gait analysis correlation.*

4. IMPACT:

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

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

What was the impact on other disciplines?

- Nothing to report

What was the impact on technology transfer?

- Nothing to report

What was the impact on society beyond science and technology?

- Nothing to report

5. CHANGES/ PROBLEMS

Changes in approach and reasons for change

- While the National Health Service (NHS) Scotland Ankle-Foot Orthosis Screening Tool has been recommended by the NHS in the UK for use in orthotic practice with AFO users, it has not yet been validated. Hence, we will video record subjects walking so that we can validate use of the NHS screening tool by comparing results obtained from it to the Gait Assessment and Intervention Tool (G.A.I.T.) which has good psychometric properties but is too complex for routine use in clinical practice. This testing will be completed by the first 30 current users at SRALab only. This component was not in the initial application, but upon further discussion, the research team felt it would be very beneficial if we capture this data.

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

- As previously reported in quarterly technical report 3, the project is behind by 6 months. With the adding of additional staff, we were able to address issues that were causing the delay. Additionally, we are still waiting on the co-sites to get HRPO approval, so that they can begin data collection. This will delay the goal of reaching 100 subjects across all sites in a specific time frame. As a remedy, SRALab has provided guidance and assistance to other sites in order for them to successfully submit their documents, as well as offering to recruit more subjects to in order to ease their burden, if needed.

Changes that had a significant impact on expenditures

- A project manager that was working on the study left the organization in October, 2017. As a result, our budget was underspent as a consequence. We committed extra effort to reduce under expenditure of contracted resources.

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:

- Nothing to report

Books or other non-periodical, one-time publications

- Nothing to report

Website (s) or other internet site (s)

- Nothing to report

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?

Rehabilitation Institute of Chicago dba Shirley Ryan AbilityLab

Name:	Allen Heinemann, PhD
Project Role:	Principal Investigator
Research Identifier:	None
Nearest person month worked:	2.34 Calendar Months
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 keeps project activities aligned with protocol timeline.
Funding Support:	None

Name:	Ontonio Jackson-Lucas
Project Role:	Research Assistant
Research Identifier:	None
Nearest person month worked:	3.91 Calendar Months
Contribution to Project:	Mr. Jackson- Lucas records minutes during the bi-weekly meetings, monitors and reports on the REDCap survey activity, tracks survey dissemination efforts and has assisted with building an endnote library for instruments and measures.
Funding Support:	None

Name:	Emily Anderson, MS
Project Role:	Project Manager
Research Identifier:	None
Nearest person month worked:	2.19 Calendar Months
Contribution to Project:	Ms. Anderson supervised support staff, assisted with IRB modifications, and assisted with data interpretation.
Funding Support:	None

Name:	Patrick Semik
Project Role:	Data Analyst
Research Identifier:	None

Nearest person month worked: 2.28 Calendar Months
Contribution to Project: Mr. Semik analyzed the online survey data and created data output reports for this project.
Funding Support: None

Name: Jamal Spraggins
Project Role: Research Assistant
Research Identifier: None
Nearest person month worked: 5.54 Calendar Months
Contribution to Project: Mr. Spraggins submitted IRB modifications, recruited physical therapists for a focus group; coded transcripts; assisted with the development of quality themes; scheduled an advisory board meeting and created a demographics table for the focus group manuscript. He also is building REDCap for data collection
Funding Support: None

Northwestern University

Name: Stefania Fatone, PhD
Project Role: Subsite PI
Researcher Identifier: None
Nearest person month worked: 2.37 Calendar Months
Contribution to Project: Collaborates with project PI especially in terms of study development, project management, orthotic management expertise, and data interpretation.
Funding Support: None

Chicago Association for Research & Education in Science (CARES)

Name: Sherri LaVela, PhD
Project Role: Subcontract PI
Researcher Identifier: None
Nearest person month worked: 1.8 Calendar Months
Contribution to Project: Participates in weekly team meetings. Helps plan methods and study strategies. Recruitment site activities, helps recruit participants and helps develop data collection tools. Dissemination efforts -- helps author manuscripts.
Funding Support: None

Name: Rodney Stuck, MD
Project Role: Co-Investigator
Researcher Identifier: None
Nearest person month worked: 0.6 Calendar Months

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

Name:	Ibuola Kale
Project Role:	Research Coordinator
Researcher Identifier:	None
Nearest person month worked:	1.2 Calendar Months
Contribution to Project:	Helps with recruitment efforts. Primary contact for IRB efforts at Hines VA. Participants 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 Calendar Months
Contribution to Project:	Preparation of regulatory documents (amendments to IRB, R&D), participation in advisory committee (conference call attendance, review of feedback), participation in bi-weekly conference calls, manuscript review, survey review, protocol development, reliability testing.
Funding Support:	None

Name:	Billie C.S. Slater, MA
Project Role:	Study Coordinator
Researcher Identifier:	None
Nearest person month worked:	3
Contribution to Project:	Preparation of regulatory Documents including Initial IRB Application, participated in bi-weekly conference calls, participated in coding of focus group transcripts, Study Coordination including: preparation of IRB amendments, study visit preparation and management, electronic data capture, audit preparation, and subject remuneration
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

Active

Award number: W81XWH-17-1-0678
Title: Perspective and Preferences for Weight Management after Spinal Cord Injury
PI: LaVela
Time commitments: 0.36 calendar months
Supporting agency: DOD
Name & address of funding agency POC/GO: Kimberly Stubbs, 5000 South Fifth Ave, Building 1, Room D312, Hines, IL 60141
Performance period: 9/30/17-9/29/20
Funding: $231,756
Aims: The major goals of this project are examine the perspectives of persons with SCI and their informal caregivers/family members regarding optimal weight management strategies (including preferences, barriers, and facilitators for physical activity and diet/nutrition); develop an informational/educational tool for weight management in individuals with SCI that incorporates the needs and preferences of persons with SCI and their caregivers/family members; and assess the feasibility of the educational tool for use with persons with SCI in health settings.
Role: Co-Investigator

Award number: 367686
Title: Clinical Adaption of the SCI-QOL Psychosocial Measures
PI: Kisala
Time commitments: 0.6 calendar months
Supporting agency: Craig H. Neilsen Foundation
Name & address of funding agency POC/GO: Angela Alcaraz; University of Delaware; 210 Hullihen Hall; Newark, DE 19716
Performance period: 4/30/16-4/30/19 (NCE)
Funding: $297,000
Aims: Goal of this project is to improve psychosocial outcomes such as emotional well-being and quality of life in individuals with SCI.
Specific Aims:
1. Establish clinically relevant scoring standards (i.e., score cut points) for the SCI-QOL Ability to Participate, Depression, Anxiety, and Resilience item banks;
2. Employ a state of the art quantitative/qualitative mixed methodology technique with extensive consumer participation to enhance the clinical relevance of the scoring standards;
3. Apply these standards to assess statistically significant change using existing SCI-QOL data sets and to develop different profiles of psychosocial adjustment following SCI;
4. Conduct a gold-standard validation study of the Depression and Anxiety cut points.
Role: Site PI

Award number: 90DP0028
Title: Texas TBI Model System of TIRR
PI: Sherer
Time commitments: 0.19 calendar months
Supporting agency: NIDILRR
Name & address of funding agency POC/GO: Nancy Smith, 909 Frostwood Ste 2: 100, Houston, TX 77024
Performance period: 9/30/17-9/29/18
Funding: $7,449
Aims: The major goal of this project is to conduct a program of research, dissemination activities, and clinical care designed to decrease emotional distress and to improve participation for persons with traumatic brain injury (TBI).

1. To contribute to the TBI Model Systems National Database,
2. To participate in collaborative module projects
3. To undertake a local project that is a randomized controlled trial of Acceptance and Commitment Therapy as compared to a devised standard of care intervention to decrease emotional distress and improve participation for persons with TBI.

