Past Projects

PROsIT: A Total Patient-Reported Outcomes Solution (Phase I)

Project ID	1 R43 MH069169			
Sponsor	National Institute of Mental Health			
Project Period	9/15/2003 - 3/31/2004			
Funding Level	$107,000			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Chih-Hung Chang, PhD	Northwestern University	Assist. Professor
	Investigator	Joshua M. Hauser, MD	Northwestern University	Instructor
Clinical Site	AIDS Clinical Trial Unit, Northwestern University			
Subjects	30			

Abstract

The PROsIT Project seeks to promote the use of Patient-Reported Outcomes (PROs) in both clinical and research practices for AIDS by developing and commercializing a comprehensive, practical and integrated system for PROs management with crossdiscipline efforts. It offers innovative solutions to user accessibility and item bank management issues.

The specific Phase 1 aims are to: 1) develop the prototype of an Item Response Theory (IRT)-based adaptive PROs assessment engine supporting access from both web and phones; 2) elicit system requirements from both patients' and physicians' perspectives; and 3) identify potential system usage barriers in clinical settings.

This study extends from our earlier work on computerized outcomes solutions for AIDS and cancers. The FAHI questionnaire will be used. Focus group discussions with physicians and patients and face-to-face interviews with pilot-testing participants will be conducted to evaluate system usability and usefulness, refine requirements, and identify potential barriers.

PROsIT is a generic outcomes collection, analysis and reporting solution applicable to AIDS and other diseases. It enables researchers to further understand the strengths and limitations of PROs in helping clinical decisions by reaching to a broader patient base. It also has wide-ranging applications for pharmaceutical companies, hospitals, insurers, and government agencies and accreditation organizations.

PROsIT: A Total Patient-Reported Outcomes Solution Phase II

Project ID	2 R44 MH069169			
Sponsor	National Institute of Mental Health			
Project Period	7/19/2005 - 7/18/2008			
Funding Level	$736,813			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Perry Nicassio, PhD	UCLA	Clinical Professor
	Co-PI	John Flaherty, MD	Northwestern University	Professor
	Investigator	Robert Murphy, MD	Northwestern University	Professor
	Investigator	Sarah Sutton, MD	Northwestern University	Assist. Professor
	Investigator	Richard Novak, MD	University Illinois at Chicago	Professor
	Investigator	Jonathan Uy, MD	University Illinois at Chicago	Assist. Professor
	Consultant	Lawrence Lin, PhD	Baxter Healthcare Corp.	Baxter Res. Scientist
	Consultant	Michael Kallen, PhD	Baylor College Medicine	Assist. Professor
Clinical Site	AIDS Clinical Trial Unit, Northwestern University Department of Infectious Diseases, University of Illinois at Chicago			
Subjects	450			

Abstract

The PROsIT Project seeks to promote the use of patient-reported outcomes (PROs) for HIV-infected patients in clinical settings by developing and commercializing a comprehensive, practical and integrated system for PROs management with crossdiscipline efforts.

In Phase I, we successfully implemented and pilot-tested an IRT-based adaptive PROs assessment engine supporting secure access from both web and phones. Patient and physician surveys showed strong support for our system usability and usefulness, providing early evidence of the commercial viability of our product.

Based on our original long-term goals and the lessons learned from the Phase I effort, our specific

Phase II aims are to: 1) allow the PROsIT System be accessible from Tablet PCs and PDAs; 2) build an HIV-focused item bank; 3) add multi-lingual support to the PROsIT System; 4) assess the value and the practicality of using the PROsIT System in clinical practice; and 5) publish our study results in peer-reviewed journals.

The end result of this project will be a generic multi-platform, multi-lingual adaptive survey system and an HIV-focused item bank that could help promote the use of PROs in routine clinical setting. The study results will also further the understanding of the value of PROs in improving patient care.

Comprehensive PRO Management for Oncology Practice: Phase I

Project ID	HHSN261200544014C			
Sponsor	National Cancer Institute			
Project Period	9/01/2005 - 3/02/2006			
Funding Level	$100,132			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Chih-Hung Chang, PhD	Northwestern University	Assist. Professor
	Investigator	Charles Bennett, MD	Northwestern University	Professor
	Investigator	Madelyn Iris, PhD	Northwestern University	Assoc. Professor
Clinical Site	Lynn Sage Breast Cancer Center, Northwestern Memorial Hospital Comprehensive Breast Cancer Center, Rush University Medical Center			
Subjects	26			

Abstract

Despite the abundant research in patient-reported outcomes (PRO) for cancer, PRO data are not routinely collected and utilized at oncology clinics due to technological and logistical constraints and lack of knowledge in interpreting, monitoring and responding to such data. Our long-term goal is to integrate patient-reported outcomes information, clinically relevant information, evidence-based medicine, and technology and methodology to provide on-demand and individualized clinical guidelines and treatment decision trees to improve cancer patients' care.

Our Phase I project aims are to (1) conduct focus groups, interviews and site visits to collect system functional and operational requirements; (2) perform literature reviews to assess scientific and technical feasibility; (3) create system design specifications; (4) develop and pilot test a prototype system; and (5) construct the initial PRO item bank focusing on breast cancer.

The proposed PRO management system is designed for both oncology clinicians and patients. The novelties are in the integration of well-developed psychometrics and advanced information technologies for daily practice and research application in clinical settings. With existing and increasing numbers of cancer patients in the U.S., the need for such an integrated system that we propose to develop is substantial.

