AWARD NUMBER: W81XWH-17-1-0285

TITLE: Supporting Patient Decisions About Upper-Extremity Surgery in Cervical Spinal Cord Injury

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REPORT DATE: Sept 2018

TYPE OF REPORT: Annual

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	**2. REPORT TYPE**	**3. DATES COVERED**
Sept 2018	Annual	01Sep2017 – 31 Aug 2018

4. TITLE AND SUBTITLE
Supporting Patient Decisions about Upper Extremity Surgery in Cervical Spinal Cord Injury

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-17-1-0285

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
WASHINGTON UNIVERSITY, THE
ONE BROOKINGS DR
SAINT LOUIS MO 63130-4862

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
Purpose: To define and communicate information about upper extremity (UE) function in spinal cord injury (SCI).
Scope: Review information about spontaneous recovery and prospectively investigate recovery with and without surgical intervention.
Major Findings: Existing information about recovery after SCI is heterogeneous and complex; predicting motor recovery over time is possible. Surgical and non-surgical participants and caregivers need individualized approaches to optimize information gathering.
Results:
1. The European Multicenter SCI database includes information on more than 500 people with cervical level SCI. Post-injury function predicts degree of motor recovery at 6-12 months post-SCI, which is critical to surgical decision making for people considering nerve transfer surgery.
2. SCI stakeholders note that people choosing/not choosing to undergo surgery have very specific reasons and priorities for their care that are likely under-recognized by surgeons and other health care providers.
3. Caregivers are under-recognized for the demands/stressors/concerns they might have.
Significance: Based on preliminary concerns about caregiver burden and other experiences posed by the advisory board, the principal investigator has modified her clinical practice to improve the perioperative planning process for people undergoing surgery and their caregivers.

15. SUBJECT TERMS
Spinal cord injury, SCI, tetraplegia, nerve transfer surgery, tendon transfer surgery, rehabilitation, caregiver, upper extremity function, hand function

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	56	**19b. TELEPHONE NUMBER** *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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1. INTRODUCTION:

The overarching aim of this project is to define key information about improvement of upper extremity function after spinal cord injury (SCI) (time and extent of recovery, outcome of surgical and non-surgical interventions and the experience thereof) and communicate this information to patients and clinicians to support their treatment decisions. This will be achieved through the following three aims:

Aim 1: Using the EMSCI database initially and unbiased recursive partitioning statistical techniques, establish the time course and variability of spontaneous recovery of upper extremity function after cervical SCI in order to identify candidates who might benefit from nerve transfer surgery.

Aim 2: Using a mixed methods research approach, patient and caretaker outcomes data will be collected over time and across groups (non-intervention, nerve transfer versus tendon transfer) and domains (medical, financial, and psychosocial experiences). Standardized surveys and semi-structured interview data will be collected and analyzed. The interview guide will be developed and refined based on input from a multidisciplinary advisory panel.

Aim 3: Using information from Aims 1 and 2, as well as input from the advisory panel, a de novo decisional support intervention will be created and pilot tested. A pre-post study design will measure participant knowledge (terms, facts that differentiate outcomes), decision self-efficacy (self-confidence in their ability to make a decision), and confidence in choice before and after use of the decisional support intervention.

2. KEYWORDS:

Spinal cord injury, SCI, tetraplegia, nerve transfer surgery, tendon transfer surgery, rehabilitation, caregiver, upper extremity function, hand function

3. ACCOMPLISHMENTS:

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

Task/Milestone **Administrative:**	Target Completion Date/Quarter	Status
Complete IRB approval at WUSM primary site		COMPLETED 7/31/2017
Complete IRB approval at VA sites after approval obtained at WUSM primary site		COMPLETED 11/22/2017 and 12/14/2017
Complete paperwork for use of EMSCI database/Dr. Steeves work		COMPLETED March, 2018; payment confirmed 5/23/18.
Prepare protocol, consent forms, patient recruitment forms with appropriate DOD language and guidelines		COMPLETED
Complete second tier DOD human subjects regulatory review and approval process by HRPO.		COMPLETED 3/1/2018 for Primary site; 3/25/18 for sub-sites.
Identify and hire research assistants and coordinator; complete paperwork including human subjects' protection training as relevant. (Human research training has already been completed by all of the currently hired personnel at the primary and VA sites; the consultants (Dr. Steeves' group will complete deidentified database work).		COMPLETED at WU/VASTL; Coordinator hired at Stanford/VA Palo Alto on 4/18/18.

Specific Aim 1: Establish the time course of spontaneous recovery of upper extremity function after cervical SCI		
Major Task 1 - Define clinically relevant data of interest within EMSCI database		
Subtask 1: Coordinate with Dr. Steeves (and team) to obtain latest data from EMSCI database.	Dec 2017 (Y1Q1)	COMPLETED Nov, 2017
Subtask 2: Define clinically relevant subgroups within EMSCI database.	Dec 2017 (Y1Q1)	COMPLETED Jan, 2018
Subtask 3: Use the EMSCI database to screen for individuals who have lost C7 function after cervical SCI and track recovery patterns for C7 function on each side of the body over the first year after injury.	Mar 2018 (Y1Q2)	COMPLETED Feb, 2018
Milestone 1: EMSCI data reviewed	Dec 2017 (Y1Q1)	COMPLETED Nov, 2017
Milestone 2: Clinically relevant subgroups identified	Mar 2018 (Y1Q2)	COMPLETED Jan, 2018
Major Task 2 - Perform statistical analysis of defined clinically relevant subgroups		
Subtask 1: Discuss and confirm statistical analysis plan with Dr. Steeves.	Mar 2018 (Y1Q2)	COMPLETED May, 2018
Subtask 2: Use descriptive statistical analysis and unbiased recursive partitioning (URP) statistics to predict what neurological and functional activity items most accurately identify surgical candidates.	July 2018 (Y1Q4)	IN PROGRESS
Subtask 3: Completion of final statistical analysis by Dr. Steeves and team.	July 2018 (Y1Q4)	IN PROGRESS
Subtask 4: Discuss summarized findings and present in layperson terms.	Sep 2018 (Y1Q4)	IN PROGRESS
Milestone(s) Achieved: EMSCI database analysis completed with clinically appropriate data summarized in layperson terms.	Sep 2018 (Y1Q4)	DELAYED

Specific Aim 2: Describe outcomes after no surgery versus nerve/tendon transfer surgery	Target Completion Date/Quarter	Status
Major Task 1 Develop Interview Guides		
Subtask 1: Phone meeting between institutions/study sites—discuss interview guides.	Dec 2017 (Y1Q1)	COMPLETED 1/10/18 and 2/22/18
Subtask 2: Assemble advisory panel.	Dec 2017 (Y1Q1)	COMPLETED Feb, 2018
Subtask 3: Develop and revise interview guides.	Dec 2017 (Y1Q1)	COMPLETED Apr, 2018
Milestone 1: Advisory panel participants identified.	Dec 2017 (Y1Q1)	COMPLETED Feb, 2018
Milestone 2: Completion of interview guide.	Dec 2017 (Y1Q1)	COMPLETED Apr, 2018
Major Task 2 Enroll and collect data		
Subtask 1: Enroll study participants for Aim 2	Dec 2019 (Y3Q1)	IN PROGRESS
Subtask 2: Complete subject interviews/surveys	Dec 2019 (Y3Q1)	IN PROGRESS
Specific Aim 3: Develop and assess a decision support intervention tool		
Major Task 1 Develop Decision Support Intervention (DSI)		
Subtask 1: Review findings of Aim 1 and 2; create decision support intervention and knowledge subtest	Mar 2020 (Y3Q2)	DELAYED START

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

We are satisfied with this project's progress to date.

Aim 1 – HRPO Log Number A-20223.1

- Obtained data from the European Multicenter Study about Spinal Cord Injury (EMSCI)
- Interim analysis report completed
- Refining of unbiased recursive partitioning (URP) statistics and analysis

- Core questions:
    - Is there a hard-stop time point after SCI for which no more natural recovery occurs?
    - If I (the person with SCI) didn't do any surgical intervention, what function might come back on its own?
    - What is the time course of recovery after SCI?
    - Are there meaningful gains in function between 6 and 12 months post SCI in some sub-populations? And if so, are the gains such that surgical intervention should be avoided and delayed at that time point?

Aim 2 – HRPO Log Numbers A-20223.2a, A-20223.2b, A-20223.2c, A-20223.2d

- Obtained all local IRB and HRPO approvals
- Advisory Board identified and convened for conference calls
- Interview guides finalized with input from Advisory Board
- Interviewers trained to ensure a standardized interviewing technique.
- Subject and caregiver enrollment underway

We plan to begin reviewing the retrospective findings of Aim 1 in the context of prospective data gathered in Aim 2 to conceptualize Aim 3. Throughout this process, we have targeted our analysis of pre-existing data (Aim 1) and interview guide development towards obtaining information that is meaningful and able to be understood by people with SCI, their caregivers and other healthcare providers (social workers, psychologists, therapists, etc.).

PROTOCOL 1 (of 2 total):

HRPO Assigned Numbers: A-20223.1 and A-20223.2a-d

Title: Supporting Patient Decisions about Upper Extremity Surgery in Cervical Spinal Cord Injury (AIM 1 and AIM 2)

Target required for clinical significance: 38 patient/caregiver pairs

STATUS:

i) Progress on subject recruitment: Number of SCI subjects reported as enrolled last quarter: 10.

	Wash U	STL VA	PA VA	Stanford	TOTAL	Y1Q4 Goal
Total Enrolled SCI Subjects	9	5	5	1	20	18
# SCI Subject Interviews Obtained to date[1]	10	2	3	2	16	
# Caregiver Interviews Obtained to date[2]	9	2	2	2	15	
Total # Interviews Obtained to date	19	4	5	4	31	

Notes: [1] Subjects are in various stages of the study (i.e., Enrolled, Baseline, Early Follow-up and Late Follow-up); thus there is not a perfect match between # enrolled and # of interviews obtained to date.

[2] Not all SCI subjects identified a caregiver to participate.

ii) Amendments: None pending.

iii) Any adverse event/unanticipated problems: None.

Aim 3 - PROTOCOL 2 (of 2 total):
HRPO Assigned Number: Not yet assigned
Title: Supporting Patient Decisions about Upper Extremity Surgery in Cervical Spinal Cord Injury (AIM 3)
STATUS:
Feedback from the IRB approval boards prompted the moving of Aim 3 into a separate planned IRB protocol submission. We will submit for IRB and DoD HRPO approvals for Aim 3 using information gained from Aims 1 & 2 and anticipate submission once a preliminary decision aid framework/prototype has been developed.

- **What opportunities for training and professional development has the project provided?**
  - Study team coordinators responsible for interviewing subjects and caregivers participated in an interview training session with Co-Investigator Aimee James, PhD, MPH on 7/5/2018. She is a social psychologist with expertise in qualitative and mixed methods research as well as training and experience in public health and health education. Training included review of 1) strategies for optimizing open-ended question techniques and use of probes to facilitate discussion; 2) discussion of field notes and other means to report relevant information; 3) framework for performing, downloading, transcribing and saving research data discussed; 4) next steps including strategies for identification of themes and representative quotations as well as the interview transcription codebook, and strategies for iterative interview guide refinement and modification based on participant answers to questions were also described.

- **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?**
  - We will work to summarize EMSCI analysis findings.
  - We will continue recruitment and enrollment of human subjects (people with SCI and caregivers) at all sites to reach Aim 2 goals.
  - We will plan and conceptualize the Decision Support Intervention (DSI) in accordance with Aim 3 goals.

4. IMPACT:

- **What was the impact on the development of the principal discipline(s) of the project?**
  - Based on preliminary concerns about caregiver burden and other experiences posed by the advisory board, the principal investigator has already modified her clinical practice to improve the perioperative planning process for people undergoing surgery and their caregivers.

- **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 -** Nothing to Report.

- **Actual or anticipated problems or delays and actions or plans to resolve them**
  - We are pleased to report that our subject enrollment, which was behind projections on previous quarterly reports, is now on track and slightly ahead of schedule.

- **Changes that had a significant impact on expenditures**
  - The study is under the initial application's predicted budget expenditure. We encountered delays in obtaining final HRPO protocol approval and subsequently staggered study team percent effort for work on the project until human subjects' enrollment was underway (see Quad Chart).

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents -** Nothing to Report.

- **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 -** Nothing to Report.

- **Website(s) or other Internet site(s) - http://nerve.wustl.edu (**Website for the Center for Nerve Injury & Paralysis at Washington University in St. Louis School of Medicine.)

- **Technologies or techniques -** Nothing to Report.

- **Inventions, patent applications, and/or licenses -** Nothing to Report.

- **Other Products –** Construction of the REDCap database for this project to collect demographic and questionnaire data for enrolled subjects (blank forms attached in appendices).

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**
  Ida Fox – no change
  Catherine Curtin – no change
  Aimee James – no change
  John Steeves – no change
  Carie Kennedy – no change
  Dirk Haupt – no change

  New to list: Name: Deborah Kenney
  Project Role: Clinical Research Coordinator at California sites
  Nearest person month worked: 2

Contribution to Project: Ms. Kenney assists in study coordination and human subject recruitment/enrollment for the Stanford University and Palo Alto Veterans Administration locations.