Role: Co-Investigator

Award number: 90RTEM0001-01-00
Title: Rehabilitation Research Training Center (RRTC) on employment for people with physical disabilities
PI: Heinemann
Time commitments: 4.2 calendar months
Supporting agency: NIDILRR
Name & address of funding agency POC/GO: Dr. Amanda Reichard, Switzer Building, 330 C Street, SW, Washington, DC 20201-1401
Performance period: 9/30/18-9/29/23
Funding: $4,375,000
Aims:

1. Conduct an RCT comparing an evidence-based, telehealth pain self-management intervention, adapted to address risk and protective factors for employment disability, to a waitlist control in adults who are employed;
2. Assess employer-, client-, job-, and environment-related barriers and facilitators of job retention after VR;
3. Evaluate an implementation science approach to employment interventions in people with Parkinson's disease; and
4. Evaluate job accommodation strategies and assistive technology resources for rural and low resource environments.

Role: Principal Investigator

Award number: W81XWH1820057
Title: Personalized Mobility Interventions using Smart Sensor Resources for Lower-limb Prostheses Users
PI: Jayaraman
Time commitments: 0.36 calendar months

Supporting agency: DOD
Name & address of funding agency POC/GO:
Performance period: 9/30/18-9/29/22
Funding: $2,440,168
Aims:

1. Determine whether a participant's prosthesis use matches the assigned K-level and/or self-reported goals and, if not, determine the reason(s) using an expert panel to evaluate data from performance-related measures, participant-reported measures, and smartphone and prosthesis sensors (clinical toolbox)
2. Quantify effects of targeted physical intervention (prosthesis repair/refit, physical rehabilitation) or psychological intervention (motivational interviewing), or both, on activity levels and patient goals
3. 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

Award number: 90SIMS0001
Title: A Multi-Center Clinical Trial to Evaluate the Effectiveness of Intermittent Hypoxia Therapy in Individuals with Spinal Cord Injury
PI: Rymer
Time commitments: 0.24 calendar months
Supporting agency: NIDILRR
Name & address of funding agency POC/GO: Patricia Barrett, Grants Management Specialist; NIDILRR, Administration for Community Living; U.S. Department of Health and Human Services; 330 C Street SW; Washington, DC 20230
Performance period: 9/30/17-9/29/22
Funding: $4,499,458
Aims: Our objective is to test whether daily AIH improves upper-limb function in persons with incomplete cervical SCI. We will 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

Complete

Award number: 90SI5009-02-00
Title: Midwest Regional Spinal Cord Injury Care System
PI: Chen & Heinemann
Time commitments: 0.24 calendar months
Supporting agency: NIDILRR
Name & address of funding agency POC/GO: Dr. Kenneth Wood, 330 C Street SW, 2511B, Administration for Community Living, Washington, DC 20201
Performance period: 10/1/11-9/29/17
Funding: $2,414,304

Aims: The goals of MRSCICS are to advance the outcomes of our previous Model Systems research, continue to study the effectiveness of innovative treatment strategies; and evaluate the benefits of a well-designed, comprehensive, coordinated, interdisciplinary continuum of care that lead to improved outcomes for persons with SCI.

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

Role: Co-Principal Investigator

Award number: 5K12HS023011-01
Title: Northwestern University Patient-centered intervention and Engagement Training
PI: Cella
Time commitments: 0.24 calendar months
Supporting agency: AHRQ
Name & address of funding agency POC/GO: Tylor Carl, Office for Sponsored Research, Northwestern University, 750 N. Lake Shore Dr. 7th Floor, Chicago, IL 60611
Performance period: 9/1/14-7/31/17
Funding: $25,000
Aims: Goal of Dr. Daniel Pinto's project is to provide a clear path to independence beginning with an innovative idea, that is, to identify the global problem of adherence to the attributes that are associated with adherence, apply preference weights tot the relative importance of these attributes using choice modeling, and build patient-centered physical activity recommendations based on an individual's preferred attributes.
Role: Faculty Mentor

Award number: H133P130013
Title: Advanced Rehabilitation Research Training in Health Services Research
PI: Heinemann
Time commitments: 0.6 calendar months
Supporting agency: NIDILRR
Name & address of funding agency POC/GO: Margaret Campbell; NIDILRR, Administration for Community Living; U.S. Department of Health and Human Services; 330 C Street SW; Washington, DC 20230
Performance period: 10/1/13-9/30/18
Funding: $60,000
Aims: The goal of this project is to provide an integrated, interdisciplinary, collaborative training program for early career scholars focusing on rehabilitation-related health services research. Health services faculty work closely with fellows to provide a rigorous and relevant interdisciplinary curriculum, integrating faculty and programs from diverse departments and centers into a unified health services research training. Through this program, six post-doctoral fellows will develop new skills to enhance their previous

training in order to pursue a research career in rehabilitation-related health services research. The program includes carefully matched mentors, didactic course work, original research, grant writing, and scientific publishing over a two-year period.
Role: PI

Sherri L. LaVela, PhD

Active

Award number: PP-1706-27896
Title: Evaluating the Use of Acute Intermittent Hypoxia to Enhance Motor Function in Persons with Multiple Sclerosis
PI: LaVela
Time commitments: 2.4 calendar months
Supporting agency: National Multiple Sclerosis Society
Name & address of funding agency POC/GO: Kathleen Zackowski, PhD, OTR; 212-476-0442; Kathleen.zackowski@nmss.org
Performance period: 11/01/18-10/31/19
Funding: $43,994
Aims: 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.
Role: PI

Complete
Award number: CHNF324723
Title: Development of a Comprehensive Screening Protocol for Depressive Symptoms in People Living with SCI.
PI: LaVela & Raad
Time commitments: 2.0 calendar months
Supporting agency: Craig H. Neilsen Foundation
Name & address of funding agency POC/GO:
Performance period: 11/30/15 – 10/31/17
Funding: $150,000
Aims: 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.
Role: Co-PI

What other organizations were involved as partners?

Organization Name: Northwestern University
Location of Organization: 750 N. Lake Shore Drive, 7th Floor, Chicago, IL 60611
Partner's contribution to the project
- Facilities;
- Collaboration;

Organization Name: Chicago Association for Research & Education in Science (CARES)
Location of Organization: (if foreign location list country): Building One, Rm C303, 5000 S. 5th Avenue, Hines, IL 60141
Partner's contribution to the project
- Financial support: Cost share Dr. Stuck's effort
- Facilities;
- Collaboration;

Organization Name: Department of Veterans Affairs- Minneapolis VA Health Care System
Location of Organization: One Veterans Drive, Minneapolis, MN 55417
Partner's contribution to the project
- Facilities;
- Collaboration;

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: Not Applicable

QUAD CHARTS: See Below

9. APPENDICES: RedCap Survey

Enhancing Quality of Orthotic Services with Process and Outcome Information

OP150034

PI: Allen Heinemann

Organization: Rehabilitation Institute of Chicago

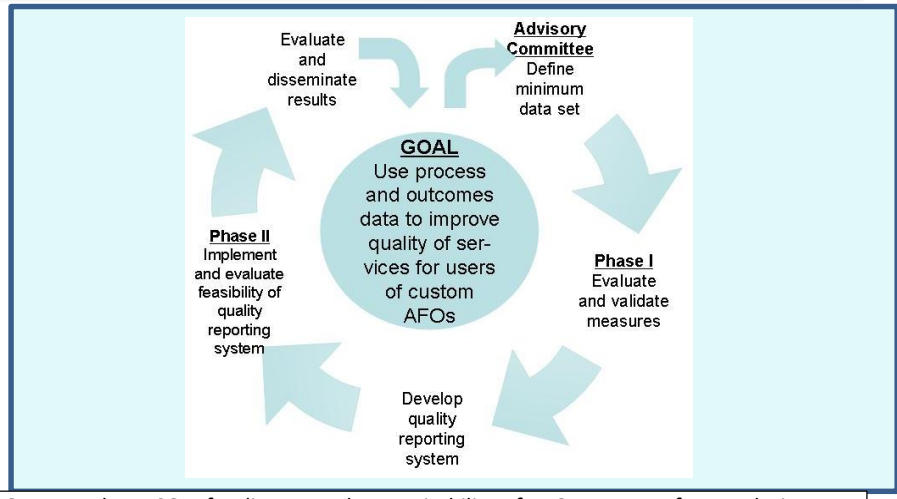
Award Amount: $1,590,406.00

Study/Product Aim(s)

- 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.
- Evaluate and validate patient-reported outcome instruments using performance instruments.
- 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.

