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W81XWH-14-1-0613

TITLE:
Fitness and Independence after SCI: Defining Meaningful Change and Thresholds

PRINCIPAL INVESTIGATOR:
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CONTRACTING ORGANIZATION:
University of Miami
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Quality of life after SCI/D is depends more on participation, mobility, and personal care independence than injury level/severity. Fitness is a major determinant of transfer and general ADL independence in persons with SCI/D. Fitness can prevent or delay further aging related independence losses. We propose fitness represents an underappreciated approach to meaningfully improve independence and thus QOL of people living with SCI/D, no matter their injury level, age, or injury duration. In Phase 1 we interview SCI/D clinicians and consumers to determine if the candidate variables for the clinical risk calculator could be collected clinically; identify clinical techniques to assess patients' fitness; and document factors clinicians and consumers identify as fitness-function relationship confounds. In Phase 2 we collect data on 300 persons with SCI/D describing personal characteristics, criterion fitness, clinical fitness predictors, neurological impairment, balance, and functional independence. In Phase 3 we analyze Phase 2 data and develop the CRC, a tool that clinicians and consumers to determine if low fitness is limiting transfer ability.

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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Unclassified	Unclassified	Unclassified	Unclassified	59	19b. TELEPHONE NUMBER *(include area code)*

Table of Contents

Page

1. **INTRODUCTION:**

This study is a three-year collaboration among the University of Miami (Miami, FL), MedStar National Rehabilitation Hospital (Washington D.C.), and George Mason University (Fairfax, VA). Our scientific objectives are to a) model the fitness-independence relationship and b) estimate fitness changes and thresholds associated with greater functional independence. Our clinical translation objective is to develop a low time burden clinical tool that calculates the probability an individual's fitness is below the transfer independence threshold. We will enroll 300 non-ambulatory persons with SCI/D, making this the largest, most comprehensive examination of the fitness-function relationship in persons with SCI. We will fill critical knowledge gaps by modeling the fitness-independence relationship and by estimating fitness gains and thresholds that support meaningful independence gains. This is the only study to date linking fitness to SCIM-III performance, data critical to strengthen future therapeutic efficacy clinical trials. Finally, our clinical translation objective will accelerate application of our results to clinical practice, thereby more quickly impacting persons with SCI.

2. **KEYWORDS:**

Spinal cord injury, fitness, independence, SCIM-III

3. **ACCOMPLISHMENTS:**

   a. **What were the major goals of the project?** See table p. 2

Table 1. Accomplishments: Major Goals

GOALS	Target Completion Date (month)	Actual Completion Date (month)	% of Completion
Major Task 1: Establish secure regulatory approvals and establish subawards			
Subtask 1: Secure Regulatory approval of Phase 1 & Phase 2 research protocols			
Milestone Achieved: Local IRB approval at UM, NRH, GMU	June 2014	**UM:** Phase 1, Sept 2014; Phase 2, August 2014	100
		NRH: Phase 1, Dec 2014; Phase 2, Sept 2014	
		GMU: Phase 1, not involved; Phase 2, Dec 2014	
Milestone Achieved: HRPO*** approval for all protocols and local IRB** approval through UM	Sept 2014	**UM:** Phase 1, March 2015; Phase 2, June 2015	100
		NRH: Phase 1, March 2015; Phase 2, July 2015	
		GMU: Phase 1, not involved; Phase 2, June 2015	
Subtask 2: Establish subaward agreements with NRH and GMU			
Milestone achieved: Subaward agreements completed	Sept 2014	**NRH:** Dec 2014	100
		GMU: Jan 2015	
Milestone achieved: Subaward agreements updated annually	NA	NA	NA
Major Task 2: Coordinate Study Staff for Phase 1			
Subtask 1: Hiring of Study Staff (UM only)			
Milestone achieved: UM RA-TBD hired	Oct 2014	June 2014	100
Subtask 2: Build Survey in RedCap database			
Milestone Achieved: Survey ready to launch	Oct 2014	March 2015	100
Subtask 3: Training of Phase 1 Study Staff			
Milestone Achieved: Phase 1 Research staff trained	Oct 2014	April 2015	100
Major Task 3: Phase 1 Participant Recruitment, Participant Interviews			
Subtask 1: Phase 1 semi-structured interviews and survey launch			
Milestone Achieved: Phase 1 surveys begin	Oct 2014	April 2015	100

Milestone Achieved: Phase 1 interviews begins	Oct 2014	April 2015	100
Milestone Achieved: 24 minimum SCI/D clinicians and consumers interviewed	Jan 2015	N=17 of 24 minimum interviews	70
Milestone Achieved: 100 clinician/100 consumer completed surveys	Mar 2015	N=101 of 100 consumer surveys N= 7 of 100 clinician surveys	50
Major Task 4: Refine Phase 2 Data Collection			
Subtask 1: Use Phase 1 results to refine Phase 2 data collection			
Milestone Achieved: Phase 2 data collection refined	Feb 2015	Not complete	0
Milestone Achieved: Phase 2 updates are local IRB approved by UM, NRH, and GMU	Mar 2015	Not complete	0
If applicable Milestone Achieved: HRPO*** approval for all protocol updates and local IRB** approval through UM	Mar 2015	Not complete	0
Milestone Achieved: Phase 2 electronic data management system created	Mar-Apr 2015	Not complete	0
Major Task 5: Coordinate Study Staff for Phase 2			
Subtask 1: Assign GRA-TBD (GMU only)			
Milestone achieved: GMU GRA-TBD selected	Mar 2015	June 2014, updated Sept 2015	100
Subtask 2: Develop Manual of Procedures			
Milestone achieved: Manual of Procedures Developed	Mar 2015	Sept 2015	80
Subtask 3: Train Study Staff			
Milestone Achieved: Phase 2 Research staff	Mar 2015	Not complete	0

trained			
Milestone Achieved: Manual of Procedures updated	Mar 2015	Not complete	0
Major Task 6: Phase 2 Participant Recruitment, Enrollment, Assessment			
Subtask 1: Phase 2 execution			
Milestone Achieved: 1st participant consented and assessed	Mar 2015	Not complete	0
Milestone Achieved: 300 SCI/D consumers enrolled and complete data sets entered into the electronic data management system	June 2017	Not complete	0
Major Task 7: Phase 3 – Data Analyses			
Subtask 1: Coordinate with Sites to monitor data collection rates and data quality			
Milestone Achieved: Participant Accrual rate stays on target and target accrual is achieved (N=300)	June 2017	Not complete	0
Milestone Achieved: Extracted Data consists of 300 complete data sets that are 'clean' and ready to analyze after final quarterly audit.	June 2017	Not complete	0
Subtask 2: Data Analyses and Results Dissemination			
Milestone Achieved: Preliminary analyses of Specific Aims 1 & 2 presented at DoD sponsored meeting (some time in year 2)	Mar 2016	Not complete	0
Milestone Achieved: Final analyses of Specific Aims 1 & 2 submitted for publication	Sept 2017	Not complete	0
Milestone Achieved: Final analyses of Specific Aim 3 (CRC)	Sept 2017	Not complete	0

submitted for publication			
Milestone Achieved: Clinical Risk Calculator (CRC) made available to SCI/D clinicians and consumers (Please note the CRC cannot be made available until the corresponding publication has been published. While the submission is targeted for Q4 of year 3, the manuscript would not be published until after the performance period. This is why the timeline for this milestone extends beyond month 36)	Oct 2017- Sept 2018	Not complete	0

b. **What was accomplished under these goals?**

i. Major Activity 1: Establish secure regulatory approvals and establish subawards

Subtask 1: Secure Regulatory approval of Phase 1 & Phase 2 research protocols

Specific objectives:

- Develop Phase 1 interview guide and survey
- Finalize Phase 1 & Phase 2 consent form and human subjects protocol
- Coordinate with Sites for IRB** protocol submission
- Coordinate with Sites for UM IRB** review
- Coordinate with Sites for Military 2nd level IRB** review (ORP/HRPO)
- Submit amendments, adverse events and protocol deviations as needed
- Coordinate with Sites for annual IRB** report for continuing review

Key Outcomes:

- Local IRB approval at UM, NRH, GMU achieved
- HRPO approval for all protocols and local IRB approval through UM achieved

Subtask 2: Establish subaward agreements with NRH and GMU

Specific objectives:

- As needed, modify subaward budgets
- Coordinate sponsored programs departments to complete subaward agreements

