Recruitment Strategies for Minority Participation: Challenges and Cost Lessons from the POWER Interview

Janet Fulton Keyzer, RNC, MPA; Joy Melnikow, MD, MPH; Miriam Kuppermann, PhD, MPH; Stephen Birch, DPhil; Christina Kuenneth, MPH; Jim Nuovo, MD; Rahman Azari, PhD; Debra Oto-Kent, MPH; Mairin Rooney

Background: The importance of recruiting and retaining women from diverse populations is well recognized; however, the recruitment process often presents greater challenges at higher costs than initially anticipated.

Objectives: To describe recruitment strategies and costs from a study evaluating women's preferences regarding tamoxifen use for primary prevention of breast cancer.

Design: Description and analysis of recruitment strategies, outcomes, and costs for a cross-sectional interview study.

Setting: University hospital and community sites.

Participants: 932 racially and ethnically diverse women respondents, of whom 771 completed the screening process (aged 27–87).

Intervention: Women were recruited and screened by using the Breast Cancer Risk Assessment Program (BCRA version 1, National Cancer Institute). Eligibility required an estimated five-year breast cancer risk of at least 1.7%. Recruitment goals targeted a high percentage of ethnic minorities.

Methods: Recruitment strategies included direct mail, flyers, newspapers, media advertising, and community outreach.

Results: Of the 771 screened women, 341 (44%) met eligibility criteria and 255 (33%) completed interviews (76.9% White, 10.6% Latina, 7.0% Asian, 3.9% African American, 1.6% Native American). Recruitment costs averaged US $113/screened participant. Direct mail and community contact yielded the largest number of participants (312 screened, 205 eligible). Radio advertising provided few participants (one screened, one eligible) at high cost.

Conclusions: Recruiting an ethnically diverse sample presented multiple challenges. We recommend that future studies budget adequately for recruitment time and costs, develop ongoing relationships with key community leaders, evaluate recruitment strategies closely, and report detailed recruitment findings to the research community. (*Ethn Dis.* 2005;15:395–406)

Key Words: Minority Recruitment, Tamoxifen, Women's Preferences

Introduction

The National Institute of Health (NIH) 1993 Revitalization Act (US Federal Register 59FR14508) was enacted to promote inclusion of women and minorities in clinical trials. Although the Revitalization Act has increased focus on minority recruitment, the efficacy of these efforts has been questioned.[1,2] Most researchers agree that including ethnically diverse populations in research studies is critical in order to extrapolate findings applicable to the general population.[3] Some argue that it is merely "bean counting."[1] According to Ramasubbu, the NIH Revitalization Act "does not appear to have improved gender-balanced enrollment."[2] Recruitment of minority women into research studies generally remains an elusive goal.[3,4]

The importance of recruiting and retaining women from minority populations is well recognized; however, the recruitment process often presents greater challenges and higher costs than initially anticipated.[3,5,6] Women actively interested in study participation may encounter study designs that inherently discourage or prohibit inclusion.[3,6,7]

Naranjo and Dirksen describe the development of recruitment methods for Hispanic women as an ongoing endeavor with hopes of refining their efforts to achieve culturally competent health care.[8] Investigators (Green) involved in recruiting African Americans for participation in research note, "despite federal recommendations highlighting the need to include special population groups (mainly minorities and women) in clinical research, recruitment and retention of these groups present a great challenge to researchers."[4]

Recruitment barriers include, but are not limited to, problems with transportation, family and work-related responsibilities, finances (study and participant), language, fear of adverse effects, lack of interest, study design issues, cultural factors, demographics, suspicion of research motives, influence of family members, emotional stress, and inaccessible research approaches.[2,3,8–11] Few studies report systematic recruitment outcomes data, and even fewer report costs and effectiveness directly related to individual recruitment strategies.[12–14] Meeting recruitment goals requires comprehensive and ongoing project review, making adjustments as necessary, and testing innovative new strategies.[3,13] Although the Revitalization Act may have shed light on minority recruitment efforts, limited support and direction exist in the research community.

From the Center for Health Services Research in Primary Care (JK, CK, RA), Department of Family and Community Medicine (JM, JN, MR, University of California, Davis; Health Education Council (DO), Sacramento; Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco (MK); California; McMaster University, Hamilton, Ontario (SB).

Address correspondence and reprint requests to Janet Fulton Keyzer, RNC, MPA; Center for Health Services Research in Primary Care; University of California, Davis; 2103 Stockton Blvd, 2nd Floor; Sacramento, CA 95817; 916-734-5543; 916-734-2349 (fax); janet.keyzer@ucdmc.ucdavis.edu

Women actively interested in study participation may encounter study designs that inherently discourage or prohibit inclusion.[3,6,7]

The Preferences of Women Evaluating Risks and Benefits of Tamoxifen for Breast Cancer Risk Reduction (POWER) Study was designed to evaluate tamoxifen preferences and decision-making among women likely to meet eligibility requirements. Tamoxifen, used for many years in breast cancer treatment, received FDA approval in 1998 for potential breast cancer risk reduction (www.fda.gov). Concerns remain regarding tamoxifen's potential adverse effects and whether this preventive approach is generally acceptable to women.[15] Substantial African-American, Latina, and Asian representation in the POWER study was a recruitment priority.

This paper describes POWER recruitment experiences with regard to effective recruitment strategies and yields, participant observations, barriers, and associated costs per participant.

METHODS

Design

The POWER Study's primary objective was to develop a deeper understanding of how an ethnically diverse group of "high-risk" women weighs risks and benefits in considering tamoxifen for primary breast cancer prevention during a one-hour face-to-face interview. Women with a previous or current history of breast cancer were excluded. Women completed a brief screening process and, if eligible, were invited to attend a one-hour in-person structured interview (in English or Spanish) containing qualitative and quantitative items.

The 15-minute screening process (to determine eligibility) and one-hour interview (offered only to eligible participants) involved minimal personal risk and required less than a two-hour time commitment for most participants. Scripts and written materials (Spanish and English) detailed our interest in women's opinions regarding tamoxifen and stressed that tamoxifen administration was not required. Interviews were conducted at a university medical center and at selected community sites. A few home visits were made to volunteers that were homebound, but home visits were not provided on a routine basis because of budget and staff constraints. Efforts were made to match interviewer/participant ethnicity whenever possible.

The interview process included a participant-completed demographic questionnaire, various open-ended and closed questions pertaining to the women's self-perceived breast cancer risk, breast cancer information source(s), relatives and/or acquaintances with breast cancer, and confidence in tamoxifen (see Figure 1). Responses to open-ended questions and other comments were transcribed verbatim directly into a data collection instrument on a laptop computer.

During the interview we conducted a 15-minute standardized educational session containing information on tamoxifen risks, benefits, and potential effects. Immediately following the educational session, interviewers administered a five-question true-false written test to assess comprehension of the basic information presented. The last section of the interview consisted of a ranking exercise using a "feeling thermometer" and a standard gamble "chance board."[16] Subjects completed an interview evaluation form and received $20 cash compensation at the close of the interview. Subjects were not compensated for completing the screening process.

