Published in final edited form as:

J Cancer Educ. 2005 ; 20(4): 235–239.

Recruiting Research Participants at Community Education Sites

GEORGIA ROBINS SADLER, BSN, MBA, PHD, MELANIE PETERSON, BS, LINDA WASSERMAN, MD, PHD, PAUL L. MILLS, PHD, VANESSA L. MALCARNE, PHD, CHERYL ROCK, PHD, SONIA ANCOLI-ISRAEL, PHD, AMANDA MOORE, BS, RAI-NESHA WELDON, BS, TENISHA GARCIA, BS, and RICHARD D. KOLODNER, PHD

Received from the Rebecca and John Moores Cancer Center, La Jolla, California (GRS, MP, AM, RW, TG, SAI, RDK, VLM, PLM, CR, LW); from the University of California, San Diego School of Medicine, La Jolla, California (GRS, SAI, RDK, PM, CR, LW); from Veterans Affairs San Diego Healthcare System, La Jolla, California (SAI); from San Diego State University, San Diego, California (VLM); and from the Ludwig Institute for Cancer Research (RDK).

Abstract

Background—Minority groups are underrepresented in research, making it difficult to apply medical advances with confidence. In this study, we explored whether community-based cancer education sites and educators serving the African American community could be used to recruit minority participants to research.

Methods—We invited Individuals at community education sites to provide buccal scrapings, saliva samples, psychometric data, and personal information anonymously.

Results—Culturally aligned community sites (100%) collaborated in the research recruitment, as did 83% of the individuals at those sites.

Conclusion—Community-based education sites offer exceptional promise for teaching about research benefits and recruiting members of minority groups to research studies.

For medical discoveries to be of equal value to all age, gender, cultural, and socioeconomic groups, it is essential that each of those groups be adequately represented in research studies.^{1–3} While recruitment of diverse participants is a vitally important goal, it is also a difficult task because most researchers lack the time, skills, and/or interest to develop, implement, and supervise community-based subject recruitment strategies.^{4–6}

An ideal partner to help the investigator achieve a diverse research sample would appear to be community health educators and the community sites where they offer their health education. Community health educators know the community, have acquired an array of specialized information dissemination skills and insights, and have well-established working relationships with minority communities' leaders and members. Such a partnership could be expected to provide the public with ongoing health promotion education, greater awareness of the importance of research studies and the variety of research studies underway, and immediate

Address correspondence and reprint requests to: Georgia Robins Sadler, Associate Director, Community Outreach, Moores University of California, San Diego Cancer Center, 9500 Gilman Drive, La Jolla, CA 92093-0658; phone: (858) 534-7611; fax: (858) 534-7628; e-mail: <gsadler@ucsd.edu>..

Supported by grants from the National Cancer Institute's Grant 2 R25 CA65745 and CA85264; the San Diego Community Foundation; the Bristol Myers Squibb Foundation; the AVON Foundation; the National Institutes of Health, Division of National Center on Minority Health and Health Disparities EXPORT Grant P60MD00220; and the National Cancer Institute Minority Institution/Cancer Center Partnership Program Grants U56 CA92079 and U56 CA92081. Educational supplies were provided by the American Cancer Society and the National Cancer Institute's Partnering on Education Tools (POET) project. Its contents are the sole responsibility of the authors and do not necessarily represent the official beliefs of the funding agencies. Preliminary data from this study were presented at the European Association for Cancer Education annual meeting in Nijmegen, Holland, May 1, 2002.

opportunities for the public to participate in research studies while providing researchers with more diverse samples and economies of scale.

In this study, we tested the concept of blending the efforts of community health educators and the community health education sites they use with scientific researchers' efforts to recruit diverse samples to their research studies. It represents a research collaboration of basic, clinical, and behavioral scientists and community health educators who developed a model to test the viability of such a merger.

