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Knowledge and Access to Information on Recruitment of Underrepresented Populations to Cancer Clinical Trials

Summary

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Introduction

The burden of cancer falls disproportionately upon the medically underserved, and research studies are essential to improving health care in general, including for medically underserved populations. Clinical trials are used to evaluate efficacious prevention and treatment interventions; however, studies often fail to recruit the planned number of participants.[1] Trials often do not include an adequately diverse population to ensure broad generalizability of results.[2] Recent studies of patients enrolled in cancer treatment trials sponsored by the National Cancer Institute (NCI) have demonstrated that the following populations are underrepresented in terms of their participation in cancer treatment trials: the elderly, those of low socio-economic status, those living in rural areas and Latino/Hispanic, Asian /Pacific Islander and American Indian/Alaska native men and women, as well as African-American men.[3,4] Since the 1980s cancer prevention trials have been conducted with participants at highest risk for disease to reduce the cancer burden, and as in treatment trials, adequate representation of underserved populations in prevention trials is desirable. Questions remain regarding the appropriate level of inclusion, i.e., whether it might depend on the prevalence of the condition/disease studied in the overall population. This issue has not been addressed adequately in the literature. Moreover, there is substantial uncertainty about what are important barriers and promoters of recruitment of underrepresented populations, and what evidence-based interventions would address them.

At the request of and with the financial support of NCI, AHRQ commissioned a systematic review of the existing evidence on the recruitment of underrepresented populations into cancer clinical trials, to be performed by the Johns Hopkins University EPC. Specifically, the EPC investigators were asked to consider six key questions:

- **Key Question 1:** What methods (e.g., survey studies, focus groups) have been used to study strategies to recruit underrepresented populations into cancer prevention and treatment trials? We defined underrepresented populations as including the elderly, adolescents, those of low socioeconomic status, those living in rural areas, African Americans, Hispanics/Latinos, Asian Americans, and American Indians.
- **Key Question 2:** What measures of success (e.g., proportional representation relative to the U.S. population; proportional representation relative to incidence in a specified population) have been used to evaluate the efficacy and/or effectiveness of strategies for recruitment of underrepresented populations into cancer prevention and treatment trials?
- **Key Questions 3 and 4:** Which recruitment strategies (e.g., media appeals, incentives, etc.) have been shown to be efficacious and/or effective in increasing participation of

underrepresented populations in cancer treatment and prevention trials?

- **Key Question 5:** What are the documented barriers to and promoters of participation of underrepresented populations in cancer prevention and treatment trials? Examples of potential barriers include access, knowledge, attitudes, eligibility, fatalism, religiosity/spirituality and exclusions by design. Examples of potential promoters include attitudes, altruism, advanced disease, financial incentives, and no-cost treatment.
  - **Key Question 5a:** Do these barriers and promoters differ by age, gender, socioeconomic status or race/ethnicity?
  - **Key Question 5b:** Are these barriers and promoters modified by cultural factors?
- **Key Question 6:** What effects do the attitudes and perceptions of health care providers have on the efficacy/effectiveness of strategies for recruitment of underrepresented populations into cancer prevention and treatment trials? Health care providers were defined as including any health professional or health care organization that provides health services to patients.

Methods

We developed a conceptual framework to guide our analysis, based on the factors leading to the acceptance or refusal of participation in a cancer clinical trial. This framework was derived from a conceptual model developed previously by two members of the EPC team.[4] The premise for the framework is that in order to accept or refuse participation in a clinical trial, one must first be aware of the availability of the trial, and have an opportunity to participate in the trial. The opportunity to participate in a clinical trial may present itself first, encouraging patients to seek information about the trial. This, in turn, may lead to the decision to accept or refuse participation in the trial. There are multiple pathways to successful recruitment to a clinical trial, including: (1) patients/clients receiving information about clinical trials in general through health care providers or their own social ties, and subsequently accepting a specific opportunity to participate in a trial; and (2) in the absence of prior awareness about clinical trials, patients/clients may consider an opportunity to participate in a trial, with the result of encouraging them to seek or receive information regarding the trial, thereby increasing trial awareness. Key questions 5 and 6 of this report address barriers and promoters of awareness, opportunity, and acceptance/refusal.