Women >40 years who were likely to meet the eligibility threshold were recruited from Sacramento, California, and surrounding communities. The POWER study protocol was reviewed and approved by the UC Davis Office of Research Protection and the Women's Health Initiative Ancillary Studies Committee (www.WHI.org). Written informed consent was obtained from each participant prior to the interview. Screening and interview tools were refined based on feedback from focus groups with risk-eligible African-American, Latina, and White women. Screening and interviews were conducted from January 2000 to August 2002.

Staff

The ethnically diverse screening/interview team consisted of White, Latina (bilingual), Asian-American, and African-American women. A nurse, nurse practitioner, physician assistant student, and health educator conducted screening and interviews following one-on-one training. Several student assistants contacted subjects and coordinated screening and interview appointments. Staff received detailed orientation materials, attended project meetings, and collaborated in discussions regarding project status, recruitment strategies, and current yields.

Recruitment Strategies

Direct Mail: Women's Health Initiative

Women were recruited from the observational section (OS) of the Women's Health Initiative[17] (WHI) by direct mail. The WHI, a widely recognized and respected long-term study, has built many positive relationships with its participants and the community. The University of California Davis Medical Center, among the top three centers in terms of WHI participants, recruited 4,000 volunteers from the Sacramento area. Because we recognized that this group was composed of largely White women (87.2% White, 3.2% African-American, 1.9% Hispanic, 1.1% American Indian/Alaskan Native,

Pre-Educational Session

- Have you heard about the drug tamoxifen? If yes, where did you hear about it?
- What have you heard about tamoxifen? Based on what you currently know about tamoxifen, how do you feel about taking it for potentially reducing your risk of breast cancer?
- At this time in your life, how concerned are you about getting breast cancer? Please give your best guess of the chance that you will have breast cancer in the next five years. Do you consider this low, medium, or high risk? What factors did you consider to determine your risk level?
- What are you currently doing, if anything, to reduce your risk of breast cancer?
- What do you think of when you hear the words "breast cancer"?
- Where do you get your information about breast cancer?

Post-Educational Session

- Considering the information just presented, how confident do you feel about the ability of tamoxifen to reduce the risk of breast cancer? What factors affect your level of confidence in tamoxifen?
- How do you feel personally about taking tamoxifen? What additional information would you need to make a decision?
- How concerned would you be about experiencing one or more of the serious side effects (blood clots, uterine cancer)? How concerned would you be about experiencing one or more of the practical problems (hot flashes, vaginal discharge, etc)?
- Is there an age when you think taking tamoxifen would not be worthwhile? Is there an age when you think taking it would be worthwhile?
- How high would your risk of breast cancer have to be for you to consider tamoxifen for prevention? What other factors would influence your decision whether to take or not to take tamoxifen? Would you be willing to take tamoxifen for the treatment of breast cancer?
- Whose opinion would be important to you when deciding about tamoxifen?
- Do you currently take any medication on a daily basis? Are you currently taking hormone replacement therapy?
- The cost of tamoxifen is approximately $100.00 per month. How would this information affect your decision about tamoxifen? If tamoxifen were available for $5.00 per month, would it affect your decision?

Fig 1. Sample interview questions

4.2% Asian/Pacific Islander, 2.4% Other/Unspecified) we planned to expand community recruitment efforts to target minority women and achieve a more representative ethnic balance for our sample.

An initial contact letter, signed by the WHI Recruitment Coordinator, described study goals, the interview process, compensation, and contact information. This letter was sent to 2,094 WHI women identified as potentially eligible (likely to meet the 1.7% five-year breast cancer risk threshold) to participate in POWER. Women were informed that nonparticipation in POWER would not affect any services received at WHI or within the University of California Davis Heath System. A second mailing, enclosed with other WHI information, was sent to women due for their third annual WHI visit. Interviews and WHI appointments were often conducted the same day.

- Women's and family practice community clinics, Planned Parenthood
- Breast Cancer Early Detection Program
- County Health Department, California State Departments (Health Services)
- American Cancer Society
- Grocery stores, laundromats, hair salons
- Churches (various denominations)
- Community events, health fairs, bulletin boards, women's business, social, and support groups
- Local senior centers
- Health System events, hospital bulletin boards, clinics, mammography waiting rooms, lobby information desk, café and cafeteria

Fig 2. Flyer/poster distribution sites

Community Outreach: Health Education Council

The Health Education Council (HEC) located in Sacramento, California, provides community-based health education and promotion programs and facilitates partnerships with other organizations to reach at-risk clients and under-served populations. We contracted HEC to recruit ethnically diverse participants from a broad geographic area likely to meet study eligibility requirements. The HEC Community Health Educators, viewed as community leaders, had cultivated successful relationships with ethnically diverse organizations and church groups on other projects.

Letters and informational flyers were mailed to >35 churches, women's organizations, and providers from the California Breast Cancer Early Detection Program. A direct mailing was sent to selected Breast Cancer Early Detection Program providers (N=125). Mailings contained study details and a request to forward information to health ministries and/or women's groups. Women considered leaders on health issues in their communities distributed flyers and made presentations to various church and ethnically diverse community-based women's groups. The POWER interviewers and HEC representatives presented study information and offered on-site screening at Latina, Asian, and African-American professional and local church groups, African-American Women's Business Groups, local breast cancer support groups, neighborhood parks, cultural centers, and various community events.

Media Advertising

Newspapers. The POWER recruitment advertisements, strategically located in sections with high female readership, appeared in a major regional newspaper for three two-week periods and included the popular Sunday edition. Study announcements appeared in several other local newspapers serving ethnically diverse populations.

Employee Newsletter. Study announcements appeared in the weekly UC Davis Health System Employee Newsletter with circulation to >7,000 university employees.

Radio. Public service study announcements aired on local National Public Radio stations, as well as three additional stations (one during a popular Sunday morning religious program) with a large senior African-American listening audience. Several Spanish radio stations (chosen by our Spanish-speaking interviewers for their large audience of women >60 years) broadcast paid study advertisements during Latina programs. One Latina station donated broadcast time for POWER announcements. A study bilingual interviewer participated in a live, on-air question-and-answer session during a popular Spanish-language health program. Our interviewer gave study details, contact information, and answered questions related to participation.

Posters/Flyers. Eye-catching bilingual posters and flyers (some with attached response cards) were distributed to locations listed in Figure 2. A variety of smaller, wallet-size, tri-fold announcements were placed in various clinic waiting areas (mammography) and rest rooms. Patients visiting the UC Davis Breast Heath Center received POWER flyers with office visit take-home materials.

Initial Screening and Eligibility

Figure 3 details the overall POWER screening process. Interested women contacted study personnel in response to a particular recruitment strategy (letter, flyer, presentation, sign-up sheet). Voicemail and faxed messages were returned within 24–48 hours in order to prevent delays in contacting interested volunteers. Initial contact, return call, pre-screening for history of breast cancer, risk assessment (if eligible) with the NCI tool, and interviewing were components of the multistep study process. Laptop computers enabled convenient screening at remote locations; however, limited battery life decreased screening efforts during early visits to churches and community events, since nearby electrical outlets were often unavailable. Additional back-up batteries were purchased, expanding screening and interview timeframes.