Comprehensive PRO Management for Oncology Practice Phase II

Project ID	HHSN261200700046C			
Sponsor	National Cancer Institute			
Project Period	9/30/2007 – 9/29/2010			
Funding Level	$749,917			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Ana Maria López, MD	University Arizona	Professor
	Co-PI	Hannah Linden, MD	University Washington	Assoc. Professor
	Investigator	Linda Larkey, PhD	University Arizona	Professor
	Investigator	Karon Cook, PhD	University Washington	Sr. Res. Scientist
	Investigator	Kendon Conrad, PhD	University Illinois Chicago	Professor
	Investigator	Michael Kallen, PhD	University Texas	Assist. Professor
	Investigator	Perry Nicassio, PhD	UCLA	Clinical Professor
Clinical Site	Arizona Cancer Center, University of Arizona Seattle Cancer Care Alliance, University of Washington (Y-Me National Breast Cancer Organization)			
Subjects	650			

Abstract

The long-term goal of this project is to build a breast cancer-specific patient-reported outcomes (PRO) system that can be integrated into clinical practice and provides clinically relevant analyses and recommendations to clinicians and patients. During our Phase I project, we have produced functional and operational requirements, a working prototype, design and planning documentations, and a pool of breast cancerspecific PRO items.

Our Phase II project aims are to 1) complete system implementation and further refine the system based on user feedback; 2) deploy and test the system in real clinical settings; 3) incorporate PROMIS adaptive PRO instruments into our system with a standardized approach; 4) implement standards-based integration solutions to exchange PRO assessment results with other EMR systems; 5) evaluate benefits of using this system in clinical practice; 6) create user manuals and tutorials; and 7) publish study results in peer-reviewed journals.

This is a novel cancer-specific PRO application addressing issues hindering the utilization of PRO

in clinical practice using well-developed methodology and advanced technology. With existing and increasing numbers of cancer patients in the U.S., the need for such an integrated system that we propose to develop is substantial. This project could also further our understanding and knowledge of the value of PRO for cancer patient care, so that better treatment decisions can be made and resources be better allocated.

Home-Centered Teleoncology Care Model Phase I (2007-2008)

Project ID	HHSN261200700055C			
Sponsor	National Cancer Institute			
Project Period	9/30/2007 – 6/30/2008			
Funding Level	$150,000			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Ana Maria López, MD	University Arizona	Professor
	Investigator	Linda Larkey, PhD	University Arizona	Professor
Clinical Site	Arizona Cancer Center of the University of Arizona			
Subjects	50			

Abstract

The long-term objective of this study is to increases access to care, empowers patient self-management and ultimately delivers better patient outcomes by uniting telemedicine technologies, patient-reported outcomes research and dialogue-based patient-provider communication. The technical objectives for this Phase I proposal are 1) develop a home-centered coordinated cancer care (HC4) model and 2) develop and evaluate a working prototype of a tracking system to monitor and facilitate the delivery of care as specified in the HC4 model.

The HC4 model will be defined from various perspectives including organization, procedure, assessment, clinical and technology. Our approach includes systematic literature review and iterative refinement of the model through discussions and interviews with physicians, nurses, patients and caregivers. The prototype system will be developed following standard object-oriented analysis and design process. Focus groups will be convened to discuss model and system design options. Several controlled pilot test runs will be conducted to gain preliminary evaluation of system design in terms of interface usability and clinical usefulness.

It is expected that Phase I results will validate the feasibility of the proposed system from the perspectives of both practicality and technology for the purpose of Phase II execution and ultimate commercialization.

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Coordinated Cancer Screening and Diagnosis Model Phase I

Project ID	HHSN261200800032C			
Sponsor	National Cancer Institute			
Project Period	9/30/2008 – 12/31/2009			
Funding Level	$149,973			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Ana Maria López, MD	University Arizona	Professor
	Investigator	Linda Larkey, PhD	Arizona State University	Professor
Clinical Site	Arizona Cancer Center of the University of Arizona			
Subjects	54			

Abstract

The long-term goal of this study is to facilitate early colorectal cancer (CRC) detection by developing a care coordination system that will facilitate both screening and diagnostic processes via e-health, telemedicine, clinical decision support, patientreported risk information, patient education, and coordinated care models and technologies. Specifically, we seek to 1) provide alerts to health care providers (HCP) to help them track CRC screening/diagnosis referrals for persons at normal risk and due for screening, and for those at greater risk due to family history or specific signs/symptoms; 2) present just-in-time, individually tailored education instructions to patients based on PRO data; 3) coordinate care team tasks with EMR/telemedicine integration; and 4) coordinate assistance from all support resources, including community health advisors.

This approach is especially important for the Latino population along the US-Mexico border in Arizona, who are often seen in Federally Qualified Healthcare Clinics (FQHCs). The technical objectives for this Phase I proposal are to 1) develop the CRCspecific screening and diagnostic care coordination model via literature review, focus groups, interviews, and a retrospective medical record review of CRC patients; 2) develop a web-based prototype system to facilitate the execution of the CRC screening and diagnosis model; and 3) evaluate the prototype in terms of usability and usefulness.

Collaborative Palliative and Hospice Care Using PRO Phase I

Project ID	HHSN261200800050C			
Sponsor	National Cancer Institute			
Project Period	9/30/2008 – 12/31/2009			
Funding Level	$149,956			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Michael Kallen, PhD	University Texas	Assistant Professor
	Investigator	Eduardo Bruera, MD	University Texas	Professor
	Consultant	Chih-Hung Chang, PhD	Northwestern University	Assoc. Professor
Clinical Site	M.D. Anderson Cancer Center of the University of Texas			
Subjects	45			

Abstract

Our long-term objective is to develop a computer system facilitating the use of patientreported outcomes (PRO) information to monitor patient status and assist clinical decision-making for cancer patients under palliative and \ hospice care. This system will integrate PRO and other clinical data with evidence-based treatment guidelines and pathways to care and interface with and foster collaborative decision-making between the patient, the caregivers, and the medical care team.

