

EFFECTIVE RECRUITMENT AND RETENTION OF MINORITY RESEARCH PARTICIPANTS

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■ **Abstract** Our ability, as leaders in public health scholarship and practice, to achieve and measure progress in addressing racial/ethnic disparities in health status and health care is severely constrained by low levels of participation of racial/ethnic minority populations in health-related research. Confining our review to those minority groups federally defined as underrepresented (African Americans/blacks, Latinos/Hispanics, and Native Americans/American Indians), we identified 95 studies published between January 1999 and April 2005 describing methods of increasing minority enrollment and retention in research studies, more than three times the average annual output of scholarly work in this area during the prior 15-year period. Ten themes emerged from the 75 studies that were primarily descriptive. The remaining 20 studies, which directly analyzed the efficacy or effectiveness of recruitment/retention strategies, were examined in detail and provided useful insights related to four of the ten factors: sampling approach/identification of targeted participants, community involvement/nature and timing of contact with prospective participants, incentives and logistical issues, and cultural adaptations. We then characterized the current state of this literature, discussing implications for future research needs and directions.

INTRODUCTION

Racial/ethnic disparities in health status and health care are subjects of ever-increasing attention, as reflected in the special segments or issues of major medical and public health journals [e.g., Lavizzo-Mourey et al. (63); Yancy et al. (119)] recently devoted to this topic. Racial/ethnic differences in socioeconomic status (SES) alone cannot account for these disparities (63). Although progress in reducing these disparities has been made for some health conditions within certain racial/ethnic groups, the magnitude of the gap has remained fairly constant overall and is increasing in some critical areas (63, 91, 100). However, our ability to assess, much less advance, this progress is hampered by the low levels of participation of racial/ethnic minority populations in health-related research (65, 77, 80). Many studies have examined the influence of the Tuskegee Study (of untreated syphilis in black men in Alabama) on public attitudes toward research participation, particularly among African Americans [e.g., Bates et al. (13); Freimuth et al. (37); Heitman & Wells (46); Shavers et al. (95); Thomas & Quinn (105)]. However, the distrust engendered by the Tuskegee study or similar historical events may be only one of a host of determinants of recruitment and retention of minority participants.

The need for increased ethnic minority participation in public health research is multifaceted and scientifically driven. The demographic composition of the United States is increasingly multiethnic and pluralistic, with no majority racial/ethnic group projected by 2060 (22). Non-Hispanic whites already comprise fewer than 50% of the population of California, the largest state in the United States (22). Adequate minority representation is needed in all types of studies, drawing samples from geographic areas in which substantial numbers of one or more minority group(s) reside for generalizability, i.e., to ensure that findings are applicable to diverse populations. Oversampling to produce proportions of minorities beyond their levels of representation in a population may be necessary to achieve adequate numbers.

Increased proportions of minorities in all studies may also allow sufficient sample size for ethnicity-specific analyses and data presentation. Subgroup-specific data are needed when ethnicity could modify the outcome, and they are also useful to document convincingly that the results are applicable to diverse groups. For example, in a review of hormone replacement–therapy studies, Nicholson & colleagues (81) found that >99% of study participants were white, and consequently, no studies presented data in subgroup analyses stratified by race. Thus, women from racial/ethnic minority groups and their physicians may have less confidence in applying the findings of these hormone replacement–therapy studies in their decision-making processes. In addition to compromising generalizability, lack of inclusiveness in treatment trials may overestimate effects by creating a best-case scenario. In prevention trials, a lack of inclusiveness may actually underestimate effects because more advantaged participants may have a diminished capacity to benefit from preventive interventions (ceiling effects) (17).

Increased numbers of intervention studies, both prevention and treatment trials, that focus on one or more minority population(s) and are culturally targeted to that (those) population(s) are necessary. Miranda et al. (72) underscore this need, asserting that enrollment of representative numbers of minorities (based on population) in efficacy trials of mental health care services is not likely to advance the literature because numbers of minorities included would be inadequate for precise analyses of effects within subgroups. As previously noted, ethnicity-specific analyses may be required to determine whether general effects apply to subgroups. This assertion is exemplified in a review of community-level, obesity-related lifestyle intervention trials, which identified only 5 of more than 600 articles published between 1970 and 2003 that targeted a general audience and presented ethnicity-specific analyses. The other 18 inclusive studies targeted one or more racial/ethnic minority groups; 9 of these resulted from a single Center for Disease Control and Prevention (CDC)-funded California Department of Health Services physical activity promotion initiative in communities of color (116).

Observational studies, both qualitative and quantitative, investigating issues specific to the health of certain racial/ethnic populations are also a priority. The Jackson Heart Study of cardiovascular disease in African Americans is one example (114). Studies investigating the disproportionate rate of prostate cancer among African American men provide another example. In addition, assessment of the reliability and validity of survey instruments measuring constructs of interest in culturally diverse populations is critical to the conduct of high-quality research so that, when necessary, appropriate adaptations are made or new instruments developed [e.g., Skelley et al. (98)]. Data collection and reporting from standardized health surveillance and health services outcomes with regard to race/ethnicity are required to increase the availability of these data for research involving secondary analyses, as well as to increase the accuracy of identifying and monitoring disparities (99).

The representation of underserved racial/ethnic groups in clinical trials and epidemiological research has increased somewhat, spurred by regulatory efforts to enhance minority participation (48, 80, 82, 90). The 1993 National Institutes of Health (NIH) Revitalization Act mandated minority inclusion in randomized clinical trials, defining underrepresented minorities as African Americans, Latinos, and American Indians (1). Subsequently, review criteria in NIH study sections have formally required minority recruitment plans or scientific justification for their exclusion (62); informally, review committees have examined and weighted, to varying degrees, investigator experience in recruiting diverse samples and documentation of support for their proposed projects for understudied communities. Federal requests for applications for studies in diverse populations have also increased. Because of their organizations' interests in increasing diversity, journals of certain professional societies such as the American Public Health Association and the American Psychological Association have also endeavored to improve their scrutiny of and consistency in describing race/ethnicity variables.