Key Outcomes: Subaward agreements completed

ii. Major Activity 2: Coordinate Study Staff for Phase 1

Subtask 1: Hiring of Study Staff (UM only)

Specific objectives:

- Develop Job description
- Advertise and interview for RA-TBD position
- Allocate space for and acquire workstation for RA-TBD

Key Outcomes: UM RA-TBD hired

iii. Major Activity 3: Phase 1 Participant Recruitment, Participant Interviews

Subtask 1: Phase 1 semi-structured interviews and survey launch

Specific objectives:

- Coordinate UM-NRH study staff to define flow chart for all study steps, interview process, interview coding, theme extraction

- Finalize iterative process for interview process, coding, interview guide update
- Phase 1 surveys begin
- Phase 1 interviews begins
- Begin subject recruitment and scheduling
- Interview participants (min 8 in each group: SCI/D military clinicians, SC/D civilian clinicians, SCI/D consumers, N=24 min total)
- Transcribe interviews, code interviews, extract themes
- Update interview guide
- Launch survey: Email survey links to potential participants
- Conference calls as needed to monitor progress and troubleshooting

Key Outcomes:

- 17 SCI/D clinicians (6) and consumers (9) interviewed
- 17 SCI/D clinicians and consumers interviews transcribed and coded by Dr. Cowan, currently being coded by Dr. Schladon.
- 7 clinician/101 consumer completed surveys

Key Findings/Major outcomes:

- Interview results
    - There were 12 factors that we are not currently measuring that SCI clinicians/consumers indicated were related to transfer and/or ADL ability (see below). We are currently discussing which of these can be feasibly added Phase 2 data collection. Some, like technique/positioning lack a criterion measure. Others, like pain, can be added easily. However, we must ensure we do not over burden our research participants and must balance an ideal data collection against what will add the most value.
        - Pain
        - Spasticity
        - Abdominal circumference (Anthropometrics)
        - Technique/Positioning
        - Motivation
        - Problem solving
        - Risk taking
        - Cognitive issues
        - Contractures
        - Medications (side effects)
        - Fatigue (only decision to do a transfer, not yes/no ability)
        - Other health conditions

All other results

- Survey results
- Interim analyses have not been completed. Survey results will be applied during the development of the CRC (in Phase 3) and have not been needed as of yet.

iv. Major Activity 5: Coordinate Study Staff for Phase 2

Subtask 1: Assign GRA-TBD (GMU only)

Specific objectives: Identify which GRA will be assisting

Key Outcomes: GMU GRA-TBD selected

Subtask 2: Develop Manual of Procedures

Specific objectives: Develop Manual of Procedures

Key Outcomes: Manual of Procedures Developed

v. The following goals were partially met or not met as planned in CY1:

Major Activity 3: Phase 1 Participant Recruitment, Participant Interviews

Subtask 1: Phase 1 semi-structured interviews and survey launched but are not complete.

Major Activity 4: Refine Phase 2 Data Collection

Subtask 1: Use Phase 1 results to refine Phase 2 data collection, obtain local IRB and HRPO approval

Major Activity 5: Coordinate Study Staff for Phase 2

Subtask 3: Train Study Staff

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

Nothing to Report

d. **How were the results disseminated to communities of interest?**

Nothing to report.

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

- Continue Phase 1 interviews
- Continue Phase 1subject recruitment and scheduling
- Continue to interview participants (min 8 in each group: SCI/D military clinicians, SC/D civilian clinicians, SCI/D consumers, N=24 min total), transcribe interviews, code interviews, extract themes
- Conference calls monitoring progress and troubleshooting

- Continue using Phase 1 results to refine Phase 2 data collection
- Obtain local IRB and HRPO approval of Phase 2 updates.
- Train study staff: mock subject testing, review and refine subject testing protocol
- Begin Phase 2 execution

4. **IMPACT**

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

   Nothing to report.

   b. **What was the impact on other disciplines?**

   Nothing to report.

   c. **What was the impact on technology transfer?**

   Nothing to report.

   d. **What was the impact on society beyond science and technology?**

   Nothing to report.

5. **CHANGES/PROBLEMS:**

   a. **Changes in approach and reasons for change**

      i. We made two changes to the inclusion/exclusion criteria of the interview: 1.) We broadened the clinician survey and interview inclusion criteria to include recreational therapists. 2.) We decreased the restriction on duration of time since last treated a patient with SCI/D with an individual's increasing years of clinical experience. (If experience is 1-5 years, must have treated SCI/D patients in previous 5 years; if experience is 6-9 years, must have treated SCI/D patients in the previous 10 years; if experience is 10-19 years, must have treated SCI/D patients in the previous 15 years; if experience is ≥20 years, no restrictions on duration of time since last treated an SCI/D patient). This was done to broaden the pool of potential participants.

   b. **Actual or anticipated problems or delays and actions or plans to resolve them**

      i. Phase 1 is currently behind schedule due to delays in local IRB approval at all three sites and difficulty in recruiting clinicians, especially military/VA clinicians. This has resulted in a delay of phase 2 activities.

      Actions taken to mitigate the delay & ensure the project is completed on time:

         1. Expedite the interview transcription process. We have identified a solution that will enable us to have the interviews professionally transcribed within 72 hours

of their recording. This will significantly decrease the total time required to extract data from the interviews.

2. Dr. Groah has developed additional VA/military contacts to identify additional potential military participants
3. Dr. Cowan has identified several local clinicians to interview and will reach out to the local VA to identify potential additional clinicians.
4. Instead of waiting until Phase 1 is fully complete (i.e. saturation) before starting Phase 2, we will begin Phase 2 once the major themes from Phase 1 have been identified. This should allow us to begin phase 2 testing in Y2 Q1.
5. Once phase 2 begins, we will implement a greater (but still achievable) monthly accrual rate

ii. Phase 2 was projected to begin enrollment in Y1 Q3. Due to delays in Phase 1, Phase 2 will begin enrollment in Y2 Q1.

Actions taken to mitigate issue:

1. UM will increase participant enrollment rate from the planned 8-9 per month in Y2 to 10 per month throughout Y2 and Y3.
2. GMU & NRH will increase participant enrollment rate from the planned 1-2 per month in Y2 to 2-3 per month throughout Y2 and Y3.
3. We project to be caught up by the end of Y3 Q3, the original projected end of our enrollment period.

c. **Changes that had a significant impact on expenditures**

i. NA

d. **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

i. **Significant changes in use or care of human subjects.** Nothing to report.

ii. **Significant changes in use or care of vertebrate animals.** NA

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

6. **PRODUCTS:**

a. **Publications, conference papers, and presentations**

Nothing to report.

b. **Website(s) or other Internet site(s)**

Nothing to report.

c. **Technologies or techniques**

Nothing to report.

d. **Inventions, patent applications, and/or licenses**

Nothing to report.

e. **Other Products**

Nothing to report.

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

a. **What individuals have worked on the project?**

Name:	*Rachel E. Cowan, Ph.D.*
Project Role:	*Lead PI*
Researcher Identifier (e.g. ORCID ID):	NA
Nearest person month worked:	2.4
Contribution to Project:	Dr. Cowan conducted Phase 1 interviews and oversaw all aspects of the project.

Name:	Jennifer L. Maher, Ph.D.
Project Role:	Research Coordinator
Researcher Identifier (e.g. ORCID ID):	NA
Nearest person month worked:	9
Contribution to Project:	Dr. Maher obtained and maintained local IRB and HRPO approval for all protocols, built and deployed the survey, recruited participants for survey and interview.

Name:	*Suzanne Groah, MD*
Project Role:	*NRH PI*
Researcher Identifier (e.g. ORCID ID):	NA
Nearest person month worked:	0.6
Contribution to Project:	Dr. Groah assisted with clinician recruitment for Phase 1 interviews and oversaw all aspects of the project locally.

Name:	*Randall Keyser, Ph.D.*
Project Role:	*GMU PI*
Researcher Identifier (e.g. ORCID ID):	NA
Nearest person month worked:	0.6

Contribution to Project:	Dr. Keyser conducted oversaw all aspects of the project locally.

Name:	Emily Tinsley
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	NA
Nearest person month worked:	5.4 (includes effort as Staff at NRH and student GRA at GMU)
Contribution to Project:	Ms. Tinsley obtained and maintained local IRB approval for NRH and GMU.