This project will leverage the BrightOutcome architecture for PRO management developed in our other SBIR efforts, already implementing CAT/IRT capability, multiple delivery platforms, graphical reports highlighting clinically meaningful PRO score changes, and alert/reminder mechanism.

Considering the project goals and our past and current R&D efforts, we define the specific Phase I technical objectives as follows: 1) Define a palliative/hospice care model to integrate PRO assessment results with evidence-based pathways to care to provide clinical decision support for clinicians and education opportunities for patients and caregiver via literature review, focus groups, and interviews; 2) Design a system architecture facilitating the sharing and transfer of PRO related medical data between cancer clinics, hospices, and patients' homes; 3) Develop a working prototype following object-oriented and knowledge-based software development methodologies; and 4) Evaluate the usability and usefulness of the prototype solution via controlled pilot tests.

It is expected that Phase I results will validate the feasibility of the proposed solution from the perspectives of both practicality and technology for the purpose of Phase II execution and ultimate commercialization.

Defining Interoperability Standards for PRO Assessments (ARRA grant)

Project ID	RC1CA146181			
Sponsor	National Cancer Institute			
Project Period	9/30/2009 – 8/31/2011			
Funding Level	$999,413			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Richard Gershon, PhD	Northwestern University	Director
	Consultant	David Cella, PhD	Northwestern University	Professor
	Consultant	Seung Choi, PhD	Northwestern University	Director
Clinical Site	M.D. Anderson Cancer Center of the University of Texas			

Abstract

There is a growing recognition of the importance of subjective patient-reported outcomes (PRO) in patient care. Several recent studies have observed positive impacts of routine use of PRO assessments in clinical practice, reporting improved physical, functional and emotional well-being, reduced hospitalization, better detections of less observable and subjective PRO concerns, and better patient-provider communication. Recognizing the value and potential of PRO assessments, the NIH is completing a 5- year $25MM Roadmap Initiative, called the Patient Reported Outcomes Management Information System (PROMIS), and in the process of funding the second round of PROMIS research activities. The goal of the PROMIS Initiative is to develop and validate a new set of standardized PRO instruments based on modern computerized adaptive testing (CAT) and item response theory (IRT). A primary benefit, amongst many others, of CAT/IRT-based instruments is that they are dynamically administered, tailored to each individual's past responses, and hence much shorter (i.e., fewer items) but without sacrificing measurement precision.

Parallel to the PROMIS endeavor, enormous interests exist within both the government and the private industry in developing interoperability standards to facilitate data exchange between heterogeneous healthcare information systems; in particular the government's Health Information Technology (HIT) Initiative that heavily leverages existing industry standards. Standardization efforts for the clinical research community are also in progress; most notably by the Clinical Data Interchange Standards Consortium (CDISC). The promotion of electronic medical records (EMR) system by the Administration as part of the healthcare reform effort furthers the cause of data standardization.

Ideally, the vast investment on EMR and data standardization and on PRO-related research such as the PROMIS project should bring the goal of wide adoption of PRO in clinical research and

practice closer to fruition. Unfortunately a major gap still exists to prevent this goal from being achieved, namely the lack of data standardization for PRO instruments and assessment results. There has been no concerted effort to bring the PRO community into any data standardization endeavors. This project thus intends to bridge this gap between the PROMIS Initiative and various standardization initiatives so that the benefits of the PROMIS project and the field of outcomes research in general can be fully realized.

Specifically, this project seeks to a) establish interoperability data standards for patient-reported outcomes (PRO) instruments and assessment results, including both the conventional static PRO questionnaires and the new adaptive item banks from the NIH PROMIS project; and b) develop interoperability reference implementations of these standards demonstrating integration scenarios with open-sourced electronic medical record (EMR) and clinical trial management (CTM) systems.

Health Information Technology to Facilitate Patient-Centered Communication in Cancer-Related Care (Phase I)

Project ID	HHSN261200900044C			
Sponsor	National Cancer Institute			
Project Period	9/30/2009 – 6/30/2010			
Funding Level	$149,992			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Ana Maria López, MD	University Arizona	Professor
	Investigator	Linda Larkey, PhD	Arizona State University	Professor
Clinical Site	Arizona Cancer Center of the University of Arizona			
Subjects	63			

Abstract

Building on top of our success in developing coordinated cancer care systems for patients either during active treatment or during screening/diagnosis processes, we are proposing in this project to focus on helping post diagnosis patients, with a special focus on the period between the diagnosis of ovarian cancer and the start of the treatment. Although this period is relatively short, it is one of the most agonizing, terrifying, and confusing period for cancer patients and their families to deal with. Communication at all levels is needed to help patients understand the disease and the treatment options and understand when and how to ask for help. Clinicians also need communication help to understand the patient's health-related priorities, beliefs, and emotional states to aid clinical decision-making.

From a patient-centered communication perspective, this project will address the topics of fostering healing relationships, exchanging information, responding to emotions, managing uncertainty, making decisions, and enabling patient selfmanagement to various degrees. One novelty of this project is the use of video clips as a major communication media. Videos produced in the local clinic setting showing the providers that patients will interface with can put a more personal touch on the information to be conveyed to patients and could be more effective.

The technical objectives for this Phase I proposal are to 1) develop an ovarian cancerspecific care model (including video scripts) for the period between diagnosis and treatment via literature review, focus groups, and interviews; 2) develop a prototype system (including video production) to deliver this care model and 3) evaluate the prototype in terms of usability and usefulness via pilot test.