Trained interviewers conducted screening by telephone or in-person by using a standardized script outlining study processes, eligibility criteria, fund-

ing source, and voluntary participation. Women's estimated five-year breast cancer risk scores were calculated by using the NCI Breast Cancer Risk Assessment Tool Version 1. Women with five-year breast cancer risk estimates ≥1.7% were eligible to participate and were scheduled for a one-hour in-person interview. The BCRA Tool Version 1 (which uses only "Black" and "White" as categories of race/ethnicity) adjusted risk for African-American women using a conversion factor obtained from the Breast Cancer Demonstration Project (BCDDP) and the Surveillance, Epidemiology, and End Results (SEER) Program. Women of all other race/ethnicities were considered to have the same baseline risk as White women. Version 2, released in 2001, assigns a separate hazard rate for Latina women.[18–21]

Recruiting an ethnically diverse sample proved more difficult and costly than initially anticipated. As the study progressed, we found current recruitment efforts inadequate to meet our initial goals for recruitment of African-American and Latina women. Following discussion and review we allocated additional resources, hired additional staff, removed potential barriers, and implemented new recruitment strategies.

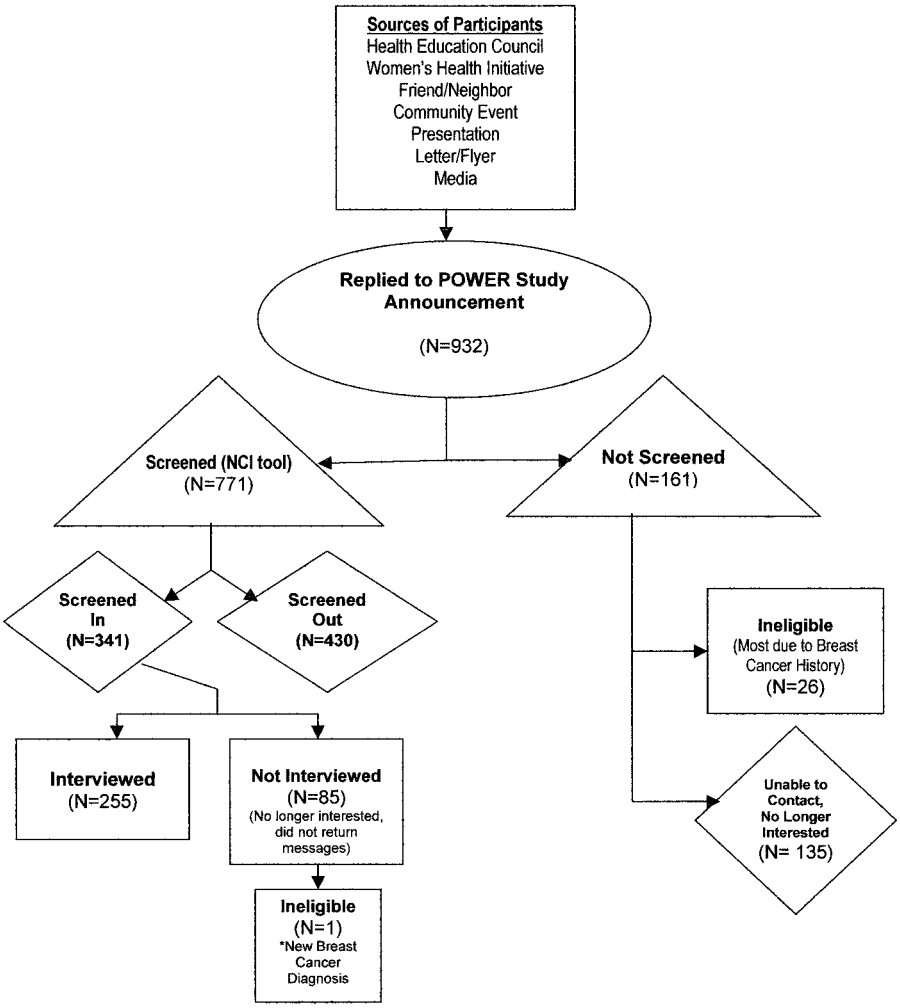

Fig 3. POWER study process

Efforts to Reduce Recruitment Barriers

An extensive literature review revealed many minority recruitment barriers.[3] To eliminate or minimize these participation barriers we provided:

- Flexible interview/screening times, including during evenings and weekends;
- Congruent interviewer/participant ethnicity;
- Bilingual (Spanish/English) study materials, advertisements, flyers, and interviewers;
- Convenient screening/interview locations at various community centers, women's groups, churches, and participants' homes;
- Follow-up phone call and letter reminders to confirm site and interview time with enclosed map containing site and parking details; and
- Information regarding public transportation and local hospital shuttle service.

Data Collection and Analysis

Potential POWER participants received a unique study identification number (SID) at the time of initial contact or at the time of actual screening. Calls, messages, screening status, and interview appointment reminders were updated in a daily logbook and computer spreadsheets. We conducted periodic queries utilizing Excel (Microsoft Corp., Redmond, WA) and a pre-established WHI Access (Microsoft Corp.) database to evaluate specific recruitment efforts. Quantitative analyses were conducted in SAS Version 8.2 (SAS Institute, Cary, NC). Through ongoing tracking and monitoring (# respondents, # screened, # eligible, # interviewed), staff feedback, and communication with recruitment partners, we evaluated the efficacy of various recruitment strategies.

Transcribed responses to open-ended questions were reviewed by a subset of the project research team. A coding scheme for analyses of qualitative responses to open-ended questions was developed based on constant comparison of individual responses.[22] The pro-

Table 1. Total responded, eligible, and interviewed by ethnicity

	White	African American	Latina	Asian	Other/ Unknown
Total responded *N*=932	479 (51.4%)	132 (14.2%)	203 (21.8%)	33 (3.5%)	85 (9.1%)
Total screened *n*=771	442 (57.3%)	103 (13.4%)	191 (24.8%)	28 (3.6%)	7 (0.9%)
Total eligible *n*=341	253 (74.2%)	16 (4.7%)	47 (13.8%)	20 (5.8%)	5 (1.5%)
Total interviewed *n*=255	196 (76.9%)	10 (3.9%)	27 (10.6%)	18 (7.0%)	4 (1.6%)

ject team derived a list of key elements through an iterative process of review (ie, by inductively assessing the recurring elements in the interview transcripts). As reviewers noted key elements, they grouped those elements that were categorically similar.[23] Classification disagreement resulted in splitting rather than lumping key elements and subcategories into separate groupings. The reviewers then developed a codebook reflecting the recurring elements important in assessing women's perceptions of risk (eg, reducing risk of breast cancer), substantive subcategories (eg, clinical visits, self-efficacy, family history), and their definitions, based on the recurring contexts in which the elements occurred. Results of the coding process were reviewed with the multidisciplinary team of co-investigators and assessed for clinical relevance.

