

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. Tulsy, PhD
CONTRACTING ORGANIZATION: University of Delaware

Newark DE 19716-0099

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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 the first year, major accomplishments were achieved on three essential initial components of this project: (1) finalizing item pools in preparation for all data collection activities, (2) developing a research infrastructure to carry out data collection activities, and (3) regulatory and administrative approvals. Human subjects regulatory approvals have been obtained at UD and at 4 collaborating sites. A total of 838 items were developed, 582 newly written and 256 curated from other well-validated measures. These underwent internal scientific review and expert content review and were winnowed to 579 items across 12 topic areas/item pools. The data collection platforms have been developed and data collection can now commence.						
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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 is obtaining human subjects regulatory approval at University of Delaware (UD) and at each of the five participating partner sites (which includes IRB and approval from the Human Research Protection Office [HRPO]). The sites also require administrative approvals prior to study initiation, including Cooperative Research and Development Agreements (CRADA) for three sites and data use agreements (DUAs) for all five sites.

What was accomplished under these goals?

Major accomplishments were achieved on three essential initial components of this project: (1) finalizing item pools in preparation for all data collection activities, (2) developing a research infrastructure to carry out data collection activities, and 3) obtaining regulatory and administrative approvals.

First, and concurrent to our regulatory pursuits (described below), we finalized 12 pools of items for cognitive interviewing and field testing (more than the originally proposed 10). We developed a total of 838 assessment items (582 newly written, 256 curated with permission from other published, well-validated PROs where highly relevant) for the following 12 domains:

- Satisfaction with Orthosis/Prosthesis
- Satisfaction with Physical Abilities/Fitness/Athleticism
- Weight Management Difficulties
- Health-Related Self-Efficacy
- Arthrosis Impact

- Resilience
- Self-Esteem
- Body Image
- Future Outlook
- Grief & Loss
- Satisfaction with Social Function & Participation
- Adjustment to Military Identity/Role Change

We simultaneously developed detailed definitions for each of the 12 domains, to assure that they make sense and are distinct from one another. We used these definitions in conducting internal expert reviews of all 838 items for quality, content validity, severity/valence (i.e., how strongly negative/positive is each question, to assure representation across the spectrum), and relevance/consistency of answer choices and contexts. Then, we conducted reviews of all items with seven outside experts. External experts were permitted to write additional proposed items if they felt an important element of a pool was missing. These rigorous reviews have yielded a set of 579 items in 12 pools (of which 407 are newly written items for this project) that are ready for cognitive interviewing and then field testing.

A second significant accomplishment is that we have developed the research infrastructure to conduct the study. To prepare for data collection, which is expected to begin in September 2018, we have developed a Manual of Procedures, and a detailed REDCap database and interface. This REDCap system we have created allows us to efficiently manage all of the items, track changes and reviews, and create data collection protocols for telephone interviews. In addition, there is a separate database for use by collaborating sites to enter medical records information about participants using only their participant identification numbers (to be later merged with data collected directly from participants with identifying data stripped). Training documents and a training protocol have also been created for UD team members who will be conducting cognitive interviews by telephone. This training will include thorough review of documents by all assigned staff, didactic training, supervised practice telephone interviews with non-participants, followed by feedback, additional practice as needed, and supervised initial telephone interviews with feedback.

Our project calls for 50 cognitive interviews to be conducted and then, in a subsequent phase, 650 participants to complete the field testing study. Our plans are to complete the initial 50 cognitive interviews by October, review all data collected and evaluate any changes to wording of items based on participant feedback, and remove any items that participants deemed problematic or insensitive. We should complete this phase by December, 2018 and will then begin the second phase of data collection, our field testing and validation of the item banks. We have extensive experience with the data analyses and associated modification of items based upon the cognitive debriefing interviews, and this will allow us to begin recruitment of our second phase of data collection (field testing) within two months of completing the cognitive interviews.