Literature Search Methods

Searching the literature included the steps of identifying reference sources, formulating a search strategy for each source, and executing and documenting each search.

Sources

Our comprehensive search plan included electronic and hand searching. In March 2004, we searched the following electronic databases: MEDLINE®, the Cochrane CENTRAL Register of Controlled Trials (Issue 1, 2003), the Cochrane Database of Methodology Reviews (CDMR), the Cumulative Index of Nursing and Allied Health Literature (CINAHL®), the Psychological Abstracts (PsycINFO), and The Campbell Collaboration's Social, Psychological, Educational, and Criminological Trials Register (C2-SPECTR).

Hand searching for possibly relevant citations took several forms. First, we identified 34 journals by asking our experts what journals were most likely to contain relevant articles. We scanned the table of contents of each issue of these journals for relevant citations from January 2003 through July 2004.

For the second form of hand searching, we used ProCite®, a reference management software, to create a database of reference material identified through an electronic search for relevant guidelines and reviews, through discussions with experts, and through the article review process. The principal investigators reviewed the articles identified as being possible review articles during the abstract review process. The references in these review articles were searched to identify any additional article for consideration. We also used MEDLINE® to search articles published by selected experts known to have interests related to our questions. Finally, we examined the reference lists of eligible articles to identify any potentially relevant articles (this was completed by the second reviewer as part of the article review process).

Study Selection

Articles included in this evidence synthesis were English-language reports of original data from published studies that addressed one of the key questions.

Data Extraction

Pairs of reviewers assessed the study quality and abstracted data for each eligible article. Data were entered into a relational database.

Results

Of the 4,436 citations retrieved by the search methods, 1,089 were eligible for abstract review and 218 of those were eligible for article review. Only 67 of the articles were eligible after article review. Many articles were excluded because they did not address underrepresented populations, did not address cancer treatment or prevention, or did not discuss recruitment to a controlled trial. Ultimately, the EPC investigators identified 14 articles on key question 1, 23 articles on key question 2, five articles on key questions 3 and 4, 45 articles on key question 5, and 10 articles on key question 6.

Key Question 1: Methods to Study Recruitment Strategies

We analyzed 14 articles to identify methods (e.g., survey studies, focus groups) that have been used to study strategies to recruit underrepresented populations into cancer prevention and treatment trials. [5-18]

- All 14 studies were of U.S. origin, primarily based in community settings, and targeting patients/participants.
- The reported study designs of the 14 studies varied, including descriptive (n = 4), randomized controlled trials (n = 3), quasi-experimental (n = 1), comparisons of two or more interventions (n = 2), survey (n = 1), qualitative (n = 1), case study (n = 1), and other (n = 1).
- There was substantial variability across the studies in the reporting of demographic variables such as age, gender, income or education levels of participants; information regarding the racial or ethnic distributions of the participants was available for only eight of these studies.
- The reporting of the studies limited our ability to accurately categorize age groups (e.g., adolescents, elderly), socioeconomic status, or residence (urban versus rural).

Overall, the evidence indicated the need for greater consistency in the reporting of target population characteristics, so that key findings may be considered in relation to specific populations. This would make it feasible, when the sample size is adequate, to conduct subgroup analyses to assess whether barriers to recruitment vary by sociodemographic and cultural factors.

Key Question 2: Measures of Success

We sought to identify what measures of success (e.g., proportional representation relative to the U.S. population, or proportional representation relative to incidence in a specified population) have been used to evaluate the efficacy and/or effectiveness of strategies for recruitment of underrepresented populations into cancer prevention and treatment trials.

- All studies (n = 23) were from the U.S. and 22 studies targeted patients/participants for the recruitment intervention; and over 50 percent of the studies were based on multi-center cancer clinical trials conducted in community settings (n = 9) or hospital centers (n = 7). [5-9, 11, 13, 16, 17, 19-32]
- Most of the reports were based on retrospective review of enrollment to a single or multiple cancer trials.
- Only two articles reported having a recruitment goal for the underrepresented group prior to enrollment in the study. The majority of studies either defined recruitment success as equaling the proportion of underrepresented selected by the researcher (n = 13) for various reasons or as the disease-specific proportion of underrepresented (n = 9). The rest of the studies defined recruitment success as equaling the geographic proportion of underrepresented (n = 2), or the local research institution's proportion of the underrepresented (n = 1).
- Very few studies evaluated recruitment success in underrepresented groups especially those with low socioeconomic status, Asian/Pacific Islanders, adolescents, and rural populations (less than three studies in each group). No study reported recruitment success measures for American Indians/Alaska Natives.