RESULTS

Nine hundred thirty-two women (aged 27–87 years) responded with interest in POWER participation (see Table 1). Of these 932 women, 350 (38%) were WHI participants, and the remaining had received information about the study from other sources. Of these 932 study volunteers, 771 (83%) completed the screening process, 341 (37%) were determined eligible, and 255 (27%) completed interviews. One hundred sixty-one women were not screened largely because they could not be reached for follow up (*n*=87) or because they lost interest in participation (*n*=30). Of the 161 unscreened women, 28 were ineligible largely because of a past history of breast cancer. One screened participant was diagnosed with breast cancer between screening and interview and was no longer eligible for the interview.

The population of Sacramento County (2000 US Census) is estimated to be 64% White, 16% Hispanic, 10% African-American, 11% Asian, and 1% American Indian/Alaskan Native. Women completing POWER screening (*N*=771) were 57% White, 25% Latina, 13% African-American, and 4% Asian. Of the 255 women completing interviews (aged 65–74 years), 77% were White, 61% had yearly household incomes between $25,000-$75,000, and 45% were college graduates. Overall retention for eligible women completing screening and interviews was highest for Asian (90%) and White women (77%), and lower for African-American (60%) and Latina women (57%). Additional details regarding participation rates by race/ethnicity and source of referral are presented in Table 2.

Recruitment response, screened, eligible, and interview comparisons for

Table 2. Recruitment strategies, ethnicity, and eligibility for screened women*

Recruitment Strategy	White *n* (%)	African American *n* (%)	Latina *n* (%)	Asian *n* (%)	Unknown ethnicity *n* (%)	Total screened by ethnicity *N*
HEC total screened	**64 (38%)**	**50 (30%)**	**47 (28%)**	**5 (3%)**	**2 (1%)**	**168**
Total eligible	24 (52%)	5 (11%)	11 (24%)	4 (9%)	2 (4%)	46
Community outreach total screened	**62 (29%)**	**23 (11%)**	**121 (57%)**	**6 (3%)**	**0 (0%)**	**212**
Total eligible	26 (45%)	3 (5%)	28 (48%)	1 (2%)	0 (0%)	58
Media total screened	**34 (62%)**	**9 (16%)**	**11 (20%)**	**0 (0%)**	**1 (2%)**	**55**
Total eligible	18 (86%)	1 (5%)	1 (5%)	0 (0%)	1 (5%)	21
Campus recruitment total screened	**5 (38%)**	**6 (46%)**	**1 (8%)**	**1 (8%)**	**0 (0%)**	**13**
Total eligible	4 (57%)	1 (14%)	1 (14%)	1 (14%)	0 (0%)	7
WHI total screened	**273 (88%)**	**12 (4%)**	**9 (3%)**	**15 (5%)**	**3 (1%)**	**312**
Total eligible	179 (87%)	5 (2%)	6 (3%)	13 (6%)	2 (1%)	205
Other referral source total screened	**4 (40%)**	**3 (30%)**	**2 (20%)**	**1 (10%)**	**1 (9%)**	**10**
Total eligible	2 (50%)	1 (25%)	0 (0%)	1 (25%)	1 (0%)	4
Total by ethnicity	**442 (57%)**	**103 (13%)**	**191 (25%)**	**28 (4%)**	**7 (1%)**	**771**
Age (mean)	**65**	**59**	**59**	**65**		

* 7 unknown ethnicity, 1 unknown source.

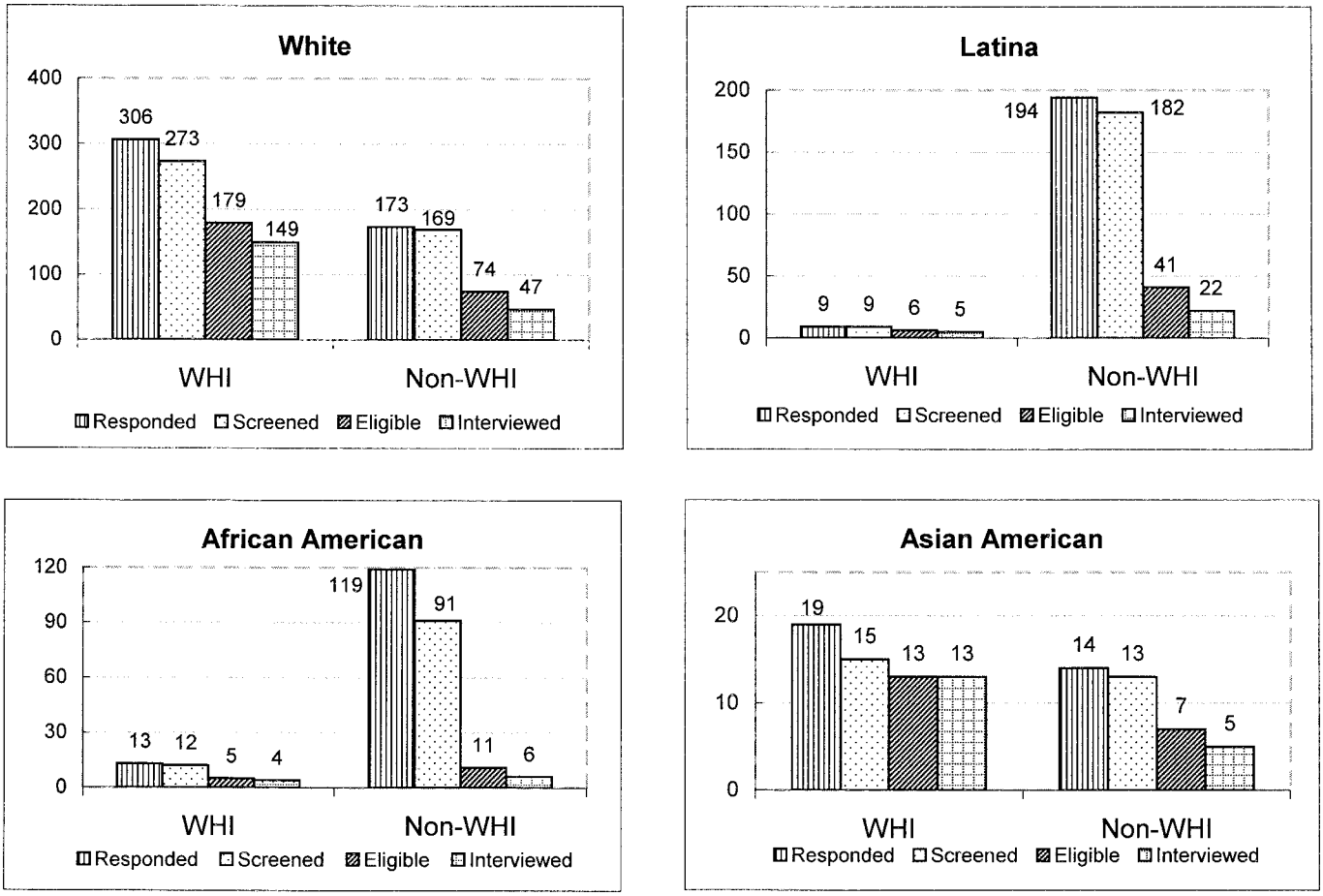

Fig 4. Responded, screened, eligible, and interviewed for WHI and non-WHI groups

women recruited from WHI and non-WHI (all other recruitment sites/strategies) are presented in Figure 4. Completion rates (interviewed/eligible) across all ethnicities for the non-WHI group were White 64%, Latina 54%, African-American 55%, and Asian 71%. Overall, of the 132 African-American women who responded to our recruitment efforts, 103 (78%) women completed screening, 16 women were determined eligible, and 10 completed interviews. Of the 203 Latina respondents, 191 (94%) women were screened, 47 were eligible, and 27 completed interviews. Of the 479 White respondents, 442 (92%) were screened, 253 were eligible, and 196 completed interviews. Overall, those participating in the interview performed well on the post-educational session test, and 80% answered all five questions correctly and fewer than 5% answered more than one question incorrectly.