Approach

This proposal builds on our on-going quality measure development efforts by identifying items and instruments that can be used to create quality measures that meet the criteria set forth by the National Quality Forum (NQF), the leading organization responsible for endorsing quality measures. In order for quality measures to be effective, they must be tailored to orthotic practice. This project engages stakeholders in the selection and development of measures that can be used to document quality of care for patients receiving custom AFOs.



Our team has PCORI funding to evaluate suitability of PRO measures for use during inpatient rehabilitation for patients with neurological disorders. No investigator has evaluated PRO measures for orthotics users as described in the figure above.

Timeline and Cost

Activities PY	1	2	3
1. Identify issues			
2. Evaluate outcome instruments			
3. Specify quality measures			
Budget ($1,590,406)	**$538,232**	**$516,989**	**$535,185**

Updated: October 22, 2018

Goals/Milestones

CY16 Tasks

T1.1 Prepare for and convene an Advisory Committee that represents multiple stakeholders to identify important issues in the quality of care for AFO users.

T1.2 Identify items and instruments that operationalize important quality of care concepts for AFO practice.

T1.3 Survey orthotists to understand their preferences, priorities & barriers to quality measure use.

T1.4 Define case-mix indicators – additional critical data elements needed for valid interpretation of quality measures.

T2.1 Select process and outcome items and instruments with optimal properties identified.

CY17 Tasks

T2.2 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.

CY18 Tasks

T3.1 Review results and recommend quality measure components to the Advisory Committee.

T3.2 Prioritize and select the most compelling quality measures.

T3.3 Design the specifications for data collection and obtain feedback about usability and feasibility from the Advisory Committee.

T3.4 Disseminate findings and promote knowledge translation.

Budget Expenditure

Projected Expenditure: $1,590,406.00

Actual Expenditure: $ 703,363.70

Health Status Change

Since your last study visit, have you experienced any changes in your health that have affected your functioning (or walking ability)"

- ◯ Yes
- ◯ No

What was the change?

- ☐ A fall (defined as inadvertently coming to rest on the ground, floor, or another lower level)
- ☐ Change in medication
- ☐ Hospitalization
- ☐ Emergency Room Visits (ER) visit
- ☐ Reduced activity due to illness or injury
- ☐ Any unusual sensory symptoms (e.g. burning, prickling, tickling, or numbness sensations in any part of the body)
- ☐ Other

Other, please explain _____

Providers often use words that patients don't understand. We are looking at words providers often use with their patients in order to improve communication between health care providers and patients. Here is a list of medical words.
Starting at the top of the list, please read each word aloud to me. If you don't recognize a word, you can say 'pass' and move on to the next word."
Interviewer: Give the participant the word list. If the participant takes more than 5 seconds on a words, say "pass" and point to the next word. Hold this scoring sheet so that it is not visible to the participant.

1) Mark all that were said aloud

- ☐ Behavior
- ☐ Exercise
- ☐ Menopause
- ☐ Rectal
- ☐ Antibiotics
- ☐ Anemia
- ☐ Jaundice

(Interviewer: If the participant takes more than 5 seconds on a word or is not able to read the word, count it as zero. Count the number of words that were read correctly. If the person reads 3 or fewer words correctly, please administer ALL remaining questions orally as an interview. If the person reads 4 or more words correctly, and they request to do so, you can let them complete the remaining questions on their own.)

1) Subject ID _____

2) Subject Group

◯ New User
◯ Current User

Demographics Characteristics

Please complete the survey below.

Thank you!

When was the date or onset of your condition/injury:
If you do not wish to answer, please enter
09-09-9999" to decline the question.

_____

Which type of injury did you sustain?

- ☐ Stroke
- ☐ Spinal Cord Injury
- ☐ Traumatic Brain Injury
- ☐ Parkinson's Disease
- ☐ Multiple Sclerosis
- ☐ Polytrauma
- ☐ Other neurological conditions
- ☐ Prefer not to answer

What is your age?
If you do not wish to answer, please enter "999".

_____

What is your sex?

- ◯ Male
- ◯ Female
- ◯ Other
- ◯ Prefer not to answer

Do you have a Latino or Hispanic background?

- ◯ Not Hispanic or Latino
- ◯ Yes, Hispanic or Latino: Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race
- ◯ Prefer not to answer

With what race do you identify?

- ◯ White or Caucasian
- ◯ Black or African American
- ◯ American Indian/Alaska Native
- ◯ Asian or Pacific Islander
- ◯ Other, Multiracial
- ◯ Prefer not to answer

What is your height?

_____
(Feet only in this line)

If you do not wish to answer, please enter "999".

What is your height?

_____
(Inches only)

If you don't wish to answer, please enter 999

How much do you weigh in pounds?
If you do not wish to answer, please enter "999".

_____

In the last 6 months, have you experienced any weight change?

- ◯ Yes, weight gain
- ◯ Yes, weight loss
- ◯ No, no change

How much have you gained or lost (lbs)?

_____

What is the highest level of education you have completed?

- ◯ 8th grade or less
- ◯ 9th through 11th grade
- ◯ High School Diploma/GED
- ◯ Associate Degree
- ◯ Bachelor's Degree
- ◯ Master's Degree
- ◯ Doctorate
- ◯ Other
- ◯ Prefer not to answer

if other, please explain _____

Currently, what is your primary occupational status?

- ◯ Working
- ◯ Homemaker
- ◯ On-the-job training
- ◯ Student
- ◯ Volunteer
- ◯ Unemployed
- ◯ Retired (disability pension)
- ◯ Retired (non-disability, age-related)
- ◯ Other (includes disability leave and medical leave)
- ◯ Prefer not to answer

What insurance primarily paid for your device?

- ◯ Private Insurance (includes 'no-fault', BCBS, United Health, Humana, etc)
- ◯ Medicare
- ◯ Medicaid
- ◯ Worker's Compensation
- ◯ Veterans Administration
- ◯ Other Government (e.g. Bureau of Indian Affairs; Crippled Children's Services; Dept. of Voc Rehab)
- ◯ No Pay (indigent, no resources)
- ◯ Private funds (e.g., self-pay; hometown fund raisers)
- ◯ Other (e.g., SCI system patient care funds, Homebound, victim's assistance funds, etc.)
- ◯ Prefer not to answer

Are you a veteran?

- ◯ Yes
- ◯ No
- ◯ Prefer not to answer

How many years have you been using an orthotic device?

_____
(If less than 1 year, please put " 1")

On which foot do you primarily wear your device?

◯ Left
◯ Right
◯ Both

How many hours per day were you instructed to wear your device?

_____
(0-24)

How many days per week were you instructed to wear your device?

_____
(0-7)

How many hours per day do you actually wear your device?

_____
(0-24)

How many days per week do you actually wear your device?

_____
(0-7)

Eq5d5l

Please click the ONE box that best describes your health TODAY.

1) MOBILITY

◯ I have no problems walking
◯ I have slight problems walking
◯ I have moderate problems walking
◯ I have severe problems walking
◯ I am unable to walk

Please click the ONE box that best describes your health TODAY.

2) SELF-CARE

◯ I have no problems washing or dressing myself
◯ I have slight problems washing or dressing myself
◯ I have moderate problems washing or dressing myself
◯ I have severe problems washing or dressing myself
◯ I am unable to wash or dress myself

Please click the ONE box that best describes your health TODAY.

3) USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

◯ I have no problems doing my usual activities
◯ I have slight problems doing my usual activities
◯ I have moderate problems doing my usual activities
◯ I have severe problems doing my usual activities
◯ I am unable to do my usual activities

Please click the ONE box that best describes your health TODAY.

4) PAIN / DISCOMFORT

◯ I have no pain or discomfort
◯ I have slight pain or discomfort
◯ I have moderate pain or discomfort
◯ I have severe pain or discomfort
◯ I have extreme pain or discomfort

Please click the ONE box that best describes your health TODAY.