- **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.

- **What other organizations were involved as partners?**
  - **1) Organization Name: Veterans' Administration Healthcare System**
    - **Location of Organization:** St. Louis, Mo
    - **Partner's contribution to the project**
      - **In-kind support**
      - **Facilities**
      - **Collaboration**
      - **Other** – Study sub site
  - **2) Organization Name: Stanford University**
    - **Location of Organization:** Stanford, CA
    - **Partner's contribution to the project**
      - **In-kind support**
      - **Facilities**
      - **Collaboration**
      - **Other** – Study sub site
  - **3) Organization Name: Palo Alto Veterans' Institute for Research**
    - **Location of Organization:** Palo Alto, CA
    - **Partner's contribution to the project**
      - **In-kind support**
      - **Facilities**
      - **Collaboration**
      - **Other** – Study sub site
  - **4) Organization Name: European Multicenter Study about Spinal Cord Injury (EMSCI)**
    - **Location of Organization:** Zurich, Switzerland
    - **Partner's contribution to the project**
      - **Collaboration** – Provided access to data for Aim 1 study activities.
  - **5) Organization Name: Health Literacy Media (HLM)**
    - **Location of Organization:** St. Louis, MO
    - **Partner's contribution to the project**
      - **Collaboration** – Providing guidance for Aim 3 study activities to make healthcare information easier to understand and act upon.

8. SPECIAL REPORTING REQUIREMENTS

- **QUAD CHARTS:** The updated Quad Chart is submitted in the appendices.

9. APPENDICES:

- Aim 1 Analysis Plan (pp. 10-13)
- Aim 1 Interim Analysis dated June 3, 2018 (pp. 14-23)
- Aim 2 Interview Guides for Subjects and Caregivers (pp. 24-40)
- Aim 2 REDCap Database blank forms (pp. 41-55)
- Quad Chart updated for Q4Y1 (p. 56)

Analysis plan of EMSCI database for guidance on identification of prospective candidates for peripheral nerve transfer surgery to restore hand function after cervical spinal cord injury (DoD grant; PI: Dr. Ida Fox)

Overall Goal: Over the first year after cervical spinal cord injury (SCI), establish the time course for the pattern of spontaneous recovery of upper extremity motor function.

The goal of this analysis is to get information that provides the exact time course and probability of gain in specific function (such as hand function) that might help patients and clinicians make decisions regarding these novel and time-sensitive surgical treatment options (nerve transfers). The end product of this analysis will need to be lay-person friendly bullet points as part of an information sheet (decision aid) that will be provided to clinicians and people with SCI contemplating intervention.

Methods: Using the database of European Multicenter study about Spinal Cord Injury (EMSCI), descriptive and analytical statistical methods (e.g. unbiased recursive partitioning, URP) will be employed to describe, on a segment by cord segment basis, neurological and functional upper extremity recovery after cervical SCI, with particular attention to defining the proportion of patients that can be accurately predicted, within the first 6 months after injury, to <u>not</u> recover hand function, but do recover biceps function for elbow flexion. Those candidates identified non-invasively could then be subsequently examined using minimally invasive electrophysiological diagnostics to confirm the direct damage and loss of motorneurons to extrinsic hand muscles (the target for possible nerve transfer surgery)

Number of patients with cervical SCI contained within the ongoing EMSCI database is >1000. EMSCI performs neurological and functional assessments at defined time points after SCI (<2 weeks, 1 month, 3 months, 6 months, 12 months). The non-invasive neurological assessment tool is the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) and includes motor and sensory grading of spinal cord segments (see ISNCSCI scoresheet attached to this outline). The functional assessment tool is the SCIM (spinal cord independence measure), which is similar to the FIM (functional independence measure), especially for items describing the degree of independence for upper extremity (self-care) functions (e.g. feeding, grooming, bathing and dressing).

For this analysis, focus will be centered on motor scores obtained from cervical cord segments C5, C6, C7, C8, T1. Initial and subsequent changes in segmental motor scores will be described. The functional motor level for each side of the body is defined as the lowest key segmental muscle function that has a grade of at least 3 out of 5, provided cervical cord segments above that level are judged to be intact (normal). SCIM scores for various neurological levels and severity of cervical injury will also be assessed and correlated with motor scores within the same individual and across similar patients.

The priority target population will be those people with intact (preserved) or recovered C5 motor function within 6 months after injury (muscle grade 5/5), but no motor function (0/5) at spinal levels C7, C8 and/or T1.

Task: Describe the pattern of motor and functional recovery from baseline (<2weeks after cervical injury) to at least 6 months after SCI. [Note: ISNCSCI records at 12 months after cervical SCI may not be available for all EMSCI participants as people are then outpatients and do not return for assessment]. People with similar motor recovery patterns will be grouped and percentages of the total population will be summarized.

1. Is there a predictive algorithm that can be developed from the neurological and functional data to identify prospective candidates for nerve transfer surgery?
2. Can we provide these candidates with clear and pertinent information/expectations about the chance of (and to what degree) spontaneous recovery of specific functions?

Examples of questions to be assessed include:

a) How many people start with a motor level of C4 (no C5 biceps function), but recover full C5 function within the first 6 to 12 months after cervical SCI? Of those recovering full motor function at C5 what is the pattern and timing for recovery of motor function within cervical segments below C5?
b) What is the pattern of segmental motor recovery over the first year after cervical SCI for people with intact (preserved) C5 motor function at baseline? How many people with preserved C5 motor function after SCI never recover motor function within C7, C8, or T1?
c) What is the pattern of segmental motor recovery over the first year after cervical SCI for people with some preserved C5 motor function at baseline (e.g. initial motor scores of 1/5, 2/5, 3/5, or 4/5)? How many people with partially preserved C5 motor function after SCI never recover motor function within C7, C8, or T1?
d) What is the pattern of segmental motor recovery over the first year after cervical SCI for people with intact (preserved) C5 and C6 motor function at baseline? How many people with preserved C5 and/or C6 motor function after SCI never recover motor function within C7, C8, or T1?
e) Does the pattern of motor recovery become stable (unchanging thereafter) at some point within the first year after cervical SCI (e.g. within the first 6 months)?
f) How often are the motor deficits and recovery patterns symmetrical on both sides of the cervical spinal cord?
g) How does the pattern of cervical motor recovery differ across SCI severities (AIS A through to AIS D)?
h) What motor score patterns (e.g. algorithm) might best predict those people that are likely candidates for subsequent electrophysiological analysis of motor nerve patency and function as a precursor to consideration for nerve transfer surgery to restore hand function?
i) Repeat the above analysis using items from the SCIM self-care sub-score (see attached) for each level and severity of cervical SCI.

Please provide comments and suggested changes on this plan using WORD track changes to John Steeves, with copy to all investigators.

INTERNATIONAL STANDARDS FOR NEUROLOGICAL CLASSIFICATION OF SPINAL CORD INJURY (ISNCSCI)

ASIA ISCOS

Patient Name _____ Date/Time of Exam _____

Examiner Name _____ Signature _____

RIGHT

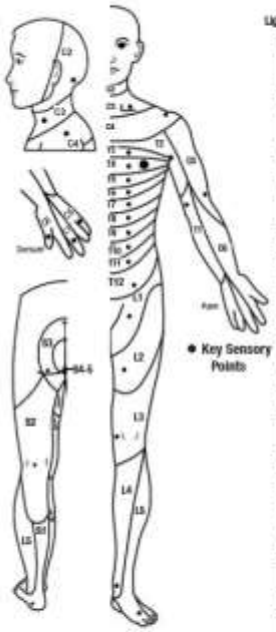
MOTOR KEY MUSCLES		SENSORY KEY SENSORY POINTS Light Touch (LTR)	Pin Prick (PPR)
	C2		
	C3		
	C4		
Elbow flexors	C5		
Wrist extensors	C6		
Elbow extensors	C7		
Finger flexors	C8		
Finger abductors (little finger)	T1		
	T2		
	T3		
	T4		
	T5		
	T6		
	T7		
	T8		
	T9		
	T10		
	T11		
	T12		
	L1		
Hip flexors	L2		
Knee extensors	L3		
Ankle dorsiflexors	L4		
Long toe extensors	L5		
Ankle plantar flexors	S1		
	S2		
	S3		
	S4-5		
RIGHT TOTALS (MAXIMUM)		(50)	(56) (56)

UER (Upper Extremity Right)

LER (Lower Extremity Right)

Comments (Non-key Muscle? Reason for NT? Pain?)

(VAC) Voluntary Anal Contraction (Yes/No) ☐



LEFT

SENSORY KEY SENSORY POINTS Light Touch (LTL)	Pin Prick (PPL)	MOTOR KEY MUSCLES	
		C2	
		C3	
		C4	
		C5	*Elbow flexors*
		C6	*Wrist extensors*
		C7	*Elbow extensors*
		C8	*Finger flexors*
		T1	*Finger abductors (little finger)*
		T2	
		T3	
		T4	
		T5	
		T6	
		T7	
		T8	
		T9	
		T10	
		T11	
		T12	
		L1	
		L2	*Hip flexors*
		L3	*Knee extensors*
		L4	*Ankle dorsiflexors*
		L5	*Long toe extensors*
		S1	*Ankle plantar flexors*
		S2	
		S3	
		S4-5	
(56)	(56)	*LEFT TOTALS* (MAXIMUM)	(50)

UEL (Upper Extremity Left)

LEL (Lower Extremity Left)

MOTOR *(SCORING ON REVERSE SIDE)*

0 = total paralysis
1 = palpable or visible contraction
2 = active movement, gravity eliminated
3 = active movement, against gravity
4 = active movement, against some resistance
5 = active movement, against full resistance
5* = normal corrected for pain/disuse
NT = not testable

SENSORY *(SCORING ON REVERSE SIDE)*

0 = absent 2 = normal
1 = altered NT = not testable

(DAP) Deep Anal Pressure (Yes/No) ☐

MOTOR SUBSCORES

UER ☐ + UEL ☐ = *UEMS TOTAL* ☐ (MAX (25) (25) (50))

LER ☐ + LEL ☐ = *LEMS TOTAL* ☐ (MAX (25) (25) (50))

SENSORY SUBSCORES

LTR ☐ + LTL ☐ = *LT TOTAL* ☐ (MAX (56) (56) (112))

PPR ☐ + PPL ☐ = *PP TOTAL* ☐ (MAX (56) (56) (112))

NEUROLOGICAL LEVELS
Steps 1-5 for classification as on reverse

1. *SENSORY* R ☐ L ☐
2. *MOTOR* R ☐ L ☐

3. *NEUROLOGICAL LEVEL OF INJURY (NLI)* ☐

4. *COMPLETE OR INCOMPLETE?* ☐
Incomplete = Any sensory or motor function in S4-5

5. *ASIA IMPAIRMENT SCALE (AIS)* ☐

ZONE OF PARTIAL PRESERVATION (for complete injuries only)
Most caudal level with any innervation
SENSORY R ☐ L ☐
MOTOR R ☐ L ☐

REV 11/19

Muscle Function Grading

0 = total paralysis

1 = palpable or visible contraction

2 = active movement, full range of motion (ROM) with gravity eliminated

3 = active movement, full ROM against gravity

4 = active movement, full ROM against gravity and moderate resistance in a muscle specific position

5 = (normal) active movement, full ROM against gravity and full resistance in a functional muscle position expected from an otherwise unimpaired person

5* = (normal) active movement, full ROM against gravity and sufficient resistance to be considered normal if identified inhibiting factors (i.e. pain, disuse) were not present

NT = not testable (i.e. due to immobilization, severe pain such that the patient cannot be graded, amputation of limb, or contracture of > 50% of the normal ROM)

Sensory Grading

0 = Absent

1 = Altered, either decreased/impaired sensation or hypersensitivity

2 = Normal

NT = Not testable

When to Test Non-Key Muscles:

In a patient with an apparent AIS B classification, non-key muscle functions more than 3 levels below the motor level on each side should be tested to most accurately classify the injury (differentiate between AIS B and C).

Movement	Root level
Shoulder: Flexion, extension, abduction, adduction, internal and external rotation **Elbow:** Supination	C5
Elbow: Pronation **Wrist:** Flexion	C6
Finger: Flexion at proximal joint, extension **Thumb:** Flexion, extension and abduction in plane of thumb	C7
Finger: Flexion at MCP joint **Thumb:** Opposition, adduction and abduction perpendicular to palm	C8
Finger: Abduction of the index finger	T1
Hip: Adduction	L2
Hip: External rotation	L3
Hip: Extension, abduction, internal rotation **Knee:** Flexion **Ankle:** Inversion and eversion **Toe:** MP and IP extension	L4
Hallux and Toe: DIP and PIP flexion and abduction	L5
Hallux: Adduction	S1

ASIA Impairment Scale (AIS)

A = Complete. No sensory or motor function is preserved in the sacral segments S4-5.

B = Sensory Incomplete. Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-5 (light touch or pin prick at S4-5 or deep anal pressure) AND no motor function is preserved more than three levels below the motor level on either side of the body.