Continued attention is required, however, to address the persistence and pervasiveness of underinclusion of racial/ethnic minority groups in public health research. This article aims to review the recent public health literature to assess our understanding of barriers to and facilitators of the recruitment of racial/ethnic minority participants in health-related research. Numerous reviews have been published on various aspects of minority underrepresentation in research, but none have broadly examined studies published since 1998 [e.g., Arean & Gallagher-Thompson (8); Baker (11); Beech & Goodman (14); Moreno-John et al. (65); Levkoff et al. (73); Miskimen et al. (77); Olin et al. (82); Shavers-Hornaday et al. (97); Swanson & Ward (104)]. A discussion of the state of this literature, including its strengths and weaknesses, with implications for future research needs and directions, follows. We elucidate some of the major variables and findings related to the success or failure of recruitment and/or retention efforts, attempting to isolate and describe retention issues as distinct from those related to initial recruitment.

METHODS

We conducted a general assessment of the available literature, including preliminary searches of electronic databases and perusal of references cited by key articles. We also contacted expert colleagues by telephone or electronic mail to retrieve nonelectronically cataloged or unpublished in-process studies. The literature addressing recruitment and retention of minorities is early in its development and is challenging to organize for several reasons: the unevenness of reporting of recruitment, enrollment, and retention statistics; the differences in use of terminology across studies; the complexity of this literature, covering disparate sample sociodemographic compositions, disease domains, and study types; and the primarily descriptive nature of most studies in this area. Each of these aspects is detailed below.

Reporting of recruitment and retention statistics by race/ethnicity is uncommon and uneven, and even race/ethnicity of enrolled subjects is not consistently reported. For example, Ness and colleagues (80) reviewed 65 clinical studies published between 1993 and 1995 that presented detailed results of participant recruitment, demonstrating that only 1%–3% of studies reported the racial/ethnic composition of potential, eligible, or refusing subjects. In fact, only 58% of these studies reported race/ethnicity of enrolled subjects versus 91% reporting gender and 80% reporting age. This represents an improvement, however, over an earlier review finding that only 20% of 50 published clinical trials of new drugs included any racial data (103). In some areas of research, particularly prevention studies involving relatively healthy volunteers, reporting of sample race/ethnicity is even less common. For example, 86% of the 231 articles included in a 2005 meta-analysis of the literature examining the effects of diet and exercise on weight- and fitness-related outcomes failed to report race/ethnicity, compared to only 11% and 4%, respectively, that failed to report outcomes by age or gender (40a).

Differences in terminology used and definitions of terms also complicate interpretation of findings. Such terms as enrollee, participant, registrant, refusal, loss to follow-up, contact failure, run-in period, attrition, and accrual are defined differently across studies and are sometimes not clearly defined. For example, prospective participants may enroll in a longitudinal cohort study by completing and mailing a registration postcard [e.g., Bell et al. (15)]. They are not considered participants until they complete the entry questionnaire. In most trials, however, the term enrollment is used to indicate full study participation [e.g., Olin et al. (82)]. This can be problematic in making comparisons across studies.

Understanding this burgeoning literature is impeded further by the complexity surrounding differences and similarities in approaches by study type (observational, experimental), nature (prevention, treatment), disease, health target or domain, sampling (probabilistic, nonprobabilistic), sample demographics (age, gender, SES, acculturation), arduousness or level of invasiveness of study procedures (phlebotomy, chemoprevention, long self-administered questionnaires, spinal taps), recruitment setting (community vs. clinical), U.S. region, residential characteristics (urban vs. rural), and whether the outcome of interest is recruitment or retention. Furthermore, great heterogeneity exists both between and within such broadly defined racial/ethnic categories as African American/Afro-Caribbean/African (relatively recent immigrant), Latino/Hispanic, and Native American/American Indian/Alaska Native (5, 100, 118), which complicates comparisons across studies involving different subgroups within the larger ethnic minority categories.

Another characteristic of the available literature is that it is primarily descriptive. The articles reporting analytical approaches to identify strategies or factors effective in sample diversification are relatively few, and most have been published only since 1999, subsequent to the review by Olin et al. (82). In their fairly comprehensive review of studies published between 1984 and 1998 detailing methods related to recruitment, participation, and retention of underrepresented racial/ethnic groups in clinical research, essentially none of the 90 directly and systematically tested hypotheses regarding the efficacy of these methods using controlled designs (82). Of those that provided any quantitative data, results were equivocal. For example, of 13 articles quantitatively comparing mass or targeted media to personalized approaches, 6 found media methods more productive, whereas seven demonstrated that personal contact between investigators or their intermediaries (with prior personalized connection with prospective participants) was more beneficial (82). The authors recommended hypothesis-testing, analytical studies of the efficacy of methods, including comparisons of method cost-effectiveness in recruiting minority and nonminority participants.

Although similarities exist in approaches to increasing sample diversity, differences can be ascribed to myriad factors. To define themes specific to minority recruitment, our general assessment of the literature described above was framed against what constitutes effective engagement (recruitment and retention) of research participants in general. Two main types of strategies for the recruitment of

study participants exist: passive and active. Passive recruitment involves disseminating information in the target population through various channels (e.g., flyers, advertisements, mailings, and public service announcements), prompting prospective participants to contact project staff. Active recruitment involves bringing the project staff directly into contact with prospective participants, i.e., telephone or in-person appeals by project staff and medical providers. The general engagement strategies for recruitment are similar to those for retention: communication of respect and benefits (personal and common good) without coercion, minimal risk, convenience (evening/weekend hours, child care, transportation, scheduling flexibility, accessibility), compensation for expenses related to participation (parking, mass-transit passes, cab vouchers), private space for data collection, communication of appreciation for investment of time and effort (verbal recognition, certificates of participation, letters of gratitude), disclosure of electronic recording, assurances of anonymity and confidentiality, full informed consent, ethical conduct, provision of incentives (monetary honoraria, food, raffle tickets), and maintenance of contact (birthday cards, reminder postcards). Certain strategies may be more appropriate to particular study designs, but practice is currently informed more anecdotally than empirically.

