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Mary Anne Fleetwood

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# Clinical Trials & Cultural Diversity

by Mary Anne Fleetwood

**S**ome experts contend that protocol medicine is better medicine. After all, it is leading edge treatment with built-in accountability and an ever-present possibility of cure. Unfortunately, equal access for all to clinical trials is the exception rather than the rule. While race-conscious grantors are encouraging cancer researchers to accelerate recruitment of minorities, not all investigators find cultural diversity easy to achieve. Minority recruitment is a process that is enhanced by commitment and by understanding the barriers to equal access and appropriate strategies for overcoming them.

## MINORITY-BASED CCOPS

The National Cancer Institute's (NCI) Minority-Based Community Clinical Oncology Program (CCOP) is a major federal program with a keen multicultural focus. It was launched in 1990 to accrue minorities onto cancer treatment and control trials. This year, NCI will award \$2.3 million to 10 minority-based (M-B) CCOPs in 8 states and Puerto Rico.\* In 1992 the 10 MB-CCOPs accrued 470 patients to treatment trials and 423 to cancer control trials. Seventy-two percent of these patients are minorities; the remaining 28 percent are economically disadvantaged whites.

"The M-B CCOP program allows us to study minorities and to determine why some are hesitant to go on clinical trials. The 10 M-B CCOPS currently funded are attracting primarily African Americans and Latinos," said Otis Brawley, M.D., Program Director in NCI's Community Oncology and Rehabilitation Branch.

"Our most important finding so far is that minority patients who are offered the opportunity to go onto clin-

ical trials do so at the same rate as majority patients." However, Brawley notes that there remain numerous barriers to accrual that vary both with the ethnic minority and geographical area. There is not just one generic list of barriers that applies to all groups nationwide.

Why are some minority patients hesitant to participate? Christopher E. Desch, M.D., Assistant Professor of Medicine and Director of Cancer Outreach and Control at the Massey Cancer Center in Richmond, Va., believes resistance to enrollment in clinical trials is driven more by socioeconomic level than by ethnicity. "For people of low socioeconomic status, recruitment may not be that aggressive. We find the very poor have less ability to keep their appointments. Sometimes they are confused about where to go. Consequently, some investigators don't put them on trials."

"Many of the urban and rural poor distrust research therapy. Some won't allow a biopsy to be done for fear of exposing a malignancy to air. This is based on the myth that a cancer, exposed to air, multiplies."

Desch said that his program placed advertisements in minority-run newspapers to recruit African Americans and Hispanic women into the Breast Cancer Prevention Trial. "There were no replies," he added.

## UNSPOKEN BARRIERS

Members of the Ochsner Community CCOP in New Orleans, La., conducted a 1993 study entitled "Barriers To Minority Recruitment: Implications for Chemo-

\*The 10 M-B CCOPS currently funded are: University of South Alabama, Mobile, Ala.; University of Illinois, Chicago, Ill.; Southfield Oncology Institute, Southfield, Mich.; Veterans' Administration Medical Center, San Juan, Puerto Rico; South Texas Pediatric M-B CCOP, San Antonio, Tex.; Grady Memorial Hospital, Atlanta, Ga.; Tulane University M-B CCOP, New Orleans, La.; King's County M-B CCOP, Brooklyn, N.Y.; San Antonio M-B CCOP, San Antonio, Tex.; and MCV/CMH M-B CCOP of Virginia, Richmond, Va.

Mary Anne Fleetwood is ACCC Staff Writer.