Health Information Technology to Facilitate Patient-Centered Communication in Cancer-Related Care Phase (II)

Project ID	HHSN261200900044C			
Sponsor	National Cancer Institute			
Project Period	09/30/2011 – 9/29/2014			
Funding Level	$749,985			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Ana Maria López, MD	University Arizona	Professor
Clinical Site	Arizona Cancer Center of the University of Arizona			
Subjects	108			

Abstract

In 2010, 207,090 new cases of breast cancer and 81,450 new cases of gynecologic cancer will be diagnosed in the United States. From diagnosis onward, communication is essential to high-quality health care. Specifically, research has linked patient-centered communication to higher overall rates of satisfaction and a better quality of life. Thus, improving effective communication could improve the lives of cancer patients. To this end, this project expands the work completed in Phase I through the following aims:

1. Product Development and Refinement: Including a) the implementation of features that were suggested by evaluation subjects and those that were designed but not implemented in Phase I; b) the extension of this model to breast/gynecologic, lung, and other common cancers; c) the integration with different EMR systems; and, d) the usability testing of the prototype.
2. Randomized Control Trial: Conducting a RCT to evaluate the effectiveness of this solution on improving the communication between patients and providers and patients and their support structure, along the six PCC dimensions from Phase I. Examination into whether or not the improvement in communication, if present, can result in tangible benefits to patients, such as better quality of life and functioning, better self-efficacy, and fewer hospitalizations.

Home-Based Cancer Symptom Management (Phase I)

Project ID	1R44CA144322-01			
Sponsor	National Cancer Institute			
Project Period	09/15/2010 – 05/31/2011			
Funding Level	$176,210			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Ana Maria Lopez, MD	UA Arizona Cancer Center	Professor
Clinical Site	Arizona Cancer Center of the University of Arizona			
Subjects	60			

Abstract

Cancer symptoms due to disease progression or side effects caused by cancer treatment are prevalent. Most cancer patients are treated in outpatient settings. Patients may be provided with patient education materials and counseled on anticipated side effects while being provided with different self-management options and warnings regarding when medical care is required. Despite these efforts, many people feel set adrift in having to self-manage treatment and illness related symptoms at home resulting in a sense of burden for the patient and the caregiver, in suboptimal patient reported outcomes (PROs) and in increased healthcare costs due to unnecessary hospitalizations or clinic visits.

The overarching goal of this project is to develop a home-based Cancer Symptom Management Model (CSMM) to promote patient self-management of cancer-related and treatment-related symptoms by facilitating remote management by the clinical care team. The anticipated benefits include improved patient self-reported outcomes, self-efficacy, patient-provider communication, and appropriate utilization of hospital and clinic care.

This work originated from a Phase I SBIR Contract project (HHSN261200700055C) with a similar overall goal of developing a home-based symptom self-management solution with breast cancer patients who used the system to report perceived symptoms and their severity via an interactive internet or phone program. The system employs a rule-based algorithm to evaluate the reported severity and determine whether to offer the patient self-management instructions and/or alert the clinical team to contact the patient for just in time tele-consultation. This multidisciplinary effort includes a team of experts in oncology, nursing, outcomes, telemedicine, psychology, communication, and computer.

Based on our successful experience and the interest in the system from patients with other malignancies as well as from other clinical providers, we built on our pilot data in breast cancer by expanding our study population to include all patients with cancer.

Specific aims are:
Aim 1: Collection and Analysis of System Requirements: conduct focus groups with patients, caregivers, oncologists, and nurses to review the prototype and identify and prioritize means to

enhance content, usability and utility of the prototype.

Aim 2: Design and Development of a Working Prototype: implement user recommendations by modifying the prototype with an object-oriented and user-centric software development process that focuses on iterative design principles involving end-users early and frequently in the design process and begin to develop just in time patient education video clips to convey symptom self-management instruction.

Aim 3: System Usability and Usefulness Evaluation: pilot test the prototype in up to 60 cancer patients in a randomized controlled design. Pre-selected clinical outcomes, self-efficacy, communication, system satisfaction, as well as health system utilization patterns will be examined from both the patient/caregiver and the clinical team perspective.

Home-Based Cancer Symptom Management (Phase II)

Project ID	1R44CA144322-01			
Sponsor	National Cancer Institute			
Project Period	9/15/2011-5/31/2014			
Funding Level				
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Ana Maria Lopez, MD	UA Arizona Cancer Center	Professor
	Investigator	Maria Bishop, MD	Southern AZ VA Heath Care System	Associate Professor
Clinical Sites	Arizona Cancer Center of the University of Arizona Southern Arizona VA Health Care System (SAVAHCS)			
Subjects	300			

Abstract

Phase II builds off of the work completed in Phase I to expand the Cancer Symptom Management system to include other cancers. The home-based Cancer Symptom Management (CSM) system is designed to promote patient self-management of cancer symptoms and treatment side effects and facilitate remote management by the care team. The anticipated benefits include improved patient self-reported outcomes, better self-efficacy, better patient-provider communication, and reduced hospital stays/clinic visits.

Our Phase II aims include:

1. The development of the final product by adding multimedia patient education contents and by thoroughly examining system architecture level issues such as performance, scalability, and maintainability; and
2. A larger-scale randomized controlled trial at two clinical sites to evaluate the efficacy of our symptom management solution.