In addition to the aforementioned general strategies for successful engagement, retention may be enhanced by flexibility in intervention protocols, incentives, minimal field staff turnover, multiple friend and family contacts to avoid mobility-related loss to follow-up, and strategies to decrease respondent burden, e.g., shifting to project staff as much of the responsibility for recordkeeping as possible (51, 53, 54). Retention is also strongly influenced by recruitment characteristics. Studies that impose substantial hurdles to enrollment, e.g., multiple screening visits or run-in or trial periods after which only those who perform at a certain level are enrolled, would generally be expected to have higher retention rates than would those that take “all-comers” and may also select differentially from different ethnic groups (58, 80). However, we found many fewer studies that focused specifically on retention as distinct from recruitment of minority participants. Coverage of retention data within the main results of studies, i.e., drop-out rates described in articles not focused on participant engagement as such [e.g., Kumanyika et al. (59)], was beyond the scope of this review.

We focused our review on recent contributions to the literature and attempted to capture the main themes of the more voluminous descriptive literature while more closely examining the smaller body of analytical studies. Examination of recruitment and retention issues among Asian Americans was beyond the scope of this review. Although Asian Americans are not federally defined as underrepresented in health research (1), this ethnic group clearly constitutes an understudied population in which many health disparities exist. However, their relatively small population size combined with marked heterogeneity with respect to language, nationality, and acculturation status, makes the sparse literature on their engagement in research difficult to interpret and worthy of a separate and focused analysis. Confining our review to those minority groups federally defined as underrepresented in research (1), we searched the MEDLINE/PubMed electronic database for

reports published between January 1999 and April 2005 using the following search terms in combination: (a) minorities, minority, race, racial, ethnic, African American, black, Hispanic, Latino, Native American, American Indian; (b) recruitment, retention; and (c) research, subjects, participants. This yielded 155 unique articles and abstracts. Thirty-nine additional articles were identified by inspection of citation lists, use of the PubMed option of retrieving articles related to those already identified, and solicitation of references from expert colleagues.

We then established the following study-inclusion criteria: study conducted in the United States; study sample comprised of living individuals; study presented as a full-length, data-based report, excluding editorials and abstracts of presentations; federally defined, underrepresented racial/ethnic minority group identified in the abstract of the article; study content area is of primary relevance to public health, excluding, for example, comparisons of clinical treatment approaches; study examined methods of engaging members of underrepresented minority groups in research as a central focus; study presented a detailed description of the methods used; and study was not duplicative of other studies included, e.g., the Women's Health Initiative article by Hays et al. (45) was excluded because Fouad et al. (34) presented the same recruitment data in greater detail.

The process of abstracting study data was performed independently in three phases by two study coauthors. First, a spreadsheet of individual study data was generated. Data were entered into a Microsoft Excel database under the following categories: lead author, title of article, year of publication, journal, study population, recruitment setting (clinical, community), study design, design of study to which participants recruited, significant predictor variables, insignificant variables, outcome variables, and other findings/comments. Data were subsequently aggregated descriptively for presentation in the first part of the Results section of this article. Second, analytical project narratives were produced. Third, recurring themes were identified among the descriptive studies, which were then collaboratively summarized. Discrepancies during any phase were highlighted for discussion between study collaborators to arrive at a consensus.

RESULTS

Ninety-five reports were identified that met our selection criteria by examining some aspect of recruitment or retention of racial/ethnic minority populations in research studies of relevance to public health. Twenty of the articles were categorized as analytical, and the rest, descriptive. Several of the descriptive studies were review articles, each focusing on a specific study type, disease domain, ethnic group, or age group. Most articles focused on recruitment to particular study designs: clinical trials, 31 (33%); prevention trials, 24 (25%); longitudinal cohort or multiwave studies, 12 (13%); cross-sectional or case control, 10 (11%); observational epidemiological studies in general, 7 (7%); and qualitative or focus-group studies, 2 (2%). Fifty percent of the articles were disease specific: 26% were in studies of cancer, 6% in hypertension and cardiovascular diseases, 5% in

Alzheimer's disease, 4% in diabetes, 3% in each of HIV/AIDS and osteoporosis, and 2% in mental health disorders. African Americans were a focus in the overwhelming majority (82%) of the articles, and Latinos were a focus in 20% of those articles that specified the race/ethnicity of the group(s) targeted. Native Americans were a focus of only 5% of the articles. (Multiethnic studies were counted in all applicable categories.) Sixteen percent focused on older populations, whereas only 3% examined children and/or adolescents.

The presentation of results is structured as follows. First, the larger body of descriptive study findings is presented in the aggregate to provide general guidance on approaches or facilitators of and barriers to recruitment and retention of these populations. Studies focused much more on recruitment than retention; retention issues distinct from those of initial recruitment were highlighted wherever possible. Second, the relatively small group of analytic studies is examined in some detail to identify specific strategies with demonstrated efficacy or lack of efficacy in recruiting or retaining participants from certain racial/ethnic minority groups.

DESCRIPTIVE STUDY FINDINGS

Seventy-five descriptive studies of methods to increase minority participation in public health research were published between January 1999 and April 2005. Most studies focused on recruitment. Ten major themes or factors emerged as influences that were either barriers to recruitment or that, if addressed appropriately, facilitated recruitment: (a) attitudes toward and perceptions of the scientific and medical community, particularly among African Americans [e.g., Gooden et al. (43)]; (b) sampling approach [e.g., Adams-Campbell et al. (2), Ahluwalia et al. (4)]; (c) study design [e.g., Lynch et al. (67)]; (d) disease-specific knowledge and perceptions of prospective participants [e.g., Hoyo et al. (50)]; (e) prospective participant psychosocial issues such as self-efficacy, depressiveness, distress, hostility, social support, and readiness to change [e.g., Woods et al. (112)]; (f) study incentives and logistics [e.g., Unson et al. (106)]; (g) community involvement [e.g., Reed et al. (86)]; (h) sociodemographic characteristics of prospective participants [e.g., Lee et al. (64), Moorman et al. (76), Sears et al. (93), Unson et al. (107)]; (i) participant beliefs, e.g., religiosity [e.g., Adrani et al. (3)]; and (j) cultural adaptations or targeting [e.g., Escobar-Chavez et al. (33)]. The major distinctions between studies were related to (a) study design—observational versus intervention, with the latter posing greater challenges; and (b) sampling approach—probability versus non-probability, with the former proving more difficult and more expensive. Selected findings related to these factors are detailed further below.