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

Nothing to report.

c. **What other organizations were involved as partners?**

1. **Organization Name:** Medstar National Rehabilitation Hospital
    a. **Location of Organization:** Washington, D.C.
    b. **Partner's contribution to the projec**t
        i. **Collaboration**: *partner's staff work with project staff on the project*
2. **Organization Name:** George Mason
    a. **Location of Organization:** Washington, D.C.
    b. **Partner's contribution to the projec**t
        i. **Collaboration**: *partner's staff work with project staff on the project*

8. **SPECIAL REPORTING REQUIREMENTS**

a. **COLLABORATIVE AWARDS:** NA

b. **QUAD CHART:** See next page

Fitness and Independence after SCI: Defining Meaningful Changes and Thresholds

SC130235/A-18535
W81XWH-14-1-0613

PI: Rachel E. Cowan, Ph.D. **Org:** University of Miami Miller School of Medicine **Award Amount:** $655,245

Study/Product Aims

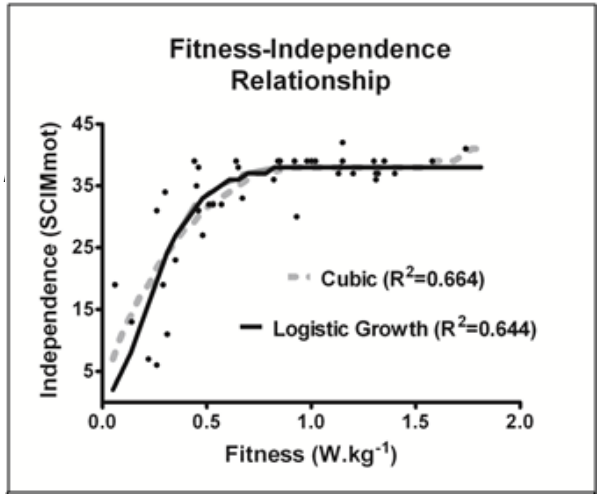
- Specific Aim 1: To define the magnitude of fitness increase required to achieve meaningful improvement in functional independence and determine if this number varies by injury level, fitness level and injury duration.
- Specific Aim 2: To define the minimum fitness required to achieve maximal transfer independence.
- Specific Aim 3: To develop a clinical risk calculator (CRC) that allows clinicians and SCI consumers to quantify the probability that fitness is less than the minimum required to enable transfer independence.

Approach

Phase 1: Interview SCI/D clinicians and consumers to 1) determine if the candidate variables for the clinical risk calculator are or could be collected clinically; 2) determine each variable's time collection burden; 3) identify clinical techniques to assess patients' fitness; and 4) document factors clinicians and consumers identify as fitness-function relationship confounds.

Phase 2: Collect data on 300 persons with SCI/D describing personal characteristics, criterion fitness, clinical fitness predictors, neurological impairment, balance, and functional independence.

Phase 3: Analyze Phase 2 data and develop the clinical risk calculator.



Phase 1 results: 1) many candidate variables can be collected clinically, 2) clinicians are willing to spend <=15 min max collecting variables, 3) clinical fitness assessments are rare, 4) we may add measures of pain, spasticity, motivation, etc.. to Phase 2

Timeline and Cost			
Activities CY	14	15	16
Phase 1 Interviews (N=9 of 8 consumers) (N=6 of 8 civilian clinicians) (N=0 of 8 military clinicians)			
Phase 1 Surveys (N=101 of 100 consumer) (N=7 of 100 clinicians)			
Phase 2 Data collection (N=0 of N=300) est. begin December 2015			
Phase 3 Analyses			
Estimated Budget ($K) (total costs)	$240	$201	$214

Updated: October, 2015

Goals/Milestones

CY14 Goal –
- ❑ Phase 1 – Complete min of 24 interviews and 200 surveys
- ❑ Phase 2 - Enroll N=58

CY15 Goals –
- ☐ Phase 2 – Enroll N=152

CY16 Goal –
- ❑ Phase 2 – Enroll N=92
- ❑ Phase 3 – Complete proposed analyses

Comments/Challenges/Issues/Concerns
- Above timeline based on original SOW
- Phase 2 delayed due to delay in Phase 1
- Phase 2 accrual rate will be increased to achieve target accrual
- Phase 1 delay due to local IRB delay and difficulty recruiting clinicians

Budget Expenditure to Date

Projected Expenditure: $118,078 (direct costs only)
Actual Expenditure: $106,835 (direct costs only)

9. APPENDICES:

- **a.** Survey – Clinician
- **b.** Survey – Consumer
- **c.** Interview Script – Clinician
- **d.** Interview Script - Consumer

Survey of feasibility of clinical and community approaches to assess fitness in persons with spinal cord injury

Please complete the survey below.

Thank you!

Introduction and Background Information

Research has shown that quality of life (QOL) after Spinal Cord Injury or Disease (SCI/D) depends more on participation, mobility, and personal care independence than on absolute severity of injury.

Transfers are particularly critical to independence, with wheelchair to car, wheelchair to wheelchair, and ground to wheelchair transfers ranked by persons with SCI as skills rated in the top seven of those most essential to daily life. Fitness level is a major determinant of transfer and general ADL (Activities of Daily Living) independence in persons with SCI/D and we suggest that it represents an underappreciated approach to meaningfully improving the independence, and thus QOL, of people living with SCI/D, no matter their age, injury severity, or time since injury.

We are developing a low time burden clinical tool that will allow you to determine the likelihood that your patient's fitness level is the reason why his or her bed, toilet-tub, or car transfers are not as independent or as easy as possible. This tool will provide you information to help your patient pursue exercise and nutrition changes that could improve his or her transfer independence.

This survey is a part of a larger study that will identify the fitness levels patients with SCI/D need in order to maximize their transfer independence. The purpose of this survey is to help us determine which variables (of the many we are collecting) we should screen for inclusion in the clinical tool. In this survey we will gather information about your ability and willingness to collect certain variables; the amount of time you are willing to spend collecting each variable or set of variables; reasons why you could not or would not collect these variables; and the total amount of time you'd be willing to spend on collecting variables for inclusion in the clinical tool.

Survey results will be integrated with the results of in-depth discussions with clinicians. If you would be willing to participate in these discussions, there will be an opportunity to provide your contact information in the following pages.

Electronic Consent

Your participation in this survey is voluntary. You may choose not to participate. If you decide not to participate in this research study, you may withdraw at any time and you will not be penalized.

Student Rights
If you are a University of Miami student, your desire not to participate, or your request to withdraw from the study, will not affect your grades or other academic standings within the University.

Employee Rights
If you are an employee of the University of Miami, your decision to participate in or to withdraw from the study will not affect your employment within the University.

This phase of the research study involves completing an online survey that will take approximately 30 minutes. If you would be willing to participate in the interview phase, you will be asked for your name and contact information. This information will not be linked to your survey responses.

All electronic records from the online survey will be stored on Miami Project to Cure Paralysis Servers which are behind the University's firewall. Within the server, records will be stored in a Working Group Folder restricted to authorized study personnel.

If you have questions about this research study, please contact Rachel Cowan, PhD at 305-243-1949 or rcowan@med.miami.edu.

Selecting the "agree" button indicates that: You have read the above information You voluntarily agree to participate You are at least 18 years of age If you do not wish to participate in the research study, please decline participation by selecting the "disagree" button.

◯ Agree
◯ Disagree

Please select 'Next Page' below and select SUBMIT on the following page to end the survey. Thank you for your time.

Would you be willing to participate in the interview portion of this study (approximately 1 hour long)?

◯ Yes
◯ No

Please provide the following information: Name: Email: Phone number: Preferred contact method (phone/email) Best day/time to call:

_____

Please answer the following 3 questions. The answers to these questions will determine your eligibility for participation in the survey.

Please indicate which degree you possess:

- ◯ Doctor of Medicine (M.D.)
- ◯ Doctor of Osteopathic Medicine (D.O.)
- ◯ Registered Nurse (R.N.)
- ◯ Physical Therapist
- ◯ Occupational Therapist
- ◯ Recreational Therapist
- ◯ Other clinical degree
- ◯ I do not have a clinical degree

Please identify your specialty:

- ◯ Family practice
- ◯ Physiatry
- ◯ Urology
- ◯ Other

Please explain _____

How long have you been working with SCI/D patients?

- ◯ < 1 year
- ◯ 1-5 years
- ◯ 6-9 years
- ◯ 10-19 years
- ◯ >20 years

Have you treated SCI/D patients in the previous 5 years?

- ◯ Yes
- ◯ No

Have you treated SCI/D patients in the previous 10 years?

- ◯ Yes
- ◯ No

Have you treated SCI/D patients in the previous 15 years?

