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

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# Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-Based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The National Cancer Institute, National Institutes of Health, requested and provided funding for this report. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome comments on this evidence report. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to **epc@ahrq.gov.**

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The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services of a particular drug, device, test, treatment, or other clinical service.

# Acknowledgments

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# Structured Abstract

**Context**: Since the enactment of the National Institutes of Health (NIH) Revitalization Act in 1993, cancer researchers have made significant efforts to develop evidence regarding barriers to participation in clinical trials, especially for ethnic minority populations. While some advances have been made in defining these barriers, significant gaps remain in the available evidence in regard to efficacious and/or effective interventions to improve enrollment to cancer clinical trials. It is essential to address these gaps in the evidence, in order to fulfill the intent of the NIH Revitalization Act. Only a small proportion of cancer patients are enrolled in clinical trials, and recent evidence indicates that racial and ethnic minorities, adolescents, the elderly, rural populations and individuals of low socioeconomic status in general, are underrepresented in cancer clinical trials funded by the National Cancer Institute (NCI). At the request and with the financial support of the NCI, the Agency for Healthcare Research and Quality 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 Evidence-based Practice Center (EPC).

**Objectives**: We developed a conceptual framework to guide our analysis of barriers and promoters of participation of underrepresented populations in cancer clinical trials. Our approach takes account of the fact that in order to participate in a trial, an individual must be aware of the trial, have the opportunity to participate, and be willing to accept participation. The barriers and promoters span the continuum from awareness to acceptance, and they differ, depending on the population and whether recruitment is to a treatment trial or to a prevention trial. We performed a systematic review of evidence concerning the effectiveness of interventions designed to improve recruitment of these underrepresented populations into cancer therapeutic and prevention trials. Our report focused on questions in the following areas: 1) methods used to study recruitment strategies; 2) measures of recruitment success; 3) comparison of two or more recruitment interventions for cancer treatment trials; 4) comparison of two or more recruitment interventions for cancer prevention trials; 5) barriers and promoters of recruitment; and 6) physician attitudes and perceptions about recruitment.

**Data 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). For hand searching, we identified 34 journals that we thought were most likely to contain relevant studies. We scanned the table of contents of the issues of these journals for relevant citations from January 2003 through July 2004.

**Study Selection**: Articles included in this evidence synthesis were English-language reports containing original data that addressed one of the specific research questions. We excluded articles that did not address underrepresented populations, did not address cancer treatment or prevention, or did not discuss recruitment to a controlled trial.

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

**Data Synthesis:** Overall, we identified 67 eligible articles that focused on the following areas: methods used to study recruitment strategies (n=13) measures of success (n=23), comparison of two or more recruitment interventions (n=5), barriers to and promoters of recruitment (n=45), and physician attitudes and perceptions regarding recruitment (n=10). These studies were heterogeneous in that they targeted community members, patients and physicians in a variety of contexts. Reports on methods to study recruitment interventions lacked consistency in reporting of target population characteristics such as age, gender, residence (urban or rural areas), socioeconomic status, and recruitment dates. All but two of the studies eligible for review regarding measures of success defined successful recruitment in a post-hoc fashion as actual participation of the targeted group; the studies rarely set specific recruitment goals *a priori*.

Only five studies compared two or more strategies to promote accrual to cancer clinical trials. 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 = 8) or acceptance (n = 40) of clinical trials. Of the 59 distinct promoters of enrollment, most (n = 28) were promoters of the opportunity to participate in a cancer trial. There is a lack of information regarding efficacious recruitment strategies for all of the underrepresented racial and ethnic minority populations. Additionally, the available evidence suggests that the lack of availability of trials is a barrier to enrollment for the adolescent population. Moreover, study exclusion criteria such as age, comorbid conditions, functional status, and sometimes unwarranted provider concerns regarding drug toxicity, limit opportunities for the elderly to participate in cancer clinical trials. Transportation is an important barrier, among others, for rural populations.

The evidence suggests that provider attitudes and perceptions have a critical influence on enrollment results for underrepresented populations. Providers have declined to enroll patients because of their age, comorbid conditions, and mistrust of researchers; and for studies that targeted minority populations, mistrust of researchers and lack of provider awareness about trials were leading provider barriers that decreased patient enrollment in clinical trials.

The strengths of the available evidence are the identification of numerous barriers and promoters of accrual to cancer screening trials, and the consistency of these barriers across the available studies. The limitations in study design and reporting of some of the available studies represent an important weakness of this evidence. Many of the studies had important limitations in: 1) representativeness; 2) justification of study methods; 3) reliability and validity of the data collection methods; 4) potential for bias/confounding based on study design; and 5) failure to control for potential sources of bias in the data analysis. Nevertheless, the evidence provides the basis for certain conclusions regarding future directions for research to improve enrollment of underrepresented populations in cancer clinical trials.

**Conclusions**: Clinical investigators need effective strategies to improve participation of underrepresented populations in cancer clinical trials. The available evidence is consistent regarding barriers that reduce awareness, the opportunity to participate, and acceptance of cancer clinical trials. However, the patterns of occurrence of these barriers differ among the underrepresented populations; and for this reason, research strategies must address the needs of

each population with some specificity. Future studies should build upon the existing evidence to further elucidate the nature of barriers and promoters of participation in cancer clinical trials. Research intervention strategies should be tailored to the specific context of an underrepresented population, to reduce barriers to awareness, opportunity, and acceptance of trial participation, and to demonstrate tangible results in terms of trial accrual. There are many barriers to enrollment in a cancer clinical trial, and piecemeal strategies will not suffice to ensure the participation of underrepresented populations. Research is needed on cost-effective strategies that bridge the cancer research center and the community in a manner that can be integrated into the context of the healthcare system and the clinical research team. Such research requires community involvement through all of its phases.

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**http://www.ahrq.gov/clinic/tp/recruittp.htm**

Agency for Healthcare Research and Quality

Evidence Report/Technology Assessment

Number 122

# 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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# Evidence Report

# Chapter 1. Introduction

## Clinical Research and the Medically Underserved

Until recently, contemporary cancer prevention and control research approaches have failed to address the basis of persistent health disparities; and they have produced mixed results in regard to the adoption, replication and diffusion of successful interventions in underserved communities. Medically underserved populations, including low-income and racial/ethnic minority populations, face substantial barriers to state-of-the-art cancer care throughout the continuum of cancer care, from preventive services to detection, to treatment and survival. Health disparities, including those related to cancer, have multiple causes, including socio-political, economic, cultural, and geographic factors. Disparities in cancer mortality rates are mediated, in part, by socioeconomic factors,[1-3] and low socioeconomic status is a predictor of the lack of preventive services.[4-6] African Americans have among the highest age-adjusted cancer incidence and mortality rates, even when controlling for poverty rates.[1,3,7-9] Disparities in cancer mortality may be due to disparities in incidence and/or in life expectancy following diagnosis.[1,10]

Differences in access to medical care, including cancer detection and treatment, may be major determinants of racial disparities in cancer mortality, as the disparities in cancer mortality rates are greater than those in incidence rates,[8] and African Americans and other minority populations are more likely to be diagnosed with advanced stage cancer than are Whites[4,8]; however, when cancer patients receive comparable treatment at the same disease stage, they experience similar treatment outcomes.[11-20] Once diagnosed, African Americans receive less intensive treatment,[9,21] and survive for a shorter duration.[22-26] The physicians who care for African Americans are less likely to be board-certified than those who care for Caucasian patients,[27] suggesting that cancer health disparities may be due, to a large degree, to disparities in the quality of care delivered by available health care systems.[18,19] Moreover, there is evidence that compared to the rest of the population, racial/ethnic minority populations are less likely to receive optimal treatment regimens following the diagnosis of cancer.[21] Therefore, to reduce these disparities, it is essential to identify and address existing barriers to care.

The goal of clinical cancer research is to advance knowledge and improve decision-making in cancer care. Clinical trials focused on cancer prevention and treatment serve health professionals and the public by translating the insights of the biological and public health sciences into effective health interventions. The National Cancer Institute (NCI) provides support for the evaluation of cancer prevention and treatment strategies through clinical trials. National research standards have been formulated to ensure that benefits and burdens of clinical research are distributed equitably in society.[1] However, many studies fail to recruit their planned number of participants; and studies that recruit too few patients might miss clinically important effects and are thus inappropriate uses of participants and resources.[28] Clinical trials are used to evaluate the efficacy and effectiveness of health promotion, prevention, and cancer care intervention strategies; however, questions often remain regarding the generalizability of trial results to a population broader than those enrolled in the clinical trials.

Medically underserved groups have been underrepresented in cancer clinical trials.[29] Since 1993, the National Institutes of Health (NIH) has required that all sponsored clinical trials,

including cancer trials, ensure that women and members of minorities and their subpopulations be included in all human subjects research.[30, 31] In addition, results must be reported so that potential differences in treatment effect can be detected between study subgroups. The NIH has sponsored several efforts to recruit women and racial/ethnic minorities into cancer clinical trials and other types of studies (e.g., cross-sectional and observational studies).[30, 31] However, more than a decade following the institution of this NIH requirement, enrollment of minority populations into cancer clinical trials remains woefully inadequate. In a review of accrual to NCI-funded clinical trials, Sateren found that certain populations were underrepresented, including racial and ethnic minorities, the elderly, adolescents, rural populations and individuals of low socioeconomic status, irrespective of race/ethnicity.[32] Barriers to participation in cancer clinical trials would differentially exclude members of these groups from the potential benefits of new treatments and ancillary care services.

According to a recent Institute of Medicine (IOM) Report:

> *"The inclusion of ethnic minority and medically underserved individuals in clinical trials and the dissemination of information to their community and health care providers are critical links connecting scientific innovation with improvements in health and health care delivery. Enhancement of these links is clearly within the purview of NCI and NIH. Although many factors pose challenges to such improvements (e.g., mistrust of the scientific establishment among many members of ethnic minority communities), without a concerted effort to enhance this process, ethnic minority and medically underserved communities will continue to lag behind the American majority in benefiting from the tremendous recent scientific achievements and medical breakthroughs in cancer prevention, treatment, and control."*[19]

Thus, the IOM underscored the urgent need to improve opportunities for culturally sensitive recruitment and accrual of underrepresented populations to cancer clinical trials, as a necessary step in addressing the public health impact of cancer health disparities.

Some investigators have systematically documented a range of factors important to participation in clinical trials in general [33] and to the recruitment of minorities to a broad range of clinical trial types.[34] More recently, systematic research on the reporting of minorities in cancer clinical trial publications has emerged. The literature in recent years has produced occasional reports of efficacious and/or effective recruitment strategies directed at medically underserved populations in cancer treatment and prevention trials. While generalization and extrapolation from other populations and disease states may be necessary, those interested in applying the evidence from clinical trials benefit most from studies conducted in specific populations with specific cancer prevention or treatment protocols.

On the basis of a systematic review of cancer prevention and treatment trials, Swanson and Bailar observed that:

- The majority of cancer clinical trial reports do not even describe the race or ethnicity of trial participants;

- When women and minorities are included in clinical trials, their participation more often appears to be by chance than by plan;

- When subgroup analyses are reported, it is rarely clearly stated whether they are done to test hypotheses or to generate hypotheses;

- When subgroups are reported, differences in treatment or prevention effect often are found;

- Trial report recommendations rarely limit the scope of their recommendations on the basis of participant gender or participant race or ethnicity; and

- Trials often do not include participant populations that are adequately diverse to ensure broad generalizability of results."[29]

The first five of these practices are clear and correctible shortcomings in clinical trials. The sixth practice limits the generalizibility of trial results.[29] However, Swanson and Bailar did not address barriers to and strategies for successful recruitment to cancer clinical trials since the 1993 change in NIH policy regarding the reporting of clinical trial accrual results for women and minority populations.

Little has been done to systematically synthesize published evidence regarding recruitment of underrepresented populations to cancer clinical trials. Such an assessment should serve to strengthen the evidence base for our knowledge about progress in increasing participation in cancer clinical research. By using the research literature to assess the state of knowledge about recruitment of underrepresented populations to cancer clinical trials, we should accomplish the following:

- Document how the problem has been studied to date,

- Ascertain proven ways to improve the recruitment,

- Unify our knowledge regarding persistent barriers to recruitment.

If nothing else, a comprehensive appraisal should serve to summarize from an evidence-based perspective what we do know and, equally importantly, what we do not know about the recruitment of the medically underserved to cancer clinical trials. Of equal importance may be reports of failed attempts to recruit underserved groups. Knowing what strategies have been ineffective can be as helpful in the process of discovery as ascertaining effective strategies. Furthermore, systematically documenting the barriers of various recruitment interventions may be equally important in future study designs.

## Recruitment of Underrepresented Populations to Cancer Clinical Trials

To summarize evidence for recruitment of underrepresented populations to cancer clinical trials, one must first overcome several barriers, not the least of which is defining "underrepresented." We adopted a definition of underrepresented similar to the "priority

populations" defined in authorizing legislation for the Agency for Healthcare Research and Quality (AHRQ) and incorporated into the National Healthcare Disparities Report.[35,36] For the purposes of this report, the following groups constitute the "underrepresented populations:" adolescents, older adults, those of low socioeconomic status, those residing in rural areas, African Americans, Hispanics/Latinos, Asian Americans, and American Indians. Although individual investigators may define each component of this definition somewhat differently, it provides a rough framework while preserving enough breadth to encompass the vast majority of populations affected by disparities in the U.S. healthcare system and in recruitment into cancer-related trials. The definition is intended to encompass populations such as the elderly, that may be underrepresented in clinical trials even if they are not always considered medically underserved otherwise.

We used a conceptual framework adapted from previous work done at Johns Hopkins University that includes various relevant factors for participation in clinical trials (see Figure 1). A multitude of factors may contribute to an individual's participation in cancer clinical trials. Research characteristics (study design, interventions) interrelate with participants' backgrounds (sociodemographic factors, knowledge, attitudes, beliefs, etc.), which in turn contribute to an individual's awareness of a clinical trial. These in combination with opportunity comprise the key determinants of participation. Literature from the past decade suggests that medically underserved populations face significant barriers to participation in clinical trials along the continuum from awareness to acceptance, and the nature and extent of these barriers may vary across specific underrepresented populations.

Heterogeneous research tools have been used to study recruitment of the medically underrepresented populations to clinical trials in a variety of geographic and social contexts. These tools range from open-ended qualitative approaches in the community to structured experimental designs in the workplace. The historical, social, and ethical context for including the underserved in clinical trials is replete with examples of abuse. This history makes the study of barriers and the testing of strategies to improve participation of the underserved potentially suspect for those appropriately concerned about abuse.

Complicating matters further, the literature shows that neither investigators nor policy makers have reached a consensus on a uniform definition of "success" in recruitment. For instance, some have suggested that if underserved minorities enroll in trials at least as often as non-underserved, success has been achieved. Others have argued that the proportion of those enrolled in a given trial should have subgroup demographics that are proportionately representative of the more immediate geographic area or the U.S. population as a whole. Arguably, the appropriate level of inclusion might depend on the prevalence of the condition/disease studied in the overall population. Others might have serious concerns about any set numerical outcome standard, relying instead on assurance of an ethically and culturally appropriate process of recruitment. Few authors have adequately discussed this problem.

Despite these challenges literature has emerged in recent years to warrant a summary of the evidence.

# Rationale for Commissioning This Evidence Report

The NCI requested this report to summarize the state of scientific knowledge regarding the recruitment of underrepresented populations to cancer clinical trials. As envisioned by NCI, this report would:

- Summarize the ways the problem has been studied to date;
- Describe the measures of success used in the literature to assess recruitment;
- Summarize strategies that have been found to be efficacious and /or effective in the recruitment of underrepresented populations to both cancer prevention and treatment trials; and
- Summarize the barriers to and promoters of participation in clinical trials for these populations.

This report is limited to recruitment to cancer clinical trials (not, for example, recruitment to observational studies) and to the underrepresented populations as defined above. This report will be used by the NCI to guide future funding opportunities, identify priority areas for researchers, and educate clinical and cancer control investigators about the effectiveness of different recruitment approaches. We expect this report to serve the overall goal of improving opportunities for underrepresented populations to participate in cancer clinical trials, thereby eventually leading to a reduction in cancer health disparities for those populations.

However, we recognize that even if members of underrepresented populations do participate in cancer clinical trials, and reporting and recruitment are adequate, the benefits of clinical trial knowledge may not translate into improved cancer outcomes for these populations due to other factors. If systemic inequities persist in the healthcare delivery system, including in access to quality care, the availability of research data may not benefit underrepresented populations so much as other populations. Therefore, recruitment efforts to cancer clinical trials must interface with other ongoing initiatives designed to address cancer health disparities through discovery, development, and delivery, and to overcome the critical disconnect between discovery and development on the one hand, and delivery of cancer care on the other.[10,38]

# Objectives and Scope of Report

This report summarizes and synthesizes the available evidence used to answer the key questions provided to the Johns Hopkins University Evidence-based Practice Center (EPC) by the NCI covering the following: research literature and study design characteristics, and proven strategies and barriers to the recruitment of the medically underserved to cancer prevention and treatment trials (see key questions in the Methods section). The report is comprehensive and current for literature published as of July 2004. In answering the above questions, we have written this report for the purpose of ongoing planning and priority setting of national cancer

research policy. In addition, we hope it will contribute to the growing national dialogue addressing disparities in health outcomes for various U.S. populations.

# Chapter 2. Methods

The NCI requested an evidence report to synthesize the available evidence on the effect of interventions to increase participation by underrepresented populations in clinical trials, with an overall goal of improving the opportunities for underrepresented populations to participate in cancer-related clinical trials. The EPC was awarded this contract in December 2003. We established a team and work plan to develop the evidence report. The project consisted of recruiting technical experts, formulating and refining the specific questions, performing a comprehensive literature search, summarizing the state of the literature, constructing evidence tables, and submitting the report for peer review.

## Recruitment of Technical Experts and Peer Reviewers

At the beginning of the project, we recruited a panel of internal and external technical experts to give us input on key steps including the selection and refinement of the questions to be examined. The panel included seven internal technical experts from the Johns Hopkins University who had expertise in various aspects of recruitment strategies for controlled clinical trials and 15 external experts who had special interests in underrepresented populations (see Appendix A[*]). Many of our external experts also were a part of the NCI Special Populations Network (SPN).[37] In addition to this panel of technical experts, we recruited a group of peer reviewers to examine a draft of the evidence report, as described further in the section on Peer Review. This group included representatives of organizations or agencies having different perspectives on the topic (See Appendix A). We also sought input throughout the project from representatives of the NCI.

## Key Questions

We refined the original questions provided by AHRQ after obtaining input from the technical experts and NCI representatives. Listed below are the Key Questions addressed in this report.

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. We included the elderly as underrepresented because of concerns that they are not recruited into trials as aggressively as younger*

[*] Note: Appendixes cited in this report are provided electronically at: http://www.ahrq.gov/clinic/tp/recruittp.htm

*patients when diagnosed as having cancer. We included adolescents as underrepresented because of concerns that they may be more resistant to participating in cancer-related trials than adults.*

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?*

3. *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 trials?*

4. *Which recruitment strategies have been shown to be efficacious and/or effective in increasing participation of underrepresented populations in cancer prevention trials?*

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 exclusion by design. Examples of potential promoters include attitudes, altruism, advanced disease, financial incentive, and no-cost treatment.*

    a. *How do these barriers and promoters differ by age, gender, socioeconomic status, or race/ethnicity?*

    b. *How are these barriers and promoters modified by cultural factors?*

6. *What effects do the attitudes and perceptions of healthcare providers have on the efficacy/effectiveness of strategies for recruitment of underrepresented populations into cancer prevention and treatment trials? Healthcare providers are defined as including any health professional or healthcare organization that provides health services to patients.*

# Conceptual Framework

We constructed a conceptual framework for our questions based on the relationships among the factors leading to a patient's decision to enroll in a cancer-related clinical trial (see Figure 1). This framework was derived from a conceptual model developed by two members of the EPC team.[39]

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 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 recruitment into a trial, including: 1) patients/clients receiving information about clinical trials in general through healthcare providers or their own social ties, and subsequently accepting a specific opportunity to participate in the 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 to and promoters of awareness, opportunity, and acceptance/refusal.