The evidence reviewed indicated that success in recruitment of underrepresented populations is defined primarily by the goal of each study. When reporting on cancer trials, investigators should give careful thought to success measures for recruitment of underrepresented populations, avoid setting such measures arbitrarily, and report recruitment results based on the recruitment strategies for individual cancer clinical trials.

Key Questions 3 and 4: Methods to Study Recruitment Strategies

We sought to identify recruitment strategies (e.g., media appeals, incentives, etc.) that have been shown to be efficacious and/or effective in increasing participation of underrepresented populations in cancer treatment and prevention trials. We found a total of five eligible articles. [6, 7, 9, 11, 17]

The results of the interventions varied from no observed improvement to an increase in recruitment into cancer clinical trials. Two studies examined enrollment differences between two different intervention methods. Two other studies compared enrollment differences between interventions to a

control group. These control groups were either no intervention (usual medical care from physicians) or a standard recruitment "intervention" of mailed letters and telephone contact. However, whether various interventions had a true effect (null, positive, or negative) was somewhat unclear. Some authors cautioned that their results could be due to factors such as changes in recruitment strategy during the duration of the intervention. To give a clearer picture, each of the five studies is discussed in detail.

Linnan et al. investigated the differences between passive and active recruitment into a home-based cancer prevention randomized trial among employees.[17] In the passive employee contact arm, the research team contacted the employees from a list of employee names and telephone numbers provided by the company. In the active employee contact arm, employees actively signed up to participate. While lower enrollment and higher attrition were observed in the passive recruitment arm, the passive method enrolled a more diverse group of participants than did the active recruitment method.

Brewster et al. examined differences in recruitment into cancer prevention clinical trials between a clinic registry method and a media campaign targeting Latina women.[6] In the media recruitment strategy, the study was advertised in flyers placed in local community businesses, and advertised in community and regional newspapers in English and Spanish. The odds of presenting to the clinic and of recruitment were nearly three times more successful via the media campaign than via the clinic registry.

Paskett et al. examined the effect of an intervention program aimed at physicians and the community to increase the number of rural patients with breast cancer or colorectal cancer in clinical trials.[7] The intervention program consisted of the installation of a rapid tumor-reporting system to improve data quality and to expedite the receipt of information on cancer patients from physicians, a nurse facilitator who would notify physicians of clinical trials, a quarterly newsletter mailed to physicians about cancer treatment and clinical trials, and a health educator who trained lay health educators and provided community-based information about cancer screening, treatment, and clinical trials. Five counties in North Carolina received an intervention program while five counties in South Carolina served as controls where usual medical care was practiced. The rates of enrollment into clinical treatment trials did not improve significantly in the intervention communities.

Moinpour et al. reported the results of a randomized trial in increasing participation of minorities.[9] Minority recruitment strategies were designed and implemented in five pilot sites: African Americans in four sites and Hispanics in one site. While each site had a minority recruiter who was given requirements and a set of tasks, the specific details of the minority recruitment interventions for each site were not given. The overall impact was minimal, and it was unclear if, and at which site the intervention was fully implemented.

Ford et al. examined recruitment differences among African Americans randomized into either a control group or three increasingly intensive intervention arms.[7] The control group used a standard method of recruitment such as a standard recruitment letter, African-American or Caucasian interviewers for eligibility screening, baseline information collection via mailed packets, and reminder phone calls and mailings for completion of the mailed packets (Arm D). The basic intervention arm (Arm A) attempted to reduce potential sociocultural and individual barriers through the use of an enhanced recruitment letter and eligibility screening by African-American interviewers. The second more intensive intervention arm (Arm B) did not use mailed packets for baseline information collection but telephone interviews to facilitate ease of participation in addition to the enhanced recruitment letter. The third, and most intensive, intervention arm (Arm C) did not use a mailing packet or telephone interview but a church-based project site to gather baseline information in addition to the enhanced recruitment letter and eligibility screening telephone calls by an African American. The authors reported significantly higher enrollment yield (3.9 percent) in the most intensive church-based, face-to-face recruitment intervention arm (Arm C), compared to the other two intervention arms (2.5 percent [Arm A] and 2.8 percent [Arm B]) or the control group (2.9 percent [Arm D]) ($p < 0.01$).