Finally, IRB and HRPO approvals have been received at UD, and the team is ready to proceed with data collection once other sites also have all necessary approvals. At Naval Medical Center San Diego (NMCS), IRB and HRPO approvals have been received, and a CRADA and DUA have each been completed and are awaiting final signature from the commanding officer. Thus, this site is ready to begin recruitment and data collection by the end of August. At University of Michigan (UM) and Spaulding Rehabilitation Hospital (SRH), IRB and HRPO approvals are in place. A CRADA is not required at either of these sites, but DUAs have been written and are awaiting final signature from site administrators. These sites are expected to be ready for recruitment and data collection in early September, and they have both been preliminarily searching hospital databases for potential participants, to gauge the available sample at their

sites. Center for the Intrepid/Brooke Army Medical Center (CFI/BAMC) has obtained IRB and HRPO approval. A CRADA and DUA are being pursued jointly with Walter Reed, as both work through the Henry M. Jackson Foundation. CFI's PI has indicated that recruitment and data collection may begin, but participants' associated medical data may not be shared until these ancillary agreements are in place. Walter Reed National Military Medical Center (WRNMMC) has obtained an Institutional Agreement for IRB Review ("Reliance Agreement") to defer to the UD IRB review, and is currently undergoing initial IRB review at WRNMMC to approve the UD protocol. Once this is approved, the WRNMMC site will undergo HRPO submission/approval. The CRADA and DUA at this site have been reviewed, and will be finalized following the IRB review. We plan to begin data collection with participants recruited from sites that are ready in September (four of five), while WRNMMC finalizes its regulatory requirements.

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 be training all recruiting and data collection staff, and actively conducting data collection. First, we will conduct 50 cognitive debriefing interviews, will analyze the feedback as described above, and will make any necessary changes to the item pools. Within two months of completion of this step, we will begin field testing the items with a new sample of participants—recruiting participants to reach our sampling target of 650 individuals. We will hold weekly meetings with collaborating sites to monitor recruitment, evaluate recruitment strategies, and to work together to manage our target goals. In this way, sites can share effective strategies they have used, and we can manage resources most efficiently.

In December, we will hold a face-to-face meeting with all project investigators at the Naval Medical Center San Diego. The timing of the meeting has been planned to coincide with the start of our field testing study.

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, during the reporting period, regulatory and administrative approvals took far longer than the 6 months allocated to them in our project plan, as described above. While we are largely through this process, one site (WRNMMC) still awaits human subjects regulatory approval. Thus, while no changes in approach have occurred, the initiation of data collection has necessarily been delayed. We have been working with sites to try to minimize the time for recruitment as described below.

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

As noted above, delays in receiving regulatory approvals have caused resultant delays in the initiation of cognitive debriefing and baseline field-testing data collection efforts. We anticipate beginning data collection early in project year 2 and will actively manage the process, meeting with sites weekly, reviewing the available pool of participants and collaboratively discussing strategies to successfully recruit as many of these eligible participants. We will hold a face-to-face meeting to discuss ways in which we can streamline recruitment and, if successful, this will allow us to make up time from the delays resulting from the regulatory process. Our ultimate goal is to assure we have collected a large, well-defined research data sample to effectuate the creation of valid, reliable rehabilitation outcome measures.

Changes that had a significant impact on expenditures

The delays described in 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. One conference oral presentation was completed and two conference presentation abstracts were submitted and accepted during the reporting period, and will be delivered during the subsequent reporting period.

1. Tulsy, D, Resnik, LJ, Castillo, RC, Slotkin, J, Tyner, CE (October, 2017). Recent Advances in Outcomes Measurement after Amputation and Major Extremity Trauma: Developing new patient reported outcome item banks to assess areas of emotional and social functioning specific to individuals with amputation and major extremity trauma. Symposium presented at the American Congress of Rehabilitation Medicine annual meeting, Atlanta, Georgia.
2. Tyner, CE, Wyatt, M, Pruziner, A, Cancio, J, Slotkin, J, Kisala, P, Dearth, C, Boulton, A, Tulsy, D (August, 2018). Quality-of-Life assessment after major extremity trauma: Developing a new patient-reported outcome Measure. Oral presentation accepted for the Military Health System Research Symposium, Kissimmee, Florida.
3. Tyner, CE, Slotkin, J, Kisala, P, Tulsy, D (October, 2018). Developing a New Patient Reported Outcome Measure for Health-Related Quality of Life After Limb Trauma. Poster presentation accepted for the American Congress of Rehabilitation Medicine annual meeting, Dallas, Texas.

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?