Tailored Telehealth Weight Management Tool for Overweight Adults with Disabilities

Project ID	1R43DK097972-01			
Sponsor	National Institute of Diabetes and Digestive and Kidney Diseases			
Project Period	5/20/2013 – 4/30/2015			
Funding Level	$696,372			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	James Rimmer, PhD	University of Alabama at Birmingham	Professor
Clinical Site	HealthSouth/Lakeshore Foundation, Birmingham, AL			
Subjects	60			

Abstract

People with disabilities experience poorer health and have much higher rates of obesity compared to the general population. In the most recent analysis of the 2009 Behavioral Risk Factor Surveillance Survey (BRFSS), people with disabilities reported a 58% higher rate of obesity compared to people without disabilities, with an alarming 37.6% of disabled adults being obese. For the 54+ million Americans with disabilities, a doctor's recommendation or warning to lose weight, eat better or start exercising is often not responded to because of the enormous barriers they experience in accessing gyms, fitness centers, and healthy foods. Moreover, nutritional guidance for someone with a spinal cord injury, for example, may require a completely different set of dietary recommendations compared to the general population because of a higher ratio of fat to lean muscle tissue and a lower resting energy expenditure. There is no customized health promotion delivery system that can guide a person with a physical disability such as spinal cord injury in losing or maintaining weight, leaving this underserved population highly vulnerable to the health effects of obesity, inactivity and poor nutrition.

Our overarching goal is to promote the health of people with disabilities. As a result of obtaining successful outcomes from these projects demonstrating weight loss in people with physical disabilities, this proposal aims to develop a web-based **P**ersonalized **O**nline **W**eight and **E**xercise **R**esponse **S**ystem (POWERS), an intelligent individualized weight management coaching solution and clinical decision support system designed specifically for individuals with disabilities. Its target users are health promotion specialists working in clinical centers, disability and health professionals working in public health programs, rehabilitation professionals, and fitness professionals who would serve as "telehealth coaches" to assist individuals with disabilities achieve weight loss and improve their health promotion behaviors (improved nutrition and increased physical activity).

POWERS follows the conceptual coaching intervention model developed in the PEP projects. The PEP model includes the use of health appraisal, goal setting, implementation plan, progress monitoring, and performance feedback to coach individuals with disabilities to achieve their weight management goals. Clinical trials from the PEP projects have demonstrated the effectiveness of this. Leveraging the design of the PEP system, POWERS is a new Web-based system that offers the additional ability for the system to *automatically* recommend 1) wellness objectives and strategies based on the participant's health appraisal profile using a rules-based approach; 2) educational content (both text and video) from NCHPAD to help implement a selected wellness strategy; and 3) local resources, displayed on Google Map, that are close to the participant's residence and can facilitate the execution of a selected strategy. A first-generation POWERS prototype has already been developed to implement the key function #1 above. The scope of this project is to implement the remaining two key functions along with other secondary and supporting features to make POWERS market-ready.

This Phase I project has three specific aims:

1. ollect feedback from 40 stakeholders on system features, usability design, and perceived usefulness via focus groups and interviews;
2. xtend the POWERS prototype with a user-centric design process including two formal usability tests involving 20 health professionals and 20 individuals with disabilities; and
3. onduct a small-scale randomized control pilot study to examine the efficacy and feasibility of this approach with 60 subjects.

Accessibility Solutions for PRO Management (Phase I)

Project ID	1R43NS067866-01A1			
Sponsor	National Institutes of Health			
Project Period	06/01/2010 – 05/31/2011			
Funding Level	$311,926			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Annette Wundes	University of Washington	Assistant Professor
Clinical Site	Department of Rehabilitation Medicine and School of Medicine, University of Washington			
Subjects	52			

Abstract

MS affects an estimated 400,000 MS patients in the United States today 1. The estimated high socioeconomic burden of lifetime costs of more than US$2 million per individual 2 is associated with early onset of disease between the second and fourth decades without significant impact on life expectancy. MS leads to various combinations of motor, sensory, endurance and/or cognitive impairments, making self report challenging. The physical impairments limit ability of MS patients to use technology to effectively self-report health status and changes MS patients also often experience physical and/or mental fatigue and cognitive difficulties, such as increased distractibility, that cause additional issues for longer questionnaires.

To address the needs of people with disabilities, such as those with Multiple Sclerosis. This project expanded the BrightOutcome domain from cancer to include the disability and rehabilitation populations and worked toward providing a comprehensive accessibility solution. The prototype developed in Phase I was based on our existing PRO management solution called BrightOutcome™, that already supports such advanced features as the administration of "adaptive" PRO measures (including PROMIS item banks), the support of multiple delivery platforms, the rules-based delivery of tailored patient education contents, and the coordination of care via reminder/alert messages. Although the BrightOutcome System was initially designed for oncology practices, it provided a solid technical foundation to expand to other disease domains. To address these accessibility concerns, our specific Phase I aims include:

Aim 1: Design and development of a PRO assessment interface. Based on a user-centered design process, we developed a system that facilitated self-reporting by MS patients with different physical and neurocognitive impairments using different technology platforms (web-enabled computers, touch-screen computers, speech-enabled computers, and phones).

Aim 2: Evaluation of system usability and user acceptance. We evaluated the system usability in monitored and un-monitored conditions. Under monitored conditions, our usability engineers observed how MS patients with various functional limitations self-report their symptoms using our target platforms. The un-monitored usability evaluation allowed MS patients use the system themselves at the clinic without the presence of our research staff. These subjects also completed a usability questionnaire after using the system.

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Telenursing Model for Management of Chemotherapy Side Effects (Phase I)

Project ID	R43NR010441			
Sponsor	National Institute of Nursing Research			
Project Period	7/16/2008 – 1/15/2009			
Funding Level	$93,382			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Ana Maria López, MD	University Arizona	Professor
	Investigator	Elizabeth Krupinski, PhD	University Arizona	Research Professor
Clinical Site	Arizona Cancer Center of the University of Arizona			
Subjects	50			

Abstract

The goal of this specific project is to develop a cost-effective proactive telenursing system for the management of chemotherapy side effects. Patients will use this system to report health status on a daily basis during treatment, either on the Web or via interactive voice response system over the phone. Depending on the reported severity, the system may deliver just-in-time, evidence-based, context-sensitive patient education materials tailored to the patient's disease status and treatment regimen, and/or alert the oncology clinical care team to provide timely remote monitoring and consultation.

