“TeleWellness Solutions for Chronic Conditions”

Submitted by:
Andrea Fairman, MOT, OTR/L, CPRP
Assistant Professor & Academic Fieldwork Coordinator
Occupational Therapy Program

A. ABSRACET:

This proposal describes a request for travel reimbursement and time spent conducting usability testing on an innovative software product called “TeleWellness Support Systems.” In 2010, colleagues, Andrea Fairman and Brad Dicianno formed a company called UbiCue, Inc. At this time the concept for a software system that would allow clinicians to remotely monitor and triage a patient population through use of smartphone applications was just beginning to evolve. Working toward this concept, in 2011, a secure portal system, called iMHere, was created. This system interfaces with a suite of specialized applications (also known as “apps”) uniquely designed for persons with spina bifida (SB). Now in 2012, clinical testing is underway to determine the clinical efficacy of using this system with a patient population of persons with SB and spinal cord injury (SCI). The aim is to determine whether this unique approach using technology to help persons manage self-care tasks will improve wellness by reducing preventable secondary conditions such as pressure ulcers and urinary tract infections. The next steps will involve expanding usage of the system to other institutions and populations. Extensive usability testing has been conducted during the design process with the SB population to refine the apps in order to best meet their needs from a cognitive, sensory and physical accessibility perspective. However, the system has not yet been tested with clinicians outside of the University of Pittsburgh Medical Center (UPMC). As we work toward commercialization of this innovative software product, we recognize the need to gather feedback from other clinicians who are likely to use such a system in clinical practice. Understanding the perceptions of clinicians outside of the UPMC system will allow us to gather information regarding workflow design issues as well as integration with various types of Electronic Medical Record (EMR) systems.

Funding provided by this grant request would specifically be utilized for Andrea Fairman’s time and travel to multiple medical centers providing clinical care to individuals with SB & SCI. Time while at these institutions will be spent gathering feedback from clinicians, such as nurses or case managers, likely to utilize the system through a formal usability testing process. Involvement of at least four institutions with representative clinicians, and up to 16 of these clinicians’ patients, in the usability testing process will best simulate clinical scenarios possibly encountered while using the system. Projected institutions include, but are not limited to:

- Children’s Hospital of Philadelphia, PA
- Children’s Hospital of Pittsburgh, PA
- Kennedy Krieger Institute, Baltimore, MD
- Rehabilitation Institute of Chicago, IL

The result will be the potential commercialization of this innovative software system to serve persons with chronic conditions and disabilities. Publications to peer-reviewed journals and proposals for presentations at national conferences will be submitted as hosted by the American Telemedicine Association (ATA), The American Occupational Therapy Association (AOTA) and the Rehabilitation Engineering Society of North America (RESNA).
B. NARRATIVE:

This proposal describes a plan to further develop a telemedicine portal [FIGURE 1 & 2] linked to smartphone applications [example - FIGURE 3] that enable clinicians to remotely monitor and triage the self-care activities of patients using a secure, two-way-communication system. The system supports the consistent performance of self-care tasks and routines via customizable apps serving as cues or reminders throughout the patients’ daily routines. By entering information into the apps, patients easily alert their clinicians and caregivers when potential problems arise (e.g. possible urinary tract infection), report specifics about their medical problems (e.g. size of a pressure ulcer), ask questions, refill medications, make appointments, or seek medical advice. This secure portal system uses a proactive approach to encourage improved self-management of chronic conditions with the apps aiding as cognitive orthoses to assist with memory and organizational skills. The system also alerts clinicians immediately when gaps in care arise (e.g. medications have not been refilled). By reviewing data collected by the apps and organized by the portal, clinicians can monitor the self-care activities being completed by numerous patients simultaneously. Clinicians receive alerts when there are potential problems allowing for the cost- and time-effective triage of large groups of patients. As a result, clinicians are able effectively utilize their time and skills to intervene quickly before more severe problems arise.

Pilot work has resulted in the development of an initial series of apps (medication management, urinary care, bowel management, mood tracking, and skin/wound care) designed for individuals with spina bifida, along with a preliminary portal providing clinical access to data from the apps. This proposal addresses evaluating the system with additional diagnostic groups, and evaluation of the portal for use by clinicians. Existing Android apps will be refined, and the portal will be redesigned to implement additional features and a more usable interface for clinicians. Software redesign will be informed by input from clinicians serving individuals with spina bifida and spinal cord injury at four institutions. Ongoing feedback regarding the design of the portal and apps will be elicited from a panel of consultants, and formal usability trials of the portal will be conducted with clinicians in a four-stage iterative design process. The final version of the apps will also be evaluated in usability trials with 16 individuals with disabilities, including both spinal cord injury and spina bifida. Data from usability trials for clinicians and people with disabilities, including user performance and user ratings, will be evaluated against benchmarks for success.

