

Clinical Research Centers: Results Coming In

By Fran Hopkins

The Foundation for Physical Therapy has funded Clinical Research Centers in Iowa and Pittsburgh.

The first Foundation-funded Clinical Research Network now is being coordinated out of California. Learn how Foundation funding is contributing to the transformation of both the physical therapy profession and patient care.



Photo by Barry Myers

"Prior to the development of the CRCs, much of Foundation funding was for individual research projects and scholarships. The individual research projects were funded based upon their scientific merit, but the relative value of the research to clinical practice was less of a consideration. The CRCs have been able to address multiple questions related to a general topic."

Nancy T White, PT, MS, OCS, president and chair of the Foundation for Physical Therapy

Anthony Delitto, PT, PhD, FAPTA, believes that his work is having a direct effect on the practice of physical therapy today. Delitto was principal investigator for a Clinical Research Center (CRC) funded by the Foundation for Physical Therapy at the University of Pittsburgh from 1997 to 2000. The results of Delitto's research, titled "Comparison of Classification-Based Physical Therapy with Therapy Based on Clinical Practice Guidelines for Patients with Acute Low Back Pain," were published last year in *Spine*.¹

"We would hope that the study demonstrated that treating patients with a classification-based approach to physical therapy after acute work-related low back pain results in faster recovery and sooner return to work than if treated with a minimalist-based approach," Delitto says. "I would also hope that physical therapists who treat patients with work-related low back pain can use our work to justify treating patients immediately after acute back pain."

Delitto is optimistic that the medical profession will take note of the CRC's results as well. "I would also hope that physicians who treat patients with work-related low back pain and who tend not to refer to physical therapy will read this work and perhaps re-think their attitudes toward the benefit of physical therapy," adds Delitto.

The National Institutes of Health's (NIH's) National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) was impressed enough with Delitto's work to award him a \$1.4 million grant in 2000 for a 4-year study of surgical versus non-surgical treatments for lumbar spinal stenosis. "Because of the Foundation CRC, I was able to list a major randomized clinical trial under the 'Preliminary Work' section of the NIH application, which I believe greatly bolstered our chances of receiving a favorable score," Delitto says.

"There is certainly a connection between the two studies," Delitto explains, "in the sense that both acute low back pain and lumbar spinal stenosis are lumbar spine problems that are 1) costly, 2) the cause of a great deal of pain and disability, and 3)

amenable to treatment by a physical therapist. In fact, we used many of the same measures of pain and disability in both studies.

"We will complete enrollment for the lumbar spinal stenosis study in August and will be following up on patients 2 years after enrollment, so we will be completely finished in August 2006," notes Delitto.

Nancy T White, PT, MS, OCS, the new president and chair of the Foundation, is convinced that Foundation-funded CRCs have enhanced the Foundation's effectiveness. The first CRC was funded at the University of Iowa from 1991 to 1994, and the second was Delitto's study at Pittsburgh. The Foundation awarded each CRC a \$600,000 grant.

"Prior to the development of the CRCs, much of Foundation funding was for individual research projects and scholarships," White explains. "The individual research projects were funded based upon their scientific merit, but



Richard K Shields, PT, PhD, director of graduate studies at the University of Iowa and a trustee of the Foundation

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the relative value of the research to clinical practice was less of a consideration. The CRCs have been able to address multiple questions related to a general topic. They have served to answer more questions more quickly and with fewer dollars," White says.

The earlier CRC at the University of Iowa was established for the study of musculoskeletal disorders. Richard K Shields,

PT, PhD, director of graduate studies at the University and a trustee of the Foundation, was a CRC project investigator. Shields describes how the results of the Iowa CRC have benefited both the physical therapy profession and patients. "We developed and introduced the first physical therapy computerized medical record for observational research," he says. "We initiated the discussion about the importance of studying 'effectiveness' through observational databases versus the more costly randomized controlled 'efficacy' trials, a topic that now is garnering attention from the NIH.

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"We also developed the Iowa Level of Assistance Scale that now is used to assess function in many centers across the country," Shields notes. "There is no question that our ability to treat these patient populations improved with our advanced understanding of their perceptions of their own health quality."

Rebecca L Craik, PT, PhD, FAPTA, professor and chair of the Department of Physical Therapy at Arcadia University in Glenside, Pennsylvania, and a Foundation trustee, was a member of the scientific panel that reviewed the proposals for the CRCs. Craik explains the "snowball" effects of initial Foundation funding of CRCs.

"The CRC can provide a reason and funding for investigators to work together on a relevant physical therapy project in addition to pursuing their own individual research," Craik says. "The publicity surrounding the CRC award can attract attention to a site, which can, in turn, serve to attract graduate students and clinicians. Data col-



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lectu from the CRC can be used to publish a refereed paper and/or provide preliminary data necessary for attracting additional research funds.

"So, the funds provided by the Foundation to the CRCs serve as seed money for a program to focus attention on a relevant theme; generate initial data that, in turn, garners additional funds; attract other qualified investigators to work at the centers; and help train future scientists through doctoral or postdoctoral degree programs," Craik summarizes.

