

Project IMPACT

Increasing Minority Participation and Awareness of Clinical Trials

By Brigette Settles Scott, MA
Closing the Gap, Working Toward Our Goal • August 2003

Research in the past few decades has uncovered significant differences among population groups in the metabolism, clinical effectiveness, and side effects of many prescription medications. The lack of information to support appropriate pharmaceutical interventions in minority patients further contributes to health disparities among people of color. Equally as important are the documented environmental, biological, cultural, and psychosocial factors which affect a patient's ability to comply with drug regimens.

"Until recently, there was no significant effort by the Food and Drug Administration to have the data that come out of clinical trials representative of the society," said Dr. Michael A. Lenoir, principal investigator for the National Medical Association's (NMA) Project IMPACT (Increasing Minority Participation and Awareness of Clinical Trials). "There are a number of studies that look at polymorphisms [naturally occurring variations in how individuals metabolize medications] and responses to medications in different ethnic groups. There is a clear distinction between how certain groups are represented by polymorphic gene pools, and how they respond to certain medications. So, consequently, most medications released in this country have never been studied adequately in minority populations, particularly African Americans."

While it is always important to talk about the preventive aspects of health promotion and disease management—early detection and early intervention—Lenoir maintains that pharmaceutical treatment is often the first line defense in minority communities because of traditionally later diagnosis and more chronic complications from various diseases.

"Often, treatment simply comes down to the medications. Currently, there is no equitable information about what effect medicines have on our people. I think it is important to ensure that pharmaceutical products, which are released for distribution to minorities, are adequately studied in the populations that represent them. We must ensure that when a drug comes to market, and people start to take it, they can be assured that it has been representatively studied in all populations," said Lenoir.

Making an IMPACT

The NMA has taken on a major effort to get more minority participation in clinical trials. Initially funded through a cooperative agreement with the Office of Minority Health (OMH), the goal of Project IMPACT is to increase knowledge and understanding, and to raise awareness about clinical trials among African American physicians and consumers, thereby increasing their participation in all aspects of clinical research.

"Our objective initially was to simply educate and train physicians to become clinical investigators because it's difficult to get people

into clinical trials unless they trust the people who are doing it," said Lenoir. "We've since expanded our program to educate African American patients about the value of participating in clinical trials," he added.

Education and training programs are the cornerstone of the project's activities. Project IMPACT has three core programs designed to teach minority physicians and other health care providers about clinical research, its benefits, and reasons why participation is important for African Americans. The training includes a one-hour presentation, *Clinical Research/Trials in Brief*; a half-day workshop, *Clinical Research Overview and Training*; and a three-day intensive investigator course, *Good Clinical Practices*.

According to Lenoir, Project IMPACT trained more than 500 doctors from across the country during the last five years. "We've provided information on ethics, regulations, what's involved in becoming a clinical researcher, and what resources are needed to do effective clinical trials. So now, we have a database of physicians who are able to talk rationally to their patient populations about clinical trials," Lenoir said.

"We also created consumer-based materials, including a great book, called *You've Got the Power: What You Should Know about Clinical Trials*. We distributed it as far as our resources have permitted to our physician base and large African American organizations," Lenoir said. "Literacy is an issue for many Americans, so we also use a lot of media tools to talk about clinical trials. We also have ambassadors, who are prepared to go and talk to community groups around the issue of clinical trials," he added.

"It is our intent to engage in an honest dialogue locally and nationally with the African American community," Lenoir continued. "We need to discuss in a rational way what clinical trials are and what the advantages and disadvantages are, so that we provide a more balanced perspective. We don't want the narrow perspective that we got from our experience with Tuskegee and other studies," said Lenoir.

As a result, Project IMPACT now reaches more than 1,000 health care providers and consumers. It introduces them to the clinical research process, and the value of participation in clinical trials. In total, the Project conducted 19 clinical trials and developed and disseminated several consumer-directed educational brochures, videos, and fact sheets.

In the future, Project IMPACT will interview the physicians who participated in the training program, but did not take part in a clinical trial to determine what the barriers are and how to overcome them. Ultimately, NMA hopes to expand the base of African American physicians who conduct clinical trials, and enroll more of the patients that they serve.



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Grassroots Effort

The Bay Area Multicultural Clinical Research and Prevention Center, located in Oakland, Calif., was founded by Lenoir to incorporate people of color in clinical research trials. The Center consists of a team of primary care and specialist physicians from within the African American community, who assist in the recruitment of patients, and serve as investigators to clinical trials.

There are very few African American investigators at the local level, where most of the research is conducted. Lenoir believes that this disparity is a “clear violation of the scientific process.” He argues that if African American participation in clinical research does not increase, the impact on the community at large will be enormous.

“Clinical trials are hard to do. You must be organized to do them. We are gradually getting more and more of our doctors to participate,” Lenoir said. “We’ve certainly been successful in engaging the community on a number of different levels about clinical trials,” Lenoir

continued. “We’ve developed four investigators in this area, and have done 10 successful clinical trials. One of our major contributions to the trials has been African American participation. When the trial is finished, African Americans will be represented in the trial’s results.”

However, these numbers are not enough. Lenoir believes that minority groups need to be more involved in clinical research if racial and ethnic disparities in health are to be eliminated. Educating physicians and helping the African American community understand both the advantages and disadvantages of clinical trials is a small step that has far-reaching implications.

“We are continuing to get more people interested in clinical trials, and we’re working diligently to get physicians interested in not only serving as investigators, but developing their own clinical trial programs,” concluded Lenoir.

For more information on Project IMPACT, call 202-347-1895. ❖

For more information on the Bay Area Multicultural Clinical Research and Prevention Center, call 510-834-4897. ❖



Project IMPACT is based on the Summit workshop “Minorities in Research: Its Impact on Health Disparities.”