Study Design

In general, regarding study design, it is more difficult to recruit subjects into intervention trials than observational studies. The major barriers for clinical trials are the use of placebos and double-blind assessments, and randomization is viewed negatively by many participants (67). Reducing respondent burden, informing

participants about the advantages of randomization, offering delayed or alternative interventions to control-group participants, and assuring that a minimum standard of care will be delivered have been used in addressing these concerns (78).

Distrust as a Barrier to Participation

Perceptions of trust and mistrust of scientific investigators, of government, and of academic institutions were found to be a central barrier to recruitment, particularly among African Americans (13, 19, 25–27, 29, 35–37, 42–44, 47, 50, 55, 66–68, 71, 77, 86, 94–96, 101, 102, 111, 113–115). For example, providing informed consent was reported by some participants, in separate studies, as relinquishing rather than protecting rights (27, 37, 47). Fears of mistreatment and exploitation, e.g., being treated as a “guinea pig,” were also reported (26, 27, 47, 96). Similarly, concerns were expressed that data would be used primarily to advance researchers’ careers and portray communities in an unfavorable light rather than to address community health problems (35, 43, 47). Knowledge of the Tuskegee Syphilis Study, however, was not necessarily negatively associated with willingness to participate in research (13, 18, 35, 36). Investigators asserted that many trust-related barriers may be eliminated by improved communication to increase prospective participants’ perception of the concordance between community goals and motivations and investigators’ goals and motivations (13, 35, 65, 66, 74, 120).

Community Involvement to Facilitate Participation

A common approach to building trust and alleviating attitudinal barriers was community involvement, particularly in the form of using lay outreach workers from the targeted population (10, 32, 39, 40, 47, 71, 82, 84–86, 114, 115). Inclusion of minority (“cultural insider”) investigators was also advanced as a community engagement strategy (10, 115). Working through community-based organizations, particularly churches, has frequently been used as an additional community involvement strategy, particularly for African Americans (21, 30, 35, 68, 77). Although churches provide captive audiences for sampling and potential facilitative relationships with trusted community leaders (particularly ministers), some investigators have identified religiosity as a barrier to subject recruitment because of fatalistic views of disease susceptibility and outcomes [e.g., Adrani et al. (3), Fouad et al. (35)]. Others have found religiosity to be positively associated with willingness to participate [e.g., Sengupta et al. (94)]. The differences in findings for religious participation may be attributable to the health problem being studied—Adrani et al. (3) focused on cancer, whereas Sengupta et al. (94) focused on HIV/AIDS—or to differences in definitions of religiosity.

Retention

Intensive follow-up and contact with subjects seems to improve both participation and retention (25, 89). The few studies addressing retention issues highlighted the importance of having the same interviewers or field staff over time; having staff

from the targeted community; providing social support; and having accessible locations for intervention implementation and/or data collection, regular telephone reminders, and timely incentive payments (7, 9, 40, 49, 83, 89, 120). Dilworth-Anderson and colleagues (32) point out the importance of the interviewers' knowledge of family dynamics and providing a toll-free phone number to participants to increase accessibility of project staff. Psychosocial distress and mental health concerns, cumbersome protocols, difficult therapeutic regimens, lack of time, residence instability, and lower SES were among the variables identified as barriers (16, 51, 64, 78, 108, 109).

ANALYTICAL STUDY FINDINGS

Twenty analytical studies of methods to increase minority engagement in research have been published since 1999. These articles reported comparisons of recruitment or retention outcomes across ethnic groups or within an ethnic group. The studies were grouped according to four of the factors or themes identified in our findings from the descriptive literature that were addressed in these articles. These factors are similar to those identified by Olin and colleagues (82): (a) sampling approach/identification of targeted participants; (b) community involvement/nature and timing of contact with prospective participants; (c) incentives and logistical issues; and (d) cultural adaptations. The study designs included cross-sectional observational comparisons, nonrandomized controlled interventions, and randomized controlled interventions. Thirteen of the 20 studies involved recruitment to clinical or prevention trials, 5 to cross-sectional observational studies, and 2 to longitudinal cohort studies. Only 5 of the 20 targeted primarily patients or individuals with disease diagnoses. The majority of analytical studies compared outreach strategies on yields of eligible and enrolled participants with associated costs.

Sampling Approach/Identification of Targeted Participants

Population-based methods were demonstrated to be time-consuming and costly in recruiting minority participants. Cabral and colleagues (20) found that the average number of hours spent per African American or Latino control recruited was 18.6 for random digit dialing and 11.4 for health care financing administration records sampling compared with less than 1 for community-based methods. To include sufficient numbers of minorities for successful renewal of a competing NIH grant application, Marquez et al. (69) added community-based recruitment methods to population-based random sampling, which had produced a 98% white sample of 699. These community-based methods, including engagement of minority communities in research planning and establishment of explicit recruitment goals, cost \$222/participant vs. \$37/participant for the population-based methods (69). McDougall and colleagues (70) also abandoned random sampling from computer-generated zip code lists for convenience sampling after the first year of an observational epidemiological study failed to produce adequate numbers

of older African Americans. The proportions of African Americans and whites recruited randomly differed significantly (57% vs, 68%, respectively) (70).

Costs of recruitment may also vary by type of community-based method employed. Jo Harris and colleagues (52), in recruiting African American smokers to a randomized clinical trial, demonstrated that proactive recruitment strategies (in-person appeals by project staff and medical providers) were less likely than were reactive strategies to produce eligible and willing participants and cost \$159/enrollee. Reactive strategies (disseminating information through various channels prompting prospective participants to contact project staff) cost only \$22/enrollee and produced 89% of those randomized (52).

