

# Dartmouth-Hitchcock Medical Center DEVELOPMENT

## Backing a landmark study By Barbra Alan

What do San Francisco, Calif.; Omaha, Neb.; and Lebanon, N.H., have in common? Each of these cities is home to a hospital that is participating in a landmark study, the Spine Patient Outcomes Research Trial (SPORT).

A \$13.5-million grant from the National Institutes of Health (NIH) has thrust this trial, which is based at Dartmouth-Hitchcock Medical Center, onto the national stage. That financial vote of confidence in the project is not only one of the largest grants ever received by DHMC, but it is also one of only a very few grants ever given to fund a multisite, multi-year, prospective randomized clinical surgical trial.

### A good SPORT

SPORT is a clinical trial comparing different ways of treating low-back and leg pain. Participating patients have been recruited from DHMC's Spine Center, as well as from 10 other sites throughout the country to ensure a diverse participant pool—a microcosm of the nation's back-pain sufferers. All 11 of the sites have Centers of Excellence for spine care. Most of them also belong to the prestigious National Spine Network, an organization whose membership is limited to comprehensive, multidisciplinary spine-care programs that have been recognized for high-quality patient care and a commitment to conservative treatment.

Recruitment for SPORT began in 1999, and to date there are 2,350 patients enrolled—all of whom have been diagnosed with one of the three

most common conditions for which back surgery is performed: lumbar intervertebral disc herniation, spinal stenosis, or spinal stenosis secondary to degenerative spondylolisthesis. Patients with a recent history of cancer, spinal deformities, or prior back surgery are not eligible for the trial. Enrollment is expected to be completed toward the end of 2004, and preliminary feedback from the study will be available shortly thereafter.

The United States spends an estimated \$30 billion annually on medical care to relieve low-back pain—more than double the amount spent on all medical care for cancer patients. Accounting for a large portion of the expense is the sharp rise in spinal surgery over the years. A startling 15-fold geographic variation in the rates of these surgeries has been documented.

But surgery is just one way to treat low-back pain; there are several nonsurgical alternatives, including physical therapy, osteopathic manipulation, and pain medication.

William Abdu, M.D., M.S., the principal site investigator for SPORT at DHMC, explains that “patients often come in with questions: Should I have surgery or not? How likely is it that this medicine will help? How likely is it that I'll get better on my own?” Unfortunately, he adds, “we don't have answers that are supported by solid data. One of our goals is to gather information to help educate patients, and the providers who counsel them, on which treatments are most effective for specific diagnoses.”

SPORT also hopes to help with

the question of how to spend the nation's health-care dollars most effectively. “Another goal is to do a cost-effective analysis of surgically treated patients versus nonsurgically treated patients,” explains Abdu.

### Of dollars and data

“We can't direct health-care dollars appropriately until we have the data to show the successes and failures of the treatments,” he continues. “Evidence is the key word in this study. Right now, there is very little evidence to support many of the treatments that we do. You just can't make a good decision without good data and evidence.”

To gather that evidence, Abdu says, “Patients who have one of the three diagnoses required for participation are introduced to the SPORT research trial. They have the opportunity to get their questions answered and to make an educated decision about whether they are willing to participate in the trial.”

The participants are then put into one of two groups: randomized and observational. The names of patients who agree to be randomized are entered into a computer, and a program—which was developed at Dartmouth—randomly assigns them a treatment: either surgery or an alternate form of nonsurgical treatment that the patient and provider determine. Patients who prefer to choose their own form of treatment are assigned to the observational group.



JOSEPH MEHLING

What are the benefits of having these two groups participate in the study? Dr. Abdu explains: “By comparing the randomized group with the observational group, we can assess whether the groups are differ-

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ent. We can see if there are biases in the observational group that might impact the results. This will help us understand how applicable the results are to the general population

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*Excellence in any department can be attained only by the labor of a lifetime; it is not to be purchased at a lesser price.*  
— Lexicographer Samuel Johnson (1709-1784)



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by comparing the results of these two groups.” This information will also help determine which patients will benefit from which treatment alternatives on a national level.

Patient progress will be monitored for up to five years through follow-up visits, surveys, and other methods of communication—most of which can be handled securely online. “We’re not just interested in how patients do after three months or six months,” says Abdu, who is also the medical director of the DHMC Spine Center and an associate professor of orthopaedic surgery at Dartmouth Medical School. “We want to see how well they’re doing five or ten years down the road,” he explains. “Are they active? Are they living productive lives? Are they pleased with their treatment?”

The results of the SPORT study will provide, for the first time, scientific evidence of the relative efficacy of surgical versus nonsurgical treatments for low-back conditions. This evidence is expected to have a major impact not

only on the amount of money Americans spend on chronic back pain each year, but also on the quality of life for those who are desperately seeking relief from their pain.

The principal investigator for the entire landmark study is James Weinstein, D.O., the chair of the Department of Orthopaedics at DMS and DHMC as well as the founding director of the institution’s Spine Center.

### Striking variations

Studying how to improve the effectiveness of clinical practice in this way is a cornerstone of Dartmouth’s Center for the Evaluative Clinical Sciences (CECS). CECS is an outgrowth of the pioneering work of DMS epidemiologist John Wennberg, M.D., M.P.H. During the early 1970s, his research revealed striking variations in health-care costs and methods of treatment within Vermont.

Even more striking was Dr. Wennberg’s conclusion: these variations were not due to differences in patients’ conditions but to differing opinions among physicians about the efficacy of various treat-

*Several experts in outcomes research are leading the way on a Dartmouth-based, 10-site study of surgical and nonsurgical treatments for back pain. James Weinstein, far left, is principal investigator for the entire \$13.5-million study, and William Abdu, near left, is its principal site investigator at DHMC.*

ment methods. This groundbreaking conclusion was the foundation of the discipline now known as outcomes research. It led to the birth of CECS in 1989 and then to the establishment of its M.S., Ph.D., and M.P.H. degree-granting programs. Now, almost every major academic medical center has a program in outcomes research.

Wennberg—who holds the Peggy Y. Thomson Professorship for the Evaluative Clinical Sciences, the country’s first endowed chair devoted to the discipline of outcomes research that he pioneered—has assembled within CECS dozens of scientists and clinician-scholars like Abdu and Weinstein. The ranks of CECS investigators also include researchers from Dartmouth’s other graduate schools and from the undergraduate faculty. Together, they conduct revolutionary research on critical medical and health issues with the goal of improving the health-care system.

The physicians, scientists, and students at CECS rely on observation, inquiry, collaboration, and investigation to produce evidence. And, as in the case of the SPORT study, this evidence is expected to have a very real, positive impact on the lives of millions of people across the nation—and around the world.

## Partners in policy

The Spine Patient Outcomes Research Trial (SPORT) described in the adjacent story is just one of the many ways that Dartmouth’s Center for the Evaluative Clinical Sciences is having a revolutionary impact on the nation’s health policy, on policy-makers’ understanding of the importance of rigorously assessing health-care outcomes, and on the application of the principles of quality improvement to health-care settings.

In simple terms, CECS researchers focus on defining what medical care is and how best to provide it. The knowledge they are developing in understanding the systems and processes of care, outcomes research, and the role and value of shared decision-making is revolutionizing health care.

The synergy among the physicians and scholars on the CECS faculty is not the only powerful collaborative force helping to shape its work. The generosity of individuals, foundations, and corporations is also a key factor in making possible the work of Drs. Wennberg, Weinstein, Abdu, and countless others.

The internationally known work that they and their colleagues accomplish under the auspices of Dartmouth’s Center for the Evaluative Clinical Sciences has a goal that is audacious in its breadth and depth—to improve the health-care system by applying to the study of clinical practice the same scientific rigor that laboratory investigators bring to their work.

The generosity of those who understand and appreciate CECS’s innovative work, and are inspired to support it, will be critical to helping ensure its continued leadership in reshaping the national health-care landscape. That improvement of health care—and the health-care system—is work that will benefit each and every one of us.