**TABLE 1: TOP 10 REASONS WHY MINORITIES ARE NOT ENTERED ONTO CLINICAL TRIALS**

- Lack of protocols specific for cancers that are seen most often in minority patients
- Lack of understanding of minorities' knowledge, attitudes, and practices regarding cancer, with resulting poor protocol planning
- Different tumor incidence in Hispanics and minorities compared with whites
- Treatment protocols not available at patient's preferred treatment site, such as HMOs and PPOs
- Financial constraints and requirements of costly diagnostic procedures at specific times
- Too much time required for patients to understand protocols and consent forms
- Lack of Spanish proficient/bilingual providers and translators, which promotes inadequate communication between patients/families and providers
- Concept of "guinea pigs" still prevalent
- Lack of awareness of existing protocols by physicians and by the community
- Too much time required for physicians and staff to explain protocols and consent forms

Source: Manuel R. Modiano, M.D., Director of Clinical Research, Hematology, and Oncology, Cancer Care Center of Southern Arizona, Tucson, Ariz.

prevention Trials" (M. Bateman, C.G. Kardinal, D. Lifsey, R.J. Gralla, A. Washington, T. Scroggins, and S. Allen). The study reiterates the findings that although African Americans have the overall highest age-adjusted cancer incidence and mortality of any U.S. population group, they are underrepresented in cancer control trials.

The study cited "unspoken barriers" that fuel the African American's distrust of high-tech research and clinical trials. These include distrust of the medical establishment and of clinical trials in particular; unpleasant experiences in public hospitals; feeling exploited by doctors in academic institutions; lingering memories of the Tuskegee syphilis experiment (in which minority patients with syphilis were given a placebo and died); the inability of women with households to comply with time-consuming protocol demands; the inability of white physicians to relate to African American patients; reliance on folk remedies; and limited knowledge of clinical trials by some family physicians with large minority practices.

#### **OF CAMPHORATED OIL AND PSYCHIC HEALING**

Joann T. Richardson, Ph.D., a researcher at the Medical College of Virginia in Richmond, studied why rural women, both African American and white, are reluctant to use mammography as early screening for breast cancer. Although her study does not explicitly deal with clinical trials, the results are relevant to minority recruitment onto trials.

Richardson found that the kind and degree of support women receive from family members and peers are critical in determining whether they opt to have screening mammography. If a woman has strong family and peer support for having mammography, she can

often overcome the main barriers to access (no health insurance, high cost, and geographic inaccessibility) and to her fears.

The study also identified cultural beliefs among rural African-American women that adversely affect their willingness to seek treatment from high tech medicine. "Many rural African-American women have a strong belief that God will take care of them. Consequently, that belief is a major barrier to cancer prevention activities," said Richardson.

Another barrier is the use of folk cures. One woman interviewed during the study recounted the story of a neighbor who believed in the use of "bag balm," an emollient used on cow udders. The neighbor used the bag balm on her own breasts when she suspected a problem. She sought medical care only after her breasts ulcerated as a result of the cancer. She underwent surgery, but subsequently died from her breast cancer.

"Another woman had been taught to self-treat irregularities of the breast with camphorated oil and a tight bra," said Richardson. "However, this woman came forth and received medical treatment for what was diagnosed as a benign breast condition. Still others would

rather pay Sister Sophie, the community healer/psychic, \$500 than a doctor \$50."

"These beliefs do not come from communities of 30 years ago; they are current," said Richardson. She believes that rural physicians and other health care providers need to educate female patients by explicitly recommending breast cancer prevention behaviors, including breast self-examination, clinical breast examination, and appropriate screening mammography.

#### **GUINEA PIGS**

In Southfield, Mich., Clarence B. Vaughn, M.D., medical oncologist with the Southfield Oncology Institute, is starting a cancer research institute. His patient population is 96 percent African American. Trying to get patients enrolled in clinical trials has been hard. "They don't want to be guinea pigs. It may take me a week to convince the patient to go onto a trial. The patient may have to first talk to the family or the significant other. But it usually happens," said Vaughn.

"I find other barriers include: limited access due to inadequate transportation; the lack of a strong support system or family to encour-

age the patient to make a commitment to being on the trial; and negativism within the physician community about the efficacy of cancer treatment.”

Vaughn takes each barrier and develops a strategy for overcoming it. His solution to inadequate geographical access was to persuade a local hospital to spend \$6,000 one year on medical transportation for minorities.