Name:	David Tulsy, PhD
Project Role:	Project PI
Researcher Identifier (e.g. ORCID ID):	none
Nearest person month worked:	2
Contribution to Project:	No change

Name:	Jerry Slotkin, PhD
Project Role:	Co-I
Researcher Identifier:	none
Nearest person month worked:	3
Contribution to Project	Dr. Slotkin has taken primary responsibility for communication with sites and for overall project management, and has contributed to item pool review.

Name:	Callie Tyner, PhD
Project Role:	Co-I
Researcher Identifier:	0000-0003-2945-392X
Nearest person month worked:	2
Contribution to Project	Dr. Tyner has taken a lead role on preparing all regulatory documents at UD and has assisted other sites in this process; has helped to manage the REDCap database, and has contributed to item pool review.

Name:	Pamela Kisala, MA
Project Role:	Co-I
Researcher Identifier:	0000-0003-3234-795X
Nearest person month worked:	2
Contribution to Project	No change

Name:	Aaron Boulton, PhD
Project Role:	Biostatistician
Researcher Identifier:	none
Nearest person month worked:	2
Contribution to Project:	Dr. Boulton has led data collection and study design efforts, to maximize data collected while minimizing participant burden

Name:	Marriah Ma, BA
Project Role:	Graduate Student Research Assistant
Researcher Identifier:	none
Nearest person month worked:	5
Contribution to Project:	No change

Name:	Alyssa Griffith, BA
Project Role:	Graduate Student Research Assistant
Researcher Identifier:	none
Nearest person month worked:	5
Contribution to Project:	No change

Name:	William Flynn
Project Role:	REDCap Developer
Researcher Identifier:	none
Nearest person month worked:	1
Contribution to Project:	Mr. Flynn has programmed and set up the REDCap databases for this project and has trained the UD team on its use and management.

Name:	Marilynn Wyatt, MA
Project Role:	Site PI, NMCSD
Researcher Identifier:	none
Nearest person month worked:	1
Contribution to Project:	Ms. Wyatt has overseen all efforts at NMCSD to prepare regulatory documents for this project and has participated in item pool review.

Name:	Alison Pruziner, DPT
Project Role:	Site PI, WRNMMC
Researcher Identifier:	none
Nearest person month worked:	1
Contribution to Project:	Dr. Pruziner has overseen all efforts at WRNMMC to prepare regulatory documents for this project and has participated in item pool review.

Name:	Jill Cancio, OTD
Project Role:	Site PI, CFI/BAMC
Researcher Identifier:	none
Nearest person month worked:	1
Contribution to Project:	Dr. Cancio has overseen all efforts at CFI/BAMC to prepare regulatory documents for this project and has participated in item pool review.

Name:	Ross Zafonte, DO
Project Role:	Site PI, SRH
Researcher Identifier:	none
Nearest person month worked:	1
Contribution to Project:	Dr. Zafonte has overseen all efforts at SRH to prepare regulatory documents for this project and has participated in item pool review.

Name:	Claire Kalpakjian, PhD
Project Role:	Site PI, UM
Researcher Identifier:	none
Nearest person month worked:	1
Contribution to Project:	Dr. Kalpakjian has overseen all efforts at UM to prepare regulatory documents for this project and has participated in item pool review.

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 Tulskey, PhD

New funding:

1. Title: Development of a Psychosocial Symptom Monitoring and Self Management System for Individuals with SCI
Funding Agency: Craig H. Neilson Foundation 439797
Agency Contact: Kim Cerise, Craig H. Neilson Foundation, kim@chnfoundation.org 818-925-1245
Project Dates: 04/30/2017-04/29/2019
Effort: 1.2 calendar months
Project Goals: This project will adapt the self-management intervention system (iManage) for individuals with SCI by incorporating 4 SCI-QOL psychosocial item banks (Depression, Anxiety, Ability to Participate, and Resilience) into the platform and developing a series of targeted self-management videos for individuals with SCI in each of these topic areas
Overlap: None
2. Title: Women's Health and Disability: Building a Clinically Relevant Outcome Measure
Funding Agency: University of Michigan/National Institutes of Health R01HD082122
Agency Contact: Susan Meikle, 6100 Executive Blvd, Rockville, MD 20852.
Project Dates: 09/16/2015 – 05/31/2020
Effort: 0.30 calendar months
Project Goals: The goals of this project are to build clinically relevant item pools of gynecological/reproductive HRQOL items to enhance clinical care and research practice for women with disabilities, to calibrate the new item pools to create computer adaptive tests, and to demonstrate feasibility of the new measures in clinical settings.
Overlap: None
3. Title: ECHO PRO Research Resource: A Developmentally-based Measurement Science Framework for Assessing Environmental Exposure and Child Health
Funding Agency: Northwestern University/National Institutes of Health U24OD023319

