In 1997, we founded the Center on Outcomes, Research and Education (CORE) at the ENH Research Institute. Our vision was broad but specific to the individual person in the healthcare setting. “We will champion the integration of the patient’s voice into outcomes research to improve health and quality of life.” After more than 10 years of research activity with many thousands of patients, we are poised to measure, analyze and interpret the individual patient’s perspective…and we always aim to make a difference.

CORE’s mission is to be a leader in health outcomes measurement, analysis and interpretation by incorporating measurement science, information technology and cross-cultural research. Our research methods and tools support and drive our research. Some of our milestones of the past 10 years are highlighted in the box to the right. Beginning with early, local clinical collaborations, we moved into pilot disease management projects and subsequently into larger scale, symptom monitoring and measurement work, primarily in oncology.

Our work in item banking science began here in 1997, with our first extramural funding in 1999. This measurement activity has resulted in several large and small grants, as well as contracts, to standardize and promote measurement of health-related quality of life.

The 2004 awarding of the “NIH Patient-Reported Outcomes Measurement Information System” (PROMIS) grant, and the NINDS contract award “Quality of Life in Neurological Disorders” (Neuro-QoL) represented a major shift in our direction. Both projects involve large scale item banking for common symptoms and functional problems faced by people with chronic diseases. These are tools that are now being delivered to the research community for use; these are exciting developments in the field of clinical outcomes research. In 2006, we
I like to tell people that I have been working for David Cella, PhD, for so long that when I started, we were both thin and neither had grey hair! When I started with Dr. Cella in 1994 at Rush-Presbyterian-St. Luke's Medical Center, Chicago, we were known as the Department of Psychosocial Oncology (the DPO for short). Maria Corona, Beth Hahn, MA, Kimberly Webster, MA, and I began working together about the same time, while Sonya Eremenco, MA, Veronica Valenzuela and Azra Muftic started about a year or so later. So we are officially the old timers on Dr. Cella’s staff – 13 years!

In 1995, we totaled about 10 people. By the time we moved with David to ENH to start CORE in 1997, our staff numbered about 17 people. All except one came to ENH, which is testament to David’s commitment to his staff and vice versa.

By 2000, CORE had grown to 44 people, which included some hospital-based staff in a CORE sub-group called Disease Management. Beth Hahn, MA, had received her first federally-sponsored grant; Sonya Eremenco, MA, had recently hired a new staff person by the name of Ben Arnold, MA, bringing the total number of people in our translations team to four; and we expanded from one suite at 1000 Central Street to two suites at 1033 University Place. In 2002, we were 64 employees strong and by 2004 we had 73 on staff. Today, we have 80 employees and we are located across three suites in Evanston, IL, one office on Northwestern University’s Chicago campus and translation staff in Zurich, Paris and Brazil. Today, we have 80 employees and we are located across three suites in Evanston, IL, one office on Northwestern University’s Chicago campus and translation staff in Zurich, Paris and Brazil!

In the first half of 2004, Dr. Cella took a six month sabbatical during which time he coordinated CORE’s submission of the SYMON-1 competing renewal grant, the PROMIS Statistical Coordinating Center grant and the NeuroQOL contract. All were funded. One can only infer that this six-month time off to refresh resulted in the most productive “vacation” in academic history. Two years later, on the shoulders of the item-banking work previously spearheaded at CORE, Richard Gershon, PhD, was awarded the NIA Toolbox contract, a $21 million project that was the largest federally funded project ever received by ENH Research Institute (see Grants & Contracts, p.7).

These large projects, accompanied by federally-funded grants awarded to Susan Yount, PhD, Beth Hahn, MA, and Jin-Shei Lai, PhD, OTR/L, coupled with the translation team’s remarkable growth, and other smaller but crucial faculty research initiatives, have resulted in CORE’s evolution from a small internally-focused research program into both a nationally and internationally recognized health outcomes research program – perhaps the largest such academic program in the world. Concurrent with the growth and recognition of CORE’s reputation for excellence in research, in 2007, Dr. Cella was awarded the Davis Family Chair in Outcomes. To have been awarded an endowed chair is considered arguably the highest honor that can be bestowed in an academic setting; this well-deserved award recognizes David’s excellence in leadership, scientific integrity and overall success in the field of research.