In the hypothesized conceptual framework, there are several factors that are promoters of or barriers to clinical trial **awareness**. First, a person must know about and believe in the value of participating in the clinical trial before one can agree to participate. Knowledge about a clinical trial involves knowing what the anticipated outcomes may be, the costs of participation in terms of money, time, and effort, as well as information about the disease. Second, a person's attitudes and beliefs regarding cancer, the medical profession, and medical research may influence their willingness to receive and attend to information about clinical trials. Third, a person's belief in his/her ability to participate in a clinical trial, or self-efficacy, may influence awareness of the clinical trial. If individuals do not believe that they can participate in the trial, then they may not be open to hearing information about the trial. Fourth, the organizational environment, which involves the physical and psychosocial environment in which the information is being disseminated as well as the trial is being conducted, may influence a person's willingness to receive information about clinical trials. If the organizational environment makes patients/clients uncomfortable or defensive, then they will be less open to recruitment efforts. The final hypothesized barrier to or promoter of clinical trial awareness is health literacy. A lack of understanding of the medical system, cancer, and health information in general lead to poor health literacy, making patients less inherently aware about clinical trials as well as more difficult to educate them about trials.

As denoted in the conceptual framework, individuals must have an **opportunity** to participate in a clinical trial before they can accept or refuse participation. Some barriers and promoters of opportunity are access to the hospital or clinical trial site, trial eligibility, advanced disease, comorbidities, and medical insurance status. Additionally, providers can play a vital role in the successful recruitment of patients to clinical trials in that they are often the gatekeepers of information about clinical trials. They can decide which patients to refer for trial participation. Therefore, provider knowledge, attitudes, and beliefs about clinical trials and their patients' abilities to enroll in the trials may influence their disseminating information about the trials (key question 6).

The third main component of the conceptual framework involves **acceptance/refusal** of trial participation. The decision to accept or refuse enrollment in a clinical trial is based on many factors, which often involves a decisional balance. For example, do the perceived benefits outweigh the perceived harms? If so, then people are more likely to agree to enroll in a trial. Also, trust in the sponsor, physician, or investigator may play a large role in whether people are willing to participate in a clinical trial. Other factors that are important to acceptance/refusal are self-efficacy, quality of life, advanced disease, no cost treatment, financial incentives, as well as personal experience with cancer, the medical system, and clinical trials. The timing of the trial may also influence the decision to participate. For an example, a person who has just been diagnosed with cancer may be more or less willing to participate than someone who is at the end-

stage of cancer. Finally, religious beliefs and altruism may play a role in the decision regarding participation.

Encompassing clinical trial awareness, opportunity, and acceptance/refusal are sociodemographic factors that serve as moderators/covariates of participation. These sociodemographic factors include race/ethnicity, age, gender, geography, language, income, social ties, education, and culture. In the hypothesized conceptual framework, each of these factors influences individual barriers to and promoters of awareness, opportunity, and willingness to participate in cancer clinical trials among underrepresented populations.

As part of this report, we evaluated **interventions** to increase accrual to cancer clinical trials (Key Questions 3 and 4). The types of interventions targeted were directed at individuals, physicians/providers, the medical system, and the community; and intervention strategies varied, including incentives, as well as media-based campaigns. Based on our conceptual framework, interventions are directed at decreasing barriers to and/or promoters of clinical trial awareness as well as opportunities for participation and willingness to participate or actual enrollment. In addition, we looked at the types of studies used to address the recruitment of underrepresented populations to clinical trials (Key Question 1). These were expected to be primarily surveys, focus groups, and concurrent controlled trials (CCT) (both randomized and non-randomized). Finally, as denoted in the bottom right of the conceptual framework, we attempted to assess whether investigators reported on measures of success (Key Question 2). For example, if a recruitment goal was stated *a priori*, was that goal achieved? We attempted to identify the different ways recruitment success was measured. Some examples of potential success measures are proportional representation relative to the U.S. population and proportional representation relative to cancer incidence.

# 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). This electronic search strategy was not limited by year of publication, and the MEDLINE database goes back to 1966

Hand searching for possibly relevant citations took several forms. Our experts identified 34 journals that were thought to be most likely to contain relevant studies (see Appendix B). 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® (ISI ResearchSoft, Berkeley, CA), a reference management software package, 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 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 articles for consideration. We also used MEDLINE to search for articles published by selected experts known to have interests related to our Key Questions.

Finally, we examined the reference lists of eligible articles to identify any potentially relevant ones. This task was completed by the second reviewer as part of the article review process (see description of article review process below).

## Search Terms and Strategies

Search strategies, specific to each database, were designed to maximize sensitivity. Initially, we developed a core strategy for MEDLINE, accessed via PubMed, based on an analysis of the Medical Subject Headings (MeSH) and text words of key articles identified *a priori*. The PubMed strategy formed the basis for the strategies developed for the other electronic databases (see Appendix C).

### General search terms

*MEDLINE general search terms:* (neoplasm [mh] OR cancer [tw] OR carcino*[tiab] OR tumor [tiab] OR oncolog*[tiab]) AND (patient selection [mh] OR recruit*[ti] OR participat*[ti] OR enrol*[ti] OR enlist*[ti]) AND eng [la] NOT (animal [mh] NOT human [mh]).

*PsychINFO general search terms:* (neoplasm or cancer or carcinogen or tumor or oncolog*) and (patient selection or TI recruit* or TI participat* or TI enrol* or TI enlist* or TI refer*) and (trial* or stud*) And LA english and human.

*CINAHL general search terms:* (neoplasm or cancer or carcino* or tumor or oncolog*) and (MW patient selection or MW research subject recruitment or TI recruit* or TI participat* or TI enrol* or TI enlist* or TI refer*) and (trial* or stud*) and LA English and human.

*Cochrane Database (CENTRAL and Methodology Review) general search terms:* (neoplasm* or cancer or carcino* or tumor* or oncolog*) and (patient selection or recruit*:ti or particip*:ti or enrol*:ti or enlist*:ti or refer*:ti) and (trial* OR stud*) NOT (animal NOT human).

*C2-SPECTR:* {neoplasm} or {cancer} or {carcino} or {tumor} or {oncolog} OR All Non-Indexed Fields: {neoplasm} or {cancer} or {carcino} or {tumor} or {oncolog} AND All Non-Indexed Fields {patient selection} or {recruit} or {participat} or {enrol} or {enlist} or {refer} AND All Non-Indexed Fields {trial} or {stud} NOT All Non-Indexed Fields {animal} NOT {human}.

## Organization and Tracking of Literature Search

Whenever possible, the results of the searches were downloaded and imported into ProCite. We used the duplication check in the bibliographic software ProCite to include in the Recruitment Citations Database only articles that were not previously retrieved. This database was used to store citations and to track the search results and sources. We also used this database

to track the results of the title and abstract review processes and the retrieval of the full text copies of articles (see Figure 2).

# Title Review

After the electronic databases were searched and citations downloaded into ProCite, the study team scanned all of the titles. During the scan, team members deleted any titles that did not apply to the study topics. Title scans were conducted in a parallel fashion by two independent reviewers. If a title was selected as irrelevant by both reviewers, it was tagged in the ProCite database and deleted from further study.

# Abstract Review

Specific inclusion and exclusion criteria were applied at each of the levels of review, with criteria becoming more stringent as the process moved from searching, to the review of titles, to the review of abstracts, and to the review of articles. After identifying a title as potentially relevant, two team members independently reviewed the abstract of the citation, and articles were included or excluded from the article review on this basis. Disagreements between reviewers were adjudicated by consensus.

## Inclusion and Exclusion Criteria

During the abstract review process, emphasis was placed on identifying all articles that could have original data pertinent to the questions about recruitment of underrepresented populations into cancer prevention and treatment trials. As previously described, representatives from NCI were consulted during the development of inclusion and exclusion criteria.

In evaluating titles and abstracts, the following criteria were used to exclude articles from further consideration:

- Not written in English.
- Did not include human data.
- No original data.
- Meeting abstract only (no full article for review).
- Did not address cancer treatment or prevention.
- Did not report a controlled trial or discuss recruitment to a controlled trial.
- Article did not apply to any of the study questions.

For citations relevant to Key Questions 3 and 4, we limited eligibility further to studies that compared at least two groups. This comparison group could include groups from randomized and non-randomized designs with concurrent or historical controls. Non-controlled designs (e.g., case series with no comparison groups) were excluded for Key Questions 3 and 4, but remained potentially eligible for Key Questions 1 and 2.

When the initial exclusion criteria were developed, "not a U.S.-based study" was an exclusion criterion. As the review process progressed, however, the EPC team determined that this exclusion criterion might delete some articles from the review that could provide important information. Abstract reviews were then conducted on articles initially excluded because they were not U.S.-based studies. A number of articles were then eligible for article review that would not have been eligible otherwise. We included studies that addressed underrepresented minority populations using whatever definitions of race/ethnicity were provided by the study authors.

## Abstract Review Process

We reviewed abstracts by printing titles and abstracts of all articles retrieved by the literature search on a standardized form and distributing them to two reviewers (see Appendix D*). The reviewers independently screened the abstracts for eligibility and classified them by research question addressed. When reviewers agreed that a decision regarding eligibility could not be made because of insufficient information, the full article was retrieved for review.

The results of the abstract review process were entered into the Recruitment Citations Database. Deleted citations were tagged with the reason for exclusion. Citations were returned to the reviewers for adjudication if there was disagreement on eligibility.

# Article Review

The purpose of the article review was to confirm the relevance of each article to the research questions, to determine methodological characteristics pertaining to study quality, and to collect evidence that addressed the research questions. Articles eligible for full review could address more than one of the Key Questions. If reviewers felt this was the case multiple forms were used.

## Quality Assessment and Data Abstraction

Forms were developed to confirm eligibility for a full article review, to assess study characteristics, and to extract the relevant data to address the study questions (see Appendix E). The forms were developed through an iterative process that included the review of forms used for previous EPC projects, discussions among team members, and pilot testing. This process was complex because of the heterogeneity of the literature. We developed a general form and question-specific content review forms for the abstraction of data to address Key Questions 1 and 2, 3 and 4, and 5 and 6. We used one form to assess the quality of articles eligible for Key Questions 3 and 4, and a separate form to assess the quality of articles eligible for Key Questions 5 and 6. A quality assessment form was not used for articles eligible for Key Questions 1 and 2 because the questions called for only a listing of methods that have been used. The forms were color coded to aid reviewers.

**Assessment of the quality of individual studies**

- The study quality assessment form Key Questions 3 and 4 had six sections and was completed only for studies that met the criteria for these Key Questions.
    - The first section addressed the representativeness of the study populations, thus allowing the reviewers to assess each study's descriptions of setting and population as well as the inclusion/exclusion criteria and the characteristics of participants/non-participants.
    - The second section was used to evaluate potential bias and confounding factors.
    - The third section assessed the description of the recruitment strategy by evaluation of the details of the flow of participants through the clinical trial and the details of the recruitment strategy.
    - The fourth section assessed the reporting of recruitment outcomes and follow-up. It included the description of the measures used to define barriers and promoters to recruitment and each study's reporting of the reasons for withdrawal from the study.
    - The fifth section assessed the statistical quality and interpretation, and the sixth covered conflict of interest. The last item called for an overall rating of the quality of the study.
- The study quality assessment form for Key Questions 5 and 6 had three sections.
    - The first section covered the representativeness of the study population in much the same manner as the quality assessment form for Key Questions 3 and 4.
    - The second section was designed to assess the quality of survey studies.
    - The third section was designed to assess the quality of qualitative studies.

**Data abstraction**

A separate general abstraction form was used for each question to abstract information such as study design, intervention, study location, objectives, target population characteristics, and timeline. Additional question-specific forms were used for Key Questions 1 and 2, Key Questions 3 and 4, and Key Questions 5 and 6. Each of these three forms addressed questions dealing specifically with the respective Key Questions.

## Article Review Process

We used a serial article review process. In this process, the quality assessment and data abstraction forms were completed by the primary reviewer. The second reviewer, after reading

the article, performed an independent assessment of the study's quality using a separate quality assessment form and then checked each item on the data abstraction form for completeness and accuracy. The reviewer pairs were formed to include personnel with both clinical and methodological expertise. A third reviewer re-reviewed all articles that were marked as "ineligible" by the first two reviewers to ensure consistency in the classification of the articles. Reviewers were not masked to the articles' authors, institution, or journal. In most instances, data were directly abstracted from the article. If possible, relevant data were also abstracted from figures.

All information from the article review process was entered in a relational database (Recruitment Evidence Database). The database was used to maintain and clean the data, as well as to create detailed evidence tables (see Appendix F[†]) and summary tables (see Tables 1 to 7).

## Grading of the Total Body of Evidence

After all articles were reviewed, we graded the total body of evidence supporting each question on the basis of its quantity, quality, and consistency. Our evidence-grading scheme followed the approach recommended by the International GRADE Working Group.[40] In terms of quantity of evidence for each question, we determined the number of studies and the total number of patients studied. We assessed the quality and consistency of evidence on each key question based on the criteria recommended by the Grade Working Group that applied to the questions (see Tables 8 to10). Although the GRADE criterion were developed primarily for treatment effectiveness questions, they are based on fundamental principles that apply to a variety of study questions. As shown in Tables 8 to 10, we downgraded our grading of the evidence if any of the following criteria were met: 1) if the studies had serious limitations in quality; 2) if the studies had important inconsistency; 3) if there was uncertainty about the directness or extent to which the people, measures and/or outcomes are similar to those of interest; 4) if data were imprecise or sparse; and 5) if the studies had high probability of reporting bias.

## Peer Review

Throughout the project, feedback was sought from the technical experts through ad hoc and formal requests for guidance. A draft of the completed report was sent to the technical experts and peer reviewers, as well as to the representatives of the NCI and AHRQ. Substantive comments were entered into a database. Revisions were made to the evidence report as warranted, and a summary of the comments and their disposition was submitted to AHRQ with the final report.

[†] Note: Appendixes cited in the report are provided electronically at: http://www.ahrq.gov/clinic/tp/recruittp.htm

# Chapter 3. Results

## Results of Literature Search and Abstract Review Process

Results from the search and the abstract review process were maintained in a database developed in ProCite. A summary of the results of the search and review process is provided in Figure 2.

Of the 4451 citations retrieved by the search methods, 341 were duplicates leaving 4110 for title review. Of these, 1089 were reviewed at the abstract level. Two hundred eighteen articles were identified as eligible for full article review through the abstract review process.

Because many articles had more than one reason to be excluded the abstract reviewers did not need to agree on the main reason for applied at the abstract level. The most frequent reason for exclusion was that the article did not report a controlled trial or discuss recruitment to a controlled trial (used by one or both reviewers to delete 460 abstracts). The next most frequent reason for exclusion was that the article contained no original data (used by one or both reviewers to delete 173 abstracts).

## Results of Article Review Process

From the abstract review process, 218 citations were identified for inclusion in the article review phase. At the article review level 151articles (70 percent) were excluded. The most frequent reasons for exclusion were that the article did not address an underrepresented population (69 articles, 45 percent), the article did not report on a controlled trial (36 articles, 24 percent), or there was no subgroup analysis (16 articles, 11 percent). A listing of excluded articles with the reasons for exclusion is included in this report.

Of the 67 articles included in this report, Key Question 1 was addressed by 13 articles, and Key Question 2 was addressed by 23 articles. Both Key Questions 3 and 4 were addressed by small numbers of articles (one and four respectively). For this reason, and the similarity of questions, the results of these two questions were combined (five total). Key Question 5 was addressed by 45 articles with questions 5a and 5b addressed by 30 and three articles respectively. Key Question 6 was addressed by 10 articles.

# Key Question 1: What Methods Have Been Used to Study Strategies to Recruit Underrepresented Populations into Cancer Prevention and Treatment Trials?

## Identification of Relevant Articles

As indicated in Figure 2, we found 13 studies that were relevant to this question. Details about these studies are shown in Table 1, and Evidence Tables 1-1, 1-2, and 1-3 in Appendix F.[b]

## Study Characteristics

All 13 studies were of U.S. origin, and most were based in a community setting.[41-49] Studies by Advani et al. and Mauer et al.[50,51] were hospital-based, with Advani et al. involving outpatients and Mauer et al. involving inpatients. One study[52] was set in the workplace or workers' homes. The specific setting for one study was unclear.[53] The reported target population for all of the studies was patients/participants except one study[44] where the target population was patient /participants and physicians. Three studies[45,46,49] targeted physicians only. The reported study designs in all studies varied. A randomized controlled trial was the reported study design for two studies. [43,52] One study was quasi-experimental,[41] and two studies compared two or more interventions.[42,46] Descriptive study designs were used in four studies.[44,47-49] One study used a survey design,[50] and another employed a qualitative design.[53] One used a case study design.[51]

These studies dealt with a range of cancers. A few investigated trials for a specific cancer; for example, breast cancer was specified in three studies,[46,47,50] and lung cancer was specified in three.[43,48,52] The balance of the studies dealt with multiple types of cancer. Two reported a general focus that included all cancers.[53] One investigated trials for any cancer type where there was an active protocol.[44]

Four studies did not report the dates on which recruitment into the study started or ended.[49,50,52,53] The recruitment ending date for one of the studies was reported as ongoing.[45] All of the studies investigated the effectiveness of methods or the delineation of barriers to recruitment of individuals into trials (Evidence Table 1-1, see Appendix F).

## Target Population Characteristics

Of the 13 eligible studies, six reported mean age,[42,43,46,47,52,53] which ranged from 43 years to 62 years (see Evidence Table 1-2 in Appendix F). Within each of these studies the actual age range of participants was quite wide. For example, Brewster et al. reported a within-study range of 17 to 78 years of age.[42] Five studies reported an age range.[42,43,48,49,53] The reported age range in four of these studies was narrower than it was for Brewster et al.[42]

Only eight studies reported the gender of the participants.[41-43,46,48,49,52,53] Four studies reported that the majority of participants were male.[43,46,50,52] The studies did not report usable information about the income or education levels of participants.

[b] Note: Appendices cited in this report are provided electronically at: http://www.ahrq.gov/clinic/epcindex.htm

Information regarding the racial or ethnic distributions of the participants was available for only a few of these studies. Four studies reported that 6 percent, 100 percent, one percent, and 100 percent, respectively, of participants were African American.[41,43, 47, 54] Sears et al. reported that 9 percent of participants were Asian/Pacific Islanders,[47] and Advani et al. reported that 33 percent of its participants were American Indian.[50] Sears et al. reported that 85 percent of participants in their study were Caucasian.[47] In other studies, Advani et al and Randall-David et al. reported 67 percent and one percent of participants as Caucasian.[50,53] Brewster et al. and Berman et al. reported that one percent of their participants were Latino/Hispanic.[41,42] None of the studies reported having any adolescent participants. Ford et al., Zhu et al., and Thornquist et al. reported that the proportions of their participants who were elderly were 100 percent, one percent, and 25 percent, respectively.[43,49,48] Over one-third (38 percent) of the participants in the study by Ford et al. reported low socioeconomic status.[43] Approximately 64 percent of the participants in the study by Advani et al. were from a rural area.[50] Three other studies reported that one percent of their participants were from rural areas.[46,51,53]

## Recruitment Methods Findings

All but two of the studies defined successful recruitment into cancer-related controlled trials as actual participation of the targeted group[50, 53] (Evidence Table 1-3, see Appendix F), and none of the studies set *a priori* recruitment goals. Eight of the studies reported recruitment start and end dates, [41-44,46-48,51] with the average reported time spent on recruitment being 33 months. Advani et al. defined successful recruitment as participants' willingness to participate in the study and not their actual participation.[50] We defined "methods" broadly as methods used to a) study recruitment, b) design the studies, c) identify the target populations, and d) recruit individuals into the clinical trials. Seven studies did not report the method used to design their recruitment strategies.[43,44,47,48,51,52]The primary outcomes of the studies varied and could be organized into primary, secondary, or tertiary categories. Linnan et al. and Zhu et al. were primary prevention projects.[49,52] One study was a survivorship/recurrence-prevention project,[45] and two were chemoprevention studies.[44,48] Each of the 13 studies initially mailed letters to recruit participants as part of the overall recruitment strategy. In addition to these mailings, telephone calls and fliers or posters strategically placed around the worksite or community were used in an attempt to recruit participants into the studies. One study advertised in community and regional newspapers that served as an important source of information for the area's Spanish speaking population.[42] These advertisements were printed in both English and Spanish. This study also used the local Spanish language television station, faith-based organizations, mental health facilities, and free clinic facilities in an attempt to get people to participate. One study used third party insurers to enlist participants.[48] Four studies also enlisted the assistance of physicians to recruit participants into their project. [44-46, 48] Incentives, both monetary and material, were used in Paskett et al.[45] One study enlisted the aid of local businesspersons to help in the recruitment of participants.[43] Finally, none of the studies reported having set a goal for recruiting a specific percentage of participants before the start of the study.