Following usability trials, a design plan will be developed including features to make the final system practical and beneficial in a clinical environment. Goals include ensuring the system is secure and robust for real-world, high-volume deployment; and evaluation of clinical efficacy.

Rationale & Significance
Almost half of all Americans, more than 145 million people, are living with chronic conditions (Kung, et al, 2008). Self-management support is one of the elements of the Chronic Care Model (Wagner, Austin & Von Korff, 1996) adopted by the World Health Organization (2002) as the basis of a framework for chronic care utilizing a preventative rather than reactive approach. Rather than responding mainly when a person becomes sick, interventions are proactive and focus on maintaining health and wellness. There are six principles of self-management: 1) Have knowledge of your condition, 2) Follow a treatment plan agreed upon with your health professionals, 3) Actively share in decision making with your health professionals, 4) Monitor and manage signs and symptoms of your condition, 5) Manage the impact of the condition on your physical, emotional and social life and 6) Adopt lifestyles that promote health. (Battersby, et al 2003). Current evidence suggests that patients with effective self-management skills make better use of health care services and have enhanced self-care (Lorig, et al., 1999). The primary objective of developing self-management skills in persons with chronic conditions, such as spina bifida, is to enable them to be actively involved in the center of their own health care in order to maximize their quality of life. Self-management involves the person “… engaging in activities that protect and promote health, monitoring and managing symptoms and signs of illness, managing the impacts of illness on functioning, emotions and interpersonal relationships and adhering to treatment regimes” (Gruman & Von Korff, 1996, p.1). Self-management also involves health care professionals in enabling individuals to “… make informed choices, to
adapt new perspective and generic skills that can be applied to new problems as they arise, to practice new health behaviors, and to maintain or regain emotional stability” (Lorig, Mazonson & Holman, 1993).

Spina Bifida (SB) is the most common permanently disabling birth defect, affecting over 100,000 Americans (SBAA, 2010). With advances in medical care, persons with SB are living longer, in fact, 85% live well into adulthood. The lack of self-management skills or inconsistent adherence to self-care routines, such as daily skin checks of insensate areas of the body, can quickly result in serious secondary medical issues for persons with SB. Cognitive impairments related to hydrocephalus often present challenges in independently carrying out routine self-care tasks for persons with SB. However, with the development of self-management skills and appropriate support many of these young adults are capable of living healthy, productive lives while residing in the community. Researchers have documented the need for increased self-management in youths with SB (Hayden et al. 1979), especially given reduced autonomy and decision-making skills which have been observed in adolescents of this population (Monsen, 1992). A pattern of dependent behavior by adolescents with SB on their parents have been observed in areas where peers have developed independent skills such as bowel management and home responsibilities (Blum, et al, 1991). Likewise, Davis and colleagues (2006) discovered delays of 2-5 years in overall autonomy and self-care skills in teens with SB through a retrospective chart review study. Sawin and colleagues (2009) note: “enhanced self-management is critical to improve the health status and quality of life” in persons with spina bifida (p. 28).

The SB and SCI populations were selected for this study due to the need to establish effective self-management strategies as well as the nature and complexity of these diagnoses which creates an opportunity for the development of a unique intervention using telerehabilitation delivery methods for on-going supports. Self-management of spina bifida varies according to the needs of the individual. The tasks and activities that many persons with spina bifida need to perform on a consistent basis to maintain health and wellness include: medication management, bowel and bladder routines, skin care, exercise, nutrition and fluid intake, health care visits and mental health maintenance. Lack of adherence to self-care routines and healthcare recommendations can quickly lead to a decline in health status and development of secondary conditions such as pressure ulcers and urinary tract infections (UTIs). While SB presents a particular need to foster and support self-management, these skills are important for anyone living with a chronic condition. This proposal seeks to expand pilot work performed for the SB population to other diagnostic groups. This will begin by exploring and applying this approach to the SCI population, where people have similar health care needs (e.g. monitoring skin integrity and bladder and bowel function) but a distinct range of physical and cognitive abilities and backgrounds. Together persons with SB and SCI, total nearly 1.4 million people in the US with these conditions. Expansion to additional populations will be explored at a later date, including Multiple Sclerosis, Autism spectrum disorders, and traumatic brain injury.