A great deal has changed in these past 13 years (10 at ENH). But to a large extent much has stayed the same: the importance of quality and focus on scientific integrity; relationship building; trust, reliance and collaboration with valued colleagues; and the ongoing expectation of being the very best clinician/researcher/colleague you can be. These are the core and CORE expectations of our workforce. We’re fortunate to have such a talented group of people on staff, and to be headed by Dr. David Cella. Congratulations!
What happens behind the scenes?
Over the past decade, the Center on Outcomes, Research and Education (CORE) has achieved international recognition as a leading health outcomes research center at ENH Research Institute. Over time, CORE has been instrumental in linking the patient’s voice to health outcomes research.

At the heart of CORE is the Research Operations group, which provides the critical function of operational support for all of our outcomes and quality of life research. This support extends along the full continuum of the research process: from pre-study planning and Institutional Review Board (IRB) submission; to primary data collection at numerous Chicago-area hospitals and clinics; to study completion, data cleaning and manuscript preparation.

When CORE was first established at Rush-Presbyterian-St. Luke’s Medical Center under the direction of David Cella, PhD, operational research support focused primarily on participant recruitment, with much less formal structure and a more narrow range of responsibilities than today. CORE’s relocation to ENH in 1997 also brought the development of an official Research Operations division led by Amy Peterman, PhD. Two of the original RAs, Maria Corona and Veronica Valenzuela, remain with the group to this day. By virtue of their history with the CORE research team, they have accrued invaluable experience with participant recruitment, with much less formal structure and a more narrow range of responsibilities than today.

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As CORE has continued to grow, so too has the need for additional study coordinators and RAs. Today, we have 14 staff members devoted solely to the research operations here, three of whom have master’s degrees and the remainder with bachelor’s degrees. These RAs are proficient at juggling multiple research studies simultaneously, many with varying assessment schedules, requirements and eligibility criteria. They frequently operate as members of a collaborative project team, which requires constant, clear communication and coordination.

The Research Operations division has developed a comprehensive collection of Standard Operating Procedures (SOPs) that guides the work performed by the RAs and directs the flow from study inception to study completion. The SOPs provide an overview of the process of operationalizing a research study, and serve as a training aid for new hires and a resource for more experienced RAs. The development of standardized procedures surfaced from the need to establish and maintain effective communication systems, processes and documentation, both internally and externally. The focus of the SOPs includes standardizing data collection forms, recording missing data, using compliance and recruitment logs, performing data quality assurance checks, conducting participant interviews and detailing the responsibilities of a study coordinator and RA, among many others.

The Research Operations division is experienced with a variety of research methods. Our research operations team is trained to administer cognitive interviews and assist with focus groups. We are also multilingual and multicultural, with expertise in conducting interviews and participant assessments in Spanish or other languages, as needed. We are also trained to collect data via various modes of administration: self-administered via paper/pencil, face-to-face interview, computer-assisted telephone interviews (CATI), computer-based assessments and online recruitment and assessment. As technology advances, our Research Operations division adapts to more sophisticated methods of recruitment and assessment to meet the needs of our research industry.

In addition to a wide range of expertise, the Research Operations staff recruits participants at a variety of diverse institutions including Evanston Northwestern Healthcare, Northwestern Memorial Hospital, John H. Stroger, Jr. Hospital of Cook County, Mount Sinai Hospital, Illinois Masonic Hospital, Rush University Medical Center and Access Clinics across Chicago. Further, the staff has experience collaborating on multisite studies with medical centers and hospitals across the nation.