# Key Question 2: What Measures of Success Have Been Used to Evaluate the Efficacy and/or Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials?

## Identification of Relevant Articles

As indicated in Figure 2, we found 23 studies that were relevant to this question (see Table 2). Details about these studies are shown in Evidence Tables 2-1, 2-2, and 2-3, Appendix F.

## Study Characteristics

All studies except one were from the United States.[54] Twelve of the studies were reviews of multiple cancer clinical trials and, therefore, had multiple study settings.[44,55-65] Nine of the studies occurred in a community setting[41-44,46,48,49,66,67] and seven involved a hospital center[42,44,51,58-60,63]. Twenty studies targeted patients/participants for the recruitment intervention[41-44,48,51,52,54-61,63-67], two studies targeted physicians, and one study targeted patients/participants and researchers.[62] Most of the study designs to evaluate recruitment success were descriptive[48,54-61,63,65] presenting recruitment results of a retrospective review of multiple cancer trials (n=11),[48,54-61,63,65] descriptive studies of enrollment into a cancer clinical trial (n=4),[44,62,64,67] or a description of enrollment into a cancer trial using a survey, qualitative, or quasi-experimental study design (n=2). The rest of the study designs were two controlled clinical trials,[42,46] two randomized controlled trials,[43,52] a case-control study,[66] and a case series.[46]

Nine studies evaluated recruitment into any cancer trial[44,54-61]; the remaining studies evaluated recruitment success for trials on breast cancer (n=6),[46,49,51,63-65] colorectal cancer (n=5),[43,46,51,63,65] prostate cancer (n=5),[43,51,62,63,65] lung cancer (n=5),[48,51,52,63,65] or cervical cancer (n=2).[42,67] Sixteen of the studies evaluated recruitment or reviewed active trial enrollment during the 1990s.[41-44,46,51,54,55,56,59,61-65,67] Three studies reported that recruitment/enrollment began in the 1980s,[48,58,60] one in the 1950s[57]; three did not report when recruitment began.[49,52,66] The studies evaluating recruitment success were cancer treatment trials alone (n=14),[44,46,51,54,56-59,61-66] cancer prevention trials alone (n=7),[41-43,48,49,52,67] or involved treatment and prevention trials (n=2)[55,60] (see Evidence Table 2-1 in Appendix F).

## Target Population Characteristics

For the eligible studies reporting mean age, the majority of the participants were middle-aged adults with a mean age between 40 to 60 years old.[42,46,52,57,64,66] The age range when documented was mostly between 40 and 80 years.[42,43,48,49,62,63] Three studies evaluating cervical cancer, smoking cessation and adolescent participation in clinical trials had a lower mean age from 20 to 40 years.[41,60,67] The gender distribution varied across studies from 0 to 100 percent male. Four studies reported information on low socioeconomic status or low annual income (less than $30,000 per year)[42,43,52,49] while four studies reported having greater than 45 percent of participants with a high school education or less.[41,49,52,66]

In these studies, we found that the percentage of study subjects who were in underrepresented groups varied widely: elderly (ranged from 15 to 100 percent with the majority ranging from 20 to 50 percent),[43,48,49,54,56,57,61,63,65,66] African Americans (ranged from 4 to 100 percent with the majority between 4 to 30 percent),[41,43,49,56,63,64,67] Latinos/Hispanics (ranged from 3 to 85 percent with the majority ranging from 3 to 6 percent),[41,42,52,56,58,63,67] Asian /Pacific Islanders (ranged from 2 to 3 percent),[63,67] American Indians/Alaska Natives (0 to 2 percent),[67] rural (100 percent in both articles evaluating rural populations),[46,51] adolescents (ranged from 21 to 33 percent),[60] and low socioeconomic status/low annual income (27 to 91 percent with the majority between 27 to 39 percent)[42,43,51,52] (see Evidence Table 2-2 in Appendix F).

## Recruitment Goals and Measures of Success

All studies defined recruitment as actual participation in a cancer trial. Only two articles reported having a specific recruitment goal for the underrepresented group prior to enrollment in the study. One was a goal for the rural population based on the recruitment results of a prior study, [51] and the other was a goal for African American men 55 years old or older based on geographic representation (i.e. percent African American elderly men in the U.S.).[62] The study by Maurer et al on rural populations met this recruitment goal while the Moinpour et al. study on African Americans did not, recruiting 4 percent instead of 8 percent.[51,62]

Recruitment success was defined differently depending on the study. To better evaluate the recruitment success measures, we grouped them into four different categories: 1) geographic proportion underrepresented (i.e., proportion of U.S. population in an underrepresented group); 2) disease-specific proportion underrepresented (i.e., proportion underrepresented with cancer or a specific type of cancer in a geographic area such as the U.S.); 3) proportion underrepresented selected by the researcher for various reasons (e.g., statistical power, convenience, or data from prior studies); and 4) research institution's proportion underrepresented (i.e., proportion of population in the institution that was in an underrepresented group).

Most of the studies defined recruitment success as equaling the proportion underrepresented that was selected by the researcher for various reasons such as convenience (n=13),[42-44,46,48,49,51,52,54-55,57,66,67] or as the disease-specific proportion underrepresented (n=9).[54-56,58,60,61,63-65] The rest of the studies defined recruitment success based on the geographic proportion underrepresented (n=2),[41,62] or the institution's proportion underrepresented at a research institution (n=1).[59]

When examining the 12 articles on cancer treatment trials, recruitment success was mainly defined as being equal to the proportion set by the researcher,[44,46,51,54,57,59,66] or the U.S. disease-specific proportion underrepresented.[54,56,58,59,61,63] For the eight articles on cancer prevention trials alone, recruitment success was defined mainly as being equal to the proportion set by the researcher.[42,43,48,49,52,67] For the 3 studies that evaluated both prevention and treatment trials, the disease-specific proportion underrepresented was the major success definition used.[55,58,64]

Christian and Trimble in an article that did not meet our strict eligibility criteria (it contained no original data), reviewed data from the cancer therapy evaluation program that reports the NCI cancer clinical trials by race (American Indian/Alaska Native, Asian/Pacific Islander, African American, and Latino/Hispanic). They used the data from the 2000 U.S. census as a comparison, thereby providing another example of geographic representation as a measure of success.[73]

*A priori* recruitment goals were rarely specified for underrepresented groups when evaluating recruitment success of cancer clinical trials. Additionally, the trials had no standard measure of

recruitment success. The majority of recruitment success measures were defined either as the proportion set by the researcher, often arbitrarily, or the disease-specific proportion of underrepresented. This was true across all underrepresented groups and regardless of whether the study addressed cancer treatment, prevention, or both. 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 Indian/Alaska Natives (see Evidence Table 2-3 in Appendix F).

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# Key Question 3: Which Recruitment Strategies Have Been Shown to be Efficacious and/or Effective in Increasing Participation of Underrepresented Populations in Cancer Treatment Trials?

# Key Question 4: Which Recruitment Strategies Have Been Shown to be Efficacious and/or Effective in Increasing Participation of Underrepresented Populations in Cancer Prevention Trials?

## Identification of Relevant Articles

As indicated in Figure 2, we found 5 studies that were relevant to these questions.[42,43,46,52,62] Details about these studies are shown in Tables 3 and 4, and Evidence Tables 3/4-1, 3/4-2, 3/4-2, 3/4-4, and 3/4-5 in Appendix F.

In reviewing the current literature on effective and/or efficacious recruitment strategies in improving participation of underrepresented populations in cancer clinical trials, we found a total of five eligible articles. Four articles examined recruitment strategies of underrepresented populations into cancer prevention trials,[42,43,52,62] and the fifth article examined strategies of recruiting underrepresented populations into cancer treatment trials.[46]

The settings of the studies ranged from participants' homes and community environments[42,43,46,52] to community-based clinics and research sites[42,62] (Evidence Table 3/4-1 see Appendix F). Three studies focused on recruitment of underrepresented populations at the participant level;[42,43,52] one study evaluated the recruitment of underrepresented populations through participants and physicians[62] and one evaluated recruitment of underrepresented population through physicians[46] (Evidence Tables 3/4-1 and 3/4-2 in Appendix F). The underrepresented populations examined included blue-collar workers in manufacturing companies, African-American and Latino/Hispanic men, Latina/Hispanic women in southern California, and cancer patients in rural counties of North and South Carolina. All five studies used randomized or non-randomized controlled trials to evaluate the efficacy or effectiveness of interventions to promote recruitment to cancer clinical trials (Evidence Table 3/4-3, Appendix F).

## Quality of Studies

The studies on Key Questions 3 and 4 varied in their limitations as summarized in Quality Evidence Table 3/4-4 in Appendix F. We specifically examined each article based on representativeness, bias and confounding, recruitment description, outcomes and follow-up, statistical quality and interpretation, and conflict of interest.

Linnan's study reported a good amount of detail on the description of the study setting and participant characteristics, inclusion and exclusion criteria, and recruitment methods. However, the authors did not adequately discuss their statistical analyses, address methods to account for bias and confounding such as randomization or blinding, state any information about definition of successful recruitment or recruitment barriers and promoters, or report their source of funding.[52]

Brewster's study overall was considered to be of fair quality. The authors described in great detail the setting and population, inclusion and exclusion criteria, key participant characteristics, information about non-participants, and statistical analyses. In addition, the researchers explained differences between the two recruited populations and the recruitment description. However, the authors did not provide adequate information about the definition of successful recruitment or recruitment barriers and promoters, or about their source of funding.[42]

While Paskett's study provided some details about the setting and population, and reported their source of funding, it was also of fair quality, due to the lack of information in certain areas. The researchers did not provide adequate information on participant characteristics or their recruitment methods, address issues of randomization or blinding, explain their statistical analyses, define recruitment success, or report reasons for withdrawal.[46]

In a good quality study, Ford and colleagues described in great detail the study setting, inclusion and exclusion criteria, participant characteristics, recruitment description, outcomes and follow-up, statistical analyses, and the source of funding. However, the researchers did not explain their randomization methods or how they addressed blinding.[43]

Moinpour's study was not graded due to the lack of information.[62]

## Results of Studies

The results of the interventions varied from no observed improvement[46] to an increase in recruitment into cancer clinical trials[42,43,52] (Tables 3 and 4, and Evidence Table 3/4-4 in Appendix F). Two studies examined enrollment differences between two or more intervention methods.[42,52] Two other studies compared enrollment differences between interventions and a control group.[43,46] These control groups featured either no intervention[45] (usual medical care from physicians) or a standard recruitment "intervention" of mailed letters and telephone contact.[43] 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 get a clearer picture, we discuss the five studies in detail.

Linnan et al. investigated the differences between passive and active recruitment into a home-based cancer prevention randomized trial among employees.[52] 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. The research team examined differences in enrollment, reach,

and attrition along with organizational factors and behavioral risk factors between the two recruitment arms. Compared to the active employee contact, the passive employee contact reached a higher proportion of employees (74.5 percent vs. 24.4 percent) and had a higher attrition rate (46 percent vs. 29.9 percent). However, the active employee contact arm enrolled a larger proportion (77.5 percent vs. 40.9 percent, P<0.0001). Besides having a higher proportion of smokers and higher consumption of high-fat diets in passive employee contact arm, no significant differences were observed in other behavioral or organizational factors. 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. The authors concluded that with the differences observed, the results provided insight into the advantages and disadvantages that researchers may encounter when designing and implementing recruitment strategies. They also noted that these different recruitment methods might not necessarily apply to all types of work sites.

Brewster et al. examined differences in recruitment into cancer prevention clinical trials between a clinic registry method and a media campaign targeting Latina/Hispanic women.[42] In the clinic registry method, all women who had visited clinics as patients or a guardian were identified from the clinic registries. 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. Women who called in response to these announcements were screened for eligibility and subsequently scheduled if eligible. Compared to the clinic registry method, the media recruitment method resulted in a significantly larger proportion of women screened as a result of the media-based strategy were eligible (81 percent vs. 75 percent, $p < 0.001$), and were more likely to give telephone consent to participate (83 percent vs. 65 percent, $p <0.001$). The odds of presenting to the clinic were three times higher for women recruited by the media campaign than for those recruited via the clinic registry (odds ratio [OR] = 3.00; 95% confidence interval [CI] 2.38 to 3.78). In addition, of the women who were screened by telephone, recruitment was nearly three times more successful via the media campaign than via the clinic registry (OR = 2.97; 95% CI 2.52 to 3.51). The authors concluded that the media campaign method was more advantageous than the clinic registry in recruiting women. The media campaign also recruited a larger number of Latina and uninsured women into the study.

Paskett et al. examined the effect of an intervention program aimed at physicians and community to increase the number of rural patients with breast cancer or colorectal cancer in clinical trials.[44] 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 to 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. Data collection on clinical trail enrollment was obtained from medical record data and to evaluate the enrollment differences between the North Carolina counties and South Carolina counties. As noted in Evidence Table 3/4-4, the percentage of breast and colorectal cancer patients from North and South Carolina recruited into cancer clinical trials changed in the five-year span between 1991 and 1996. In North Carolina, 15 percent (n = 24) of breast cancer patients and 4 percent of colorectal cancer patients were enrolled in clinical trials in 1991 while 6 percent (n=14) of breast

cancer patients and 5 percent of colorectal cancer patients were enrolled in 1996. In South Carolina, 6 percent (n = 6) of breast cancer patients and 5 percent of colorectal cancer patients were enrolled in 1991 while 50 percent (n = 16) breast cancer patients and no colorectal cancer patients were enrolled in 1996. The authors ultimately concluded that the rates of enrollment into clinical treatment trails did not improve significantly in the intervention communities.

However, the available data remain open to interpretation despite the varied changes in percentage of enrolled patients from 1991 to 1996 in each region. The reported numbers and percentage of enrolled breast cancer patients in North and South Carolina were presented for both 1991 and 1996, but only the percentage of enrolled colorectal cancer patients was given for each area. The number of colorectal cancer patients in North and South Carolina were given as one aggregate number. Thus, without the definitive numbers distinguishing colorectal cancer patients in North Carolina from those in South Carolina, it is unknown whether the reported percentages of enrolled colorectal cancer patients in 1991 and 1996 in both regions indicate an increase or decrease in enrolled patients into cancer clinical trials. In addition, the authors noted incomplete data on breast cancer cases in South Carolina in 1996 were obtained thus dictating caution in making comparisons.

Moinpour et al. reported the results of a randomized trial in increasing participation of minorities.[62] 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, according to the percentage of people recruited among the five sites before and after the implementation of the recruitment strategies. Four of the sites reported a decrease in percent enrolled (-0.3 percent, -0.5 percent, -2.8 percent, -0.6 percent) while only one site reported an increase in percent enrolled (+0.5 percent). Statistical significance of these results was not reported. The authors indicated that evaluation of the effectiveness of these strategies was difficult because execution of these interventions occurred near the end of the recruitment period.

Ford et al. examined recruitment differences among African Americans into cancer screening trials who were randomized into either three increasingly intensive intervention arms or a control group.[43] The control group utilized 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-only interviewers. The second increasingly-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 call by an African American. The authors reported significantly higher enrollment yield (3.9 percent) in the most intensive church-based 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]) ($p < 0.01$).

## Grading of the Total Body of Evidence

Overall, the mixed results of the interventions mentioned in these studies denote a continuing need for trials that evaluate additional interventions (Table 8). The studies were limited to specific populations in certain locations. Also, very few studies were available to answer our proposed questions. The available information necessitates cautious interpretation due to limitations in the quality of the studies as summarized in Evidence Table 3/4-4 (see Appendix F).

# Key Question 5: What are the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials?

We sought to identify the documented barriers and promoters of participation for underrepresented populations in cancer prevention and treatment trials; to assess whether these barriers and promoters differ by age, gender, socio-economic status or race/ethnicity; and whether they vary by cultural factors. We abstracted data from each of the eligible studies, and according to our conceptual framework (see Figure 1), we organized the barriers and promoters of enrollment, based on their likely effect on awareness about clinical trials, the opportunity to participate in a trial, and decision-making about whether or not to participate in a trial. Some of the barriers and promoters (e.g., lack of cultural competence) had the potential to affect multiple domains of the framework, e.g., both awareness and the opportunity to participate. We subdivided the identified barriers into the patient-, provider- and healthcare system level barriers. In addition, to the extent feasible we analyzed the eligible studies based on the type of trial(s) to which accrual was studied, namely, therapeutic trials, mixed trials (therapeutic and prevention), and prevention trials. We subdivided prevention trials into chemoprevention trials, smoking cessation trials, and screening trials. Primary prevention trials other than smoking cessation were not included in this systematic review.

## Study Characteristics

Our search yielded 45 eligible studies that were conducted in a variety of settings[32,41-44,46-48,50,53,58,60-62,64,66,69-97] including in the community (n = 25),[41-44,46-48,53,66,70,71,73,75,77,79,80,81,83,86,88-90,92-94] hospital inpatient and outpatient settings (n = 22),[42,44,50,58,60,62,64,69,70,72-74,76,78,87,89,85,87,91,95,96,97] a study based on recruitment logs of clinical trials groups (n = 1),[62] and databases consisting of all NCI-funded clinical trials (n = 2).[32,61] Most of the studies used patients/research participants as the primary respondents,[32,41-44,47,48,50,53,69-81,83,85-87,89,90,93,94,96,97] while a few included interviews of healthcare professionals, including physicians, clinical research associates and data managers.[44,46,62,66,79,80,87,84,88,91,92,95] Among the underrepresented populations in cancer clinical trials, the available studies targeted African Americans primarily (n = 27)[32,41,43,47,50,58,62,64,66,69-71,74,75,79-81,85,86,88-94,97] and some of these focused exclusively on women (n = 5)[47,73,74,86,93] or men (n = 4).[43,62,85,94] The available studies also targeted other under-represented populations: Latinos / Hispanics (n = 7)[32,41,42, 62,66,74,93]; American Indian/Alaska

Natives (n = 2)[32,53, ,93]; the elderly (n = 14)[32,43,48,61,66,75-78,83,84,87,95,96]; adolescents (n = 3)[60,72,73]; rural populations (n = 2)[52,53]; and Asian/Pacific Islanders (n = 2).[32,91] While a large proportion of the available studies included low socioeconomic status (SES) populations, only one did so by design[43]; and the studies generally reported low SES in association with minority status. The designs of the eligible accrual studies were predominantly descriptive and/or qualitative, but also included case-control studies (n = 2)[50,66] as well as controlled trials (n = 6)[42,43,46,47,62,78] (both randomized and non-randomized). The studies provided evidence on enrollment to therapeutic trials (n = 29),[32,44,46,47,50,53,58,60,61,64,66,69,70,72,73,75-79,81-84, 91,93-96] prevention trials (n = 11),[41-43,48,62,71,74,85,86,87,90] both (n = 5).[80,88,89,92,97]

Participation in a therapeutic trial typically involves accrual to a pre-randomization (or run-in) phase, followed by randomized allocation of eligible subjects to the treatment arms. While most of the eligible studies addressed barriers to enrollment, few examined barriers to randomization of those enrolled in clinical trials. This report focuses on barriers and promoters of enrollment (see Evidence Table 5-3 in Appendix F), and it does not address barriers to retention of underrepresented populations in cancer clinical trials. Moreover, most of the available studies did not provide evidence on barriers to participation in early phase versus phase III cancer clinical trials. Therefore, we did not make a distinction between these two types of trials in the review.

## Target Population Characteristics

Tables 5 and 6 present selected characteristics of participants in eligible studies. The search strategy yielded 40 U.S.-based studies. In addition, because of the modest number of U.S.-based studies, we also included 5 non-U.S.-based studies[76,87,83,87,96] that featured evidence of interest to this systematic review, including a study about the perspective of clinical research associates.[87] The sample size varied among the studies, from 23 to 59,300, and in two studies, it was not reported. The reporting of age was not consistent across the studies, and it included reports of the mean age (n = 8),[41,46,47,64,66,74,79,81] an age range (n = 18),[32,44,48,60,69,70,73,75-77,83,84,86,87,90,91,95,96] or both (n = 7),[42,43,53,71,72,89,97] however some (n = 12)[50,58,61,62,78,80,87,85,88,92-94] did not provide age information. Similarly, only some studies reported the income levels of the participants (n = 5).[42,50,75,89,90] The proportion of males ranged from 0 to 100 percent, depending on the type of cancer trial (e.g., cervical cancer vs. prostate cancer) to which recruitment efforts were directed. Few of the studies reported the participation of American Indian/Alaska Natives, Asian/Pacific Islanders, adolescents or rural dwellers.[52,53,60,72,73,84, 91,93] More studies addressed barriers to accrual of African Americans (n = 27) than of any other racial/ethnic group. Among African Americans, there were four studies of barriers to accrual in males, and five in females.