Increasing knowledge of one’s health status is one method of intervention. The more comfortable persons are in their health knowledge and ability to carry out tasks the more likely they are to believe that engaging in such activities will result in desired outcomes (Nodhturft, et al, 2000). Therefore, a self-management support system which increases comfort and self-confidence through a usable interface, appropriate feature set, and secure communication with a health care provider could have a significant impact on the abilities of people with chronic disabilities to manage their health care.

Innovation
To support self-management, a mobile clinical IT solution is proposed that enables clinicians and caregivers to monitor and communicate with patients in real-time, and track the patients’ self-care activities. This software platform provides interventions when and where needed by using commercially-available smartphones. Smartphone applications remind patients of important events to maintain health and wellness, including medications, appointments, and self-care activities. Patients in turn are able to communicate back to their clinicians and caregivers via a secure, HIPAA compliant portal system. The combination of interactive, real-time medical monitoring with patient self-care offers a powerful,
unique solution for patients living with chronic illnesses and complex medical conditions, where cognitive as well as physical disabilities present significant barriers to effective self-care.

The solution has been built on a Software-As-A-Service (SaaS) infrastructure called iMHere developed by the University of Pittsburgh’s Rehabilitation Engineering Research Center (RERC) on Telerehabilitation. The iMHere platform allows data captured on a wireless device such as a smartphone to be transmitted to a clinician or caregiver who monitors this information on a Web Portal in real-time and can in turn respond to patients’ needs instantaneously. The transmitted data are secure, archived, and sent via standard messaging communications protocols. Multiple applications have been developed on the platform, including:

1. **MyMeds - Medication Management**
2. **TeleCath - Self-Catheterization & urinary tract infection detection**
3. **BMQ's - Bowel Management**
4. **MyMood - Depression symptom detection and tracking**
5. **SkinCheck – Skin self-exam reminders, pressure ulcer detection and wound tracking**

The iMHere smartphone applications can work when connected to the Portal, or in an off-line mode, when Wi-Fi/internet connectivity is not available. Communication security is provided via SSL, and each mobile device is individually authenticated using the device ID. Additional security capabilities allow data to be erased or locked remotely, in the event of device loss. The current set of applications has been developed for Android devices.

Mobile phones can serve as an ideal platform to deliver self-management applications due to their ubiquitous characteristics and pervasiveness. Mobile cellular technology has been rapidly adopted technology with over 4.6 billion subscribers utilizing basic mobile services (i.e. mobile telephony and SMS) (ITU, 2009). Likewise, research conducted within our own geographic region specific to adults with SB shows that over 68% utilize cell phones (Dicianno, et al., 2009). Smartphones facilitate the potential adoption of new mobile applications. In addition, the rapidly evolving technologies used for mobile phones, namely smartphone applications (“apps”) increase the potential of mobile phones by allowing for the unique development and customization by facilitating ideal functions for persons with chronic disabilities.

Initial usability testing was conducted during summer 2011 through spring 2012 to evaluate usability of the applications with young adults with SB. This testing allowed for the refinement of the applications to meet unique needs of persons with cognitive, sensory and motor limitations. This testing is being completed with funding support from the National Institute of Disability and Rehabilitation Research (NIDRR) and the Verizon Foundation provided as a grant to the University of Pittsburgh. Six individuals with spina bifida completed this usability study. Three participants (2 male 1 female, ages 22-30) evaluated the MyMeds, TeleCath, and BMQ’s apps, and three distinct participants (2 male 1 female, ages 32-35) evaluated the MyMood and SkinCheck apps, as well as a nutrition app. Subjective self-report measures were gathered using the IBM Post-Study Usability Questionnaire (PSSUQ; Lewis, 1993). The PSSUQ is primarily a close-ended questionnaire that has been found to be both a valid and reliable instrument for usability testing. The scale has been adapted slightly to meet the needs of this usability study, but continues to use a 7-point likert scale format, with scores closer to 1 indicating a more positive opinion of the system. Scores were averaged across participants for each PSSUQ question, and the range of scores across 12 questions is provided for each app. Based on participant feedback and researcher observations, five apps were revised (with major revisions of the MyMed and MyMood apps) and evaluated in a second round of usability trials. Although the nutrition app received high scores for usability, it was determined that, as written, it does not provide the intended clinical function for the user population. The nutrition app is undergoing more extensive revisions and will be incorporated at a later stage of development.