This research project tested three hypotheses:

1. At least 25% of the culturally aligned cancer education sites invited to participate and at least 10% of the community members at those sites will agree to participate. These minimal rates of accrual to research studies were arbitrarily chosen because they could produce a measurable improvement in sample diversity of studies.
2. Community-based settings will yield at least 80% usable biological and questionnaire data.
3. At least 50% of the participants who take part in 1 cluster of similar studies will take part in another cluster of different studies.

MATERIALS AND METHODS

The strategy of blending these 2 sets of activities was tested using African American community health educators and the community health education sites they routinely used such as beauty salons, churches, community health fairs, and social and civic groups.^{7,8}

University of California, San Diego's Institutional Review Board (IRB) approved data- and specimen-sample collection for 7 investigators' studies (GRS, LW, PLM, VLM, CR, SAI, RDK). Clustered into 3 groups, the first cluster included the collection of 2 buccal scrapings for breast cancer and an additional 2 buccal scrapings for colorectal cancer DNA analysis, plus 1 saliva sample for cortisol analysis (time required: up to 10 minutes). The second study cluster included the collection of food frequency data and buccal scrapings to determine whether buccal cells (instead of blood samples) would consistently produce sufficient quantities of cellular material to allow relationships to be established between reported dietary beta carotene intake and cellular beta carotene levels (time required: up to 45 minutes). If a consistent relationship could be established, the data and specimen collection for the second cluster would continue. The third cluster of studies was the collection of data to validate several standardized self-report questionnaires for their use in underrepresented populations (time required: up to 45 minutes; see Table 1).

For this study, the health educator was trained to administer each of the study clusters because they were relatively simple for a lay person to learn. Had the studies required that the study coordinator have more sophisticated training, an alternate strategy would have been to have the study coordinator working synergistically with the community health educator.

The setup for data collection was determined by the site. In all settings, the community health educator sequentially invited people to participate as they arrived. Once they selected the study cluster(s) in which they would participate, they moved into smaller groups where they were simultaneously taken through the participant instruction process. Those who elected to participate in more than 1 cluster, could select the order of cluster participation and join the appropriate data collection group.

For health fairs, social/civic sites, and churches, a set of tables and chairs were arranged in separate areas for each cluster of studies. As individuals gathered, a community health educator guided participants in each cluster thru the process. For this study, up to 25 people could be simultaneously taken through the consenting process.

At the beauty salons, participants were recruited and consented 1-by-1. After participants consented and engaged in completing their study tasks, there was the opportunity to recruit, consent, and set other salon clients to work on their tasks before returning to the first participant with further instructions.

The cancer educators paraphrased the 8-page consent document while the potential participant followed along and reviewed each paragraph. The consent document included a lengthy explanation of the role that research plays in advancing medical knowledge, the importance of having minority representation in samples, and the various research studies being offered for their consideration. This educational content was not necessary for IRB approval but offered educational content about human subjects' research participation that was a key educational goal of this outreach effort and was also anticipated to reduce the refusal rate among potential participants.

Participants signed the consent document and then checked the study cluster or clusters they wished to join. If they checked only 1 cluster of studies, they were given the option of selecting an additional cluster of studies after finishing the first. "Refusal to participate" was defined as "a person who had received a complete or partial explanation of the study and then declined to participate." Because no identifiable data were collected, the consent document was filed separately from all other project paperwork without the assigned unique identifier numbers that were attached to the data and specimens collected.

Scrip, valued at \$5, was offered for completion of each study cluster. Because DNA was being collected, it was essential that no identifiable data were collected. Scrip is a bank redeemable that offers complete confidentiality since the payee's name is not printed on the scrip and no identification is required to cash the scrip.

Data analysis was performed using SPSS (Version 12.0; SPSS Inc., Chicago). Chi-square tests (χ^2) explored differences in study participation between gender, age groups, and personal/family history of cancer for each cluster group. To test the relationship of cluster participation between each cluster, Phi coefficients were run. In addition, the Wilcoxon signed rank test was used to detect any significant differences between the distributions of the cluster groups' participation rates. A *P* value of $\leq .05$ was considered statistically significant. For the second hypothesis, the percentage of acceptable data was calculated for each questionnaire and biological specimen.

