

AWARD NUMBER: W81XWH-17-1-0335

TITLE: Assessing Rehabilitation Outcomes after Severe Neuromusculoskeletal Injury: Development of Patient Reported Outcomes Assessment Instruments

PRINCIPAL INVESTIGATOR: David S. Tulsky, PhD

CONTRACTING ORGANIZATION: University of Delaware, Newark, DE

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PREPARED FOR: U.S. Army Medical Research and Development Command
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14. ABSTRACT Currently, there is a paucity of patient reported outcomes (PRO) measures of secondary health effects and complications that result from neuromusculoskeletal injuries, which greatly limits the clinical care and successful rehabilitation, reintegration, and return to duty/work of injured individuals. This study will create valid, standardized, psychometrically robust, and clinically useful PRO measures for traits and symptoms relevant to understanding quality of life and the health and rehabilitation outcomes of Wounded Warriors and civilians with neuromusculoskeletal trauma. Furthermore, this study will develop clinical score reports in an actionable format to improve the clinical workflow and standard of care for individuals with traumatic limb injuries. During year five, we completed the baseline recruiting and data collection phases of the study, completed the one-year and one-week follow-up field testing interviews, prepared for two-year field testing, initiated psychometric data analysis and item analysis work, and requested and received a no-cost extension for year six. In total, 589 participants completed baseline, 203 completed 1-year follow-ups, and 160 completed 1-week retest. Despite challenges from the COVID-19 pandemic on recruitment, we have been able to make up time by adding recruiting sites and we are now poised to complete all data collection and item calibration during year 6.						
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1. INTRODUCTION

Currently, there is a paucity of patient reported outcomes (PRO) measures of secondary health effects and complications that result from neuromusculoskeletal injuries, which greatly limits the clinical care and successful rehabilitation, reintegration, and return to duty/work of injured individuals. This study will create valid, standardized, psychometrically robust, and clinically useful PRO measures for traits and symptoms relevant to understanding quality of life and the health and rehabilitation outcomes of Wounded Warriors and civilians with neuromusculoskeletal trauma. Furthermore, this study will develop clinical score reports in an actionable format to improve the clinical workflow and standard of care for individuals with traumatic limb injuries.

2. KEYWORDS

Traumatic Limb Injuries, PRO Measures, Neuromusculoskeletal Trauma, Upper/Lower Extremity Amputation, Psychosocial Functioning, Outcomes Measurement

3. ACCOMPLISHMENTS

What were the major goals of the project?

The major goals of this project are: (1) to develop pools of items that measure secondary physical and psychosocial health effects and rehabilitation outcomes. which includes several major steps, including expert reviews, cognitive debriefing interviews, baseline and longitudinal field testing; (2) to create, using Item Response Theory, computer adaptive test (CAT) forms and fixed-length “short forms” for each content domain, based on rigorous statistical analyses; (3) to develop scientifically based clinical score reports for these measures, to be used in clinical care; and (4) to integrate tests and reports into a “package” for applied use. A precursor to a majority of these activities was obtaining human subjects regulatory approval at University of Delaware (UD) and at each of the participating partner sites (which includes IRB and approval from the Human Research Protection Office [HRPO]). The sites also required administrative approvals prior to study initiation, including Cooperative Research and Development Agreements (CRADA) for three sites and data use agreements (DUAs) for all sites.

What was accomplished under these goals?

During year 1, major accomplishments were achieved on three essential initial components of this project: (1) preparing initial item pools for cognitive interviewing; (2) developing a research infrastructure to carry out data collection activities; and 3) obtaining regulatory and administrative approvals. The details of these accomplishments were described in the 2018 annual report.

During year 2, major accomplishments were achieved on four essential components of this project: (1) All cognitive interviews were completed; (2) Item pools were revised and finalized based on feedback gathered during cognitive interviews; (3) A data collection plan was developed and finalized for the large-scale field testing; and (4) Regulatory and administrative approvals were secured at the remaining sites. The details of these accomplishments were described in the 2019 annual report.