Agency Contact: Chermay Mason Chernay.Mason@nih.gov 240-669-2992

Project Dates: 09/21/2016-08/31/2019

Effort: 0.6 calendar months

Project Goals: The overall objective of ECHO is to capture the adverse impact of early environmental exposures on children's health by bringing together several existing studies of the influence of the environment on prenatal, postnatal and early childhood health. This project provides services as the core for measurement.

Overlap: None

Previous funding:

- Effect of Treatment on Outcome after TBI in Children and Adolescents (5U01CE002196-02) ended 9/29/2017
- RRTC on Improving Measurement of Medical Rehabilitation Outcomes (H133B090024) ended 9/29/2016
- The University of Michigan Model Spinal Cord Injury Care System (H133N11002) ended 9/29/2016
- Quality of Life in Caregivers of traumatic brain injury: The TBI-CareQOL (R01NR013658) ended 6/30/2018

Jerry Slotkin, PhD

New funding:

1. Title: ECHO PRO Research Resource: A Developmentally-based Measurement Science Framework for Assessing Environmental Exposure and Child Health
Funding Agency: Northwestern University/National Institutes of Health U24OD023319
Agency Contact: Chermay Mason Chernay.Mason@nih.gov 240-669-2992
Project Dates: 09/21/2016-08/31/2019
Effort: 5.4 calendar months
Project Goals: The overall objective of ECHO is to capture the adverse impact of early environmental exposures on children's health by bringing together several existing studies of the influence of the environment on prenatal, postnatal and early childhood health. This project provides services as the core for measurement.
Overlap: None
2. Title: ARMADA: Advancing Reliable Measurement in Alzheimer's Disease and Cognitive Aging
Funding Agency: Northwestern University/National Institutes of Health/NIA 1U2CAG057441
Agency Contact: Jessica Perez perezj@nia.nih.gov 301-496-1472
Project Dates: 11/01/2017-04/30/2020
Effort: 2.2 calendar months
Project Goals: Cognitive decline and dementia due to Alzheimer's Disease, both associated with advancing age over 65, are increasing in the US due to the reduction of other illnesses that, in the past, limited life expectancy. This project will provide a brief, comprehensive assessment tool (in English and Spanish versions), applicable to diverse populations, to screen for a decline in cognitive health and associated neurological functions. The burden of age-related cognitive decline and dementia on older adults and the health care system make their early identification a critical public health goal in order to pave the way for prevention trials.
Overlap: None

Callie Tyner, PhD**New funding:**

1. Title: ECHO PRO Research Resource: A Developmentally-based Measurement Science Framework for Assessing Environmental Exposure and Child Health
Funding Agency: Northwestern University/National Institutes of Health U24OD023319
Agency Contact: Chermay Mason Chernay.Mason@nih.gov 240-669-2992
Project Dates: 09/21/2016-08/31/2019
Effort: 2.4 calendar months
Project Goals: The overall objective of ECHO is to capture the adverse impact of early environmental exposures on children's health by bringing together several existing studies of the influence of the environment on prenatal, postnatal and early childhood health. This project provides services as the core for measurement.
Overlap: None
2. Title: Development of a Psychosocial Symptom Monitoring and Self Management System for Individuals with SCI
Funding Agency: Craig H. Neilson Foundation 439797
Agency Contact: Kim Cerise, Craig H. Neilson Foundation, kim@chnfoundation.org 818-925-1245
Project Dates: 04/30/2017-04/29/2019
Effort: 1.8 calendar months
Project Goals: This project will adapt the self-management intervention system (iManage) for individuals with SCI by incorporating 4 SCI-QOL psychosocial item banks (Depression, Anxiety, Ability to Participate, and Resilience) into the platform and developing a series of targeted self-management videos for individuals with SCI in each of these topic areas
Overlap: None