Description of Sample

Of the 378 consented participants, 130 were male, and 248 were female. (Overrecruitment of female participants explains this gender imbalance.) Men's ages ranged from 18 to 73 years (mean = 43, median = 44, SD = 13.13). The women's ages ranged from 18 to 81 years (mean = 43, median = 42, SD = 14.87). A personal or family history of cancer was reported by 137 participants (45 men and 92 women), while 227 reported no awareness of a personal or family history of cancer, suggesting that familial cancer was not likely to have been the motivator of this participation. The remaining 8 did not provide sufficient information to determine cancer exposure.

RESULTS

Hypothesis 1

At least 25% of the culturally aligned cancer education sites invited to participate and at least 10% of the community members at those sites will agree to participate—Leaders from 100% of the invited community sites agreed to their organization's participation and actively encouraged their constituents' participation. For individuals with whom study participation was discussed, the refusal rate was 14% (63 of 441), with most reporting lack of time as their reason for not participating. Because data were difficult to gather from nonparticipants, it is impossible to determine whether gender or age correlated with refusal rates. As regards the community's tolerance for data and specimen collection in these community sites, no one raised concerns with the site leaders or the IRB about the appropriateness or acceptability of the project.

Hypothesis 2

Community-based settings will yield at least 80% usable biological and questionnaire data—The saliva samples were found to be adequate for cortisol research. Of the 288 participants who provided saliva samples, 216 were assayed to date, and 190 of those samples (88%) contained sufficient volume for cortisol analysis. Collecting a second saliva sample would be the simplest way to assure that all participants' specimens were sufficient for cortisol research. There was no problem with mold contamination since all specimens were kept on dry ice until delivered to a -80°C freezer by the community health worker.

Of the same 288 participants who agreed to provide 4 buccal swabs for 2 studies involving DNA research, 100% of the participants' buccal swabs contained sufficient genetic material for DNA research. Indeed, there were only 2 instances in which the first swab alone was insufficient. Specifically, DNA was extracted from the buccal swabs using commercially available extraction kits. Then the extracted DNA was used in polymerase chain reaction-based genotyping assays.

These findings were considerably different from the outcomes with the buccal swabs for the third study cluster. For these buccal swabs, the research team overcame the technical hurdles of minimizing the light exposure of the beta carotene buccal samples and keeping them cold enough, but none of the samples produced a sufficient quantity of cellular tissue to accurately measure beta carotene levels. Although no one refused to participate in this cluster, because the primary goal of this particular facet of the research project was to determine if buccal scrapings could reliably replace the collection of blood samples in the field, this phase of the data collection was stopped after analysis of the first 44 samples. Future studies will evaluate alternate methods of beta carotene collection.

Of the 347 who agreed to provide psychosocial data, the instruments were completed to varying degrees (see Table 1). The African American Acculturation Scale was most frequently reported to contain items that were offensive to the participants. Higher completion rates were generally found for the shortest scales.

Hypothesis 3

At least 50% of the participants who take part in 1 cluster of similar studies will take part in another cluster of different studies—Of the total 378 study participants, 288 participated in the buccal swab and saliva studies cluster, 347 in the psychometric studies cluster, and 44 in the beta carotene cluster before it was terminated for technical reasons. Participation in 1 study cluster was correlated with participation in an additional study cluster.

For the 319 participants for whom only the 2 study clusters were offered, 257 (81%) took part in both study clusters. Participants who took part in the buccal swab and saliva study cluster were significantly more likely to take part in the food frequency and buccal swab study ($\phi = .145, P = .01$). Participants who took part in the psychometric study cluster were more likely to participate in the food frequency study cluster ($\phi = .108, P = .04$). In contrast, participants who took part in the buccal swab and saliva study cluster were slightly less likely to participate in the psychometric study cluster ($\phi = -.167, P = .00$). There were no participation differences between personal/family history of cancer or age groups for any of the 3 clusters. Only Cluster 3 showed gender bias in favor of female participants solely because beauty salons were the predominant data collection sites during the early data collection ($\chi^2_1 = 7.539, P = .01$).