## Quality of Studies

The articles were rated in terms of quality in each of five areas or domains: 1) representativeness, 2) justification of study methods, 3) reliability and validity of data collection methods, 4) potential for bias/confounding, and 5) data analysis. Selected aspects of quality are summarized in Evidence Table 5-4 (see Appendix F). In terms of representativeness, ten of 45 studies provided adequate descriptions of study participants.[42,47,50,60,64,69,70,77,78,87] For justification of study methods, six studies provided excellent documentation for the basis for their studies,[43,69,75,79,84,93] and 27 other studies provided good documentation.[41,42,46-48,50,58,60,64,66,70,72-

[74,77,80,81,83,85-92,97] With the exception of two studies,[50,53] the study instruments used in the surveys and data collection methods used in the qualitative studies did not show adequate reliability and validity. While 14 studies[46,58,66,70,75,81,85,86-91,93] made notable efforts to protect against confounding or other types of bias, only four were rated as excellent in this regard.[58,70,86,92] For studies that used surveys as part of data collection, potential sources of confounding included participant response rates and selection of subjects; for studies that used qualitative techniques to collect data, the selection of subjects was a potential source of confounding. In terms of the description of the data analysis, all but three studies[43,48,90] were inadequate in their reporting.

## Overall Barriers and Promoters of Participation in Cancer Therapeutic and Prevention Trials

Tables 5 and 6 present a summary of information regarding barriers to participation in cancer prevention and treatment trials (see Evidence Table 5-3 in Appendix F for additional detail).

**Types of Barriers 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. Across all of the studies, these barriers include eight barriers to awareness of cancer clinical trials, 80 barriers to the opportunity to participate in a cancer trial, and 40 barriers to acceptance of enrollment. Among these, 63 barriers were relevant at the patient level, 31 at the provider level, 20 at the study design level and seven at the healthcare systems level (see Evidence Table 5-3 in Appendix F for additional detail).

**Types of Promoters Identified.** The eligible studies identified 59 distinct promoters of enrollment to cancer clinical trials, including 36 promoters of enrollment to therapeutic trials, 14 promoters of enrollment to prevention trials, and 17 promoters of enrollment to both therapeutic and prevention trials. Overall, these promoters include six promoters of awareness of cancer clinical trials, 29 promoters of the opportunity to participate in a cancer trial, and 25 promoters of the decision to enroll. We identified promoters at the patient level (n = 40) (see Evidence Table 5-3 in Appendix F for additional detail), at the provider level (n = 12), at the study design level (n = 6), and at the healthcare system level (n = 2) (see Evidence Table 5-3 in Appendix F for additional detail).

## Barriers and Promoters of Participation in Cancer Therapeutic and Prevention Trials for African Americans

**Barriers to Accrual to Cancer Therapeutic Trials in African American Populations.** Overall, there were 19 studies of barriers to accrual of African Americans to cancer therapeutic trials, and on average, each reported eight barriers (range: 0 to 20). Among the 85 barriers to accrual to therapeutic trials, there were six barriers to awareness, and the most frequently reported among them were lack of education about trials (n = 5),[50,79,80,92,93] lack of dissemination of study opportunities to patients/providers (n = 3),[88,92,93] and lack of knowledge about origins of cancer (n = 2).[76,94] Of the reported 56 barriers to opportunity, the most frequently reported were costs (n = 5),[58,79,80,88,92] functional status (n = 2), [58,69] time commitment or additional time required (n = 5),[47,79,81,93,97] lack of or inadequate health insurance (n = 3),[32,64, 81] and provider

attitudes (n = 4).[79,91,92,94] Of the 28 barriers to acceptance, the most frequently reported were perceived harms of clinical trial participation (n = 8),[45,80,81,89,91,92,94,97] mistrust of research, researchers, and the medical system (n = 10),[62,74,79-81,89-94,97] and fear (n = 5).[88, 91-94]

**Promoters of Accrual to Therapeutic Trials in African American Populations.** Among the 19 studies of accrual of African Americans to cancer therapeutic trials, each reported, on average, two promoters (range: 0 to 8). Among the 34 promoters of accrual to therapeutic trials, there were six promoters of awareness, including education programs for community physicians (n = 1),[79] adequate knowledge about study (n = 1),[80] and workshop on trials (n = 1).[80] Of the reported 14 promoters of opportunity, the most frequently reported were culturally relevant education about trials (n = 3),[92-94] and providing transportation (n = 2).[80,97] Of the 14 promoters of acceptance, the most frequently reported were altruism (n = 3),[50,81,89] perceived benefits of trial participation (n = 5),[50,89,93,94,97] and incentives (n = 5).[80,81,93,94,97]

## Barriers and Promoters of Accrual to Therapeutic Trials in Other Underrepresented Populations

Because of the limited evidence available regarding barriers and promoters of participation in cancer therapeutic trials in populations other than African Americans, we discuss these barriers and promoters together within each of the following paragraphs.

**Barriers and Promoters in Other Racial and Ethnic Minority Populations.**

***Latinos/Hispanics.*** Overall, three studies reported evidence on barriers to accrual of Latinos/Hispanics to cancer therapeutic trials, and on average, each reported seven barriers (range: 0 to 9).[32,66,93] For this population, there were two barriers to awareness, and three barriers to acceptance. The reported 13 barriers to opportunity included age (n = 1),[66] toxicity of treatment (n = 1),[66] comorbid conditions (n = 1),[66] and disease stage (n = 1).[66] Two studies reported evidence on promoters of enrollment of Latinos/Hispanics to cancer therapeutic trials.[32,93]

***American Indian/Alaska Natives.*** The amount of evidence available for the American Indian and Alaska Native population with regard to accrual to clinical trials was very limited. The aggregate number of American Indian/ Alaska Native participants in all of the eligible studies for which data on population subgroups was reported was 15.[53,72,73,93] Most of the evidence regarding this population comes from focus groups conducted by Roberson (n = 28), which included African American, Latino/Hispanic and American Indian/ Alaska Native (n = 10) respondents, and addressed behavioral intention to participate in both cancer treatment and prevention trials.[93] When asked "Why do you think people of your race do not participate in experimental studies?", the responses included "lack of information", "do not get involved", and "mistrust—do not like to be treated as guinea pigs." All of the participating groups reported "mistrust of white people" as a barrier. In a publication that was technically ineligible for this review, some investigators found that it took several years to build trust and lay the foundation for the conduct of cancer clinical trials with an American Indian/Alaska Native population.[103] Roberson reported that the American Indian/Alaska Native participants suggested that programs and studies be set up on reservations, and details, including benefits, be explained. They also suggested videos, fliers, free food and money as potential incentives for participation.

***Asian/Pacific Islanders.*** We did not find any evidence regarding barriers or promoters of participation in any type of cancer clinical trial for the Asian/Pacific Islander population. The only available evidence was that this population is under-represented in NCI-funded cancer clinical trials.[32]

**Barriers and Promoters in the Elderly.** Overall, there were 11 studies of barriers and promoters of enrollment of the elderly to cancer therapeutic trials. On average, each of these studies reported four barriers (range: 0 to 9). Among the studies of accrual to therapeutic trials, there were no promoters of awareness, two studies of promoters of opportunity, and six studies of promoters of acceptance. Of the 25 barriers to opportunity, the most frequently reported were age (n = 5),[66, 77,78,95,96] comorbidity exclusions (n = 3),[61,76,84] transportation (n = 2),[84,95] lack of or inadequate health insurance (n = 1),[84] and inability to understand the trial (n = 2).[84,95] In this population, concern about drug toxicity among both providers and participants (n = 2)[66,84] was an important barrier to participation, even though such concern may not be substantiated in the literature on the basis of elderly status alone.[104] Interestingly, in a study of protocol exclusion criteria that reduced the participation of the elderly in cancer clinical trials, Lewis and colleagues found that trials that did not specify life expectancy as an exclusion criteria resulted in relatively greater participation of elderly subjects than those that included this exclusion criteria.[61]

**Barriers and Promoters in Adolescents.** Only two of the available studies yielded evidence for our review of barriers to accrual of adolescents to therapeutic trials. Krailo and colleagues documented the lack of available trials as a significant barrier to enrollment of adolescents.[60] In addition, Broome and colleagues reported that adolescents who enrolled in a trial had traveled long distances and tended to be highly anxious; however, neither distance nor being anxious constituted a barrier to enrollment.[72] Similarly, financial incentives were neither a barrier nor a promoter of participation. Promoters of participation for this population included the perceived benefits of trial participation, including a chance for better treatment, and altruistic motives. However, some of the study participants had a limited understanding of a randomized controlled trial.

**Barriers and Promoters in Rural Populations.** Only two of the available studies focused on barriers to accrual of rural populations to cancer clinical trials. Paskett conducted serial cross-sectional surveys for an aggregate sample size of 360 physicians who serve a rural population.[46] The respondents identified the lack of education about clinical trials, and the lack of physician awareness about trials, as barriers. Additionally, they reported a number of barriers that reduced their opportunity to participate in clinical trials, including the logistical burden of trial participation, transportation, and established referral patterns. Moreover, the barriers to acceptance of trial participation were cost to the patient, perceived treatment risk, mistrust of research and of the medical system, the need to see an unfamiliar physician, and the perceived harms of trial participation. Randall-David conducted focus groups in the community on barriers to participation in prevention and treatment trials.[53] This study identified similar barriers and promoters to those reported by Paskett and colleagues, and included the lack of dissemination of study opportunities to providers and patients, the method of presentation of the trial to physicians and patients, and religious belief, as additional barriers. This study also included altruism and incentives (financial and otherwise) as promoters.

## Barriers and Promoters of Accrual to Prevention Trials in African-American Populations

Overall, there were 13 studies of barriers and promoters to accrual of African Americans to cancer prevention trials. These included three studies of accrual to a chemoprevention trial,[62,71,90] baseline data from the African American Men's (AAMEN) study,[43] and three studies of accrual to smoking cessation trials.[41,86,97] However, we did not include studies of accrual to other types of primary prevention trials (e.g., diet and exercise) in this systematic review.

**Barriers to Accrual to Prevention Trials in African-American Populations.** On average, each of these studies reported five barriers (range: 0 to 20). Among the 41 barriers to accrual to prevention trials, there were five barriers to awareness, and the most frequently reported among them were lack of education about clinical trials (n = 3)[74,80,92] and lack of dissemination of study opportunities to patient/provider (n = 2).[88,92] Of the reported 24 barriers to opportunity, the most frequently reported were costs (n = 3), [80,88,92] the study's duration and visit structure (n = 2),[88,92] the time commitment (n = 1), [97] and lack of transportation (n = 1).[97] Of the 13 barriers to acceptance, the most frequently reported were fear (n = 3),[74,88,92] mistrust of research and medical system (n = 8),[62,74,80,88-90,92,97] perceived harms of clinical trial participation (n = 4),[80,89,92,97] and family considerations (n = 1).[74]

***Chemoprevention Trials.*** [62,71,90] On average, each of the chemoprevention trials reported two barriers (range: 1 to 2). There were no barriers to awareness, two barriers to opportunity,[62,71] and three barriers to acceptance with mistrust of research reported in two studies.[62,90]

***Smoking Cessation Trials .***[41,86,97] Out of the three smoking cessation trials in African American populations, only one trial reported barriers to accrual.[97] The barriers were: transportation problems, time and family considerations, communication / methods of presentation, mistrust of medical research, perceived harms of trial participation, reluctance to quit smoking, and job issues.

***Screening Trials.*** [43] The AAMEN study is a randomized trial comparing four different strategies for accrual of African American men into the Prostate, Lung, Colorectal, and Ovarian (PLCO) trial. According to the baseline data from this enrollment trial, having an unlisted phone number was a statistically significant barrier to enrollment. Because the enrollment procedures included telephone-based recruitment, having an unlisted phone number functioned as a barrier to awareness about the study. Those who had been screened by the prostate-specific antigen-screening test within the previous three years were excluded from participation in the study. Interestingly, having a lower income level was a promoter of participation, suggesting both the lack of access to screening services in the targeted low-income African-American population, and the screening study as an opportunity for low-income men to access these services.

**Promoters of Accrual to Cancer Prevention in African-American Populations.** Among the 13 studies of barriers and promoters to accrual of African Americans to cancer prevention trials, each reported, on average, three promoters (range: 0 to 8). Among the 29 promoters of accrual to prevention trials, there were four promoters of awareness, each reported in a single study: reminder phone call,[97] adequate knowledge about the study,[80] a workshop on clinical trials,[80] and culturally relevant education about trials.[88] Of the 14 reported promoters of opportunity the most frequently reported was provision of transportation (n = 2).[80,97] Of the 12 promoters of acceptance, the most frequently reported was the use of incentives (n = 2).[80.97]

***Chemoprevention Trials.*** [62,71,90] Of the three chemoprevention trials that enrolled African Americans, only Mouton's study[90] reported promoters for a total of two promoters to acceptance: preference for the study's principal investigator to be Black, and perception that it is better to be treated by research doctors.

***Smoking Cessation Trials.*** [41,86,97] On average, each of the three smoking cessation trials reported five promoters (range: 3 to 8). While no promoters of awareness were reported, 11 promoters of opportunity were reported including provision of transportation,[97] communication/method of presentation,[41] and employment status.[86] The five reported promoters of acceptance were incentives, support, encouragement, prayer, the certainty of receiving actual medication, the impact of diagnosis on risk perception, and perceived benefit of trial participation.

***Screening Trials .***[43] Because the AAMEN study targeted a low-income African-American population, having a lower income level was a promoter of participation.

## Barriers and Promoters of Accrual to Prevention Trials Among Other Underrepresented Populations

Because of the limited evidence available regarding barriers and promoters of participation in cancer prevention trials in populations other than African Americans, we discuss these barriers and promoters together within each of the following paragraphs.

**Barriers and Promoters in Other Racial and Ethnic Minority Populations.**

***Latinos/Hispanics.*** Overall, there were four studies that reported evidence on barriers and promoters to accrual of Latino/Hispanics to cancer prevention trials,[41,42,62,74] and on average, each reported four barriers (range: 0 to 8). For this population, there was only one reported barrier to awareness, the lack of education about clinical trials.[74] Of the reported seven barriers to opportunity, the most frequently reported was transportation (n = 2).[42,74] Of the seven barriers to acceptance, the most reported was mistrust of research and the medical system (n = 2).[62,74]

***American Indian/Alaska Natives.*** The limited amount of evidence available for the American Indian/Alaska Native population with regard to accrual to clinical trials in general, was discussed in the section on barriers and promoters to accrual to therapeutic trials.

***Asian/Pacific Islanders.*** We did not find any evidence regarding barriers or promoters of awareness, opportunity or acceptance of cancer clinical trials for this population. The only available evidence was that this population is underrepresented in NCI-funded cancer clinical trials.[32]

**Barriers and Promoters in 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).[43,48] On average, each of these studies reported one barrier (range: 0 to 3). 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,[87] age,[48] and low-income status.[43]

**Barriers and Promoters in 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.[46,53]

## Grading of the Total Body of Evidence

The overall evidence denotes a wide variety of barriers and promoters that have an influence on the participation of underrepresented populations into cancer clinical trials. However, the overall was considered to be very low due to the limitations in quality and precision as well as the lack of strong evidence within the studies (see Table 9). In addition, a high probability of reporting bias existed within the studies. The evidence is based on 45 studies, 34 of which addressed cancer treatment trials, 16 of which addressed cancer prevention trials, and five of which addressed trials for both cancer treatment and prevention. While the studies were heterogeneous and contained over 35,000 participants in total, the majority of the studies generally focused on an African American population and an elderly population. Other underrepresented populations such as Latinos/Hispanics, Native Americans/Alaska Natives, Asian/Pacific Islanders, adolescent or rural populations were scarcely evaluated.

## 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 socio-demographic factors: age (n = 16)[32,43,47,48,50,58,60,64,66,75,77,78,86,90,95,96]; gender (n = 3)[32,70,75]; SES (n = 4)[32,43,44,86]; race/ethnicity (n = 4).[32,41,47,75] These barriers and promoters related most frequently to study design barriers, including exclusion by age (n = 3),[58,60,64] study duration and visit structure (n = 4),[44,79,88,92] comorbid conditions (n = 7),[44,58,61,69,76,84,92] and functional status (n = 4).[58,60,68,75] 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.

Few of the eligible studies attempted to assess whether the identified barriers or promoters varied by SES. However, some included measures of SES, such as income, education, suburban residence, and having a functioning telephone, in association with recruitment outcomes. A relatively large proportion of eligible studies reported on barriers or promoters of accrual of African Americans (n = 27). However, in this population as well as other groups, it was difficult to separate race/ethnicity and SES, central defining characteristics of some of the under-represented populations, from the barriers themselves.

## Key Question 5b: Effects of Cultural Factors

Three of the studies reported that barriers or promoters of enrollment varied by cultural factors, 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: What Effects do the Attitudes and Perceptions of Healthcare Providers Have on the Efficacy/Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials?

## Identification of Relevant Articles

In reviewing the current literature on question 6, we found a total of 10 eligible articles.[46,56,64,66,84,88,92,95,100,101] Details about these studies are given in Table 7, and Evidence Tables 6-1, 6-2, 6-3, and 6-4 in Appendix F.

## Study Characteristics

Of the 10 studies eligible for review, two were published before 1990,[95,101] three were published between 1990 and 1999,[55,88,100] and five were published after 2000[46,64,66,76,92](see Evidence Table 6-1 in Appendix F). The study designs used were concurrent controlled trial (n=1),[46] case-control (n=1),[66] or descriptive (n=8)[56,64,84,88,92,95,100,101] with three of the studies also employing qualitative techniques to facilitate in-depth assessments of physician attitudes and perceptions. Nine were U.S.-based studies and one was a British-based study. All were recruiting into treatment trials; three of the studies were also recruiting into prevention trials.

## Target Population Characteristics

Seven studies[46,56,84,88,95,100,101] targeted physicians, one targeted physicians/investigators[92] and two studies[64,66]targeted patients/participants as the study group of interest. Specific methods and techniques employed in these studies included surveys (n=8) that were implemented either via mail,[46,56,84,100,101] telephone,[66] or other methods. Other methods employed to assess physician barriers to enrolling patients into clinical trials were focus groups,[92] workshops,[88] and face-to-face interviews[95] (Evidence Table 6-2 in Appendix F).

Two studies employed physician interventions to increase patient accrual to clinical trials[46,88]with only one measuring the outcomes of their interventions.[46]

Six of the studies targeted at least one of the underrepresented populations as a primary goal of the study. Three studies targeted either racial or ethnic minorities[88,92] two studies targeted the elderly,[66,84] and one study targeted rural populations.[46] Four studies did not target an underrepresented population as a primary endpoint; however, data were presented on advanced age[92,95,100] and social class (non-U.S. study)[106] to merit their inclusion in this report.

## Quality of Studies

We evaluated the quality of studies in each of five areas or domains: 1) representativeness, 2) justification of study methods, 3) reliability and validity of data collection methods, 4) potential

for bias/confounding, and 5) data analysis. Selected aspects of study quality are summarized in Evidence Table 6-3 (see Appendix F).

In terms of representativeness, the studies were fairly well described (four clearly described study participants). For justification of study methods, five studies adequately documented the rationale for their studies. With the exception of one study,[100] the study instruments used in the surveys and the data collection methods used in the qualitative studies had serious limitations in reliability and validity. Five studies used adequate measures to protect against bias or confounding. For studies that used surveys as part of data collection, this was based on participant response rate and selection of subjects; for studies that used qualitative techniques to collect data, this was based on the selection of subjects. In terms of the description of the data analysis, all studies were inadequate in their reporting.

## Results of Studies

**Role of provider attitudes.** 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[46,66,92,101] while one study found provider attitudes to be a promoter of patient accrual.[84] The studies also reported that patient age,[66,95,101] comorbidity,[66,95] disease stage,[66] mistrust of researchers,[88,92] and lack of physician awareness about trials[88,92]were factors that prevented providers from enrolling their patients into clincial trials. Two studies[56,100] 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.[84]

For studies that targeted minority populations,[64,88,92] mistrust of researchers and lack of provider awareness about trials were leading provider barriers[88,92]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.[64]

For studies that targeted the elderly, provider attitudes regarding clinical trials prevented them from sharing information about trials to their patients in one study,[66] and increased their willingness to enroll patients in clinical trials in another study[84] (Evidence Table 6-4 in Appendix F).