Pamela Kisala, MA**New funding:**

1. Title: Development of a Psychosocial Symptom Monitoring and Self Management System for Individuals with SCI
Funding Agency: Craig H. Neilson Foundation 439797
Agency Contact: Kim Cerise, Craig H. Neilson Foundation, kim@chnfoundation.org 818-925-1245
Project Dates: 04/30/2017-04/29/2019
Effort: 2.4 calendar months
Project Goals: This project will adapt the self-management intervention system (iManage) for individuals with SCI by incorporating 4 SCI-QOL psychosocial item banks (Depression, Anxiety, Ability to Participate, and Resilience) into the platform and developing a series of targeted self-management videos for individuals with SCI in each of these topic areas
Overlap: None
2. Title: Clinical Adaptation of the SCI-QOL Psychosocial Measures
Funding Agency: Craig H. Neilson Foundation 367686
Agency Contact: Kim Cerise, Craig H. Neilson Foundation, kim@chnfoundation.org 818-925-1245
Project Dates: 04/30/2016-04/29/2019

Effort: 2.4 calendar months

Project Goals: This project will develop and validate clinically relevant scoring standards for SCI-QOL psychosocial item banks to improve clinical utility of these measures

Overlap: None

3. Title: Women's Health and Disability: Building a Clinically Relevant Outcome Measure

Funding Agency: University of Michigan/National Institutes of Health R01HD082122

Agency Contact: Susan Meikle, 6100 Executive Blvd, Rockville, MD 20852.

Project Dates: 09/16/2015 – 05/31/2020

Effort: 1.20 calendar months

Project Goals: The goals of this project are to build clinically relevant item pools of gynecological/reproductive HRQOL items to enhance clinical care and research practice for women with disabilities, to calibrate the new item pools to create computer adaptive tests, and to demonstrate feasibility of the new measures in clinical settings.

Overlap: None

4. Title: Disability and Rehabilitation Research Program (TBIMS)

Funding Agency: Gordon and Betty Moore Foundation 5299

Agency Contact: Janet Corrigan

Project Dates: 12/05/2017 – 12/04/2020

Effort: 0.60 calendar months

Project Goals: How to best apply current, existing patient-reported outcomes measures (PROMs) to support evidence-based practice and person- and family-centered medicine for persons with cognitive/communicative disorders.

Overlap: None

Previous funding:

- Effect of Treatment on Outcome after TBI in Children and Adolescents (5U01CE002196-02) ended 9/29/2017
- RRTC on Improving Measurement of Medical Rehabilitation Outcomes (H133B090024) ended 9/29/2016
- The University of Michigan Model Spinal Cord Injury Care System (H133N11002) ended 9/29/2016
- Evaluating the Sensitivity, Specificity, and Clinical Utility of the SCI-QOL CDEs (Rick Hansen Institute: G2015-26) ended 02/28/2017

Marilynn Wyatt, MA

Nothing to report

Alison Pruziner, DPT

Nothing to report

Jill Cancio, OTD

Nothing to report

Ross Zafonte, DO**New funding:**

1. Title: Spaulding New England Regional Spinal Cord Injury Center
Agency: National Institute on Disability, Independent Living, and Rehabilitation Research
Contracting/Grants Officer: Patricia Barrett (202) 795-7303 and Marlene Spencer (202) 795-7422
Performance Period: 10/01/16 – 09/30/21
Annual Funding: \$459,759
Level of Effort: 1.44 Calendar Months
Description: The major goals of this project is to develop and improve our multidisciplinary system of rehabilitation care designed specifically to meet the needs of individuals with SCI, contribute to the SCI model systems national database and therefore facilitate the longitudinal assessment of long term SCI outcomes, and contribute to improved long term SCI outcomes conducting a site-specific research project and participating in a collaborative research project.
Overlap: None

Previous funding:

- Spaulding Harvard Spinal Cord Injury Model System (NIDRR H133N110010), ended 09/30/2016
- Treatment of the Persistent Post-Concussion Syndrome with Transcranial Light Emitting Diodes, ended 01/26/2017