**Approach**

Preliminary work has resulted in an initial version of the iMHere system, including extensive usability testing by people with spina bifida (SB). The goals of this research effort will be to evaluate the clinical efficacy of this system for a range of chronic disabilities, considering clinical efficacy and usability for people with disabilities and clinicians in the context of real-world use and real-world medical infrastructures. The goals of this proposal will be to (1) determine the feasibility
of expanding the user group for this system to other diagnostic groups by evaluating the usability and desirability of the system for people with SCI and clinicians serving this population; (2) determine the feasibility of introducing this system into real-world clinical contexts by evaluating the necessary features of the system with clinicians serving people with SB and SCI and (3) evaluating the usability of the clinician portal. These goals will be pursued through a 4-cycle iterative design process informed by feedback from consultants serving people with SB and SCI and the results of usability tests involving clinicians and people with SB and SCI.

Consultant Feedback
Design of the prototype will be informed by consultants with expertise in the clinical care of people with SB and SCI at Kennedy Krieger Institute, Rehabilitation Institute of Chicago, and Children’s Hospital of Philadelphia, as well as the University of Pittsburgh and University of Pittsburgh Medical Center. We will initially meet with these consultants to determine the list of features which the clinician portal should include, including such issues as patient confidentiality, clinical workflow, and compatibility with electronic medical records. The results of these interviews will be analyzed to determine consistent themes. Resulting features will be evaluated to determine which can be implemented and which can be represented in the user interface without being functionally implemented.

After each iteration of the prototype, screen designs will be reviewed with consultants prior to software implementation. In addition, the prototype user interface will be informally evaluated by the consultants prior to formal usability tests, to determine whether any issues need to be addressed prior to the usability trials. The final prototype will be evaluated by our consultants to determine whether it addresses the key functional and usability features needed for a practical clinical solution.

Refine the Clinician Web Portal
The clinician web portal developed in pilot work provides a view of data entered into the apps. Additional features will be incorporated to support clinical activities. Three principal features are planned. First, the portal will be revised to support more communication from the clinician to patients, including the ability of the clinician to trigger or schedule alerts which the patient will receive on his or her smartphone, as well as supporting real-time communication (e.g. phone calls). Second, features will be added to allow the clinician to record activities taken in response to the app data outside the apps themselves (e.g. scheduling an in-person appointment, changing the frequency of an exercise regimen). Third, features will be added to allow the clinician to track his or her time spent on remote clinical care for the patient. In addition to these features, other features may be added in response to feedback from our consultants and, following early iterations of the user testing, feedback from usability test participants. Finally, the portal user interface will be redesigned for improved usability and ease of use.

Partners:

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<tr>
<th>UbiCue, Inc.</th>
<th>University of Pittsburgh</th>
<th>Philadelphia University</th>
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<tr>
<td>Edmund Lopresti, PhD – Principle Investigator, Software Engineer</td>
<td>Brad Dicianno, MD – Principle Investigator, Physiatrist</td>
<td>Andrea Fairman, MOT, OTR/L, CPRP – Co-Investigator, Clinical Consultant</td>
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<tr>
<td>Jason Baim, MBA – Product Commercialization</td>
<td>Bambang Parmanto, PhD – Co-Investigator, Informatics</td>
<td>Gede Parmana, MS, Software Developer</td>
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<td>Gede Parmana, MS, Software Developer</td>
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Recruitment Sites—Sites who will identify the testers

- University of Pittsburgh Medical Center (UPMC)
- Rehabilitation Institute of Chicago (RIC)
- Children’s Hospital of Philadelphia (CHOP)
- Kennedy Krieger Institute (KKI)
- Children’s Hospital of Pittsburgh (CHP)

Andrea has been involved in the on-going development of this technology for her dissertation research at the University of Pittsburgh since its inception. She has served in providing clinical guidance to create the apps and portal described. Currently, Andrea is conducting a randomized clinical trial (RCT) with the spina bifida population to determine the efficacy of use of this system in clinical practice. The potential to successfully commercialize the software system not only has considerable promise for changing the way clinical interventions are delivered, but also will launch Andrea’s career in research as well as an entrepreneur through the business aspect of project.

Attachments:

I. Figures
II. Timeline
III. CV / Biosketch
IV. Budget
V. References
I. FIGURES:

Figure 1: iMHere Application Start Screen and Web Portal

Figure 2: Skin Check Application on Portal with Input from Wound Checking

Figure 3: Skin Care Mobile Application
II. **TIMELINE**—targeted completion date: June 30, 2013

| Activity                  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 |
|---------------------------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Consultant Feedback       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Refine Web Portal         |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Usability Testing         |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Refine Patient Apps       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Evaluate Benchmarks       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Phase II System Plan      |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
III. BIOGRAPHICAL SKETCH

NAME
Andrea D. Fairman, MOT, OTR/L, CPRP

POSITION TITLE
Assistant Professor, Department of Occupational Therapy
– Philadelphia University
Adjunct Faculty Member & PhD Candidate – University of Pittsburgh

eRA COMMONS USER NAME
fairman

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)

