AWARD NUMBER: W81XWH-16-2-0065

TITLE: Needs, Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation

PRINCIPAL INVESTIGATOR: Dr. Linda Resnik, PhD, PT

CONTRACTING ORGANIZATION: Ocean State Research Institute, Inc.
Providence, RI 02908

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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14. ABSTRACT

Quality gaps in care of military and Veterans with upper limb amputation have been reported. In 2008, amputees who received prosthetic care in the VA were reported to be less satisfied than their counterparts receiving care in the private sector. In 2011, reported widespread dissatisfaction amongst combat Veterans with upper limb amputation reported by the Office of the Inspector General led to calls for efforts to evaluate needs of Veterans with traumatic upper limb amputations to improve their satisfaction. Major efforts to improve the quality of prosthetic care have been made since these studies were conducted. In 2009, the VA reorganized its amputation system of care, and in 2014 the VA and DoD released the Evidence-Based Clinical Practice Guidelines (CPGs) for the rehabilitation of persons with upper limb amputation. It is now time for a comprehensive study to assess the current state of quality and outcomes of amputation rehabilitation and satisfaction with prosthetic care for upper limb amputees and to track quality and outcomes over time.

15. SUBJECT TERMS

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1. **INTRODUCTION:**

Quality gaps in care of military and Veterans with upper limb amputation have been reported. In 2008, amputees receiving prosthetic care in the VA were reported to be less satisfied than counterparts receiving care in the private sector. In 2011, reported widespread dissatisfaction amongst combat Veterans with upper limb loss led to calls for efforts to evaluate needs of Veterans with traumatic upper limb amputations to improve satisfaction. Major efforts to improve quality of prosthetic care have been made since these studies were conducted. In 2009, the VA reorganized its amputation system of care, and in 2014 the VA and DoD released the Evidence-Based Clinical Practice Guidelines (CPGs) for the rehabilitation of persons with upper limb amputation. It is now time for a comprehensive study to assess the current state of quality and outcomes of amputation rehabilitation for upper limb amputees and to track quality and outcomes over time. Our objective is to provide comprehensive cross-sectional and longitudinal data on function, needs, preferences, and satisfaction of Veterans and service members with major upper limb amputation.

2. **KEYWORDS:**

Keyword summary: Upper limb amputation; upper limb amputee; quality of care; Evidence-Based Clinical Practice Guidelines; prosthetic device; care satisfaction; amputation rehabilitation; amputation outcomes.

3. **ACCOMPLISHMENTS:**

- **What were the major goals of the project?**

There are 3 major goals/aims in the approved statement of work (SOW) for this project:

Aim 1: Describe patterns of prosthesis use; identify the impact of amputation and prosthesis use on function, activities and participation; and identify unmet prosthetic needs

Aim 2: Conduct a one year longitudinal follow-up survey to examine changes in satisfaction with care and prosthetic services, physical performance, self-reported quality of life and physical function to assess the implementation of new clinical practice guidelines (CPGs)

Aim 3: Quantify physical function using a battery of performance based tests.

The table below shows the major tasks associated with each aim/goal, the target completion date, actual completion date (if relevant) and percent complete.

Aim	Activities	Target Completion Date	Completion Date	Percent Complete
Aims 1&2	Regulatory approvals	Month 3	May 2017	100%
	Prepare study staff for survey administration	Month 9	April 2017	100%
	Prepare study data (VA sample)	Month 7	May 2017	100%
	Prepare study data (DoD sample)	Month 7		10%
	Conduct surveys (Aim 1)	Month 19	June 2018	100%
	Conduct surveys (Aim 2)	Month 31		30%
	Data analysis (Aim 1)	Month 19		50%
	Data analysis (Aims 1 & 2)	Month 33		25%
	Dissemination	Month 36		0%
Aim 3	Regulatory approvals	Month 8	July 2017	100%
	Prepare study staff	Ongoing		90%
	Study coordination	Month 33		65%
	Data collection (Visit 1)	Month 21		74%
	Data collection (Visit 2)	Month 33		8%
	Data Analysis	Month 36		0%
	Dissemination	Month 36		0%

- **What was accomplished under these goals?**

1& 2) Specific objectives and major activities

Specific objectives and major activities accomplished during the Year 2 reporting period (30th September 2017 – 29th September 2018) are described below:

Aims 1 & 2

Specific Objective 1: Maintain regulatory approvals (fully met)
Major Activities:

- Submitted all study modifications to HRPO
- Obtained initial IRB approval from the USF IRB, and HRPO approval for the USF site
- Obtained continuing review approval from the VA CIRB, FDA IRB, University of Massachusetts IRB and HRPO

Specific Objective 2: Identify Aim 1 & 2 sample (partially met)
Major Activities:

- Modified DART request to include access to DaVINCI datasets, for the purpose of identifying the DoD population
- Identified the total number of potential participants in DoD population (N=1080), unable to obtain contact information in DaVinci data at this time

Specific Objective 3: Complete Aim 1 data collection (fully met).
Major Activities:

- Completed Aim 1 data collection in June 2018 (808 Aim 1 participants)
- Tracked participation and mailed gift cards to all Aim 1 participants.

Specific Objective 4: Begin Aim 2 data collection (fully met)
Major Activities:

- Mailed Aim 2 recruitment packages
- Completed 206 Aim 2 surveys to date
- Tracked participation and mailed gift cards to Aim 2 participants

Specific Objective 5: Begin Aim 1 data analysis (fully met)
Major Activities:

- Cleaned Aim 1 database and created codebook
- Identified and planned analyses for journal articles
- 5 draft manuscripts in progress

<u>Aim 3</u>

Specific Objective 1: Maintain regulatory approvals for data collection sites (fully met)
Major Activities:

- Submitted all study modifications to HRPO
- Obtained continuing review approval from the VA CIRB, FDA IRB, CFI, and HRPO

Specific Objective 2: Complete Aim 3 Visit 1 data collection (partially met)
Major Activities:

- Continued Aim 3 Visit 1 data collection (93 completed to date, 10/25/2018)
- Expanded recruitment to include non-Veterans and initiated recruitment methods to identify additional sources
- Tracked participation and provided gift cards to Aim 3 Visit 1 participants

Specific Objective 3: Begin Aim 3 Visit 2 data collection (fully met)
Major Activities:

- Developed the testing manual and data collection instrument for Aim 3 local site data collection (instrument available by request).
- Began Aim 3 (Visit 1) data collection at all local data collection sites
- Tracked participation and provided gift cards to Aim 3 Visit 2 participants (13 completed to date)

Specific Objective 4: Begin Aim 3 preliminary analysis (fully met)
Major Activities:

- Created codebook for Aim 3 data
- Completed initial analysis for prosthetic component data
- Validated and enhanced prosthetic description data
- Identified and planned analyses for initial prosthetic device papers

3) Significant Results or Key Outcomes

Data collection is complete for Aim 1 and ongoing for Aims 2 & 3
Aim 2: 808 complete (final N)
Aim 2: 206 completed as of 10/25/2018
Aim 3 Visit 1: 93 completed as of 10/25/2018
Aim 3 Visit 2: 13 completed as of 10/25/2018

4) Other Achievements

Infrastructure development

- Executed Year 2 subcontract awards for the 4 VA sites (Seattle, Richmond, Tampa, Gainesville), University of Massachusetts, Center for the Intrepid, and University of South Florida

- Continued regular communications to facilitate coordination and insure study fidelity, including:
    - Weekly phone meetings held with the overall study coordinator and staff at Aim 3 data collection sites
    - Monthly Aim 3 local site coordinator meetings
    - Quarterly Aim 3 study assessor meetings
    - Monthly Aim 1 study staff meetings (PVAMC and University of Massachusetts)

Data access and use

- Identifying the DoD study population for Aims 1 and 2 required data use agreements (DUA) with two different DoD agencies. The DUA with the Naval Health Research Center (NHRC) was submitted and is currently under review. We received a draft DUA in August 2018, but it was retracted and the DUA team at NHRC is continuing to work on the document. We have also worked with the DaVINCI team to identify DoD participants in DaVINCI databases. The team was able to pull select data fields which allowed us to identify the potential sample size of service members with upper limb (N=1080) using the specified inclusion criteria. However, DaVinci does not have fields for participant contact information. It is unclear whether we will be able to obtain contact information from this dataset in the future. At this time, we do not know if or when we will be able to identify the DoD population.

