Broadening Recruitment for Minorities, the Elderly

Researchers struggle to make cancer studies more representative of all populations

“If a new cancer therapy is tested only on young white men, can we generalize that an elderly Hispanic woman will have the same response to the treatment?”

So asks Gwendolyn P. Quinn, PhD, associate professor of oncologic sciences at the University of South Florida’s College of Medicine. With colleagues at the Moffitt Cancer Center, Quinn has developed a Spanish-language DVD and booklet based on feedback from a focus group of Hispanic cancer patients and caregivers.

More than a third of the U.S. population belongs to a minority group, yet minorities make up less than 1% of adult cancer patients enrolled in clinical trials. The results of a recent analysis of nearly a quarter-million patients from the California Cancer Registry reaffirmed this long-recognized disparity. Blacks were less likely than whites to enroll in cancer clinical trials, at rates of 0.48% versus 0.67%, respectively (Ann Surg 2011;254:438–443). And while nearly half of all patients in the study cohort were 65 or older, this population represented just over a quarter of those participating in cancer trials.

These ethnic and age disparities have far-reaching implications. Minorities and elderly people face higher cancer rates than the population as a whole—and they comprise a growing proportion of America’s populace. In addition to the genetic differences between racial groups, populations that are underrepresented in clinical trials may have different cultural and lifestyle factors (such as diet and environmental exposures) that affect their response to cancer therapies.

CROSSING BARRIERS

The Moffitt Cancer Center’s DVD proved effective in boosting Hispanic patients’ willingness and intention to participate in a cancer clinical trial, according to preliminary research. But language is just one barrier to minority participation in clinical trials. The National Cancer Institute’s (NCI) Minority-Based Community Clinical Oncology Program has cited limited education, fear and mistrust of the health care system and clinical research, economic pressures, and transportation difficulties as other key factors. Lack of insurance or insufficient insurance also may deter potential participants.

Minority populations and people with low socioeconomic status are more likely to have a lower level of health literacy than white people and those who are financially secure. But the problem is most prevalent among the elderly, as surveys show that more than two thirds of adults in the United States age 60 and older possess inadequate or marginal health literacy skills. Explaining the nuances of a clinical trial to a person with low health literacy takes additional time and effort, say health professionals.

To complicate matters further, older people and certain minority populations are prone to conditions such as uncontrolled hypertension and obesity, which may exclude them from trials. Both conditions boost cardiovascular risk, a concern with many chemotherapy agents.

However, medical oncologists cannot automatically assume that an older or minority patient is not interested in participating in a trial. Keith Flaherty, MD, director of developmental therapeutics at Massachusetts General Hospital’s Cancer Center, notes that while people might assume that a 40-year-old cancer patient with 2 children would be more motivated to participate in a study than an 82-year-old, this is not necessarily true. “When you walk into a room to meet a patient for the first time, you don’t know where they’re coming from until you have an initial discussion,” he says.

One strategy to increase enrollment of elderly patients is educating their family members—not just about the trial itself, but also about progress in treating cancer over the past 40 years and the importance of clinical trials, says Nicholas J. Petrelli, MD, medical director at Christiana Care Health System’s Helen F. Graham Cancer Center in Newark, Delaware. “If a patient’s son or daughter is on board, the patient often will agree to participate,” he says.

TRAINING FOR TRIALS

The clinical trial system itself can contribute to the problem, comments Mona Fouad, MD, MPH, a professor in the Division of Preventive Medicine at the University of Alabama at Birmingham (UAB) and principal investigator for the Enhancing Minority Participation in Clinical Trials (EMPaCT) program. The program features a consortium of 5 institutions: UAB, Johns Hopkins University, the University of Minnesota, the University of Texas M.D. Anderson Cancer Center, and the University of California, Davis, with a goal of reaching African-American/black, Asian, Pacific Islander, Hispanic, and American Indian populations.

Initial findings from EMPaCT reveal that many physicians and research nurses never receive formal training on how to recruit patients for clinical trials. They also lack opportunities to interact with colleagues about recruitment-related issues. In response, the EMPaCT research team will develop a Web portal to train researchers on how to recruit all types of patients to cancer clinical trials and give these researchers in training a chance to chat with other colleagues within the consortium.

Another initiative involves patient navigators, people trained to offer culturally sensitive, personalized help to patients and their families during treatment. Navigators could extend their reach by helping patients decide if they would consider a clinical trial, and if so, help them with the consent paperwork and answer their questions, says Dr. Fouad. —Julie Corliss