Claire Kalpakjian, PhD**New Funding:**

1. Title: Pregnancy, SCI and Decision Making: Development of a Decision Making Tool
Agency: Craig H. Neilsen Foundation
Grant Officer: Joy Guihama, 16830 Ventura Boulevard, Suite 352, Encino, CA 91436
Performance Period: 04/30/2018 – 04/30/2021
Funding Amount: \$400,000
Level of Effort: 2.16 calendar months
Project Goals: The objective in this proposed project is to determine decision-making needs and develop and pilot test an Internet-based pregnancy decision-making tool designed expressly for women with SCI.
Overlap: None
2. Title: Decision Making, Disability & Pregnancy: Content Development of a Pregnancy Decision Making Tool for Women with Physical Disabilities
Agency: National Institutes of Health
Grant Officer: Bryan Clark, MBA, (NICHD), Telephone: 301-435-6975
Performance Period: 04/01/2018 – 03/30/2020
Funding Amount: \$426,250
Level of Effort: 3.00 calendar months
Project Goals: The work will advance the field by addressing the needs of women with physical disabilities in pursuit of two specific aims: 1) determine informational and decision-making needs among a diverse sample of women with physical disabilities to develop the scope and content of a pregnancy decision-making tool; and 2) design and pilot test a decision-making tool prototype.
Overlap: None

3. Title: Michigan Institute for Clinical and Health Research (MICHR) - U-award
Supporting Agency: Department of Health and Human Services – National Institutes of Health
Grants Officer: Todd Wilson, NIH-NCATS, 6701 Democracy Blvd, BG 1DEM Rm 914, Bethesda MD 20817
Performance Period: 06/01/2017 – 02/28/2022
Funding Amount: \$48,220,260
Level of Effort: 1.20 calendar months
Project Goals: The Michigan Institute for Clinical & Health Research (MICHR) is a catalytic hub that significantly impacts the translation of investigative science into innovative improvements in clinical care and health policy. Our objective is to empower researchers and research communities within and outside the University of Michigan (U-M), creating a positive impact on health across local, regional, national, and global scales.
Overlap: None

Previous funding:

- Michigan Institute for Clinical and Health Research (MICHR) - U-award, ended 05/31/2017
- Targeting Sedentary Behavior Reduction in Adults with Cerebral Palsy using a Real-time Behavioral Intervention, CK effort ended 1/2018
- The University of Michigan Advanced Rehabilitation Research Training Program in Community Living and Participation, CK effort ended 5/21/2018
- The Menopause Transition in Women with Traumatic Brain Injury, project ended 09/29/2016
- The University of Michigan Model Spinal Cord Injury Care System, project ended 09/30/2016

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

Please see Appendix B for attached abstracts from research presentations described in question 6.



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.

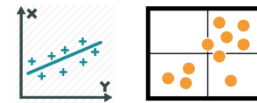
Approach: This study will create valid, standardized, psychometrically robust, and clinically useful PRO measures for traits and symptoms that are of critical importance to understanding the health and rehabilitation outcomes of Wounded Warriors and civilians with neuromusculoskeletal trauma. Furthermore, 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.

Aim 1. Finalize 10 item pools and conduct field testing.



Aim 2. Calibrate item banks and develop CATs

Aim 3. Evaluate Test Properties



Aim 4. Develop Clinical Score Reports



Accomplishments: In the fourth quarter of this project, we have completed all external expert item reviews, and have finalized all items so that data collection can begin. We have also received IRB approval for a modification at UD necessary to begin data collection. We await human subjects regulatory approval at WRNMMC, and administrative approval at NMCSD, SRH, and UM. Databases have been developed and staff are being trained, so that data collection can begin in September 2018.

Revised Timeline and Cost

Activities	Year 1	Year 2	Year 3	Year 4	Year 5
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

Updated: 27-Aug-2018

Revised Goals/Milestones

Year 1

- Obtain regulatory approval (IRB & HRPO; complete at 5 of 6 sites)
- 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:

We continue to await regulatory and/or administrative approvals at sites, which has caused a delay in the initiation of data collection. Our goal is to make up as much of this time during the planned data collection period as possible. Regardless, we will ensure that all necessary data will be collected.

Budget Expenditure to Date:

Projected Expenditure: **\$883,679**
Actual Expenditure: **\$360,203**

(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. Tulsky, D, Resnik, LJ, Castillo, RC, Slotkin, J, Tyner, CE (October, 2017). Recent Advances in Outcomes Measurement after Amputation and Major Extremity Trauma: Developing new patient reported outcome item banks to assess areas of emotional and social functioning specific to individuals with amputation and major extremity trauma. Symposium (consisting of five separate talks) presented at the American Congress of Rehabilitation Medicine annual meeting, Atlanta, Georgia.

