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The University of Illinois at Chicago Experience

by Consuelo Skosey, R.N., C.C.R.A.

In the following section, staff at the University of Illinois at Chicago in Chicago, Ill., The Moses H. Cone Regional Cancer Center in Greensboro, N.C., and the South Jersey Hospital System in Millville, N.J., share their experiences in improving accrual of minority populations to clinical trials.

They discuss the challenges of establishing and maintaining a clinical research program in three singular communities. Despite varied environments and patient populations, common themes emerge. Successful programs are run by staff who understand the culture of the population being served and the most commonly encountered barriers to care. The ability to communicate with patients of various backgrounds helps to overcome some of those barriers.

It is my personal view that the inclusion of minorities and the underserved in clinical trials should not be motivated by the NIH Revitalization Act of 1993 alone. I encourage efforts to accrue minorities and the underserved to clinical trials out of a sense of social justice. The availability of clinical trials leads to the availability of state-of-the-art therapy; therefore, people of all races, ethnicities, and incomes should have the opportunity to participate. Ultimately, participation in clinical research studies improves the care we give all our patients.

—Otis Brawley, M.D., program director, Community Oncology and Rehabilitation Branch of the National Cancer Institute

National Institutes of Health (NIH) policy clearly states that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless there is a clear and compelling rationale that their inclusion is inappropriate to the health of the subject or the purpose of the research.[1] The NIH requires that clinical trials be available to eligible patients wishing to participate regardless of race, gender, or economic status.[2]

Recruitment of minorities to clinical research is of utmost importance because of the broad social impact that clinical trials, particularly Phase III trials, have on behavioral or therapeutic interventions and standard of care. Ideally, results of these clinical trials provide a scientific foundation upon which changes in health policy or standard of care are based. Without the participation of minority populations in clinical research, there is no way to assure that the biologic response to any treatment will be the same for patients belonging to different racial groups. Thus, the makeup of participants should accurately represent the patient population, both minority and non-minority, as a whole.

The principal requirement for ensuring a valid analysis is to design the study so that participants of both genders and from different racial/ethnic groups are allocated to either the intervention or control groups by an unbiased process such as randomization.[3,4] A valid analysis of differences in intervention effect can only be accomplished through the participation of minorities and women in clinical trials.

Unfortunately many barriers prevent minority patients from participating in clinical trials. Several studies have identified these impediments, which include limited access to primary medical care, distrust of the medical/scientific community, and lack of knowledge about clinical research. On the provider side, a long-standing alienation of minority health professionals has hampered cooperative strategies for recruitment. In addition, an overall lack of knowledge on the part of clinical providers about language and cultural barriers has stunted efforts to penetrate non-English-speaking communities.[5,6]

The University of Illinois at Chicago (UIC), near downtown Chicago, has been forced to confront these obstacles as a major cancer care provider within a community increasingly comprised of the underserved. The UIC Health Sciences Center includes a health system comprised of a teaching

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hospital, an urban veterans hospital, and a network of clinics and community health centers primarily involved in the care of minorities. The University of Illinois at Chicago Hospitals and Clinics serves a population that is predominantly minority based and of low socioeconomic status. In fiscal year 1996, 51 percent of admissions to these institutions were African American, 27 percent were Hispanic, and 21 percent were Caucasian. In 1995 the financial class analysis of patients treated at the University of Illinois Hospitals and Clinics showed 7 percent commercial insurance, 17 percent Medicare, 52 percent Medicaid, 17 percent HMO/PPO, and 6 percent "self-pay."

Recruitment and retention of all, but especially minority, patients to clinical trials began with an institutional commitment to develop the infrastructure needed to support programs vital to accrual, such as community and patient education. This process required a concerted effort on the part of the principal investigator, support staff (research nurses and clinical research associates), and the local community.

A study by Gorelick and colleagues cites that as minorities generally have been underrepresented in the health care system, they may be less likely to participate in clinical trials or other studies. These investigators conclude that the success of clinical research and other health programs is largely dependent on community acceptance.[7] Therefore, pre-program planning in cooperation with the community is vital. Community leaders are a valuable resource and can provide many avenues for disseminating information to its members regarding the safety and benefits of the research programs as well as information on the institution itself, the investigators, and their fluency with other languages.

In 1997 UIC applied for and was awarded funding for a Minority-Based Community Clinical Oncology Program (MB-CCOP). The MB-CCOP grant stipulated the establishment of a minority headquarters within the Clinical Trials Office, which uses the research bases of the Pediatric Oncology Group (POG), the Gynecologic Oncology Group (GOG), and the Cancer and Acute Leukemia Group B (CALGB).

