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TITLE: Systematic Assessment of Caregiving Skill Performance by Individuals with Tetraplegia and Their Caregivers

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14. ABSTRACT The objective of the proposed study is to create an assessment tool for use by clinicians during inpatient rehabilitation to systematically evaluate and describe competence in self-direction of care and caregiving skills. Key findings derived from rehabilitation chart reviews include the following: The persons who receive caregiver education during the inpatient rehabilitation stay are varied, including spouses, children, parents, and friends of the person with tetraplegia, as well as hired attendants. Instructional methods include discussion and verbal presentation of information, provision of written materials, demonstration of skills, and opportunities to practice skills with feedback from clinicians. A wide variety of topics related to self-care, activities of daily living, equipment use, secondary complications, emergency preparedness, and medical issues appeared in clinical documentation of patient and caregiver training. Clinicians use several techniques to assess the ability of persons with tetraplegia and their caregivers to direct care or perform care tasks. A variety of descriptors are used to characterize the ability of persons with tetraplegia and/or their caregivers to direct or perform care tasks. These include the level of independence with which a task is performed or directed, quality ("good", "fair", "poor"), accuracy ("correctness"), frequency (compared with what is ideal), completeness, and extent to which further training is needed.					
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Annual Report for 30-Sep-2013 to 29-Sep-2014

1. INTRODUCTION

The objective of the proposed study is to create an assessment tool for use by clinicians during inpatient rehabilitation to systematically evaluate and describe competence in self-direction of care and caregiving skills. These sets of skills are unaddressed by functional outcome measures currently used in inpatient care and rehabilitation research. As a result, current measures are inadequate to describe progress made during inpatient rehabilitation by persons with tetraplegia (PWTs), for whom training in self-direction of care and family training in caregiving skills are important areas of rehabilitation intervention. (Note that “caregiving” and “self-care” refer broadly to the performance of basic and advanced activities of daily living (ADLs), medical treatments such as suctioning, mobility, maintenance of a healthy living environment, and all other tasks needed to maintain health, well-being, and productivity for PWTs.) The proposed project will address this gap in assessment by creating a tool specifically designed to assess competence in self-direction of care and caregiving skills. The project has four specific aims: (1) Identify rehabilitation goals related to self-direction of care and caregiver performance of care tasks, indicators of progress toward those goals, and criteria for establishing competency that are meaningful to SCI clinicians, PWTs, and their caregivers. (2) Create an assessment tool that reflects these goals, indicators, and criteria. (3) Assess the comprehensiveness and utility of the tool in inpatient rehabilitation qualitatively, by piloting its use in that setting and obtaining feedback from end-users. (4) Based on this feedback, create a refined version of the assessment tool suitable for further development and evaluation in subsequent research.

2. KEYWORDS

Rehabilitation, spinal cord injury, assessment, qualitative research, caregiving

3. RESEARCH ACCOMPLISHMENTS

What were the major goals of the project?

Major goals over the past year were to:

- (1) Obtain required regulatory approvals at all sites once the transfer of the grant to Kessler Foundation was completed
- (2) Conduct chart reviews to gather preliminary data on treatment goals related to direction of care/caregiving, the content of education provided to address these goals, and methods used to evaluate and describe progress toward those goals
- (3) Conduct focus groups and/or interviews with persons with tetraplegia, caregivers and SCI clinicians to identify relevant content for the assessment tool

Note: While this progress report appears to cover Year 2 of the project based on the original date of funding (9/30/2012) the project was on hold for a period of approximately 9 months from 1/18/2013 to 10/9/2014 during the transfer of the grant from Mount Sinai School of Medicine to Kessler Foundation. The goals stated above take this delay into account.

What was accomplished under these goals?

Major Activities. Activities during the reporting period included completion of the transfer of the grant from Mount Sinai School of Medicine to Kessler Foundation, establishing subaward agreements with collaborating sites, obtaining and renewing regulatory approvals, recruitment and training of new staff, participant recruitment, chart review data collection, qualitative analysis of chart review data, and preparation for focus groups. Further information on these activities is given below.