- ◯ Yes
- ◯ No

You do not meet the inclusion criteria for this study. Please select 'Next Page' below and select SUBMIT on the following page to end the survey. Thank you for your time.

Please answer the following questions about yourself.

In which of the following environments do you practice? (Select all that apply)

- ☐ Civilian clinical setting
- ☐ Military clinical setting
- ☐ Veterans Affairs clinical setting
- ☐ Other

Please explain. _____

Which of the following best describes your practice environment?

- ◯ Academic
- ◯ Private

Gender

- ◯ Male
- ◯ Female

Location of practice

- ◯ US
- ◯ Outside of US

Select state

◯ Alabama
◯ Alaska
◯ Arizona
◯ Arkansas
◯ California
◯ Colorado
◯ Connecticut
◯ Delaware
◯ Florida
◯ Georgia
◯ Hawaii
◯ Idaho
◯ Illinois
◯ Indiana
◯ Iowa
◯ Kansas
◯ Kentucky
◯ Louisiana
◯ Maine
◯ Maryland
◯ Massachusetts
◯ Michigan
◯ Minnesota
◯ Mississippi
◯ Missouri
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◯ Nebraska
◯ Nevada
◯ New Hampshire
◯ New Jersey
◯ New Mexico
◯ New York
◯ North Carolina
◯ North Dakota
◯ Ohio
◯ Oklahoma
◯ Oregon
◯ Pennsylvania
◯ Rhode Island
◯ South Carolina
◯ South Dakota
◯ Tennessee
◯ Texas
◯ Utah
◯ Vermont
◯ Virginia
◯ Washington
◯ West Virginia
◯ Wisconsin
◯ Wyoming

Fill in your country _____

Racial ethnicity

◯ Hispanic or Latino
◯ American Indian or Alaska Native
◯ Asian
◯ Black or African-American
◯ Native Hawaiian or Other Pacific Islander
◯ White
◯ Other
◯ I would prefer to not answer this question

Please fill in your racial ethnicity: _____

Year of birth

- ◯ 1997
- ◯ 1996
- ◯ 1995
- ◯ 1994
- ◯ 1993
- ◯ 1992
- ◯ 1991
- ◯ 1990
- ◯ 1989
- ◯ 1988
- ◯ 1987
- ◯ 1986
- ◯ 1985
- ◯ 1984
- ◯ 1983
- ◯ 1982
- ◯ 1981
- ◯ 1980
- ◯ 1979
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- ◯ 1977
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- ◯ 1947
- ◯ 1946
- ◯ 1945
- ◯ 1944
- ◯ 1943
- ◯ 1942
- ◯ 1941
- ◯ 1940

As a reminder, this survey will gather information about your ability and willingness to collect certain variables, the amount of time you are willing to spend collecting each variable or set of variables, reasons why you could not or would not collect these variables, and the total amount of time you'd be willing to spend on collecting variables for inclusion in the clinical tool. We will use this information to identify a small subset of tests and questionnaires that will take the least amount of time and provide the greatest predictive power.

Please indicate which of the following information is feasible to collect in your clinic and if you would be willing to enter it into the clinical tool.

Patient's age	◯ Yes ◯ No
Patient's gender	◯ Yes ◯ No
Patient's age at SCI/D onset	◯ Yes ◯ No
Time post SCI/D onset	◯ Yes ◯ No
SCI/D etiology	◯ Yes ◯ No
If patient is receiving treatment for muscle spasms? (For example: prescription medication, surgical, recreational drugs, massage, acupuncture, etc.)	◯ Yes ◯ No
If patient can voluntarily use the muscles of his legs to help him transfer?	◯ Yes ◯ No
Assuming you were both willing and able to collect ALL of the above information and enter it into the tool, how much time would you be willing to spend doing so?	◯ < 30 sec ◯ 31-60 sec ◯ 61-90 sec ◯ > 90
For the items that you selected 'no', please select all of the reasons why you would not be wiling to collect these items.	☐ It would take too long ☐ It requires too much personnel ☐ I am worried about insurance reimbursements ☐ other
Please explain.	_____

Please indicate which of the following information is feasible to collect in your clinic and if you would be wiling to enter it into the clinical tool.

Patient's height : Measurement of the length of patient's body when lying down	◯ Yes ◯ No
Patient's weight	◯ Yes ◯ No
The length of each of your patient's arms (both left and right)	◯ Yes ◯ No
Patient's arm span (Patient holds arms out to the side. Arm span is the distance from the tip of the right middle finger, up the arm, across the chest, down the left arm to the tip of the left middle finger.)	◯ Yes ◯ No
Distance from the base of the back of your patient's neck (C7) to the top of his cushion as he leans forward	◯ Yes ◯ No
Wheelchair fit: Angle of your patient's right elbow when his or her hand is at the top center of the pushrim	◯ Yes ◯ No
Assuming you were both willing and able to collect ALL of the above information and enter it into the tool, how much time would you be willing to spend doing so?	◯ < 2 min ◯ 3 min ◯ 4 min ◯ > 5 min
For the items that you selected 'no', please select all of the reasons why you would not be wiling to collect these items.	☐ It would take too long ☐ It requires too much personnel ☐ I am worried about insurance reimbursements ☐ other
Please explain.	_____

Please indicate which of the following information is feasible to collect in your clinic and if you would be wiling to enter it into the clinical tool.

Primary wheelchair used (Manual, power assist, power, other)	◯ Yes ◯ No
Wheelchair manufacturer & model (Colours, Invacare/Top End, Quickie, Tilite, etc.)	◯ Yes ◯ No
Wheelchair frame type (Rigid or folding)	◯ Yes ◯ No
Front wheel size/tire type (3", 4", 5", 6", other/ Solid or Pneumatic)	◯ Yes ◯ No
Rear wheel size/tire type (24", 25", 26" / Solid or Pneumatic)	◯ Yes ◯ No
Number of years your patient has been using this wheelchair	◯ Yes ◯ No
Assuming you were both willing and able to collect ALL of the above information and enter it into the tool, how much time would you be willing to spend doing so?	◯ < 30 sec ◯ 31-60 sec ◯ 61-90 sec ◯ > 90
For the items that you selected 'no', please select all of the reasons why you would not be wiling to collect these items.	☐ It would take too long ☐ It requires too much personnel ☐ I am worried about insurance reimbursements ☐ other
Please explain.	_____

The following item is a performance-based assessment. Please read the description and indicate if it would be feasible to perform in your clinic, if you would be willing to do so and then enter the results into the tool.

6 Minute Manual Wheelchair Propulsion Test (6MPT):

The 6MPT is a fitness measure that requires the patient to complete as many laps as possible on a short course in 6 minutes. To conduct this test, you will need a hallway of at least 15 m (approximately 50 ft) long and 3 m (approximately 10 ft) wide for the testing, cones, a measuring device and a stop watch.

Including set-up, testing and evaluation and scoring, this test will take approximately 15 minutes to conduct.

Would you be willing and able to perform this assessment in your clinic?

- ◯ Yes
- ◯ No

Why not?

- ☐ It would take too long
- ☐ It requires too much personnel
- ☐ I am worried about insurance reimbursements
- ☐ I don't have enough space
- ☐ I don't have the necessary equipment
- ☐ other

Please explain. _____

The following item is a performance-based assessment. Please read the description and indicate if it would be feasible to perform in your clinic, if you would be willing to do so and then enter the results into the tool.

Modified Functional Reach Test (mFRT):

The mFRT will measure the patient's balance. It will involve the patient reaching forward as far as he or she can without losing balance and taking a measure of how far the patient reached. The patient will have to perform this task 5 times (2 practice, 3 measured). This test requires a padded surface to sit on as this test is not performed in the wheelchair, and a ruler for measuring distance reached.

The test will take approximately 15 minutes to set-up and perform.

Would you be willing and able to perform this assessment in your clinic?

- ◯ Yes
- ◯ No

Why not?

- ☐ It would take too long
- ☐ It requires too much personnel
- ☐ I am worried about insurance reimbursements
- ☐ I don't have enough space
- ☐ I don't have the necessary equipment
- ☐ other

Please explain. _____

The following item is a performance-based assessment. Please read the description and indicate if it would be feasible to perform in your clinic, if you would be willing to do so and then enter the results into the tool.

Aerobic Capacity Test (VO2max):

A VO2max test is a measure of an individual's aerobic capacity. It is a standard research laboratory technique for determining an individual's fitness level and requires the use of open-circuit spirometry. A metabolic cart, arm ergometer or stationary arm bike and ECG system and/or heart rate monitor is required for this test.