During year 3, major accomplishments were achieved in four main areas: (1) Preparing to launch large-scale field testing, which included finalizing the data collection system for baseline interviews, standardizing procedures, and training staff; (2) Launching large-scale field testing

baseline data collection; (3) Working to continue data collection and meet our sample targets amid challenges from the COVID-19 pandemic; and (4) Developing detailed data analytic specifications and beginning to write program syntax and code to speed up the analytic process once the sample has been collected. The details of these accomplishments were described in the 2020 annual report.

During year 4, our efforts were focused in the following key areas: (1) Continuing to recruit new participants and advance baseline data collection; (2) Preparing for one-year follow-up field testing as well as test-retest data collection, including database preparation and quality assurance, writing detailed procedures for participant communication and data collection, and training staff; (3) Launching one-year follow-up testing and one-week retesting; and (4) Coding data analysis scripts according to the plan developed in year 3, in anticipation of the completion of baseline field testing.

During year 5, major accomplishments were achieved in the following areas: (1) Completing the baseline recruiting and data collection phases of the study; (2) Completing the one-year and one-week follow-up field testing interviews; (3) Initiating a subaward with an outside site (University of Texas at Austin) to assist with data analysis and beginning psychometric data analysis and item analysis work; (4) Developing item response theory (IRT) calibrations (which set up the decision logic for computer adaptive testing) for 8 of the item banks and scales to assess new domains of functioning (Resilience, Future Outlook, Health-Related Self Efficacy, Body Image, Vocational Impact, Grief/Loss, Self-Esteem, Weight Satisfaction) while data analyses continue on other item banks; (5) Initiating a subaward with an outside site (Northwestern University) to assist with computer programming of final CATs and short forms, allowing for broader access and distribution at both civilian and military sites; (6) Preparing for long-term (two-year) follow-up field testing, including database preparation and quality assurance, writing detailed procedures for participant communication and data collection, and training staff; (7) Requesting a no-cost extension (NCE), which was granted to allow this project to continue for year six, through 7/31/2023.

Large-scale data collection for baseline testing continued in earnest in year 5. We completed 105 baseline interviews in year 5, bringing our total completed interviews to 589 as of the end of the project year. Baseline recruitment and data collection are now completed. (Of note, for the purpose of IRT-based item calibration, we are using data from 603 participants, which includes several cases where the participants started the baseline interview but did not complete it.) During year 5, we also conducted 182 one-year follow-up interviews and 147 one-week retest interviews, bringing our totals to 203 and 160, respectively. Statistical power analysis indicated that these samples are more than sufficient to conduct the planned reliability and validation analyses, and so the one-year and one-week retest phases of data collection are also considered completed.

Another major initiative during year 5 was to organize long-term (two-year) follow-up testing. We are planning to recontact participants approximately two years after their baseline interview to conduct another interview to gauge any changes in functioning. We spent time in year 5 finalizing study design, coding the data collection platform in REDCap, conducting database quality assurance, and training research assistants in the data collection procedures, highlighting especially any differences in the conduct of interviews vis-à-vis baseline and one-year testing. We plan to initiate two-year interview data collection in year 6, quarter 1. Participants will be contacted throughout year 6 and interviews will be conducted until we reach our sample acquisition targets. We plan to test at least 100 participants for two-year follow-up. This will provide us with sufficient power to conduct analyses of responsiveness and map participant trajectories.

Subaward documentation has been initiated with two new sites, one to conduct data analysis (University of Texas at Austin) and a second to program CATs and short forms (Northwestern University) into an application programming interface (API) through Northwestern, which allows for broader access to the measures developed as part of this project (e.g., through REDCap, EPIC systems). During year 5, we completed a significant effort of data cleaning and quality assurance as part of preparing for data analysis.