5) ANXIETY / DEPRESSION

◯ I am not anxious or depressed
◯ I am slightly anxious or depressed
◯ I am moderately anxious or depressed
◯ I am severely anxious or depressed
◯ I am extremely anxious or depressed

6)

We would like to know how good or bad your health is TODAY.

This scale is numbered from 0 to 100.

100 means the best health you can imagine.
0 means the worst health you can imagine.

Please click on the scale to indicate how your health is TODAY.

0 - The worst health you can imagine

50

100 - The best health you can imagine

(Place a mark on the scale above)

FINAL RESULTS

T-score _____

Standard Error _____

PAININ9

In the past 7 days
How much did pain interfere with your day to day activities?

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

PAININ22

In the past 7 days
how much did pain interfere with work around the home?

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

PAININ31

In the past 7 days
How much did pain interfere with your ability to participate in social activities?

◯ Not at all
◯ A little bit
◯ Somewhat
◯ Quite a bit
◯ Very much

PAININ34

In the past 7 days
How much did pain interfere with your household chores?

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

PAININ12

In the past 7 days
How much did pain interfere with the things you usually do for fun?

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

PAININ36

In the past 7 days
How much did pain interfere with your enjoyment of social activities?

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

PAININ3

In the past 7 days
How much did pain interfere with your enjoyment of life?

◯ Not at all
◯ A little bit
◯ Somewhat
◯ Quite a bit
◯ Very much

PAININ13

In the past 7 days
How much did pain interfere with your family life?

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

FINAL RESULTS

T-score _____

Standard Error _____

SRPPER11_CaPS

I have trouble doing all of my regular leisure activities with others

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Usually
- ◯ Always

SRPPER18_CaPS

I have trouble doing all of the family activities that I want to do

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Usually
- ◯ Always

SRPPER23_CaPS

I have trouble doing all of my usual work (include work at home)

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Usually
- ◯ Always

SRPPER46_CaPS

I have trouble doing all of the activities with friends that I want to do

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Usually
- ◯ Always

SRPPER15_CaPS

I have to limit the things I do for fun with others

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Usually
- ◯ Always

SRPPER28r1

I have to limit my regular activities with friends

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Usually
- ◯ Always

SRPPER14r1

I have to limit my regular family activities

◯ Never
◯ Rarely
◯ Sometimes
◯ Usually
◯ Always

SRPPER26_CaPS

I have trouble doing all of the work that is really important to me (include work at home)

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Usually
- ◯ Always

FINAL RESULTS

T-score _____

Standard Error _____

SRPSAT06r1

I am satisfied with my ability to do things for my family

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

SRPSAT33_CaPS

I am satisfied with my ability to do things for fun with others

◯ Not at all
◯ A little bit
◯ Somewhat
◯ Quite a bit
◯ Very much

SRPSAT34r1

I feel good about my ability to do things for my friends

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

SRPSAT49r1

I am satisfied with my ability to perform my daily routines

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

SRPSAT33r1

I am satisfied with my ability to do things for fun outside my home

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

SRPSAT46_CaPS

I am satisfied with my ability to meet the needs of my friends

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

SRPSAT09r1

I am satisfied with my ability to do the work that is really important to me (include work at home)

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

SRPSAT45_CaPS

I am satisfied with my ability to meet the needs of my family

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

Please respond to each item by choosing one answer per statement. The following questions ask about your ability to stand and move with and without support. "Support" means using items such as canes, walking sticks, walkers and leg braces, or other people.

Can you walk 25 feet on a level surface (with or without support)? ◯ Yes ◯ No

	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
Are you able to walk a block on flat ground?	◯	◯	◯	◯	◯
Are you able to walk up and down two steps?	◯	◯	◯	◯	◯
Are you able to run at a fast pace for two miles?	◯	◯	◯	◯	◯
Are you able to do yard work like raking leaves, weeding, or pushing a lawn mower?	◯	◯	◯	◯	◯

	Not at all	Very little	Somewhat	Quite a lot	Cannot do
Does your health now limit you in doing strenuous activities such as backpacking, skiing, playing tennis, bicycling or jogging?	◯	◯	◯	◯	◯
Does your health now limit you in hiking a couple of miles on uneven surfaces, including hills?	◯	◯	◯	◯	◯

	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
Are you able to wash and dry your body?	◯	◯	◯	◯	◯
Are you able to get in and out of bed?	◯	◯	◯	◯	◯
Are you able to bend down and pick up clothing from the floor?	◯	◯	◯	◯	◯
Are you able to push open a heavy door?	◯	◯	◯	◯	◯
Are you able to reach and get down an object (such as a can of soup) from above your head?	◯	◯	◯	◯	◯

	Not at all	Very little	Somewhat	Quite a lot	Cannot do

Does your health now limit you in doing eight hours of physical labor?	○	○	○	○	○

How easy, or difficult, is it for you to:

Get into and out of the tub or shower?
- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?
- ◯ Yes
- ◯ No

Dress your lower body?
- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?
- ◯ Yes
- ◯ No

Get on and off the toilet?
- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?
- ◯ Yes
- ◯ No

Get up from the floor?
- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?
- ◯ Yes
- ◯ No

Balance while standing?
- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?
- ◯ Yes
- ◯ No

Stand for one- half hour?

- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?

- ◯ Yes
- ◯ No

Pick up an object from the floor while standing?

- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?

- ◯ Yes
- ◯ No

Get up from a chair?

- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?

- ◯ Yes
- ◯ No

Get into and out of a car?

- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?

- ◯ Yes
- ◯ No

Walk around indoors?

- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?

- ◯ Yes
- ◯ No

Walk outside on uneven ground?

- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?

- ◯ Yes
- ◯ No

Walk in bad weather (snow, rain , wind)?
- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?
- ◯ Yes
- ◯ No

Walk up to two hours?
- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?
- ◯ Yes
- ◯ No

Walk up a steep ramp?
- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?
- ◯ Yes
- ◯ No

Get on and off an escalator?
- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?
- ◯ Yes
- ◯ No

Climb one flight of stairs with a rail?
- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?
- ◯ Yes
- ◯ No

Climb one flight of stairs WITHOUT a rail?
- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?
- ◯ Yes
- ◯ No

Run one block?

- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?

- ◯ Yes
- ◯ No

Carry a plate of food while walking?

- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Do you typically wear an orthotic device to perform this activity?

- ◯ Yes
- ◯ No

Put on and take off your orthotic device?

- ◯ Very Easy
- ◯ Easy
- ◯ Slightly Difficult
- ◯ Very Difficult
- ◯ Cannot Do This Activity
- ◯ Prefer not to answer

Note: For the questions below, the term "physical condition" refers to the reason you use an anklefoot orthosis

1) How much do you keep to yourself to avoid people's reactions to your need for a device?
- ◯ Not At All
- ◯ A Little
- ◯ A Fair Amount
- ◯ A Great Deal
- ◯ Excessively
- ◯ Prefer not to answer

2) To what extent do you find that people's attitudes toward your physical condition are insulting?
- ◯ Not At All
- ◯ A Little
- ◯ A Fair Amount
- ◯ A Great Deal
- ◯ Excessively
- ◯ Prefer not to answer

3) To what extent are you prevented from doing what you want to do because of social attitudes, the law, or environmental barriers?
- ◯ Not At All
- ◯ A Little
- ◯ A Fair Amount
- ◯ A Great Deal
- ◯ Excessively
- ◯ Prefer not to answer

4) How much does pain interfere with your activities (including both work outside the home and household duties)?
- ◯ Not At All
- ◯ A Little
- ◯ A Fair Amount
- ◯ A Great Deal
- ◯ Excessively
- ◯ Prefer not to answer

5) To what extent do you accomplish less than you would like because of your physical condition?
- ◯ Not at all
- ◯ A Little
- ◯ A Fair Amount
- ◯ A Great Deal
- ◯ Excessively
- ◯ Prefer not to answer

6) To what extent do you accomplish less than you would like because of emotional problems?
- ◯ Not At All
- ◯ A Little
- ◯ A Fair Amount
- ◯ A Great Deal
- ◯ Excessively
- ◯ Prefer not to answer

7) How much does your physical condition restrict your ability to run errands?
- ◯ Not At All
- ◯ A Little
- ◯ A Fair Amount
- ◯ A Great Deal
- ◯ Excessively
- ◯ Prefer not to answer

8) How much does your physical condition restrict your ability to pursue a hobby?