This test will need to be performed in an exercise/clinical laboratory and will take approximately 60 minutes to set-up and perform.

Would you be willing and able to perform this assessment in your clinic?

- ◯ Yes
- ◯ No

Why not?

- ☐ It would take too long
- ☐ It requires too much personnel
- ☐ I am worried about insurance reimbursements
- ☐ I don't have enough space
- ☐ I don't have the necessary equipment
- ☐ other

Please explain. _____

The following is related to a questionnaire. Please read the description and indicate if you would be willing to administer the questionnaire in your clinic and enter the results into the tool.

The Wheelchair User Shoulder Pain Index (WUSPI):

The WUSPI is a 15 item questionnaire designed to measure shoulder pain during daily activities in individuals who use wheelchairs. The patient will mark an 'x' along a line to denote where his or her level of pain falls where 'no pain' is all the way to the left and 'worst pain ever experienced' is the far right. It requires a ruler for scoring.

This questionnaire will take approximately 10 minutes to complete and score.

Would you be willing and able to administer this questionnaire in your clinic?

- ◯ Yes
- ◯ No

Why not?

- ☐ It would take too long
- ☐ It requires too much personnel
- ☐ I am worried about insurance reimbursements
- ☐ other

Please explain. _____

The following is related to a questionnaire. Please read the description and indicate if you would be willing to administer the questionnaire in your clinic and enter the results into the tool.

The Quality of Life Basic Data Set:

The Quality of Life Basic Data Set is a questionnaire to assess your patient's level of satisfaction with life in general and specifically physical and psychological health. The patient will select a number between 0 and 10 based on how satisfied he or she feels with that aspect of his or her personal life.

This questionnaire will take approximately 5 minutes to complete.

Would you be willing and able to administer this questionnaire in your clinic?

- ◯ Yes
- ◯ No

Why not?

- ☐ It would take too long
- ☐ It requires too much personnel
- ☐ I am worried about insurance reimbursements
- ☐ other

Please explain. _____

The following is related to a questionnaire. Please read the description and indicate if you would be willing to administer the questionnaire in your clinic and enter the results into the tool.

The Self-reported Mobility Disability Questionnaire:

The Self-reported Mobility Disability Questionnaire will ask the patient to rate his or her difficulty level with pushing on a level surface, performing a level transfer (wheelchair to bed) and transfers between wheelchair and the floor. The patient will select a number between 1 and 4 based on how difficult the task is to perform.

This questionnaire will take approximately 5 minutes to complete.

Would you be willing and able to administer this questionnaire in your clinic?

- ◯ Yes
- ◯ No

Why not?

- ☐ It would take too long
- ☐ It requires too much personnel
- ☐ I am worried about insurance reimbursements
- ☐ other

Please explain. _____

The following is related to a questionnaire. Please read the description and indicate if you would be willing to administer the questionnaire in your clinic and enter the results into the tool.

The Falls Concerns Scale:

The Falls Concerns Scale is a 16 item questionnaire that will ask questions regarding how concerned the patient is about falling when doing various daily activities. The patient will select a number between 1 and 4 based on the amount of concern.

This questionnaire will take approximately 10 minutes to complete.

Would you be willing and able to administer this questionnaire in your clinic?

- ◯ Yes
- ◯ No

Why not?

- ☐ It would take too long
- ☐ It requires too much personnel
- ☐ I am worried about insurance reimbursements
- ☐ other

Please explain. _____

The following is related to a questionnaire. Please read the description and indicate if you would be willing to administer the questionnaire in your clinic and enter the results into the tool.

The Spinal Cord Independence Measure III (SCIM-III):

The SCIM-III is a 25 item questionnaire asking about the amount of assistance or adaptation the patient needs to eat, drink, bathe, groom, get dressed, manage bladder and bowel programs, move his or her body and move around the home and community.

This questionnaire will take approximately 15 minutes to complete.

Would you be willing and able to administer this questionnaire in your clinic?

- ◯ Yes
- ◯ No

Why not?

- ☐ It would take too long
- ☐ It requires too much personnel
- ☐ I am worried about insurance reimbursements
- ☐ other

Please explain. _____

The following is related to a questionnaire. Please read the description and indicate if you would be willing to administer the questionnaire in your clinic and enter the results into the tool.

The Spinal Cord Independence Functional Index (SCI-FI):

The SCI-FI is a computer-based test consisting of four small questionnaires. Questionnaire items will focus on the patient's basic ability to move around (basic mobility); to perform self-care activities like eating, bathing, dressing, bowel and bladder routines (self-care); to use his or her hands (fine motor); and to use his or her wheelchair (wheelchair mobility).

The SCI-FI requires 15 minutes to complete.

Would you be willing and able to administer this questionnaire in your clinic?

- ◯ Yes
- ◯ No

Why not?

- ☐ It would take too long
- ☐ It requires too much personnel
- ☐ I am worried about insurance reimbursements
- ☐ other

Please explain. _____

As a reminder, you would input a series of items into this tool and it would determine the likelihood that your patient's fitness level is the reason why his or her bed, toilet-tub, or car transfers are not as independent or as easy as possible. This tool will provide information to help your patient pursue exercise and nutrition changes that could improve his or her transfer independence.

What would be your preferred format for the consumer tool? (Select all that apply)

- ☐ Hard copy/ paper and pencil
- ☐ Online/website
- ☐ Application for mobile device
- ☐ Integrated EMR
- ☐ Other

Please explain. _____

How much time would you be willing to spend per patient on collecting information and measurements that you typically do not collect in clinic and would be collecting solely for input into the Clinical Risk Calculator?

- ◯ < 5 min
- ◯ < 10
- ◯ < 15 min
- ◯ 15-30 min
- ◯ 31-45 min
- ◯ 46-60 min
- ◯ >60 min

Survey of feasibility of clinical and community approaches to assess fitness in persons with spinal cord injury

Please complete the survey below.

Thank you!

Introduction and Background Information

Research has shown that quality of life (QOL) after Spinal Cord Injury or Disease (SCI/D) depends more on participation, mobility, and personal care independence than on absolute severity of injury. Transfers are particularly critical to independence, with wheelchair to car, wheelchair to wheelchair, and ground to wheelchair transfers ranked by persons with SCI in the top seven skills most essential to daily life. Fitness level is a major determinant of transfer and general ADL (Activities of Daily Living) independence in persons with SCI/D and we suggest that it represents an underappreciated approach to meaningfully improving the independence, and thus QOL, of people living with SCI/D, no matter their age, injury severity, or time since injury.

We are developing an easy to use tool that will allow you to determine the likelihood that your fitness level is the reason why your toilet-tub, or car transfers are not as independent or as easy as possible. This tool will provide you information about exercise and nutrition changes that could improve your transfer independence.

This survey is a part of a larger study that will identify the fitness levels the people with SCI/D need in order to maximize their transfer independence. The purpose of this survey is to help us determine which variables (of the many we are collecting) we should screen for inclusion in this tool. In this survey we will gather information about your ability and willingness to collect certain variables; the amount of time you are willing to spend collecting each variable or set of variables; reasons why you could not or would not collect these variables; and the total amount of time you'd be willing to spend on collecting variables for inclusion in this tool.

Survey results will be integrated with the results of in-depth discussions with people with SCI/D. If you would be willing to participate in these discussions, there will be an opportunity to provide your contact information in the following pages.

Electronic Consent

Your participation in this survey is voluntary. You may choose not to participate. If you decide not to participate in this research study, you may withdraw at any time and you will not be penalized.

Student Rights
If you are a University of Miami student, your desire not to participate, or your request to withdraw from the study, will not affect your grades or other academic standings within the University.

Employee Rights
If you are an employee of the University of Miami, your decision to participate in or to withdraw from the study will not affect your employment within the University.

This phase of the research study involves completing an online survey that will take approximately 30 minutes. If you would be willing to participate in the interview phase, you will be asked for your name and contact information. This information will not be linked to your survey responses.

All electronic records from the online survey will be stored on Miami Project to Cure Paralysis Servers which are behind the University's firewall. Within the server, records will be stored in a Working Group Folder restricted to authorized study personnel.

If you have questions about this research study, please contact Rachel Cowan, PhD at 305-243-1949 or rcowan@med.miami.edu.

Selecting the "agree" button indicates that: You have read the above information You voluntarily agree to participate You are at least 18 years of age If you do not wish to participate in the research study, please decline participation by selecting the "disagree" button.