<table>
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<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE</th>
<th>YEAR(s)</th>
<th>FIELD OF STUDY</th>
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<tr>
<td>Duquesne University, Pittsburgh, PA</td>
<td>BS</td>
<td>Aug 1995 - May 1999</td>
<td>Health Sciences</td>
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<td></td>
<td>MOT</td>
<td>June 1999 - May 2001</td>
<td>Occupational Therapy</td>
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<td></td>
<td></td>
<td>Aug 2003 - Jan 2007-potent</td>
<td>Rehabilitation Science and Technology</td>
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Professional Certifications

Licensure: 2001 – present
Pennsylvania OT- License #: OC008195

Certification: 2001- present
# 1056812, National Board Certification (NBCOT)

Certification: 2002 - present
# 158643, Certified Psychiatric Rehabilitation Practitioner

A. Personal Statement
Ms. Fairman has been a practicing occupational therapist for over 10 years and has almost 20 years of experience working in human services. The majority of her clinical work has been based in non-traditional community settings. Program development and funding procurement has been the common thread in the various positions she has held. Ms. Fairman served as Executive Director of the Spina Bifida Association of Western Pennsylvania where she designed and implemented several new community-based programs, including the original in-person Wellness Program which was funded by the Highmark Foundation. This program has served to provide the pilot data to launch several others, including this research project. Andrea has also served on panels and workgroups for several national organizations including the Centers for Disease Control (CDC) and the National Spina Bifida Association, as well as local organizations. Her research interests include developing interventions to decrease the functional impact of cognitive impairments in persons with disabilities specifically: traumatic brain injury, spina bifida, autism spectrum disorders, schizophrenia and other psychiatric and cognitive disabilities. Ms. Fairman is interested in developing innovative intervention strategies which include use of assistive technology and delivery of services using telerehabilitation practices. For this research project, Andrea has been involved in the research design and development process. If this grant is awarded, she will be directly involved in subject recruitment, testing, analysis and publication of the results as well as future research initiatives.

B. Selected Research and/or Professional Experience

01/12 – Present
Assistant Professor & Academic Fieldwork Coordinator, Philadelphia University, Department of Occupational Therapy

08/09 – Present
Adjunct Faculty Member, University of Pittsburgh, Dept. of Rehabilitation Science & Technology

08/08 – 08/09
Graduate Student Researcher, University of Pittsburgh, funded through NIDRR for the RERC-TR and Integrative Graduate Education & Research Traineeship (IGERT)

07/05 – 08/08
Executive Director, The Spina Bifida Association of Western Pennsylvania

01/06 – 12/08
Adjunct Faculty Member, Duquesne University, Department of Occupational Therapy
08/04 – 06/05  Graduate Assistant, Duquesne University, Department of Occupational Therapy
02/02 – 01/12  Home Health / School-based Occupational Therapist, AOT, Inc.
05/01– 07/07  Mobile Therapist / Behavioral Specialist Consultant, part-time, Family Counseling Center of Armstrong County (FCC), a community mental health center and Base Service Unit (BSU)
04/03 – 06/05  Clinical Supervisor - Regional Autism Director, full-time, Family Behavioral Resources, Inc.
05/01 - 04/03  Certified Psychiatric Rehabilitation Specialist (CPRP), full-time, FCC
05/01 - 08/03  Health & Wellness Camp Clinical Supervisor, part-time, FCC

Professional Societies

Membership, American Telemedicine Association (ATA)
Membership, Rehabilitation Engineering and Assistive Technology Society of North America (RESNA)
Membership, American Occupational Therapy Association (AOTA)
Professional Member, United States Psychiatric Rehabilitation Association (USPRA)

C. SELECTED PEER-REVIEWED JOURNAL ARTICLES:

IV. GRANT BUDGET FORM

**Personnel:**
Faculty Stipend: $2,000.00
(Up to $2,000 per faculty member only available for the summer)
(Please do not include travel on this line. Travel should be listed below.)

**Supplies, software, other:** Please describe.
Atlas.ti Qualitative Research software
powerful and sophisticated qualitative analysis tool

$625.00

**Travel:** Please list destination and cost.
- Rehabilitation Institute of Chicago $1,500.00
- Kennedy Krieger Institute, Baltimore, MD 650.00
- Children’s Hospital of Pittsburgh, PA 50.00
- Children’s Hospital of Philadelphia, PA 50.00

**TOTAL BUDGET REQUESTED:** $4,875.00
(Maximum $5,000)
V. REFERENCES:


