

## UNC'S COLLABORATIVE STUDIES COORDINATING CENTER

# Controlling quality, managing data, *changing the practice of medicine*

BY MARGARITA DE PANO

In 1967, a committee chaired by Dr. Bernard Greenberg, then chair of the UNC Department of Biostatistics (and later dean of the School of Public Health), wrote a report for the National Heart Institute (now the National Heart, Lung, and Blood Institute) that outlined the way clinical trials should be run. A major component of the document, which came to be known as the “Greenberg Report,” was the recommendation that data produced by multi-site clinical trials be managed by a “data coordinating center.” (See [www.sph.unc.edu/cph/weblinks](http://www.sph.unc.edu/cph/weblinks).)

Four years after the release of Greenberg’s report, the UNC Collaborative Studies Coordinating Center (CSCC) opened its doors as one of the first such data coordinating centers in the United States. It operates today under the three-pronged mission of “improving public health by coordinating important health research, developing innovative research methodology, and providing training in the application of research methods.”

Since 1971, the CSCC has coordinated the activities of more than 30 multi-site clinical trials and epidemiology studies in the United States and other countries, says Dr. Lisa LaVange, director of the CSCC and professor

of biostatistics at the UNC School of Public Health.

Trials take place in hundreds of clinical and field centers and involve thousands of patients, LaVange says.

“The CSCC oversees the accuracy, quality and consistency of clinical trial and observational study data by ensuring that all clinical or field sites follow identical procedures, use correct statistics and publish unbiased results,” LaVange says. “We focus on quality control, providing state-of-the-art data management and statistical analysis services. At the same time, we handle the smallest details of what’s involved in organizing a study, such as managing meetings, training clinical staff, and developing protocols and manuals of operation. We

coordinate the whole process, from study design to final delivery of public use datasets.”

The CSCC, part of the UNC Department of Biostatistics, also conducts research to continuously improve the way multi-site studies are designed and analyzed. “One of our investigators, for instance, has done a lot of research on how thousands of data fields involving physical activity—collected via monitors people wear on their belts—can be reduced to meaningful statistics,” LaVange says.

In compliance with CSCC’s mission, all the learning that comes from organizing the various components of clinical trials gets passed on to students and various scholars. Dr. Ed Davis, director of the CSCC from 1991 to 1997, says one of the advantages of being housed within a topnotch biostatistics department and a topnotch public health school is that staff at the CSCC are able to train some of the world’s future public health leaders.

At any given time, the CSCC has six to 12 graduate students from the School working on CSCC projects and using CSCC data for their dissertations. Postdoctoral fellows and visiting faculty from other countries collaborate with the CSCC to write manuscripts. Meanwhile, CSCC faculty teach in the classroom what they learn on the job. “I have taught a course for many years on how to design and conduct a clinical trial,” says Davis.

The training component of the CSCC’s mission distinguishes it from non-academic data-coordinating centers that provide simi-

lar services, LaVange says. While university-based data coordinating centers are now fairly common, CSCC is the oldest such university-based center in existence today. “We’d like to think we have the advantage in years—that we have developed cutting-edge processes, and that, in our 37-year history, we have worked on studies that have advanced the practice of modern medicine,” LaVange says.

CSCC’s work impacts numerous therapeutic areas but can be felt most keenly in the field of cardiology. In March 1984, the center published the results of the first major clinical trial to show that people can reduce their risk of heart disease by lowering their cholesterol levels. Shortly afterwards, *TIME* magazine published a cover story titled, “Cholesterol... and now the bad news,” effectively disseminating CSCC’s research to millions of people worldwide. “We’d like to think we’ve prevented a lot of heart attacks through that,” Davis says.

CSCC also coordinated:

- The first clinical trial to show that giving an Angiotensin-Converting Enzyme (ACE) Inhibitor to people suffering from congestive heart failure can reduce their mortality risk;
- The first clinical trial to establish the superiority of carotid endarterectomy (a surgical procedure that removes plaque from inside

arteries) over drug therapy in the treatment of a narrowing in the lumen of the carotid artery; and

- Several pioneering trials that monitored the cardiovascular and cerebrovascular health of people in China, Pakistan, Poland and Russia.

“Today, every person in the world who has heart failure gets an ACE-inhibitor, and carotid endarterectomy is used as a common treatment to prevent strokes,” Davis says. “The results of these trials have crossed over into standard practice.”

Overall, the CSCC has produced more than 1,000 research publications on cardio-

2001 to 2005. Some of its ongoing studies include:

- Atherosclerosis Risk in Communities (ARIC),
- Longitudinal Studies of Child Abuse and Neglect (LONGSCAN),
- Folic Acid for Vascular Outcome Reduction in Transplantation (FAVORIT), and
- Randomized Intervention for Children with Vesicoureteral Reflux (RIVUR).

One of CSCC’s challenges is the competitive nature of its work. “The CSCC is fully dependent on research dollars,” LaVange

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vascular disease, cerebrovascular disease, periodontal disease, kidney disease, respiratory disease, mental health, child health, and nutrition and obesity, says Dr. Lloyd Chambless, research professor of biostatistics at the School, who directed the center from

says. “We have to write a lot of proposals and win a lot of projects. We cannot afford to have a bad year.” Meanwhile, securing funding from the NIH is an extremely competitive process. “A typical NIH multi-site study involves funding as many as 20 field sites but only one coordinating center. It can be tough. Fortunately, we are doing very well. Our receipts have grown steadily since 2005.”

One sign of this is the CSCC’s recent NIH award to coordinate the Hispanic Community Health Study/Study of Latinos (HCHS/SOL), a prospective epidemiological study of 16,000 Hispanics living in the United States. The project examines the impact of acculturation—adapting to life in a new environment and culture—on the health of this minority population.

“The study will be the most comprehensive assessment of health ever done in this rapidly growing segment of the U.S. population,” LaVange says. Study results will be shared with communities involved in the research to help improve public health at the local level.

For more information on the Collaborative Studies Coordinating Center, visit <http://www.csccl.unc.edu/csccl/index.php>. ■



Dr. Lisa LaVange

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