Community Involvement/Nature and Timing of Contact with Prospective Participants

INTERVENTION TRIALS Several large national prevention intervention trials successful in engaging substantial proportions of racial/ethnic minority participants identified direct mail solicitation as their primary recruitment vehicle. Of those expressing initial interest in the Women's Health Initiative (WHI), African Americans had the highest randomization yields in the dietary modification component (15.2%), and Hispanics had the highest in the hormone-replacement component (10.2%), a result nearly meeting the clinical trial arm's 20% minority accrual goal at 18.5% of 68,135 (34). Mass mailing of brochures/flyers with personalized letters were the primary recruitment source across ethnic groups (African American, 61%; American Indian, 55%; Hispanic 50%; white, 61%); however, the secondary source was referral by a friend for Hispanics and African Americans and newspaper ads/articles and brochures for whites (34). Six of the 9 minority-recruitment centers developed a culturally tailored flyer, and 5 of the 6 indicated that their recruitment yields increased substantially after substitution of this flyer for the general audience brochure. The fact that recruitment strategies were not applied uniformly (in terms of timing or strategy mix) across the 10 centers (of 40 total) selected as minority-recruitment sites must be considered in interpreting the WHI findings (45).

In the Diabetes Prevention Program, which recruited to a randomized controlled trial nondiabetics with impaired glucose tolerance, Rubin and colleagues (88) also found that direct mail produced the largest proportion of randomized participants (29%) among, and was more likely to be cited as the source of trial information by, African Americans, Hispanics, and whites. Hispanics were more likely than others to have been recruited via family/friends and phone calls, and American Indians were more likely to cite community screenings and events and medical referrals as their recruitment source (88). Wide variation in recruitment strategies between clinic sites and ethnic groups must be considered in interpreting this recruitment data (88), as in that of the WHI (34, 45).

In a multicenter hypertension control feeding study, responses to passive recruitment strategies of African American (60% of sample) and white (34% of sample) participants followed a similar pattern in which mass mailing of individual

brochures produced nearly half of enrollees (42% and 38%, respectively), more than twice that of the next most prolific strategy, word-of-mouth (18% and 20%, respectively) (6). Yields of 5.1–11.3 enrollees per 10,000 mailings were reported (6).

In a single-center randomized controlled prevention trial of a nutrition-physical activity intervention on body composition in African American women, direct mail solicitation using local zip codes of a purchased black women's magazine subscriber list generated so many willing and eligible prospective participants that recruitment was discontinued more than one year before intervention delivery began for the final cohort (117). Because this strategy was not initiated at the outset of the trial, its contribution to the final distribution of recruitment sources is likely to have been understated. Recruitment strategies involving personal contact were identified by 70% of participants. The study engaged a sample of predominantly working- and middle-class black women, demonstrating that recruitment source may also vary between important subgroups within an ethnic group (117). The likelihood of being recruited through media channels was significantly lower among the more obese participants, and obesity was correlated with lower SES (117).

The utility of community involvement by project staff or using community-based organizations as intermediaries was nearly universally cited as critical to recruitment success in descriptive studies but was examined analytically in only three studies. Wisdom & colleagues (110) recruited African Americans with Type 2 diabetes to a diabetes self-management intervention implemented in four faith-based organization sites. Recruitment through the health system produced a higher randomization yield (61%) than did newspaper and radio public service announcements (19%) or faith-based organization (14%) sources; however, among both intervention and control participants, recruits from faith-based organizations were more likely to attend four or more sessions (110). Similarly, among minority patients with depression or anxiety targeted by two randomized controlled trials of mental health interventions, the yield of "consumer-centered" recruitment methods (e.g., addition of community input, personalized mailings and face-to-face solicitation, ethnically matched staff) was not superior to that of traditional methods (e.g., scientific consultation, media recruitment, provider referrals, community lectures); however, study retention was improved by these methods (7). In recruiting hypertensive African American women to a physical activity intervention, Banks-Wallace and colleagues (12) tested the effectiveness of preintervention meetings between African American research team members and potential participants in increasing study enrollment among interested women. Of 38 women responding to passive recruitment strategies of flyers, radio public service announcements, and word-of-mouth dissemination, 21 attended an optional 3-hour preintervention session and 17 did not. Fifteen out of 21 attendees (71%) enrolled in the study compared with 6 out of 17 (35%) of nonattendees. However, the small sample size, potential selection bias (self-selection), and absence of data on study eligibility rates in each group preclude conclusions about the utility or validity of this strategy.

OBSERVATIONAL STUDIES Two studies used randomized controlled trials to compare methods for increasing survey return rates between African Americans and whites. An advance notice letter was independently associated with completion of a mailed patient satisfaction survey in white ambulatory-care patients but did not improve return rates for African Americans (79). In contrast, follow-up telephone calls to Adventists who had enrolled in a longitudinal cohort study by returning a postcard, but had not returned the survey, increased survey completion more than threefold in blacks but not at all in whites (15).

Personalized recruitment methods were compared with media-based methods in an investigation of engaging minority women in longitudinal community-based research. Gilliss and colleagues (41) found that face-to-face recruitment produced the highest yield of eligible and willing participants among African Americans, Mexican and Central Americans, and whites. Direct referrals (word-of-mouth dissemination) were second in recruitment yield for African Americans and whites but similar to printed materials for Latinas. Broadcast media produced the highest numbers of prospective participants but high rates of ineligibility and refusal (41). Attrition at one year was generally low (8% for African Americans and whites, 14% for Latinas) and, although not significantly associated with recruitment source, trends suggested higher retention for those recruited by personal contact among African Americans and lower retention for African American and white broadcast-media recruits (41).