C = Motor Incomplete. Motor function is preserved at the most caudal sacral segments for voluntary anal contraction (VAC) OR the patient meets the criteria for sensory incomplete status (sensory function preserved at the most caudal sacral segments (S4-5) by LT, PP or DAP), and has some sparing of motor function more than three levels below the ipsilateral motor level on either side of the body.
(This includes key or non-key muscle functions to determine motor incomplete status.) For AIS C – less than half of key muscle functions below the single NLI have a muscle grade ≥ 3.

D = Motor Incomplete. Motor incomplete status as defined above, with at least half (half or more) of key muscle functions below the single NLI having a muscle grade ≥ 3.

E = Normal. If sensation and motor function as tested with the ISNCSCI are graded as normal in all segments, and the patient had prior deficits, then the AIS grade is E. Someone without an initial SCI does not receive an AIS grade.

Using ND: To document the sensory, motor and NLI levels, the ASIA Impairment Scale grade, and/or the zone of partial preservation (ZPP) when they are unable to be determined based on the examination results.

ASIA
AMERICAN SPINAL INJURY ASSOCIATION

INTERNATIONAL STANDARDS FOR NEUROLOGICAL CLASSIFICATION OF SPINAL CORD INJURY

ISCOS
INTERNATIONAL SPINAL CORD SOCIETY

Steps in Classification

The following order is recommended for determining the classification of individuals with SCI.

1. Determine sensory levels for right and left sides.
The sensory level is the most caudal, intact dermatome for both pin prick and light touch sensation.

2. Determine motor levels for right and left sides.
Defined by the lowest key muscle function that has a grade of at least 3 (on supine testing), providing the key muscle functions represented by segments above that level are judged to be intact (graded as a 5).
Note: In regions where there is no myotome to test, the motor level is presumed to be the same as the sensory level, if testable motor function above that level is also normal.

3. Determine the neurological level of injury (NLI)
This refers to the most caudal segment of the cord with intact sensation and antigravity (3 or more) muscle function strength, provided that there is normal (intact) sensory and motor function rostrally respectively.
The NLI is the most cephalad of the sensory and motor levels determined in steps 1 and 2.

4. Determine whether the injury is Complete or Incomplete.
(i.e. absence or presence of sacral sparing)
*If voluntary anal contraction = **No** AND all S4-5 sensory scores = **0** AND deep anal pressure = **No**, then injury is **Complete.***
*Otherwise, injury is **Incomplete.***

5. Determine ASIA Impairment Scale (AIS) Grade:

Is injury Complete? **If YES, AIS=A** and can record ZPP (lowest dermatome or myotome on each side with some preservation)

NO ↓

Is injury Motor Complete? **If YES, AIS=B**

NO ↓

(No—voluntary anal contraction OR motor function more than three levels below the motor level on a given side, if the patient has sensory incomplete classification)

Are at least half (half or more) of the key muscles below the neurological level of injury graded 3 or better?

NO ↓ **AIS=C** YES ↓ **AIS=D**

If sensation and motor function is normal in all segments, AIS=E
Note: AIS E is used in follow up testing when an individual with a documented SCI has recovered normal function. If at initial testing no deficits are found, the individual is neurologically intact; the ASIA Impairment Scale does not apply.

Date: June 3, 2018

Unbiased recursive partitioning (URP) analysis of segmental motor recovery after cervical spinal cord injury (SCI) with focus on which neurological and functional characteristics could suggest which people may be candidates for more detailed electrophysiological and reflex testing as a precursor for consideration of peripheral transfer surgery to improve lower arm and hand function.

Interim report to Dr. Ida Fox

Analysis completed by Dr. John Steeves and Dirk Haupt

Data source = European Multicenter study about Spinal Cord Injury (EMSCI)

Sample size = 558 - 771 patients screened (depends on scenarios outlined below)

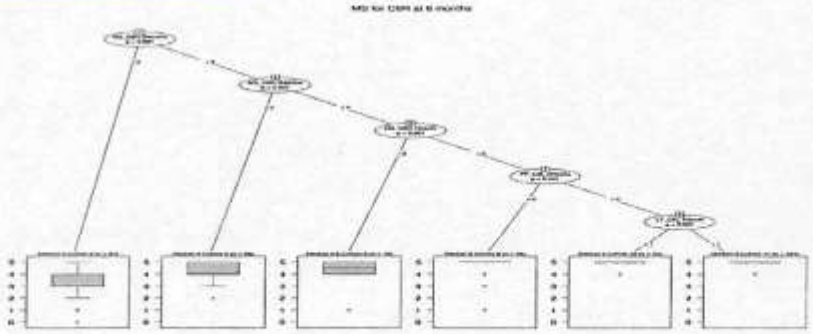
Intact cord segment = initial motor score of 4/5 or 5/5 for the identified segments (i.e. for segments C5, C6, and C7). In the case of the C4 segment, intact means normal (2/2) light touch (LT) and pin prick (PP) sensation for the initial examination < 2 weeks of cervical SCI .

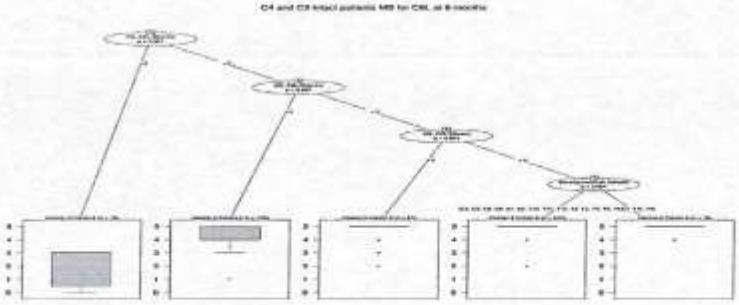
Poor motor recovery = motor score for the segment being examined must have a median score of 1/5 or 0/5 at 6 months after injury. This can be predicted at 3 months after cervical SCI (given the scenarios outlined below). Note: the segment immediately below the intact functional cervical cord will always show the best recovery. This is not a surprising finding and has been repeatedly reported in the past.

Recommendation = peripheral electrophysiological or reflex-testing follow-up (as a prelude to any surgical intervention; nerve or tendon transfer) for a cervical cord segment exhibiting poor recovery of motor function ($\leq$ 1/5) at 6 months after cervical SCI is worth discussion when the cord segment in question is at least 2 spinal cord segments below the motor intact cervical cord.

Scenario #1: C4 and C5 functions are intact within the first 2 weeks after cervical SCI. What predicts a poor motor recovery of the left C6 or right C6 segments at 6 months (each side is analyzed independently)?

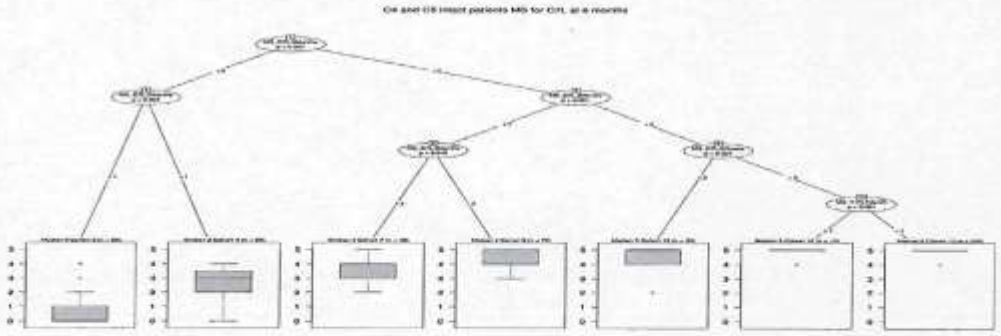
Answer: In this patient subset, very few patients show poor motor recovery at C6L or C6R. For example, in the diagram below, the best predictor of a C6 motor score at 6 months is the C6 motor score at 3 months after SCI. Note: a motor score (MS) of <3/5 for the C6 segment still results in a MS of 3/5 or better (see histogram at bottom left of diagram; denoted as median 3, cohort 2, n= 51). Total sample size = 770. All other cervical SCI patients with intact C4 and C5 motor scores indicate good C6 recovery. Nerve transfers from C4 or C5 to innervate a denervated C6 muscle is not recommended as C6 is likely to spontaneously recover.

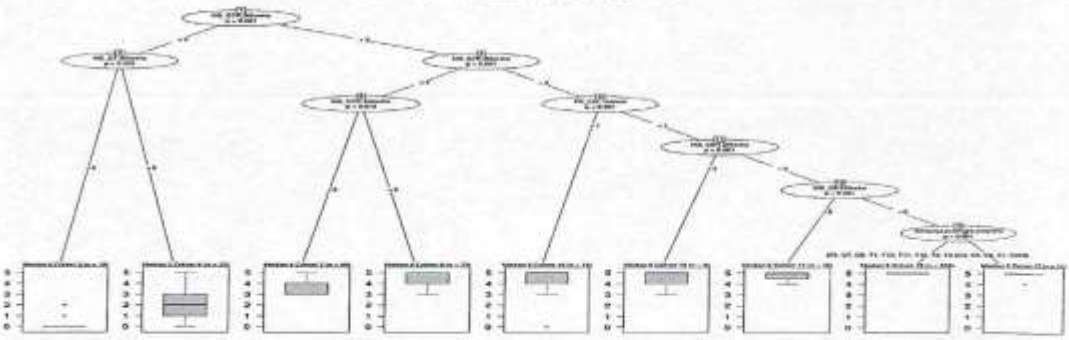




Scenario #2: C4 and C5 functions are intact within the first 2 weeks after cervical SCI. What predicts a poor motor recovery of the left C7 or right C7 segments at 6 months (each side is analyzed independently)?

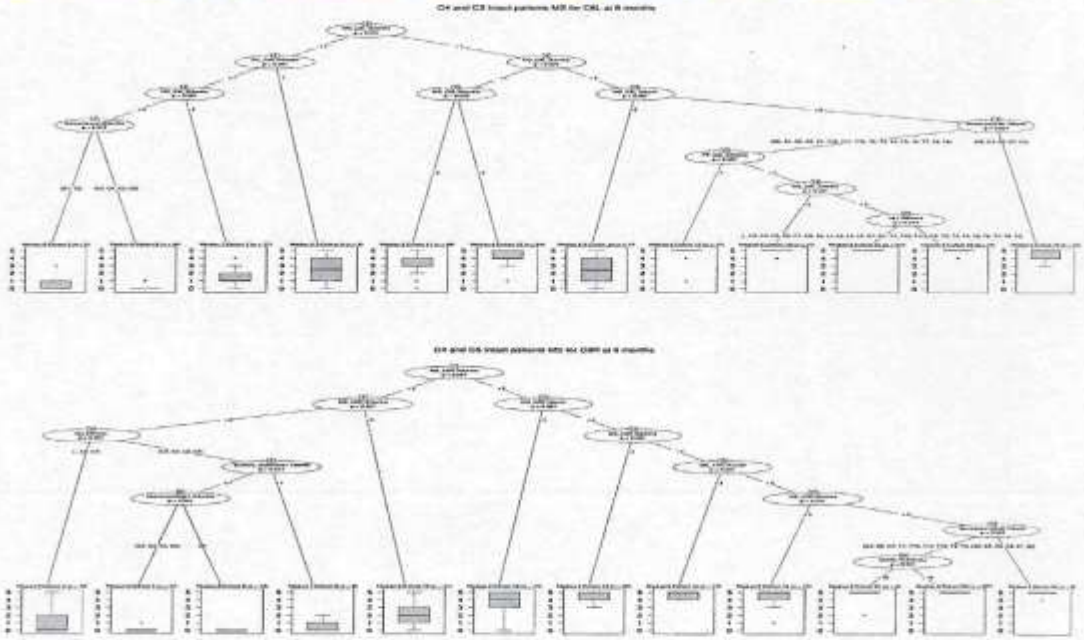
Answer: In this patient subset, a small number of patients might be candidates for a C4 or C5 nerve transfer if they have a C7 motor score at 3 months of ≤ 1/5 for C7L (29 of 770 people) or 0/5 for C7R at 3 months after cervical SCI (16/771). The only cohorts of interest here are cohorts 3 (lower left-side histograms) The more stringent requirements for a poor recovery of C7R are likely due to the fact that more people are right-handed.





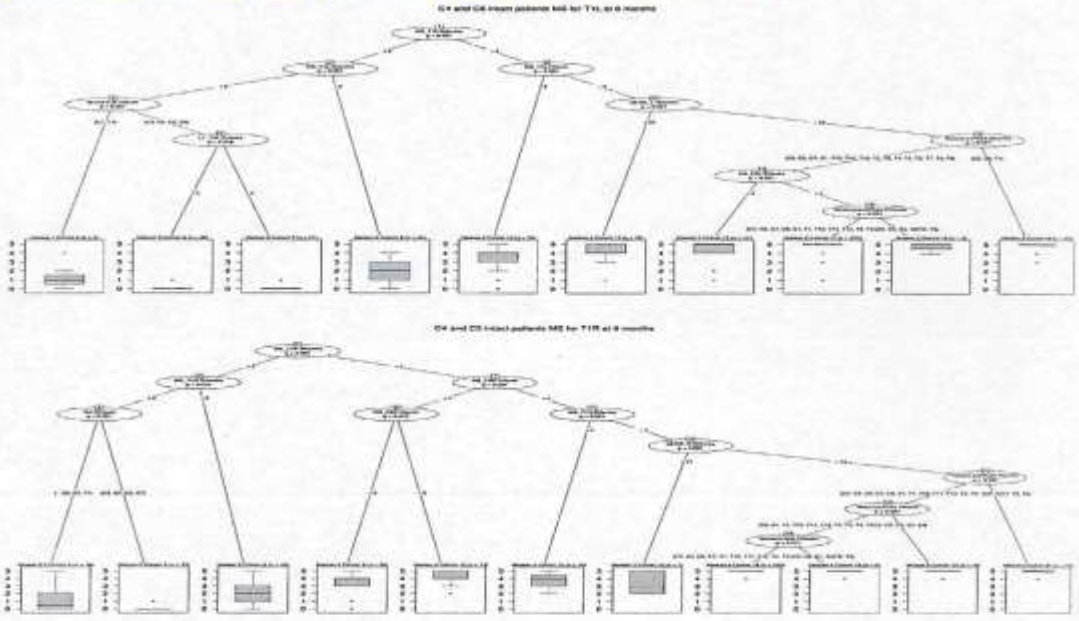
Scenario #3: C4 and C5 function is intact within the first 2 weeks after cervical SCI. What predicts a poor motor recovery of the left C8 or right C8 segments at 6 months (each side is analyzed independently)?