There is only scant evidence in support of specific interventions to improve recruitment to cancer clinical trials, as indicated by the small number of studies comparing interventions.

Key Question 5: Barriers and Promoters of Recruitment

We sought to identify the documented barriers and promoters of participation for underrepresented populations in cancer prevention and treatment trials. Our search yielded 45 eligible studies that were conducted in a variety of settings.[3,5, 8, 13, 22, 23, 25, 26, 29, 33-63] Among the underrepresented populations, the available studies targeted African Americans primarily (n = 27), as well as Latinos/Hispanics (n = 7); American Indian/Alaska Native (n = 4); the elderly (n = 14); adolescents (n = 3);rural populations (n = 2); and Asian/Pacific Islanders (n = 2). While a large proportion of the available studies included populations

with low socioeconomic status, only one did so by design.[9] The search strategy yielded 40 U.S.-based studies, and we included evidence from 5 non-U.S.-based studies that featured relevant evidence.[22]

Barriers and promoters of participation in cancer prevention and treatment trials

Types of barriers and promoters identified. Overall, the eligible studies identified 118 distinct barriers to accrual to cancer clinical trials, including 97 barriers to accrual to therapeutic trials, 18 barriers to accrual to prevention trials, and 32 barriers to accrual to both therapeutic and prevention trials. There were more reported barriers to opportunity (n = 80) than to awareness (n = 7) or acceptance (n = 40) of clinical trials. Of the 59 distinct promoters of enrollment, most (n = 29) were promoters of the opportunity to participate in a cancer trial.

Barriers and promoters of accrual of African Americans to cancer treatment trials. Overall, there were 19 studies of accrual of African Americans to cancer therapeutic trials, which reported 85 barriers to accrual to therapeutic trials, including barriers to opportunity (n = 56), barriers to acceptance (n = 28), and awareness (n = 6). Of the 28 barriers to acceptance, the most frequently reported were perceived harms of clinical trial participation (n = 8), mistrust of research, researchers, and the medical system (n = 10), and fear (n = 5). Promoters were predominantly of promoters of awareness (n = 6). Of the reported 14 promoters of opportunity, the most frequently reported were culturally relevant education about trials (n = 3), and providing transportation (n = 2). Of the 14 promoters of acceptance, the most frequently reported were altruism (n = 3), perceived benefits of trial participation (n = 5), and incentives (n = 5).

Barriers and promoters of accrual to therapeutic trials in other underrepresented populations. *Latinos/Hispanics.* Four studies reported evidence on barriers to accrual of Latinos/Hispanics to cancer therapeutic trials. The reported eight barriers to opportunity were dominated by transportation (n = 2), age (n = 1), toxicity of treatment (n = 1), comorbid conditions (n = 1), and disease stage (n = 1). Of the seven barriers to acceptance, the most frequently reported was mistrust of research and the medical system (n = 2). Only two of the eligible studies for this question reported evidence on promoters of enrollment of Latinos/Hispanics. Brewster and colleagues found that a media-based strategy was superior to a clinic based strategy in recruiting Latino-Hispanic women.[6] Others have reported the lack of adequate health insurance, incentives, culturally relevant education about trials and the perceived benefits of trial participation as additional promoters of accrual for Latinos/Hispanics.[5, 55]

American Indians/Alaska Natives. The amount of evidence available for the American Indians/Alaska Natives population with regard to accrual to clinical trials, in general, was very limited. The aggregate number of American Indians/Alaska Natives in all of the eligible studies for which data on population subgroups was reported, was 19.[35, 41, 43, 55]

Asian and Pacific Islanders. We did not find any evidence regarding barriers or promoters of participation in cancer prevention or treatment trial for the Asian and Pacific Islander population.

