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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 by persons with tetraplegia (PWTs) and provision of care by their caregivers. 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. Project activities completed to date include 1) obtaining local IRB approval at all sites, 2) submitting applications to the Office of Human Research Protections for all sites, and 3) submitting requested documentation to support the transfer of the award from Mount Sinai to Kessler Foundation. As of 9/29/13, the request to transfer the award was under review.					
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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.

BODY - RESEARCH ACCOMPLISHMENTS

Transfer of Award from Mount Sinai School of Medicine to Kessler Foundation

Resources to support successful conduct of the study. During the current reporting period, Dr. Zanca accepted a position at the Kessler Foundation. This new environment has extensive resources that will facilitate the successful performance of the study. Kessler Foundation works in close partnership with Kessler Institute for Rehabilitation (KIR), ranked as the #2 rehabilitation hospital in the nation by US News and World Report. Kessler Foundation and KIR are highly-respected centers of excellence in spinal cord injury research, and form one of only 14 SCI Model Systems funded by the National Institute for Rehabilitation Research. Kessler’s SCI program serves more than 1,500 outpatients each year and more than 200 inpatients (a number approximately twice that of Mount Sinai’s program), and has a highly-developed program for serving persons with high-level tetraplegia. Thus, an extensive pool of participants is available for the chart review, focus group, and pilot testing portions of the study. Kessler has also been a lead or collaborating center in recent studies to develop improved outcome measures for health-related quality of life after SCI,¹⁻⁷ and is well-positioned to support the creation of the proposed assessment tool. We will retain the expertise of Dr. Marcel Dijkers by supporting his participation as a co-investigator in the project via a subcontract with Mount Sinai School of Medicine.

Efforts made to facilitate transfer of the grant to Kessler Foundation. Dr. Zanca ended her position at Mount Sinai on 1/18/2013, with a start date at Kessler Foundation of 1/28/2013. Prior to Dr. Zanca's departure, Mount Sinai agreed to allow the grant to be transferred, and documentation to support the transfer request was provided by Mount Sinai and Kessler Foundation by 2/15/2013, as requested by the Grant Specialist assigned to the transfer (Josh Disbennett). Details of exchanges between Kessler Foundation and the sponsor through 6/30/2013 are given in the previous Quarterly Report, dated 7/10/2013. As of 7/23/2013, we were informed by our project officer (Patricia Henry) that the transfer had been recommended for approval by her, by the safety office, and by the Grants Officer Representative, and was in the queue of our contract specialist (Margaret Lesnow, at that time) for modification of the assistance agreement. On 7/29/2013, we were informed by Josh Disbennett that he had been re-assigned to serve as contract specialist for the transfer. We revised the budget forms and provided additional documentation requested by Mr. Disbennett, and submitted these items on 8/16/2013. Approximately one month later (9/17/2013), we were informed that budget items were under review by our project officer, after which they would be sent to the program manager for approval. On 9/24/2013, we were informed by our project officer that the program manager had recommended approval of the transfer, and that the contracts officer would modify the contract and then forward to the legal department for review. That same day, a request for additional documentation related to Kessler Foundation's corporate status was requested by Josh Disbennett. As of the end date of this annual reporting period (9/29/2013), that documentation was being prepared by the Kessler Foundation. Thus as of 9/29/2013, transfer of the grant from Mount Sinai to Kessler Foundation remained in process.

As described on the project's current Statement of Work, two tasks were to have been addressed during the current reporting period. Progress related to each task through 9/29/2013 is described below.

Statement of Work - Task 1: Preparations - Obtain Regulatory Approvals at All Sites.

IRB applications were submitted at all sites (Mount Sinai, Kessler Foundation, Shepherd Center, and the East Orange Campus of the VA New Jersey Health Care System). Institutional Review Board (IRB) approval was granted by all local site IRBs. Applications for each site were submitted to the Human Research Protection Office (HRPO). Initial review of all applications by HRPO was completed by Melanie Frank. Ms. Frank informed us that all requirements for HRPO approval of the project at Kessler Foundation were met, and that the activities to take place at Mount Sinai post-transfer would no longer be considered human subjects research. Ms. Frank notified Dr. Zanca that final HRPO approval to initiate human subjects research activities at Kessler Foundation would be given upon receipt of a letter from the Mount Sinai IRB documenting its determination that activities to take place at Mount Sinai post-transfer would be considered Not Human Subjects Research (NHSR).

Dr. Zanca was informed by the Mount Sinai IRB that the required NHSR letter could not be provided until Mount Sinai received documentation of the grant's transfer to the Kessler Foundation. Since the transfer had not yet been approved as of 9/29/2013, final HRPO approval to begin human subject research activities remained pending as of the end of this reporting period.

Statement of Work - Task 2: Complete Project Phase I - Content Identification

Content identification for the proposed assessment tool was to have begun in April 2013, with recruitment of participants whose rehabilitation charts could be reviewed to identify goals and performance criteria related to self-direction of care and caregiving. However, as described above, HRPO approval to commence human subject research activities had not yet been provided because the grant transfer had not yet been approved as of 9/29/2013. Thus, Task 2 could not begin.

Our request for transfer of the grant from Mount Sinai School of Medicine to Kessler Foundation has been in process for approximately 8 months as of the end date of the current reporting period (9/29/2013). Once we receive notification of the transfer's approval, we will immediately notify our HRPO reviewer so that the process of obtaining HRPO approval may be completed. We will also communicate with our project officer after approval of the transfer to discuss the impact of the lengthy transfer approval process on the completion of data collection and instrument development activities.

We will make every effort to conduct activities as efficiently as possible once the grant transfer is approved to recover lost time due to the delayed transfer. However, we anticipate that it will be difficult to accomplish tasks in the timeframes proposed in the Statement of Work that was submitted in support of the transfer request. If deemed appropriate, we may request to modify the proposed schedule of activities at a later time, in consultation with our project officer and with approval of the sponsor.

KEY RESEARCH ACCOMPLISHMENTS

- Local IRB approval obtained at all sites (Kessler Foundation, Mount Sinai, Shepherd Center, East Orange Campus of the VA New Jersey Healthcare System)
- Initial review of HRPO applications for all sites is complete; final approval to commence human subject research activities to be given after completion of grant transfer

REPORTABLE OUTCOMES

Preparations for data collection are underway and there are no reportable outcomes at this time.

CONCLUSIONS

All local site IRBs have given approval for human subjects research activities associated with the project and approval from HRPO will be provided following approval of the transfer of the grant from Mount Sinai School of Medicine to Kessler Foundation.

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APPENDICES

None

SUPPORTING DATA

Not applicable at this time.