Answer: In this patient subset, there are now more eligible patients for nerve transfer surgery. The potentially eligible patients are (once again) best and easily defined by a C8 MS at 3 months of ≤ 1/5 on either the left or right side (cohorts 4, 7, 8, 9 on bottom histograms for C8R and cohorts 5, 6, 7 for C8L). The total number of potential SCI participants for surgery are 70/769 (cohorts 5,6,7) for C8L and 54/771 (cohorts 4,7,8,9) for C8R. Once again there are slightly more stringent criteria for C8R.



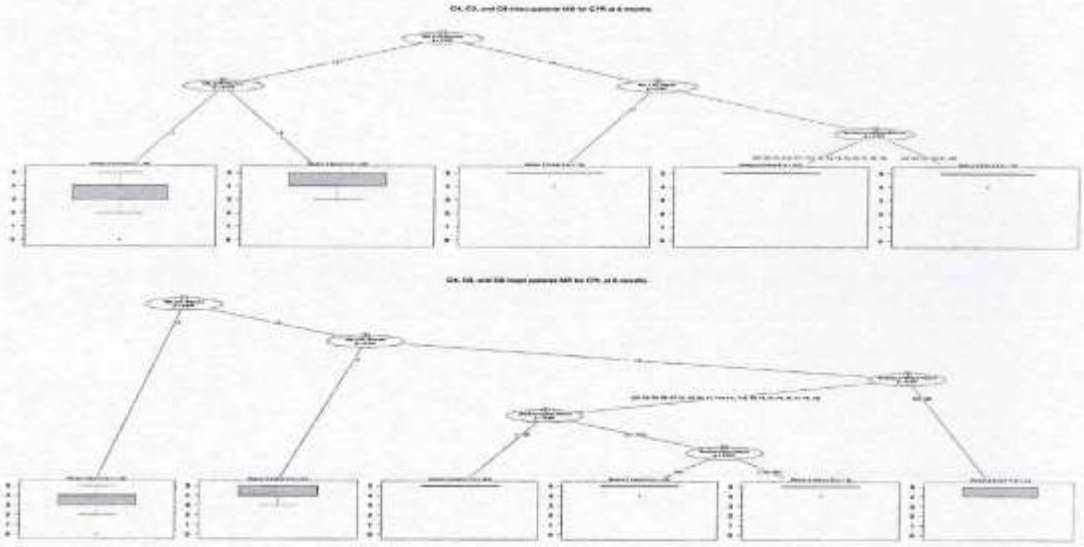
Scenario #4: C4 and C5 function is intact within the first 2 weeks after cervical SCI. What predicts a poor motor recovery of the left T1 or right T1 segments at 6 months (each side is analyzed independently)?

Answer: In this patient subset, the easiest predictors of T1 MS at 6 months are T1 MS at 3 months but neurological level of injury (NLI) at 2 weeks after cervical SCI or motor level at 1 month after SCI can also predict poor recovery of T1 motor function. The total number of participants showing poor T1L recovery are found in cohorts 4, 6, 7 (74/769) and in cohorts 4 and 5 for T1R (71/771). Whether T1 function is highly important to people after cervical SCI is undecided.



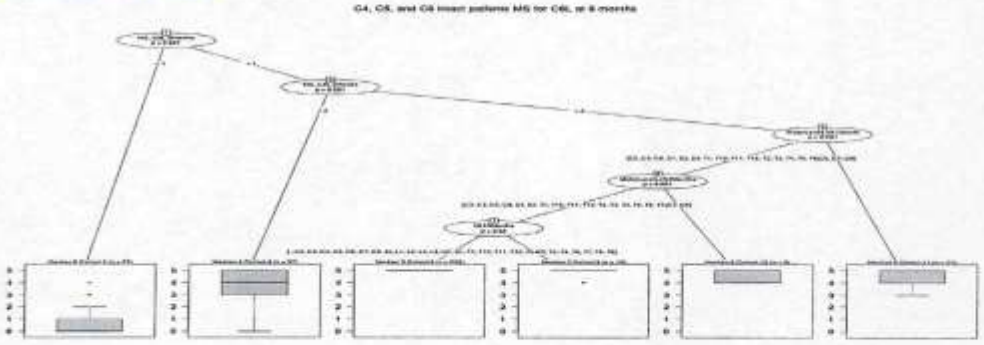
Scenario #5: C4, C5 and C6 function is intact within the first 2 weeks after cervical SCI. What predicts a poor motor recovery of the left C7 or right C7 segments at 6 months (each side is analyzed independently)?

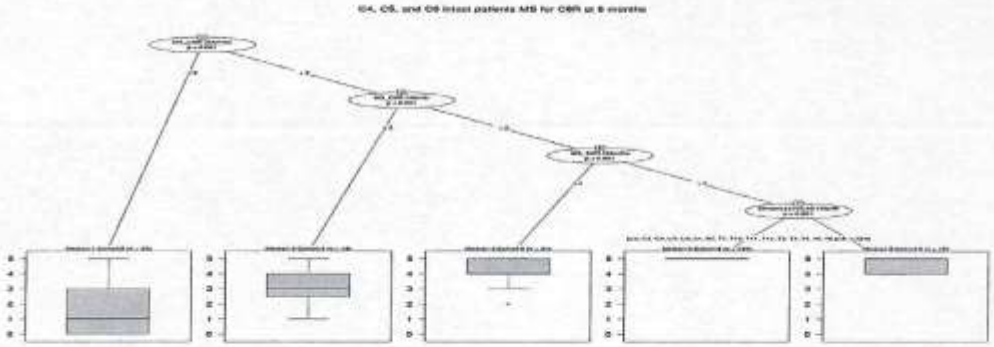
Answer: In this patient subset, the easiest predictors of C7 MS at 6 months are C7 MS at 3 months, but the spontaneous recovery trend continues. Since C7 is adjacent to the intact functioning cervical cord segments of C4-C6, the motor recovery is substantial and none of the participants are deemed potential recipients for a nerve transfer (or tendon transfer) surgery. Of the 612 people screened for C7R or C7L function, the lowest median score for any cohort was 4/5.



Scenario #6: C4, C5 and C6 function is intact within the first 2 weeks after cervical SCI. What predicts a poor motor recovery of the left C8 or right C8 segments at 6 months (each side is analyzed independently)?

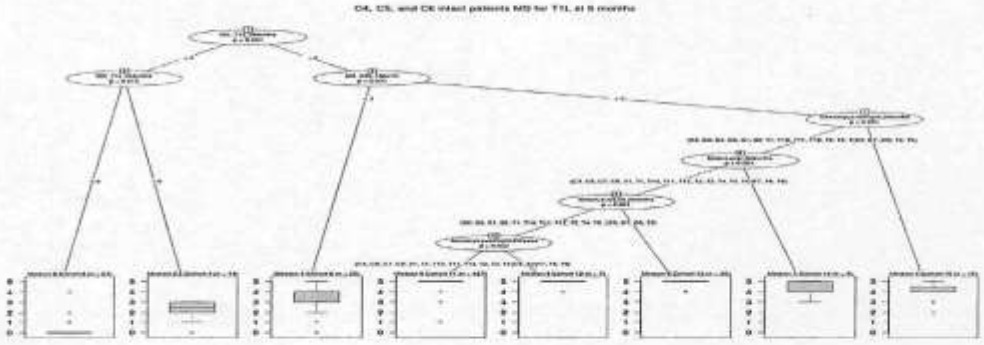
Answer: In this patient subset, the best predictor of C8 function is the MS for C8 at 3months. The total number of potential recipients for peripheral surgery are found in cohorts 2. There are 22/611 people in cohort 2 for C8L with a median MS of 0/5 and 29/612 people in cohort 2 for C8R with a median MS of 1/5.

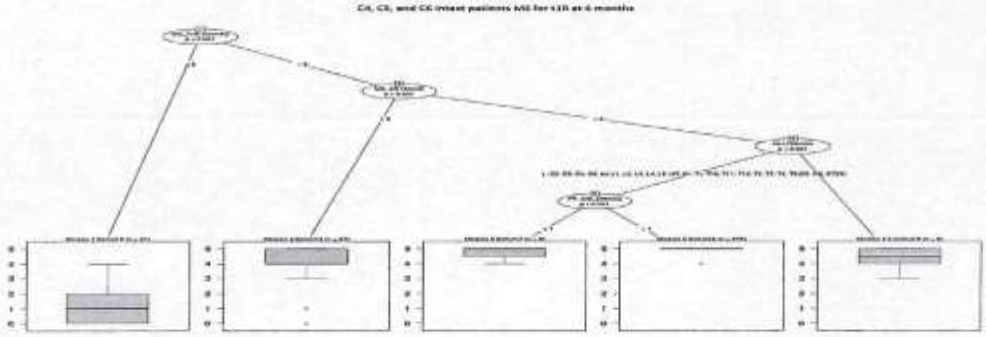




Scenario #7: C4, C5 and C6 function is intact within the first 2 weeks after cervical SCI. What predicts a poor motor recovery of the left T1 or right T1 segments at 6 months (each side is analyzed independently)?

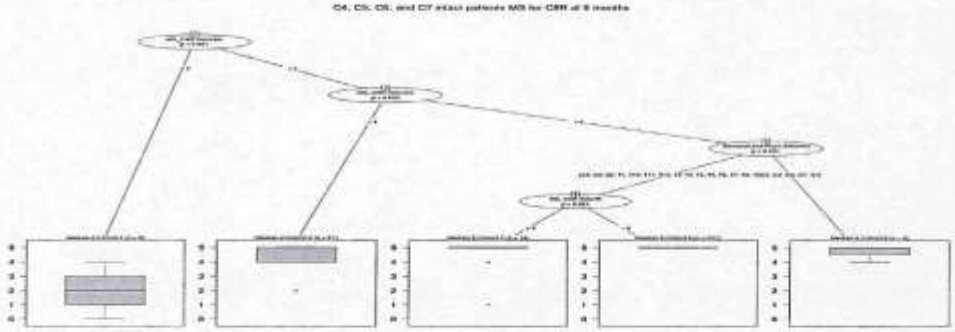
Answer: Best predictor of T1 motor function at 6 months is a T1 motor score (MS) ≤ 2/5 at 3 months. There are 24/611 T1L participants in cohort 3 that might be considered for surgical intervention and 41/612 people in cohort 2 for the T1R subset.

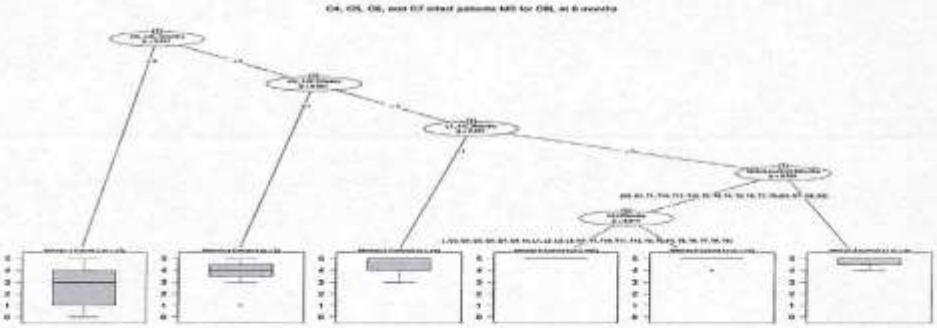




Scenario #8: C4, C5, C6 and C7 function is intact within the first 2 weeks after cervical SCI. What predicts a poor motor recovery of the left C8 or right C8 segments at 6 months (each side is analyzed independently)?

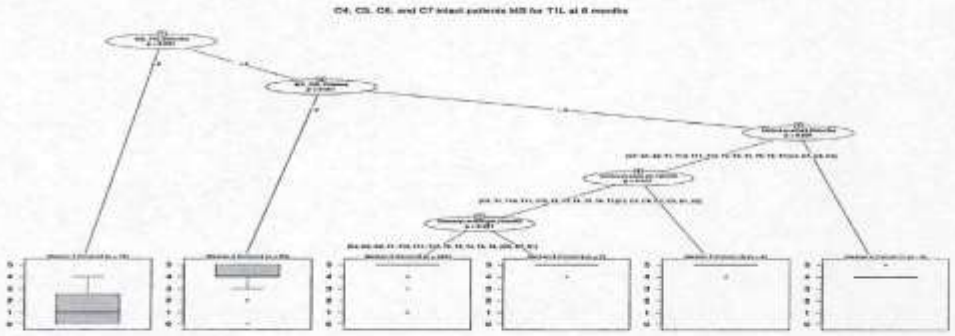
Answer: As before, since the C8 segment (left or right) is adjacent to intact functional cervical cord segments, there are likely very few patients that can be recommended for surgery. The lowest median MS is 2/5 for cohort 2 in the C8R subset and for the C8L subset at 6 months, the lowest median score is 3/5 (see cohort 2). Total sample size for each side was 558 patients.

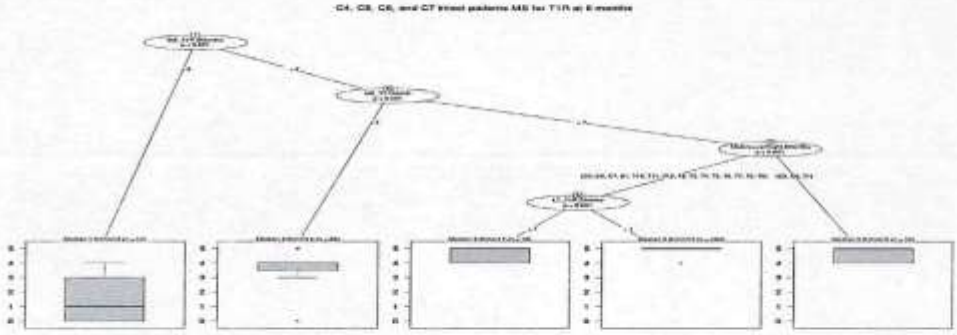




Scenario #9: C4, C5, C6 and C7 function is intact within the first 2 weeks after cervical SCI. What predicts a poor motor recovery of the left T1 or right T1 segments at 6 months (each side is analyzed independently)?

Answer: T1 motor score at 3months after cervical SCI is the best predictor of T1 motor function at 6 months, but only a small percentage of people will be eligible. Specifically, only 16/558 of T1L and 14/559 of T1R people will show poor motor recovery (median score of 1/5 in cohorts 2).





Semi-Structured Interview Guide — for Surgery Subjects

Thank you for allowing us this time to interview you. I will be asking you questions about your experiences with health care providers and therapies for your spinal cord injury, and questions about information you were given or found out about your hand and arm function. There are no right or wrong answers to any of my questions. My goal is to try to understand your experiences with spinal cord injury and treatments for hand and arm function specifically.

Baseline interview questions:

1. **Can you tell me about your injury, in terms of what happened, how old you were, and when it was?** (*Intro question to get them talking.)

2. **We have information about your current function and abilities from the survey you/we just completed. Can you now tell me some of the hand and arm abilities that you miss *most*?**

    a. Probe: Why do you miss that activity the most?
    (*for example, one person said something along the lines of 'what I miss most is the ability to shake hands b/c that is what 'makes a man a [business] man'.)

3. **What treatment or therapies have you had to improve your arm and\or hand function? What therapies or treatments are you thinking of getting in the future?**
    a. Probe:
        i. Can you tell me how you learned about these interventions and what information helped you decide to have or not have the interventions?

4. **Looking back, what do you wish someone had told you about the loss of hand and arm function right after your injury?**

5. **How do you find out or get information about your hand and arm function and your surgery?** (Give them a chance to answer, then probe with format options.)
    a. Probe:
        i. Overall, in what format would you prefer to receive health information?
            - On a mobile phone, through an app or by browsing online
            - On the computer
            - On paper such as a pamphlet, brochure, etc.
            - In person, from a doctor, nurse or health care provider
6. **How did you find out about the nerve/tendon transfer surgery?**
    a. Probes:
        i. Tell me about the person who first introduced you to the possibility of surgery to improve hand and arm function. (i.e. friend, PM&R doctor, internet search, therapist, etc.)

ii. If it wasn't a health care provider, did that person have surgery?
iii. How did you find your surgeon?

7. **Walk me through your decision making process when deciding to get surgery.**
    a. Probes:
        i. What motivated you to have surgery?
        ii. What was it about this surgery that made it seem like a good fit for you?
        iii. What were the drawbacks of this surgery?
        iv. If you were trying to decide between nerve and tendon transfer, what made you choose one over the other?

8. **What do you know or what have you heard about nerve or tendon transfer surgery so far?**

9. **Using your own words, how would you describe the benefits and risks of surgery for hand and arm function to someone else with a spinal cord injury?**

10. **Can you describe any challenges you have faced in getting surgery?**
    a. Probe on: finances (i.e. insurance), caretaker issues, finding a surgeon, getting referral, getting in to see surgeon

11. **How have you prepared for the recovery the time right after surgery (When you get home?)? Have you made any special plans or arrangements?**
    a. Probes:
    i. Any extra caregivers?
    ii. Rental or special equipment obtained (such as Hoyer lift, electric wheelchair)
    iii. Activities that you might have to pause (such as sports, self-catheterization, any others?)?

12. **I'd like know about your expectations and goals for surgery. What do you hope to gain from this surgery?**
    a. Probes:
        i. What are your greatest concerns or fears about surgery?
        ii. Describe your expectations for recovery and rehab after surgery.
        iii. What questions do you still have about surgery, are there other things you might want to know?
        iv. What could your surgeon have explained better?

For VA patients: **Do you have any concerns right now that you need help in addressing? Sometimes talking about these subjects can be hard and if you feel distressed or sad by some of what we have talked about, we want to provide you with the numbers of the VA St. Louis Healthcare System Spinal Cord Injury Unit SW and/or psychologist who might be able to provide you with further information—please let us know.**

Can I answer any other questions? Thank you so much for your time.

Early Follow-up interview questions:

Last time we spoke, you told me a little bit about your injury, treatments you'd done up until that point, your decision making process to have surgery as well as your expectations about it. I will ask some of the same questions again and I will add some new questions as well. There are no right or wrong answers. My goal is to try to understand your experiences with spinal cord injury and treatments for hand and arm function specifically.

1. **So it's been about a month since we last checked in with you- tell me how things are going with your hand and arm function.**
    a. Probe:
        i. Have you been at home, or at an inpatient facility? (*If Inpt, ask LOS)
        ii. Was that your preferred place? Do you think it would it have made a difference to be someplace else?
        iii. How have you been coping?

2. **Can you talk about any gains or losses in your hand and arm function since the surgery?**
    a. Probe:
        i. Are there some or any tasks that you need more help with?
        ii. Are there some/any tasks that you need less help with?
        iii. Describe the types of technology or assistive devices you have and use for everyday function.
        iv. Have you had to rely on others more? If so- share more about what that experience has been like.

3. **Describe any other health issues that may have affected your hand and arm function. (i.e., urinary tract infection or flu prevented exercising/working out)**

4. **Tell me what, if anything, you're doing in regards to therapy.**
    a. Probe:
        i. Intensiveness, frequency, PT vs OT, things you did on your own….
        ii. Probe on: getting to therapy *[Note to interviewer: before asking, figure out whether they are doing inpatient or outpatient therapy]*
        iii. Tell me what therapies or exercises you've found to be most or least helpful.
        iv. If you have missed any therapy sessions, please tell me about the reasons that prevented you from going.

5. **Can you tell me a little bit about your experience with hand and upper extremity <u>pain</u> and other side effects of surgery? Has it affected your functioning?**
    a. Probes:
        i. Is your pain related to surgery or not?
        ii. If it is due to the surgery is it more or less than you expected?
        iii. How do you try to deal with it?

iv. What helps lessen your pain?
v. What would you tell someone who is considering surgery about post op pain they might expect?

6. **Describe any challenges you have had in getting treatments and therapies to improve hand and arm function.**
    a. Probe:
        i. Can you describe whether finances have been a barrier to getting treatment or therapies?
        ii. Can you describe if you've run into any problems with insurance? Had to pay out of pocket for things? Or go without care because of it?

7. **Can you describe your experience right after surgery when you couldn't use your hand and/or arm in the same way as before surgery?**
    a. Probe:
        i. What things did you need to stop or change due to surgery?
        ii. Did you need extra caregivers, or any special or rented equipment?
        iii. How did these needs match up to what you had expected before surgery?
        iiii. What could have been explained better before surgery to prepare you for the post-operative time?

8. **What was the easiest thing about the surgery? The hardest thing?**
    a. Probe:
        i. Overall, has anything about the surgery, including the surgery itself, therapy and recovery afterwards, or your functioning, been different from what you expected going into it?

9. **Looking back to when you were first injured, is there anything you know now about spinal cord injury and your surgery that you wish someone had explained to you early after injury?**

10. **What would you say to someone else thinking about having this surgery?**

For VA patients: **Do you have any concerns right now that you need help in addressing? Sometimes talking about these subjects can be hard and if you feel distressed or sad by some of what we have talked about, we want to provide you with the numbers of the VA St. Louis Healthcare System Spinal Cord Injury Unit SW and/or psychologist who might be able to provide you with further information—please let us know.**

Can I answer any other questions? Thank you so much for your time.

Late Follow-up interview questions:

Some time has passed since we last spoke. In previous interviews you have told me a little bit about your injury, treatments you'd done up until that point, your decision making process to have surgery as well as your expectations about it. For this final interview, I'd like to ask some similar questions to the last time we talked, and some new questions as well. There are no right or wrong answers. My goal is to try to understand your experiences with spinal cord injury and treatments for hand and arm function specifically.

1. **What changes if any, have you noticed in your hand and upper extremity function?**
    a. Probe: What types of things are easier/harder/have not changed?

2. **What was the easiest thing about the surgery? Hardest thing?**
    a. Probe:
        i. Overall, has anything in regards to surgery, including the surgery itself, therapy and recovery afterwards, or your functioning, been different from what you expected going into it?

3. **Describe any barriers you have encountered in accessing treatments and therapies, including surgery, to improve hand and arm function.**
    a. Probe:
        i. Can you describe whether finances have been a barrier to getting treatment or therapies?
        ii. Can you describe if you've run into any problems with insurance? Had to pay out of pocket for things? Or go without care because of it?

4. **Tell me a little bit about how you think your current hand and arm function has impacted your caregivers and/or personal care assistants.**

5. **Looking back, what do you wish someone had told you about spinal cord injury and treatment right after your injury?**

6. **Think back to the expectations and goals you had for your surgery before you had it done. How did those expectations match up with what actually happened? This includes any expectations about the surgery process (actual surgery, recovery, etc). Did you meet the goals you had for surgery?**
    a. Probe: Describe anything about your surgery that you did not expect or that was surprising.

7. **Thinking back to any extra care needed, any special equipment you had to obtain, and any activities that you had to pause in order to have surgery – Was it worth it?**

8. Are you now considering additional surgery(ies) or treatments to improve your hand and arm function? Why, why not?

9. Pretend you're talking to someone else considering having surgery to get more hand and arm function, what would you say to them?

For VA patients: **Do you have any concerns right now that you need help in addressing? Sometimes talking about these subjects can be hard and if you feel distressed or sad by some of what we have talked about, we want to provide you with the numbers of the VA St. Louis Healthcare System Spinal Cord Injury Unit SW and/or psychologist who might be able to provide you with further information—please let us know.**

Can I answer any other questions? Thank you so much for your time.

Semi-Structured Interview Guide - for Non-Surgery Subjects

Thank you for agreeing to this interview. I will be asking you questions to better understand your experiences with spinal cord injury, including your experiences with health care providers. We will also talk about information and treatment for your spinal cord injury. There are no right or wrong answers to any of my questions. My goal is to try to understand your experiences with spinal cord injury and treatments for spinal cord injury.

Baseline Interview questions:

13. **Can you tell me about your injury, in terms of what happened, how old you were, and when it was?** (*Intro question to get them talking.)

14. **We have information about your current function and abilities from the survey we/you just completed. Can you now tell me some of the hand and arm abilities that you miss *most*?**

    a. Probe: Why do you miss that activity the most?
    (*for example, one person said something along the lines of 'what I miss most is the ability to shake hands b/c that is what 'makes a man a [business] man'.)

15. **What treatment or therapies have you had to improve your arm and\or hand function? What therapies or treatments are you thinking of getting in the future?**
    a. Probe: Can you tell me how you learned about these treatments? What information helped you decide to have or not have the treatment?

16. **Looking back, what do you wish someone had told you about the loss of hand and arm function right after your injury?**

17. **How do you find out or get information about your hand and arm function?** (*Give them a chance to answer, then probe with format options.)
    a. Probe:
        i. Overall, in what format would you prefer to get health information?
            - On a mobile phone, through an app or by browsing online
            - On the computer
            - On paper such as a pamphlet, brochure, etc.
            - In person, from a doctor, nurse or health care provider

18. **Tell me what you know or have heard about surgery choices to get more hand and arm function.**
    a. If they haven't heard, or were told they weren't a candidate: **STOP THERE**.
    b. If yes, PROBE: What surgeries have you heard of? And did you think about having surgery done at any point?
    c. If they say yes, but decided against, PROBE: Why did you think that wasn't a good fit for you? What made you decide not to do this? (i.e., fear, didn't think it would help, cost, caregiver issues)

d. Are you doing anything else to get more hand and arm function? (i.e., therapy, stem cells, waiting for cure, etc.)

For VA patients: **Do you have any concerns right now that you need help in addressing? Sometimes talking about these subjects can be hard and if you feel distressed or sad by some of what we have talked about, we want to provide you with the numbers of the VA St. Louis Healthcare System Spinal Cord Injury Unit SW and/or psychologist who might be able to provide you with further information—please let us know.**

Can I answer any other questions? Thank you so much for your time.

<u>Early Follow-up interview questions:</u>

Last time we spoke, you told me a little bit about your injury and any treatments you'd done up until that point. I will ask some of the same questions again and I will add some new questions as well. There are no right or wrong answers. My goal is to try to understand your experiences with spinal cord injury and treatments for hand and arm function specifically.

11. **So it's been about # months since we last checked in with you- tell me how things are going with your hand and arm function.**
    a. Probe: How have you been coping?

12. **Can you talk about any gains or losses in your hand and arm function since we last spoke?**
    a. Probe:
        i. Are there some or any tasks that you need more help with?
        ii. Are there some/any tasks that you need less help with?
        iii. Describe the types of technology or assistive devices you have and use for everyday function.
        iv. Have you had to rely on others more? If so- share more about what that experience has been like.

13. **Describe any health issues that may have affected your hand and arm function. (i.e., flu prevented exercising/working out)**

14. **What are you currently doing to get more hand and arm function?**

15. **Tell me what, if anything, you're doing in regards to therapy.**
    a. Probe:
        i. How often are you doing this, how intense it is, PT vs OT, things you did on your own….
        ii. Probe on: getting to therapy
        iii. Tell me what therapies or exercises you've found to be most or least helpful.
        iv. If you have missed any therapy sessions, please tell me about the reasons that prevented you from going.

16. **Can you tell me a little bit about your experience with hand and upper extremity <u>pain</u>? How does it affect your daily life?**
    a. Probes:
        i. How do you try to deal with it?
        ii. What helps lessen your pain?

17. **Describe any challenges you have had in getting treatments and therapies to improve hand and arm function.**
    a. Probe:
        i. Can you describe whether finances have been a barrier to getting treatment or therapies?
        ii. Have you had any problems with health insurance? Had to pay out of pocket for things? Or go without care because of health insurance?

18. **Looking back, what do you wish someone had told you about spinal cord injury and treatment right after your injury?**

For VA patients: **Do you have any concerns right now that you need help in addressing? Sometimes talking about these subjects can be hard and if you feel distressed or sad by some of what we have talked about, we want to provide you with the numbers of the VA St. Louis Healthcare System Spinal Cord Injury Unit SW and/or psychologist who might be able to provide you with further information—please let us know.**

Can I answer any other questions? Thank you so much for your time.

<u>Late Follow-up interview questions:</u>

Some time has passed since we last spoke. The last time we talked, you told me a little bit about your injury and any treatments you'd done up until that point. For this final interview, I'd like to ask some similar questions, and some new questions as well. There are no right or wrong answers. My goal is to try to understand your experiences with spinal cord injury and treatments for hand and arm function specifically.

1. What changes if any, have you noticed in your hand and arm function?

a. Probe: What types of things are easier/harder/have not changed?

2. Are you doing anything else to get more hand and arm function? Why, why not?

3. How do you think your experiences so far with your hand and arm function has impacted your caregivers?

4. Looking back, what do you wish someone had told you about spinal cord injury and treatment right after your injury?

5. Based on your experience, what would you tell someone who just lost hand and arm function due to an SCI?

a. Probe: Tell me a little bit about your choices or experiences that you would change, and why you would change them.

For VA patients:

Do you have any concerns right now that you need help in addressing? Sometimes talking about these subjects can be hard and if you feel distressed or sad by some of what we have talked about, we want to provide you with the numbers of the VA St. Louis Healthcare System Spinal Cord Injury Unit SW and/or psychologist who might be able to provide you with further information—please let us know.

Can I answer any other questions? Thank you so much for your time.

Semi-Structured Interview Guide—for SCI Caregiver (surgery pts)

Introduction

Thank you for agreeing to this interview. A lot of the focus right after a spinal cord injury and during treatment is on the patient, but we want to hear about things from your point of view. My goal is to try to understand your experiences caring for someone with spinal cord injury and how you feel about treatments for hand and arm function. I will be asking you questions about your experiences with health care providers. We will also talk about treatment and information you were given or found on your own. There are no right or wrong answers to any of my questions.

(Complete the caregiver intake form.)

Baseline interview questions:

1. (If applicable after filling out the intake form) Tell me about your relationship with (NAME) prior to his/her injury. How has your relationship changed since the injury?

Probe: What was that change like for you?

2. (If applicable after filling out the intake form) You named several people who help in providing care for (NAME). Please describe how their roles are different or similar from yours.

3. What is the hardest part about your caregiver role?

4. How do you find out or get information about spinal cord injury and options to improve hand and arm function? (Give them a chance to answer, then probe with format options.)

a. Probe:

i. Overall, in what format would you prefer to receive health information?

- On a mobile phone, through an app or by browsing online
- On the computer
- On paper such as a pamphlet, brochure, etc.
- In person, from a doctor, nurse or health care provider

5. Since (NAME's) initial injury, what changes have you noticed in his/her hand and arm function?

Probe: function and activities of daily living; new activities, if any; quality of life changes; or anything else you can think of; etc.

6. Describe the process of looking for different treatment options to improve hand and arm function with (NAME).

Probes:

a. What resources did you turn to for information?

b. What do you think is important when it comes to treatment options? In your opinion, what factors did you like about the treatment options? What factors did you dislike?

c. Did you have a preference between the options? Were you both in agreement with the final decision?

7. How have you prepared for the time after (NAME) has surgery? What plans have you made?

Probe:

i. Any extra caregivers?

ii. Rental or special equipment obtained

iii. Activities that you might have to pause?

For VA patient caregivers:

Do you have any concerns right now that you need help in addressing? Sometimes talking about these subjects can be hard and if you feel distressed or sad by some of what we have talked about, we want to provide you with the numbers of the VA St. Louis Healthcare System Spinal Cord Injury Unit SW and/or psychologist who might be able to provide you with further information—please let us know.

Thank you so much for your time. Can I answer any other questions?

Early follow up questions:

Intro: The last time we spoke, you talked about your role as a caregiver. This time, I'd like to discuss what's been going on since that time. There are no right or wrong answers. My goal is to try to understand your experiences caring for someone with spinal cord injury and how you feel about treatments for hand and arm function.

(Complete the caregiver intake form.)

1. Since (NAME) had surgery, how has the type or amount of care that you give to him/her changed?

Probes:

a. How did his/her post-op recovery change your routine? More work vs. less work?

2. Where has (NAME) been during this post-operative time?

Probes:

a. At home, or at an inpatient facility? (*If inpatient, ask for length of stay)

b. Was that your preferred place? Do you think it would it have made a difference for him/her to be someplace else? In what way?

c. How have you been coping during this post-operative time?

3. Since the surgery, what have any therapy or other treatments been like for (NAME) from your perspective?

Probes:

a. Have they started therapy? (i.e. intensiveness, frequency)

b. What has that experience been like for you?

c. Could anything have made the therapy sessions or scheduling easier or better?

d. What barriers may have gotten in the way of receiving therapy or treatments?

4. Where do you turn to get support about your role as a caregiver?

5. Where do you turn to get information on your role as a caregiver?

Probes:

a. What information do you wish was out there?

6. Tell me about any challenges or frustrations you've experienced as a caregiver since the surgery (i.e., getting pt to f/u visits or therapy?).

7. How do your experiences so far match up with your original expectations about recovery after surgery?

Probes:

a. Was anything unexpected or surprising to you about the process, the surgery, the recovery, the outcome?
b. Did you need extra caregivers; any special or rented equipment; any activities that you had to pause?
c. Did the surgery affect your financial situation?
d. Any issues with hand or arm pain? How did you handle that?
e. Knowing what you know now, what would you tell others? Can you tell me about that? How has this affected (NAME)'s function and your need to provide assistance?

For VA patient caregivers:

Do you have any concerns right now that you need help in addressing? Sometimes talking about these subjects can be hard and if you feel distressed or sad by some of what we have talked about, we want to provide you with the numbers of the VA St. Louis Healthcare System Spinal Cord Injury Unit SW and/or psychologist who might be able to provide you with further information—please let us know.

Can I answer any other questions? Thank you so much for your time.

Late follow up questions:

Intro: Some time has passed since we last spoke about your role as a caregiver. For this final interview, I'll ask questions to learn about changes since we last talked. Some questions will be similar to the last time we talked. There are no right or wrong answers. My goal is to try to understand your experiences caring for someone with spinal cord injury and how you feel about treatments for hand and arm function.

(Complete the intake form.)

1. With respect to hand and arm function, how has the kind or amount of support that you give to (NAME) changed since he/she had surgery.

Probes:

a. i.e., physical, emotional, financial support
b. Where has (NAME) been during this post-operative time?
c. How did his/her post-op recovery change your routine? More work vs. less work?

2. Where do you turn to get support about your role as a caregiver?

3. Where do you turn to get information on your role as a caregiver?

Probes:

a. What information do you wish was out there?

4. Looking back, what do you wish someone had told you about spinal cord injury and treatment right after (NAME'S) injury?

Probes:

a. What information could have helped you during the decision-making process?
b. Are there any resources you would have liked to have or anyone you would have liked to talk to?
c. What do you think the doctors, nurses, or healthcare team could do to make the treatment and recovery process easier?

5. As a caregiver, what are your overall thoughts about the surgery?

Probes:

a. How has the surgery changed your life?
b. What would you say were the hardest and easiest things for you as a caregiver?
c. What do you see as the main changes in (NAME)'s function?
d. Would you say the outcome has been more positive or more negative?

6. How do your experiences so far match up with your original expectations about recovery after surgery?

Probes:

a. Was anything unexpected or surprising to you about the process, the surgery, the recovery, the outcome?
b. Did you need extra caregivers; any special or rented equipment; any activities that you had to pause?
c. Did the surgery affect your financial situation?
d. Any issues with hand or arm pain? How did you handle that?
e. Knowing what you know now, what would you tell others? Can you tell me about that? How has this affected (NAME)'s function and your need to provide assistance?

7. If someone else was trying to decide if they should have surgery to get more hand or arm function after a spinal cord injury, what would you tell them and their caretaker?

Probe: Had you heard any stories of people who had surgery? What should someone know before going in? (i.e. equipment, practical aspects)

For VA patient caregivers:

Do you have any concerns right now that you need help in addressing? Sometimes talking about these subjects can be hard and if you feel distressed or sad by some of what we have talked about, we want to provide you with the numbers of the VA St. Louis Healthcare System Spinal Cord Injury Unit SW and/or psychologist who might be able to provide you with further information—please let us know.

Can I answer any other questions? Thank you so much for your time.

Semi-Structured Interview Guide—for SCI Caregiver (non-surgery)

Introduction

Thank you for agreeing to this interview. A lot of the focus right after a spinal cord injury and during treatment is on the patient, but we want to hear about things from your point of view. My goal is to try to understand your experiences caring for someone with spinal cord injury and how you feel about treatments for hand and arm function. I will be asking you questions about your experiences with health care providers. We will also talk about treatment and information you were given or found on your own. There are no right or wrong answers to any of my questions.

(Complete the caregiver intake form.)

Baseline interview questions:

1. (If applicable after filling out the intake form) Tell me about your relationship with (NAME) prior to his/her injury. How has your relationship changed since the injury?

Probe: What was that change like for you?

2. (If applicable after filling out the intake form) You named several people who help in providing care for (NAME). Please describe how their roles are the same or different from yours.

3. What is the hardest part about your caregiver role?

4. How do you find out or get information about spinal cord injury and options to improve hand and arm function? (Give them a chance to answer, then probe with format options.)

a. Probe:

i. Overall, in what format would you prefer to receive health information?

- On a mobile phone, through an app or by browsing online
- On the computer
- On paper such as a pamphlet, brochure, etc.
- In person, from a doctor, nurse or health care provider

5. Since (NAME's) initial injury, what changes have you noticed in his/her hand and arm function?

Probe: function and activities of daily living; new activities, if any; quality of life changes; or anything else you can think of; etc.

6. Tell me what you know or have heard about surgery choices to get more hand and arm function.

d. If they haven't heard, or were told that subject wasn't a candidate: **STOP THERE**.

e. If yes, PROBE: What surgeries have you heard of? What do you think is important when it comes to treatment options? In your opinion, what factors did you like about the treatment options? What factors did you dislike?

f. If they say yes, but subject decided against, PROBE: Why do you think that wasn't a good option? (i.e., fear, didn't think it would help, cost, caregiver issues)

d. Is (NAME) doing anything else to get more hand and arm function? (i.e., therapy, stem cells, waiting for cure, etc.)

For VA patient caregivers:
Do you have any concerns right now that you need help in addressing? Sometimes talking about these subjects can be hard and if you feel distressed or sad by some of what we have talked about, we want to provide you with the numbers of the VA St. Louis Healthcare System Spinal Cord Injury Unit SW and/or psychologist who might be able to provide you with further information—please let us know.

Can I answer any other questions? Thank you so much for your time.

<u>Early follow up questions:</u>

<u>Intro</u>: The last time we spoke, you talked about your role as a caregiver. This time, I'd like to discuss what's been going on since that time. There are no right or wrong answers. My goal is to try to understand your experiences caring for someone with spinal cord injury and how you feel about treatments for hand and arm function.

(Complete the caregiver intake form.)

1. Since we last spoke, how has the type or amount of care that you give to (NAME) changed in terms of his/her hand and arm function?

2. What have therapies or treatments been like for (NAME) from your perspective?

<u>Probes</u>:
a. Are they doing some type of therapy? (i.e. intensiveness, frequency)
b. What has that experience been like for you?
c. Could anything have made the therapy sessions better? Or scheduling easier?
d. What barriers may have gotten in the way of therapy or treatments?

3. Tell me about any challenges or frustrations you've experienced as a caregiver (i.e., getting pt to f/u visits or therapy?).

4. Where do you turn to get support about your role as a caregiver?

5. Where do you turn to get information on your role as a caregiver?

<u>Probes</u>:
a. What information do you wish was out there?

For VA patient caregivers:
Do you have any concerns right now that you need help in addressing? Sometimes talking about these subjects can be hard and if you feel distressed or sad by some of what we have talked about, we want to provide you with the numbers of the VA St. Louis Healthcare System

Spinal Cord Injury Unit SW and/or psychologist who might be able to provide you with further information—please let us know.

Can I answer any other questions? Thank you so much for your time.

Late follow up questions:

Intro: Some time has passed since we last spoke about your role as a caregiver. For this final interview, I'll ask questions to learn about changes since we last talked. Some questions will be similar to the last time we talked. There are no right or wrong answers. My goal is to try to understand your experiences caring for someone with spinal cord injury and how you feel about treatments for hand and arm function.

(Complete the caregiver intake form.)

1. How has the type or amount of care that you give to (NAME) changed in terms of his/her hand and arm function?

2. What have therapies or treatments been like for (NAME) from your perspective?

Probes:

a. Are they doing some type of therapy? (i.e. intensiveness, frequency)
b. What has that experience been like for you?
c. Could anything have made the therapy sessions better? Or scheduling easier?
d. What barriers may have gotten in the way of therapy or treatments?

3. Where do you turn to get support about your role as a caregiver?

4. Where do you turn to get information on your role as a caregiver?

Probes:

a. What information do you wish was out there?

5. Looking back, what do you wish someone had told you about spinal cord injury and treatment right after (NAME'S) injury?

Probes:

d. Are there any resources you would have liked to have, or anyone you would have liked to talk to?
e. What do you think the doctors, nurses, or healthcare team could do to make the treatment and recovery process easier?

For VA patient caregivers:

Do you have any concerns right now that you need help in addressing? Sometimes talking about these subjects can be hard and if you feel distressed or sad by some of what we have talked about, we want to provide you with the numbers of the VA St. Louis Healthcare System Spinal Cord Injury Unit SW and/or psychologist who might be able to provide you with further information—please let us know.

Can I answer any other questions? Thank you so much for your time.

Demographics

Participant study ID _____

Study Group
- ◯ No Surgery
- ◯ Nerve Transfer
- ◯ Tendon Transfer

Tendon Group
- ◯ Tendon Transfer Only
- ◯ Tendon and Nerve Transfer

Zip code of home residency _____

Sex
- ◯ Male
- ◯ Female

Current Age _____

Race
- ☐ American Indian or Alaska Native
- ☐ African American or Black
- ☐ Asian or Pacific Islander
- ☐ White
- ☐ Refused
- ☐ Not Reported

(check all that apply)

Ethnicity
- ◯ Hispanic
- ◯ Non-Hispanic
- ◯ Refused

Veteran
- ◯ No
- ◯ Yes
- ◯ Not Reported

Date of spinal cord injury _____

Age at time of spinal cord injury _____

Injury etiology
- ◯ Sports/leisure
- ◯ Assault
- ◯ Transport
- ◯ Fall
- ◯ Other traumatic cause
- ◯ Non-traumatic spinal cord lesion
- ◯ Not reported

Type of injury
- ◯ Blunt
- ◯ Penetrating
- ◯ Unknown

Initial hospital name _____

Rehab hospital name _____

Place of current therapy _____

Major medical comorbidity
- ☐ None
- ☐ Cardiovascular
- ☐ Diabetes
- ☐ Lung
- ☐ CVA-TIA

Other comorbidity

- ☐ None
- ☐ UTI
- ☐ Previous pressure sores
- ☐ Spasticity

Any spine surgery?

- ◯ Yes
- ◯ No
- ◯ Not Reported

Any arm (upper extremity/hand) surgery?

- ◯ Yes
- ◯ No
- ◯ Not Reported

List any past surgery to spine, shoulders, arms or hands before or after spinal cord injury:

_____

Current employment status:

- ◯ Working part-time
- ◯ Working full-time
- ◯ On disability
- ◯ Unemployed/looking for work
- ◯ Unemployed/not looking for work
- ◯ Not reported

Current living situation:

- ◯ Live by self with caregiver coming in
- ◯ Live by self plus live-in caregiver
- ◯ Assisted living/rehab
- ◯ Live with family or other person
- ◯ Other (specify)

Who provides support for your daily activities?

- ◯ Family/partner
- ◯ Friend
- ◯ Paid person who is not related
- ◯ Other (specify)

Specify your other support for daily activities:

_____

What is the highest level of education you have completed?

- ◯ Less than high school
- ◯ High school diploma or GED
- ◯ Associate degree or trade school
- ◯ Some college without degree
- ◯ Bachelor's degree
- ◯ Master's degree
- ◯ Doctorate
- ◯ Not reported

Hand dominance prior to SCI?

- ◯ Right
- ◯ Left

Current hand dominance?

- ◯ Right
- ◯ Left

Surgery

Was surgery done?
- ◯ No
- ◯ Yes

Date of Surgery
_____

Type of Surgery
- ◯ Nerve Transfer
- ◯ Tendon Transfer

Goal of Surgery
- ☐ Elbow extension
- ☐ Finger extension
- ☐ Wrist extension
- ☐ Finger flexion
- ☐ Anticlaw
- ☐ Other

(check all that apply)

Other goal of surgery (please specify)
_____

Laterality
- ◯ Right
- ◯ Left
- ◯ Bilateral

Hospital LOS (days)
_____

Scim

Date SCIM completed _____

SELF-CARE

1. Feeding
- ◯ I need artificial feeding or stomach tube
- ◯ I need total assitance with eating/drinking
- ◯ I need partial assistance etc
- ◯ I eat/drink independently but I need adaptive devices etc
- ◯ I eat/drink independently etc

2a. Bathing - Upper Body
- ◯ I need total assistance
- ◯ I need partial assistance
- ◯ I am independent but need adaptive etc
- ◯ I am independent and do not need adaptive etc

2b. Bathing - Lower Body
- ◯ I need total assistance
- ◯ I need partial assistance
- ◯ I am independent but need adaptive etc
- ◯ I am independent and do not need adaptive etc

3a. Dressing - Upper Body
- ◯ I need total assistance
- ◯ I need partial assistance, even with easy etc
- ◯ I do not need assistance with easy etc
- ◯ I am independent with easy etc need asistance with difficult etc
- ◯ I am completely independent

3b. Dressing - Lower Body
- ◯ I need total assistance
- ◯ I need partial assistance, even with easy etc
- ◯ I do not need assistance with easy etc
- ◯ I am independent with easy etc need asistance with difficult etc
- ◯ I am completely independent

4. Grooming
- ◯ I need total assistance
- ◯ I need partial assistance
- ◯ I am independent with adaptive devices
- ◯ I am independent without adaptive devices

RESPIRATION and SPHINCTER MANAGEMENT

5. Respiration
- ◯ I need a respiratory (tracheal) tube as well as etc assited ventilation
- ◯ I need a respiratory (tracheal) tube as well as extra oxygen and a lot of assistance coughing etc
- ◯ I need a respiratory (tracheal) tube as well as little assistance coughing etc
- ◯ I do NOT need a respiratory tube but I need extra oxygen etc
- ◯ I do NOT need a respiratory tube and only little assistance etc coughing
- ◯ I do NOT need a respiratory tube and can breath and cough independently etc

6a. Use of an indwelling catheter

- ◯ Yes
- ◯ No

6b. Intermittent catheterization

- ◯ I need total assistance
- ◯ I do it myself with assistance
- ◯ I do it myself without assistance
- ◯ I do not use it

6c. Use of external drainage instruments

- ◯ I need total assistance for using them
- ◯ I need partial assistance for using them
- ◯ I use them without assistnace
- ◯ I am continent etc do not use external drainage

7a. Do you need assistnace with bowel management?

- ◯ Yes
- ◯ No

7b. My bowel movements are

- ◯ Irregular or seldom (less than once in 3 days)
- ◯ Regular (once in 3 days or more)

7c. Fecal incontinence happens

- ◯ twice a month or more
- ◯ once a month
- ◯ not at all

8. Please think about the use of the toilet, cleaning etc

- ◯ I need total assistance
- ◯ I need partial assitance and cannot clean myself
- ◯ I need partial assitance but can clean myself
- ◯ I do not need assitance but I need adaptive devices
- ◯ I do not need any assistance or adaptive devices

MOBILITY (room and toilet)

9. How many of the following can you perform wtihout assitance or electrical aids: Turning your upper body in bed; Turning yoru lower body in bed; Sitting up in bed; Doing push-ups in wheelchair

- ◯ None
- ◯ One
- ◯ Two or three
- ◯ All of them

10. Transfers: bed to wheelchair

- ◯ I need total assistance
- ◯ I need partial assistance, supervision or assistive devices
- ◯ I do not need any assistance or devices OR I do not use a wheelchair

11. Transfers: wheelchair to toilet to tub

- ◯ I need total assistance
- ◯ I need partial assistance, supervision or assistive devices
- ◯ I do not need any assistance or devices OR I do not use a wheelchair

MOBILITY (indoors and outdoors)

12. Moving around indoors indoors

- ◯ I use a wheelchair. To move around I need total assistance
- ◯ To move around I need an electric wheelchair or partial assist with a manual chair
- ◯ I am independent in a manual wheelchair
- ◯ I walk indoors and I need supervision while walking (with or without devices)
- ◯ I walk indoors with a walking frame or cruches swinging both feet forward
- ◯ I walk indoors with crutches or two canes setting one foot before the other
- ◯ I walk indoors with one cane
- ◯ I walk indoors with a leg orthosis only
- ◯ I walk indoors without walking aids

13. Mobility for moderate distances (10-100 meters)

- ◯ I use a wheelchair. To move around I need total assistance
- ◯ To move around I need an electric wheelchair or partial assist with a manual chair
- ◯ I am independent in a manual wheelchair
- ◯ I walk moderate distances and I need supervision while walking (with or without devices)
- ◯ I walk moderate distances with a walking frame or cruches swinging both feet forward
- ◯ I walk moderate distances with crutches or two canes setting one foot before the other
- ◯ I walk moderate distances with one cane
- ◯ I walk moderate distances with a leg orthosis only
- ◯ I walk moderate distances without walking aids

14. Mobility outdoors (more than 100 meters)

- ◯ I use a wheelchair. To move around I need total assistance
- ◯ To move around I need an electric wheelchair or partial assist with a manual chair
- ◯ I am independent in a manual wheelchair
- ◯ I walk more than 100 meters and I need supervisio while walking (with or without devices)
- ◯ I walk more than 100 meters with a walking frame or cruches swinging both feet forward
- ◯ I walk more than 100 meters with crutches or two canes setting one foot before the other
- ◯ I walk more than 100 meters with one cane
- ◯ I walk more than 100 meters with a leg orthosis only
- ◯ I walk more than 100 meters without walking aids

15. Stair management

- ◯ I am unable to go up and down stairs
- ◯ I can go up and down at least 3 steps but only with assistance or supervision
- ◯ I can go up and down at least 3 steps but only with devices
- ◯ I can go up and down at least 3 steps but only without any assistance, supervision or devices

16. Transfers: wheelchair to car

- ◯ I need total assistance
- ◯ I need partial assistance, supervision or assistive devices
- ◯ I do not need any assistance or devices OR I do not use a wheelchair

17. Transfers: ground to wheelchair

- ◯ I need assistance
- ◯ I do not need any assistance OR I do not use a wheelchair

Health Survey Sf36

Health Survey (SF-36)

Date Health Survey completed _____

Participant Data

1) In general, would you say your health is:

- ◯ Excellent
- ◯ Very good
- ◯ Good
- ◯ Fair
- ◯ Poor

2) Compared to one year ago, how would you rate your health in general now?

- ◯ Much better than one year ago
- ◯ Somewhat better than one year ago
- ◯ About the same as one year ago
- ◯ Somewhat worse now that one year ago
- ◯ Much worse than one year ago

3) Does your health now limit you in these activities?