◯ Agree
◯ Disagree

Please select 'Next Page' below and select SUBMIT on the following page to end the survey. Thank you for your time.

Would you be willing to participate in the interview portion of this study (approximately 1 hour long)?

◯ Yes
◯ No

Please provide the following information: Name: Email: Phone number: Preferred contact method (phone/email) Best day/time to call:

_____

Please answer the following 3 questions. The answers to these questions will determine your eligibility for participation in the survey.

Can you walk by yourself without support or help from braces, other assistive devices, or people?	◯ Yes ◯ No
Start with your arms fully extended at your side. Can you bend at the elbow and bring your forearm all the way up to your upper arm (like a bicep curl)?	◯ Yes ◯ No
EXCLUDING spasms, do you use the muscles in your legs to assist in transfers?	◯ Yes ◯ No

You do not meet the inclusion criteria for this study. Please select 'Next Page' below and select SUBMIT on the following page to end the survey. Thank you for your time.

Please answer the following questions regarding your injury level and completeness.

What site on your spinal cord is injured? (Choose 1 from drop-down menu)

- ◯ C1
- ◯ C2
- ◯ C3
- ◯ C4
- ◯ C5
- ◯ C6
- ◯ C7
- ◯ C8
- ◯ T1
- ◯ T2
- ◯ T3
- ◯ T4
- ◯ T5
- ◯ T6
- ◯ T7
- ◯ T8
- ◯ T9
- ◯ T10
- ◯ T11
- ◯ T12
- ◯ L1
- ◯ L2
- ◯ L3
- ◯ L4
- ◯ L5
- ◯ Sacral

Can you feel touch in the anal area?

- ◯ Yes
- ◯ No

Can you feel light touch below your lesion level?

- ◯ Yes
- ◯ No

Can you feel the difference between sharp and dull below your lesion level?

- ◯ Yes
- ◯ No

Can you lift your legs against gravity?

- ◯ Yes
- ◯ No

Can you voluntarily tighten the anal sphincter

- ◯ Yes
- ◯ No

Please answer the following questions about yourself.

Gender

◯ Male
◯ Female

Location

◯ US
◯ Outside of US

Select state

◯ Alabama
◯ Alaska
◯ Arizona
◯ Arkansas
◯ California
◯ Colorado
◯ Connecticut
◯ Delaware
◯ Florida
◯ Georgia
◯ Hawaii
◯ Idaho
◯ Illinois
◯ Indiana
◯ Iowa
◯ Kansas
◯ Kentucky
◯ Louisiana
◯ Maine
◯ Maryland
◯ Massachusetts
◯ Michigan
◯ Minnesota
◯ Mississippi
◯ Missouri
◯ Montana
◯ Nebraska
◯ Nevada
◯ New Hampshire
◯ New Jersey
◯ New Mexico
◯ New York
◯ North Carolina
◯ North Dakota
◯ Ohio
◯ Oklahoma
◯ Oregon
◯ Pennsylvania
◯ Rhode Island
◯ South Carolina
◯ South Dakota
◯ Tennessee
◯ Texas
◯ Utah
◯ Vermont
◯ Virginia
◯ Washington
◯ West Virginia
◯ Wisconsin
◯ Wyoming

Fill in your country _____

Racial ethnicity

◯ Hispanic or Latino
◯ American Indian or Alaska Native
◯ Asian
◯ Black or African-American
◯ Native Hawaiian or Other Pacific Islander
◯ White
◯ I prefer to not provide this information
◯ Other

Please fill in your racial ethnicity: _____

Year of birth

- ◯ 1997
- ◯ 1996
- ◯ 1995
- ◯ 1994
- ◯ 1993
- ◯ 1992
- ◯ 1991
- ◯ 1990
- ◯ 1989
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- ◯ 1941
- ◯ 1940

Year of injury

- ◯ 2015
- ◯ 2014
- ◯ 2013
- ◯ 2012
- ◯ 2011
- ◯ 2010
- ◯ 2009
- ◯ 2008
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◯ 1945
◯ 1944
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◯ 1940

The following questions are related to the cause of your injury. When a question is presented, please select the option that best describes the cause of your injury. It may appear repetitive; however, each question provides unique information that we need.

Were you participating in a sporting activity (professional, recreational, or leisure) when you were injured? (For example, swimming, diving, horseback riding, biking, etc.)

- ◯ Yes
- ◯ No

Please select the sporting activity

- ◯ Diving (into pool, ocean, lake, etc)
- ◯ Swimming
- ◯ Surfing
- ◯ Motocross/dirt bike riding
- ◯ Cycling
- ◯ Gymnastics
- ◯ Equestrian sports (riding or racing)
- ◯ Other

Other _____

Did your injury occur as the result of an assault, attack, or act of violence? (For example, gunshot, stab wound, hit by a blunt object, etc.)

- ◯ Yes
- ◯ No

Please select from the following

- ◯ Gunshot
- ◯ Stab wound
- ◯ Hit with blunt object
- ◯ Explosion
- ◯ Other

Other _____

Were you in, on, or using a vehicle of any sort when you were injured (for example, a car, boat, bicycle, motorcycle, etc.)?

- ◯ Yes
- ◯ No

Please select the vehicle

- ◯ Car
- ◯ Truck
- ◯ ATV
- ◯ Motorcycle
- ◯ Bicycle
- ◯ Boat
- ◯ Aircraft
- ◯ Other

Other _____

Was your injury the result of a fall? (For example, falling down stairs, out of a window, after a trip or slip, etc.)

- ◯ Yes
- ◯ No

Please select from the following

- ◯ From height or level ground
- ◯ Trip over an object
- ◯ Slipping on wet surface
- ◯ Other

Other _____

It appears the cause of your SCI/D did not fall into one of the core classifications. Can you please briefly describe the cause of your SCI/D? _____

Highest level of education completed

◯ Some high school
◯ High school degree
◯ Some college
◯ College degree
◯ Some graduate classes
◯ Graduate degree

Current work status

◯ Employed, full-time (> 40 hours per week)
◯ Employed, part-time (< 40 hours per week)
◯ Unemployed
◯ Student
◯ Volunteer/Other
◯ Homemaker
◯ Retired

Current marital status

◯ Married
◯ Separated
◯ Divorced
◯ Widowed
◯ Single; not in a long-term relationship
◯ Single; in a long-term relationship but not married

Annual household income

◯ Less than $7,500
◯ $7,500 - $15,499
◯ $15,500 - $24,999
◯ $25,000 - $49,999
◯ More than $50,000

The following section describes information and measurements that we would use in the consumer tool.

Please read each item and think about the following:
Is it realistic for you to collect each item?
Are you willing to collect each item?

If you answer "yes" to both questions, you will answer "yes" on the survey. Otherwise, you will answer "no".

Age	◯ Yes ◯ No
Gender	◯ Yes ◯ No
Age when SCI/D occurred	◯ Yes ◯ No
How long ago did SCI/D occur	◯ Yes ◯ No
Cause of SCI/D	◯ Yes ◯ No
If you are receiving treatment for muscle spasms? (For example: prescription medication, surgical, recreational drugs, massage, acupuncture, etc.)	◯ Yes ◯ No
If you can voluntarily use the muscles of your legs to help you transfer?	◯ Yes ◯ No
Assuming you were both willing and able to collect ALL of the above information and enter it into the tool, what is the maximum amount of time would you be willing to spend doing so?	◯ < 30 sec ◯ 31-60 sec ◯ 61-90 sec ◯ > 90 sec
For the items that you selected 'no', please select all of the reasons why you would not be wiling to collect these items.	☐ I don't remember or know this information ☐ I don't understand what information you are asking for ☐ It would take too long to find the information ☐ I would not want to share this piece of information ☐ other
Please explain.	_____

The following section describes information and measurements that we would use in the consumer tool.

Please read each item and think about the following:
Is it realistic for you to collect each item?
Are you willing to collect each item?

If you answer "yes" to both questions, you will answer "yes" on the survey. Otherwise, you will answer "no".