Most importantly, we have begun data analysis and psychometric item analysis to prepare for IRT calibrations. Calibrations have been developed for 8 of our item banks: Resilience, Future Outlook, Health Related Self Efficacy, Body Image, Vocational Impact, Grief/Loss, Self-Esteem, Weight Satisfaction. Analyses continue on additional item banks and several PROMIS, Neuro-QoL, and related scales that were also administered to the participants. Analyses will be completed by Year 6, Quarter 2, and the item bank calibrations and item selection for short forms will be provided to the Northwestern team for CAT and short form programming into its API.

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

Nothing to Report

How were the results disseminated to communities of interest?

Nothing to Report

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

During the next reporting period, we will complete two-year longitudinal data collection. Our goal is to complete these interviews by the final quarter of Year 6.

We will complete all IRT analyses of the baseline interview data to calibrate all items tested and finalize item banks. We will provide all relevant psychometric data and item banks to Northwestern to program into its API during Year 6, with a goal of programming completion by the end of Year 6. Once longitudinal data collection is completed, we will do final data cleanup and then conduct analyses to evaluate time effects on participants.

We will plan for a face-to-face investigator meeting during Year 6 to review progress and analyses and prepare dissemination activities.

We will make significant progress on associated manuscripts for publication based on our extensive analytical work. We will actively work on dissemination activities and will contact journal editors of leading rehabilitation and orthopedic journals with a request to organize a special issue focusing on the results obtained from the baseline data collection.

4. IMPACT

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

Nothing to Report

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

There have been no changes in objective or scope of this project. However, as described in previous reports, regulatory and administrative approvals took far longer than the 6 months allocated to them in our project plan.

As the pandemic continued, data collection proceeded at a pace somewhat slower than originally planned when this project began. We were able to work with sites to identify challenges and enlisted the assistance of four additional data recruitment sites. Recruitment is now complete, with a well-balanced sample of 603 individuals, half of whom are from a military population and a third of whom have a qualifying upper limb injury.

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

As a result of many of our initiatives, including problem-solving meetings with our recruitment sites, close monitoring of site performance, and the addition of new recruitment sites, baseline testing is now complete. The pandemic did cause challenges for sites, as access to prospective participants was hindered in many cases. However, we have succeeded in collecting a well-stratified sample. To make up time in completing data analyses, we have initiated a subaward with the University of Texas at Austin and have developed item calibrations for 8 of the item banks to date.

Furthermore, as a result of delays in starting and completing baseline testing, one-year follow-up testing and one-week retesting were affected, but we ultimately succeeded in interviewing the number of participants needed for this timepoint to yield results with appropriate statistical power. Additionally, the cascade of delays in starting and conducting retests has pushed back long-term follow-up testing to the start of Year 6, but we are similarly optimistic that our efforts will lead to completing that phase during Year 6.

Changes that had a significant impact on expenditures

The delays described in our data collection efforts and implementation have caused some delays in spending for data collection. However, we anticipate that the effect of this will be neutral on the budget over the life of the project.

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.

Nothing to Report

Significant changes in use of biohazards and/or select agents.

Nothing to Report

6. PRODUCTS

Publications, conference papers, and presentations

Journal publications. Nothing to Report

Books or other non-periodical, one-time publications. Nothing to Report

Other publications, conference papers, and presentations.

Slotkin, J., Tyner, C.E., Boulton, A., Tulsy, D.S. (accepted). Development of New Quality-of-Life Assessments for Limb Trauma and Amputation. Oral presentation accepted for the 29th annual conference of the International Society for Quality of Life Research (ISO-QOL) in Prague, Czech Republic, October 19-22, 2022.

Tulsy, D.S., Boulton, A., Slotkin, J., & Tyner, C.E. (accepted). Validating PRO Measurement Scales in Individuals with Major Upper Extremity Trauma and Amputation. Oral presentation accepted for the 29th annual conference of the International Society for Quality of Life Research (ISO-QOL) in Prague, Czech Republic, October 19-22, 2022.

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?

Note: Values for nearest person month worked listed below are for the current reporting period.