Participants were significantly more likely to take part in the psychometric cluster than the buccal swab and saliva cluster (Wilcoxon signed ranks = $-5.36, P < .00$). This preference was not correlated with the order in which the studies were presented in the consent document. Before the third cluster of studies was terminated, 44 participants were offered all 3 study clusters. Of those 44 participants, 41 took part in all 3 clusters, 4 took part in 2 of the clusters, and 4 took part in only 1 of the clusters.

Equally important, although placing several studies into 1 cluster prolonged the participants' time commitment, it did not appear to deter the majority of participants from agreeing to complete a study cluster, nor was there a pattern of withdrawing from participation partway through the lengthy process.

DISCUSSION

While the National Institutes of Health have mandated representation of all ethnic groups in research studies,⁵ and there is much to be gained by having the country's diverse communities represented in research studies, the barriers to their participation have proven difficult to overcome. In this study, we demonstrated that a marriage between scientific researchers and community health educators and the community health education sites where they work would be a viable, productive partnership to facilitate African Americans' education about clinical research and recruitment to research studies.

The study showed that community health educators can successfully (1) deliver education on the importance of participating in research studies; (2) recruit African Americans to research studies; (3) adhere to study protocols in spite of field conditions; and (4) recruit participants for multiple studies simultaneously and collect enough viable scientific data and specimens to achieve cost savings, eg, staff travel time, mileage, the consenting process, or dry ice use.

By clustering research studies through 1 recruitment strategy, there is a greater chance that persons who are favorably disposed toward participating in research studies will find a study that interests them and for which they are eligible. The fact that participation in study Cluster 1 was inversely related to participation in study Cluster 2 underscores this point. The overlap in participation in the 3 clusters also shows that when participants are highly receptive to research participation, there is a high likelihood that they will participate in more than 1 study cluster.

Although many studies cannot be done in community settings, some researchers may be able to conduct a preliminary phase of their studies in the community. A breast cancer prevention study for high-risk women began with community-based data collection to calculate women's Gail Model Scores rather than distributing flyers that invited them to a distant clinic to be evaluated for eligibility.¹⁴⁻¹⁶

Even with these adaptations, recruitment for many therapeutic clinical trials cannot be effectively done in community sites largely because the referral window is so brief, and clinical decisions must be made so quickly, ie, a study between biopsy and initiation of cancer treatment.¹⁷ While clinicians will be the best referral source, as community health workers' reputation for access to clinical information grows, members of the community will seek their guidance during health crises. Since these referrals will be predominantly from members of communities that are underrepresented in studies, they are of disproportionately greater value to the research mission.

The concept of bringing multiple investigators' projects together and the high incidence of participation in more than 1 study or study cluster will allow researchers from different disciplines to collaborate on the analyses of their pooled data. For example, the psychometrician's validated instrument can immediately be used to help interpret another researcher's clinical data.

This marriage also addressed the community's oft-reported frustration that researchers disappear once their data is collected. Community educators offer a permanent community presence that addresses this issue and also enables researchers' findings to be disseminated community wide. Clustering study recruitment under the watchful eye of a community health educator also helps reduce community members' confusion about similar sounding studies and difficult-to-interpret variations in study eligibility criteria.

Having a trusted community health educator working beside the researcher can help reduce problems. For example, even the most caring researcher can unintentionally make an insensitive comment secondary to a lack of cultural sensitivity. Community members may less harshly judge researchers who make a faux pas when they are the guest of the educator, whereas outsiders' every word is to be weighed and judged.

Another beneficial outcome of this symbiotic relationship is that researchers will gain access to community members who can serve as sounding boards during a study's conceptualization, design, implementation, and interpretation phases. IRBs and investigators can benefit from community guidance as they weigh a study's risks, benefits, and ethical considerations. The community members who participate in such deliberations with the research community are also individuals with a demonstrated interest in facilitating scientific advances while assuring the protection of community interests. As such, they are community members who may be receptive to invitations to participate on an IRB.