Two studies examined recruitment efficacy in very specific and narrowly defined clinical populations. Royal et al. (87) found that physician referrals and tumor registries produced 35 of the 43 families recruited, to date, to a study of hereditary prostate cancer in African Americans. However, only 2% of the substantial 41% of prospective participants who contacted project staff expressing interest by phone or mail were eligible (87). A focus group study examining determinants of access to ambulatory care services recruited an ethnically diverse sample of veterans who used Veterans Administration (VA) health services and veterans who did not use VA health services. Personalized recruitment strategies prevailed: Most veterans were recruited by liaison with community centers, accounting for 28% of the total recruitment and 36% of Latino participation (31). VA on-site recruitment accounted for 21% (33% among African Americans) of the total sample, and word-of-mouth dissemination, 17% of the total sample; metropolitan newspapers produced low yields except for whites (23%), and ethnic newspaper advertisements generated neither African American nor Latino participants (31).

Incentives and Logistical Issues

Incentives are often provided to increase participant engagement, particularly in the provision of data. In a cross-sectional survey of relatively affluent African American and white breast cancer survivors, half the sample received payment in advance, and the other half, a payment promise (9). The timing of the incentive did not influence survey return rates in either ethnic group (9). Satia et al. (92)

examined responses among African Americans to a cancer-prevention surveillance survey when incentives were included, excluded, and promised. They also found that timing of incentives was not important but were able, in addition, to demonstrate that incentives increased response rate (24% vs. 16%) (92). Timely payment of promised incentives, however, was found to improve retention in the single-center nutrition-physical activity intervention trial cited earlier (116a, 117). Retention rates at the 6-month assessment dipped to just above 60% from more than 85% at the 2-month assessment because of a bureaucratic error in the university accounting department that delayed mailing of the \$50 incentive checks during the early period of 6-month data collection. Word-of-mouth dissemination of skepticism by disgruntled participants about ever receiving payment within the tight social network of black professional women in Los Angeles suppressed other participants' presenting for assessment during the latter period of 6-month data collection. Resolution of the issue by supplying the checks on-site, immediately upon completion of the final assessment at 12 months, restored favorable word-of-mouth assessments of the project, and the retention rate rebounded to more than 70% for the 12-month assessment (116a).

Cultural Adaptations and Targeting

Six studies examined the influence of cultural adaptations: three of racial/ethnic matching of project staff and prospective participants, two of recruitment materials, and the other of intervention content. Kiernan and colleagues randomly assigned 561 Hispanic employees to receive a flyer promoting a work site dietary intervention, the flyer plus a personalized hand-signed letter reporting heart-disease risk statistics for the U.S. population overall, and the flyer plus a personalized letter with disease statistics for Hispanics. The personalized letter with general statistics to accompany the flyer produced a significantly higher (7.8%) response rate than did that of the flyer alone (2.1%). The personalized letter with Hispanic statistics, however, did not further increase response rate significantly (9.1%). Sattia et al. (92) also found that a culturally tailored approach letter was no more effective than was a generic approach letter in generating responses from African Americans to their cancer-prevention survey, regardless of whether incentives were offered.

With regard to study retention, Kumpfer et al. (60) reviewed four studies comparing outcomes of generic and culturally adapted interventions to enhance family cohesiveness targeting urban and rural African American, Hispanic, and Ojibwa Indian substance abusers and their children. Overall, the culturally adapted versions increased the proportion of families completing the program but produced somewhat lower effect sizes. However, the study design lacked rigor: Not only was family selection nonrandom, but also the two versions were implemented sequentially rather than simultaneously (60).

Racial/ethnic matching of project staff and participants is invoked as necessary to recruitment nearly as often as is community involvement. The several analytical studies addressing this issue attest to the complexity of understanding the impact

of this approach. In a case-control breast cancer study, cooperation rates upon initial contact were higher among both black and nonblack women when prospective participants and interviewers were concordant on race (75). Solicitation by an experienced recruiter or a recruiter from the targeted community, however, was more likely to result in older minorities' agreement to participate in mental health intervention research than simply having an ethnically matched recruiter (7). Similarly, Hispanic participants randomly assigned to receive training as lay advocates referred and enrolled significantly more of their peers into the WHI than did a matched group of Hispanic and white enrollees in an attention control condition in which they met regularly and were supplied only with brochures (61). No whites were trained as lay advocates, precluding an interethnic comparison (61).

DISCUSSION

Overview of Review Findings

First and most strikingly, there has been a substantive increase in scholarly work, both quantitatively and qualitatively, on the topic of minority recruitment and retention; 194 articles and abstracts were initially identified by the various search strategies, and 95 studies were included in our review of the 5¹/₄-year period between January 1999 and early April 2005, compared with 403 articles and abstracts initially identified, through various search strategies, by Olin et al. (82) and 90 studies included in their review of publications during the 15-year period between 1984 and 1998 (18.3 per year versus 6 per year). The numbers of more systematic or analytical quantitative examinations directly assessing recruitment/retention efficacy has also increased appreciably from 0 out of 90 for the period of 1984–1998 to 20 out of 95 for January 1999–early 2005.

We are most confident about those findings arising from the relatively analytical examinations of recruitment and retention outcomes because these studies were specially designed to compare recruitment or retention approaches. With the important caveat that the findings from these studies may be specific to the disease, health, or community context in which they were conducted, our impressions from these studies follow.

- Mass mailing is efficacious in recruiting African Americans, at least for those of middle and higher SES, to clinical and prevention trials. Personal contact, however, continues to be the primary recruitment vehicle for most studies, both intervention and observational. This finding has particular implications for recruiting higher-risk participants to prevention studies (e.g., lower SES, more obese) in that word-of-mouth dissemination requires more time to generate responses than do media-based strategies.
- Population-based sampling strategies are unlikely to produce sufficient numbers of ethnic minority individuals for reliable ethnicity-specific analyses within the expertise and resource constraints of most studies.