**Study design barriers.** Eight studies evaluated the role a clinical trial's study design plays in the ability to accrue underrepresented populations to cancer clinical trials. Four studies reported issues with the protocol itself with the length of the trial and visit structure being issues in two studies,[88,92] the strictness of the protocol in one study,[92] and the amount of travel, failure to use the most effective drug, and the number of required lab tests being issues in one study.[94] We also found that accrual to cancer treatment trials was decreased by study design issues including comorbid conditions,[84,92] age exclusion,[84,92] eligibility criteria,[56] issues with randomization,[92] medication exclusion,[64] treatment toxicity and side-effects,[95] life expectancy,[84] and disease stage/location[100] (Evidence Table 6-4 in Appendix F).

**Health care system.** Two studies[88,92] reported that the healthcare system itself played a role in decreased patient accrual to cancer clinical trials. Both studies found that a lack of dissemination of study opportunities to providers made it difficult for them to match potentially eligible patients to cancer clinical trials. Additionally, Pinto et al.[92] found that a lack of cultural

competence among providers and/or staff as well as a lack of patient access to institutions conducting the clinical trials made it difficult to accrue patients to these trials. McCaskill-Stevens et al.[88] found that a lack of minority investigators and personnel impeded accrual (Evidence Table 6-4 in Appendix F).

Clearly the impact of the provider on accrural has not been completely elucidated. While our review highlights that the role of individual level provider factors, study design and system level factors may be important to the accrual process, it is still unclear how these factors relate to each other, which are most important, if temporal or spatial effects occur or if any of these factors are synergistic.

## Grading of the Total Body of Evidence

As summarized in Table 10, we assessed the quantity, quality, and consistency of evidence on Question 6 and concluded that the studies merited an overall "very low" evidence grade. This grade is based primarily on the fact that all ten studies scored below the 50th percentile in the quality rating, with two scoring below the 25th percentile, based on study representativeness, justification, bias, reliability/validity, and statistical analysis. Additionally, points were deducted for imprecision or sparcity of data as well as the high probability of reporting bias, based on the study designs. Thus, the evidence was insufficient to determine with any confidence how healthcare providers' attitudes and perceptions influence the efficacy/effectiveness of strategies for recruitment of underrepresented populations into cancer treatment and prevention trials. This evidence is based on studies where approximately 1,178 providers were interviewed or surveyed. Furthermore, the studies were heterogeneous in what underrepresented population they targeted.

# Chapter 4. Discussion

Since the enactment of the NIH Revitalization Act in 1993,[31] cancer researchers have made significant efforts to discover evidence regarding barriers to participation in clinical trials, especially for ethnic minority populations. While some advances have been made in defining these barriers, significant gaps remain in the available evidence in regard to efficacious and/or effective interventions to improve enrollment to cancer clinical trials. It is essential to address these gaps in the evidence to fulfill the intent of the NIH Revitalization Act. Only a small proportion of cancer patients are enrolled in cancer clinical trials and recent evidence indicates that racial and ethnic minorities, adolescents, the elderly, rural populations and individuals of low socioeconomic status in general, are underrepresented in NCI-funded cancer clinical trials.[68] We undertook a systematic review to: 1) assess existing evidence regarding barriers and promoters of participation in cancer clinical trials; 2) understand the influence of physicians' attitudes on the accrual process; and 3) gain insight into research strategies to further develop the evidence in support of interventions to improve accrual to cancer clinical trials. While African American women are not underrepresented in cancer clinical trials, we examined the evidence from that population, as it may be relevant to barriers and promoters of enrollment of African American men to cancer clinical trials.

## Questions 1 and 2. Methods to Study Recruitment Strategies

The available evidence is limited by the methods that have been used to date to study barriers and promoters of accrual to cancer clinical trials. A large proportion of the eligible studies were developed by convenience, i.e., as a way to describe investigators' experience with recruitment of underrepresented populations. The available literature included some well-designed qualitative as well as quantitative studies, including controlled clinical trials. However, the methodological limitations of the available studies leave serious gaps in knowledge and information about efficacious and effective strategies to improve participation of underrepresented populations in cancer clinical trials. These gaps must be addressed in the context of well-designed studies that are informed by the accumulated evidence.

One component missing in the literature is an agreement on what constitutes a "success measure" in terms of enrollment. The lack of agreed upon measures of success may be a key determinant of the lack of representation of certain population subgroups in accrual to cancer clinical trials. Several of the available studies offer excellent examples of approaches to characterize accrual data in a meaningful way in relation to a specific population. One approach is to obtain proportional representation relative to the U.S. population.[32, 61] Another is to include a study population that features enrollment of population subgroups in proportion to the relative cancer incidence in each of the subgroups. In certain instances, investigators may also over-sample certain underrepresented populations in an effort to enable meaningful subgroup analyses of underrepresented groups (e.g., the proportion necessary for subgroup analysis). The planning, design, implementation, and evaluation of a recruitment strategy are integral to the successful conduct of a clinical trial. Therefore, investigators should give careful thought to success

measures for recruitment of underrepresented populations, and avoid setting such measures arbitrarily. Additionally, researchers should evaluate and report recruitment results for underrepresented groups more frequently. Such reports should not be based on the aggregate experience from multiple trials, but they should be based on the recruitment strategies for individual cancer clinical trials. Using better measures of success will help investigators improve the generalizability of cancer trial results to many different populations. It will also help identify effective recruitment strategies for underrepresented populations. Moreover, success in recruitment of these populations may provide novel insights into risk factors and the natural history of disease through hypothesis-driven subgroup analyses.

## Questions 3, 4, 5, and 6. Barriers and Promoters of Participation in Cancer Clinical Trials

We developed a conceptual framework to guide our analysis of barriers and promoters of participation of underrepresented populations in cancer clinical trials. Our approach takes account of the fact that in order to participate in a clinical trial, an individual must be aware of the trial, have the opportunity to participate, and be willing to accept participation. The barriers and promoters span the continuum from awareness to acceptance, and they differ depending on the population and whether recruitment is to a treatment trial or to a prevention trial. Moreover, within cancer treatment trials, the barriers may differ when comparing early-phase trials to phase III, controlled clinical trials; however, we did not address this question because very few of the eligible studies distinguished between trial phases. While a number of publications have contributed important evidence regarding key barriers and promoters of participation in cancer clinical trial, the evidence remains limited. Based on our systematic review, the most frequently reported barriers across multiple underrepresented populations are: 1) mistrust of researchers and the medical system[44,46,53,62,74,79-82,88-94,97]; 2) the perceived harms of participation in a cancer clinical trial[46,50,53,79,81,82,89,91,92,94,97]; 3) the availability of transportation[42,44,46,53,74,82,84,95,97]; 4) lack of education about clinical trials[46,50,53,74,79,80,91-94]; and 5) the time commitment required for participation in a trial.[42,47,53,79,81,91,93,97] The most frequently reported promoters are: 1) patient[80-82,93,94,97] and provider incentives[44,53,92]; 2) altruism[50,53,72,81,82,89]; and 3) culturally relevant education about trials.[88,92-94] Consistent with our conceptual framework, these documented barriers and promoters intervene at the level of awareness about clinical trials, the opportunity to participate, and decision-making about participation in a trial.

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. The studies reported included seven barriers to awareness of cancer clinical trials, 80 barriers to the opportunity to participate in a cancer trial, and 40 barriers to acceptance of enrollment. Among these, 63 barriers were relevant at the patient level, 31 at the provider level, 20 at the study design level and seven at the healthcare systems level. The available evidence suggests that barriers that reduce the opportunity to participate in a trial are the most frequent factors limiting enrollment to both cancer prevention and treatment trials, especially for the elderly and racial and ethnic minority populations. The barriers that limit accrual opportunities include study design barriers such as age, exclusion criteria (e.g., comorbidity and functional status), lack of transportation, and lack

of adequate health insurance. The high frequency of opportunity barriers signals the need for interventions directed to this type of barrier.

Despite an extensive list of documented promoters of participation, we were able to identify only five studies that compared two or more interventions to improve enrollment to cancer clinical trials. These included one well-designed randomized controlled trial comparing multiple intervention strategies for accrual to the Prostate, Lung, Colorectal and Ovarian (PLCO) cancer screening trial.[43] In that study, we learned that a face-to-face recruitment strategy is superior to other, less intensive recruitment strategies in the context of the screening trial. However, the available evidence on efficacious strategies to improve participation in cancer clinical trials remains woefully inadequate.

The nature and extent of the barriers and promoters of accrual differ across the underrepresented populations. For example, while the elderly have access to Medicare, many clinical trials remain functionally inaccessible to this population, because of study design barriers, including age restrictions, as well as provider fears about drug toxicity, that in many instances may be unsubstantiated.[104] For adolescents,[60,72] the major barrier is the lack of accessible trials; and for rural populations, transportation is a major barrier.[46,53] For African-American[32,41,43,47,50,58,62,64,66,69-71,74,75,79-81,85,86,88-94,97] and Latino/Hispanic populations[32,41,42,62,66,74,93] there are identifiable barriers through the continuum from awareness to acceptance of participation. However, we found no available evidence on barriers and promoters of enrollment to cancer clinical trials for the Asian and Pacific Islander population, and only one for the American Indian and Alaska Native population.[93] Strategies for acquiring evidence to improve participation of underrepresented populations in cancer clinical trials must be informed by this diversity of barriers and promoters, and gaps in available evidence. Moreover, because of the overlap across the identified underrepresented populations and the geographic dispersion and cultural heterogeneity within each of the underrepresented populations, interventions to improve accrual to cancer clinical trials will need to be tailored to the cultural background of the targeted population and grounded in the local reality.

Overall, the mixed results of the interventions mentioned in these studies denote a continuing need for future evaluations of additional recruitment interventions, including clinical trials that compare the relative efficacy of promising interventions to improve accrual. This lack of consistency also reflects the limitation of available studies on specific populations in varying locations.

So, given the extensive list of barriers and promoters and the heterogeneity of the underrepresented populations, where do we begin? Clearly, it would be difficult to address each of the types of identified barriers individually, considering that each individual targeted for enrollment is likely to present multiple barriers to participation. Since the available evidence indicates that certain barriers may be universal, strategic interventions directed at some of the most frequent barriers may indeed be efficacious, effective and cost-effective, to improve cancer clinical trial enrollment. However, investigators must approach this issue with caution, given the uncertainty regarding the available evidence. Future research studies should give consideration to system-level interventions to address multiple barriers and promoters, with tailoring based on known, culturally specific, as well as patient-identified barriers. Several of the eligible studies recommended the use of personnel who are known to the community, in efforts to improve accrual to cancer clinical trials. Such individuals can be trained to promote awareness about cancer clinical trials in the community and to identify and solve barriers for individual patients in collaboration with the research team. The efficacy and cost-effectiveness of this approach needs

to be evaluated further as a comprehensive solution for barriers to accrual to cancer clinical trials. In addition, the research designs should emphasize interventions that have a high likelihood of institutionalization, through their integration into the routine conduct of cancer clinical trials in comprehensive cancer centers, cancer research centers, and in the wider community. Indeed, the evaluation of the relative cost-effectiveness of different intervention strategies to improve accrual to cancer clinical trials is a serious gap that will need to be addressed in future studies.

For several of the eligible publications, the primary outcome variable in regard to trial accrual was behavioral intention, rather than actual participation in a cancer clinical trial.[50,53,71-75,77,79-85,88-95] Primary prevention, chemoprevention and screening trials target individuals who do not have disease, and studies of attitudes and behavioral intention toward participation in clinical trials have been used in preparation for both cancer prevention trial, and for the implementation of educational campaigns to improve accrual to clinical trials. The literature provides few examples of translation of the results of studies of behavioral intention to participate in clinical trials into studies of accrual to therapeutic trials. It remains unclear whether behavioral intention expressed by individuals at risk for cancer is a good predictor of actual participation in cancer treatment trials. This is particularly salient when viewed within the context of the change in perceived risks to cancer and the immediacy of the perceived risks and benefits of trial participation following the diagnosis of cancer. To develop the evidence needed to improve accrual strategies for cancer therapeutic trials, investigators will need to use studies of behavioral intention to prepare and refine recruitment intervention strategies that would eventually be applied to patients, and emphasize studies of accrual to actual trials.

The evidence suggests that special attention needs to be given to the barriers to participation in cancer clinical trials at the physician level. Clinicians form relationships with patients before they are diagnosed with cancer and they play an influential role in advising patients regarding participation in a trial. However, they often have limited awareness about opportunities to participate in trials, the trials often do not make sense to them from a fiscal point of view, and for elderly patients, some providers have serious concerns about the risks of participation in cancer clinical trials. Like cancer patients and individuals at risk for cancer, healthcare providers base their decisions on the balance of risks and benefits of trial participation, as well as their individual and organizational interests. While several studies have suggested the use of provider incentives [44,53,92] as a strategy for improving trial accrual, this idea has not received the appropriate level of attention in the available evidence. Here again, given the heterogeneity of clinical practice contexts, intervention strategies must be adapted to this context and have a high likelihood of being sustainable.

## Limitations

This systematic review addresses barriers and promoters of participation to cancer clinical trials among populations that have been underrepresented in NCI-funded cancer clinical trials, namely, the elderly, adolescents, African Americans, Latinos/Hispanics, American Indians/Alaska Natives, rural populations and populations of low socioeconomic status in general. There is extensive overlap across these populations, and the population descriptions in

the available studies may not always have captured the extent of such overlap, in terms of race/ethnicity, residence, socioeconomic status, or even age.

Our search strategy included strict eligibility criteria, and it is possible that some relevant evidence was not included in the review. We found several articles that did not meet our initial eligibility criteria, but that contained important information regarding barriers and promoters of accrual to cancer clinical trials.[76,82,83,87,96] For this reason, although the eligible articles were initially limited to U.S.-based studies, we included some relevant evidence from non-US based studies.

We found some excellent examples of well-designed studies of enrollment to cancer screening programs,[102,103,104] but the systematic review was limited to studies about recruitment of patients into cancer clinical trials. Nevertheless, we believe that some of the strategies that have been used in those programs may be relevant, especially to enrollment strategies for cancer prevention and screening trials.

Within cancer treatment trials, the barriers may differ when comparing early-phase trials to phase III, controlled clinical trials. However, we did not find enough evidence to specifically address this question.

We have pointed out some of the limitations of the available evidence in regard to: 1) representativeness; 2) justification of study methods; 3) reliability and validity of data collection methods; 4) the potential for bias/confounding; and 5) data analysis. We used a standardized approach to generate the body of evidence that is presented in this review, and although individually some of the studies limit our ability to reach firm conclusions, the sum of the evidence and its consistency across multiple studies allow us to formulate some recommendations for future research.

# Conclusions

The results of many of the studies that we reviewed necessitate cautious interpretation, due to limitations of the study designs and settings, and the limited quality of a large proportion of the available publications. However, the available studies have generated, and in a few instances tested, hypotheses about determinants of accrual to cancer clinical trials. In addition, they have provided evidence for a large number of barriers and promoters of participation, some barriers and promoters being consistent across multiple studies and across underrepresented populations.

Our search yielded limited information on certain populations, most notably the Asian/Pacific Islander, American Indian/Alaska Native, Latino/Hispanic, rural, and adolescent populations. This limits the depth of possible recommendations for these populations. Similarly, there is a continuing need for evidence of interventions that work for African-American men. Moreover, the evidence base needs to address how sociodemographic and cultural norms, values, and beliefs modify the known barriers. This is strongly suggested by the available evidence, but it is not defined.

We found very few studies comparing two or more strategies in regard to their efficacy to increase accrual of underserved populations to cancer clinical trials.[41,43,45,52,62] This is an important gap in the evidence base that must be overcome.

Overall, the grade of the evidence on barriers and promoters of accrual of underserved populations to cancer clinical trials is low. However, the consistency of some of the barriers and

the sheer number of barriers suggest the need for evidence-based interventions to address multiple barriers to accrual to cancer clinical trials.

We recognize that even if members of underrepresented populations do participate in cancer clinical trials, and reporting and recruitment are adequate, the benefits of clinical trial knowledge may not translate into improved cancer outcomes for these populations due to other factors. If systemic inequities in the healthcare delivery system persist, including in access to high quality care, the availability of perfect research data may not benefit underrepresented populations so much as other populations.[5] Therefore, recruitment efforts to cancer clinical trials must interface with other ongoing initiatives designed to address cancer health disparities through discovery, development, and delivery, and to overcome the critical disconnect between discovery and development on the one hand, and delivery of cancer care on the other.

## Recommendations and Research Opportunities

- 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.

- Because of many underrepresented populations' mistrust of researchers and of research institutions,research efforts to improve participation of underrepresented 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 treatment trials.

- There is an urgent need to understand why participation of the Asian / 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 Latina/Hispanic women) have been shown to be effective in increasing accrual to clinical trials. Such interventions should be replicated, for use in recruitment to different types of cancer trials, and where appropriate, the results should be disseminated widely.

- To advance the evidence regarding efficacious strategies for improving enrollment to cancer clinical trials,recruitment 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 healthcare system and of the research team. To facilitate the integration of recruitment interventions into healthcare 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, and to 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.