A limitation of partnerships between community health education and participant recruitment is that community health workers may have a difficult time shifting between their roles. Indeed, they may even see them as cognitively inconsistent. Another consideration is the challenges associated with identifying a collection of studies that lend themselves to recruitment simultaneously via community health educators, a process complicated by delays for securing IRB approval to conduct multiple studies under 1 consent document.

CONCLUSIONS

Minority groups will continue to be underrepresented in the research process unless culturally sensitive strategies are identified that can directly address the needs of the under-represented communities. With shrinking budgets, increasing expenses, and greater numbers of studies recruiting the same small group of interested and study-eligible participants, better ways are needed to increase the pool of potential applicants, attract greater representation from members of traditionally underrepresented communities, and contain costs. A symbiotic working relationship between researchers and community health workers appears to offer a viable option for overcoming some of the barriers researchers have encountered in recruiting

representative samples of participants. The methodology we described in this study has the potential to address all of these issues.

Acknowledgements

For their assistance with community outreach and data collection, the authors thank the following community outreach workers: Julius Phillips, Ricardo Olivo, Ricky Pope, Starlyn Hawes, Cindy Tso, Kathy Gustafson, and Irma Hernandez. The authors would also like to thank the community leaders and the hundreds of community members who took part in this research as well as the owners and managers of the following community-based sample collection sites: Devine Deliverance Church of God in Christ, Vista, CA; Black Men United of San Diego; Linda Vista Second Baptist Church. Special thanks to the following San Diego stylists and their salons whose contribution to this research study to improve the well-being of African Americans was invaluable: Brenda Adams, Craig Allen, Tarva Armstrong, Charlene Baker, Barbara Ball, Jhonine Barber, Tranita Barnett, Wanda Blocker, Hazel Bomer, Tessie Bonner, Oma Black, Rachelle Brown, Al Bryant, Robert Butler, Toi Butler, William Calhoun, Lucille Cannon, Laticia Carrington, Leslie Chea, Veva Cockell, Geneva Cole, Jonna Council, Gary Davis, Kimmie Davis, Ann Denny, Denise Dulin, Josette Desrosiers, Pride Erwing, Thommie R. Flanagan, Shelton Flournoy, Flower Floyd, Brenda Forte-Pierce, Dellilah Gordon, DeBorah Green, Marilyn Hardy, Jan Harris, Shelby Harris, Carmel Honeycutt, the late Phoebe Hutcherson, James Hyndman, Carol James, Ariella Angie Johnson, Cheryl Johnson, Ena Johnson, the late Rosemary Jones, Thea Jones, Phyllis Lee, Catherine Leggett, Darlene Loving, Ronnie Martin, Sheryl Martin, Zanola Maxie, De'Borah McCampbell, Valerie McGee, Kenisha McGruder, Janet D. Miller, Jennifer Mitchell, Lloydessa Moore, Paula Morgan, Carl Mohammad, Sharon Mohammad, Sandra Pearson, Kia-Tana Price, Ethel M. Perkins, Jerry Piatt, Demetra Robinson, Marsha Ryder, Lynette Shine, Ann Smith, Gladys Smoot, Kandi Stephens, Beverly Taylor, Latasha Thomas, Mary Thomas, Beverly Tolbert, Bob Valero, Kim Vasser, Monica Vasser, Jeanne Walsh, Barbara Washington, Clara Watson, Kloria Wilkins, Redell Williams, Sherrice Williams, Julia Wilson, and Sabrina Woods. Special thanks also to the community leaders who enthusiastically helped the authors implement this community-based program: Victoria Butcher, Crystal Butcher, Reverend Alyce Smith-Cooper, Bishop George McKinney, Barbara Odom RN CDE, Reverend George Walker Smith, Robin Ross, and Dr Robert Ross.