- ◯ Not at all
- ◯ A Little
- ◯ A Fair Amount
- ◯ A great deal
- ◯ Excessively
- ◯ Prefer not to answer

9) How much does your physical condition restrict your ability to do chores?

- ◯ Not At All
- ◯ A Little
- ◯ A Fair Amount
- ◯ A Great Deal
- ◯ Excessively
- ◯ Prefer not to answer

10) How much does your physical condition restrict your ability to do paid work?

- ◯ Not At All
- ◯ A Little
- ◯ A Fair Amount
- ◯ A Great deal
- ◯ Excessively
- ◯ Prefer not to answer

11) To what extent have you cut down on work or other activities because of your physical condition?

- ◯ Not At All
- ◯ A Little
- ◯ A Fair Amount
- ◯ A Great Deal
- ◯ Excessively
- ◯ Prefer not to answer

12) To what extent have you cut down on work or other activities because of emotional problems?

- ◯ Not At All
- ◯ A Little
- ◯ A Fair Amount
- ◯ A Great Deal
- ◯ Excessively
- ◯ Prefer not to answer

During the past week, how often have you...

1) felt full of life?
- ◯ All the time
- ◯ Most of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time
- ◯ Prefer not to answer

2) felt calm and peaceful?
- ◯ All the time
- ◯ Most of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time
- ◯ Prefer not to answer

3) had a lot of energy?
- ◯ All the time
- ◯ Most of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time
- ◯ Prefer not to answer

4) been happy?
- ◯ All the time
- ◯ Most of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time
- ◯ Prefer not to answer

5) been very nervous?
- ◯ All the time
- ◯ Most of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time
- ◯ Prefer not to answer

6) felt so down in the dumps that nothing could cheer you up?
- ◯ All the time
- ◯ Most of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time
- ◯ Prefer not to answer

7) felt downhearted and depressed?
- ◯ All the time
- ◯ Most of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time
- ◯ Prefer not to answer

8) felt worn out?

- ◯ All the time
- ◯ Most of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time
- ◯ Prefer not to answer

9) felt tired?

- ◯ All the time
- ◯ Most of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time
- ◯ Prefer not to answer

10) been easily bothered or upset?

- ◯ All the time
- ◯ Most of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time
- ◯ Prefer not to answer

11) had difficulty concentrating or paying attention?

- ◯ All the time
- ◯ Most of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time
- ◯ Prefer not to answer

Please mark the response that most closely reflects your opinion.

My ankle foot orthosis fits well

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

The weight of my ankle foot orthosis is manageable

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

My ankle foot orthosis is comfortable throughout the day

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

It is easy to put on my orthosis

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

My orthosis looks good

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not answer

My orthosis is durable

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

My clothes are free of wear and tear from my orthosis

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

My skin is free of abrasions and irritations

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

My orthosis is pain free to wear

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

I can afford to repair or replace my orthosis within a reasonable amount of time

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

I can afford the out-of-pocket expenses to purchase and maintain my orthosis

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

I received an appointment with an orthotist within a reasonable amount of time

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

I was shown the proper level of courtesy and respect by the staff

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

I waited a reasonable amount of time to be seen

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

Clinic staff fully informed me about AFO choices

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

The orthotist gave me the opportunity to express my concerns regarding my AFO

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

The orthotist was responsive to my concerns and questions

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Prefer not to answer
- ◯ Don't Know/ Not Applicable

I am satisfied with the training I received in the use and maintenance of my orthosis

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

The orthotist discussed problems I might encounter with my AFO

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

The staff coordinated their services with my therapists and doctors

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

I was a partner in decision-making with clinic staff regarding my care and AFO

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neither Agree nor Disagree
- ◯ Strongly Disagree
- ◯ Don't Know/ Not Applicable
- ◯ Prefer not to answer

Please answer Yes or No to the following questions

1) Turning over in bed: Do you turn over from your back to your side without help?
◯ Yes
◯ No
◯ Prefer not to answer

2) Lying to sitting: From lying in bed, do you get up to sit on the edge of the bed on your own?
◯ Yes
◯ No
◯ Prefer not to answer

3) Sitting balance: Do you sit on the edge of the bed without holding on for 10 seconds?
◯ Yes
◯ No
◯ Prefer not to answer

4) Sitting to standing: Do you stand up from any chair in less than 15 seconds and stand there for 15 seconds, using hands and/or an aid if necessary?

Aid: An assistive device designed to help assist a person perform a particular task (ex. canes, walker, crutches, etc.)

◯ Yes
◯ No
◯ Prefer not to answer

5) Transfer: Do you manage to move from bed to chair and back without any help?
◯ Yes
◯ No
◯ Prefer not to answer

6) Walking inside: Do you walk 10 meters, with an aid if necessary, but with no standby help?

Aid: An assistive device designed to help assist a person perform a particular task (ex. canes, walker, crutches, etc.)

◯ Yes
◯ No
◯ Prefer not to answer

7) Stairs: Do you manage a flight of stairs without help?
◯ Yes
◯ No
◯ Prefer not to answer

8) Walking outside: (even ground): Do you walk around outside, on pavements, without help?
◯ Yes
◯ No
◯ Prefer not to answer

9) Walking inside: Do you walk 10 meters inside, with no caliper, splint, or other aid (including furniture or walls) without help?

Aid: An assistive device designed to help assist a person perform a particular task (ex. canes, walker, crutches, etc.)

◯ Yes
◯ No
◯ Prefer not to answer

10) Picking up off floor: Do you manage to walk five meters, pick something up from the floor, and then walk back without help?
◯ Yes
◯ No
◯ Prefer not to answer

11) Walking outside: (uneven ground): Do you walk over uneven ground (grass, gravel, snow, ice, etc.) without help?
◯ Yes
◯ No
◯ Prefer not to answer

12) Bathing: Do you get into/out of a bath or shower to wash yourself unsupervised and without help?
- ◯ Yes
- ◯ No
- ◯ Prefer not to answer

13) Up and down four steps: Do you manage to go up and down four steps?
- ◯ Yes
- ◯ No
- ◯ Prefer not to answer

14) Running: Do you run 10 meters without limping in four seconds (fast walk, not limping, is acceptable)?
- ◯ Yes
- ◯ No
- ◯ Prefer not to answer

How satisfied are you with,

1) the dimensions (size, height, length, width) of your ankle foot orthosis?

- ◯ Not Satisfied At All
- ◯ Not Very Satisfied
- ◯ More or Less Satisfied
- ◯ Quite Satisfied
- ◯ Very Satisfied
- ◯ Prefer not to answer

2) the weight of your ankle foot orthosis?

- ◯ Not Satisfied At All
- ◯ Not Very Satisfied
- ◯ More or Less Satisfied
- ◯ Quite Satisfied
- ◯ Very Satisfied
- ◯ Prefer not to answer

3) the ease in adjusting (fixing, fastening) the parts of your ankle foot orthosis?

- ◯ Not Satisfied At All
- ◯ Not Very Satisfied
- ◯ More or Less Satisfied
- ◯ Quite Satisfied
- ◯ Very Satisfied
- ◯ Prefer not to answer

4) how safe and secure your ankle foot orthosis is?

- ◯ Not Satisfied At All
- ◯ Not Very Satisfied
- ◯ More or Less Satisfied
- ◯ Quite Satisfied
- ◯ Very Satisfied
- ◯ Prefer not to answer

5) the durability (endurance, resistance to wear) of your ankle foot orthosis?

- ◯ Not Satisfied At All
- ◯ Not Very Satisfied
- ◯ More or Less Satisfied
- ◯ Quite Satisfied
- ◯ Very Satisfied
- ◯ Prefer not to answer

6) how easy it is to use your ankle foot orthosis?