Height : Measurement of the length of your body when lying down	◯ Yes ◯ No
Your weight	◯ Yes ◯ No
The length of each of your arms (both left and right)	◯ Yes ◯ No
Your arm span (If you hold your arms out to the side, this is the distance from the tip of your right middle finger, up your arm, across your chest, down your left arm to the tip of your left middle finger tip.)	◯ Yes ◯ No
Distance from the base of the back of your neck (C7) to the top of your cushion as you lean forward	◯ Yes ◯ No
Wheelchair fit: Angle of your right elbow when your hand is at the top center of the pushrim	◯ Yes ◯ No
Assuming you were both willing and able to collect ALL of the above information and enter it into the tool, how much time would you be willing to spend doing so?	◯ < 2 min ◯ 3 min ◯ 4 min ◯ > 5 min
For the items that you selected 'no', please select all of the reasons why you would not be wiling to collect these items.	☐ I don't remember or know this information ☐ I don't understand what information you are asking for ☐ It would take too long to find the information ☐ I would not want to share this piece of information ☐ I would not be willing or able to find someone to help me collect the information ☐ I don't know where I could get weighed ☐ other
Please explain.	_____

The following section describes information and measurements that we would use in the consumer tool.

Please read each item and think about the following:
Is it realistic for you to collect each item?
Are you willing to collect each item?

If you answer "yes" to both questions, you will answer "yes" on the survey. Otherwise, you will answer "no".

Primary wheelchair used (Manual, power assist, power, other)	◯ Yes ◯ No
Wheelchair manufacturer & model (Colours, Invacare/Top End, Quickie, Tilite, etc.)	◯ Yes ◯ No
Wheelchair frame type (Rigid or folding)	◯ Yes ◯ No
Front wheel size/tire type (3", 4", 5", 6", other/ Solid or Pneumatic)	◯ Yes ◯ No
Rear wheel size/tire type (24", 25", 26" / Solid or Pneumatic)	◯ Yes ◯ No
Number of years you have been using this wheelchair	◯ Yes ◯ No
Assuming you were both willing and able to collect ALL of the above information and enter it into the tool, how much time would you be willing to spend doing so?	◯ < 30 sec ◯ 31-60 sec ◯ 61-90 sec ◯ > 90 sec
For the items that you selected 'no', please select all of the reasons why you would not be wiling to collect these items.	☐ I don't remember or know this information ☐ I don't understand what information you are asking for ☐ It would take too long to find the information ☐ I would not want to share this piece of information ☐ I would not be willing or able to find someone to help me collect the information ☐ I don't know how to find or collect the information ☐ other
Please explain.	_____

The following section describes a performance-based physical assessment that we would use in the consumer tool.

Please read each item and think about the following:
Is it realistic for you to collect each item?
Are you willing to collect each item?

6 Minute Manual Wheelchair Propulsion Test (6MPT):

The 6MPT is a fitness measure that requires you to manually propel your wheelchair and complete as many laps as possible on a short course in 6 minutes. To conduct this test, you will need a hallway of at least 15 m (approximately 50 ft) long and 3 m (approximately 10 ft) wide, as well as cones, a yardstick and a stop watch.

Including set-up, testing and evaluation and scoring, this test will take approximately 15 minutes to conduct.

Would you be willing and able to collect this information?

- ◯ Yes
- ◯ No

Why not?

- ☐ I don't remember or know this information
- ☐ I don't understand what information you are asking for
- ☐ It would take too long
- ☐ I would not want to share this piece of information
- ☐ I would not be willing or able to find someone to help me collect the information
- ☐ I don't know how to find or collect the information
- ☐ other

Please explain. _____

The following section describes a performance-based physical assessment that we would use in the consumer tool.

Please read each item and think about the following:
Is it realistic for you to collect each item?
Are you willing to collect each item?

Modified Functional Reach Test (mFRT):

The mFRT will measure your balance. It will involve you reaching forward as far as you can without losing your balance and taking a measure of how far you reached. You will have to practice this task twice and record your measurements 3 more times. You will need a padded surface to sit on as this test is not performed in your wheelchair, and a ruler for measuring distance reached.

The test will take approximately 15 minutes to set-up and perform.

Would you be willing and able to collect this information?

- ◯ Yes
- ◯ No

Why not?

- ☐ I don't remember or know this information
- ☐ I don't understand what information you are asking for
- ☐ It would take too long
- ☐ I would not want to share this piece of information
- ☐ I would not be willing or able to find someone to help me collect the information
- ☐ I don't know how to find or collect the information
- ☐ other

Please explain. _____

The following section describes a performance-based physical assessment that we would use in the consumer tool.

Please read each item and think about the following:
Is it realistic for you to collect each item?
Are you willing to collect each item?

Aerobic Capacity Test (VO2max):

A VO2max test is a measure of an individual's aerobic capacity. It is a standard research laboratory technique for determining an individual's fitness level and requires the use of open-circuit spirometry. A metabolic cart, arm ergometer or stationary arm bike and ECG system and/or heart rate monitor is required for this test. This test will need to be performed in an exercise/clinical laboratory and may require that you pay an out of pocket fee.

This test will take approximately 60 minutes to set-up and perform.

Would you be willing and able to collect this information?
- ◯ Yes
- ◯ No

Why not?
- ☐ I don't remember or know this information
- ☐ I don't understand what information you are asking for
- ☐ It would take too long
- ☐ I would not want to share this piece of information
- ☐ I would not be willing or able to find someone to help me collect the information
- ☐ I don't know how to find or collect the information
- ☐ I'm concerned about the potential cost of this test
- ☐ other

Please explain. _____

The following section describes questionnaires that we would use in the consumer tool.

Please read each item and think about the following:
Is it realistic for you to collect each item?
Are you willing to collect each item?

The Wheelchair User Shoulder Pain Index (WUSPI):

The WUSPI is a 15 item questionnaire designed to measure shoulder pain during daily activities in individuals who use wheelchairs. You will mark an 'x' along a line to denote where your level of pain falls; where 'no pain' is all the way to the left and 'worst pain ever experienced' is the far right. It requires a ruler for scoring.

This questionnaire will take approximately 10 minutes to complete and score.

Would you be willing to complete this questionnaire?
◯ Yes
◯ No

Why not?
☐ It would take too long
☐ I don't want to share this information
☐ other

Please explain. _____

The Quality of Life Basic Data Set:

The Quality of Life Basic Data Set is a questionnaire to assess an individual's level of satisfaction with life in general and specifically, physical and psychological health. You will select a number between 0 and 10 based on how satisfied you feel with that aspect of your personal life.

This questionnaire will take approximately 5 minutes to complete.

Would you be willing to complete this questionnaire?
◯ Yes
◯ No

Why not?
☐ It would take too long
☐ I don't want to share this information
☐ other

Please explain. _____

The Self-reported Mobility Disability Questionnaire:

The Self-reported Mobility Disability Questionnaire will ask you to rate your difficulty level with pushing on a level surface, performing a level transfer (wheelchair to bed) and transfers between wheelchair and the floor. You will select a number between 1 and 4 based on how difficult the task is for you to perform.

This questionnaire will take approximately 5 minutes to complete.

Would you be willing to complete this questionnaire?
◯ Yes
◯ No

Why not?
☐ It would take too long
☐ I don't want to share this information
☐ other

Please explain. _____

The following section describes questionnaires that we would use in the consumer tool.

Please read each item and think about the following:
Is it realistic for you to collect each item?
Are you willing to collect each item?

The Falls Concerns Scale:

The Falls Concerns Scale is a 16 item questionnaire that will ask questions regarding how concerned you are about falling when doing various daily activities. You will select a number between 1 and 4 based on the amount of concern.

This questionnaire will take approximately 10 minutes to complete.

Would you be willing to complete this questionnaire?
◯ Yes
◯ No

Why not?
☐ It would take too long
☐ I don't want to share this information
☐ other

Please explain. _____

The Spinal Cord Independence Measure III (SCIM-III):

The SCIM-III is a 25 item questionnaire asking about the amount of assistance or adaptation you need to eat, drink, bathe, groom, get dressed, manage bladder and bowel programs, move your body (transfers) and move around the home and community.

This questionnaire will take approximately 15 minutes to complete.

Would you be willing to complete this questionnaire?
◯ Yes
◯ No

Why not?
☐ It would take too long
☐ I don't want to share this information
☐ other

Please explain. _____

The Spinal Cord Independence Functional Index (SCI-FI):

The SCI-FI is a computer-based test consisting of four small questionnaires. Questionnaire items will focus on your basic ability to move around (basic mobility); to perform self-care activities like eating, bathing, dressing, bowel and bladder routines (self-care); to use your hands (fine motor); and to use your wheelchair (wheelchair mobility).

The SCI-FI requires 15 minutes to complete.