Name:	David Tulsky, PhD
Project Role:	Project PI
Researcher Identifier (e.g. ORCID ID):	0000-0002-4335-4509
Nearest person month worked:	2
Contribution to Project:	No change

Name:	Jerry Slotkin, PhD
Project Role:	Co-I
Researcher Identifier:	0000-0001-8199-3056
Nearest person month worked:	2
Contribution to Project:	No change

Name:	Callie Tyner, PhD
Project Role:	Co-I
Researcher Identifier:	0000-0003-2945-392X
Nearest person month worked:	2
Contribution to Project:	No change

Name:	Pamela Kisala, MA
Project Role:	Co-I
Researcher Identifier:	0000-0003-3234-795X
Nearest person month worked:	1
Contribution to Project:	No change

Name:	Aaron Boulton, PhD
Project Role:	Biostatistician
Researcher Identifier:	0000-0001-7349-162X
Nearest person month worked:	1
Contribution to Project:	No change

Name:	Stella Dilts, BA
Project Role:	Research Assistant
Researcher Identifier:	None
Nearest person month worked:	10
Contribution to Project:	No change

Name:	Alexis Silverman, MA
Project Role:	Graduate Student Research Assistant
Researcher Identifier:	None
Nearest person month worked:	1
Contribution to Project:	No change

Name:	Trevor Kingsbury, MA
Project Role:	Site PI, NMCSD
Researcher Identifier:	0000-0001-5298-8725
Nearest person month worked:	1
Contribution to Project:	No change

Name:	Josef Butkus, MS, OTR/L
Project Role:	Site PI, WRNMMC
Researcher Identifier:	None
Nearest person month worked:	1
Contribution to Project:	No change

Name:	Christopher Dearth, PhD
Project Role:	Co-I, WRNMMC
Researcher Identifier:	None
Nearest person month worked:	1
Contribution to Project:	No change

Name:	W. Lee Childers, PhD, CP
Project Role:	Site PI, CFI/BAMC
Researcher Identifier:	0000-0002-6119-983X
Nearest person month worked:	1
Contribution to Project:	No change

Name:	Ross Zafonte, DO
Project Role:	Site PI, SRH
Researcher Identifier:	None
Nearest person month worked:	1
Contribution to Project:	No change

Name:	Claire Kalpakjian, PhD
Project Role:	Site PI, UM
Researcher Identifier:	0000-0001-6652-1245
Nearest person month worked:	1
Contribution to Project:	No change

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

All PIs and key personnel are listed below, along with any changes in the active support of each (if applicable).

David Tulsy, PhD

New funding:

1. Title: SCIRP iManage Depression and Anxiety Efficacy
Funding Agency: Department of Defense
Project dates: 7/22/2022 – 08/31/2023

Effort: 0.5 academic

Description: This work will address the recent priority areas of depression, resilience, and self-management advanced by the DoD SCI Research Program (SCIRP).

Overlap: none

2. Title: iManage-Sexual Wellness: Development of a symptom-monitoring/self-management program to enhance sexual wellness after SCI and TBI
Funding Agency: National Institute on Disability, Independent Living, and Rehabilitation Research
Project dates: 2/4/2022 – 08/31/2025
Effort: 1.2 academic, 0.66 summer
Description: The goal of this five-year project is to create and evaluate a web-based symptom-monitoring/self-management system to improve sexual wellness in individuals with SCI or TBI.
Overlap: none

Previous funding:

- Online Symptom-Monitoring/Self-Management for Pandemic-Related Emotional Distress (ACCEL), ended 06/30/2022

Jerry Slotkin, PhD

New funding:

1. Title: SCIRP iManage Depression and Anxiety Efficacy
Funding Agency: Department of Defense
Project dates: 7/22/2022 – 08/31/2023
Effort: 0.3 calendar
Description: This work will address the recent priority areas of depression, resilience, and self-management advanced by the DoD SCI Research Program (SCIRP).
Overlap: none
2. Title: iManage-Sexual Wellness: Development of a symptom-monitoring/self-management program to enhance sexual wellness after SCI and TBI
Funding Agency: National Institute on Disability, Independent Living, and Rehabilitation Research
Project dates: 2/4/2022 – 08/31/2025
Effort: 0.48 calendar
Description: The goal of this five-year project is to create and evaluate a web-based symptom-monitoring/self-management system to improve sexual wellness in individuals with SCI or TBI.
Overlap: none

Previous funding:

- Online Symptom-Monitoring/Self-Management for Pandemic-Related Emotional Distress (ACCEL), ended 06/30/2022

Callie Tyner, PhD

New funding:

1. Title: iManage-Sexual Wellness: Development of a symptom-monitoring/self-management program to enhance sexual wellness after SCI and TBI
Funding Agency: National Institute on Disability, Independent Living, and Rehabilitation Research

Project dates: 2/4/2022 – 08/31/2025

Effort: 0.24 calendar

Description: The goal of this five-year project is to create and evaluate a web-based symptom-monitoring/self-management system to improve sexual wellness in individuals with SCI or TBI.

Overlap: none

Previous funding:

Nothing to report

Pamela Kisala, MA

New funding:

1. Title: SCIRP iManage Depression and Anxiety Efficacy
Funding Agency: Department of Defense
Project dates: 7/22/2022 – 08/31/2023
Effort: 5.4 calendar
Description: This work will address the recent priority areas of depression, resilience, and self-management advanced by the DoD SCI Research Program (SCIRP).
Overlap: none
2. Title: iManage-Sexual Wellness: Development of a symptom-monitoring/self-management program to enhance sexual wellness after SCI and TBI
Funding Agency: National Institute on Disability, Independent Living, and Rehabilitation Research
Project dates: 2/4/2022 – 08/31/2025
Effort: 1.6 calendar
Description: The goal of this five-year project is to create and evaluate a web-based symptom-monitoring/self-management system to improve sexual wellness in individuals with SCI or TBI.
Overlap: none

Previous funding:

- Online Symptom-Monitoring/Self-Management for Pandemic-Related Emotional Distress (ACCEL), ended 06/30/2022

Aaron Boulton, PhD

New funding:

1. Title: iManage-Sexual Wellness: Development of a symptom-monitoring/self-management program to enhance sexual wellness after SCI and TBI
Funding Agency: National Institute on Disability, Independent Living, and Rehabilitation Research
Project dates: 2/4/2022 – 08/31/2025
Effort: 0.12 calendar
Description: The goal of this five-year project is to create and evaluate a web-based symptom-monitoring/self-management system to improve sexual wellness in individuals with SCI or TBI.
Overlap: none

Previous funding:

Nothing to report

Trevor Kingsbury, MA

Nothing to report

Josef Butkus, MS OTR/L

Nothing to report

W. Lee Childers, PhD, CP

Nothing to report

Ross Zafonte, DO

New funding:

1. Title: Opioid Dose Reduction in Comprehensive Inpatient Rehabilitation: A pharmacobehavioral approach
Funding Agency: NIH
Project Dates: 8/15/2021-7/31/2026
Effort: 0.0
Description: Pain is a common, highly distressing symptom for patients hospitalized in comprehensive rehabilitation that may disrupt recovery and rehabilitation efforts (e.g., avoidance of physical therapy)
Overlap: none

Previous funding:

- Optimizing Rehabilitation for Phantom Limb Pain Using Mirror Therapy and tDCS, ended 4/30/2022
- Training Program in Recovery and Restoration of CNS Health and Function, ended 6/30/2022
- NFLPA/Harvard Accelerated Research Collaboration to Protect and Improve the Health of Football Players, ended 6/30/2022
- Ross Zafonte Billing Agreement – Harvard Football Players Health Study (NFLPA award), ended 6/30/2022
- Ross Zafonte Billing Agreement – Prevalence of Brain Health Versus Neurodegeneration in Professional Football Reserves, ended 6/30/2022

Claire Kalpakjian, PhD

New funding:

1. Title: Implementation of an All-Cause Deterioration Model for Adult Inpatients
Funding Agency: The Doctors Company Foundation
Project Dates: 11/2021-10/2023
Effort: 0.12 calendar months
Description: The main objective of this project is to reduce patients' risk of experiencing

adverse events during their hospital stay by deploying our PICTURE early warning system.