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Taylor KM, Kelner M. Interpreting physician participation in randomized clinical trials: the Physician Orientation Profile. J Health Soc Behav 1987;28(4):389-400.
**other: does not address underserved populations**

Taylor KM, Margolese RG, Soskolne CL. Physicians' reasons for not entering eligible patients in a randomized clinical trial of surgery for breast cancer. N Engl J Med 1984;310(21):1363-7.
**other: does not address underserved populations**

Taylor KM. Physician participation in a randomized clinical trial for ocular melanoma. Ann Ophthalmol 1992;24(9):337-44.
**other: no barriers to an underserved group reported**

Trauth JM, Musa D, Siminoff L, et al. Public attitudes regarding willingness to participate in medical research studies. J Health Soc Policy 2000 ;12(2):23-43.
**other: does not address underserved populations**

Tworoger SS, Yasui Y, Ulrich CM, et al. Mailing strategies and recruitment into an intervention trial of the exercise effect on breast cancer biomarkers. Cancer Epidemiol Biomarkers Prev 2002;11(1):73-7.
**other: primary prevention trial**

Wang LD, Zheng S, Zheng ZY, et al. Primary adenocarcinomas of lower esophagus, esophagogastric junction and gastric cardia:in special reference to China. World J Gastroenterol 2003;9(6):1156-64.
**no original data**

Weijer C, Freedman B, Shapiro S, et al. Assessing the interpretation of criteria for clinical trial eligibility: a survey of oncology investigators. Clin Invest Med 1998;21(1):17-26.
**does not report a controlled trial or recruitment to a controlled trial**

Weinrich SP, Ellison GL, Boyd M, et al. Participation in prostate cancer screening among low-income men. Psychol Health Med 2000;5(4):439-450.
**does not report a controlled trial or recruitment to a controlled trial**

Weinrich SP, Greiner E, Reis-Starr C, et al. Predictors of participation in prostate cancer screening at worksites. J Community Health Nurs 1998;15(2):113-29.
**does not report a controlled trial or recruitment to a controlled trial**

Weinrich SP, Weinrich M, Mettlin C, et al. Urinary symptoms as a predictor for participation in prostate cancer screening among African American men. Prostate 1998;37(4):215-22.
**does not report a controlled trial or recruitment to a controlled trial**

Winn RJ, Miransky J, Kerner JF, et al. An evaluation of physician determinants in the referral of patients for cancer clinical trials in the community setting. Prog Clin Biol Res 1984;156:63-73.
**other: does not address underserved populations**

Woods VD, Montgomery SB, Herring RP. Recruiting black/African American men for research on prostate cancer prevention. Cancer 2004;100(5):1017-25.
**does not report a controlled trial or recruitment to a controlled trial**

Wright JR, Crooks D, Ellis PM, et al. Factors that influence the recruitment of patients to Phase III studies in oncology: the perspective of the clinical research associate. Cancer 2002;95(7):1584-91.
**other: does not address underserved populations**

Yancey AK, Miles OL, McCarthy WJ, et al. Differential response to targeted recruitment strategies to fitness promotion research by African-American women of varying body mass index. Ethn Dis 2001;11(1):115-23.
**other: primary prevention trial**

Yeomans-Kinney A, Vernon SW, Frankowski RF, et al. Factors related to enrollment in the breast cancer prevention trial at a comprehensive cancer center during the first year of recruitment. Cancer 1995;76(1):46-56.
**other: does not address underserved populations**

Yoder LH, O'Rourke TJ, Etnyre A, et al. Expectations and experiences of patients with cancer participating in phase I clinical trials. Oncol Nurs Forum 1997;24(5):891-6.
**other: does not address underserved populations**

Yu M, Seetoo AD, Hong OS, et al. Cancer screening promotion among medically underserved Asian American women:integration of research and practice. Res Theory Nurs Pract 2002;16(4):237-48.
**does not report a controlled trial or recruitment to a controlled trial**

Zabora JR, Morrison C, Olsen SJ, et al. Recruitment of underserved women for breast cancer detection programs. Cancer Pract 1997;5(5):297-303.
**does not report a controlled trial or recruitment to a controlled trial**

**Figure 1. Conceptual Framework.**

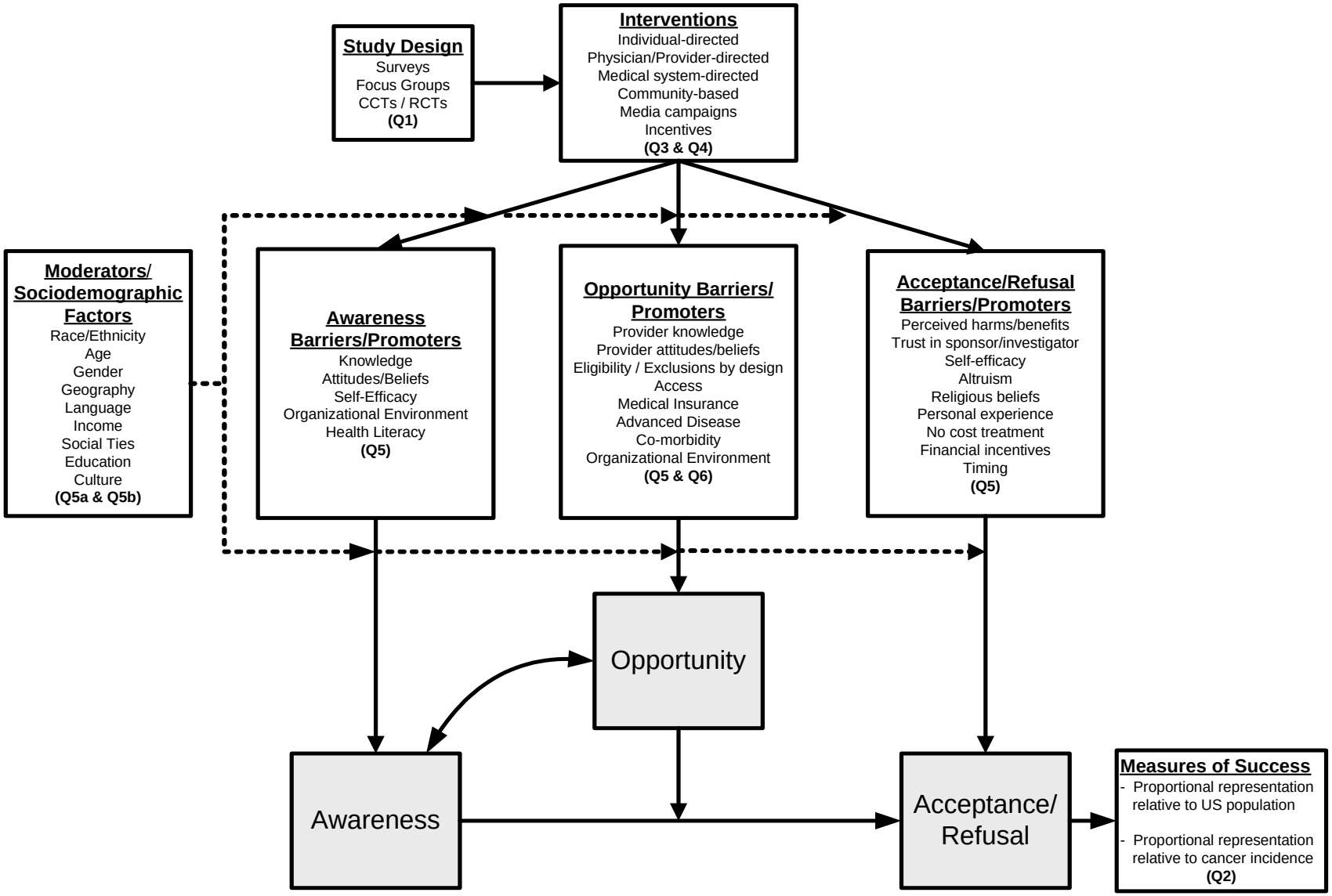
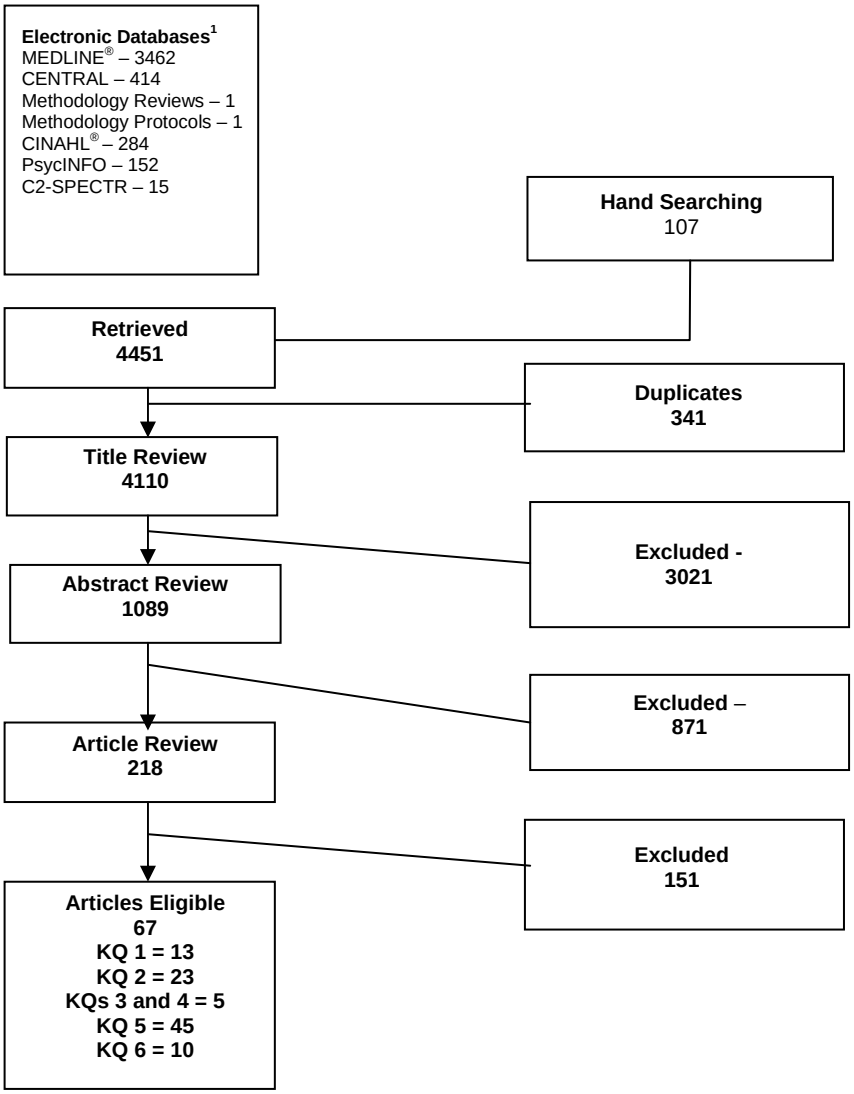


**Figure 2. Summary of literature search and review process (number of articles).**




[1] CENTRAL - the Cochrane CENTRAL Register of Controlled Trials; CINAHL® - Cumulative Index of Nursing and Alliance Health Literature; PsycINFO - ; C2-SPECTR – The Campbell Collaboration's Social, Psychological, Educational, and Criminological Trials Registry; KQ, Key Question

**Table 1. Summary of the Characteristics of Studies about Strategies to Recruit Underrepresented Populations to Cancer Prevention and Treatment Trials (Key Question 1).**

| Author, Year | Study Setting | Study Design | Study Objective(s) | Type of Cancer Studied | Target Population | Sample Size | Mean Age, y | % Male | % Under-represented | Recruitment Dates |
|---|---|---|---|---|---|---|---|---|---|---|
| Advani, 2003 | Hospital outpatient | Case-control | A. To determine if AA oncology patients are less willing to participate in clinical trials.<br>B. To better delineate existing barriers to recruitment in AAs.<br>C. To compare attitudes of oncology patients who were treated in rural areas compared to a major medical center. | Solid or hematologic malignancy (excluding melanoma) | Patients/ Participants | 218 | NR | NR | 33% AIAN; 64% rural | NR |
| Berman, 1998 | Community | Quasi-experimental | To determine whether there are racial and ethnic differences in recruitment. | Smoking cessation | Patients/ Participants | 435 | NR | 0 | 15% AA; 85% Latino/ Hispanic | 1990-1992 |
| Brewster, 2002 | Community; Hospital outpatient | CCT | To review and compare the recruitment strategies associated with recruiting Latinas into cancer prevention trials. | Cervical | Patients/ Participants | 2,583 | 43 | 0 | 78% Latino/ Hispanic; 39% with <$10,000/ yr income | 1999-2000 |
| Ford, 2004 | Community | RCT | A. To demonstrate that low-income and moderate to high income older AA men can be recruited into a cancer trial.<br>B. To identify a method for increased participation of older AA men in cancer screening trials. | Prostate, lung, colorectal | Patients/ Participants | 12,400 | 62 | 100 | 100% AA; 100% elderly; 35% low SES | 1996-2001 |
| Kaluzny, 1993 | Community; Hospital outpatient; Group practice | Qualitative | To describe the early implementation of the MBCCOP and identify the challenges that have emerged in developing a network aimed at increasing the participation of minority populations in clinical trials. | All | Patients/ Participants ; Physicians | NR | NR | NR | NR | 1990-1992 |

**Table 1. Summary of the Characteristics of Studies about Strategies to Recruit Underrepresented Populations to Cancer Prevention and Treatment Trials (Key Question 1). (continued)**

| Author, Year | Study Setting | Study Design | Study Objective(s) | Type of Cancer Studied | Target Population | Sample Size | Mean Age, y | % Male | % Under-represented | Recruitment Dates |
|---|---|---|---|---|---|---|---|---|---|---|
| Linnan, 2002 | Work site; Workers' homes | CCT | A. Describe organizational factors associated with each selected employee - recruitment method.<br>B. Investigate differences in employee reaction to enrollment and attrition based on elected recruitment method.<br>C. Compare self-reported health behaviors and motivational readiness to change among employees enrolled in home-based intervention study by recruitment method. | Lung | Patients/ Participants | 10,014 | 43 | 53 | 6% Latino/ Hispanic; 27% with <$29,999/ yr income | NR |
| Maurer, 2001 | Hospital inpatient | Case series | To determine whether participation in clinical trials would lead to generalizeable changes in patterns of care from before to after implementation. | Breast, colon, rectum, lung, prostate | Patients/ Participants | 75 | NR | NR | 100% rural | 1993-1997 |
| Paskett, 1995 | Community | Descriptive | A. Evaluate a Rural Cancer Care Intervention.<br>B. Assess rural-based primary care physician knowledge, attitudes, and beliefs about patient and physician barriers to cancer clinical trials and accrual to clinical treatment trials. | Colorectal | Physicians | 2,079 | NR | NR | NR | 1991-1993 |
| Paskett, 2002 | Community | CCT | To develop and test an intervention to involve community physicians in clinical trial research. | Breast, colorectal | Physicians | 364 | 47 | 84 | 100% rural | 1993-1996 |

**Table 1. Summary of the Characteristics of Studies about Strategies to Recruit Underrepresented Populations to Cancer Prevention and Treatment Trials (Key Question 1). (continued)**

| Author, Year | Study Setting | Study Design | Study Objective(s) | Type of Cancer Studied | Target Population | Sample Size | Mean Age, y | % Male | % Under-represented | Recruitment Dates |
|---|---|---|---|---|---|---|---|---|---|---|
| Randall-Davis, 2001 | Unclear | Qualitative | To elicit perceptions of urban and rural adults regarding participation in cancer clinical trials. | All | Patients/ Participants | 37 | 55 | 0 | 100% rural | NR |
| Sears, 2003 | Community | RCT; Retrospective | To examine recruitment, retention, and predictors of participation. | Breast | Patients/ Participants | 2,242 | 57 | NR | 6% AA; 9% Asian/PI | 1999-2000 |
| Thornquist, 1991 | Community | Descriptive; Retrospective | To describe any differences in accrual and adherence to trial by age group or by gender. | Lung | Patients/ Participants | 2284 | NR | 53 | 23% elderly | 1985-1988 |
| Zhu, 2000 | Community | Descriptive; Qualitative | Present the strategy and outcomes of recruitment strategies to recruit elderly AA women in prevention and control studies. | Breast | Physicians | 367 | NR | 0 | 100% AA; 100% elderly; 91% with <$15,000/ y income | NR |

AA = African American
AIAN =American Indian/ Alaskan Native
CCT = Concurrent controlled trial
MBCCOP = Minority Based Community Clinical Oncology Programs
NR = not reported
PI = Pacific Islander
RCT = Randomized clinical trial
SES = socioeconomic status

**Table 2. Studies about Measures of Success used to Evaluate the Effectiveness of Strategies for Recruitment of underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2).**

| Author, Year | Country | Mean Age, y (Range) | % Male | % Under-represented group(s) | Study Setting | Target Population | Study Design | Type of Cancer Studied | Was Recruitment Goal Stated a Priori (Y/N). If yes, what was goal (in %)? | Recruitment Success Measure | For Which Underserved Group was Measure of Success Used? |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Treatment Trials** | | | | | | | | | | | |
| Benson, 1991 | U.S. | NR | NR | 10% AA; 6% Lat/Hisp; 51% elderly | Clinical Trials Cooperative Group (1839 hospitals, 194 universities) | Patients/ Participants | Cross-sectional; Retrospective | All | NA | Disease-specific proportion in U.S. | AA; Lat/Hisp |
| Goodwin, 1988 | U.S. | 53 | NR | 15% elderly | SWOG | Patients/ Participants | Cross-sectional; Retrospective | All | NA | Researcher set: New Mexico non-SWOG cancer trials proportion of underserved groups | Elderly |
| Hunter, 1987 | U.S. | NR | 43 | 4% AA; 3% Lat/Hisp | Hospital inpatient; Hospital outpatient; | Patients/ Participants | Cross-sectional; Retrospective | All | NA | Disease-specific proportion in U.S.: Compared CCOP participation to SEER data from 1973-1977 | AA; Elderly |
| Kaluzny, 1993 | U.S. | NR | NR | | Community; Hospital outpatient; Group practice | Patients/ Participants; Physicians | Descriptive | All | NA | Researcher set: Proportion of minority-based CCOP eligible patients compared to annual proportion of CCOP eligible patients who entered trials from 1985-89 | AA; Lat/Hisp |

**Table 2. Studies about Measures of Success used to Evaluate the Effectiveness of Strategies for Recruitment of underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2). (continued)**

| Author, Year | Country | Mean Age, y (Range) | % Male | % Under-represented group(s) | Study Setting | Target Population | Study Design | Type of Cancer Studied | Was Recruitment Goal Stated a Priori (Y/N). If yes, what was goal (in %)? | Recruitment Success Measure | For Which Underserved Group was Measure of Success Used? |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Kemeny, 2003 | U.S. | 48 (young group), 74 (older group) | 0 | 50% elderly | Community | Patients/ Participants | Case-control | Breast | NA | Researcher set: Proportion underserved offered a cancer trial | Elderly |
| Kladbunde, 1999 | U.S. | NR | 29 | 29% AA | CCOP, Hospitial inpatient | Patients/ Participants | Retrospective | All | NA | Research institution proportion | AA |
| Lewis, 2003 | U.S. | | | 32% elderly | NCI cooperative groups | Patients/ Participants | Cross-sectional; Retrospective | All | NA | Disease-specific proportion in U.S. | Elderly |
| Maurer, 2001 | U.S. | NR | | 100% rural | Hospital inpatient | Patients/ Participants | Case series | Breast, colon, rectum, lung, prostate | No elderly goal, Yes-rural goal; 40% of incident cancer cases & 54% would be eligible | Researcher set: proportion underserved based upon elements from another study for rural and proportion underserved participated in trial for elderly | Elderly, rural |
| Murthy, 2004 | U.S. | NR (30-57) | 32 | 9% AA; 2% Asian/PI; 3% Lat/Hisp; 32% elderly | Hospital inpatient; Hospital outpatient | Patients/ Participants | Cross-sectional; Retrospective | Breast, colorectal, lung, prostate | NA | Disease-specific proportion in U.S. | AA; Asian/ PI; Lat/Hisp; Elderly |
| Paskett, 2002 | U.S. | 47 | 87 | 100% rural | Community | Physicians | CCT | Breast , colorectal | No | Researcher set: Proportion underserved enrolled pre and post intervention | Rural |

**Table 2. Studies about Measures of Success used to Evaluate the Effectiveness of Strategies for Recruitment of underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2). (continued)**

| Author, Year | Country | Mean Age, y (Range) | % Male | % Under-represented group(s) | Study Setting | Target Population | Study Design | Type of Cancer Studied | Was Recruitment Goal Stated a Priori (Y/N). If yes, what was goal (in %)? | Recruitment Success Measure | For Which Underserved Group was Measure of Success Used? |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Trimble 1994 | U.S. | NR | NR | 100% elderly | All NCI-sponsored trials in 1992 | Patients/ Participants | Descriptive; Retrospective | Lung, prostate, colorectal, pancreas, leukemia, ovarian, breast | NA | Disease specific proportion in U.S. | Elderly |
| Yee, 2003 | Canada | NR | NR | 22% elderly | Canada NCIC CTG treatment trials & U.S. SWOG treatment trials | Patients/ Participants | Cross-sectional; Retrospective | All | NA | 1) Disease-specific proportion in Canada. 2) Researcher set: proportion underserved compared to U.S SWOG cancer treatment trial rates. | Elderly |
| **Prevention Trials** | | | | | | | | | | | |
| Berman, 1998 | U.S. | NR | 49 | 85% Lat/Hisp; 15% AA | Community | Patients/ Participants | Quasi-experimental | Smoking cessation | No | Geographic representation: proportion underserved group in school district. | Lat/Hisp, AA |
| Brewster, 2002 | U.S. | 43 (17-78) | 0 | 78% Lat/Hisp; 39% low annual income | Community; Hospital outpatient | Patients/ Participants | CCT | Cervical | No | Researcher set: Proportion underserved that agreed to participate in study | Lat/Hisp |

**Table 2. Studies about Measures of Success used to Evaluate the Effectiveness of Strategies for Recruitment of underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2). (continued)**

| Author, Year | Country | Mean Age, y (Range) | % Male | % Under-represented group(s) | Study Setting | Target Population | Study Design | Type of Cancer Studied | Was Recruitment Goal Stated a Priori (Y/N). If yes, what was goal (in %)? | Recruitment Success Measure | For Which Underserved Group was Measure of Success Used? |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Ford, 2004 | U.S. | 63 (55-74) | 100 | 100% AA; 100% elderly; 38% low SES | Community | Patients/ Participants | RCT | Prostate, lung, colorectal | No | Researcher set: 1)Proportion enrolled compared to enrollment in the standard recruitment arm and 2)proportion enrolled in another geriatric study | AA |
| Linnan, 2002 | U.S. | 43 | 53 | 6% Lat/Hisp; 27% low annual income | Work site; Workers homes | Patients/ Participants | RCT | Lung | NA | Researcher set: Proportion underserved eligible for trial | Low SES; persons with high school education or less |
| Moinpour, 2000 | U.S. | NR (51-91) | 100 | 4% AA; 3% Lat/Hisp | Hospital outpatient; NCI Compre-hensive Cancer Center | Patients/ Participants; Researchers | Descriptive | Prostate | Yes; 8% AA | Geographic representation: U.S. Proportion underserved | AA |
| Schiffman, 2000 | U.S. | 27 (18-81) | NR | 31% AA; 2% AIAN; 3% Asian/PI; 5% Lat/Hisp | Community; Group practice | Patients/ Participants | Descriptive | Cervical | No | Researcher set: Proportion underserved enrolled in the trial | AA |