Our Phase I aims are to (1) design a telenursing model with the special focus on tailored patient instructions via systematic literature review, web resource review, focus group discussions, and personal interviews; and (2) develop a working prototype based on the resultant telenursing model and conduct controlled pilot study in realistic settings to evaluate technical feasibility, the acceptance level by providers and patients, and the effects on clinical outcomes and perceived intervention effectiveness. The initial focus of the Phase I feasibility study is on neutropenia, fatigue and nausea, three of the common chemotherapy side effects, for lymphoma patients and will be extended to other side effects and cancer sites in Phase II.

This project is consistent with our long-term strategic direction to improve access to care, promote patient self management, facilitate provider-patient communication, and ultimately improve clinical outcomes and reduce healthcare costs with multidisciplinary approaches integrating telehealth and e-health technologies, evidence-based medicine, patient-reported outcomes methodologies, and patient education research.

Tracking Needs, Increasing Awareness, and Supporting Decisions: A Guideline Based Tool for Increasing Cancer Screening Rates (Phase I)

Project ID	200-2011-M-41083			
Sponsor	Centers for Disease Control and Prevention			
Project Period	9/12/2011 – 3/11/2012			
Funding Level	$149,952			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Michael Kallen, PhD	Northwestern University	Assistant Professor
	Investigator	Robert Volk, PhD	MD Anderson Cancer Center, Houston	Professor
	Investigator	Jassica Hwang, MD	MD Anderson Cancer Center, Houston	Assistant Professor
Clinical Site	MD Anderson Cancer Center, Houston, TX			
Subjects	27			

Breast, cervical, and colorectal cancer can be successfully prevented and/or diagnosed and successfully treated at the earliest stages through the use of appropriate and timely screening as well as adequate follow-up and care coordination. Recognizing the importance of cancer screening, groups such as the American Cancer Society and the United States Preventative Services Task Force have developed various cancer screening guidelines. The long-term goal of this study is to increase breast, cervical, and colorectal cancer screening rates by developing a guideline-based cancer screening decision support and tracking system that will provide cancer screening decision support, a tracking system that allows physicians to follow patients as they progress through the screening continuum, a feedback report that alerts physicians to the status of their practice's screening rates, and finally, relevant patient education/edutainment materials.

Abstract

The technical objectives for this Phase I proposal are to:

1. ather user interface and system function requirements via patient focus groups, provider interviews, and expert panel;
2. evelop a web-based working prototype system following user-centric and object-oriented software development methodologies; and,
3. valuate the prototype by patients as well as primary care providers in a pilot study in terms of clinical usefulness, system usability, and acceptability.

Tracking Needs, Increasing Awareness, and Supporting Decisions: A Guideline Based Tool for Increasing Cancer Screening Rates (Phase II)

Project ID	200-2012-52873			
Sponsor	Centers for Disease Control and Prevention			
Project Period	9/30/2012 - 9/30/2014			
Funding Level	$999,992			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Michael Kallen, PhD	Northwestern University	Research Associate Professor
	Investigator	Richard Gershon, PhD	Northwestern University	Associate Professor
	Investigator	Karen Kaiser, PhD	Northwestern University	Research Assistant Professor
Clinical Site	None			
Subjects	None			

Abstract

Breast, cervical, and colorectal cancer can be successfully prevented and/or diagnosed and successfully treated at the earliest stages through use of appropriate and timely screening and adequate follow-up and care coordination. Recognizing the importance of cancer screening, groups like the American Cancer Society and the United States Preventative Services Task Force have developed cancer-screening guidelines. The long-term goal of this project is to increase breast, cervical, and colorectal cancer screening rates by developing a two-pronged, consumer and provider-based application that is a guideline-based cancer screening decision support and tracking system that will provide cancer screening decision support to the general public and physicians; a tracking system that allows physicians to follow patients as they progress through the screening continuum; a feedback report that alerts physicians to the status of their practice's screening rates; and relevant patient education materials.

The technical objectives for this Phase II proposal are to:

Continue developing and refining system features related to cancer screening tracking and decision support; Develop integration solutions to allow this product to co-exist with other commercial EHR systems; and Evaluate the consumer-based and provider-based products to assess their usability, acceptability, and effectiveness at increasing cancer screening guideline adherence.

Comparative Effectiveness of Management Strategies for Acute Low Back Pain, University of Utah (Subcontract)

Sponsor	Julie Fritz, PhD	University of Utah
Project Period	09/29/2010 – 09/29/2014	

Description

The research PI designed this study to compare the effectiveness and cost-effectiveness of two different lower back pain management strategies: usual care and intervention (physical therapy). To assist in the execution of this project, BrightOutcome developed a data collection and reporting system and continues to provide ongoing technical support.

This system contains the following features:

Subject Portal:

- Assigns a unique log-in ID and password
- Automatically assigns relevant, time-based surveys to subject's current session (based on study arm and study visit)
- Directs subjects to fill-out the required surveys based on time in study
- Provides a seamless delivery of assigned surveys
- Automatically checks for unanswered questions and provides prompts to subject to complete them

Investigator Portal:

- Log-in with unique ID and password
- Ability to enter subject-related data (surveys and exam) on specified visits, view previously entered data from the subject portal, read-only mode for previous data
- Receive automated weekly status reports on subject activities (delinquent, incomplete, and upcoming)
- Monthly data export file emailed to statistician

Physical Therapist Portal:

- Log-in with unique ID and password
- Ability to enter subject-related data for physical therapy sessions
- Ability to view read-only versions of previous subject-completed surveys and previous physical therapy sessions

Online Progress Tracking, Evidence-Based Practice Institute (Subcontract)

Sponsor	**Kelly Koerner, PhD**	**Evidence-Based Practice Institute**
Project Period	10/1/2010 – 7/5/2013	
Description	OPT will seamlessly link an online assessment engine that gathers and displays progress monitoring (PM) data from patients and practitioners with online EBP training, expert consultation, and peer community to work like a GPS, locating the progress of the therapy or training process relative to benchmarks, and providing context-specific assistance when practitioners need help implementing or learning EBPs and serve as a platform for implementation research. Current features include: Client Portal • Unique log-in ID and password • Online delivery of assessment instruments • Instrument accessibility pre-determined and controlled by the client's therapist • System sends reminders to the client to complete assessments before visit with therapist Therapist Portal • Unique log-in ID and password • Ability to assign assessments to clients • Record new assessments with client • View past assessment results in an interactive trend chart	

Personalized Online Weight Management and Exercise Response System for Youth with Disabilities (Subcontract)

Sponsor	**James Rimmer, PhD**	**University of Illinois as Chicago**
Project Period	12/1/2010 – 06/31/2011	

The Personalized Online Weight and Exercise Response System (POWERS) is an intelligent weight management portal for wellness coaches working with people with disabilities. Based on the popular open source Drupal framework, POWERS delivers goal-oriented lifestyle recommendations tailored to the needs and conditions of each individual being coached based on a variety of health risk factors using rules-based inference logic. Using location-based technologies, POWERS can also make localized lifestyle recommendations. Individual performance in achieving recommended goals, as well as aggregate performance for each type of lifestyle recommendations, can be monitored in interactive charting. Wellness coaches can receive support and training not only from system-recommended multimedia resources, but also from peer coaches and our expert trainers at NCPAD via social media.

System Features:

1. Health Appraisal and Profile (HAP) – Provides the background information about each participant. (ie, personal characteristics, eating and exercise behaviors, barriers to healthy eating and exercise, environmental mapping to determine what is available in the community.)
2. Plan – Provides pre-written goals from a drop-down menu that the 'coach' can choose from regarding physical activity, nutrition or health behavior. Also allows the 'coach' to set up the program delivery plan – ie, Go to this gym. Start with these home-based activities.
3. Delivery– Day-to-Day implementation that provides a drop down menu of activities that the 'coach' can select from (ie, use exercise video clips; switching to baked vs. fried potato chips or lower salt pretzels)
4. Monitor – calendar-base weight, activity, and nutrition tracker
5. Coach's Corner – new research, ideas, tips

Manage Prostate Cancer, Northwestern University (Subcontract)

Sponsor	David Victorson, PhD	Feinberg School of Medicine, Northwestern University
Project Period	11/5/2010 – 9/5/2011	

Description

iManage is a system designed to provide prostate cancer patients with a trustworthy and easy-to-use place to establish and track healthy living habits, record and monitor prostate cancer-related symptoms, receive symptom-specific educational videos and materials, and participate in a discussion forum that is monitored by a health professional.

We developed an online system that allows post-treatment prostate cancer patients to establish and track health goals (diet, exercise, smoking and drinking cessation) that are designed to improve treatment side-effects and to reduce further incidences of cancer. Additionally, iManage administers electronic Patient Reported Outcomes to the patients to help them track their symptoms overtime with automatically generated educational content that is presented based upon the worsening or improvement of the previous week's symptom assessments. Finally, iManage provides patients with support from a community of other prostate cancer patients through a discussion forum.

Key Features:

- Electronic delivery of Patient Reported Outcome Measures (PROMIS Global, EPIC 26, Max PC Scale, CAPS, SOMS Anxiety, SOMS Bladder, SOMS Bowel)
- Built-in scoring algorithms for the automatic calculation of PRO scores
- Dynamic trend charts that give patients a historical visual depiction of their PRO scores
- Dynamic health goal setting and tracking tool that allows patients to establish goals and update or change said goals over time.
- Strategies to overcoming barriers that are associated with particular health goals
- Access to tailored educational materials (text and video) based upon the patient's PRO scores
- Support from a community of prostate cancer patients in the discussion forum
- Access to a library of educational sources/links

My Quality of Life Kidney Cancer Registry (MYQOL), Northwestern University (Subcontract)

Sponsor	**David Cella, PhD**	**Feinberg School of Medicine, Northwestern University**
Project Period	6/15/2011 - Current	

Cancer patients in general benefit from understanding how they are progressing in the treatment of their cancer and how this progression has impacted their quality of life over time. Researchers at Northwestern University wanted to create a Kidney Cancer Registry that would not only act as a personal health monitor for kidney cancer patients, but also serve as a resource to advance patient-relevant research in kidney cancer.

We developed an online Kidney Cancer Registry, called MyQOL, that would act as a registry for researchers and a health-tracking tool for registrants. Registry participants enter information about their disease, treatment, symptoms, health status, and quality of life into an on-line, password-protected database on a quarterly basis. The information can be used by participants to track and monitor their symptoms and health status over time, and to compare themselves with others (including other people in the registry). Participants can also choose to give relevant information from their saved files in the registry to their health care providers. The data from the registry can be used by research scientists to better understand the impact of disease symptoms and treatments on the health status and quality of life of those with kidney cancer. The registry also serves as a resource for patients and scientists interested in research. Scientists have access to a pool of eligible research participants and participants are offered opportunities to join in other research studies.