- Documentation was submitted as requested by Josh Disbennett and colleagues involved in the processing of the grant transfer. The grant transfer was approved on 10/9/2014.
- Notification of approval of the project by the Human Research Protection Office (HRPO) was obtained on 12/17/2014. (Note that all necessary documentation to obtain approval for human subject research activities was submitted to HRPO well before this date, but approval could not be granted until after the grant transfer was approved.)
- Subaward agreements were established with all collaborating sites.
- Dr. Zanca trained G. Melissa Garcia, a Research Assistant who was part of the study team from November 2013 to early March 2013. Following Ms. Garcia's departure, Dr. Zanca recruited and trained a new Research Assistant, Ms. Ashleigh Quinn, who joined the research team in June 2014. The Research Assistants contributed to subject recruitment, data collection, and abstraction of data from chart documentation.
- 8 participants were enrolled in the chart review portion of Phase I of the study.
- Medical record documentation for all consented participants was obtained. This process required problem-solving with staff in the Medical Records Department of Kessler Institute for rehabilitation to identify an alternative means of accessing records when a technical issue prevented access in the manner originally planned. A work-around was identified to allow access to the required records.
- A data abstraction guide was developed to provide detailed information about the types of patient/caregiver-clinician interaction documentation that should be abstracted and give guidance on the mechanics of abstraction (replacement of proper names for patients and caregivers with "patient" or "patient's wife," for example). The guide served as a means of documenting decisions made during data abstraction and provided clear

instructions to the team so that data were collected in a consistent manner. The guide was updated on an ongoing basis as questions arose.

- Topics of direction of care/caregiving skill training, instructional techniques, and methods for assessing and describing skill level were identified from data obtained via chart review (see significant results below).
- Preparation for focus groups and interviews is underway. Focus group implementation checklists have been developed for all sites to aid preparations for the focus group portion of Phase I of the project. Recruitment of participants for the focus groups has begun.

Significant Results. Results reported here were obtained from content analysis of goals related to self-direction of care/caregiving skills, descriptions of progress toward those goals, and education/training provided to persons with tetraplegia and their caregivers as documented by clinicians in the rehabilitation charts of persons with tetraplegia who received rehabilitation at Kessler Institute for Rehabilitation.

The persons who receive caregiver education during the inpatient rehabilitation stay are varied, including spouses, children, parents, and friends of the person with tetraplegia, as well as home health aides or personal care attendants who may be hired by the person with tetraplegia to facilitate his/her return to home. Instructional methods include discussion and verbal presentation of information, provision of written materials, demonstration of skills, and opportunities to practice skills with feedback from clinicians. A wide variety of topics related to self-care, activities of daily living, equipment use, secondary complications, emergency preparedness, and medical issues appeared in clinical documentation of patient and caregiver training (see Table 1).

Clinicians use several techniques to assess the ability of persons with tetraplegia and their caregivers to direct care or perform care tasks. These include: (1) “quizzing” patients or caregivers orally to assess knowledge relevant to task performance; (2) asking patients or caregivers to demonstrate (verbally or physically as applicable) how they would instruct or perform a task; and (3) observing their behavior (without specifically asking for a skill to be demonstrated) to assess the extent to which they have integrated tasks into their daily routine (such as requesting a weight-shift from a caregiver at a specified interval).

A variety of descriptors are used to characterize the ability of persons with tetraplegia and/or their caregivers to direct or perform care tasks (see Table 2). These descriptors appear in goals (particularly short-term goals) set by the clinical team and in progress notes.

Table 1. Themes for Topics and Subtopics of Direction of Care and/or Caregiver Training	
<i>Main Topic</i>	<i>Subtopics</i>
Activities of Daily Living (ADLs)	Bathing (in bed, in shower chair) Dressing upper and lower body Bed mobility Transfers (to bed, shower chair, etc.) Bowel and bladder care Electronic ADLs (setup of a tablet computer or cell phone for use by person with tetraplegia, for example)
Durable Medical Equipment (Features and Use)	Shower commode chair Mechanical lift (sling setup, operation to perform transfer) Manual wheelchair (use of manual tilt-in-space, wheel locks, traversing curbs/ramps, etc.) Power wheelchair (use on wheelchair lift, attendant drive, etc.) Hospital bed Rotating mattress Positioning devices (such as resting hand splint, wheelchair seating components)
Management and Prevention of Secondary Complications	Pain management techniques Skin integrity preservation (skin inspection, skin care, weight-shifting, positioning, etc.) Passive range of motion Autonomic dysreflexia (signs, symptoms, interventions) Orthostatic hypotension (signs, symptoms, interventions) Respiratory care (swallowing techniques to avoid aspiration, assisted cough, etc.)
Emergency Preparedness	Emergency ventilation (using manual bag technique) Evacuation methods (chair bumping, two person lift)
Other Medical Issues	Breathing (ventilator use, supplemental oxygen use, etc.) Medication management

Table 2. Themes and Examples of Descriptors of Direction of Care/Caregiving Skill Performance Ability	
<i>Descriptor</i>	<i>Examples (Quotations from Medical Record)</i>
Level of independence (includes need for verbal cueing)	“Patient’s spouse required moderate verbal cues for technique, minimal verbal cues for safety, and moderate assistance with use of mechanical lift.” “Patient requested to be re-positioned in manual recliner wheelchair. Therapist asked for patient to instruct him on appropriate/safe handling techniques to assist with his request. Pt able to complete with minimal verbal cues.” “Patient demonstrated independence in instruction of others for completion of activities of daily living, bed positioning and functional transfers ...”
Quality of demonstration of a task	“Demonstrated task with good return/successful demonstration.”
Accuracy of task performance or knowledge demonstration	“Patient able to recall weight shift protocol with 100% accuracy.” “Patient will instruct home health aide on set up of sling and patient lift in preparation to perform mechanical lift transfer to/from shower commode chair and bed with 100% accuracy.”
Timing of task performance	“Patient will initiate at least one weight shift at appropriate intervals...”
Frequency with which task is performed correctly	“Patient will instruct others with set up of mechanical sling with 100% accuracy 2/5 treatment sessions.”
Completeness of knowledge verbalized upon request	“Patient will verbalize 50% of bony prominences most prone to skin breakdown without verbal cues from this therapist.”
Need for further training	“Requires further training.”

The topics addressed during training and descriptors of ability used by clinicians will be discussed in the focus groups and considered for inclusion in the assessment tool.

Discussion of Stated Goals Not Met. At the time of the last quarterly report (submitted in July 2014), stated goals included recruitment of 2 additional participants for the chart reviews (bringing the total to 10). While we have identified additional potential participants who may be enrolled, we have focused efforts thus far on review and analysis of the records in hand. The data we are seeking are found throughout the record rather than in a specific section, requiring review of a considerable amount of narrative material to identify the content of interest. This

effort has been fruitful, identifying content that will contribute the development of the assessment tool this study aims to create. However, it has been very time-consuming given the structure of the records and the long lengths of stay of the individuals whose charts are being reviewed. We are concerned that the new data gained from review of two more charts will not justify the time and effort required for data abstraction and analysis. We will consult with our Project Officer about this issue to determine how best to proceed.

Another stated goal at the time of the last quarterly report was to conduct the focus groups at Kessler. Since the time of that report, we were successful in identifying an alternative means of acquiring records that were previously inaccessible due to a technical issue with electronic medical record system. The result was that we had a large influx of new material to review and analyze. Ms. Quinn's time commitment to the study was increased to 50-75% percent to allow faster abstraction of data. However, other commitments outside the project during the past quarter made it difficult for Dr. Zanca to devote extra time to analysis of new data. Those commitments have ended as of the date of submission of this report, and Dr. Zanca will be better able to structure her activities over the next quarter to devote greater than 30% effort to the project to accelerate its progress.

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

Nothing to Report (Data collection and analyses are ongoing)

How were the results disseminated to communities of interest?

Nothing to Report (Data collection and analyses are ongoing)

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

Activities during the next reporting period will include:

- Further analyses of data collected to date to prepare for dissemination of findings to interested parties
- Submission of renewal applications to the local IRBs of participating sites and to HRPO
- Recruitment of participants for focus groups and interviews
- Conduct of focus groups and interviews, beginning first at the lead site (Kessler)

4. IMPACT

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

Nothing to Report (Data collection and analyses are ongoing)

What was the impact on other disciplines?

Nothing to Report (Data collection and analyses are ongoing)

What was the impact on technology transfer?

Nothing to Report (Data collection and analyses are ongoing)

What was the impact on society beyond science and technology?

Nothing to Report (Data collection and analyses are ongoing)

5. CHANGES/PROBLEMS**Changes in Approach and Reasons for Change**

None

Actual or Anticipated Problems or Delays and Actions or Plans to Resolve Them

The completion of tasks in the proposed project has been delayed due to the prolonged period of time (approximately 9 months) required to complete the processing of the transfer of the grant from Mount Sinai School of Medicine to Kessler Foundation, family leave taken by Dr. Zanca (which started 8-Jan-2014 and ended on 7-Apr-2014), a vacancy in the Research Assistant position, and unexpected difficulties accessing a portion of the medical records needed for the project.