**Table 2. Studies about Measures of Success used to Evaluate the Effectiveness of Strategies for Recruitment of underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2). (continued)**

| Author, Year | Country | Mean Age, y (Range) | % Male | % Under-represented group(s) | Study Setting | Target Population | Study Design | Type of Cancer Studied | Was Recruitment Goal Stated a Priori (Y/N). If yes, what was goal (in %)? | Recruitment Success Measure | For Which Underserved Group was Measure of Success Used? |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Thornquist, 1991 | U.S. | NR (45-74) | 53 | 23% elderly | Community | Patients/ Participants | Descriptive; Retrospective | Lung | No | Researcher set: Wanted enough elderly participants to evaluate them in study. Also wanted equal participation in 5-year age groups. | Elderly |
| Zhu, 2000 | U.S. | NR (65-85+) | 0 | 100% AA; 100% elderly; 91% low annual income | Community | Physicians | Qualitative | Breast | No | Researcher set for African-American elderly women: Authors noted participation rates were high, compared to other study with participation rate 20-48% | AA; Elderly |

**Table 2. Studies about Measures of Success used to Evaluate the Effectiveness of Strategies for Recruitment of underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2). (continued)**

| Author, Year | Country | Mean Age, y (Range) | % Male | % Under-represented group(s) | Study Setting | Target Population | Study Design | Type of Cancer Studied | Was Recruitment Goal Stated a Priori (Y/N). If yes, what was goal (in %)? | Recruitment Success Measure | For Which Underserved Group was Measure of Success Used? |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Both Prevention and Treatment Trials** | | | | | | | | | | | |
| Alexander, 2000 | U.S. | NR | 41 | 1.9% Asian/PI, 26% elderly | All NCI-sponsored trials from 1994 to 1998 | Patients/ Participants | Cross-sectional; Retrospective | All | NA | Disease-specific proportion in U.S. for Asian/PI; Researcher set for elderly: proportion younger Asian/PIs in the NCI-supported treatment trials | Asian/ PI; elderly |
| Krailo, 1993 | U.S. | NR (0-19) | NR | 33% adolescent | Hospital inpatient; Hospital outpatient | Patients/ Participants | Cross-sectional; Retrospective | All | NA | Disease-specific proportion in county: proportion underserved with cancer in county | Adolescents |
| Simon, 2004 | U.S. | 55 | 0 | 32% AA | NCI Compre-hensive Cancer Center | Patients/ Participants | Descriptive | Breast | No | Disease-specific proportion: proportion underserved group with cancer(taken from the SEER database) in Detroit | AA; Elderly |

**Table 2. Studies about Measures of Success used to Evaluate the Effectiveness of Strategies for Recruitment of underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2). (continued)**

AA = African American
CCOP = Community Cooperative Oncology Program
CCT = Concurrent controlled trial
CTG = Clinical Trials Group
Lat/Hisp = Latino/Hispanic
NA = not applicable
NCI = National Cancer Institute
NCIC = Cancer Institute of Canada
NR = Not reported
PI = Pacific Islander
SEER = Surveillance, Epidemiology, and End Results Program
SES = Socioeconomic status
SWOG = Southwest Oncology Group

**Table 3. Summary of Study and Target Population Characteristics on the Efficacy or Effectiveness of Recruitment Strategies for Increasing Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Questions 3 and 4).**

| Author, Year | Study Setting | Study Design | Cancer Studied | Target Population | Study Subgroup | Sample Size | Mean Age, y | Mean Education, y | % male | % AA | % Cauc | % Lat/Hisp |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brewster, 2002 | Community; Outpatient hospital | CCT | Cervical | Participants | Clinic registry | 405 | 44 | < HS graduate (54.7%) | 0 | 0 | 27 | 73 |
| | | | | | Media campaign | 535 | 42 | < HS graduate (48.5%) | 0 | 0 | 17 | 83 |
| Ford, 2004 | Community; Faith-based organization | RCT | Prostate, Lung, Colorectal | Participants | AA, Arm A | 3,079 | NR | NR | 100 | 100 | 0 | 0 |
| | | | | | AA, Arm B | 3,075 | | | | | | |
| | | | | | AA, Arm C | 2,949 | | | | | | |
| | | | | | AA, Arm D | 3,297 | | | | | | |
| Linnan, 2002 | Community | RCT | Lung | Participants | Passive employee contact | 891 | 41 | ≤ HS graduate (50.4%) | 53 | NR | 90 | 5 |
| | | | | | Active employee contact | 1,015 | 44 | ≤ HS graduate (39.5%) | 53 | NR | 95 | 2 |
| Moinpour, 2000 | Outpatient hospital | RCT | Prostate | Participants; Researchers | AA, Site A, 1995 | NR | NR | NR | 100 | NR | NA | NR |
| | | | | | AA, Site A, 1996 | | | | | | | |
| | | | | | AA, Site B, 1995 | | | | | | | |
| | | | | | AA, Site B, 1996 | | | | | | | |
| | | | | | AA, Site C, 1995 | | | | | | | |
| | | | | | AA, Site C, 1996 | | | | | | | |
| | | | | | AA, Site D, 1995 | | | | | | | |
| | | | | | AA, Site D, 1996 | | | | | | | |
| | | | | | Lat/Hisp, Site E, 1995 | | | | | | | |
| | | | | | Lat/Hisp, Site E, 1996 | | | | | | | |
| Paskett, 2002 | Community | CCT | Breast, Colorectal | Physicians | South Carolina 1993 | 72 | 44 | NR | 92 | NR | NR | NR |
| | | | | | North Carolina 1993 | 124 | 49 | NR | 84 | NR | NR | NR |
| | | | | | South Carolina 1996 | 62 | 45 | NR | 85 | NR | NR | NR |
| | | | | | North Carolina 1996 | 102 | 49 | NR | 87 | NR | NR | NR |

**Table 3. Summary of Study and Target Population Characteristics on the Efficacy or Effectiveness of Recruitment Strategies for Increasing Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Questions 3 and 4). (continued)**

AA = African American
Cauc = Caucasian
CCT = Concurrent controlled trial
HS = High School
Lat/Hisp = Latino/Hispanic
NR = Not reported
RCT = Randomized controlled trial

**Table 4. Summary of Outcome Point Estimates on the Efficacy or Effectiveness of Recruitment Strategies for Increasing Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Questions 3 and 4).**

| Author, Year | Descriptor of Point Estimate %, OR, difference) | Point Estimate (value) | Measure of Spread / Significance ( 95% CI, P value) | Author Conclusion |
|---|---|---|---|---|
| Brewster, 2002 | OR of women presenting to clinic (media campaign vs. clinic registry) | 3.0 | 2.38 - 3.78 | Media campaign recruitment yielded better recruitment results compared to the clinic registry recruitment strategy. |
| | OR of women screened by telephone (media campaign vs. clinic registry) | 3.0 | 2.52 - 3.51 | |
| Ford, 2004 | Difference of enrollment between Arm C vs. Arm D (%) Arm C = intervention included enhanced mailing process and church-based sessions Arm D = control group which received standard recruitment procedures | 1.0 | P = .02 | Arm C, the most intensive of the arm interventions, yielded higher enrollment compared to the control (Arm D) and other intervention arms (Arms A and B). |
| Linnan, 2002 | Difference of enrollment between passive employee contact and active employee contact (%) | 36.6 | P < .0001 | Active recruitment had lesser reach, higher enrollment, and smaller attrition rate. Passive recruitment had wider ethnic and financial diversity. No significant differences in organizational factors comparing active and passive recruitment. |
| Moinpour, 2000 | Change in Site A enrollment from 1995 to 1996 (%) | 0.3 | NR | It was difficult to evaluate effectivenes of minority recruitment strategies since the strategies were used at the final period of accrual. |
| | Change in Site B enrollment from 1995 to 1996 (%) | 0.5 | NR | |
| | Change in Site C enrollment from 1995 to 1996 (%) | 2.8 | NR | |
| | Change in Site D enrollment from 1995 to 1996 (%) | 0.6 | NR | |
| | Change in Site E enrollment from 1995 to 1996 (%) | 0.5 | NR | |
| Paskett, 2002 | Change in enrollment of breast cancer patients from 1991 to 1996, North Carolina (%) | 9.0 | NR | No improvement in enrollment of cancer patients into cancer clinical trials was observed after intervention. |
| | Change in enrollment of colorectal cancer patients from 1991 to 1996, North Carolina (%) | 1.0 | NR | |
| | Change in enrollment of breast cancer patients from 1991 to 1996, South Carolina (%) | 44.0 | NR | |
| | Change in enrollment of colorectal cancer patients from 1991 to 1996, South Carolina (%) | 5.0 | NR | |

CI = Confidence interval
OR = Odds ratio

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5).**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Adams-Campbell, 2004 | AA (235) | Hospital inpatient; Hospital outpatient | Breast, colorectal, head and neck, lung, prostate | Tumor registry review | | **Study Design Barriers**: Comorbidity exclusion; Functional status; Diagnostic test result cut-off; Lack of available protocols | | | | |
| Advani, 2003 | AA, Whites (218) | Hospital outpatient | Solid or hematologic malignancy (excluding melanoma) | Case-control | **Patient Barriers**: Lack of education about trials* | **Patient Barriers:** Distance to clinic* | **Patient Barriers:** Perceived harms of trial participation*; Chance of side-effects* | | **Patient Promoters**: Younger age* | **Patient Promoters:** Altruism*; Perceived benefits of trial participation |
| Barofsky, 1979 | AA (76) | Community Hospital inpatient | Histologically confirmed soft-tissue or osteosarcoma | Qualitative: Semi-structured interviews | | | | | **Patient Promoters:** Being male* | |
| Broome, 2001 | Adol (34) | Community;Hospital inpatient; Hospital outpatient | Hematological malignancy or solid tumors | Qualitative: interviews | | | | | | **Patient Promoters**: Chance for better treatment; altruism |
| Broome, 2003 | Adol (34) | Hospital inpatient | Ewing's sarcoma, or hematological malignancy | Qualitative: Semi-structured interviews | | | | | | **Patient Promoters**: Family considerations; Trust; communication; and love of parents |

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Brown, 2003 | AA, Whites (438) | Community | NR | Cross-sectional; Descriptive (telephone surveys) | | **Patient Barriers**: African American older age*; Lower income* | | | **Patient Promoters:** Male gender* | |
| Chen, 2000 | Elderly (68) | Hospital inpatient | Aggressive Histology Lymphoma | Hospital registry review; Retrospective | | **Study Design Barriers:** Comorbidity exclusion; Functional status; Previous cancer | **Patient Barriers:** Patient refusal **Provider Barriers:** Physician choice | | | |
| Comis, 2003 | Elderly (887) | Community | NR | Cross-sectional; Descriptive (Telephone interview) | | **Patient Barriers:** Age | | | | |
| Diener-West, 2001 | Elderly (4,191) | Hospital inpatient; Hospital outpatient; Group practice; Solo practice | Eye | RCT | | **Patient Barriers**: Age*; Living near treatment center* | | | **Study Design Promoters:** Large tumor size* | |

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Fouad, 2000 | AA (103) | Community | NR | Qualitative: Focus groups / key informant interviews | **Patient Barriers**: Lack of education about trials | **Patient Barriers:** Time commitment; Indirect costs; Lack/ inadequate health insurance **Provider Barriers:** Provider attitudes **Study Design Barriers:** Length of study/visit structure; Complexity of forms | **Patient Barriers:** Mistrust of research and medical system; Blood draw; Radiation involvement; Past experiences **Provider Barriers:** Skepticism about low-income patients' ability to participate; Concern that their patients would be randomized | **Provider Promoters:** Education programs for community physicians; Involvement of providers in prevention trials | **Study Design Promoters:** Easy to read consent forms, Using recruiters who are known to community | **Patient Promoters:** Benefit to family; Benefit to church |
| Fouad, 2001 | AA | Community | NR | Qualitative: Focus groups / Key Informant Interviews | **Patient Barriers:** Lack of education about trials; Lack of knowledge about origins of cancer; Culturally relevant education about clinical trials | **Patient Barriers:** Job issues; Indirect costs | **Patient Barriers:** Mistrust of research and medical system; Cultural barriers; Perceived harms of trial participation | **Patient Promoters:** Adequate knowledge about the study; Workshops on trials | **Patient Promoters:** Provide transportation; Flexible scheduling | **Patient Promoters:** Provide childcare; Incentives (free meals); Trust |

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Green, 2000 | AA (103) | Community | NR | Qualitative: Focus groups | | **Patient Barriers:** Time commitment | **Patient Barriers:** Mistrust of research and medical system; Family considerations; Perceived harms of trial participation; Radiation involved in treatment | | | **Patient Promoters**: Altruism*; Incentives*; No cost treatment* |
| Grunfeld, 2002 | CRAs (29) | Hospital inpatient | NR | Qualitative: Semi-structured interviews | | **Patient Barriers:** Transportation; Language barrier; **Provider Barriers:** Provider attitudes; Commun-ication / method of presentation **Study Design Barriers:** Excessive requirements of study | **Patient Barriers:** Mistrust of researcher and medical system; Perceived harms of clinical trial participation; Physician expertise; Physician discouragement **Provider Barriers:** Physician beliefs about patient preference | | | **Patient Promoters:** Incentives (financial or other); Trial beneficial to them; Hope for care; Receive extra care; Benefit future generations |

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Hunter, 1987 | AA, Whites (17,773) | Group practice; Hospital inpatient | Any | Descriptive; Qualitative; Retrospective | | **Patient Barriers:** Treatment toxicity; Costs **Study Design Barriers:** Comorbidity exclusion; Age exclusion; Functional status/Poor performance | **Patient Barriers:** Experimenta-tion **Provider Barriers:** Physicians' preference for specific treatment or alternative therapy | | | |

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Kaluzny, 1993 | NR | Community Hospital outpatient; Group practice | NR | Descriptive; Qualitative | **Patient Barriers:** Limited education or low literacy | **Patient Barriers:** Transportation; Language barriers; Socio-economic conditions **Provider Barriers:** Mistrust of researchers; Provider attitudes; time available per patient; Lack of interest in protocols; Lack of support staff **Study Design Barriers:** Comorbidity; Length of study/ visit structure; Late stage disease; **Healthcare System Barriers:** Lack of dissemination of study opportunities to provider/patient; Lack of language services; lack of support staff to facilitate protocol | **Patient Barriers:** Mistrust of researchers; Fear; Family considerations; Job issues; Indirect costs | | **Provider Promoters:** Incentives | |

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Kemeny, 2003 | Elderly women vs. Younger women (154) | Community | Breast | Case-control | | **Patient Barriers**: Age*; Disease stage*; Number of comorbidities* **Provider Barriers**: Toxicity of treatment; Thought patient ineligible; Patient comorbidity; | | | | |
| Kemp, 1984 | Population in Great Britain - Elderly (1,022) | Community | Breast, bone | Descriptive; Cross-sectional | | | | | | **Patient Promoters:** Less control over health decisions |
| Kornblith, 2002 | Elderly (156) | Hospital inpatient | Breast | Cross-sectional; Descriptive (Questionnaire targeting physicians) | | **Patient Barriers**: Transportation; Lack/ inadequate health insurance; Toxicity of treatment; Comorbidity; Patient unable to understand trial **Study Design Barriers**: Comorbidity exclusion; Life expectancy | | | **Provider Promoters:** Provider attitudes; Communica-tion/ method of presentation | |

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Krailo, 1993 | Adol (2,788) | Hospital inpatient; Hospital outpatient | All | Hospital registry review, Qualitative | | **Study design Barriers**: Age; Treatment policies; Lack of available protocols | | | | |
| Lewis, 2003 | Elderly (59,300) | NCI cooperative groups | NR | Cross-sectional; Descriptive; Retrospec-tive (Secondary analysis of national databases) | | **Patient Barriers**: Protocol exclusions **Study Design Barriers**: Comorbidity exclusion; Functional status; Diagnostic test cut-off | | | **Study design Promoters**: Life expectancy | |
| McCaskill-Stevens, 1999 | AA (89) | Community | All | Qualitative (Discussion, questionnaires of physician) | **Provider Barriers:** Lack of physician awareness of trials **Healthcare System Barriers**: Lack of dissemination of study opportunities to provider/patient | **Patient Barriers:** Poverty/cost to patient **Provider Barriers:** Insufficient resources **Study Design Barriers:** Length of study/visit structure **Healthcare System Barriers:** Lack of minority personnel/ investigators | **Patient Barriers:** Mistrust of research and medical system**;** Fear; Cultural barriers **Provider Barriers:** Mistrust of researchers ; Lack of proven therapy | **Patient Promoters:** Culturally relevant education about clinical trials | | |

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Millon-Underwood, 1993 | AA (220) | Community | NR | Descriptive; Cross-sectional | | | **Patient Barriers:** Mistrust of medical research; Perceived harms of trial participation | | | **Patient Promoters:** Hope; Altruism; Perceived efficacy |
| Outlaw, 2000 | AA (56) | Hospital inpatient | NR | Qualitative: Surveys of physicians and data managers | | **Patient Barriers:** Language barriers; Lack of education about trials; Culturally relevant education about clinical trials; Lack of access to healthcare **Provider Barriers:** Provider attitudes; Lack of support staff; Time required; Concern in patient's age/frailty ; Lack of minority providers **Study Design Barriers:** Complexity of clinical trials; disease stage | **Patient Barriers:** Mistrust of medical research; Fear; Cultural barriers; Indirect costs; Religious/ spiritual beliefs; Perceived harms of trial participation; Lack of comfort with high technology care; Lack of family support; Perceived discrimination **Provider Barriers:** Mistrust of researchers; Discomfort | | | |

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Paskett, 2002 | Rural (360) | Community | Breast, colorectal | CCT | **Patient Barriers**: Lack of education about trials | **Patient Barriers:** Transportation; Costs; Lack//inadequate health insurance **Provider Barriers:** Logistical burden, Cost to patient, Established referral patterns; Perceived treatment risk **Study Design Barriers:** Eligibility | **Patient Barriers:** Mistrust of research & medical system,; Perceived harms of trial participation; Unfamiliar physician; Discomfort | | | |

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Pinto, 2000 | AA (73) | Community | NR | Qualitative: Focus groups with physicians | **Patient Barriers**: Lack of education about trials **Provider Barriers**: Lack of provider awareness about trial; **Healthcare System Barriers:** Lack of dissemination of study opportunities to provider/ patient; | **Patient Barriers:** Physicians do not offer trials; Cost **Provider Barriers:** Lack of time; Provider attitudes **Study Design Barriers:** Comorbidity exclusion, Length of study/visit structure, Protocols too complex; Randomization **Healthcare System Barriers:** Lack of cultural competence among provider and/or staff; Lack of access to institution conducting trial | **Patient Barriers:** Mistrust of medical research; Fear; Cultural barriers, Perceived harms of participation **Provider Barriers:** Mistrust of researchers; Cultural barriers; Racial bias | | **Patient Promoters:** Culturally relevant education about clinical trials **Provider Promoters:** Incentive (financial or other) | |

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Randall-David, 2001 | Rural (37) | Community | All | Qualitative: Focus groups | **Patient Barriers:** Lack of education about trials **Healthcare System Barriers:** Lack of dissemination of study opportunities to provider/patient | **Patient Barriers:** Transportation; Time commitment **Provider Barriers:** Communication/ method of presentation | **Patient Barriers:** Mistrust of medical research; Fear; Lack of knowledge about origins of cancer; Family considerations, Religious/spiritual beliefs; Perceived harms of trial participation **Provider Barriers:** Mistrust of researcher | | **Patient Promoters**: Incentives (reimburse-ment) | **Patient Promoters:** Altruism ; Perceived benefit of trial participation |
| Roberson, 1994 | AA, AIAN, Lat/ Hisp (28) | Community | NR | Qualitative: Surveys | **Patient Barriers**: Lack of education about trials; Lack of information/ awareness | **Patient Barriers:** Time commitment; Language barriers; Cultural barriers; Access to information | **Patient Barriers:** Mistrust of medical research; Fear; Do not like to get involved | | **Patient Promoters:** Culturally relevant education about trials | **Patient Promoters:** Incentives; Perceived benefits of trial participation |