- Reactive or passive strategies are more likely to produce higher randomization yields when study-eligibility rates in the targeted population are high; proactive strategies are associated with higher recruitment yields when eligibility is rare. The effect of eligibility constraints on recruitment yield (and, consequently, resources necessary to produce a given sample size) is especially important to consider in light of the higher likelihood of chronic disease morbidities or comorbidities in individuals from racial/ethnic minority groups. Too many restrictions on eligibility may limit both the ability to generate sample sizes sufficient for statistical power and the degree to which the sample represents the target population.
- Community involvement by project staff may be more critical to retention than to initial recruitment of African Americans and Latinos.
- Survey response rates are likely to be improved by telephone follow-up in African Americans; advance notice letters may not be effective in this group. Incentives are also likely to produce modest increases in survey response rates, but their timing does not necessarily seem to matter; thus, promised incentives may be more cost-effective than those provided in advance of cooperation. Timely incentive payments, however, have improved retention in both observational and intervention studies.
- Cultural adaptations may positively influence study participation and retention, although it is not clear from the data to what extent, if any, these adaptations contribute to recruitment success. Personalized letters may be more effective than generic approach letters. Content-related cultural tailoring of letters may not further increase response rates, but other aspects of cultural tailoring (e.g., racial/ethnic matching of subjects depicted in materials) have yet to be systematically examined. Racial/ethnic matching of project staff and prospective participants may not be sufficient to ensure recruitment success; recruiter experience and community ties are also important attributes. Whether racial/ethnic matching is necessary remains to be proven, but a serious test of this adaptation should encompass a variety of aspects, e.g., ethnicity of project leadership not just recruiters or other line staff, investigator and institutional reputation in target community (also see discussion of the limitations of the evidence base below).

These findings echo and reinforce some but not other themes apparent in the descriptive literature. For example, the finding that community ties are more important recruiter attributes than is ethnic matching reinforces the notion that establishment of trust is necessary to support research endeavors in historically exploited or disenfranchised populations. Similarly, optimal communication channels or vehicles were found to vary between and within racial/ethnic groups, supporting the notion that nonpersonal or media-based strategies are more effective in engaging more affluent, less marginalized populations. However, evidence is equivocal or contradictory of some widely held and promulgated notions of recruitment effectiveness necessity, e.g., racial/ethnic matching of project staff and prospective participants. Community involvement and relationship building are fundamental

to establishing trust and are central tenets of community-based participatory research, so that an empirical test is unlikely to be sociopolitically, logistically, or ethnically feasible. A number of studies found that race/ethnicity did not influence key recruitment or retention variables (3, 6, 38, 42, 55, 108), whereas others confirmed a significant association (10, 19, 64, 70, 75, 76, 95, 107). Again, this may reflect differences, e.g., in disease or health condition studied or U.S. region of residence. In many cases, analytical study findings bolster evidence for good recruitment and retention practice for any population, e.g., placing convenience of participants ahead of that of project staff; communicating effectively study benefits for the individual and family, as well as the common good; utilizing incentives as a tangible recognition of the value of the participants' time and effort.

QUALITY OF THE EVIDENCE BASE: STRENGTHS AND LIMITATIONS

The burgeoning body of evidence in this field reflects some consistency in descriptive themes and early systematic examination of key aspects of recruitment and retention, which may guide investigators and funding agencies in continuing to diversify the study samples in their portfolios. However, the nature of that evidence must qualify the interpretation of these findings. A number of limitations of the evidence base are apparent. As underscored earlier, there are relatively few analytical studies directly testing hypotheses regarding the efficacy or effectiveness of these approaches, especially given the host of sociodemographic variables that could influence the outcomes, e.g., SES, level of acculturation, and gender of subjects, region of the country in which the study is conducted. Almost none of the studies are population-based, and thus, findings may not be representative even of prospective participants of similar sociodemographic characteristics in that region. There are relatively few studies of Latinos, currently the largest U.S. minority group, and even fewer studies of Native Americans, with their tremendous intraethnic heterogeneity. In fact, heterogeneity between and within groups generally limits extrapolation between studies because these racial/ethnic groups are not monolithic. SES is a particularly key distinguishing attribute and explains many, but not all ethnic differences in research engagement—lower SES whites are underrepresented in public health research but comprise a relatively low proportion of the white population, while substantial numbers and in some cases a majority of African Americans, Latinos and Native Americans have low SES. Also, the studies cover a range of disease and health topics. Obstacles to subject recruitment and retention likely vary by individual and community perceptions of and attitudes toward different diseases/health risks and their public health importance and impact, e.g., HIV/AIDS, mental health disorders, or tobacco use. Cancer-related studies dominate this literature in terms of disease domain, and cancer likely evokes more extreme responses than do many other conditions of interest. Studies of intervention trials are also much more common than those of observational research efforts. Further, recruitment evaluation is generally an afterthought to the primary

objective of study, limiting the rigor of designs and investment of resources in this area.

Defining the nature and extent of a study's cultural adaptations is a major and overarching challenge in interpreting this evidence base. How competently cultural adaptations are made can greatly affect outcomes, and minimal space is usually devoted in the text or graphics of the articles to describing these processes. Kreuter and colleagues (56) divided cultural appropriateness enhancement strategies into five main, and sometimes overlapping, categories: peripheral, packaging to appeal to a particular group using certain colors, images, graphics, pictures of group members, or declarative titles; evidential, increasing perceived relevance by presenting data documenting the impact of the relevant health issue on that group; linguistic, increasing accessibility by using the preferred native language or dialect of the group and providing questionnaires written at an appropriate reading level for the target population; constituent involving, drawing directly on the experiences of group members through their inclusion as project staff or their substantive engagement in project decision making; and sociocultural, integrating the group's normative attitudes, values, and practices into messages and approaches. Cultural targeting of a printed brochure may involve content (e.g., health data on the targeted group, message themes and tone), stylistic features (e.g., ethnicity of the people depicted, color/pattern choices, art), and/or language/idiom (e.g., actual translation or word choice, grammar, etc., reflecting the dialect of the targeted audience). For example, the recruitment messages (themes) of greatest apparent cultural resonance for the working and middle-class African-American women in the previously cited nutrition-physical activity prevention trial (116a, 117) were the opportunity presented to contribute to the success of an African-American physician-researcher (greater cultural valuation of community than individual benefit) and the assertion that they were deriving less benefit from their tax dollars spent on research because of low African-American study participation rates (widespread cultural perception of continuing exploitation). Insufficient description of cultural adaptations is generally available to attribute differences in response rates solely to communication channel when level of cultural proficiency in engaging a particular group is also critical. More sophisticated approaches to this cultural engagement are evolving, e.g., cultural tailoring or personalizing messages based on an individual's level of cultural identification in certain domains (57) such that assessment of the quality of cultural adaptation will assume even greater importance in comparisons of study outcomes in future research.

