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Recruiting for a randomized controlled trial from an ethnically diverse population: Lessons from the Maternal Infection and Preterm Labor Study

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- OBJECTIVES: To compare recruitment rates for Caucasians and minorities in a randomized, controlled trial based in a family practice residency clinic.
- STUDY DESIGN: A retrospective chart review of all patients eligible for the Maternal Infection and Preterm Labor (MIPTL) study.
- POPULATION: All prenatal patients at 1 clinic site presenting for care at earlier than 34 weeks' gestation.
- OUTCOMES MEASURED: Patients choosing to enroll in the MIPTL study (n = 70) were compared with those who did not (n = 210) on a variety of demographic variables, including self-reported ethnicity, ability to speak English, and socioeconomic factors.
- RESULTS: African American patients were recruited at the same rate as Caucasians (28% of each eligible population). Immigrants and patients requiring a translator were less likely to enroll (P = .014 and .008, respectively).
- CONCLUSIONS: Clinic-based research studies in a family practice residency program can successfully recruit African American patients. Immigration status and the ability to speak English were important factors that affected participation. More research is needed to understand the role of clinic-based research in the recruitment of minorities for clinical trials.

key words **Ethnicity; African American; clinical trials; recruitment. (J Fam Pract 2002; 51:760)**

The national research agenda encourages recruitment of minority populations, yet they are underrepresented in most clinical trials.[1,2] Minority populations need to be included in research for several reasons. Minority populations may have a disproportionate disease burden, such as certain cancer rates among black persons.[3] Minority populations may have different responses to medications, such as with antihypertensive medications in the African American population. Lastly, clinical trials can offer state-of-the-art care, which should be freely available to minorities. The National Institutes of Health Revitalization Act of 1993 requires all investigators receiving National Institutes of Health funding to include minority subjects.[4]

Most literature on minority recruitment focuses on African American subjects' participation in clinical research.[1,5-9] Information about other ethnic groups' participation in clinical trials,[9-11] particularly those involving non-English-speaking participants,[12] is more limited. No data have been systematically compiled to evaluate the effectiveness of minority recruitment in a clinic-based research study.

This study used the data set from a primary care, clinic-based, randomized controlled trial, the Maternal Infection and Preterm Labor Study (MIPTLS).[13] We examined rates of recruitment for different ethnicities, for immigrants, and for non-English-speaking patients in a trial that had no specific plan for minority recruitment.

METHODS

We conducted a retrospective chart review of all pregnant women presenting for prenatal care at Smiley's Clinic from September 1996 through December 1997 during the time of the MIPTLS. This study was a multisite investigation of the effect of vaginal pH testing on early detection and treatment of bacterial vaginosis in pregnant women and subsequent maternal and infant outcomes.[13] Smiley's Clinic is a community-based family practice residency clinic in Minneapolis, which serves a diverse, low-to middle-income population. Sixty percent of prenatal patients seek care in the main clinic and see the same provider throughout their pregnancy. Smiley's Clinic also operates a medically indigent prenatal clinic called "Birthpartners" that is staffed by a full-time registered nurse and rotating faculty and residents. Forty percent of prenatal patients seek care at Birthpartners; they do not see the same provider throughout their pregnancy.

All women presenting for prenatal care at less than 34 weeks' gestation were eligible for the MIPTL study. All women presenting for care were asked to participate in the study by the certified medical assistant, registered nurse, and/or their physician. The patient's own physician, registered nurse, or certified medical assistant obtained informed consent for all patients to be studied, and a physician collected the data from the patient at each subsequent prenatal visit. For this chart review, we divided this population of women into those who enrolled in the trial and those who did not enroll.

Data abstracted from the medical record included age, ethnicity, parity, history of previous pregnancy complications, and history of sexually transmitted disease. Ethnicity data were based on self-report and abstracted from 1 of 2 standard locations in the chart-a patient demographics form and prenatal database. "African" patients denoted either their native country or Africa on their database; "African American" patients' self-reported their ethnicity as well. For the purpose of this study, Native American and biracial women were categorized as "Other." Women who did not have ethnicity data in either location were not assigned an ethnicity.

We analyzed the data using SPSS software (SPSS Inc, Chicago, IL); t tests were used for continuous data and chi-square tests for categorical data, with a 2-sided $P < .05$ as significant. The Institutional Review Board of the University of Minnesota approved this study.