Presented Symposium Abstract

There have been several recent initiatives to advance the science of outcomes measurement for individuals after amputation and major extremity trauma. There is a growing need for evidence-based assessments specific for this patient population, given the unique rehabilitation needs of this group compared with traditional orthopedic patients. This symposium describes several recent, cutting-edge efforts to use research and theory to guide the assessment of outcomes in this population, including systematic literature reviews, longitudinal studies using advanced measurement approaches, development of a Toolbox of recommended measures, qualitative focus group research, and new item development. Major extremity trauma and amputation have become a particular focus of military treatment facilities (MTFs) and the Departments of Defense (DoD) and Veterans Affairs (VA) in recent years, as an unprecedented number of wounded warriors from the recent military operations have sustained combat related traumatic musculoskeletal injuries, including major amputations of upper and/or lower limbs. Nearly half of combat-injured personnel sustain trauma to the extremities, with many experiencing significant psychosocial challenges in addition to physical functioning/activity limitations. An ideal approach to outcomes assessment in this patient population would be generalizable across treatment settings and across the full range of impairment/symptom severity, so that outcomes metrics could be used across the continuum of care (i.e., from acute post-injury stage, through rehabilitation, to community-based follow-up). Work presented in this symposium will describe efforts to understand the challenges important to this unique group of individuals. Furthermore, this symposium will report on efforts to validate modern assessment approaches in this population and to develop new measurement tools and systems specifically for these individuals.

(The symposium included five oral presentations, only one of which was directly related to this project)

Relevant Presentation Outline

Title: *Developing new patient reported outcome item banks to assess areas of emotional and social functioning specific to individuals with amputation and major extremity trauma*

Presenter: Callie Tyner, PhD

- a. Description of a multisite qualitative study using focus groups with patients (n = 56) and their providers (n = 34) to discuss quality of life in individuals with amputation and/or major extremity trauma.
- b. Provide an overview of the qualitative analysis and discuss the gaps in existing measurement tools (e.g., resilience).

- c. Report on new item banks that have been developed to fill these measurement gaps (i.e., Resilience, Body Image, Satisfaction with Physical Abilities, Adjustment to Identity/Role Change, Satisfaction with Orthosis/Prosthesis).

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2. Tyner, CE, Wyatt, M, Pruziner, A, Cancio, J, Slotkin, J, Kisala, P, Dearth, C, Boulton, A, Tulskey, D (August, 2018). Quality-of-Life assessment after major extremity trauma: Developing a new patient-reported outcome Measure. Oral presentation accepted for the Military Health System Research Symposium, Kissimmee, Florida.

Accepted Oral Presentation Abstract

Background: Major extremity trauma represents a significant cause of disability among military Service Members, with corresponding physical and psychosocial consequences that may persist even after return to duty or community reintegration. Limb injuries are also pertinent to Veterans and civilians, with more than 20,000 new extremity injuries occurring every year in the United States. These injuries are heterogeneous and complex, and injury severity alone does not adequately predict long-term disability and return to duty. Quality of life following major extremity trauma is impacted by numerous factors, including physical symptoms and health status, adaptation to use of assistive technology, emotional functioning, personal factors related to coping and adjustment, and psychosocial factors relevant to participation and community integration. Currently, there is a lack of population-specific measures designed to quantify quality of life after major extremity trauma. This represents a major challenge for researchers and clinicians who intend to quantify these outcomes, as existing measurement tools designed for other uses may not adequately capture the experience of these individuals. The present research project intends to fill this gap. Specifically, this work was designed to develop a high-quality, rigorously tested, reliable and valid set of measurement tools that can be used to evaluate individuals in this clinical population in a way that is simultaneously comprehensive and precise. The primary goal of this study was to develop new items in approximately 10 new content domains, which were considered highly salient for this clinical population. This work represents a major step in the process to develop a new patient reported outcome measure of quality of life after major extremity trauma.