Vigorous activities

- ◯ Yes limited a lot
- ◯ Yes limited a little
- ◯ Not limited at all

((for example: running lifting heavy objects, participating in strenuous sports))

Moderate activities

- ◯ Yes limited a lot
- ◯ Yes limited a little
- ◯ Not limited at all

((for example: moving a table, pusing a vacuum cleaner, bowling or playing golf))

Lifting or carrying groceries

- ◯ Yes limited a lot
- ◯ Yes limited a little
- ◯ Not limited at all

Climbing several flights of stairs

- ◯ Yes limited a lot
- ◯ Yes limited a little
- ◯ Not limited at all

Climbing one flight of stairs

- ◯ Yes limited a lot
- ◯ Yes limited a little
- ◯ Not limited at all

Bending, kneeling or stooping

- ◯ Yes limited a lot
- ◯ Yes limited a little
- ◯ Not limited at all

Wheeling more than a mile

- ◯ Yes limited a lot
- ◯ Yes limited a little
- ◯ Not limited at all

Wheeling several blocks	◯ Yes limited a lot ◯ Yes limited a little ◯ Not limited at all
Wheeling one block	◯ Yes limited a lot ◯ Yes limited a little ◯ Not limited at all
Bathing or dressing yourself	◯ Yes limited a lot ◯ Yes limited a little ◯ Not limited at all

During the past 4 weeks, have you had any of the following problems with your work or other regular activities as a result of your physical health?

4a) Cut down on the amount of time you spent on work or other activities	◯ No ◯ Yes
4b) Accomplished less than you would like	◯ No ◯ Yes
4c) Were limited in the kind of work or other activities	◯ No ◯ Yes
4d) Had difficulty performing the work or other activities	◯ No ◯ Yes ((i.e. it took extra effort))

During the past 4 weeks, have you had any of the following problems with your work or other regular activities as a result of any emotional problems?

5a) Cut down on the amount of time you spent on work or other activities	◯ No ◯ Yes
5b) Accomplished less than you would like	◯ No ◯ Yes
5c) Didn't do work or other activities as usual	◯ No ◯ Yes

During the last 4 weeks:

6) To what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups?	◯ Not at all ◯ Slightly ◯ Moderately ◯ Quite a bit ◯ Extremely
7) How much physical pain have you had?	◯ None ◯ Very mild ◯ Mild ◯ Moderate ◯ Severe ◯ Very severe

8) How much did pain interfere with your normal work (including both work outside the home and housework)

- ◯ Not at all
- ◯ A little bit
- ◯ Moderately
- ◯ Quite a bit
- ◯ Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. Please give the one answer that is closest to the way you have been feeling for each item.

9a) Did you feel full of life?

- ◯ All of the time
- ◯ Most of the time
- ◯ A good bit of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time

9b) Have you been a very nervous person?

- ◯ All of the time
- ◯ Most of the time
- ◯ A good bit of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time

9c) Have you felt so down in the dumps that nothing could cheer you up?

- ◯ All of the time
- ◯ Most of the time
- ◯ A good bit of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time

9d) Have you felt calm and peaceful?

- ◯ All of the time
- ◯ Most of the time
- ◯ A good bit of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time

9e) Did you have a lot of energy?

- ◯ All of the time
- ◯ Most of the time
- ◯ A good bit of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time

9f) Have you felt downhearted and blue?

- ◯ All of the time
- ◯ Most of the time
- ◯ A good bit of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time

9g) Did you feel worn out?

- ◯ All of the time
- ◯ Most of the time
- ◯ A good bit of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time

9h) Have you been a happy person?

- ◯ All of the time
- ◯ Most of the time
- ◯ A good bit of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time

9i) Did you feel tired?

- ◯ All of the time
- ◯ Most of the time
- ◯ A good bit of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time

During the past 4 weeks:

10) How much of the time has your physical health or emotional problems interfered with your social activities?

- ◯ All of the time
- ◯ Most of the time
- ◯ Some of the time
- ◯ A little of the time
- ◯ None of the time

((Like visiting with friends, relatives, etc.))

How TRUE or FALSE is each of the following statements for you?

11a) I seem to get sick a little easier than other people

- ◯ Definitely true
- ◯ Mostly true
- ◯ Don't know
- ◯ Mostly false
- ◯ Definitely false

11b) I am as healthy as anybody I know

- ◯ Definitely true
- ◯ Mostly true
- ◯ Don't know
- ◯ Mostly false
- ◯ Definitely false

11c) I expect my health to get worse

- ◯ Definitely true
- ◯ Mostly true
- ◯ Don't know
- ◯ Mostly false
- ◯ Definitely false

11d) My health is excellent

- ◯ Definitely true
- ◯ Mostly true
- ◯ Don't know
- ◯ Mostly false
- ◯ Definitely false

Caregiver Form

Date of data collection _____

How many caregivers are listed?
- ◯ One
- ◯ Two
- ◯ Three

Relationship #1

Relationship
- ◯ Parent
- ◯ Partner/spouse
- ◯ Sibling
- ◯ Child
- ◯ Grandparent
- ◯ Aunt/Uncle
- ◯ Cousin
- ◯ Neighbor
- ◯ Friend
- ◯ Agency/hired professional
- ◯ Other (specify)
- ◯ Unknown

Other Relationship _____

Age _____

Gender
- ◯ Male
- ◯ Female

Date when this person first assumed responsibilities for care? _____

Date assumed responsibilities is unknown
- ☐ Unknown

Lives in home with person with SCI/D?
- ◯ Full-Time
- ◯ Part-Time
- ◯ No

Average hours spent caring for person with SCI/D per week _____

Caregiving Responsibilities
- ☐ Activities of Daily Living
- ☐ Instrumental Activities of Daily Living
- ☐ Rest and Sleep
- ☐ Education
- ☐ Work
- ☐ Play
- ☐ Leisure
- ☐ Social Participation

Paid for caregiving?
- ◯ No
- ◯ Yes

Relationship #2

Relationship
- ◯ Parent
- ◯ Partner/spouse
- ◯ Sibling
- ◯ Child
- ◯ Grandparent
- ◯ Aunt/Uncle
- ◯ Cousin
- ◯ Neighbor
- ◯ Friend
- ◯ Agency/hired professional
- ◯ Other (specify)
- ◯ Unknown

Other Relationship _____

Age _____

Gender
- ◯ Male
- ◯ Female

Date when this person first assumed responsibilities for care? _____

Date assumed responsibilities is unknown
- ☐ Unknown

Lives in home with person with SCI/D?
- ◯ Full-Time
- ◯ Part-Time
- ◯ No

Average hours spent caring for person with SCI/D per week _____

Caregiving Responsibilities
- ☐ Activities of Daily Living
- ☐ Instrumental Activities of Daily Living
- ☐ Rest and Sleep
- ☐ Education
- ☐ Work
- ☐ Play
- ☐ Leisure
- ☐ Social Participation

Paid for caregiving?
- ◯ No
- ◯ Yes

Relationship #3

Relationship	◯ Parent ◯ Partner/spouse ◯ Sibling ◯ Child ◯ Grandparent ◯ Aunt/Uncle ◯ Cousin ◯ Neighbor ◯ Friend ◯ Agency/hired professional ◯ Other (specify) ◯ Unknown
Other Relationship	_____
Age	_____
Gender	◯ Male ◯ Female
Date when this person first assumed responsibilities for care?	_____
Date assumed responsibilities is unknown	☐ Unknown
Lives in home with person with SCI/D?	◯ Full-Time ◯ Part-Time ◯ No
Average hours spent caring for person with SCI/D per week	_____
Caregiving Responsibilities	☐ Activities of Daily Living ☐ Instrumental Activities of Daily Living ☐ Rest and Sleep ☐ Education ☐ Work ☐ Play ☐ Leisure ☐ Social Participation
Paid for caregiving?	◯ No ◯ Yes

Question 3

How well do you manage with your current household income	◯ Very Well ◯ Rather Well ◯ Adequately ◯ Rather Poorly ◯ Very Poorly ◯ Refused to Answer ◯ Unknown ◯ Not Applicable

Amount of Time (Hours Per Week)

Caregiving for person with SCI/D _____

Caregiving for person(s) other than person with SCI/D _____

Activities of Daily Living _____

Instrumental Activities of Daily Living _____

Rest and Sleep _____

Paid Employment _____

Unpaid employment/volunteer activities _____

Leisure Activities _____

Social Participation _____

Satisfaction Rating

Caregiving for person with SCI/D
- ◯ Not Satisfied
- ◯ Somewhat Satisfied
- ◯ Very Satisfied
- ◯ Not Applicable
- ◯ Unknown

Caregiving for person(s) other than person with SCI/D
- ◯ Not Satisfied
- ◯ Somewhat Satisfied
- ◯ Very Satisfied
- ◯ Not Applicable
- ◯ Unknown

Activities of Daily Living
- ◯ Not Satisfied
- ◯ Somewhat Satisfied
- ◯ Very Satisfied
- ◯ Not Applicable
- ◯ Unknown

Instrumental Activities of Daily Living
- ◯ Not Satisfied
- ◯ Somewhat Satisfied
- ◯ Very Satisfied
- ◯ Not Applicable
- ◯ Unknown

Rest and Sleep
- ◯ Not Satisfied
- ◯ Somewhat Satisfied
- ◯ Very Satisfied
- ◯ Not Applicable
- ◯ Unknown

Paid Employment
- ◯ Not Satisfied
- ◯ Somewhat Satisfied
- ◯ Very Satisfied
- ◯ Not Applicable
- ◯ Unknown

Unpaid employment/volunteer activities

- ◯ Not Satisfied
- ◯ Somewhat Satisfied
- ◯ Very Satisfied
- ◯ Not Applicable
- ◯ Unknown

Leisure Activities

- ◯ Not Satisfied
- ◯ Somewhat Satisfied
- ◯ Very Satisfied
- ◯ Not Applicable
- ◯ Unknown

Social Participation

- ◯ Not Satisfied
- ◯ Somewhat Satisfied
- ◯ Very Satisfied
- ◯ Not Applicable
- ◯ Unknown

Question 5

How burdensome you feel caring for or accompanying the person with SCI/D at the moment

Not at all straining — Much too straining

(Place a mark on the scale above)

Supporting Patient Decisions about Upper Extremity Surgery in Cervical Spinal Cord Injury

Log Number: **SC160046**

Award Number: **W81XWH-17-1-0285**

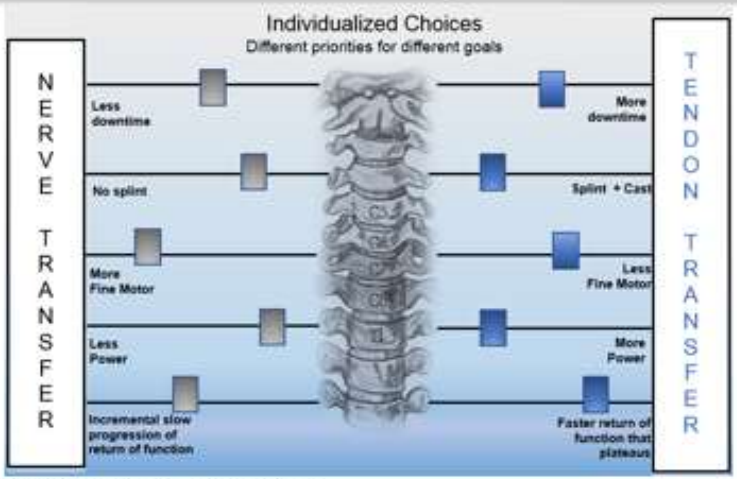
PI: Ida K. Fox, M.D. **Org:** Washington University in St. Louis School of Medicine **Award Amount:** $701,402

Study/Product Aim(s)

- Aim 1: Establish the time course of spontaneous recovery of upper extremity function after cervical spinal cord injury (SCI).
- Aim 2: Describe outcomes after no intervention compared to surgical intervention (nerve/tendon transfer) groups.
- Aim 3: Develop and assess a decision support intervention tool.

Approach

The overarching aim of this project is to define key information about improvement of upper extremity function after SCI (time and extent of recovery, outcome of surgical and non-surgical interventions and the experience thereof) and communicate this information to patients and clinicians to support their treatment decisions.



Accomplishments this quarter:
AIM 1- EMSCI dataset analysis being refined and summarized.
AIM 2- Human subject enrollment ahead of goal.

Timeline and Cost

Activities	CY '16	'17	'18	'19	'20
Grant Submission / Final HRPO Approval					
Aim 1					
Aim 2					
Aim 3					
Estimated Budget $702K		**$55K**	**$173K**	**$244K**	**$230K**

*Note projected use of funds shifted to reflect delayed subject enrollment.

Updated: 09/26/2018

Goals/Milestones

CY16 Goal – Assemble research group and formulate grant proposal
☑ Complete grant submission
CY17 Goals – Aim 1 and 2
☑ Obtain IRB/HRPO approval
☑ Begin EMSCI database analysis
☑ Create interview guides
CY18 Goal – Aim 1, 2
☐ Summarize findings of EMSCI database analysis
☑ Enroll Aim 2 subjects for outcomes collection (interviews/surveys)
CY19 Goal – Aim 2, 3
☐ Create and test decision support intervention tool

Comments/Challenges/Issues/Concerns

- Timeline issues: None.
- Spending comment: None.

Budget Expenditure to Date

Projected Expenditure: $223,231.00
Actual Expenditure: $165,576.84 (lower than planned due to necessity to stagger effort prior to human subjects enrollment)