Recruitment Response

Our three most successful recruitment strategies in terms of cost effectiveness (measured by cost per screened participant) and highest yield were:

• Direct mail to the Women's Health Initiative—350 women responded to our WHI direct mailing (N=2094), and of this group 312 women (White 88%, Asian 5%, African-American 4%, Latina 3%) completed POWER screening (see Table 2). White women were over-represented largely because of WHI demographics (87% White).

• Presentations and on-site screening at various churches, community centers, and health fairs to "enriched" (those likely to meet eligibility) women's groups—212 women responded to our community outreach efforts and completed screening. Of this group, 58 women (48% Latina, 45% White, 5% African-American, and 2% Asian) were determined eligible. Latina women were over-represented largely because of on-site visits to Latina churches and various community events by our bilingual study staff. Of the 121 Latina women who completed screening at churches or community events, 28 women (23%) were determined eligible. Of these 121 women, 93 (77%) were ineligible largely because of their age (<60) with breast cancer risk scores substantially below the 1.7% eligibility threshold.

• Recruitment by the Health Edu-

cation Council (HEC)—of the 771 screened women, 168 (22%) were recruited by the Health Education Council (HEC). Of the 168 women, 46 (27%) were determined eligible (52% White, 24% Latina, 5% African-American, and 9% Asian). The HEC successfully recruited 99 African-American women, 50 of these women completed screening, and 5 women were eligible for interviews. Many African-American women were ineligible because of the apparent "ethnicity effect" of the NCI screening tool.

Losses in the Multistep Process

The multistep screening and interview process (Figure 3) presented challenges for all potential participants. Women called our office, leaving messages on a study mailbox with both Spanish and English options, and POWER nurses made callbacks from voicemail, conducted screening, determined eligibility, and scheduled interview appointments. In certain situations women were lost during this phone process. In some cases the voicemail message system became a barrier to women who preferred to speak with a live person rather than navigate the automated system.

Women also were lost during the multistep community recruitment process. The HEC community leaders presented detailed study announcements at community events and churches and distributed sign-up interest sheets. These volunteer lists were faxed to our office by HEC staff, and callbacks to women were made within 24–48 hours. Contacting women by phone presented various challenges (women did not recall signing interest list, did not return calls, may not have identified with a university researcher as opposed to a community contact, or were no longer interested) and was often unsuccessful. In the not screened group (n=161), 87 women (54%) did not respond to 4 or more callback messages.

Eligibility Barriers for African-American Women

While screening groups of African-American women with the computerized National Cancer Institute Breast Risk Assessment Tool V1, we discovered that many African-American women with risk factors identical to White women failed to meet eligibility requirements (risk scores <1.7%). Many African-American women were excluded (132 responded, 16 eligible) because of NCI Breast Cancer Screening Tool risk calculations below the 1.7% threshold. These women were ineligible despite various breast cancer risk factors (previous breast biopsies and diagnosed first-degree family members) and expressed interest in sharing their opinions about tamoxifen and their disappointment when informed they were ineligible. Of the 119 non-WHI recruited women, 91 completed screening, 11 were determined eligible, and 6 completed the interview process (see Figure 4). The issue here was not one of lower response rates for African-American women but rather of eligibility based on the BCRA Tool risk estimates.

The mean age of screened African-American women was 59 (minimum screened age 37, maximum screened age 84) compared to White women (mean age 65), Asian women (mean age 65), and Latina women (mean age 59).

Recruitment Barriers for Latinas

The POWER bilingual interviewers perceived Latina volunteers as somewhat intimidated and overwhelmed by the University Medical Center. Many Latinas had difficulty with transportation to interviews at the Medical Center. Others faced difficulties locating our hospital-based interview office given that asking directions in Spanish was frequently unsuccessful. This aspect alone may have discouraged some women from participating. Of the 191 screened Latina women (mean age 59), 144 (75%) were ineligible, 47 (25%) were eligible, 27 (14%) were interviewed, and 20 (10%) were lost to follow up. Many Latina women were ineligible because of age rather than the effects of the NCI tool. Women expressing interest at community events were screened and not turned away, regardless of age.

Recruitment Barriers for White Women

White women noted similar participation barriers, although many were already familiar with research as active WHI participants and comfortable with study protocols and the university medical center environment. Two hundred fifty-three White women were determined eligible for interviews, and of this group, 196 (77%) completed interviews, and 57 (23%) were not interviewed because of lost interest in the study, personal issues, family emergencies, disconnected phone numbers, and non-response after four attempts to contact them. Some women noted work and scheduling conflicts as well as transportation challenges despite available interview appointments during evening and weekend hours. Others experienced difficulties finding our office within a large ambulatory care complex.

Other Observations

Many women expressed excitement and satisfaction about participating in POWER. One woman commented, "I'm doing this for my granddaughter." Another remarked, "Your study is providing a community service." Others sought to increase their knowledge about tamoxifen and had seen or heard recent advertisements or articles in magazines, newspapers, and radio. One woman noted, "when it first came out there was some controversy, does it really work. . .then there is a lot on the radio." Another said, "I've heard that it causes or can cause hot flashes, and I've read that it can help prevent women from getting breast cancer."

Several Asian and African-American

women voiced concerns surrounding the phrasing of certain screening questions. For example, a few women found the question "Have you ever had breast cancer?" unacceptable since they felt merely asking the question somehow "predisposed" them to illness. The question was re-worded: "You have not had breast cancer, is that correct?" Some women found this approach more acceptable. A few confused the drug Taxol with tamoxifen. One woman stated (prior to the educational session), "I know it's from a tree, it was something that would prevent/suppress breast cancer." Another woman said, "I've heard it comes from the bark of a tree, now they make it artificially, it can prevent a recurrence of breast cancer." Still others, adamant and committed to declining tamoxifen under any condition, felt we were uninterested in their opinions.

All written and verbal communications (newspaper, flyers, letters, etc) contained clear statements regarding our goals (to gain greater insight on women's opinion to take or not to take tamoxifen) and funding (California Breast Cancer Research Program and the National Cancer Institute). Despite this disclosure, several women voiced concerns that POWER received funding directly from pharmaceutical companies and that study participation would somehow convince them to *take* tamoxifen. One woman left a voicemail message stating, "You should be ashamed of yourselves." Some felt we had an "underlying agenda" with a pharmaceutical company. Others, particularly those without previous research study participation, may have felt uncomfortable leaving a message containing personal contact information to someone unknown, or may have had issues with the voicemail system.