Continued on page 4

By Jane Langan, MA & Juliette Song
The roles of a study coordinator and RA are crucial to the mechanics of a research study. The primary goals of the study coordinator are to assist the principal investigator with study start-up and to monitor and maintain day-to-day study operations. As outlined in the Study Coordinator Standard Operating Procedure, “A coordinator transitions the study protocol and research goals into an operating research project complete with efficient study enrollment, organized data collection and management, and comprehensive study reports and queries.”

While the study coordinator oversees the conduct of the research study, the RA bears the responsibility of performing participant recruitment and data collection in a highly accurate, protocol-driven, efficient and ethical manner, thus moving the study toward its accrual goals. At CORE, the RA is often an inconspicuous but integral member of the research team. Out in the “field,” the RA is an external representation of CORE and must demonstrate excellent interpersonal skills and the ability to interact in a professional and sensitive manner with medical personnel, research participants and other research staff at various sites.

As CORE’s research has expanded in breadth and volume, our Research Operations division has likewise grown into a large, skilled and specialized group of research professionals. At the hub of a complex research system here at CORE, the Research Operations team constitutes a critical element of the research infrastructure, enabling a diverse group of investigators, statisticians, programmers and data-entry specialists to function efficiently and productively. While not always the faces and the names associated with CORE’s research portfolio, this invaluable team contributes vitally to keeping CORE moving forward.

The faces of Research Operations
Dr. Susan Yount is a Principal Investigator on many studies here at CORE, and also brings her leadership expertise as the Director of our Research Operations group. Working along side her is Kimberly Webster, MA, as the Assistant Director of Research Operations.

In addition to Dr. Yount, Ms. Webster and RAs, the Research Operations group includes CORE’s Institutional Review Board coordinator. This individual serves as the primary contact for the ENH Research Institute and other research sites on all IRB-related matters, thus providing critical communication, monitoring and documentation for CORE investigators and CORE’s research partner institutions. The IRB coordinator works closely with principal investigators and study coordinators to ensure that studies are IRB-approved at ENH and at various collaborating sites. Additional responsibilities include facilitating the IRB application processes for CORE investigators and study coordinators, educating and training the Research Operations division and CORE scientists on IRB-related issues, and serving as a resource, liaison and consultant on issues related to the protection of human subjects.

...keeping CORE moving forward.
New Grants

Patient-Centered Care in Ambulatory Cancer Care Settings

Elizabeth Hahn, MS

The challenges of maintaining quality care in an ambulatory setting are numerous. One of the challenges is to provide patients with continuity and clear communication about their illness and care. For diseases whose symptomatology and treatment are multifactorial as cancer, ambulatory care often involves a complex collaboration of multiple disciplines (surgical, medical, radiation, social, rehabilitation, laboratory) to coordinate patient care services. This care requires careful planning, scheduling and communication across disciplines and departments, as well as across healthcare facilities. Much of the responsibility for following up with important tests, procedures and appointments rests solely with the patient.

The Institute of Medicine report “Crossing the Quality Chasm” earmarked patient-centered care, which is responsive to individuals’ preferences and values, as one of its six recommended aims to improve the healthcare system. Patient-centered care focuses on building a collaborative process between physician and patient. The physician and patient share power and responsibility; the physician gains an understanding of the patient’s illness experience, and the patient’s knowledge of the illness is broadened so that s/he can begin to better manage the illness.

The Agency for Healthcare Research and Quality (AHRQ) recently created a program for the purpose of improving the safety and quality of ambulatory healthcare in the U.S. This program includes an emphasis on the role of health information technology. Investigators at CORE were awarded a three-year grant by AHRQ, titled “Implementing a low-literacy, multimedia IT system to enhance patient-centered cancer care” (R18-HS017300; PI: Hahn). The overall objective of this project is to test whether a low-literacy, multimedia information and assessment system used in daily clinical practice enhances patient-centered care and improves patient outcomes. This project is combining two existing assessment tools: a) a computerized adaptive tests could be from the pedsPCF item bank such as social and family function and specific concerns), anorexia/cachexia and fatigue. Given these obstacles, a brief, yet precise and individualized measurement is needed to screen patients who may benefit from more comprehensive assessment. Based on a review of the literature and a survey of neuro-oncologists, it was concluded that a psychometrically sound pedsPCF measurement tool may fulfill this need. To address the need for a standardized instrument to screen for neuropsychological tests, in this three-year project, a pedsPCF item bank is being developed. Ultimately, applications from the pedsPCF item bank such as computerized adaptive tests could be implemented in clinics to screen patients for further comprehensive assessment.