Stated goals not met

While we have made significant progress, we have experienced some challenges in meeting stated goals:

1. Prepare study data (DoD population)
    a. Goal - By Month 7; Actual - Unknown

As described above, we have experienced delays in accessing Department of Defense data for this project. There are two databases we wish to access to identify the study population – the Military Health System Data Repository (MDR) and Expeditionary Medical Encounter Database (EMED). Our EMED data use agreement with the NHRC is currently under review. The MDR data will be accessed through DaVINCI. We modified our DART (Data Access Request Tracked) for this project to include DaVINCI databases, and are currently waiting on the data extract. The DaVINCI team identified a sample (N=1080) based on our inclusion criteria, however they have not been able to provide the list with contact information. It is unclear at this time whether we will be able to access contact information in this dataset.

2. Complete Aim 3 Visit 1 data collection
    a. Goal – Month 21: Actual: We anticipate completing Visit 1 data collection in February 2019 (Month 29)

Aim 3 Visit 1 data collection activities have taken longer than anticipated due to challenges in recruiting subjects. We had planned to be complete with Visit 1 and begin Visit 2 during Year 2. We have broadened our recruitment strategies to achieve the target goal and will continue collecting Visit 1 data during Year 3. The upper limb amputee population is small and difficult to recruit – our local data collection sites first prioritized local participants, and more recently traveled referrals from Aim 1 to the data collection locations. In addition, we received IRB approval to expand recruitment to include non-Veterans. We partnered with the Amputee Coalition of America (AC) to recruit from their membership base. We expect this partnership to be successful and that we will be able to meet Aim 3 recruitment goals by February 2019.

Extending Visit 1 data collection into Year 3 means that we will not be able to collect Visit 2 data on participants who are enrolled during Year 3, given that these follow-up visits would take place after the funding period is complete (September 29, 2019). If we have sufficient carryforward funding and are awarded a no-cost extension, we would be able to complete Visit 2 data collection for some of the participants enrolled during Year 3.

- **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 (Year 3), we anticipate accomplishing the following activities to meet the project goals and objectives:

Project Activity	Goal Completion Date
Complete Aim 2 survey data collection for the VA population	Month 21
Complete Aim 3 Visit 1 data collection	Month 29
Continue Aim 3 Visit 2 data collection	Month 36
Perform and interpret analyses	Month 36
Submit 2 abstracts to national conferences	Month 36
Submit 2 publications to scientific journals	Month 36

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**

During Year 2, we made the following changes to the study approach:

  - We opened up recruitment for Aim 3 to non-Veterans in order to meet recruitment goals. Inclusion of non-Veterans will allow us to meet recruitment goals in a timely manner.

- **Actual or anticipated problems or delays and actions or plans to resolve them**
  As mentioned above, recruitment into Aim 3 was slower than anticipated. We broadened inclusion criteria to address this issue.

We continued to experience problems with access to DoD These problems and associated actions or plans to resolve any issues are discussed below.

DoD data access: As previously discussed in Section 3, We are waiting to find out if the DaVINCI team will be able to obtain contact information. If this information is not available we will not be able to utilize DaVINCI data. We are also waiting for the NHRC team to complete the Data Use Agreement. We are in regular communication with these groups, but are uncertain whether the data will become available to us during the funding period.

- **Changes that had a significant impact on expenditures**

The following changes impacted our expenditures:

1. Delays in Aim 3 recruitment: We had a pool of funded allocated for participant travel, but because we did not meet our recruitment goals we did not use all of this funding because we did not have the participants. We would like to carry these funds forward to support participant travel during Year 3. Our recent recruitment efforts have yielded a significant number (at least 50) of non-Veteran upper limb amputees who are eligible for the study. Most are not local to our sites and will need to be traveled to the local data collection site to participate in the study.

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. Several papers are under construction and will be submitted by the end of 2018.

- **Books or other non-periodical, one-time publications.**

  Nothing to report.

- **Other publications, conference papers, and presentations.**

  Nothing to report.

- **Website(s) or other Internet site(s)**

  Nothing to report.

- **Technologies or techniques**

  Nothing to report.

- **Inventions, patent applications, and/or licenses**

  Nothing to report.