CRCs and Education

Someone whose education and training directly benefited from her participation in the Pittsburgh CRC is Julie M Fritz, PT, PhD, ATC. Fritz was the lead author of the Delitto study.

"I had the great fortune of being able to participate in the CRC as a doctoral student at Pitt," Fritz says. "The CRC provided me with a mechanism to fund my doctoral training, but being involved in the program had many more



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benefits for me that have extended well beyond the conclusion of the actual study.

“I have been involved in authoring several papers that came directly from our experiences with the CRC,” Fritz continues. “In addition, the CRC generated many new research hypotheses that have turned into research projects funded by the Foundation for Physical Therapy and other granting agencies. These funds have been used to train additional graduate students who have taken an aspect of the data generated from the CRC and turned it into a research agenda of their own.”

Concludes Fritz, “The cumulative productivity of these individuals will continue to be a return on the investment of the Foundation in this project.”

Vision 2020 and Clinical Research Networks

Fritz’s experiences echo APTA’s “Vision 2020,” which outlines key elements of the future direction of the physical therapy profession, including doctoral training, the provision of evidence-based service, and the importance of basic and clinical research to patient care.

Marilyn Moffat, PT, PhD, FAPTA, CSCS, former APTA president and a Foundation trustee, elaborates on Vision 2020. “APTA’s vision is that the physical therapy profession will be a doctorally practicing profession that bases as much of our practice on evidence as possible. The more that is

based on evidence, the stronger the practice,” she says. “The Foundation is committed to supporting the research endeavors of the profession.”

This commitment to research, coupled with the success of the CRCs, gave rise to even more ambitious plans. Jayne L Snyder, PT, MA, Nancy White’s predecessor as president of the Foundation, describes this evolution.

“The Orthopaedic Section [of APTA] was concerned that we weren’t answering physical therapy questions for practicing clinicians fast enough,” Snyder says. “Nancy White, Rebecca Craik, and I formed a task force to determine how to answer more questions in a shorter period of time. We consulted with NIH and came up with a prototype research network involving multiple clinical sites.”

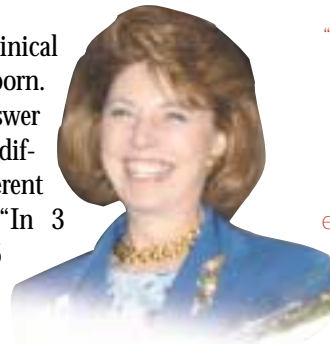
Thus the idea for the Clinical Research Network (CRN) was born. “We wanted to be able to answer numerous questions involving different aged patients with different diagnoses,” Snyder explains. “In 3 years, we want to have maybe 15 answers versus one question being answered.”

As a result, in the Fall of 2002, the Foundation’s Board of Trustees awarded a 3-year, \$1.5 million grant to Carolee J

Winstein, PT, PhD, FAPTA, at the University of Southern California for the establishment of PTClinResNet. Winstein details the components of her winning proposal to the Foundation:

“We proposed to establish PTClinResNet, a clinical research network for the evaluation of the efficacy of physical therapist interventions to enhance muscle performance in patients with physical disabilities,” Winstein says. The three specific aims of PTClinResNet are as follows:

1) To generate evidence to evaluate the efficacy of resistance exercise-based physical therapist interventions designed to improve muscle performance and movement skill. Investigations include one multisite phase II/III and three phase II randomized clinical trials (RCTs).



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The Foundation for Physical Therapy

The Foundation for Physical Therapy was established in 1979 as a national, independent, nonprofit corporation to support the physical therapy profession’s research needs in three areas:

- ❖ Scientific research, to create a solid platform for future clinical research
- ❖ Clinical research, to assess the efficacy of physical therapy intervention and help define best practice
- ❖ Health services research, to assess the effectiveness of physical therapy practice in the emerging health care delivery models for physical therapy

Among the activities of the Foundation to advance its objectives are:

- ❖ Assisting clinicians, researchers, and academicians in their doctoral programs
- ❖ Expanding funding for emerging researchers
- ❖ Supporting clinically relevant research
- ❖ Strengthening the Foundation’s capacity to promote the profession’s research agenda

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2) To create the infrastructure necessary to develop and sustain clinical trials research in physical therapy.

3) To provide education and training opportunities for present and future clinical researchers in physical therapy and for the physical therapy practice community at large in its support of evidence-based practice.

The four RCTs include studies of strength training effectiveness post-stroke (STEPS); muscle-specific strength training effectiveness post-lumbar microdiscectomy (MUSSEL); pediatric endurance development and limb strengthening (PEDALS); and strengthening and optimal movements for painful shoulders in chronic spinal cord injury (STOMPS). "All four RCTs have begun in earnest, with the flagship RCT, STEPS, leading the way with 29 out of 80 subjects recruited to date," Winstein notes.