Key Features:

Patient / Registrant Portal

- Electronic delivery of Patient Reported Outcome (PRO) measures (FKSI, FACT-G, FACIT, FACT-AntiA, PROMIS Global) on a quarterly basis to registrants
- Built-in scoring algorithms for the automatic calculation of PRO scores
- Dynamic trend charts that give patients a historical visual depiction of their PRO scores as they compare to the general U.S. population, general cancer population, and other registrants in the MyQOL registry
- Dynamic online surveys for medical background that allows for saving incomplete forms to complete later, and the delivery of questions that are only relevant to the registrant so that the registrant does not have to view unnecessary fields.
- Access to PDFs of the registrant's previous PRO responses
- Ability to withdraw from and re-enroll in the registry

Researcher Portal

- View the registrant pool's status in terms of those enrolled, active, delinquent, and withdrawn
- An automatic and dynamic contact list for delinquent registrants
- Email capabilities to send to delinquent or other selected registrants in the registry
- Filter registrant pool by specific parameters
- Ability to export all survey-based data in registry
- Ability to withdraw a registrant from the registry

Rush On-Schedule, Rush University Medical Center (Commercial/Clinical)

Sponsor	Rush University Medical Center	Rush University Medical Center
Project Period	11/2/2005 – 11/2/2012	
Description	OnSchedule is a web-based scheduling and reporting application that allows users to staff the cost centers throughout the hospital with float pool or agency personnel. The application provides the associated detail and summary level financial reports to capture the costs and hours associated with all schedule items. The Rush On-Schedule system provides users with the ability to accept needs from cost centers, accept availability from float pool personnel (and agencies), and allows the users complete control over which personnel they would like to assign to cost centers with open needs. OnSchedule also allows users to pre-schedule personnel months in advance or create ad hoc schedules as requested. System Features: • Provides multiple perspectives of schedules. Users have the ability to view things from an availability perspective or a needs perspective. • A person can be prescheduled based on the Monthly Availabilities form • A person can be scheduled via the Preschedule screen for multiple days at a time • A person can be manually scheduled to fill one specific need • A person can be auto scheduled if their skill/ and start/end times exactly match that of the need • Nurses can submit availabilities remotely via VPN access • Offers a variety of business reports, including the utilization report and the cost estimate report implemented in Business Objects. • The application is serviced from the Rush's WebLogic environment with integration with Business Objects and Active Directory.	

Tacasi Questionnaire Phone and Web Administration System, CDC/Cerner (Commercial/Clinical)

Sponsors	Marcus Durham, M.S. (CDC) Kathy Wood, RN (Cerner)	CDC/Cerner
Project Period	10/1/2006 – Ongoing	

Description

This is a sub-project under the CDC HIV Outpatient Study (HOPS) and uses interactive voice response (IVR) technology to collect longitudinal behavior data from HIV patients at eight HIV clinics across the country. Patients can use the system both at the clinic or at home. The questionnaire includes questions about smoking, medication, drug use, and sexual behaviors. To date, about 3,000 records have been collected. The number of questions per survey session has been between 13 and 53 with a median of 30; mostly within 4-6 minutes. Completion rate has been over 99%.

System Features:

- IVR-based phone surveys.
- Web-based administrative interface.
- Conditional logic to implement question branching.
- Automated weekly recruitment status reports in Excel.
- Automated monthly data export in Excel.

Fatigue Assessment System, MD Anderson Cancer Center (Commercial/Clinical)

Sponsor	Carmen Escalante, MD	MD Anderson Cancer Center
Project Period	03/1/2010 – 9/30/2012	

Description

Fatigue is a common and life-interrupting symptom or side-effect of cancer and cancer treatment. M.D. Anderson Cancer Center has a Fatigue Clinic that is dedicated to treating cancer-related fatigue. During a clinic visit at the Fatigue Clinic, a patient completes several paper-based patient-reported outcome (PRO) measures that are designed to help the provider understand the impact of fatigue on the patient's life and the effect, if any, of the treatments administered to reduce fatigue. The administration of these PRO measures was paper-based, which was time-consuming and error-prone. A Web-based system, accessible from an iPad, was developed to deliver, score, and report PRO measures electronically. This system has been used in an actual clinic setting and our study of the impact of the system has shown reduced patient assessment time from 30 minutes to about 12-15 minutes and reduced provider assessment interpretation time from 15 minutes to essentially 0 minutes, resulting in much improved clinic flow.

In order to adequately determine the impact of fatigue and the impact of the prescribed treatments for fatigue on the life of the cancer patient, the providers at the Fatigue Clinic selected several different PRO measures to administer electronically. These measures are designed to assess: the apathy of the patient (AES_S) the caregiver (AES_I) and the provider's perceived apathy of the patient (AES_C); the cancer patient's fatigue level (BFI); the pain experienced by the cancer patient (BPI), the impact on the caregiver from providing care to the cancer patient (CRAI), the depression and anxiety experienced by the cancer patient, if any (DASS21), the level of sleepiness experienced by the cancer patient (Epworth Sleepiness Scale), and a general assessment of common cancer symptoms (MDASI).

We developed an online, HIPAA compliant, system that allows the Fatigue Clinic to electronically administer these PRO measures to the patient in clinic. The application has administrative functions designed to allow the healthcare team to select which PRO measures to administer to the patient and review the missing answers with the patient through use of a "skipped report" to ensure complete data entry. The system automatically calculates the scores for the PRO measures and provides the results in an easy-to-consume table to the provider with the score change from the previous visit. Finally, the system requires the provider to complete a provider-specific measure about the patient's medical status before that patient's file can be "closed," enforcing proper workflow control.