As an occupational therapist, Dr. Lai always wishes to bring her psychometric expertise to clinic. Since 2002, Dr. Lai has developed instruments to measure quality of life for childhood brain tumor survivors (physical function, illness experience, emotion, social and family function and specific concerns), anorexia/cachexia and fatigue. The pedsPCF project is actually a continuation of her previous work, in particular, in the area of brain tumors. For more information on this project please contact Dr. Lai at: js-lai@northwestern.edu

REFERENCE LIST

Dr. Lai Receives Pediatric Grant from NCI

Jin-shei Lai, PhD, OTR/L, Research Scientist, CORE, Associate Professor of Pediatrics and the Institute for Healthcare Studies at Northwestern University’s Feinberg School of Medicine, was recently awarded a three-year, $1 million grant from the National Cancer Institute, “Perceived Cognitive Function Item Bank for Children Who Undergo Cancer Treatment.” The aim of the project is to develop a measurement system that monitors a pediatric patient’s cognitive functioning through various developmental stages.

Cognitive difficulties are among the most prominent concerns for pediatric CNS tumor survivors and their families. Early identification of these cognitive sequelae is critical for prompt intervention. While neuropsychological test batteries are typically used to evaluate these concerns, they are not routinely implemented due to their length, expense and vulnerability to practice effects. Given these obstacles, a brief, yet precise and individualized measurement is needed to screen patients who may benefit from more comprehensive assessment. Based on a review of the literature and a survey of neuro-oncologists, it was concluded that a psychometrically sound pedsPCF measurement tool may fulfill this need. To address the need for a standardized instrument to screen for neuropsychological tests, in this three-year project, a pedsPCF item bank is being developed. Ultimately, applications from the pedsPCF item bank such as computerized adaptive tests could be implemented in clinics to screen patients for further comprehensive assessment.

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Principal Investigator, National Cancer Institute (R01CA125677-01A) Perceived Cognitive Function Item Bank for Children Who Undergo Cancer Treatment, 09/30/07 -07/31/10
Recently Published Articles – CORE Staff


Grants & Contracts – PROMIS, Neuro-QOL and the NIH Toolbox

As Dr. Cella stated in his article, “Celebrating A Decade of Outcomes Science at CORE” (p. 1), there were major shifts in our direction and source of funding in 2004 due to two key federally-funded projects awarded CORE. Here is a snapshot of these two federally-funded grants as well as a third multi-year NIH project awarded to CORE in 2006.

**PROMIS: (Cella, D., PI)**  
[www.nihpromis.org](http://www.nihpromis.org)

In late 2004, a group of outcomes scientists from seven institutions and the National Institutes of Health (NIH) formed a cooperative network funded under the NIH Roadmap for Medical Research Initiative to re-engineer the clinical research enterprise. CORE is the Statistical Coordinating Center of this project.

This initiative, “Patient-Reported Outcomes Measurement Information System” (PROMIS), aims to revolutionize the way patient-reported outcome tools are selected and employed in clinical research and practice evaluation. It will also establish a national resource for accurate and efficient measurement of patient-reported symptoms and other health outcomes in clinical practice. As part of the NIH Roadmap, NIH funded six primary research sites and a statistical coordinating center as the PROMIS network. PROMIS aims to develop ways to measure patient-reported symptoms, such as pain and fatigue, and aspects of health-related quality of life across a wide variety of chronic diseases and conditions. Clinical outcome measures, such as X-rays and lab tests, have minimal immediate relevance to the day-to-day functioning of patients with chronic diseases such as arthritis, multiple sclerosis and asthma, as well as chronic pain conditions. Often, the best way patients can judge the effectiveness of treatments is by perceived changes in symptoms. One main goal of the PROMIS initiative is to develop a set of publicly available computerized adaptive tests for the clinical research community.

