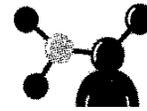


PATIENTS PILOT PROJECT APPLICATION

PATient-centered Involvement in Evaluating the effectiveNess of TreatmentS



PATIENTS
engaged in research

Application Title: After Spinal Cord Injury: Empowering Patient Directed Care during Transition from Rehabilitation to Community

Principal Investigator: Paula Richley Geigle PT PhD

Principal Investigator Qualifications:

I am a senior research physical therapist with expertise in aquatic therapy, spinal cord injury, and epidemiology, and hold an adjunct appointment as Assistant Professor in Neurology at the UMSOM. My doctoral education prepared me to utilize both qualitative and quantitative research methodologies (dissertation: What do physical therapy educators define as clinical decision-making, and how are the definitions evidenced in their teaching?) and my post-doctoral experience added clinical epidemiology and biostatistics training. As a co-PI with Dr. Gorman, and with this application's co-investigators, I recently completed a 4 year, DOD sponsored randomized crossover clinical trial of aquatic therapy vs. robotic assisted therapy in persons with motor incomplete spinal cord injury. In addition, my 33 years of clinical practice provides me with insight into the challenges individuals with SCI/D face as they attempt to transition to community living.

Co-investigator(s): Peter Gorman MD, Henry York MD, Sara Kate Frye MS, OTR/L

Co-investigator(s) Qualifications: Dr. Peter Gorman is Associate Professor in the Department of Neurology, UMSOM and Chief, Division of Rehabilitation Medicine at UM Rehab and Ortho Institute. Dr. Henry York is Associate Professor in the Department of Neurology, UMSOM and Director of the Spinal Cord Injury Unit at UM Rehab and Ortho Institute. Both physicians are board certified in their respective fields (Neurology and Physiatry) as well as in Spinal Cord Injury (SCI) Medicine. Their collective clinical practice encompasses 39 years of capably and compassionately offering care to people with spinal cord injury and dysfunction. Dr. Gorman held PI roles on multiple federally funded and industry funded clinical trials in SCI. Dr. York also participated in clinical trials, and both faculty presented this work at numerous national meetings and published in peer-reviewed journals. Recent studies focused on the use of robotic treadmill training in motor incomplete SCI, the comparison of robotic and aquatic therapy, and the use of acupuncture for neuropathic pain in those with SCI. Ms. Frye is an Occupational Therapist and clinician/researcher with advanced training and experience in qualitative research methodology. Sara's clinical skills superbly incorporate expertise and a true willingness to include each client in his/her rehabilitation plan. All three of these co-investigators demonstrate the ability to acquire, execute and publish research results, but personal client connection drives their' ability to conduct meaningful patient centered outcome research.

Relevance and Future Goals: Using no more than three sentences, describe the relevance of this pilot project to the PATIENTS infrastructure building and/or training activities. In this section, be succinct and use plain language that can be understood by a general, lay audience.

The transition from acute inpatient rehabilitation to community living for persons with new spinal cord injury/dysfunction is challenging, with current practice offering little support after discharge, leaving patients unprepared to self-manage their care. During this transition, complex individual patient needs mandate an individualized approach based on multi-faceted guidance from patients, informal caregivers, and specialty providers with particular regard to how health disparity impacts this transition period. To effect system-wide improvement, we will utilize PATIENTS funded focus groups and other activities (delineated in the "Aims" section) to optimally direct an externally funded multi-center research comparative study of novel interventions aimed at improving transition outcomes.

Estimated Budget: Using the space below, please detail proposed expenses.

<i>Item</i>	<i>Amount</i>	<i>Brief Justification</i>
Consults – Statistical & Technical	\$████	Statistician to evaluate design and data analysis - (3 hrs @ \$████ per hr) = \$████ Technology consult to inform potential intervention for next phase protocol development - (3 hrs @ \$████ per hr) = \$████
Focus Group Expense – Leaders & Transcription	\$████	Focus group leaders trained in qualitative data collection and analysis – (1.5 hrs @ \$████ per hr for 6 FGs) = \$████ Professional academic transcription service to ensure data consistency and ethical handling – (\$████ per min. for 6 75min. FGs) = \$████
Participant honorariums – Focus Group s and Advisory Board	\$████	Honorariums to compensate patient and community member participation in Focus Groups – (\$████ to 5 pts each at 6 FGs) = \$████ Honorariums to compensate patient and community members of Research Advisory Board – (\$████ to 2 members each at 6 Board meetings) = \$████
Personnel: Research Coordinator –	\$████	Manage communications; organize FGs including space, recording, participants, honorariums; manage human research protections; manage budgets; recruit and enroll members; support reporting and proposal development – (< 4% FTE + 30% fringe)
Total	\$4,975	

Overall Patient Centered Research Goal: The overall goal of this research is to improve the transition from inpatient rehabilitation to community living for people with newly acquired spinal cord injury (SCI/D) or dysfunction. Our plan is to develop a patient, caregiver, and service provider centered structure to identify problems, barriers, and resources currently existing with a particular regard to existing health disparities. Three focus groups at our rehabilitation center and another center will gather information regarding transition to the community from individuals living with SCI/D, family and care givers, and resource/service personnel. The groups will provide their understanding and life experiences, to augment current rehabilitation center discharge to community living practices. After successful completion of this pilot work, we will develop a hypothesis driven protocol comparing the outcomes of novel method(s) of improving this transition in comparison with standard care. This work will require expansion of our existing partnerships with local, regional, and national patient communities, healthcare systems, and resource agencies. We will apply for external funding (PCORI, or possibly other sources such as DOD, Neilsen Foundation, PVA) to rigorously investigate potential best practice transition options. Ultimately, we hope to better inform patient-centered health care decision making as well as healthcare system standard of care for individuals transitioning to community living after spinal cord injury.

PATIENTS Pilot Aims:

Aim 1. Identify and develop new community partners and expand existing relationships to better understand the needs of individuals after experiencing spinal cord injury/dysfunction (SCI/D). Specifically we plan to increase family member, spiritual, community support (Maryland State Department Education Division of Rehabilitation Services (DOR), Baltimore Adapted Recreation and Sports), and specialty care providers such as urology and mobility system specialists.

Hypothesis 1. Our current SCI/D support group participants and service providers are willing to provide their input. However a more diverse group will provide more comprehensive understanding of transition from rehabilitation to community during the first year after SCI/D.

Aim 2. Complete a total of 3 focus groups at 2 regional rehabilitation centers to gather input from patients, family and caregivers, and community service providers regarding the transition from rehabilitation to community during the first year after SCI/D.

Hypothesis 2. This focus group information will direct the proposal development for a funded comparative trial to gather patient centered outcome data comparing methods for facilitating the transition from rehabilitation to community during the first year after SCI/D.

Aim 3. Consult an advanced statistics group to assist with designing a study to insure the best use of patient centered data and time.

Hypothesis 3. A multiple site and arm proposal will require advanced statistical guidance to develop a research plan optimizing the time and energy of patients, clinicians, family members, and community support providers.