Recruitment Costs

Figure 5 provides a detailed account of recruitment costs associated with various recruitment strategies.

- Staff costs for recruitment and screening span a two-year recruitment period and apply to various recruitment strategies and screening encounters (interview time was not included in this cost).
- Media advertisements (targeted largely to minority women) at high cost ($7,414, $135/screened participant) yielded 55 participants (62% White, 16% African-American, 20% Latina).
- Direct mail to an already active and largely White research pool (initial recruitment costs paid by WHI) was cost efficient ($773, $2.48/screened participant) and yielded 312 women but few minority participants (88% White, 4% African-American, 3% Latina, 5% Asian).
- Health Education Council (HEC), with many pre-established direct community cultural links, referred 168 women (38% White, 30% African-American, 28% Latina, and 3% Asian) who completed screening at an average cost of US $149/participant. The HEC costs ($25,009 one-year expenses) include those related to HEC staff, direct mail, community presentations, and events.
- Total recruitment and screening costs (not including interview staff costs) totaled US $87,112. Cost per screened participant was approximately US $113.

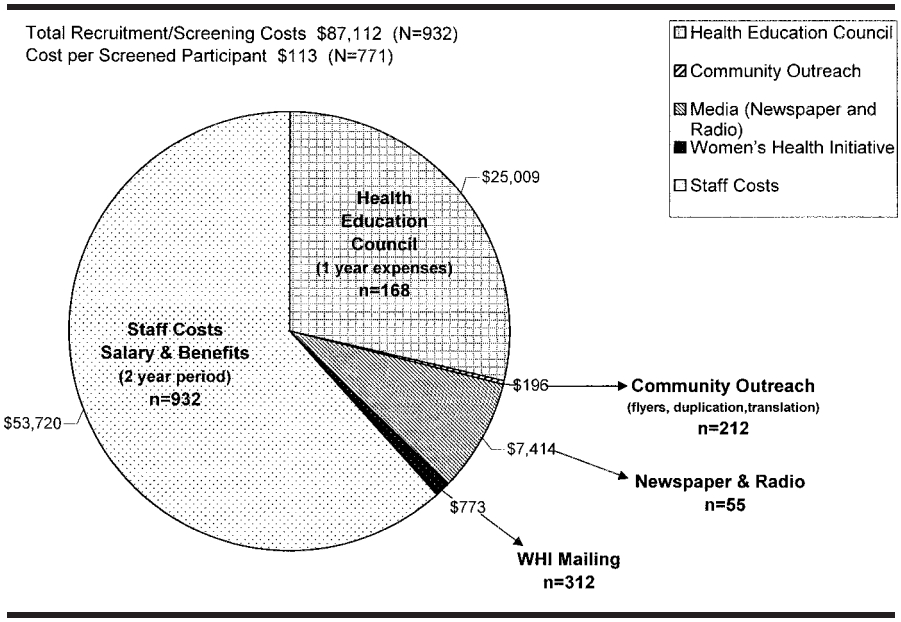

Fig 5. Recruitment costs per screened participant

DISCUSSION

The use of tamoxifen for potential breast cancer risk reduction is an innovative approach requiring participants to weigh multiple factors. The complexity of this decision-making process alone may have discouraged women from responding to our recruitment efforts. The POWER study identified 932 potentially eligible women by using multiple recruitment strategies and tracked recruitment outcomes by ethnicity and cost. Of these 932 women, 771 (83%) completed screening. Of these 771 women, 341 (44%) were determined eligible, and 255 (33%) completed interviews.

Effective Strategies

We successfully recruited and screened a study population reflective of the general population of Sacramento County with an enriched group of African-American, Latina, and Asian women (Sacramento County is 64%

White, 16% Hispanic, 10% African-American, 11% Asian, and 1% American Indian/Alaskan Native. Women screened (N=771) were 57% White, 25% Latina, 13% African-American, and 28% Asian).

Collaboration with WHI to recruit women from their active pool of research volunteers by direct mail provided the highest number of participants (350 responded, 312 screened, 173 interviewed) at the lowest cost, although our ability to obtain an ethnically diverse sample from this mostly White group was limited. These women, part of an established pool of active WHI participants (N=4000), were self-selected as interested in research and study participation and do not represent the general public. The POWER study saved substantial initial recruitment costs associated with this group since they were already recruited and actively participating in a research study and perhaps more inclined to participate in other studies. Recruitment costs associated with this pre-selected group of women were already expended by WHI. Ultimately, this group composed 68% of our final interview group. The WHI women were more likely to be eligible in all ethnic categories, although this group offered limited diversity.

Successful minority recruitment by direct mail and media has been reported by various studies including the Women's Health Trial. Per Lewis, "mass mailings were a particularly effective means of recruitment [and] they can also carry endorsements to improve the response from members of a particular demographic group. This proved particularly effective in improving the rates of response from members of ethnic minorities." [9]

In our experience, direct contact and visits to churches and various community events by ethnically congruous and culturally linked bilingual interviewers proved the most effective means for recruiting minority women. These visits provided a familiar and comfortable environment, increasing women's confidence in the study process. Among those interviewed at the hospital, many experienced access and navigation challenges (parking, complicated site maps), and the setting was viewed by some as a place to treat illness and not a friendly place for those who are healthy. We screened 121 Latina women during community visits; however only 28 met eligibility and 12 completed interviews. Many of these women fell outside our target group since they were younger and not at higher risk for breast cancer.

In our experience, direct contact and visits to churches and various community events by ethnically congruous and culturally linked bilingual interviewers proved the most effective means for recruiting minority women.

The Health Education Council, a well-known and respected community partner with established relationships with minority community leaders, successfully screened 102 ethnically diverse women through community visits and presentations at community centers, churches, and events; however, only 20 of these women were determined eligible for interviews.

Ineffective Strategies

Although we successfully screened 771 women by using various strategies, we failed to meet our recruitment goals (33%-33%) for African-American and Latina women. During the screening process we became acutely aware of the NCI breast cancer risk tool and its disproportionate effect on the eligibility of African-American respondents. This pool of eligible participants was dramatically reduced largely because of the effect of the screening tool. The overall incidence of breast cancer in African-American women in the United States is lower than the incidence in White women, although incidence in younger women (age 20–39) and mortality from breast cancer at all ages is higher among African Americans.[24–27] Eligible African-American (AA) women completed interviews at rates comparable to other ethnic groups (WHI: Asian 100%, White 83%, Latina 83%, African American 80%, and non-WHI: Asian 71%, White 64%, African American 55%, Latina 54%, see Figure 4), although sample size for several of these groups is small. Poor recruitment, particularly in this case, was not a racial issue, but rather a combination of race differences in eligibility plus completion rates across all ethnicities.

