Clinical Drug Trials: Black Patients Are Needed

BY NANCY WALSH
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NEW YORK — Racial disparities in access to health care will disappear only when adequate and representative samples of patients of color 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 socioeconomics.

But a widespread mistrust of the U.S. health care system among people of African descent—not least because of past abuses such as the Tuskegee Syphilis Study, in which black patients went untreated for many years despite the availability of effective therapy— has led to an unwillingness among African Americans to participate in 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 people of color 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 (August 2005, page 74).

"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.

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Dr. Christopher L. Edwards of Duke University's psychiatry department says black patients can be recruited successfully.

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.

Because of this, black patients tend to experience more toxicity, and efficacy may be compromised, he said. "It's not surprising to me now that many of my patients over the years have had great difficulty getting better, relapsed a lot quicker, come back to the hospital frequently, and ended up in the legal system because of clinical issues that were not addressed medically," Dr. Bailey said.

"In psychiatry, it's as if we did all our studies on inpatients and none on outpatients, or in suburban communities rather than inner cities. The distinctions are apparent and actually affect medical decision making, he said, adding that these issues also are relevant in cardiovascular medicine, neurology, ob.gyn., and other areas of medicine. Audience member William Lawson, M.D., brought up the work of Surgeon General David Satcher, M.D., Ph.D., in his 1999 report "Mental Health: A Report of the Surgeon General." One of the points made in this report was that virtually all U.S. psychiatric studies included primarily white males, so almost all the available psychiatric drugs had less than 1% African American representation, said Dr. Lawson, chair of psychiatry, Howard University, Washington.

"And the consequences have been awful. For example, once the second-generation antipsychotic medications came on the market it became clear that the risk of obesity, diabetes, and metabolic syndrome was much more of a problem for African Americans and Hispanics than for whites. We don't want to improve the mental health of our patients at the expense of giving them complications that can be lethal," Dr. Lawson said. ■

Some Groups Call for Mandates on Minority Participation

BY JOYCE FRIEDEN
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WASHINGTON — More needs to be done to encourage minority patients and providers to participate in clinical drug trials, several speakers said at a meeting sponsored by the Alliance of Minority Medical Associations, the National Association for Equal Opportunity in Higher Education, and the Department of Health and Human Services.

"If you go to the package insert of a lot of drugs currently on the market and look for information on minority participation in clinical trials, what you frequently will see is the phrase, 'No data available,' " said Basil Halliday, founder of BDH Clinical Research Services, a clinical trial consulting firm in Ridgemont, N.C. "It's high time we get rid of that phrase in the package insert."

One of the most important changes would be a federal mandate to include minority patients in clinical trials as a condition of approval by the Food and Drug Administration. "We also need specific guidance on the degree of representation," Mr. Halliday said. "I don't want to hear you say that you 'encourage it,' 'support it,' or 'want to see more of it.' You need to give specific numbers because that's the only time the industry will respond. I say mandate, mandate, mandate."

B. Waine Kong, Ph.D., CEO of the Association of Black Cardiologists, suggested that the FDA establish an Office of Minority Affairs to address issues relating to minorities, including increasing their participation in clinical trials. Several barriers impede minority participation in trials, among them a lack of minority physicians, who are six times more likely to treat minority patients, compared with white physicians, Mr. Halliday said. "As for African American physicians doing clinical trials, it's almost nonexistent."

Mr. Halliday's company has started the Clinical Research Investigator Support Program to encourage more minority physician participation. "We need to do a better job of creating a pipeline of future physicians, minority scientists, and researchers who are culturally competent and culturally sensitive to the people they're six times more likely to treat," he said. "We need to involve those people in the process early."

Minority physicians have a lot of reservations about participating in clinical trials, he continued. "A lot of physicians I have talked to over the years don't know that the pharmaceutical industry had nothing to do with Tuskegee," Mr. Halliday said, referring to an experiment conducted by the U.S. Public Health Service in which African American men were deliberately left untreated for syphilis.

Dr. Kong noted that minority physicians also face a variety of entry barriers to clinical trials, such as complex, technical forms to fill out and the need for capital investment. Further, many minority physicians are reticent to refer patients to trials being run by other physicians "because of a belief that if they send that patient to another doctor, they may lose that patient. That's not necessarily true."

On the patient side, minority patients need to be better educated about the benefits of trial participation, such as free, state-of-the-art medical care and better outcomes due to more frequent physician visits, Mr. Halliday said.

He said that his company also has started a minority community outreach and education program with institutional review boards. "It doesn't make sense that the folks sitting on the IRB and approving protocols don't accurately reflect the communities in which they live," he said. He complimented one board, Essex IRB in Lebanon, N.J., for changing its board makeup to allow for more minority participation.

Mr. Halliday urged the National Institutes of Health to start grant reviewer education programs about minority inclusion in clinical trials. "The same folks, year after year, get money from NIH, but there's no demand on those people to change. We need to hold them accountable for putting minorities in the clinical trial process." ■