- **Other Products**

  Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name:	Linda Resnik
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	4
Contribution to Project:	Dr. Resnik has performed work in the area of overall study overnight, data quality monitoring, data analysis, manuscript preparation and oversight for the work of Ms. Biester (Ekerholm), Mr. Borgia and Ms. Gill.
Funding Support:	*n/a*

Name:	Sarah Biester (Ekerholm)
Project Role:	Project Manger
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	7 (maternity leave)
Contribution to Project:	Ms. Biester has performed work in the area of study coordination across all study sites, regulatory document preparation and submission, and other reporting requirements. Ms. Biester has also coordinated the submission of data use agreements, maintains the overall study budget, approves invoices, prepares HR and contracting paperwork, and other administrative tasks as required.
Funding Support:	*n/a*

Name:	Anisha Gill
Project Role:	Deputy Project Coordinator
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	9
Contribution to Project:	Ms. Gill has performed work in the area of maintenance of study databases and preparation of study data, data cleaning, mailings for Aims 1 & 2, and quality control reviews for Aim 3 data collection. In addition, she has assisted Ms. Biester with study coordination, and provided technical support to Aim 3 local site coordinators in data collection and entry procedures.
Funding Support:	*n/a*

Name:	Matthew Borgia
Project Role:	Biostatistician/Analyst
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	4
Contribution to Project:	Mr. Borgia has performed work to, clean and update contact information and prepare study data for Aim 1 mailings, create codebooks for study data, clean data and conduct preliminary analyses.
Funding Support:	n/a

Name:	Jacqueline Siven
Project Role:	Research Assistant/Coordinator (Tampa)
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	6
Contribution to Project:	Ms. Siven has coordinated data collection activities for the Tampa site, including subject recruitment, travel, reimbursement, tracking, data collection and data entry. In addition, Ms. Siven has coordinated required regulatory submissions for the Tampa site and assisted with prosthetic description data dissemination planning.
Funding Support:	*n/a*

Name:	Matthew Jerrell
Project Role:	Research Assistant/Coordinator (Seattle)
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	6
Contribution to Project:	Mr. Jerrell has coordinated data collection activities for the Seattle site, including subject recruitment, travel, reimbursement, tracking, data collection and data entry. In addition, Mr. Jerrell has coordinated required regulatory submissions for the Seattle site.
Funding Support:	*n/a*

Name:	Ashley Soon
Project Role:	Research Assistant/Coordinator (Gainesville)
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	6
Contribution to Project:	Ms. Soon has coordinated data collection activities for the Gainesville site, including subject recruitment, travel, reimbursement, tracking, data collection and data entry. In addition, Ms. Soon has coordinated required regulatory submissions for the Gainesville site.
Funding Support:	*n/a*

Name:	Mandeesha Singh
Project Role:	Research Assistant/Coordinator (Richmond)
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	6
Contribution to Project:	Ms. Singh has coordinated data collection activities for the Richmond site, including subject recruitment, travel, reimbursement, tracking, data collection and data entry. In addition, Ms. Singh has coordinated required regulatory submissions for the Richmond site.
Funding Support:	*n/a*

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

There have been some changes to active support for the PI and senior/key since Year 1 of our study. These changes are listed below. None of these changes have impacted level of effort on this project.

Dr. Linda Resnik: The following changes have been made to Dr. Resnik's support*:*

New

Title: Validation of patient reported outcomes for female Veterans with Upper Limb Amputation
Sponsor: VA RR&D A2936-R
Veterans Affairs (10P9R)
Patricia A. Dorn, Ph.D. Director, Rehab R&D Service
810 Vermont Avenue, NW
Washington, DC 20420
Time Commitment: Consistent with VA APPT
Period of Performance:10/1/2018-9/30/2021
Amount Funded: $588,343
Project Goals: The long-term goal of this proposed research is to improve the quality of prosthetic care for female Veterans with upper limb amputation.
Specific Aims: 1) Refine the Trinity Amputation and Prosthetic Experience Scale (TAPES) Satisfaction subscale and the Orthotics Prosthetics Users Survey (OPUS) Client Satisfaction with Device (CSD) scales to incorporate issues of concern to women, and then evaluate reliability, validity, and gender-based scoring. 2)Develop and evaluate reliability, validity, and gender-based scoring of a modified version of the OPUS Upper Extremity