Similar missed expectations are cited in the literature for studies involving both men and women. The Breast Cancer Prevention Trial (BCPT), which recruited 13,388 female participants by using the NCI Breast Cancer Screening tool to assess risk/eligibility, reported 2% African-American enrollment and 3% total minority enrollment.[15] The ethnicity effect of the NCI Breast Cancer Screening Tool likely played a role in the eligibility of African-American women in the BCPT. The Prostate Cancer Prevention Trial (Moinpour) reports a desired minority accrual of 8%, but despite increased recruitment efforts and additional consultants, this trial only achieved 4% minority participation.[28] Early initiation of comprehensive and overlapping recruitment strategies is essential, and a long term perspective is desired; however, few studies link specific recruitment strategies to costs and yields.[3,9,28]

Various POWER recruitment strategies proved costly and ineffective. The Health Education Council's mailing to 125 Breast Cancer Early Detection Program providers yielded no responses; however targeted mass mailings were

not attempted. Radio and newspaper advertisements, targeted to diverse ethnic audiences at high cost ($7,414), provided only 55 responses and 14 interviews. Bilingual flyers and sign-up sheets distributed at various hospital sites, community meetings, and presentations yielded only 8 participants. Overall, media recruitment strategies targeting minority populations (such as radio) incurred significantly higher costs than those directed toward the general community and yielded few participants.

Strategies for Future Studies

Further efforts to streamline the screening/interview process to a single event to close contact delays could have minimized women lost to follow up. Delays in contacting interested volunteers could have been minimized with expanded staff presence at off-site recruitment efforts; however, staffing levels and schedule conflicts often prohibited extended coverage at off-site locations and events. Offering one-stop screening and interview opportunities could have facilitated participation. Because of scheduling and participant availability, the time period between screening and interview occasionally spanned a week or more. The joint demands of work and home provided narrow windows for scheduling, and at times we were unable, despite our best efforts, to meet participant needs.

Allocating additional time and resources during the early recruitment phase might have increased participation. Mailings containing personalized endorsements from community leaders could have increased awareness and trust.[3,9] Providing at-home interviews and transportation to and from screening/interview sites may have increased participation for some women who specifically requested this option.

Collaboration with other investigators, studies, and locations could provide significant recruitment rewards. Sharing established and successful minority participant pools with other relevant studies would provide an excellent preliminary recruitment base. Obtaining informed consent to be contacted for other research studies should be routine. We successfully recruited 322 minority women and did not obtain this consent; therefore, our established database of interested minority women is unavailable to other researchers.

Recommendations for Researchers Recruiting Diverse Populations

Overall we were successful in recruiting 368 women from ethnically diverse populations for our study. Despite our best recruitment efforts, and the willingness of certain groups of women to participate, the eligibility process and pre-determined eligibility thresholds prevented certain groups of women from completing the interview process. We recommend that other studies:

- Conduct extensive pilot testing of eligibility tools for unexpected recruitment effects;
- Track and evaluate minority recruitment strategies (yields and costs);
- Closely evaluate the eligibility process and its effects on recruitment yields;
- Budget adequately from the onset for the increased costs and time to recruit minority participants;
- Develop ongoing relationships and support from key minority gatekeepers and groups; and
- Report detailed recruitment findings to the research community.

Taking these steps may ultimately increase minority participation and findings applicable to the entire community, not just those with historically high participation rates.

ACKNOWLEDGMENTS

Funded by the California Breast Cancer Research Program Grant #5PB–0110, and the National Cancer Institute RO1 CA 86043 NCI. The authors offer their sincere appreciation to POWER participants, John Robbins, MD, WHI Staff, project interviewers, student assistants, Cassie Bush, the Center for Health Services Research in Primary Care, Geeta Mahendra, and Gale Spears (Health Education Council). Without their dedication and support these findings would not be possible. Thanks also to David Keyzer (University of the Pacific, McGeorge School of Law) for his detailed review of the manuscript, and Hugh and Mary Fulton for their ongoing support.

REFERENCES

1. Vastag B. Researchers say changes needed in recruitment policies for NIH trials. *JAMA.* 2003;289:536.
2. Ramasubbu K, Gurn H, Litaker D. Gender bias in clinical trials: do double standards still apply? *J Womens Health Gender Based Med.* 2001;10(8):757–764.
3. Lovato LC, Hill K, Hertert S, Hunninghake DB, Probstfield JL. Recruitment for controlled clinical trials: literature summary and annotated bibliography. *Control Clin Trials.* 1997;18(4):328–352.
4. Green BL, Partridge EE, Founad MN, Kohler C, Crayton EF, Alexander L. African-American attitudes regarding cancer clinical trials and research studies: results from focus group methodology. *Ethn Dis.* 2000;10(1):76–86.
5. Grunbaum JA, Labarthe DR, Ayars C, Harrist R, Nichman MZ. Recruitment and enrollment for Project Heartbeat! Achieving the goals of minority inclusion. *Ethn Dis.* 1996; 6(3–4):203–212.
6. Ness RB, Nelson DB, Kumanyika SK, Grisso JA. Evaluating minority recruitment into clinical studies: how good are the data? *Ann Epidemiol.* 1997;7(7):472–478.
7. Janson SL, Alioto ME, Boushey HA. Attrition and retention of ethnically diverse subjects in a multicenter randomized controlled research trial. *Control Clin Trials.* 2001;22: 236S–243S.
8. Naranjo LE, Dirksen SR. The recruitment and participation of Hispanic women in nursing research: a learning process. *Public Health Nurs.* 1998;15(1):25–29.
9. Lewis CE, George V, Fouad M, Porter V, Bowen D, Urbam N. Recruitment strategies in the women's health trial-feasibility study in minority populations. WHT: FSMP Investigators Group. Women's Health Trial: Feasibility Study in Minority Populations. *Control Clin Trials.* 1998;19(5):461–476.
10. Brown DR, et al. Recruitment and retention of minority women in cancer screening, prevention, and treatment trials. *Ann Epidemiol.* 2000;10(suppl 8):13S–21S.
11. Prout MN, Fish SS. Participation of women in clinical trials of drug therapies: a context for the controversies. *Medscape Womens Health.* 2001;6(5):1.
12. Folmar S, Oates-Williams F, Shart P, et al. Recruitment of participants for the Estrogen