At the outset we knew that meeting the objectives of the MB-CCOP and operating a successful recruitment effort depended on our ability to solidify relationships with health-related and other community organizations. We pursued the following cooperative strategies:

Strengthening relationships with community health centers. While preparing the MB-CCOP grant application, cancer program leaders identified and met with several directors from health centers within the UIC community. The centers include: the Midwest Latino Health Research, Training, and Policy Center; Miles Square Health Center, where a large number of minority patients are cared for by UIC physicians and residents; the National Black Leadership Initiative on Cancer; Center for Research on Women and Gender; African-American Cultural Center; Asian Interdisciplinary Program; Women's Affairs Program; and the West Side Veterans Administration Women's Health Medical Center. These organizations became familiar with the demographic, socioeconomic, cultural, and health characteristics of the UIC community and established an advisory board to help strengthen their community liaisons. Our relationships with several of these centers continue through their participation as consultants and collaborators in various research projects.

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Expanding the network of primary care clinics. We have recently added an affiliate institution and its clinical trials program to the MB-CCOP. This affiliate has a large network of primary care clinics within the Hispanic and African-American communities. Eighty percent of all patients seen at this institution belong to minority groups that are equally divided among those who are African American (40 percent) and those who are Hispanic (40 percent). This institution will have access to clinical trials through membership in the CALGB; its participation will increase our overall accrual to NCI-approved studies.

Enlisting a research team of investigators, co-investigators, and support staff with diverse ethnic backgrounds. Efforts must be increased to provide opportunities for minorities in biomedical research. Governmental and private agencies can expand these opportunities by enlisting more minority institutions as participants in federally sponsored biomedical research programs.[8] At the same time, institutions with large minority populations must make basic research a priority. By engaging in mentorship programs, institutions can encourage minorities to seek careers in the sciences.

Through the efforts of one of our Hispanic investigators, we have begun to develop closer ties with the Hispanic medical community. Our faculty and research staff represent Hispanics, African Americans, Asian Americans, and Caucasians of both genders. An appreciation of bicultural and bilingual differences continues to be

integral to our efforts in recruiting patients to clinical trials. The UIC has a commitment to train women and minority investigators. We believe these efforts will help to reverse the trend of alienating minority health professionals in biomedical research.

In a nine-month period, from June 30, 1997, to February 28, 1998, a total of thirty-four patients (twenty-nine onto treatment protocols and five onto cancer prevention/control studies) were accrued to approved National Cancer Institute protocols. Eighteen of the thirty-four patients enrolled (53 percent) were minorities. Total patient enrollment for all studies (investigator-initiated, pharmaceutical, and other contract studies) from July 1, 1996, until June 30, 1997, was 105. Sixty patients, or 57 percent of this total, were minorities. Thus far, from July 1, 1997, until May 31, 1998, a total of 150 patients have been registered to studies, with fifty-seven patients, or 38 percent, representing minorities.

Although our accrual lags behind our intended goal, this overall total is quite good considering that the infrastructure of the clinical research program for the Section of Hematology/Oncology has been in place for just two years. Initially a significant amount of time went into submitting the trials to the institutional review board, developing policies and procedures to effectively manage a data management office, and orientating support staff. Additionally, the faculty were new to the institution, which required a major effort on their part to familiarize themselves with institutional policies and procedures, develop relationships with colleagues from other departments, and identify collaborators.

FUTURE DEVELOPMENTS

UIC continues to focus on expanding its research bases. The University of Illinois has been an affiliate GOG member through the University of Chicago. The principal investigator for this research base has recently submitted an application to attain full membership, which will allow the principal investigator to receive communications directly from the GOG office. This change in administration will expedite the activation of trials from the GOG research base.

Through the involvement and efforts of several investigators from the UIC MB-CCOP who have recently been appointed to the Cancer Control and Minority Consortia Committees in CALGB, UIC expects to develop a research study that addresses its patient population. One of these investigators is collecting pilot data within the MB-CCOP and evaluating the informed consent process in patients with less than a high school education to ultimately improve patient comprehension by simplifying the informed consent process. These data may lead to a proposal for a group-wide study within CALGB, which would give MB-CCOP credit.

Two investigators have joined forces to develop a program that will bring trials to African-American men who are at risk for developing prostate cancer or who have had a previous diagnosis of prostate cancer. A research nurse has been hired specifically to facilitate the access and accrual of these patients to prevention and treatment protocols. The university's School of Public Health will bring its expertise to study the effectiveness and outcome of education, screening, and prevention efforts.

Another co-investigator is the chairman of the National Black Leadership Initiative on Cancer, a program of the NCI that creates cancer awareness in the African-American community to reduce the disproportionately high incidence and mortality rates of cancer in this population. This connection to the NCI enables UIC to improve education on prevention and early detection of cancer and allows for better treatment and support of cancer patients in the African-American community.

Several investigators have met with the deputy commissioner of the Chicago Department of Public Health to address the possibility of a formal interaction to establish UIC as its provider in cancer and hematological care. This interaction will provide UIC the opportunity to define and implement cancer control initiatives within the context of the City Clinic Network.

We are pleased with the efforts made by our faculty and staff at the University of Illinois at Chicago, who are bringing state-of-the-art treatment and prevention studies to minority patients in this community. We believe the direction we propose to take in the future will continue to increase our sensitivity to the barriers and access to care issues necessary to achieve a representative sample in our studies.

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