Functional Scale, the P-UEFS, which measures perceived difficulty in activity performance when using an upper limb prosthesis. 3)Assess the reliability, validity and gender based scoring of the Prosthetics Evaluation Questionnaire (PEQ) utility and residual limb health subscales.
4)Use the new metrics to compare prosthetic satisfaction, self-reported activity performance, prosthetic utility and residual limb health of male and female Veterans by amputation level, and device type.
Overlap: None

Title: Which Post-Acute Care Setting is Best for Patients' Outcomes? (Administrative Supplement)
Sponsor: 3R01AG054656-02S1 (PI Gozalo)
Time Commitment: .83 CM (Brown Appt)
Period of Performance: 0/12/18-5/31/19
Amount Funded: $312,980
Project Goals/Specific Aims: Post-acute care is widely used and costly. While patients have options for PAC services between different post-acute settings, there is little information on how these alternative post-acute care settings impact outcomes for different patient groups. ADRD patients are a particularly vulnerable group with different PAC needs and at higher risk of long-term institutionalization. The results of our study will help inform the referral of patients in need of PAC, and help guide policy aimed at improving PAC patient outcomes.
Overlap: None

Title: Initial Treatment Approaches and Healthcare Utilization aong Veterans with Low Back Pain (Schmidt PI)
Sponsor: CoHSTAR
Audrey Kydd
121 S. Main Street
Brown University
Providence, RI 02903
Time Commitment: .12 CM (Brown Univ. Appt)
Period of Performance: 2/15/18-2/14/19
Amount Funded: $25,000
Project Goals/Specific Aims: The objective of this research is to gain a better understanding of the initial intervention approaches and important health and utilization outcomes among Veterans with a new diagnosis of LBP.
Overlap: None

Title: Innovative Approaches to Examine Post-Acute Care Outcomes of Older Adults with Traumatic Brain Injury (Thomas PI)
Sponsor: NIA
Time Commitment: .24 CM (Brown Univ Appt)
Period of Performance: 04/01/18 – 03/31/20
Amount Funded: $448,094
Project Goals/Specific Aims: The overall objective of this proposal is to determine the predictors of outcomes, particularly functional and cognitive improvement and the ability to

return home, among older adult patients with TBI.
Overlap: None

Completed

Title: RFTO # 24 Error Rate Reduction Regarding Lower Limb Prosthesis (LLP)
Sponsor: Agency for Healthcare Research and Quality (AHRQ) HHSA290201500002
Lionel L. Bañez, M.D.
Medical Officer
US Department of Health and Human Services
5600 Fishers Lane 06E69D
Rockville, MD 20857
Time Commitment: .60 CM (Brown Univ Appt)
Period of Performance: 06/20/16 08/21/18
Amount Funded: $218,462
Project Goals/Specific Aims: The goal of this systematic review (SR) will be to summarize the analytic validity (reliability), clinical validity (including predictive validity with respect to K-Levels actually attained), and utility (impact on patient-relevant outcomes) of OMTs; it will also describe how these relate to patient- and LLP-specific factors.
Overlap: None

Title: Smart Control Modes for Facilitating Use of Multi-DOF Upper-Limb Prosthetics
Sponsor: CDMRP, USAMRMC BAA 13-1
Subcontract to Yale University
Andrew B. Rudczynski, Ph.D.
Associate Vice President for Research Administration
47 College St
New Haven, CT 06510-3209
Time Commitment: 1.2 CM (Brown Univ APPT)
Period of Performance: 06/01/15 – 05/31/18
Amount Funded: $115,960
Project Goals/Specific Aims: This proposal will develop "smart" control modes, combined with multisensor volitional control, to enable easy use of a multi-DOFs wrist and one DOF terminal device. The development efforts will be complemented by pre-pilot and pilot human subject studies.
Overlap: None

Title: A Modular Multi-DOF Prosthetic Wrist and Low-Level Autonomous Control for Ease-of Use
Sponsor: DOD, USAMRMC BAA 13-1
Subcontract to Yale University
Andrew B. Rudczynski, Ph.D.
Associate Vice President for Research Administration
47 College St
New Haven, CT 06510-3209
Time Commitment: .72 CM (Brown Univ APPT)

Period of Performance: 09/01/15 – 08/31/18
Amount Funded: $137,236
Project Goals/Specific Aims: This project centers on developing and evaluating a novel class of spherical prosthetic wrist that provides a range of motion equal to the unaffected human wrist while adding only two inches to the length of the residual limb.
Overlap: None