RECOMMENDATIONS FOR ADVANCING INCLUSIVE RESEARCH

The following recommendations would, if followed, begin to redress the low levels of engagement of communities of color, particularly low-income communities, in research. Recommendations for federal and state agencies, scientific organizations and professional associations, and academic institutions are provided in the areas of

research support, grant review criteria, reporting of study recruitment and retention outcomes for scientific publication, “pipeline programs” to increase the diversity of the investigator pool, the promotion and tenure process, and “academic public health practice.”

Federal and state public health agencies should

- support analytical or hypothesis-testing recruitment and retention research studies that are planned at the outset of studies of various designs. For example, supplements to NIH and CDC P01s and R01s may be created to fund nested projects to engage senior investigators with research interests in recruitment/retention in creating more rigorous study designs from study inception. Although current administrative supplements to NIH grants for mentoring minority investigators may be used in this way, a greater and more focused investment is needed to advance the science, especially because these supplements do not generally cover funding for increasing or diversifying samples.
- allow sufficient resources (time and funding) for the conduct of feasibility studies, which are part of any standard protocol for implementing large scientific investigations, because they are useful in determining the most practical and potentially efficacious approaches or strategies for recruiting and retaining sampled populations in an identified setting or context.
- establish the inclusion of sufficient numbers of at least one minority group for the conduct of subgroup analyses stratified by race/ethnicity as a formal review criterion for all federally funded research studies. Studies may be exempted if there is a strong scientific rationale, but serious deliberation and consideration in grant review committee discussions must be incentivized to accelerate the proportion of studies achieving substantive inclusiveness. This regulatory approach has been successful in the recent past, as reflected in the valuable information gained by Marquez and colleagues (69) when the competitive renewal of their grant was contingent on their achieving more substantive minority engagement. Similarly, the National Cancer Institute program staff and review committee members spurred an increased black Adventist recruitment goal to approximately one third of the total sample of the Adventist Health Study-2 by communicating a high scientific priority for this inclusiveness in their comments and scoring.
- provide training to reviewers of grants to increase their expertise in recognizing adequate plans for minority recruitment and retention.
- invest more heavily in supporting “pipeline” programs to diversify the public health investigator pool.

Public health scientific organizations, professional associations, and governing bodies should

- establish journal standards for the reporting of sampling frame (population from which sample is drawn), sample composition, study recruitment,

eligibility, and enrollment and retention statistics by race/ethnicity, including consistency in usage of terminology. Sociodemographic data should be provided, to the extent possible, on nonresponder, drop-out, refuser, and/or ineligible subjects. Indeed, this is part of standard research practice. It must not be considered acceptable to assume a sample is European American white unless otherwise specified, much as it is no longer acceptable to assume a sample is male unless otherwise specified.

- organize interest groups to examine the challenges to minority recruitment and retention, and make recommendations for their redress.

Public health academic institutions should

- change the promotion and tenure process to reward the conduct of research in understudied ethnic groups and in settings in underserved communities, and to recognize the more time-consuming and, consequently, lower academic productivity rate for intervention research in lower SES and ethnic minority populations.
- link with local public health practice agencies, such as public health departments, which serve the needs of and may provide access to low-income ethnic minority populations: establishment of true collaborative relationships from research project inception may infuse different perspectives and expertise into the generation of hypotheses and research questions, as well as recruitment, implementation and evaluation approaches, that may have greater cultural relevance and resonance.

CONCLUSIONS AND IMPLICATIONS

Although many factors cannot be predicted or controlled, our sense is that there are key principles about recruitment on which investigators can depend. More factors will undoubtedly emerge as this literature matures. Some scholars and bureaucrats might skeptically assert that recruitment success is idiosyncratic to secular events, individual investigator personalities, or other serendipitous factors. However, the level of thematic consistency of the current literature, even in its immature and imperfect state, indicates otherwise. Undoubtedly, the few prevention research projects that are successful in engaging large minority samples rely heavily on the extraordinary relationships with the community cultivated over time by the lead investigators (116a). This may, in fact, hinder their replicability. This hindrance, however, results in part from the minimal academic value associated with cultivating these strong and long-term community ties for the senior researcher and impediment to academic advancement that this substantial investment creates early in a researcher's career.

One must recognize that overarching contributors to health disparities are inherent in minority engagement challenges. There are relatively few investigators from underrepresented racial/ethnic minority groups in the academy, reflecting the

skewed SES distribution and sociopolitical marginalization of these populations compared with white European Americans. Increased involvement in scientific leadership of investigators from populations with substantive health disparities is critical. Distribution of lead investigator roles within a more diverse scientific community, including cultural insiders, would expand current thinking in creating theoretical models; identifying central research questions; and developing appropriate study designs, culturally, and scientifically grounded interventions, and rigorous yet pragmatic evaluation strategies. These investigators must also play a greater role in the oversight of science, including participating on review committees and in journal article review and assuming editorial responsibilities. However, to accomplish this, an academic environment that values and supports the professional development of these researchers must be constructed (23, 24, 28).

Recognition is increasing of the need for systemic or environmental intervention, extrinsic to the health services infrastructure, to address most health determinants. Thus, our scientific approaches must extend and expand beyond this controlled and well-studied infrastructure to a variety of increasingly multicultural real-world settings in which the gold-standard randomized controlled trial is impracticable or impossible. Our approaches must also better balance the trade-offs between initial selectivity, which improves retention and homogeneity (internal validity), and broader inclusivity, which preserves relevance to the reference population (external validity). Making more accurate scientific inferences enhances our ability to achieve our ultimate goal of solving public health problems. Innovative thinking by an ethnically and culturally diverse pool of multidisciplinary investigators must inform the scientific endeavor necessary to create meaningful and substantial improvements in the public's health, including eliminating health disparities.

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ERRATA

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