The elderly. In the 11 available studies, barriers and promoters of opportunity were predominant in this population. Of the 22 barriers to opportunity, the most frequently reported were age (n = 2).

Adolescents. Only two of the available studies yielded evidence, and reported the lack of available trials as a significant barrier to enrollment of adolescents. Promoters of participation for this population included the perceived benefits of trial participation, including a chance for better treatment, and altruistic motives.

Rural populations. Only two of the available studies focused on recruitment of rural populations to cancer clinical trials, including cross-sectional surveys of physicians,[11] and focus groups. The studies reported numerous barriers to awareness, opportunity and acceptance of trial participation. They also reported altruism and incentives (financial and otherwise) as promoters.[43]

Barriers and promoters of accrual to prevention trials in African-American populations. Overall, there were 13 studies of barriers and promoters of accrual of African Americans to cancer prevention trials. We did not include studies of accrual to other types of primary prevention trials (e.g., diet and exercise) in this systematic review. Among the 41 barriers to accrual to prevention trials, barriers to opportunity (n = 24) were predominant, and of the 13 barriers to acceptance, mistrust of research and the medical system (n = 8), and the perceived harms of clinical trial participation (n = 4) were the most frequently reported. Promoters included provision of transportation (n = 1) and incentives (n = 2).

Chemoprevention trials.[9, 37, 56] On average, each of the chemoprevention trials reported two barriers (range: 1 to 2). There were no barriers to awareness, two barriers to opportunity, and three barriers to acceptance with mistrust of research reported in two studies. In one study, promoters included preference for the study's principal investigator to be

black, and the perception that it is better to be treated by research doctors.

Smoking cessation trials.[5,56,60] Out of the three smoking cessation trials in African-American populations, only one trial reported barriers to accrual, and not being ready to quit may have been a confounding factor. The reported promoters were incentives, support, encouragement, prayer, the certainty of receiving actual medication, and the impact of diagnosis on risk perception.

Screening trials.[7] The results of this one study were discussed in detail under key questions 3 and 4.

Barriers and promoters of accrual to prevention trials among other underrepresented populations.
Latinos/Hispanics. Overall, there were four studies reporting primarily barriers to opportunity (n = 7), especially transportation (n = 2). Mistrust of research and the medical system (n = 2) and family considerations or issues (n = 2) were the most frequent barriers to acceptance.

American Indians/Alaska Natives and Asian and Pacific Islanders. As discussed in the section on accrual to therapeutic trials, very little information is available on these two populations.

The elderly. Overall, there were three studies of barriers and promoters of enrollment to cancer prevention trials in the elderly. These studies reported three distinct barriers, age being the most frequently cited (n = 2). Among the three promoters of accrual to prevention trials, there were no promoters of awareness or acceptance. The three reported promoters of accrual were the entry criteria, age and low-income status.

Rural populations. The available evidence on barriers and promoters of accrual of rural populations to cancer prevention and treatment trials is based on two studies that we discussed in the section on barriers and promoters of accrual to therapeutic trials.[10,43]

Key Question 5a: Effects of Demographic Factors

Overall, the available evidence for key question 5 suggested that accrual to or intention to participate in a trial varied by the following sociodemographic factors: age (n = 16); gender (n = 3); socioeconomic status (n = 4); and race/ethnicity (n = 4). These barriers and promoters related most frequently to study design barriers, including exclusion by age (n = 6), study duration and visit structure (n = 4), comorbid conditions (n = 7), and functional status (n = 6). Few trials were available for adolescents; and as expected, parental influence was reported as a factor in decision-making only in this population. However, the available evidence did not suggest age as a factor that reduced awareness or acceptance of participation.

Key Question 5b: Effects of Cultural Factors

Three of the studies reported that barriers or promoters of enrollment varied by cultural factors,[39,55,60] however, it is not entirely clear whether such "cultural factors" refer to cultural norms, values or beliefs. For the elderly population, enrollment barriers and promoters did not vary by culturally relevant factors other than race or ethnicity. The heterogeneity of the available evidence and the definitional overlap among several of the underrepresented populations limited our ability to synthesize the evidence regarding whether some barriers or promoters vary by cultural factors.