Title: Community reintegration, functional outcomes and QOL after upper and lower extremity trauma
Sponsor: BADER
Subcontract to University of Delaware
Laura V. Paller, MPA, CRA
Contract & Grants Specialist
Office of Sponsored Programs
210 Hullihen Hall
Newark, DE | 19716
Time Commitment: Consistent with A9264-S (VA APPT)
Period of Performance: 05/01/15 – 09/29/18
Amount Funded: $192,688
Project Goals/Specific Aims: This grant will bring together a diverse team of stakeholders (individuals who have had catastrophic limb trauma clinicians, policy makers, and research investigators) with many representatives from our participating sites to discuss and agree on a series of common measures and scales that can help bring standards and uniformity to the field, and will test the toolkit of measures in a population with traumatic upper limb injury.
Overlap: None

Title: Variation in Hospital-Based Rehabilitation Services in Joint Replacement and its Impact on Post- Acute Outcomes
Sponsor: CLDR
University of Texas Medical Branch
301 University Boulevard
Galveston, TX 77555-1137
Time Commitment: .02 CM (Brown Univ Appt)
Period of Performance: 07/01/17 – 06/30/18
Amount Funded: $40,000
Project Goals/Specific Aims: The objectives of this proposal are to: 1) estimate and identify source of the hospital-level variation associated with the utilization of hospital-based rehabilitation services after lower extremity joint replacement and 2) examine the association between receipt of hospital-based rehabilitation services and two post-acute outcomes: a. discharge destination and b. hospital readmission
Overlap: None

Title: Impact of Hospital-Based Physical Therapy Services on Hospital Readmission: Implications for Bundled Payment
Sponsor: CoHSTAR
Audrey Kydd

121 S. Main Street
Brown University
Providence, RI 02903
Time Commitment: .02 CM (Brown Univ Appt)
Period of Performance: 2/15/17-2/14/18
Amount Funded: $25,000
Project Goals/Specific Aims: The overall objective is to develop a new method of quantifying physical therapy utilization using Medicare data, use that method to explore the variation in hospital-based physical therapy services, and its association with unplanned hospital readmissions
Overlap: None

Title: GAPcare: The Geriatric Acute & Post-acute Care Coordination Program for Fall Prevention in the Emergency Department (Goldberg-PI0 Role Mentor)
Sponsor: NIA R03AG056349-01
Time Commitment: .02 CM (VA Appt)
Period of Performance:7/15/17 -5/31/18
Amount Funded: $120,750
Project Goals/Specific Aims: The overall objective of this investigation is to gather preliminary data on the feasibility of an ED-based multidisciplinary fall prevention intervention. The central hypothesis is that an in-ED intervention involving PT and pharmacy-led assessments and training will lead to fewer falls by giving patients tools for improving function and by decreasing adverse drug events
Overlap: Career Scientist

Title: Smart Control Modes for Facilitating Use of Multi-DOF Upper-Limb Prosthetics
Sponsor: CDMRP
Subcontract to Yale University, USAMRMC BAA 13-1
Andrew B. Rudczynski, Ph.D.
Associate Vice President for Research Administration
47 College St,
New Haven, CT 06510-3209
Time Commitment: 1.2 CM (Brown Univ APPT)
Period of Performance: 06/01/15 – 05/31/18
Amount Funded: $115,960
Project Goals/Specific Aims: This proposal will develop "smart" control modes, combined with multisensor volitional control, to enable easy use of a multi-DOFs wrist and one DOF terminal device. The development efforts will be complemented by pre-pilot and pilot human subject studies.
Overlap: None

Dr. Jill Cancio: The following change has been made to Dr. Cancio's support:

New:

US Army Medical Research and Materiel Command Tulsky (PI) 07/1/2017-06/30/2022

Assessing Rehabilitation Outcomes after Severe Neuromusculoskeletal Injury: Development of Patient Reported Outcomes Assessment Instruments
Annual Costs: $125,485
Role: Site PI **Time Commitment:** 1.2 Cal. Months
Project Goals: To examine the way that outcomes are assessed in injured service members and make recommendations for change.
Specific Aims:
1. Recruit participants and conduct cognitive interviews.
2. Conduct medical record abstraction for consented participants (to include relatively basic information such as date of injury, mechanism of injury, ICD-10 diagnosis code(s), height, weight, limb(s) affected, injury severity score (ISS)).
3. Recruit clinicians to participate in cognitive debriefing interviews about the content of score reports
Grants Officer: Vanessa C. Foreman
Sr. Business Administrator
Center on Assessment Research and Translation
University of Delaware STAR Campus
540 S. College Avenue STAR Annex Room 111
Newark, Delaware 19713
Overlap: None