- ◯ Not Satisfied At All
- ◯ Not Very Satisfied
- ◯ More or Less Satisfied
- ◯ Quite Satisfied
- ◯ Very Satisfied
- ◯ Prefer not to answer

7) how comfortable your ankle foot orthosis is?

- ◯ Not Satisfied At All
- ◯ Not Very Satisfied
- ◯ More or Less Satisfied
- ◯ Quite Satisfied
- ◯ Very Satisfied
- ◯ Prefer not to answer

8) how effective your ankle foot orthosis is (the degree to which your device meets your needs)?

- ◯ Not Satisfied At All
- ◯ Not Very Satisfied
- ◯ More or Less Satisfied
- ◯ Quite Satisfied
- ◯ Very Satisfied
- ◯ Prefer not to answer

9) the service delivery program (procedures, length of time) in which you obtained your ankle foot orthosis?

- ◯ Not Satisfied At All
- ◯ Not Very Satisfied
- ◯ More or Less Satisfied
- ◯ Quite Satisfied
- ◯ Very Satisfied
- ◯ Prefer not to answer

10) the repairs and servicing (maintenance) provided for your ankle foot orthosis?

- ◯ Not Satisfied At All
- ◯ Not Very Satisfied
- ◯ More or Less Satisfied
- ◯ Quite Satisfied
- ◯ Very Satisfied
- ◯ Prefer not to answer

11) the quality of the professional services (information, attention) you received for using your ankle foot orthosis?

- ◯ Not Satisfied At All
- ◯ Not Very Satisfied
- ◯ More or Less Satisfied
- ◯ Quite Satisfied
- ◯ Very Satisfied
- ◯ Prefer not to answer

12) the follow-up services (continuing support services) received for your ankle foot orthosis?

- ◯ Not Satisfied At All
- ◯ Not Very Satisfied
- ◯ More or Less Satisfied
- ◯ Quite Satisfied
- ◯ Very Satisfied
- ◯ Prefer not to answer

13) Here is a list of the same 12 satisfaction items. PLEASE SELECT THE THREE ITEMS that you consider to be the most important to you.

- ☐ Dimensions
- ☐ Weight
- ☐ Adjustment
- ☐ Safety
- ☐ Durability
- ☐ Easy to use
- ☐ Comfort
- ☐ Effectiveness
- ☐ Services delivery
- ☐ Repairs/ servicing
- ☐ Professional service
- ☐ Follow-up services
- ☐ Prefer not to answer

This survey asks about your experience at your last visit to the orthotics clinic. For this survey, we use the term "visit" for services related to your orthosis, for example a fitting visit or visit to check the device. We refer to "facility" as the place where you received your orthosis. Do not include any other visits in your answers.

Before your visit, did anyone from the facility give you all the information you needed about your visit?
- ◯ Yes, definitely
- ◯ Yes, somewhat
- ◯ No
- ◯ Prefer not to answer

Before your visit, did anyone from the facility give you easy to understand instructions about getting ready for your visit?
- ◯ Yes, definitely
- ◯ Yes, somewhat
- ◯ No
- ◯ Prefer not to answer

Did the check in-process run smoothly?
- ◯ Yes, definitely
- ◯ Yes, somewhat
- ◯ No
- ◯ Prefer not to answer

Was the facility clean?
- ◯ Yes, definitely
- ◯ Yes, somewhat
- ◯ No
- ◯ Prefer not to answer

Were the receptionists at the facility as helpful as you thought they should be?
- ◯ Yes, definitely
- ◯ Yes, somewhat
- ◯ No
- ◯ Prefer not to answer

Did the clerks and receptionists at the facility treat you with courtesy and respect?
- ◯ Yes, definitely
- ◯ Yes, somewhat
- ◯ No
- ◯ Prefer not to answer

Did the doctors, nurses, orthotists and therapists make sure you were as comfortable as possible?
- ◯ Yes, definitely
- ◯ Yes, somewhat
- ◯ No
- ◯ Prefer not to answer

Did the doctors, nurses, orthotists and therapists explain your visit in a way that was easy to understand?
- ◯ Yes, definitely
- ◯ Yes, somewhat
- ◯ No
- ◯ Prefer not to answer

Discharge instructions include things like symptoms you should watch for after your visit, instructions about medicines, and home care.
Before you left the facility, did you get written discharge instructions?
- ◯ Yes, definitely
- ◯ Yes, somewhat
- ◯ No
- ◯ Prefer not to answer

Did anyone from the facility prepare you for what to expect during the orthotic evaluation, fitting, and delivery process?

- ◯ Yes, definitely
- ◯ Yes, somewhat
- ◯ No
- ◯ Prefer not to answer

At anytime after leaving the facility, did you have pain as a result of your orthotic device

- ◯ Yes, definitely
- ◯ Yes, somewhat
- ◯ No
- ◯ Prefer not to answer

Using any number from 0 to 10, where 0 is the worst facility possible and 10 is the best facility possible, what number would you use to rate this facility?

- ◯ 0 Worst facility possible
- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7
- ◯ 8
- ◯ 9
- ◯ 10 Best facility possible
- ◯ Prefer not to answer

Would you recommend this facility to your friends and family?

- ◯ Definitely no
- ◯ Probably no
- ◯ Probably yes
- ◯ Definitely yes
- ◯ Prefer not to answer

In general, how would you rate your overall health?

- ◯ Excellent
- ◯ Very good
- ◯ Good
- ◯ Fair
- ◯ Poor
- ◯ Prefer not to answer

In general, how would you rate your overall mental or emotional health?

- ◯ Excellent
- ◯ Very good
- ◯ Good
- ◯ Fair
- ◯ Poor
- ◯ Prefer not to answer

How well do you speak English?

- ◯ Very well
- ◯ Well
- ◯ Not well
- ◯ Not at all
- ◯ Prefer not to answer

Do you speak a language other than English?

- ◯ Yes
- ◯ No

What is that language? _____

Did someone help you complete this survey?

- ◯ Yes
- ◯ No

How did that person help you? Check all that apply ?

- ☐ Read the questions to me
- ☐ Wrote down the answers I gave
- ☐ Answered the questions for me
- ☐ Translated the questions into my language
- ☐ Helped in some other way

6 Minute Walk Test

Please remember to measure distance at both the 2 and 6 minute time points.

Please read aloud to subject "The aim of this test is to walk as far as possible in six minutes. You will walk back and forth in the hallway. Six minutes is a long time to walk, so you will be exerting yourself. You may get out of breath or become tired. You are allowed to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able. Remember the aim is to walk as far as possible, but do not run or jog." Are you ready to do that?"

[Attachment: "Outcomes standardization_ (002).pptx"]

Testing condition

- ◯ With AFO
- ◯ Without AFO

Level of assistance provided

- ◯ None
- ◯ Supervision (helper within arm reach)
- ◯ Contact guard (helper has arms on patient but no effort)
- ◯ Minimal assistance (helper provides up to 25% effort)
- ◯ Moderate assistance (helper provides up to 50% effort)
- ◯ Maximum assistance (helper provides up to 75% effort)
- ◯ Total assistance (helper provides 100% effort)

Distance covered in 2 minutes (meters)

_____
(0.01)

Number of breaks in 2 minutes (>5 seconds)

_____

Did subject walk for the the full 6 minutes, without taking a seat?

- ◯ Yes
- ◯ No

What minute mark did the subject end the test on?

_____

What was the distance? (meters)

_____
(0.01)

Distance covered in 6 minutes (meters)

_____
(0.01)

Total number of breaks in 6 minutes (>5 seconds)

_____

What was the distance?

_____
(0.01)

Assistive device used

- ☐ Single point cane
- ☐ Quad cane
- ☐ Forearm crutches
- ☐ Axillary crutches
- ☐ Walker
- ☐ None

Is this a new user and is this their second or third visit?

- ◯ Yes, the participant is a new user & this is their SECOND visit
- ◯ Yes, the participant is a new user and this is their THIRD visit
- ◯ No, this is a current user OR a new user, but their first visit.