Overlap: none

2. Title: The Menopause Transition in Women with Traumatic Brain Injury
Funding Agency: Wayne State University/Administration for Community Living
Project Dates: 9/2021-9/2022
Effort: 0.30 calendar months
Description: The purpose of this project is to examine menopause symptoms and other changes in women with moderate to severe TBI; specifically, this award will focus on the dissemination of findings.
Overlap: none
3. Title: Addressing knowledge gaps by multi-level research design to optimize clinical trial development in order to reduce fracture burden for adults with neurodevelopmental disabilities
Funding Agency: NIH
Project Dates: 9/2021-8/2024
Effort: 0.36 calendar months
Description: The purpose of this research is to examine barriers and facilitators of participation in clinical trials to reduce fracture risk and burden among adults born with developmental disorders.
Overlap: none

Previous funding:

- Pregnancy, SCI and Decision Making: Development of a Decision-Making Tool for Women with SCI, ended 7/2022

What other organizations were involved as partners?

- **Organization Name:** Walter Reed National Military Medical Center
- **Location of Organization:** Bethesda, MD
- **Partner's contribution to the project:**
 - In-kind support
 - Collaboration

- **Organization Name:** Center for the Intrepid/Brooke Army Medical Center
- **Location of Organization:** San Antonio, TX
- **Partner's contribution to the project:**
 - In-kind support
 - Collaboration

- **Organization Name:** Naval Medical Center San Diego
- **Location of Organization:** San Diego, CA
- **Partner's contribution to the project:**
 - In-kind support
 - Collaboration

- **Organization Name:** Spaulding Rehabilitation Hospital
- **Location of Organization:** Charlestown, MA
- **Partner's contribution to the project:**
 - Collaboration

- **Organization Name:** University of Michigan
- **Location of Organization:** Ann Arbor, MI
- **Partner's contribution to the project:**
 - Collaboration

8. SPECIAL REPORTING REQUIREMENTS

Collaborative Awards:

n/a

Quad Charts:

Please see Appendix A for the most current quad chart.

9. APPENDICES

See Appendix A for Quad Chart.

See Appendix B for Presentation Abstracts.



Appendix A: Assessing Rehabilitation Outcomes after Severe Neuromusculoskeletal Injury: Development of Patient Reported Outcomes Assessment Instruments

Log Number BA160178

Award Number: W81XWH-17-1-0335

PI: David Tulsy, Ph.D.

Organization: University of Delaware

Award Amount: \$4,126,339

Specific Aims

- 1: Finalize 10 item pools which measure secondary physical and psychosocial health effects and rehabilitation outcomes and field test the item pools in a large sample of Wounded Warriors and civilians with severe neuromusculoskeletal injuries.
- 2: Calibrate item banks using IRT analysis and develop computer adaptive tests (CATs) for each item bank.
- 3: Evaluate the psychometric properties (e.g., reliability, validity, and responsiveness) of the newly developed CATs.
- 4: Develop scientifically based clinical score reports that will allow the scales to be used in orthopedic research and clinical practice.

Approach: This study will create valid, standardized, psychometrically robust, and clinically useful PRO measures for traits and symptoms that are of critical importance to understanding the health and rehabilitation outcomes of Wounded Warriors and civilians with neuromusculoskeletal trauma. Furthermore, this study will develop clinical score reports in an actionable format to improve the clinical workflow and standard of care for individuals with traumatic limb injuries. We will first conduct expert item reviews and cognitive debriefing interviews to refine the 10 preliminary item pools into clear and comprehensive sets of items that are ready for large-scale calibration testing. Then, we will conduct large-scale field testing, administering the newly developed item pools to individuals with a history of major extremity trauma (upper- and lower-limb amputation and limb preservation) recruited from 5 data collection sites. Data will be analyzed to calibrate the items and develop computer adaptive tests (CATs). Last, clinical score reports will be designed based on needs identified in clinician focus groups and revised based on expert feedback from cognitive debriefing.