**Assessment Center**  
[www.assessmentcenter.net/ac1](http://www.assessmentcenter.net/ac1)

The Assessment Center is a web-based software application developed under the PROMIS study that allows researchers to centralize all research activities. Assessment Center includes features that promote instrument development, study administration, data management and storage of statistical results. PROMIS is sponsoring two half-day workshops to help researchers understand and use Assessment Center.

**Assessment Center Workshops:**

July 17, 2008

**Assessment Center Workshop I**  
*Basics of Item Response Theory (IRT) and Computer Adaptive Testing*  
*Location: Chicago, IL*

**Assessment Center Workshop II**  
*Introduction to the Assessment Center Application*  
*Location: Chicago, IL*

For questions, contact assessmentcenter@enh.org or visit www.nihpromis.org.

**Neuro-QOL: (Cella, D., PI)**  
[www.neuroqol.org](http://www.neuroqol.org)

Neuro-QOL is a five year, multi-site NINDS funded project to develop a health-related quality of life (HRQL) assessment tool for adults and children based on common neurological disorders. These tools are intended to be responsive to the needs of clinical researchers and facilitate comparison of results across clinical trials in different diseases. Based upon input from patients, experts and the published literature, we chose to focus on pain, fatigue, emotional distress, physical function and social function. During the first phase of the study (now completed) we conducted a survey of physicians and clinical trials researchers in order to identify the criteria for acceptance of HRQOL measures in the neurology research community. Selected neurological conditions were based on disease prevalence, impact of the disease and treatment upon quality of life and preferences of the neurology clinical trials community. Conditions selected are: stroke, multiple sclerosis, Parkinson’s disease, adult pediatric epilepsy, ALS and muscular dystrophy. For more information please contact Vitali Ustsinovich, MA, project coordinator, at vustsinovich@enh.org.

**NIH Toolbox: (Gershon, R., PI)**  
[www.nihtoolbox.org](http://www.nihtoolbox.org)

In 2006, we were awarded the largest federally-funded contract in ENH/CORE history. The NIH Toolbox for the Assessment of Neurological and Behavioral Function initiative seeks to assemble brief, comprehensive assessment tools that will be useful to clinicians and researchers in a variety of settings, with a particular emphasis on measuring outcomes in longitudinal epidemiologic studies and prevention or intervention trials across the lifespan. The Toolbox will ensure that assessment methods will be capable of comparison with existing and completed studies. Advances in psychometric research methodology, including computerized adaptive testing and virtual reality, combined with traditional performance-based tools, should lead to the efficient, flexible and responsive assessment of cognition, emotion, motor functioning and sensation.

**Toolbox Public Conference:**

October 27, 2008

**Building the NIH Toolbox**  
*Location: Marriott Bethesda North Hotel & Conference Center*  
*Bethesda, MD*

Abstracts for poster presentations will be accepted in May 2008. Please visit www.nihtoolbox.org for details. For more information email Maggie Heydt (mheydt@enh.org), communications director.
followed PROMIS and Neuro-QOL item bank successes with the NIA Toolbox award. The “NIH Toolbox for Assessment of Neurological and Behavioral Function” project is a large contract to produce and standardize measurement tools for the assessment of sensation, cognition, emotion and motor function. It is very gratifying to see our work receive national and even international attention through publications in major journals, and through the awarding of local endowments such as the Davis Family Chair of Outcomes Research.

Behind our work are the people whose talents make it possible (please see “The CORE Community” p. 2). I am deeply indebted to my colleagues at CORE and at other institutions across the United States and the world. I am honored to have been the Executive Director of this amazing group of people at CORE, and look forward to our continued collaboration.