Testing condition

- ◯ With AFO
- ◯ Without AFO

Level of assistance

- ◯ None
- ◯ Supervision (helper within arm reach)
- ◯ Contact guard (helper has arms on patient but no effort)
- ◯ Minimal assistance (helper provides up to 25% effort)
- ◯ Moderate assistance (helper provides up to 50% effort)
- ◯ Maximum assistance (helper provides up to 75% effort)
- ◯ Total assistance (helper provides 100% effort)

Distance covered in 2 minutes (meters)

_____
(0.01)

Number of breaks in 2mins (>5 seconds)

_____

Did subject walk for the the full 6 minutes, without taking a seat?

- ◯ Yes
- ◯ No

What minute mark did the subject stop on

_____

What was the distance covered?

_____
(meters)

Distance covered in 6 minutes (meters)

_____
(0.01)

Total number of breaks within 6 minutes (>5 seconds)

_____

Assistive device used

- ☐ Single point cane
- ☐ Quad cane
- ☐ Forearm crutches
- ☐ Axillary crutches
- ☐ Walker
- ☐ None

10 Meter Walk Test

Please complete the survey below.

Thank you!

Standardization
Performed using a "flying start."

Patient walks 10 meters (33 feet). The time is measured for the middle 6 meters (20 feet).

The stopwatch should start when the leading foot crosses the 2-meter line and end when the leading foot crosses the 8-meter line.

You will conduct the test four times total. Twice at a comfortable speed and twice at a fast speed.

Please use the following instructions

Comfortable walking speed - "Please walk down this hallway at your normal comfortable pace when I say go and stop when you reach the far mark"

Fast-velocity - "Please walk down this hallway as fast as you safely can when I say go and stop when you reach the far mark."
Do not speak to the patient while testing (may decrease speed)

[Attachment: "Outcomes standardization_ (002).pptx"]

Testing condition

◯ With AFO
◯ Without AFO

Time taken to ambulate: Trial 1 at comfortable speed

_____
(0.01 seconds)

Time taken to ambulate: Trial 2 at comfortable speed

_____
(0.01 seconds)

Time taken to ambulate: Trial 1 at fast speed

_____
(0.01 seconds)

Time taken to ambulate: Trial 2 at fast speed

_____
(0.01 seconds)

Assistive device used

☐ Single point cane
☐ Quad cane
☐ Forearm crutches
☐ Axillary crutches
☐ Walker
☐ None

Level of assistance

- ◯ None
- ◯ Supervision (helper within arm reach)
- ◯ Contact guard (helper has arms on patient but no effort)
- ◯ Minimal assistance (helper provides up to 25% effort)
- ◯ Moderate assistance (helper provides up to 50% effort)
- ◯ Maximum assistance (helper provides up to 75% effort)
- ◯ Total assistance (helper provides 100% effort)

Is this a new user and is this their second or third visit?

- ◯ Yes, the participant is a new user & this is their SECOND visit
- ◯ Yes, the participant is a new user and this is their THIRD visit
- ◯ No, this is a current user OR a new user, but their first visit.

Testing condition

- ◯ With AFO
- ◯ Without AFO

Time taken to ambulate: Trial 1 at comfortable speed

_____
(0.01 seconds)

Time taken to ambulate: Trial 2 at comfortable speed

_____
(0.01 seconds)

Time taken to ambulate: Trial 1: fast speed

_____
(0.01 seconds)

Time taken to ambulate: Trial 2 at fast speed?

_____
(0.01 seconds)

Assistive device used

- ☐ Single point cane
- ☐ Quad cane
- ☐ Forearm crutches
- ☐ Axillary crutches
- ☐ Walker
- ☐ None

Level of assistance

- ◯ None
- ◯ Supervision (helper within arm reach)
- ◯ Contact guard (helper has arms on patient but no effort)
- ◯ Minimal assistance (helper provides up to 25% effort)
- ◯ Moderate assistance (helper provides up to 50% effort)
- ◯ Maximum assistance (helper provides up to 75% effort)
- ◯ Total assistance (helper provides 100% effort)

Timed up and go (TUG)

Please complete the survey below.

Thank you!

Standardization

Time starts the moment you say " go"

Time stops when the participant's back is positioned against the back of the chair

This test is performed twice

Please read aloud to the patient: When I say "go" you will rise from your chair, walk to the end of the cone (3 meters) at a comfortable and safe pace, turn and walk back to the chair and sit down, making sure your back touches the chair.

[Attachment: "Outcomes standardization_ (002).pptx"]

Testing condition

- ◯ With AFO
- ◯ Without AFO

Time for trial 1

_____
(0.01 seconds)

Time for trial 2

_____
(0.01 seconds)

Assistive device used

- ☐ Single point cane
- ☐ Quad cane
- ☐ Forearm crutches
- ☐ Axillary crutches
- ☐ Walker
- ☐ None

Is this a new user and is this there second or third visit?

- ◯ Yes, the participant is a new user & this is their SECOND visit
- ◯ Yes, the participant is a new user and this is their THIRD visit
- ◯ No, this is a current user OR a new user, but their first visit.

Testing condition

- ◯ With AFO
- ◯ Without AFO

Time for trial 1

_____

Time for trial 2

_____

Assistive device used

- ☐ Single point cane
- ☐ Quad cane
- ☐ Forearm crutches
- ☐ Axillary crutches
- ☐ Walker
- ☐ None

Rivermead Performance

Please complete the survey below.

Thank you!

1) Can the patient stand for 10 seconds without any aid?

(Aid: An assistive device designed to help assist a person perform a particular task) (e.g. canes, walker, crutches, etc.)

◯ Yes
◯ No

Device Adherence (Clinician reported)

Reason for wearing device/clinical goals ? Check all that apply

- ☐ Improve function/ Activities of daily living
- ☐ Prevent or delay corrective surgery
- ☐ Reduce pain
- ☐ Correct alignment
- ☐ Improve appearance
- ☐ Improve mobility/gait
- ☐ Decrease contracture
- ☐ Promote safety
- ☐ Inhibit further deformity
- ☐ Other

Other: _____

Ankle design of current device

- ☐ Flexible ankle (an AFO that allows motion by having trimlines posterior to the malleoli)
- ☐ Solid ankle (trimlines anterior to the malleoli)
- ☐ Articulated ankle (an AFO that allows or assists motion with joints)
- ☐ Dorsiflexion assist (an articulated ankle that provides assistance to dorsiflexion motion of the ankle)
- ☐ Dorsiflexion stop (an articulated ankle that blocks all or some amount of dorsiflexion motion of the ankle)
- ☐ Plantarflexion stop (an articulated ankle that blocks all or some amount of plantarflexion motion of the ankle)
- ☐ Semi-rigid (trimlines at midline of the malleoli)
- ☐ GRAFO (a solid ankle AFO with an anterior or pretibial shell close to the knee that is intended to assist knee extension)

AFO Ankle Angle _____

Shank-to-vertical angle _____

Foot plate length

- ◯ Full length
- ◯ Sulcus length
- ◯ Metatarsal length

Material Type

- ◯ Polypropylene
- ◯ Copolymer
- ◯ Metal/leather
- ◯ Laminated

Thickness of plastic

- ◯ 1/8"
- ◯ 5/32"
- ◯ 3/16"
- ◯ 1/4"
- ◯ Not applicable

Gait Assessment: NHS Screening tool

1) How was this test performed?
- ◯ With AFO
- ◯ With shoes only

Swing phase (affected leg off the ground)

2) Can swing phase be initiated satisfactorily? (ie can patient easily lift foot off of the floor?)
- ◯ Yes
- ◯ No

3) Can the patient clear the ground safely when bringing their affected leg through to take a step?
- ◯ Yes
- ◯ No

4) Does the patient swing their leg out to the side when stepping?
- ◯ Yes
- ◯ No

Initial contact (when affected foot hits the ground)

5) Heel contact?
- ◯ Yes
- ◯ No

6) Foot flat contact?
- ◯ Yes
- ◯ No

7) Forefoot contact?
- ◯ Yes
- ◯ No

Mid stance (weightbearing on affected leg)

Foot and ankle position

8) Foot flat on floor?
- ◯ Yes
- ◯ No

9) Does the patient go over on unstable ankle?
- ◯ Yes
- ◯ No

10) Lower leg leaning back?
- ◯ Yes
- ◯ No

11) Lower leg leaning forward?
- ◯ Yes
- ◯ No

12) Knee position?
- ◯ Neutral
- ◯ Slightly flexed
- ◯ Flexed
- ◯ Hyper extended

Hip/ pelvic position

13) Hip flexed/ retracted

◯ Yes
◯ No

Late stance (just before leg leaves the ground)

14) Heel off achieved

◯ Yes
◯ No

15) Knee

◯ Neutral
◯ Flexed
◯ Hyper extended

16) Hip flexed/retracted

◯ Yes
◯ No

Gait Assessment: G.A.I.T

How was this test performed?