Would you be willing to complete this questionnaire?
◯ Yes
◯ No

Why not?
☐ It would take too long
☐ I don't want to share this information
☐ other

Please explain. _____

As a reminder, you would input a series of items into this tool and it would determine the likelihood that your fitness level is the reason why your bed, toilet-tub, or car transfers are not as independent or as easy as possible. This tool will provide information to help you pursue exercise and nutrition changes that could improve your transfer independence.

What would be your preferred format for the consumer tool? (Select all that apply)

- ☐ Hard copy/ paper and pencil
- ☐ Online/website
- ☐ Application for mobile device
- ☐ Other

Please explain. _____

IRB Protocol #20140397

Clinician Interview Script

This interview is designed to take place immediately following the participant's verbal consent to participate in the study. The script below represents an initial point of departure. As each participant is interviewed, the researcher will apply what she has learned in the course of the interview with subsequent participants. The interview should take about 60 minutes, but could last up to 90 minutes.

Interviewer: This conversation is the first phase of a larger study. The core purpose of the larger study is to quantify the relationship between fitness and ADL function in non-ambulatory persons with SCI. To help translate our findings to clinical practice, we will develop a clinical risk calculator. This risk calculator will quantify the link between a patient's ADL function and their fitness level using information that clinicians can collect and generate output to help guide care.

The purpose of this conversation is twofold. First, your input will help shape the data we collect in the larger study to help ensure we are measuring variables that are related to the fitness-ADL function relationship. Second, your input will shape the output of the clinical risk calculator to make it as useful to your clinical efforts as possible.

Eligibility verification

Before we get to the heart of the interview, I'll need to collect a few pieces of information about you and your clinical environment. The purpose of this information is to ensure you qualify to participate in this interview and ensure we interview clinicians of different genders, professions (such a doctors, therapists, and nurses), and practice environments. We'll move through this part quickly.

1. What clinical degree(s) do you possess? [If none, end interview, person does not qualify]
2. How long have you been working with SCI/D patients? [If less than 5 years, end interview, person does not qualify]

3. Are you currently treating SCI/D patients? [If no] Have you treated SCI/D patients within the last 5 years? [If no, end interview, person does not qualify]

Demographic Information

4. Would you describe your practice environment as civilian, veterans' administration, other military, or something else? [If civilian] Would you describe you practice environment as academic, private, or both? What percentages of your practice is inpatient vs. outpatient? Is your practice in the United States? [If yes] What state? [If no] What country? Would you describe your practice location as urban, suburban, or rural?
5. What is your gender?
6. What is your race and ethnicity?

Initial Probes:

Okay, now that we've finished the basic information, we'll start on the heart of the interview.

1. What patient centered symptoms or characteristics affect a patient's ability to perform various types of transfers, such as bed, shower, toilet, car and ground transfers? Do you regularly measure any of these factors during clinic?
2. Do you in any way assess your patient's fitness during clinic visits?
3. If we could give you data that linked your patient's fitness level to ADL difficulties, could this information help you better direct their care? [If yes] How so?
4. If we could give you data that showed your patient's fitness was less than the amount required to support a desired functional level and if we provided nutritional and exercise conditioning treatment options, would you be willing and able to use the information to pursue these treatment options? What format would make the result most useful to you? [For example – graphs, text, treatment options, prescription templates] What format would be most useful for inclusion in your patient's medical record? How do you see communication of these data to your patients being implemented into your daily practice?

5. If we could provide data linking fitness and function in a manner that improved your ability to care for your patients, how much time would you be willing to spend collecting this data? What barriers would prevent you from collecting this data? How do you see collection of this data implemented in your daily practice?

IRB Protocol #20140397

Consumer Interview Script

This interview is designed to take place immediately following the participant's verbal consent to participate in the study. The script below represents an initial point of departure. As each participant is interviewed, the researcher will apply what she has learned in the course of the interview with subsequent participants. The interview should take about 60 minutes, but could last up to 90 minutes.

Interviewer: This conversation is the second part of the first phase of a larger study. The core purpose of the larger study is to quantify the relationship between fitness and independence in daily activities in non-ambulatory persons with spinal cord injury. To help our results more quickly help people with spinal cord injury we want to develop a tool for SCI/D consumers that generates a report showing how their fitness level was related to their ability to perform daily activities like dressing, bathing, transferring, or pushing a chair; how their your fitness level was less than what was needed for them to easily complete a transfer they wanted or needed to perform; and provided diet and exercise suggestions to improve transfer performance.

This conversation has two purposes. First, your input will help shape the information we collect in the larger study to help ensure we are measuring items that affect the relationship between fitness and performance of daily activities like bathing, dressing, and transfers. Second, your input will help make the consumer tool user friendly and shape the report it generates so it is as helpful as possible to people with SCI.

Eligibility verification

Before we get to the heart of the interview, I'll need to collect a few pieces of information about you. The purpose of this information is to ensure you qualify to participate in this interview and ensure we interview people of different genders, ages, injury levels, injury durations, and education levels. We'll move through this part quickly.

1. How old are you? [If <18, end interview, person does not qualify]
2. Have you had your SCI/D for at least 6 months? [If no, end interview, person does not qualify]
3. What was the cause of your injury? [If cause is a progressive disease end interview, person does not qualify]
4. Are you able to walk, stand, or lift your legs against gravity? [If yes, end interview, person does not qualify]
5. Can you bend both elbows against gravity? [If no, end interview, person does not qualify]
6. Can you actively use your leg muscles to help transfer? [If yes, end interview, person does not qualify]

Demographic Information

7. What is your gender?
8. What is your race/ethnicity?
9. What is your injury level?
10. How long have you been injured?
11. Did you attend college? [If yes] What degrees have you earned? [If none] How long did you attend college? [If no to attend college] Did you complete high school or get your GED? [If no] What was the highest grade you completed?

Initial Probes:

Okay, now that we've finished the basic information, we'll start on the heart of the interview.

1. What types of transfers do you perform on a daily basis? About how many transfers do you perform each day? Is there any transfer you cannot perform that you would like to? Are there any transfers that you would like to be able to perform easier or faster?

2. Besides affecting which muscles work, is there anything about you, your health, or your spinal cord injury that has ever affected your ability to perform bed, shower, toilet, car, ground, or any other type of transfer? Do these items have the same amount of impact?

3. In your opinion does fitness level affect a person's ability to perform daily activities such as dressing, bathing, transferring, or pushing a wheelchair? Do you think fitness has a big or little effect on these activities?

4. Is there anything you do or experience that lets you know if your fitness is getting better or worse? [If an example is needed] [For example, I have a spinal cord injury and use a manual wheelchair. When my transfers start getting harder or easier, I know either my fitness level or weight has changed.

5. If we could give you a report that showed how your fitness level was related to your ability to perform daily activities like dressing, bathing, transferring, or pushing a chair, would this report be useful to you? [If yes] Can you give us ideas about how you might use the information in the report?

6. If we could give you a report that showed you that your fitness level was less than what was needed for you to easily complete a transfer that you wanted or needed to perform and if we provided diet and exercise suggestions that could improve your transfer abilities, would you be willing and able to use the report and suggestions to change your diet and exercise habit? How could we present the information in the report to make it as useful to you as possible?

7. If we could provide a report that described how your fitness level is affecting your ability to perform daily activities in a manner that you found very useful, how much time would you be willing to spend collecting all the information needed to generate that description?

a. Would you be willing to complete several questionnaires? How long would you be willing to spend on questionnaires?

b. Would you be willing to complete several performance-based assessments?

    i. Do you use a manual wheelchair? [If no, skip to next question] [If yes] Would you be willing to perform a test that requires you to push your manual wheelchair up and down a hall as many times as possible in 6 minutes? Would you be able to obtain access to a hallway that is at least 50 ft long and 10 ft wide (50 ft is approximately 5 car lengths? [If no, ask if they could find an indoor basketball court to use] Would you be able to find someone who is willing keep time for the test and count the number of laps you can complete? Would you be willing to spend up to 15 minutes on this assessment?

    ii. Would you be willing to test your balance seated on a padded surface with your feet on the floor? Would you be able to find someone to measure how far forward you could reach while seated on this surface? Would you be willing to spend up to 15 minutes on this assessment?

    iii. Would you be willing to complete a test that requires you to use a stationary arm bike and exercise until you are exhausted? This would have to take place in an exercise laboratory or doctor's office; would you know any place where you could have a test like this done? Would you be willing to pay for this test? [If yes, How much would you be willing to pay]

8. Finally, would you prefer to get this report from a health care provider, like a Doctor or Physical Therapist, or would you prefer to be able to get this report on your own like from the web or by using an app?