Although the CRN is being centrally coordinated out of Winstein's USC location, sites for the RCTs include Northwestern University in Chicago (STEPS); Southwest Missouri State University, Springfield, Missouri (PEDALS); University of California at Los Angeles (PEDALS); Rancho Los Amigos National Rehabilitation Center, Downey, California (STEPS, STOMPS); and at USC, PT Associates, Los Angeles, (along with 12 additional outpatient facilities for MUSSEL and STEPS).

"One thing that is clear is that a critical objective for our profession is to examine the efficacy of what we do through sound scientific methods of clinical research," Winstein says. "The unique collaborative arrangement that the funding from the Foundation has allowed us to build in PTclinResNet is designed to foster cutting-edge clinical research now and into the future, and

across a wide domain of physical therapy practice.

"We believe that, by combining the talent and resources at many institutions and clinics, we can accomplish much more than if we were all working separately," Winstein continues. "Indeed, we anticipate that the concept of a clinical research network, which the Foundation had the vision to promote, eventually may become recognized as the optimal arrangement for carrying out clinical research, and that PTclinResNet will be the first of many such networks."

Winstein is confident that the results of the CRN will benefit both patients and the profession. "We will be able to determine a direct cause-and-effect relationship between the intervention protocol and the benefit to the patient across the range of disablement (impairment, function, disability) under inves-

tigation," she says. "There is much value in determining a direct effect from a therapeutic protocol. This information can be used by the profession to promote the efficacy of what we do with quantifiable outcomes.

"In addition, our results will stimulate more research into the mechanisms for these therapeutic effects, and that research will help us design even more effective therapeutic interventions in the future," Winstein predicts.

One Foundation trustee with a unique perspective on the value of the CRN concept is Tom Campanaro, founder, president, and chief executive officer of efi/Total Gym in San Diego, California. efi/Total Gym is a major contributor to both the Foundation and the CRN. Campanaro explains why:

"Our company has been involved with marketing products to the [physical therapy] profession for over 25 years," Campanaro says. "We were in a position to finally give back to the physical therapist to bolster the profession's credibility within the health care industry.

"The CRN has enabled the Foundation to focus on larger funded programs and have multiple facilities do the research," Campanaro says. "As a supplier, this means that both the visibility and the viability of the funded projects will have more of an effect on the physical therapy profession."

Looking to the Future

Indeed, Foundation President White is enthusiastic about the future of physical therapy. "One of the exciting developments that I see these days is the increased interest by physical therapy clinicians in research," she says. "Clinicians realize that they no longer can rely upon anecdotal examples and clinical wisdom when making decisions about patient care. Physical therapists are using scientific evidence more than ever in our history."

That's why White is so convinced that the ultimate results of the CRCs and the CRN are critically important. "Clinicians like myself are much better

able to determine treatment interventions and establish a prognosis for a patient with the information derived from these research studies," she says. "As Foundation president, I would like to make physical therapists more aware of the importance of Foundation-funded research in the development of evidence for their practice. It is my hope


that this awareness will result in a professional commitment by physical therapists to support the work of the Foundation."¹

Fran Hopkins is a freelance writer.

Reference

1 Fritz JM, Delitto A, Erhard RE. Comparison of classification-based physical therapy with therapy based on clinical practice guidelines for patients with acute low back pain. *Spine*. 2003;28:1363-1372.

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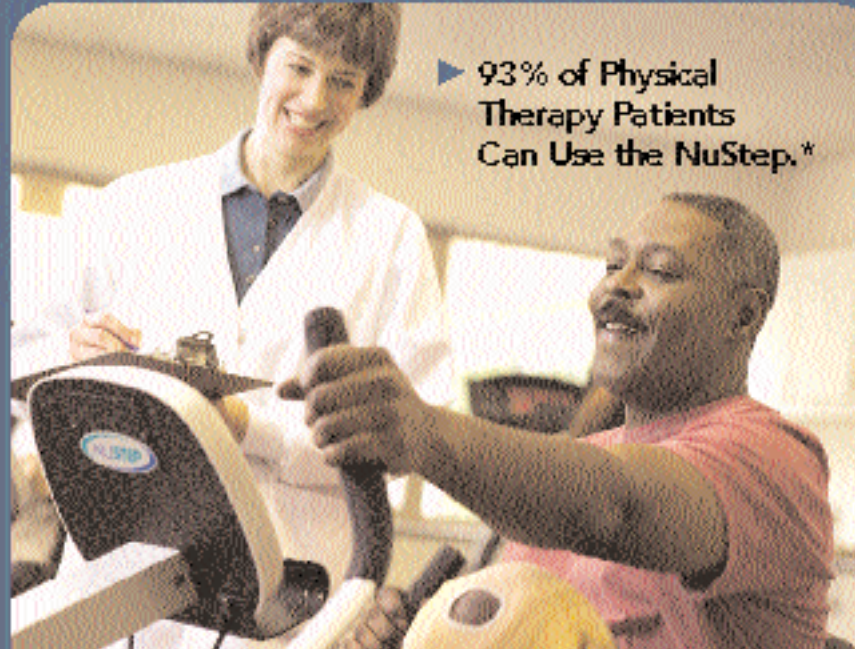
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