- ◯ With AFO
- ◯ With shoes only

Stance and swing phase

1. Shoulder position? _____

2. Elbow flexion? _____

3. Arm swing? _____

4. Trunk alignment (static)? _____

Stance Phase

5. Trunk posture/ movement (dynamic) (sagittal plane) (lateral view)? _____

6. Trunk posture/ movement (dynamic) (coronal plane) (front /back view)? _____

7. Weight shift (lateral displacement of head, trunk and pelvis) (coronal plane) (front/back view)? _____

8. Pelvic position (coronal plane) (front/back view)? _____

9. Hip extension (sagittal plane) (lateral view)? _____

10. Hip rotation (coronal plane) (front/back view)? _____

11a. Knee-initial contact phase

- ◯ A
- ◯ B

11b. Knee-initial contact: Score: _____

12a. Knee loading response phase (sigittal plane) (lateral view)

- ◯ A
- ◯ B

12b. Knee loading response phase (sigittal plane) (lateral view): Score _____

13a. Knee- midstance phase (sagittal plane) (lateral view)

- ◯ A
- ◯ B
- ◯ C
- ◯ D

13b. Knee - midstance phase (sagittal plane) (lateral view) Score: _____

14. Knee - terminal stance phase/pre-swing phase (heel-rise to toe-off) (sagittal plane) (lateral view) _____

15a. Ankle movement (sagittal plane) (lateral view)

- ◯ A
- ◯ B

15b. Ankle movement Score: _____

16. Ankle inversion (coronal plane) (front/back view) _____

17. Plantarflexion during terminal stance/pre-swing (heel-rise to toe-off) (sagittal plane) (lateral view) _____

18. Toe position (sagittal plane) (lateral view) _____

Swing Phase

19. Trunk posture/movement (Dynamic) (sagittal plane) (lateral view) _____

20. Trunk posture/movement (Dynamic) (coronal plane) (front/back view) _____

21. Pelvic position (coronal plane) (front/back view) _____

22. Pelvic position (sagittal plane) (lateral view) _____

23. Pelvic rotation as limb swings forward (transverse plane) (top view) _____

24. Hip flexion (sagittal plane) (lateral view) _____

25. Hip rotation (coronal plane) (front/back view) _____

26. Knee - initial swing (sagittal plane) (lateral view) _____

27. Knee - midswing (sagittal plane) (lateral view) _____

28. Knee - terminal swing (sagittal plane) (lateral view) _____

29. Ankle movement (sagittal plane) (lateral view) _____

30. Ankle inversion (coronal plane) (front/back view) _____

31. Toe position (sagittal plane) (lateral view) _____

TOTAL SCORE _____

Gait Assessment Gait round 2

1) How was this test performed?
- ◯ With AFO
- ◯ With shoes only

Stance and swing phase

2) 1. Shoulder position? _____

3) 2. Elbow flexion? _____

4) 3. Arm swing? _____

5) 4. Trunk alignment (static)? _____

Stance Phase

6) 5. Trunk posture/ movement (dynamic) (sagittal plane) (lateral view)? _____

7) 6. Trunk posture/ movement (dynamic) (coronal plane) (front /back view)? _____

8) 7. Weight shift (lateral displacement of head, trunk and pelvis) (coronal plane) (front/back view)? _____

9) 8. Pelvic position (coronal plane) (front/back view)? _____

10) 9. Hip extension (sagittal plane) (lateral view)? _____

11) 10. Hip rotation (coronal plane) (front/back view)? _____

12) 11a. Knee-initial contact phase
- ◯ A
- ◯ B

13) 11b. Knee-initial contact: Score: _____

14) 12a. Knee loading response phase (sigittal plane) (lateral view)
- ◯ A
- ◯ B

15) 12b. Knee loading response phase (sigittal plane) (lateral view): Score _____

16) 13a. Knee- midstance phase (sagittal plane) (lateral view)
- ◯ A
- ◯ B
- ◯ C
- ◯ D

17) 13b. Knee - midstance phase (sagittal plane) (lateral view) Score: _____

18) 14. Knee - terminal stance phase/pre-swing phase (heel-rise to toe-off) (sagittal plane) (lateral view) _____

19) 15a. Ankle movement (sagittal plane) (lateral view)
- ◯ A
- ◯ B

20) 15b. Ankle movement Score: _____

21) 16. Ankle inversion (coronal plane) (front/back view) _____

22) 17. Plantarflexion during terminal stance/pre-swing (heel-rise to toe-off) (sagittal plane) (lateral view) _____

23) 18. Toe position (sagittal plane) (lateral view) _____

Swing Phase

24) 19. Trunk posture/movement (Dynamic) (sagittal plane) (lateral view) _____

25) 20. Trunk posture/movement (Dynamic) (coronal plane) (front/back view) _____

26) 21. Pelvic position (coronal plane) (front/back view) _____

27) 22. Pelvic position (sagittal plane) (lateral view) _____

28) 23. Pelvic rotation as limb swings forward (transverse plane) (top view) _____

29) 24. Hip flexion (sagittal plane) (lateral view) _____

30) 25. Hip rotation (coronal plane) (front/back view) _____

31) 26. Knee - initial swing (sagittal plane) (lateral view) _____

32) 27. Knee - midswing (sagittal plane) (lateral view) _____

33) 28. Knee - terminal swing (sagittal plane) (lateral view) _____

34) 29. Ankle movement (sagittal plane) (lateral view) _____

35) 30. Ankle inversion (coronal plane) (front/back view) _____

36) 31. Toe position (sagittal plane) (lateral view) _____

37) TOTAL SCORE _____

Gait Assessment NHS Screening round 2

1) How was this test performed?
- ◯ With AFO
- ◯ With shoes only

Swing phase (affected leg off the ground)

2) Can swing phase be initiated satisfactorily? (ie can patient easily lift foot off of the floor?)
- ◯ Yes
- ◯ No

3) Can the patient clear the ground safely when bringing their affected leg through to take a step?
- ◯ Yes
- ◯ No

4) Does the patient swing their leg out to the side when stepping?
- ◯ Yes
- ◯ No

Initial contact (when affected foot hits the ground)

5) Heel contact?
- ◯ Yes
- ◯ No

6) Foot flat contact?
- ◯ Yes
- ◯ No

7) Forefoot contact?
- ◯ Yes
- ◯ No

Mid stance (weightbearing on affected leg)

Foot and ankle position

8) Foot flat on floor?
- ◯ Yes
- ◯ No

9) Does the patient go over on unstable ankle?
- ◯ Yes
- ◯ No

10) Lower leg leaning back?
- ◯ Yes
- ◯ No

11) Lower leg leaning forward?
- ◯ Yes
- ◯ No

12) Knee position?
- ◯ Neutral
- ◯ Slightly flexed
- ◯ Flexed
- ◯ Hyper extended

Hip/ pelvic position

13) Hip flexed/ retracted

◯ Yes
◯ No

Late stance (just before leg leaves the ground)

14) Heel off achieved

◯ Yes
◯ No

15) Knee

◯ Neutral
◯ Flexed
◯ Hyper extended

16) Hip flexed/retracted

◯ Yes
◯ No