As circumstances permit, Zanca and the new Research Assistant (Ms. Quinn) will devote greater than the originally planned levels of effort to make up for time lost to date. We anticipate that a new timeline of task completion that involves an Extension Without Funds (EWOFF) will need to be created, and have been advised that this would be done toward the end of the current award. We will consult with the Grant Officer's Representative in the future about this issue as needed.

Changes that had a Significant Impact on Expenditures

Fewer funds have been expended than were expected by this point in the project because (1) human subject research activities were required to be on hold until the grant was officially transferred to Kessler Foundation (2) Dr. Zanca took unpaid family leave in early 2014 and (3) there was a vacancy in the Research Assistant position from March to June 2014. We anticipate catching up on expenditures over the course of the coming year as additional effort is devoted to the project to accelerate the pace of its progress.

Significant Changes in Use or Care of Human Subjects, Vertebrate Animals, Biohazards, and/or Select Agents

None

6. PRODUCTS

Nothing to Report (Data collection and analyses are ongoing)

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Jeanne Zanca
Project Role:	Principal Investigator
Nearest Person Month Worked:	▪ 3 (Due to a three month family leave during the reporting year, this calculation is based on 9 months in the year rather than 12)
Contribution to Project:	▪ Obtained and renewed all regulatory approvals for the project ▪ Worked with grants administration offices at all collaborating sites to establish subaward agreements ▪ Recruited, trained, supervised Research Assistant for the project ▪ Conducted qualitative analysis of chart review data obtained ▪ Leading planning for focus groups

Name:	G. Melissa Garcia
Project Role:	Research Assistant (<i>former</i>)
Nearest Person Month Worked:	▪ 1 (Ms. Garcia joined the project team in November 2013 and left in early March 2014)
Contribution to Project:	▪ Obtained informed consent from participants to obtain access to medical charts as part of Phase I data collection ▪ Worked with medical records staff to acquire medical records for consented participants ▪ Assisted with data abstraction ▪ Maintained study documentation of informed consent and communications with subjects

Name:	Ashleigh Quinn
Project Role:	Research Assistant (<i>present</i>)
Nearest Person Month Worked:	▪ 2 (Ms. Quinn joined the project team in June 2014)
Contribution to Project:	▪ Abstracted data for qualitative analysis ▪ Communicated with potential participants for focus groups ▪ Maintained study documentation

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

The principal investigator (Zanca) has had an increase in her active support over the past year due to two new grants being received. Specific information on each of these two grants is given below.

Mind-Body Interventions for Self-Management of Pain Post-SCI: A Pilot Study

Principal Investigator: Jeanne M. Zanca, PhD, MPT

Funding: 288925, Craig H. Neilsen Foundation, \$93,511

Period: 4/01/14 - 03/31/2015

FTE: 10%

Objective: To assess the feasibility and potential benefits of a program of guided imagery and meditation for persons with chronic pain and spinal cord injury (SCI).

Improving Functioning in Persons with Chronic Pain Post-SCI through Virtual Classroom Delivery of a Mindfulness-Based Chronic Pain Management Program

Principal Investigator: Jeanne M. Zanca, PhD, MPT

Funding: CSCR14IRG019, New Jersey Commission on Spinal Cord Research, \$450,635

Period: 6/15/14 – 6/30/17

FTE: 10%

Objective: This project will examine the feasibility and potential benefits of a web-based Mindfulness-Based Chronic Pain Management intervention for persons with chronic pain post-SCI.

What other organizations were involved as partners?

Organization Name:	East Orange Campus of the VA New Jersey Health Care System
Location of Organization:	East Orange, NJ
Partner's contribution to the project:	Collaboration (e.g., partner's staff work with project staff on the project)

Organization Name:	Icahn School of Medicine at Mount Sinai
Location of Organization:	New York, NY
Partner's contribution to the project:	Collaboration (e.g., partner's staff work with project staff on the project)

Organization Name:	Shepherd Center
Location of Organization:	Atlanta, GA
Partner's contribution to the project:	Collaboration (e.g., partner's staff work with project staff on the project)

8. SPECIAL REPORTING REQUIREMENTS

Not Applicable

9. APPENDICES n/a