To keep newly enrolled patients in trials, Vaughn links recently enrolled minority patients with a minority patient of similar age and background who has experience being on a clinical trial. The support system gives patients a source of strength when they feel weak and vulnerable.

Vaughn even conducts training for physicians on leading edge cancer treatment, etiology, diagnosis, and screening. “We have to educate doctors because some have negative, fatalistic beliefs about cancer.”

On a positive note, Vaughn cites recent findings that show tumor-size and survival rates are about the same for middle class African American and white women. “This shows that African Americans are getting diagnosed for breast cancer earlier.”

### **OVERCOMING SUSPICIONS**

The principal investigator of the M-B CCOP at the University of South Alabama, Marcel Conrad, M.D., said that his African-American patients will go on treatment trials but are hard to enroll in cancer control trials. Low income people can rarely afford to have mammograms and tend to be highly suspicious of research and institutions. Getting them in cancer control trials is difficult.

“There’s also a belief in predestination among some African Americans. These patients feel that

if they get cancer, it’s God’s will, and there is nothing that can humanly be done to change it.” Conrad has spoken at African-American churches about cancer control but found little or no interest in it.

Thomas Lad, M.D., medical oncologist and principal investigator at the University of Illinois M-B CCOP, where there are primarily African-American patients in an inner-city catchment area, sees his program as “moderately successful” in minority recruitment. “It’s not true that minority patients won’t enroll,” said Lad. “Inner city residents with a low educational level realize they’re not able to understand the complexities of the disease. They acknowledge that and defer to me about what treatment is appropriate.”

Lad believes there is a difference between the inner city and middle class view of cancer. “People of low socioeconomic status tend to be very fatalistic. They watch their friends and family die of cancer. They don’t care about seeking out the best treatment because they aren’t sure there is one. You can’t appeal to these patients on the basis that the trial provides cutting-edge treatment. African Americans also have an aversion to surgery and tend to avoid trials where it is involved. For example, 25 percent of our African-American patients say no to surgery for low-stage lung cancer because of the belief that if you open up the body, the cancer grows,” said Lad.

“We’ve also found that inner city patients are not willing to make a long-term commitment to a long-term cause with short-term toxicity. They typically do not take a long-term view of things and tend to sign up for phase II and randomized trials.”

Lad agrees that African

Americans tend to sign up for treatment rather than prevention trials. “These are healthy people who would have to take a pill every day. Would you do that?” he asked. To encourage minority participation in prevention trials, the hospital provides cancer risk assessments for minority candidates. Once the candidates assess their risks for getting cancer, they are apt to sign on.

### **FINDING THE RIGHT PROTOCOL**

Louis Baez, M.D., Chief of Hematology/Oncology at the Central Medical Center in San Juan, describes how the Hispanic patients in the Puerto Rican M-B CCOP give decision-making power to their extended family. The client population is low income and mostly uninsured. The patient’s extended family decides whether the patient will go onto the trial. Baez may even be asked by the patient to confer with the priest. If one family member is not consulted and later comes forth to challenge the family’s choice, the patient will be taken off the trial. “This has happened more than once because everybody in the family must agree. It takes a long time to get the consent form signed.” In spite of this, Baez has a high rate of accrual.

The absence of appropriate protocols is a significant barrier to minority recruitment for Jose Lopez, M.D., principal investigator for the San Antonio M-B CCOP. “Many of our patients have gall bladder, liver, and stomach cancer. Although these types of cancer are common among Hispanics, there are no available protocols for these tumor sites,” said Lopez.

“Although protocols are available for breast and colorectal cancers, many patients would not be eligible for adjuvant studies due to the advanced stages at presentation. Women often delay seeking care for

breast tumors because they are not informed about screening, early diagnosis, and routine normal health habits. Likewise, men may not come forward because they are afraid to subject themselves to the diagnostic procedures that may be used."

Another barrier is the significant comorbid disorders seen in these patients. Diabetes and renal, heart, and hypertensive diseases render many patients ineligible for study.