Accomplishments: In year 5, quarter 4 of this project, we continued large-scale field testing. Baseline, 1-year, and 1-week retest interviewing has been completed, with **589** participants having completed the baseline interviews **203** participants having completed 1-year interviews (**11** in Y5, Q4) and **160** having completed 1-week retest. Preparations were made for launching 2-year interviews next quarter. Extensive quality assurance/reconciliation was completed on baseline data, and IRT calibration and DIF analyses have begun, to be completed by year 6, Q2.

Revised Timeline and Cost

Activities	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
IRB & HRPO Approval	█					
Expert Item Review	█					
Data Collection: Cognitive Interviewing		█				
Data Collection: Field Testing (Baseline)		█	█	█	█	
Data Collection: Medical Record Abstraction		█	█	█	█	
Data Collection: Field Testing (1 year Follow-Up)			█	█	█	█
Data Analyses: IRT Calibrations				█	█	█
CAT programming					█	█
Data Collection: Field Testing (2 year Follow-Up)				█	█	█
Data Analyses: Longitudinal Data					█	█
Clinician Focus Groups					█	█
Score Report Development and Refinement					█	█
Cognitive Debriefing Interviews with Clinicians					█	█
Implementation of Scales & Reports					█	█
Estimated Budget (\$K)	\$884	\$867	\$875	\$820	\$680	NCE

Updated: 31-August-2022

Revised Goals/Milestones

Year 1

- Obtain regulatory approval (IRB & HRPO)
- Conduct expert item review (internal scientific reviews & external expert reviews complete)

Year 2

- Conduct data collection: Cognitive Interviewing
- Begin data collection: Field Testing

Year 3

- Continue data collection: Field Testing
- Begin data analyses: IRT calibrations

Year 4

- Continue data collection: Field Testing
- Complete data analyses: IRT calibrations
- Conduct CAT programming

Year 5

- Complete data collection: Field Testing
- Conduct longitudinal data analyses
- Conduct clinician focus groups
- Develop clinical score reports
- Implement scales and reports

Comments/Challenges/Issues/Concerns: Despite regulatory and COVID-19 delays, baseline and 1-year field testing are now complete. Changes have been made to the timeline to reflect the overall project impacts (shown in light blue) and to show the work remaining for the no-cost extension ("Year 6") period (purple).

Budget Expenditure to Date:

Projected Expenditure: **\$4,126,339**

Actual Expenditure: **\$2,694,357**

(Note: differences are primarily due to timing and delayed start of data collection.)

APPENDIX B – Presentation Abstracts

Abstracts for research presentations described in question 6 above.

1. Poster Presentation Abstract

Slotkin, J., Tyner, C.E., Boulton, A., Tulskey, D.S. (accepted). Development of New Quality-of-Life Assessments for Limb Trauma and Amputation. Oral presentation accepted for the 29th annual conference of the International Society for Quality of Life Research (ISO-QOL) in Prague, Czech Republic, October 19-22, 2022.

Aims: Currently, there is a paucity of patient reported outcomes measures of secondary health effects and complications that result from neuromusculoskeletal injuries, which greatly limits the clinical care and successful rehabilitation, reintegration, and return to duty/work of injured individuals. This study seeks to 1) create new item banks measuring traits and symptoms relevant to understanding quality of life and the health and rehabilitation outcomes of Wounded Warriors and civilians with severe limb trauma that results in significant functional deficits or amputation; 2) calibrate these item banks in a large sample using Item Response Theory (IRT).

