Clinical Trials Need Minority Patients to Close Gap

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NEW YORK — Racial disparities in access to health care will disappear only when adequate and representative samples of minorities participate in clinical trials, Winston Price, M.D., said at the annual meeting of the National Medical Association.

That disparities in delivery of health care exist is not in question. The Institute of Medicine report "Unequal Treatment: Confronting Racial and Ethnic Disparities in Healthcare" revealed the extent of the problem, showing that disparities remain even after adjustment for factors such as insurance coverage and socioeconomic status.

But a widespread mistrust of the U.S. health care system among minorities—not least because of past abuses such as the Tuskegee Syphilis Study, in which blacks went untreated for many years despite the availability of effective therapy—has led to an unwillingness among African Americans to participate in the clinical trials that might directly benefit their own health.

An increasing understanding of genetic differences and racial differences in response to medications now makes it imperative that minorities be included and their needs addressed in the drug development process, said Dr. Price of the State University of New York Health Science Center, Brooklyn.

The experience with BiDil, a fixed-dose combination of isosorbide dinitrate and hydralazine approved specifically for the treatment of heart failure in black patients, shows it can be done (July 2005, page 1).

"You had 1,050 African Americans who enrolled in the study, and the attrition rate was zero," Dr. Price, who is also president of the NMA, said in a press briefing. "Every single one stayed with that study until completion. The drug was approved by the Food and Drug Administration on June 23, not because it was the right thing to do but because it was pure science and evidence based. All we're asking for is parity."

Other model programs also are demonstrating that blacks can be recruited successfully, Christopher L. Edwards, Ph.D., said at the briefing.

Programs that are successful tend to be well entrenched in the community; they have significant outreach and education and strong, ongoing relationships with local organizations such as churches and fraternities, Dr. Edwards said.

They do not pressure potential study participants, but rather provide information and allow patients to process the information at home and respond to the investigators when they are ready, he said.

Successful investigators are available to the community not only when recruiting; they are able to articulate the tangible benefits of participation, not only for patients themselves but also for future generations. Dr. Edwards' program in the department of psychiatry at Duke University Medical Center, Durham, N.C., is an example.

"We make ourselves available for interviews on television, religious radio, and pop radio. In one creative marketing plan, we placed advertisements for one of our genetic studies on the side of 20 city buses, and have seen a significant number of patients responding," he said.

The overall strategy of information dissemination is to go where the patients are, and not to rely on them to come to us, he said. "With the bus advertisements, the demographic we were recruiting was reliant on public transportation," he added. And the advertisements provided phone numbers, not e-mail addresses or Web sites because these would not be particularly helpful for a population that doesn't own computers.

In the Duke program, the relevant stakeholders are at the table when recruiting programs are being designed. "If we are recruiting college students, we had students who sat on review panels and advisory boards to give us guidance as to what they would respond to, how, and in what setting," Dr. Edwards said.

Another panel member, Rahn K. Bailey, M.D., said that throughout his career he has been interested in issues such as differences in drug metabolism between African Americans and other patients. For example, about 40% of black patients are slow or intermediate metabolizers of many psychiatric medications, said Dr. Bailey of the department of psychiatry and human behavior, University of Texas, Houston, and chair of the NMA psychiatry and behavioral sciences section. ■