If the patient is eligible and a protocol is offered, said Lopez, patients in general are entered into a trial. "We have not had problems with compliance," he adds.

#### **TRANSLATING SUCCESS**

Manuel R. Modiano, M.D., is former Director of Minority Outreach at the Arizona Cancer Center in Tucson and currently Director of Clinical Research, Hematology, and Oncology at the Cancer Care Center of Southern Arizona in Tucson. He conducted a study entitled "The Top Ten Reasons Why Minorities Are Not Entered Onto Clinical Trials." Results are summarized in Table 1. The minorities in the patient population were Hispanic and Native American.

Minority patients have unique characteristics that need to be considered when developing clinical trials, Modiano explained. These include the different incidence of certain neoplasms, many of which are uncommon among whites, and specific issues, such as the need for strong family and community support. It is not realistic to expect accrual of Hispanics, for example, into an early stage multiple myeloma trial because the incidence of myeloma in this population is significantly lower than in African Americans or whites.

The use of bilingual translators, however, can make a difference in recruitment results, according to

Ellen Chase, Director of the Arizona Cancer Center Clinical Trials Office and SWOG Program Administrator. In addition to maintaining Spanish-version consent forms, the Arizona Cancer Center ensures that a bilingual translator works with Hispanic cancer patients in a supportive role, both in the Cancer Center Multidisciplinary Clinics and inpatient services and in its Tucson community outreach programs. The translator communicates with the patient when he or she goes into the hospital, and there is a follow-up call at home. The translator explains anything that is confusing for the patient. The translator/buddy is there for the patient and family during the decision-making process involved in entering a clinical trial and throughout treatment and follow-up. Chase said the system works and has been a priority program commitment both at the Cancer Center and in the surrounding Tucson outreach program. Moreover, it has potential applications to overcome other recruitment barriers.<sup>1</sup>

#### **INADEQUATE ACCESS TO HEALTH CARE**

Native American patients enter trials, said Chase. "But we only now are developing the rural outreach mechanisms to recruit them."

Echoing her remarks, Larry P. Ebbert, M.D., a medical oncologist in Rapid City, S.D., finds no problem recruiting Native Americans onto clinical trials. Almost 10 percent of Ebbert's practice is Native American—all Sioux from the Pine Ridge, Eagle Butte, and Rose Bud reservations. The major barrier is that they have to be referred from the public health system on the reservation to the specialist if they are to be entered into trials. Too often, that referral is not made,

according to Ebbert.

Ebbert believes that Native Americans do not have the same level of access to health care as do other Americans, despite having the same incidence of breast, colon, and lung cancer as the white population.

"Native Americans want long-term, stable relationships, but the docs on the reservation are there for a few years and then leave," he said.

"Native Americans do not find high-tech modern medicine at odds with their medicine. They are on clinical trials and simultaneously do the sweatlodge and practice their own medicine. They do not see the two as competitive." Ebbert and Chase both note that there is much to do to recruit more Native Americans onto clinical trials.

#### **LIKELY SCENARIOS**

What about the future? The multicultural vision of grantors is unlikely to be realized until cultural diversity in clinical trials is achieved on a much wider scale. Minorities, such as African Americans and Native Americans, now underserved, are likely to have more equitable access in the future. In addition, more intensive outreach may be extended into rural or isolated communities, and building onsite, bilingual and/or culturally-specific support for patients enrolled in clinical trials will probably continue because it works.

Much remains to be done to assure minority participation. By all appearances, investigators have just begun to reach for the rainbow. ■

<sup>1</sup>Chase, M Modiano, R Brooks, J Schwartz, TP Miller: Minorities Participation in Cancer Cooperative Clinical Trials: Preliminary Arizona Cancer Center (ACC) Experience. In *Proceedings of First North American Conference on Cancer in Hispanics*, Tucson, Ariz. September 12-14, 1991 (Abstract 30).