Completed

US Army Medical Research Acquisition Authority Tulsky (PI) 5/1/2015 – 9/30/2017
BADER Toolbox Study: Community Reintegration, Functional Outcomes, and Quality of Life After Extremity Trauma
Annual Costs: $74,749
Role: Site PI **Time Commitment:** 0.1 Cal. Months
Project Goals: Assist the Military Treatment Facilities (MTF) in providing evidence-based orthopedic rehabilitation care for individuals with extremity trauma.
Specific Aims:
1. Characterize health, physical functioning, community re-integration and emotional functioning in individuals with limb trauma and upper limb amputations who receive outpatient services at MTFs and VAs by using a standardized Toolbox of measures
2. Examine the reliability and concurrent and divergent validity of the Toolbox measures in military samples.
Grants Officer: Vanessa C. Foreman
Sr. Business Administrator
Center on Assessment Research and Translation
University of Delaware STAR Campus
540 S. College Avenue STAR Annex Room 111
Newark, Delaware 19713
Overlap: None

Dr. Jeffrey Heckman: The following changes have been made to Dr. Heckman's support:

Completed

Title: Self-management to improve function following amputation
Time commitments: 0.6 calendar months
Supporting agency: VA RR&D (No. 1I01RX001143-01A1)
Contracting/Grants Officer contact info:
Tiffany Asqueri,
VA Rehabilitation Research and Development
Tiffany.asqueri@va.gov
Performance period: 10/1/2013-9/30/2017
Level of funding: $1,099,042.
Project goals: The primary goal of this multi-site RCT is to examine efficacy of group-based self-management to improve physical and psychological functioning following limb loss.
Specific aims: Aim 1: Randomized Controlled Trial – Primary Outcomes
Determine the impact of a group-based self-management intervention for Veterans with limb loss (VETPALS) upon physical and psychosocial functioning
Aim 2: Randomized Controlled Trial – Secondary Outcomes
Determine the impact of a group-based self-management intervention (VETPALS) upon self-efficacy, patient activation, problem solving, quality of life, and positive affect.

Dr. Joseph Webster: The following changes have been made to Dr. Webster's support:

Completed

Title: Employment Considerations and Barriers in Veterans with Traumatic Amputations: Rehabilitation Research and Training Center on Physical Disabilities
Time Commitment: 60 calendar months (1%)
Contracting/Grants Officer contact info: Virginia Commonwealth University (VCU) Rehabilitation Research and Training Center (VCU-RRTC)
Role: Collaborator
Supporting Agency: US Department of Education (CDF 84.133b-4)
Performance Period: 2013-2018
Level of Funding: $4,353,686
Goals/Aims: Determine barriers and facilitators of employment in Veterans with traumatic amputation.
List of Specific Aims:
1. Identification of barriers to employment in Veterans with traumatic amputation
2. Facilitation of successful employment in Veterans with traumatic amputation
Overlap: None

Title: Percutaneous Osseointegrated Docking System for Above-Elbow Amputees
Time Commitment: 3%
Contracting/Grants Officer contact info: Western Institute of Biomedical Research (WIBR)
Role: Collaborator / Consultant
Supporting Agency: Joint Warfighter Medical Research Program (JWMRP)
Performance Period: 10/01/2015 – 09/30/2017

Goals/Aims: Define the statistical variability of residual bone and soft tissues following amputation.
List of Specific Aims: Define the statistical variability of residual bone and soft tissues following above-elbow amputation.
Overlap: None

Dr. Jason Highsmith: The following changes have been made to Dr. Highsmith's support:

Completed

Title: The Effect of Prosthetic Socket Interface Design on Perspiration and Residual Limb Skin Condition for the Transfemoral Amputee
Supporting Agency: U.S. Department of Defense
Contracting/Grants Officer contact info:
Ebony Simmons, USAMRAA, 820 Chandler St., Ft. Detrick, MD 21702
Performance Period: 09/15/2015-09/14/2017
Level of funding: $912,628
Project Goals: The primary objective of this clinical trial is to determine if the DS and Sub-I alternative interface designs will decrease skin temperature, perspiration and pistoning; and improve balance, stability, gait, comfort and be preferred over the standard of care IRC interface.
Specific Aims: 1. Determine if transfemoral amputees of non-dysvascular etiology will experience an improved environment for the skin following accommodation with DS and Sub-I interfaces compared to the standard of care IRC interface. 2. Determine if transfemoral amputees of non-dysvascular etiology will prefer DS or Sub-I interfaces compared to the standard of care IRC interface, following accommodation.