Key Question 6: Role of Provider Attitudes and Perceptions

Nine studies presented data on how provider attitudes/perceptions were barriers to and promoters of accrual to cancer clinical trials. Four studies found provider atttitudes as a barrier to enrollment[11,23,44,64] while one study found provider attitudes to be a promoter of patient accrual.[23] The studies also reported that patient age,[23,59,65] comorbidity,[23,59] disease stage,[23] mistrust of researchers,[23,31] and lack of physician awareness about trials[44,52] were factors that prevented providers from enrolling their patients into clincial trials. Two studies[64, 66] found that provider communication or method of presentation were barriers to patient enrollment, whereas one study found it to be a promoter of trial enrollment.[41]

For studies that targeted minority populations,[29,44,52] mistrust of researchers and lack of provider awareness about trials were leading provider barriers [44,52] that decreased patient enrollment in clinical trials. Additionally, concerns about patient non-compliance and a lack of available protocols were reasons cited for not talking to patients about clinical trials.[29] For studies that targeted the elderly, provider attitudes regarding clinical trials prevented them from sharing information about trials with their patients in one study,[23] and increased their willingness to enroll patients in clinical trials in another study.[41]

Discussion

Research Quality

Since the enactment of the National Institutes of Health (NIH) Revitalization Act in 1993,[67] cancer researchers have put increased emphasis on recruitment of underrepresented populations to clinical trials. However, this aspect of the human research enterprise has received attention primarily in the secondary analysis of ongoing clinical trials, rather than as an area of focused scholarship. This reality is clearly reflected in the quality of studies available for this evidence report. One of the

positive aspects of the studies available for our review is that they have described a number of barriers and promoters of participation in clinical trials. However, most of the evidence is not based on rigorous studies, and a large proportion of the available studies were not driven by any clear hypotheses. A major weakness of the available evidence is the limited number of studies that compared two or more interventions, especially randomized controlled trials. The quality of the evidence summarized raises some questions about its adequacy to answer our questions regarding barriers and promoters of participation in cancer clinical trials. However, because of the consistency and patterns of occurrence of the identified barriers and promoters, it does provide important insights into future research directions.

Recommendations and Future Research

Key Questions 1 and 2

- Much of the available body of evidence was developed as "evidence by convenience" in the context of recruitment difficulties, or in retrospective analyses of recruitment of underrepresented populations across multiple clinical trials. There is a need for well-designed, controlled studies of strategies to improve accrual to cancer prevention and treatment trials. These studies should be hypothesis-driven, and include defined measures of success. They should also meet the usual standards of the NIH peer review process.
- Investigators should give careful thought to success measures for recruitment of underrepresented populations, and they should avoid setting such measures arbitrarily. Additionally, researchers should evaluate and report recruitment results for underrepresented groups more consistently.
- More attention should be focused on issues of trial design. If studies are not designed to address problems that are relevant to patients in underserved communities, then even the best recruitment strategies will be ineffective. Similarly, trials that exclude patients with chronic conditions will preferentially exclude the elderly, members of minority groups, and patients with lower socioeconomic status, because they are more likely to have chronic conditions. Hence, recruitment efforts must proceed hand-in-hand with initiatives to design relevant and pragmatic trials.[68]

Key Questions 3, 4, 5, and 6

- Because of many underrepresented populations' mistrust of researchers and of research institutions, research efforts to improve participation of underserved populations in cancer clinical trials should be developed within the framework of community-based participatory research, with community involvement through all phases of the research.
- The need remains for community-based studies to understand barriers to accrual in the community, including attitudes toward clinical trial participation. Whenever possible, such studies should be linked to the implementation of cancer clinical trials, and include actual recruitment as a major outcome. For example, several studies have suggested culturally relevant education as a strategy for improving accrual to cancer clinical trials. There is a need to further investigate the efficacy of culturally relevant education as a strategy to improve accrual to cancer prevention trials and cancer treatment trials.
- There is an urgent need to understand why participation of the Asian American/Pacific Islander and American Indian/Alaska Native populations in cancer clinical trials is minimal to non-existent. Studies of barriers and promoters of their participation should be linked to opportunities to participate. New research initiatives in this area may require several years before they are fruitful in terms of trial enrollment results.
- Similarly, there is a continuing need to better understand and improve upon strategies for recruitment of African-American males and Latinos/Hispanics into cancer clinical trials. Ideally, such studies should include documentation of existing barriers within a population as a basis for tailored interventions across the spectrum of barriers and promoters, including awareness, opportunity and decision-making.
- There is a need for further investigation of effective communication strategies, including investigations on the best approach to deliver information about clinical trials, both at the community level and at the point of interaction with the potential participant.
- In communities lacking established efforts to promote awareness about clinical trials, sufficient time should be allowed for relationships to be built with community members, including community-based providers, before accrual can begin. The period for building such

relationships may take several years, but it would vary depending on the community and the existing relationships prior to an intervention.