Methods: The items written for this new measure were based on results of focus group feedback with military service members with a history of major extremity trauma and/or amputation. Focus groups were conducted at three Military Treatment Facilities and one Veterans hospital. Participants were Service Members and Veterans (n = 56) with a history of limb trauma and/or amputation, and their clinical providers (n = 34). Individuals with injuries had experienced upper and/or lower limb trauma, including amputation as well as limb preservation. Clinical providers included physical and occupational therapists, physiatrists, and mental health professionals. Focus group dialogues were recorded, and transcripts were analyzed for content. Statements were grouped categorically according to International Classification of Functioning, Disability and Health (ICF) criteria. New item pools were defined based on the frequency of conceptual statements, and transcripts were used to generate content for newly written items. Item pool definitions were written to guide content of new items around central themes, hypothesized to be unidimensional constructs. The item writing process included a literature review of existing measurement tools to supplement transcript content. Items were refined for grammar, clarity, pertinence to construct, and translatability.

Results: A total of 582 new items were written in 11 conceptual content domains, tentatively titled: 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, Orthosis/Prosthesis, Arthritis Impact, Resilience, and Future Outlook. Newly written items were supplemented with 256 existing items from measures in the field.

Specifically, relevant items were included from the Patient-Reported Outcomes Measurement Information System (PROMIS®), the Quality of Life in Neurological Disorders Measurement System (Neuro-QoL), the Adult Sickle Cell Quality of Life Measurement Information System (ASCQ-Me®), the Spinal Cord Injury Quality of Life Measurement System (SCI-QOL), and the Traumatic Brain Injury Quality of Life Measurement System (TBI-QOL). These existing measures provided sources for item content that are pertinent to multiple causes of disability, which were judged relevant to this population. Notably, existing measures with relevant, high-quality items were not available in some pertinent content domains, for example Orthosis/Prosthesis satisfaction and functioning, Diet and Weight, and Adjustment to Identity/Role Change for Military Personnel. This highlighted the critical need for new, high-quality items to assess quality of life for this population accurately and comprehensively.

Conclusion: This work represents an initial but essential step in the process to develop a new patient reported outcome measurement system to serve the needs of clinicians and researchers who wish to measure quality of life after major extremity trauma in military Service Members, Veterans, and civilians. These methods are in line with the high standards recommended for new measurement development by the National Institutes of Health PROMIS® initiative, which outlines a specific process for using qualitative work and item response theory to develop reliable and valid patient reported outcomes measures. In future work, newly developed items will be tested with additional qualitative methods, including feedback from experts in the field, cognitive debriefing interviews with Service Members, Veterans, and civilians who have experienced major extremity trauma, as well as quantitative methods, including large-scale field testing to calibrate the items, analysis of item bias or differential item functioning, and responsiveness.

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3. Tyner, CE, Slotkin, J, Kisala, P, Tulskey, D (October, 2018). Developing a New Patient Reported Outcome Measure for Health-Related Quality of Life After Limb Trauma. Poster presentation accepted for the American Congress of Rehabilitation Medicine annual meeting, Dallas, Texas.

Accepted Poster Presentation Abstract

Research Objectives: There is a paucity of reliable and valid metrics for quantifying health-related quality of life (HRQOL) after major extremity trauma. The goal of this research project is to develop new items in approximately 10 new content domains based on results of focus group feedback with military service members with a history of major extremity trauma and/or amputation.

Design: Focus group transcripts were analyzed for content and statements were grouped categorically. New items were written based on the frequency of conceptual statements. Item pool definitions were written to guide content of new items around central themes, hypothesized to be unidimensional constructs. The item writing process included a literature review of existing measurement tools to supplement transcript content. Items were refined for grammar, clarity, pertinence to construct, and translatability.

Setting: Focus groups were conducted at military treatment facilities and one Veterans hospital.

Participants: Participants were service members (n = 56) with a history of limb trauma and/or amputation, and their clinical providers (n = 34).

Interventions: n/a

Main Outcome Measure(s): n/a

Results: A total of 582 new PRO items were written, in 11 conceptual content domains. Newly written items were supplemented with 256 existing items measures in the field. Notably, existing measures were not available in all pertinent content domains, highlighting the need for new, high-quality PRO items for understanding HRQOL in these individuals.

Conclusions: This work has paved the way for a new PRO measurement system to be developed and tested, to serve the needs of measuring HRQOL after major extremity trauma. Newly developed items will be tested in future research with cognitive debriefing interviews, and further refined. Refined items will be calibrated using large-scale field testing.