References

1. Adams-Campbell LL, Ahaghotu C, Gaskins M, et al. Enrollment of African Americans onto clinical treatment trials: study design barriers. *J Clin Oncol* 2004;22:730–734. [PubMed: 14966098]
2. Johnson MS. Perspectives in medicine. Generalizability of homogenous samples in clinical trials. *J Assoc Acad Minor Phys* 1990;1:31–33. [PubMed: 2135695]
3. NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research—Amended, October 2001. Available at: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm Accessed August 26, 2004
4. Marquez MA, Muhs JM, Tosomeen A, Riggs BL, Melton LJ III. Costs and strategies in minority recruitment for osteoporosis research. *J Bone Miner Res* 2003;18:3–8. [PubMed: 12510799]
5. Giuliano AR, Mokuau N, Hughes C, et al. Participation of minorities in cancer research: the influence of structural, cultural, and linguistic factors. *Ann Epidemiol* 2000;10(suppl 8):S22–S34. [PubMed: 11189089]
6. Daunt DJ. Ethnicity and recruitment rates in clinical research studies. *Appl Nurs Res* 2003;16:189–195. [PubMed: 12931333]
7. Sadler GR, Escobar R, Ko CM, et al. African American women's perceptions of their most serious health problems. *J Natl Med Assoc* 2005;97:31–40. [PubMed: 15719869]
8. Hurd TC, Muti P, Erwin DO, Womack S. An evaluation of the integration of non-traditional learning tools into a community based breast and cervical cancer education program: the witness project of Buffalo. *BMC Cancer* 2003;3:18. [PubMed: 12775219]
9. De Jong N, Courtens AM, Abu-Saad HH, Schouten HC. Fatigue in patients with breast cancer receiving adjuvant chemotherapy: a review of the literature. *Cancer Nurs* 2002;25:283–297. [PubMed: 12181497]
10. Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: the PANAS scales. *J Pers Soc Psychol* 1988;54:1063–1070. [PubMed: 3397865]
11. Strahan R, Gerbasi KC. Short, homogeneous versions of the Marlowe-Crowne social desirability scale. *J Clin Psychol* 1972;28:191–193.
12. Landrine H, Klonoff EA. The African American Acculturation Scale: Development, reliability, and validity. *J Black Psychol* 1994;20:104–127.

13. Landrine H, Klonoff EA. The schedule of racist events: A measure of racial discrimination and a study of its negative physical and mental health consequences. *J Black Psychol* 1996;22:144–168.
14. Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989;81:1879–1886. [PubMed: 2593165]
15. Costantino JP, Gail MH, Pee D, et al. Validation studies for models projecting the risk of invasive and total breast cancer incidence. *J Natl Cancer Inst* 1999;91:1541–1548. [PubMed: 10491430]
16. Sadler GS, York C, Madlensky L, et al. Health parties for African American study recruitment. *Journal of Cancer Education*. 2006Accepted for Publication In Press
17. Mills PJ, Ancoli-Israel S, Parker B, Dimsdale JE, Sadler GR. The relationship between fatigue and quality of life and inflammation during anthracycline-based chemotherapy in breast cancer. *Biol Psychol* 2005;69:85–96. [PubMed: 15740827]

Table 1

Frequency of Survey Completion

Psychometric Instrument (No. of Items)	Total Administered	Completeness of Instruments			
		100% Complete		90% Complete	
		%	No.	%	No.
Multidimensional Fatigue Symptoms Inventory (83) ⁹	347	55	191	92	319
Positive and Negative Affect Schedule (20) ¹⁰	347	94	326	95	331
Marlow-Crowne Social Desirability Scale (10) ¹¹	347	95	328	97	336
African American Acculturation Scale (48) ¹²	347	64	223	92	320
Experiences with Racism Scale (19) ¹³	347	74	257	84	291
Barriers to Clinical Trials Participation Scale (63) [*]	347	81	218	90	311

^{*} A new instrument to determine predictors of research participation.