RESULTS

During the study period, 310 women presented for prenatal care to Smiley's Clinic before 34 weeks' gestation and were thus eligible for the MIPTL trial and our chart review. Seventy-one subjects chose to enroll in the trial, leaving 239 who refused. We could not locate 1 chart; the data set thus included 70 patients enrolled in the MIPTL study and 239 patients not enrolled (309 total charts reviewed). Complete data were available for most subjects; 297 charts had complete ethnicity data, 273 charts had complete data on education level, and 291 charts reported need for a translator (96%, 88%, and 94% complete, respectively). In all other areas, data collection was complete.

Participants and nonparticipants were similar with regard to most characteristics **Table 1**. Most subjects who agreed to participate in the trial were Caucasian; one-quarter were African American **Table 2**.

Although more Caucasian than African American participants enrolled by number, the percentage of those enrolling of the total eligible was the same, 28%. The ethnicities of patients enrolling was different from those declining to enroll ($P = .042$) **Table 2**. Specifically, the enrollment rate for African participants was half that for African American patients. Of 23 eligible patients, no Hispanic or Asian patients were enrolled in the trial. Only 12% of the enrollees were immigrants,

compared to the 88% who declined to be studied (P = .014). Only 1 subject who required an interpreter was enrolled (P = .008).

DISCUSSION

Our study was successful in recruiting African American patients. Unlike other studies, African American individuals were as likely to enroll as their Caucasian counterparts. Our success in minority recruitment is even more significant in that there was no specific strategy used to recruit minority women.

Perceptions about research participation and barriers to enrolling in clinical trials have been studied in African American populations.[5,6,8,10,11,14,15] Lack of trust in and fear of medical research is still prevalent in the African American community.[6,8,11,14,15] In the past, medical experimentation had been perpetrated on African American individuals without their consent, as illustrated by the Tuskegee Experiment and by medical procedures carried out on slaves without their consent.[16] These acts have justifiably made some patients distrustful of the medical establishment and research.[1,14] Lack of transportation, lack of childcare, and lack of time for study activities have also been cited as barriers to patient participation in other studies.[6,11,15]

We believe that having the patient's own physician or nurse performing enrollment, including obtaining informed consent, improved recruitment. Our patients did not have to see any outside providers or study personnel in order to be enrolled. Recruitment was high, even though 96% of the physicians involved were not members of a minority group.

We believe that having enrollment performed and all data collected quickly at routine patient visits may have assisted recruitment. In addition, we have on-site childcare for patients and their families, and such service may have removed barriers to participation.

We found that patients who were immigrants, especially those requiring translators, were much less likely to enroll in this trial. Cultural factors were likely to play a role.[17] Most of our African patients were from East Africa (Somalia and Ethiopia), and nearly all had undergone ritual circumcision. Our experience with this patient population has shown that they prefer to limit vaginal examinations.

Little research exists about the recruitment of individuals with ethnicities other than African American for research trials. Swanson and Ward[15] reviewed the research on recruiting minorities for clinical trials and concluded with 20 steps needed to recruit more minorities into research trials. Only 1 trial of minority perceptions (other than African American) about research could be located. Roberson[11] conducted phone surveys of inner city African American, Native American, and Hispanic individuals to see which factors about enrolling in cancer clinical trials were important to them. She found that the study subjects "knew little about cancer clinical trials and basically had no opportunity to participate." All 3 minority groups expressed concerns about being treated like "guinea pigs" and a "mistrust of white people." Hispanic subjects specifically expressed concerns about communication in their own language.

Several studies have described successful recruitment of minority populations (other than African American) for clinical trials. Two studies have shown successful recruitment of Hispanic and African American women for clinical trials on primary prevention using mass mailings and media announcements.[10,18] Small and coworkers[12] trained and then used bicultural interviewers to successfully recruit 3 non-English-speaking immigrant populations for a study of maternal satisfaction with hospital birthing in Australia. These studies, however, did not take place in a primary care clinic setting. Our study provides new information about the recruitment of minorities for a clinical trial in such a setting.

The strength of this study was in its completeness of data. The data were collected systematically from forms currently used routinely in the medical record, thereby reducing bias. This study was limited by the lack of direct information regarding reasons for refusal among women declining enrollment.

Proven methods of increasing minority participation in research of all kinds are crucially needed. Our study suggests that clinic-based research, with enrollment by a patient's primary care physician or nurse, can have a significant positive effect on recruitment. In addition, a different approach to immigrants, especially those not conversant in English, will be needed for successful recruitment in future studies. Further research should be both quantitative and qualitative to better

understand the recruitment process in underserved and ethnically diverse patient populations.

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