- **What other organizations were involved as partners?**

  Nothing to report

8. **SPECIAL REPORTING REQUIREMENTS**

- **COLLABORATIVE AWARDS:**

  Nothing to report, not applicable.

- **QUAD CHARTS:** See attached.

9. **APPENDICES:** No attachments.

Needs, Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation

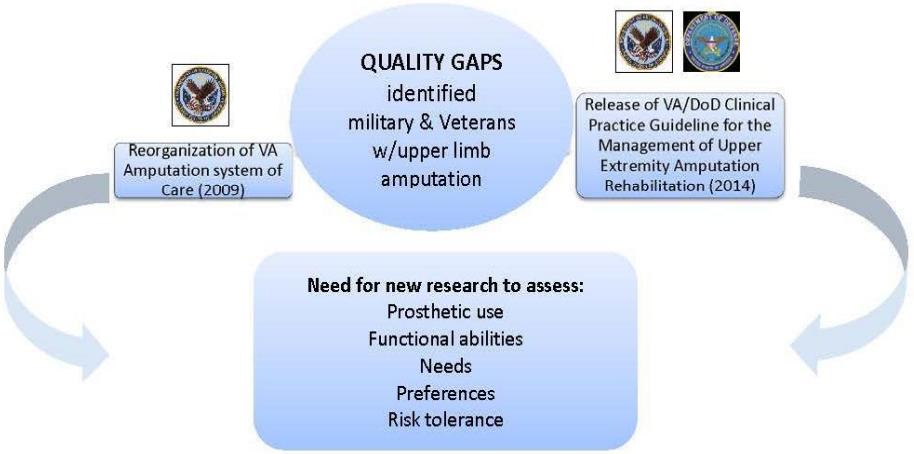
PI: Linda Resnik, PT, PhD **Org:** Providence VA Medical Center **Award Amount:** $2,497,349

Study/Product Aims

1. Describe patterns of prosthesis use; identify the impact of amputation and prosthesis use on function, activities and participation; and identify unmet prosthetic needs.
2. Conduct a one year longitudinal follow-up survey to examine changes in satisfaction with care and prosthetic services, physical performance, self-reported quality of life and physical function to assess the implementation of new clinical practice guidelines (CPGs)
3. Quantify physical function using a battery of performance based tests.

Approach

This 3-part study will provide cross-sectional and longitudinal survey and performance data. Data collection will be done through surveys and functional performance testing. Part 1 will be a cross-sectional survey. Part 2 is a one year longitudinal follow-up survey of respondents from Part 1. Part 3 is an in-person study to collect performance based measures of physical function at two time points, about one year apart.



Timeline and Cost

Activities / Project Year (PY)	Year 1	Year 2	Year 3
Identify sampling frame and train interviewers			
Data collection – Part 1			
Data collection – Part 2			
Data collection – Part 3			
Data analysis/dissemination			
Estimated Budget ($K)	**$723,929**	**$920,694**	**$852,816**

Updated: (10-26-2018)

Goals/Milestones

PY1 Goals – Study Launch

- ✓ All IRB Approvals Received
- ✓ Interviewers trained
- ✓ Sampling frame identified
- ✓ Database development complete
- ✓ Part 1 Surveys administered

PY2 Goals – Data collection and early analysis

- ✓ Part 2 surveys administered
- ✓ Gift cards issued Part 2
- ✓ Conduct analyses Aim 1, and preliminary analyses Aim 2

PY3 Goals – Analysis and dissemination

- ❑ Analyze data Parts 2 and 3
- ❑ Submit abstracts and manuscripts

PY2 Budget Expenditure to Date

Projected Expenditure: $920,694
Actual Expenditure: $810,621.87 as of 9/30/2018