- Some interventions (e.g., media-based strategy for Hispanic women) have been shown to be effective in increasing accrual to clinical trials. Such interventions should be replicated, and where appropriate, the results should be disseminated widely.
- To advance the evidence regarding efficacious strategies for improving enrollment to cancer clinical trials, intervention studies will need to be linked to one or more clinical trials, depending on sample size requirements. The studies should include collection of baseline information regarding prevalent risk factors in the study population. Systematic data collection about barriers and promoters of trial participation should be linked to concrete plans for designing interventions to address such barriers. Moreover, the next generation of studies of barriers and promoters of accrual should be multidisciplinary, including the involvement of community-based participatory researchers, social and behavioral scientists, as well as health economists.
- There are many barriers to care, and it is unlikely that piecemeal strategies to address these barriers will be effective to promote participation in cancer clinical trials. There is a need for a cost-effective strategy to address barriers to care on multiple levels, and in a manner that can be integrated into the context of the health care system and of the research team. To facilitate the integration of recruitment interventions into health care systems, especially the research team, a study should compare the efficacy of a recruitment intervention specialist to that of usual, opportunistic recruitment practices. The recruitment intervention specialist would be a professional or paraprofessional staff member who is appropriately trained to promote awareness about clinical trials in the community and to help patients overcome barriers to opportunity. Ideally, the recruitment intervention specialist would be indigenous to, or at least have extensive familiarity with, the community targeted by the recruitment effort. Thus, this role would be analogous to that of a patient navigator for clinical trials, and its cost-effectiveness should be investigated.
- Research to improve enrollment of underrepresented populations in cancer clinical trials must interface with other ongoing initiatives designed to address cancer health disparities through discovery, development, and delivery. Such efforts must overcome the critical disconnect between discovery and development on the one hand, and delivery of cancer care on the other.
- Substantial resources will need to be dedicated to research efforts to build upon the existing evidence on strategies for improving enrollment of underrepresented populations in cancer clinical trials. Many of the initiatives that contributed to the available evidence were probably not funded. NCI should dedicate adequate funds for well-designed studies of barriers and promoters of accrual to cancer clinical trials.

Further investigation is needed on barriers to recruitment of all of the underrepresented populations, as defined in this report, into cancer-related clinical trials. The specific populations are: African Americans (especially men), Hispanics, American Indians/Alaska Natives, Asian and Pacific Islanders, adolescents, the elderly, and rural populations. Future studies should include the evaluation of culturally tailored strategies to promote awareness about cancer clinical trials among underrepresented populations. Different types of intervention approaches should be considered to promote accrual to cancer therapeutic trials and cancer prevention trials. Research and evaluation of recruitment strategies may yield stronger evidence about ways to improve participation of underrepresented populations in cancer clinical trials. The principal need is for hypothesis-driven research, and ultimately randomized controlled trials, to evaluate the most promising strategies for recruiting underrepresented populations into cancer treatment and prevention trials.

Availability of the Full Report

The full evidence report from which this summary was taken was prepared for the Agency for Healthcare Research and Quality (AHRQ) by the Johns Hopkins University Evidence-based Practice Center, under Contract No. 290-02-0018. It is expected to be available in June 2005. At that time, printed copies may be obtained free of charge from the AHRQ Publications Clearinghouse by calling 800-358-9295. Requesters should ask for Evidence Report/Technology Assessment No. 122, *Knowledge and Access to Information on Recruitment of Underrepresented Populations to Cancer Clinical Trials.* In addition, Internet users will be able to access the report and this summary online through AHRQ's Web site at www.ahrq.gov.

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