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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 six, we began long-term (2-3 year) field testing. All other phases of field testing are complete (baseline, 1-year, 1-week retest). In year six, we finished data analyses for item calibrations and 10 scales were finalized, with short form and computer adaptive test programming completed as well. We requested and received a no-cost extension for year seven. In total, 589 participants completed baseline, 203 completed 1-year follow-ups, 160 completed 1-week retest, and 271 have completed long-term follow-ups. 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 study activities during year seven.

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

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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.

During year 6, large-scale data collection for longitudinal interviewing continued. We had a goal to interview at least 100 participants for long-term (2-3 year) follow-up. As of the end of year 6, we have interviewed 271 participants for long-term follow-up. This will provide us with sufficient power to conduct analyses of responsiveness and map participant trajectories, and will help position us to understand long-term patterns of QOL after major extremity injury. As of the end of year 6, of the 589 participants who completed baseline interviews, 333 (57%) have also completed at least one follow-up interview. Moreover, 141 (24%) of the baseline participants have completed both 1-year and long-term follow-up interviews for this study. As we continue to interview more follow-up participants, we will have more robust data to evaluate the stability of our measures and possible change over time.

Data analysis (including psychometric item analysis and item response theory calibration) were finalized for 10 item banks in year 6: Resilience, Future Outlook, Health-Related Self Efficacy, Body Image, Vocational Impact, Grief/Loss, Self-Esteem, Weight Satisfaction, Satisfaction with Orthosis/Prosthesis, and Satisfaction with Physical Fitness and Athleticism. Analyses continue on several PROMIS, Neuro-QoL, and related scales that were also administered to the study participants.

Data analyses for item calibration with the subaward site University of Texas at Austin were completed during year 6. CAT and short form programming with the subaward site Northwestern University was also completed, so that the measures will be available via the application programming interface (API) through Northwestern. This will allow for broader

access to the measures developed as part of this project (e.g., through REDCap, EPIC systems).

We have also made significant progress on associated manuscripts for publication based on our extensive analytical work. We have contacted 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, and this has been positively received. A current peer-reviewed journal specializing in outcomes measurement is reviewing our request to publish a set of manuscripts (e.g., between 10-15 manuscripts) in a single issue.

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 continue long-term (2-3 year) longitudinal data collection, contacting all available participants. Our goal is to conduct follow-up interviews with as many participants as possible, to develop as complete a dataset as possible for surveillance purposes and to evaluate QOL trajectories. Once longitudinal data collection is completed, we will do final data cleanup and then conduct analyses to evaluate time effects on participants. We will work with the investigator team to address the project goal of developing scientifically based clinical score reports.

We will plan for a face-to-face investigator meeting during Year 7 to review progress and analyses and to discuss and plan for collaborative dissemination activities. We plan to submit a set of manuscripts submitted for peer-review during this grant year.

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 was successfully completed, 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

Our success in collecting a large, well-stratified sample took additional time due to the pandemic and other factors noted above. To make up time in completing data analyses, we brought on collaborators from the University of Texas at Austin with a subaward to develop item calibrations for the item banks. This allowed us to complete this analytic work with high quality during year 6.

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 pushed back long-term follow-up testing to the start of Year 6, but we have been able to meet and exceed our initial targets 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., Tulsky, D.S. (presented). 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 (ISOQOL) in Prague, Czech Republic, October 19-22, 2022.

Tulsky, D.S., Boulton, A., Slotkin, J., & Tyner, C.E. (presented). 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:	4
Contribution to Project:	No change

Name:	**Stella Dilts, BA**
Project Role:	Research Assistant
Researcher Identifier:	None
Nearest person month worked:	6
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 Tulsky, PhD

New funding:

Nothing to report

Previous funding:

Nothing to report

Jerry Slotkin, PhD

New funding:

Nothing to report

Previous funding:

- ARMADA: Advancing Reliable Measurement in Alzheimer's Disease and cognitive Aging, ended 12/31/2022

Callie Tyner, PhD

New funding:

Nothing to report

Previous funding:

Nothing to report

Pamela Kisala, MA

New funding:

Nothing to report

Previous funding:

Nothing to report

Aaron Boulton, PhD

New funding:

Nothing to report

Previous funding:

Nothing to report

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 Tulsky, Ph.D. **Organization:** University of Delaware **Award Amount:** $4,126,339

Specific Aims

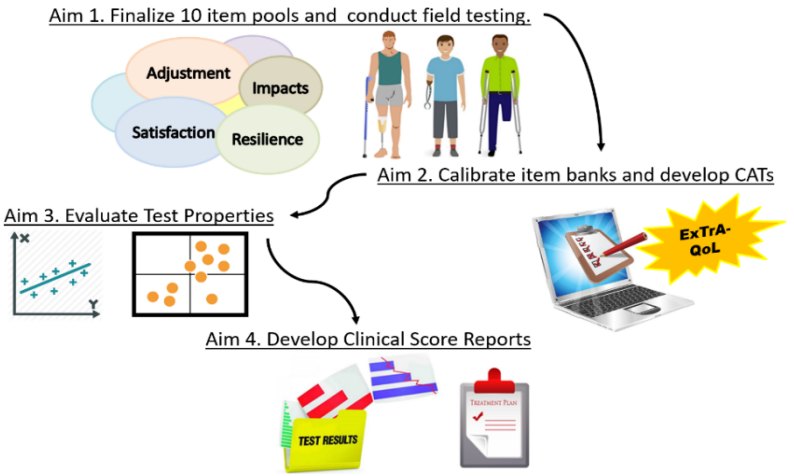
1: Finalize 10 item pools which measure secondary physical and psychosocial health effects and rehabilitation outcomes and field test the item pools in a large sample of Wounded Warriors and civilians with severe neuromusculoskeletal injuries.

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 6, quarter 4 of this project, we continued long-term (2-3-year) follow-up interviews. All other phases of field testing are complete (baseline, 1-year, 1-week retest). In this quarter, 90 interviews were completed, bringing us to a total of 271 long-term follow-up interviews. Data analysis for IRT calibration and DIF analyses were completed for all 10 scales, and CAT and short form programming was finalized. Manuscript planning has continued, including negotiating a special section for a series of foundational manuscripts on the 10 new measures in a peer-reviewed journal. A second NCE request was submitted and was approved by CDMRP.

Revised Timeline and Cost

Activities	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
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 (2-3 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*	*NCE*

Updated: 30-August-2023

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, 1-year, and 1-week retest 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 periods ("Year 6" in purple; "Year 7" in light purple).

Budget Expenditure to Date:
Projected Expenditure: **$4,126,339**
Actual Expenditure: **$3,203,613**
(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., Tulsky, D.S. (presented). 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 (ISOQOL) 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

Tulsky, D.S., Boulton, A., Slotkin, J., & Tyner, C.E. (presented). 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.