Replacement and Atherosclerosis (ERA) trial. A comparison of costs, yields, and participant characteristics from community-and-hospital based recruitment strategies. *Control Clin Trials.* 2001;22(1):13–25.
13. Bjornson-Benson WM, Stibolt TB, Manske KA, Zavela KJ, Youtsey DJ, Buist AS. Monitoring recruitment effectiveness and cost in a clinical trial. *Control Clin Trials.* 1993; 14(suppl 2):52S–67S.
14. Gilliss CL, Lee KA, Gutierrez Y, et al. Recruitment and retention of healthy minority women into community-based longitudinal research. *J Womens Health Gender Based Med.* 2001;10(1):77–85.
15. Fischer B, et al. Tamoxifen for prevention of breast cancer: report of the National Surgical Adjuvant Breast and Bowel Project P-1 Study. *J Natl Cancer Inst.* 1998;90(18):1371–1388.
16. Furlong W, Feeny D, Torrane G, Barr R, Horsman J. *Guide to Design and Development of Health State Utility Instrumentation.* Ontario: McMaster University; June 1990. CHEPA Working Paper Series #90–9.
17. Design of the Women's Health Initiative clinical trial and observational study. The Women's Health Initiative Study Group. *Control Clin Trials.* 1998;19(1):61–109.
18. Anderson SJ, Ahnn S, Duff K. *NSABP Breast Cancer Prevention Trial Risk Assessment Program, Version 2.* Pittsburgh, Pa: Dept. of Biostatistics, University of Pittsburgh; 1992.
19. Gail MH, Costantino JP, Bryant J, et al. Weighing the risks and benefits of tamoxifen treatment for preventing breast cancer. *J Natl Cancer Inst.* 1999;91(21):1829–1846.
20. Rockhill B, Spiegelman D, Byrne C, Hunter DJ, Colditz GA. Validation of the Gail et al model of breast cancer risk prediction and implications for chemoprevention. *J Natl Cancer Inst.* 2001;93(5):358–366.
21. Costantino JP, Gail MH, Pee D, et al. Validation studies for models projecting the risk of invasive and total breast cancer incidence. *JNCI Cancer Spectrum.* 1999;91(18):1541–1548.
22. Dentin NK, Lincoln VS, eds. *Handbook of Qualitative Research.* 2nd ed. Thousand Oaks, Calif: Sage Publications; 2000.
23. Lofland J, Lofland LH. *Analyzing Social Settings.* Belmont, Calif: Wadsworth Publishing; 1995.
24. Greenlee RT, Hill-Harmon MB, Murray T, Thun M. Cancer statistics, 2001. *CA Cancer J Clin.* 2001;51(1):15–36.
25. Pathak DR, Osuch JR, He J. Breast carcinoma etiology: current knowledge and new insights into the effects of reproductive and hormonal risk factors in Black and White populations. *Cancer.* 2000;88(suppl 5):1230–1238.
26. Miller BA, Kolonel LN, et al. *Racial/Ethnic Patterns of Cancer in the United States 1988–1992.* Bethesda, Md: National Cancer Institute; 1996.
27. Brinton LA, Benichou J, Gammon MD, Brogan DR, Coates R, Schoenberg JB. Ethnicity and variation in breast cancer incidence. *Int J Cancer.* 1997;73:349–355.
28. Moinpour CM, et al. Minority recruitment in the prostate cancer prevention trial. *Ann Epidemiol.* 2000;10(suppl 8):85S–91S.

BIBLIOGRAPHY

Brown BA, Long HL, Weitz TA, Milliken N. Challenges of recruitment: focus groups with research study recruiters. *Women Health.* 2000;31(2–3):153–166.

Blumenthal DS, Sung J, Coats R, Williams J, Liff J. Recruitment and retention of subjects for a longitudinal cancer prevention study in an inner city Black community. *Health Serv Res.* 1995;30(1, pt 2):197–205.

Mouton CP, Harris S, Rovi S, Solorzano P, Johnson MS. Barriers to Black women's participation in cancer clinical trials. *J Natl Med Assoc.* 1997;89(11):721–727.

Sung JF, Coates RJ, Williams JE, et al. Cancer screening intervention among Black women in inner city Atlanta—design of a study. *Public Health Rep.* 1992;107(4):391–398.

Marin G, Vanoss Marin B, Perex-Stable EJ, Vanoss B. Feasibility of a telephone survey to study a minority community: Hispanics in San Francisco. *Am J Public Health.* 1990;80(3): 323–326.

Pletsch PK, Howe C, Tenney M. Recruitment of minority subjects for intervention research. *J Nurs Sch.* 1995;27(3):211–215.

DiMattio MJ. Recruitment and retention of community-dwelling, aging women in nursing studies. *Nurs Res.* 2001;50(6):369–373.

Kelly PJ, Cordell JR. Recruitment of women into research studies: a nursing perspective. *Clin Nurse Spec.* 1996;10(1):25–28.

Smedira HJ. Practical issues in counseling healthy women about their breast cancer risk and use of tamoxifen citrate. *Arch Intern Med.* 2000; 160(20):3034–3042.

Giuliano AR, Mokuau N, Hughes C, et al. Participation of minorities in cancer research: the influence of structural, cult, and linguistic factors. *Ann Epidemiol.* 2000;10(suppl 8): 22S–34S.

Ashing-Giwa K. The recruitment of breast cancer survivors into cancer control studies: a focus on African-American women. *J Natl Med Assoc.* 1999;91(5):255–260.

Husaini BA, Sherkat DE, Bragg R, et al. Predictors of breast cancer screening in a panel study of African-American women. *Women Health.* 2001;34(3):35–51.

Kiernan M, Phillips K, Fair JM, King AC. Using direct mail to recruit Hispanic adults into a dietary intervention: an experimental study. *Ann Behav Med.* 2000;22(1):89–93.

Gavalier JS, Bonham-Leyba M, Castro CA, Harman SE. The Oklahoma Postmenopausal Women's Health Study: recruitment and characteristics of American Indian, Asian, Black, Hispanic, and Caucasian women. *Alcohol Clin Exp Res.* 1999;23(2):220–223.

Lee RE, McGinnis KA, Sallis JF, Castro CM, Chen AH, Hickmann SA. Active vs passive methods of recruiting ethnic minority women to a health promotion program. *Ann Behav Med.* 1998;19(4):378–384.

Gorelick PB, Richardson D, Hudson E, et al. Establishing a community network for recruitment of African Americans into a clinical trial. The African-American Antiplatelet Stroke Prevention Study (AAASPS) experience. *J Natl Med Assoc.* 1996;88(11):701–704.

Ashing-Giwa K. The recruitment of breast cancer survivors into cancer controlled studies: a focus on African-American women. *J Natl Med Assoc.* 1999;91(5):255–260.

Sutton-Tyrrel K, Crow S, Hankin B, Trudel J, Faille C. Communication during the recruitment phase of a multicenter trial: the recruitment hotline. *Control Clin Trials.* 1996;17(5): 415–422.

Whelton PK, Lee JY, Kusek JW, et al. Recruitment experience in the African-American Study of Kidney Disease and Hypertension (AASK) Pilot Study. *Control Clin Trials.* 1996;17(suppl 4):17S–33S.

Gerace TA, George VA, Arrango IG. Response rates to six recruitment mailing formats and two messages about a nutrition program for women 50–70 years old. *Control Clin Trials.* 1995;16(6):422–431.

Daunt D. Ethnicity and recruitment rates in clinical research studies. *Appl Nurs Res.* 2003; 16(3):189–195.

AUTHOR CONTRIBUTIONS

Design and concept of study: Keyzer, Azari, Birch, Kuppermann, Melnikow, Nuovo, Rooney

Acquisition of data: Keyzer, Melnikow, Nuovo, Oto-Kent, Rooney

Data analysis and interpretation: Keyzer, Azari, Birch, Kuenneth, Kuppermann, Melnikow, Nuovo, Rooney

Manuscript draft: Keyzer, Birch, Kuenneth, Kuppermann, Melnikow, Oto-Kent

Statistical expertise: Azari, Kuenneth, Melnikow, Rooney

Acquisition of funding: Birch, Melnikow

Administrative, technical, or material assistance: Keyzer, Birch, Nuovo, Oto-Kent, Rooney

Supervision: Keyzer, Melnikow, Nuovo