Methods: Eleven distinct item pools were developed in domains identified through numerous focus groups with patients with lived experience (n = 56) and their clinicians (n = 34). Items were edited and winnowed through expert review and cognitive debriefing interviews with patients. Ultimately, 582 items were administered to 604 participants (mean age 42; 78% male; 72% white; 13% Hispanic; 47% civilian, 22% active-duty military, 31% veteran) with severe, sudden-onset limb injury and/or amputation at nine participating civilian and military medical centers (Walter Reed National Military Medical Center, Brooke Army Medical Center, Naval Medical Center San Diego, Spaulding Rehabilitation Hospital, University of Michigan, University of Pennsylvania, McGill University, TIRR Memorial Hermann, and Kessler Institute for Rehabilitation). Two-parameter IRT analyses were conducted to create final item calibrations.

Results: Eleven item banks or fixed form scales covering issues specific to individuals with amputation and major limb trauma have been prepared as part of a comprehensive assessment of HRQOL in this population. These item banks and scales, which utilized PROMIS development standards and methodology, include: Self-Esteem, Body Image, Diet and Weight, Health-Related Self Efficacy, Satisfaction with Physical Fitness, Adjustment to Identity/Role Change: General, Adjustment to Identity/Role Change: Military, Satisfaction with Orthosis/Prosthesis, Arthrosis Impact, Resilience, and Future Outlook.

Conclusion: Eleven new item banks have been developed, targeting key psychosocial outcomes domains for those who have experienced traumatic limb injury and/or amputation. These banks have been developed specifically for this rehabilitation population and will allow for informative yet parsimonious assessment of these individuals that can aid healthcare providers assessing HRQOL in this population.

2. Poster Presentation Abstract

Tulskey, D.S., Boulton, A., Slotkin, J., & Tyner, C.E. (accepted). Validating PRO Measurement Scales in Individuals with Major Upper Extremity Trauma and Amputation. Oral presentation accepted for the 29th annual conference of the International Society for Quality of Life Research (ISO-QOL) in Prague, Czech Republic, October 19-22, 2022.

Aims: Upper extremity (UE) amputation or severe, sudden-onset UE injury is life-changing and profoundly impacts several areas of functioning, yet, there is a dearth of research on this

population. This study examines the construct validity of several patient reported outcomes (PRO) item banks (from PROMIS, Neuro-QOL, and those developed for rehabilitation populations like spinal cord and traumatic brain injury) for use in a UE population. The study also examines the factor structure underlying a comprehensive assessment of multiple domains of health-related quality of life (HRQOL).

Methods: A battery of 33 scales from PROMIS, Neuro-QOL, SCI-QOL, SCI-FI, and TBI-QOL were administered to a sample of 191 individuals with a major UE injury (n = 87 Amputation; n = 96 UE Surgically Treated; n = 8 had amputation and UE transplantation). The PROMIS Pain Interference, Pain Intensity, Fatigue, Anger, Anxiety, and Depression and Neuro-QOL Upper Extremity Function, Mobility, Positive Affect and Well-Being, and Ability to Participate scores were compared with a general population control sample (n = 191) that was extracted from the calibration samples of the measures. Propensity matching on key demographic variables (age, gender, race, education level, and household income) identified the control sample and scores between the UE and control group were compared using t-tests and examining effect size. Factor structure was evaluated by developing multiple models of HRQOL and examining common fit statistics (CFI, TLI, RMSEA) to determine the best-fitting model.

Results: Known group comparisons indicated that there were significant differences and effect sizes for physical variables like upper extremity function ($p < .01$; Cohen's $d = -1.64$) and Pain Interference ($p < .01$; Cohen's $d = 0.59$) between UE and control samples, but small effect sizes for emotional variables. The factor structure indicated a complex structure with multiple domains, including positive and negative affect, social, physical medical, and physical functioning.

Conclusion: The results are similar to those obtained in recent analyses of similar HRQOL data with individuals with traumatic brain and spinal cord injuries and collectively offer evidence of the construct validity of several PRO item banks for use in individuals with major UE injury and amputation.