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Robinson, 1996 | AA men (46) | Community | Prostate | Qualitative: Focus groups | **Patient Barriers:** Lack of knowledge of origins of cancer **Healthcare System Barriers:** Lack of dissemination of study opportunities to provider/ patient | **Patient Barriers:** Lack of education about clinical trials **Provider Barriers:** Provider attitudes; Communication/ method of presentation | **Patient Barriers:** Mistrust of research and medical system, Fear, Perceived harms of trial participation; Concerns about randomization **Provider Barriers:** Mistrust of researchers | | **Patient Promoters:** Culturally relevant education about trials | **Patient Promoters:** Incentives; Perceived benefits of trial participation **Provider Promoters:** Competent/ experienced physician/ researcher; Compassionate provider **Healthcare System Promoters:** Reputation of medical facility |
| Sateren, 2002 | AA (24,332) | All patients from NCI-funded trials between April 1998-April 1999 | All | Cross-sectional; Descriptive; Retrospective (Secondary analysis of national database) | | **Patient Barriers:** Lack/ inadequate health insurance*; Being Black male aged 30-59 years*; Asian / Latino/ Hispanic adults* | | | **Patient Promoters:** Place of residence; Higher SES **Provider Promoters:** Higher number of oncology specialists **Healthcare System Promoters:** Presence of cancer programs | |

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Sears, 2003 | AA, White women (558) | Community | Breast | RCT | | **Patient Barriers**: Time commitment; Willingness to travel; Stress; >65 years old; minority; Not married **Study Design Barriers**: Medication exclusion; Metastatic disease | | | | |
| Simon, 2004 | AA, White women (319) | Hospital inpatient | Breast | Descriptive; Qualitative (Secondary analysis of NCI patient log data; Interviews from site visits) | | **Patient Barriers**: Lack/ inadequate health insurance **Provider Barriers**: Patient likely to be non-compliant; No protocol available for disease stage **Study Design Barriers**: Age exclusion; Medication exclusion | **Patient Barriers:** Leaving care of physician to participate in trial* | | | |

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Spaight, 1984 | Elderly (23) | Hospital inpatient | NR | Qualitative: Structured interviews of physicians | | **Patient Barriers:** Age; Transportation; Inability to understand protocol; Cost **Study Design Barriers:** Participation requires too much travel; Failure to use most effective drug; Too many lab tests | **Patient Barriers:** Patient resistance or potential noncompliance | | | **Provider Promoters:** Advancement of cancer field |
| Twelves, 1998 | Elderly women (4,688) | Hospital inpatient; Hospital outpatien; Solo practice | Breast | Retrospective; Tumor registry review | | **Patient Barriers**: Age* | | | **Patient Promoters:**: Place of initial treatment* **Provider Promoters:** Surgeons with high case load*; Referral to an oncologist* | |

**Table 5. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Treatment Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Woods, 2002 | AA (120) | Hospital outpatient | NR | Qualitative: Focus groups, Interviews | | **Patient Barriers:** Transportation problems; Time commitment; Family considerations; **Provider Barriers:** Training in communicating with patients; Communication/ method of presentation | **Patient Barriers:** Mistrust of medical research; Perceived harms of clinical trial participation; Not ready to quit smoking; Job issues | **Study Design Promoters:** Reminder phone call | **Patient Promoters:** Transportation support **Study Design Promoters:** Length of study/visit structure | **Patient Promoters:** Incentives; Perceived benefit of trial participation; Support/ encouragement/ prayer; Certainty of receiving actual medication |

AA = African American
Adol = Adolescent
AIAN = American Indian/Alaska Native
CCT = Concurrent controlled trial
CRA = Clinical research associates
Lat/Hisp = Latino Hispanic
NCI = National Cancer Institute
NR = Not reported
Pop. = Population
RCT = Randomized controlled trial
SES = Socioeconomic status

**Table 6. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention Trials (Key Question 5).**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| **Chemoprevention** | | | | | | | | | | |
| Bieniasz, 2003 | AA women (66) | Community | Cervical (dysplasia) | Qualitative: Semi-structured interviews | | **Patient Barriers:** Intervention characteristics* | | | | |
| Ling, 2000 | Elderly (1,206) | Hospital inpatient; Hospital outpatient | NR | Qualitative: Surveys | | | | | **Study Design Promoters:** Entry criteria | |
| Moinpour, 2000 | AA and Lat/Hispmen (NR) | Hospital outpatient; NCI Compre-hensive Cancer Center | Prostate | RCT | | **Study Design Barriers:** Lack of time to establish presence in communities | **Patient Barriers:** Mistrust of research | | | |
| Mouton, 1997 | AA, White women (80) | Community | Breast, colorectal | Descriptive; Cross-sectional (telephone surveys) | | | **Patient Barriers:** Mistrust of research and medical system*; Perception of researchers not caring about patient | | | **Patient Promoters:** Preference for study's Principal Investigator to be Black; Perception that it is better to be treated by research doctors |
| Thornquist, 1991 | Elderly (1,284) | Community | Lung | Cohort; Prospective | | **Patient Barriers:** Age (50-54; 65-69)* | | | **Patient Promoter:** Age (60-64; 55-59)* | |

**Table 6. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| **Smoking cessation** | | | | | | | | | | |
| Berman, 1998 | Lat/Hisp, AAs (435) | Community | Smoking cessation | Quasi-experimental. | | | | | **Patient Promoters:** Latinos**:** Lack/ inadequate health insurance; Opportunistic strategies **Provider Promoters:** Communica-tion or Method of presentation | |
| Lerman, 1994 | AA women (271) | Community | Breast | Descriptive; Cross-sectional (Structured telephone interview) | | | | | **Patient Promoters:** > HS educ: marriage, unemployment, # of affected relatives; ≤HS educ: age, employment; Age* | **Patient Promoters:** Impact of diagnosis on risk perception* |
| Woods, 2002 | AAs (12) | Hospital outpatient | NR | Qualitative: Focus groups, Interviews | | **Patient Barriers:** Transportation; Time; Family **Provider Barriers:** Training in communicating with patients; Communication/ method of presentation | **Patient Barriers:** Mistrust of research; Perceived harms of trial participation; Not ready to quit smoking; Job issues | **Study Design Promoters :** Reminder phone call | **Patient Promoters:** Transportation support **Study Design Promoters:** Length of study/visit structure | **Patient Promoters:** Incentives; Perceived benefit of participation; Support/ encourage-ments/ prayer; Certainty of receiving actual medication |

**Table 6. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| **Screening trial** | | | | | | | | | | |
| Ford, 2003 | AA men (34,376) | Community | Prostate, lung, and colorectal | RCT | **Patient Barriers:** Unlisted telephone number* | **Patient Barriers:** Age* | | | **Patient Promoters:** Low income level* | |
| **Other** | | | | | | | | | | |
| Brewster, 2002 | Lat/ Hisp women (545) | Community; Hospital outpatient | Cervical | CCT | | **Patient Barriers:** Family considerations (childcare problems); Work conflict; No time; Transportation; Other insurance /physician/clinic | **Patient Barriers:** Did not wish to participate in a "study"; Modesty/ embarrassment Uncomfortable with test | | | |
| Brown, 2000 | AA, Lat/Hisp, and White women (434) | Hospital outpatient | Breast and cervical | Descriptive (Surveys, Interviews) | **Patient Barriers:** Lack of education about clinical trials | **Patient Barriers:** Transportation Lack of health insurance / inadequate health insurance | **Patient Barriers:** Fear; Family considerations; Taste of drug; Mistrust of research and medical system | | | |
| Fouad, 2001 | AAs (103) | Community | NR | Qualitative: Focus groups / Key informant interviews | **Patient Barriers:** Lack of education about trials; Lack of knowledge about origins of cancer; Culturally relevant education about clinical trials | **Patient Barriers:** Job issues; Indirect costs | **Patient Barriers:** Mistrust of research and medical system; Cultural barriers; Perceived harms of trial participation | **Patient Promoters:** Adequate knowledge about study; Workshops on trials | **Patient Promoters:** Provide transportation; Flexible scheduling | **Patient Promoters:** Provide childcare; Incentives (free meals); Trust |

**Table 6. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Lee, 1999 | AA men (165) | Hospital inpatient | Prostate | Descriptive; Cross-sectional (Surveys) | | | | | | **Patient Promoters:** Willingness to take pills |
| McCaskill-Stevens, 1999 | AAs (89) | Community | All | Qualitative: Discussions, Questionnaires | **Provider Barriers:** Lack of physician awareness of trials **Healthcare System Barriers**: Lack of dissemination of study opportunities to provider/patient | **Patient Barriers:** Poverty/cost to patient **Provider Barriers:** Insufficient resources **Study Design Barrier:** Length of study/visit structure **Healthcare System Barriers:** Lack of minority personnel; Lack of minority investigators | **Patient Barriers:** Mistrust of research and medical system; Fear; Cultural barriers **Provider Barriers:** Mistrust of researchers; Lack of proven therapy | **Patient Promoter**: Culturally relevant education about trials | | |
| Millon-Underwood, 1993 | AAs (220) | Community | NR | Descriptive; Cross-sectional (Surveys) | | | **Patient Barriers:** Mistrust of medical research; Perceived harms of clinical trial participation | | | **Patient Promoters:** Hope; Altruism; Perceived efficacy |

**Table 6. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention Trials (Key Question 5). (continued)**

| Author, Year | Pop. (N) | Setting | Type of Cancer | Method | Barriers Associated with Decrease in Reported Enrollment | | | Promoters Associated with Increase in Reported Enrollment | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Awareness | Opportunities | Decision-Making | Awareness | Opportunities | Decision-Making |
| Pinto, 2000 | AAs (73) | Community | NR | Qualitative: Focus groups | **Patient Barriers**: Lack of education about trials **Provider Barriers**: Lack of provider awareness about trial **Healthcare System Barriers:** Lack of dissemination of study opportunities to provider/ patient | **Patient Barriers:** Physicians do not offer trials; Cost **Provider Barriers:** Lack of time; Provider attitudes **Study Design Barriers:** Comorbidity exclusion, Length of study/visit structure, Protocols too complex; Randomization **Healthcare System Barriers:** Lack of cultural competence among providers and/or staff; Lack of access to institution conducting trial | **Patient Barriers:** Mistrust of medical research; Fear; Cultural barriers, Perceived harms of participation **Provider Barriers:** Mistrust of researchers; Cultural barriers; Racial bias | | **Patient Promoter:** Culturally relevant education about clinical trials **Provider Promoter:** Incentive (financial or other) | |

**Table 6. Summary of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention Trials (Key Question 5). (continued)**

CCT = Concurrent controlled trial
HS = High school
NCI = National Cancer Institute
NR = Not reported
Pop. = Population
PSA = Prostate specific antigen
RCT = Randomized controlled trial
AA = African American
Lat/Hisp = Latino/Hispanic

**Table 7. Summary of Studies on the Effects of Attitudes and Perceptions of Healthcare Providers on the Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 6).**

| Author, year | Study Setting | Target Population | Targeted Under-represented Population | Sample Size | Study Design | How Measured | Type of Cancer Studied | Study Objective(s) | Type of Cancer Trial into Which Recruiting |
|---|---|---|---|---|---|---|---|---|---|
| Benson, 1991 | Community | Physicians | NR | 252 | Descriptive | Mailed survey | NR | Investigate the reasons physicians do not place patients in trials. | Treatment |
| Fallowfield, 1997 | Community | Physicians | NR | 357 | Descriptive | Mailed survey | All | Compare results of physician orientation profile used in the ECOG study with that obtained from surveying 357 British oncologists. | Treatment |
| Kemeny, 2003 | Hospital inpatient | Patients; Participants | Elderly | 154 | Case-control | Telephone survey; Interview | Breast | A. Test the extent to which eligible older breast cancer patients (older than 65 years) were offered clinical trials compared to younger patients. B. Assess reasons why oncologists choose not to offer a trial to their older patients and why patients chose to, or refused to participate. | Treatment |
| Kornblith, 2002 | Hospital inpatient | Physicians | Elderly | 156 | Descriptive | Mailed survey | Breast | Test the magnitude of barriers to recruitment among elderly breast cancer patients from physician perspective. | Treatment |
| McCaskill-Stevens, 1999 | Community | Physicians | Minorities | 90 | Qualitative | Open-ended questionnaire | Breast, Colorectal, Lung, Prostate | Identify barriers and solutions to African American accrual to cancer trials. | Treatment / Prevention |
| Paskett, 2002 | Community | Physicians | Rural | 196 (in 1993) 168 (in 1996) | CCT | Mailed survey | Breast, colorectal | A. Evaluate a Rural Cancer Care Intervention. B. Assess rural based primary care physician knowledge, attitudes, and beliefs about patient and physician barriers to cancer clinical trials and accrual to clinical treatment trials. | Treatment |

**Table 7. Summary of Studies on the Effects of Attitudes and Perceptions of Healthcare Providers on the Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 6). (continued)**

| Author, year | Study Setting | Target Population | Targeted Under-represented Population | Sample Size | Study Design | How Measured | Type of Cancer Studied | Study Objective(s) | Type of Cancer Trial into Which Recruiting |
|---|---|---|---|---|---|---|---|---|---|
| Pinto, 2000 | Community | Physicians; Investigators | Minorities | 73 | Qualitative | Focus groups | All | Identify barriers to accrual of minority patients and develop solutions to these barriers from physician's perspective. | Treatment / Prevention |
| Richardson, 1986 | Community | Physicians | NR | 59 | Descriptive | Mailed survey | NR | Assess attitudes and perceptions of medical oncologists regarding cancer trial participation. | Treatment |
| Simon, 2004 | Hospital inpatient | Patients; Participants | AA | 319 | Descriptive | Survey | Breast | Understand factors associated with accrual to breast cancer trials. | Treatment / Prevention |
| Spaight, 1984 | Community | Physicians | NR | 23 | Descriptive/ Qualitative | Face-to-face interview | NR | Assess factors influencing clinical trials participation from the perspective of medical oncologists and hematologists. | Treatment |



AA = African Americans
CCT = Concurrent controlled trial
ECOG = Eastern Cooperative Oncology Group
NMA = National Medical Association
NR = Not reported

**Table 8. Grading of the Quality of Evidence on the Efficacy or Effectiveness of Strategies for Recruiting Underserved Populations Into Cancer Prevention and Treatment Trials (Key Questions 3 and 4).**

| | |
|---|---|
| Quantity of Evidence:<br>Number of studies | 4 |
| Total number of patients studied | 2,846 |
| Quality and Consistency of Evidence:<br>Were study designs randomized trials (high quality), non-randomized controlled trials (medium quality), or observational studies (low quality)? | Medium |
| Did the studies have serious (-1) or very serious (-2) limitations in quality? (Enter 0 if none) | Very serious (-2) |
| Did the studies have important inconsistency? (-1) | Inconsistent (-1) |
| Was there some (-1) or major (-2) uncertainty about the directness or extent to which the people, interventions and outcomes are similar to those of interest? | None (0) |
| Were data imprecise or sparse? (-1) | Sparse (-1) |
| Did the studies have high probability of reporting bias? (-1) | No (0) |
| Did the studies show strong evidence of association between intervention and recruitment outcome? ("strong" if significant relative risk or odds ratio > 2 based on consistent evidence from 2 or more studies with no plausible confounders (+1); "very strong" if significant relative risk or odds ratio > 5 based on direct evidence with no major threats to validity (+2)) | No (0) |
| Did the studies have evidence of a dose-response gradient? (+1) | No (0) |
| Did the studies have unmeasured plausible confounders that most likely reduced the magnitude of the observed association? (+1) | No (0) |
| Overall grade of evidence (high, medium, low, very low) | Very low* |

*According to the evidence grading system recommended by the international GRADE Working Group, the overall grade was based on the initial assessment of the study designs (medium quality) with lowering of the grade by one or two levels for each of the limitations identified. "Very Low" grade of evidence means that any estimate of effect is very uncertain.

**Table 9. Grading of the Quality of Evidence on Barriers to and Promoters of Participation of Underserved Populations in Cancer Prevention and Treatment Trials (Key Question 5).**

| | For Treatment Trials | For Prevention Trials | For Treatment and/or Prevention Trials |
|---|---|---|---|
| Quantity of Evidence:<br>Number of studies | 32 | 13 | 3 |
| Total number of patients studied | 28,689 | 7,948 (excluding AAMEN)<br>24,119 (assumed with minimum of 16,171 who are the same throughout the three AAMEN studies) | 413 |
| Quality and Consistency of Evidence:<br>Were study designs appropriate for determining effects of providers' attitudes and perceptions? (Yes = high quality; no = low quality) | Yes | Yes | Yes |
| Did the studies have serious (-1) or very serious (-2) limitations in quality? (Enter 0 if none) | -1 | -1 | -1 |
| Did the studies have important inconsistency? (-1) | 0 | 0 | 0 |
| Was there some (-1) or major (-2) uncertainty about the directness or extent to which the people and measures are similar to those of interest? | 0 | 0 | 0 |
| Were data imprecise or sparse? (-1) | -1 | -1 | -1 |
| Did the studies have high probability of reporting bias? (-1) | -1 | -1 | -1 |
| Did the studies show strong evidence of association? ("strong" if significant relative risk or odds ratio > 2 based on consistent evidence from 2 or more studies with no plausible confounders (+1); "very strong" if significant relative risk or odds ratio > 5 based on direct evidence with no major threats to validity (+2)) | 0 | 0 | 0 |
| Did the studies have unmeasured plausible confounders that most likely reduced the magnitude of the observed association? (+1) | 0 | 0 | 0 |
| Overall quality grade (high, medium, low, very low) | Very Low | Very Low | Very Low |

*According to the evidence grading system recommended by the international GRADE Working Group, the overall grade was based on the initial assessment of the study designs (medium quality) with lowering of the grade by one or two levels for each of the limitations identified. "Very Low" grade of evidence means that any estimate of effect is very uncertain.

**Table 10. Grading of the Quality of Evidence on the Effects of Attitudes and Perceptions of HealthCare Providers on Recruitment of Underserved Populations Into Cancer Prevention and Treatment Trials (Key Question 6).**

| | |
|---|---|
| Quantity of Evidence:<br>Number of studies | 10 |
| Total number of patients studied | 1,651 |
| Quality and Consistency of Evidence:<br>Were study designs appropriate for determining effects of providers' attitudes and perceptions? (Yes = high quality; no = low quality) | Yes |
| Did the studies have serious (-1) or very serious (-2) limitations in quality? (Enter 0 if none) | -1 |
| Did the studies have important inconsistency? (-1) | 0 |
| Was there some (-1) or major (-2) uncertainty about the directness or extent to which the people and measures are similar to those of interest? | 0 |
| Were data imprecise or sparse? (-1) | -1 |
| Did the studies have high probability of reporting bias? (-1) | -1 |
| Did the studies show strong evidence of association? ("strong" if significant relative risk or odds ratio > 2 based on consistent evidence from 2 or more studies with no plausible confounders (+1); "very strong" if significant relative risk or odds ratio > 5 based on direct evidence with no major threats to validity (+2)) | 0 |
| Did the studies have unmeasured plausible confounders that most likely reduced the magnitude of the observed association? (+1) | 0 |
| Overall quality grade (high, medium, low, very low) | Very Low* |

*According to the evidence grading system recommended by the international GRADE Working Group (REF), the overall grade was based on the initial assessment of the study designs (medium quality) with lowering of the grade by one or two levels for each of the limitations identified. "Very Low" grade of evidence means that any estimate of effect is very uncertain.

# Appendixes

**Appendix A. EPC Recruitment: Technical Experts and Peer Reviewers**
**Appendix B. EPC Recruitment: Journals Hand Searched**
**Appendix C. EPC Recruitment: Search Strategies**
**Appendix D. EPC Recruitment to Clinical Trials Abstract Review Form**
**Appendix E. EPC Recruitment: Article General Abstraction Form**
**Appendix F. Evidence Tables**

# EPC Recruitment: Technical Experts and Peer Reviewers

## External Technical Experts and Peer Reviewers

Luis Baez, M.D.
Division of Hemetology and Oncology
University of Puerto Rico
San Juan, PR

Michaele Christian
National Cancer Institute
U.S. National Institutes of Health
Bethesda, MD

Mona Fouad, M.D., M.P.H.
The University of Alabama at Birmingham
Birmingham, AL

Cary Gross, M.D.
Yale University
New Haven, CT

Melissa Hudson, M.D.
Department of Hematology-Oncology
Director, After Completion of Therapy Clinic
St. Jude Children's Research Hospital

Chanita Hughes, Ph.D.
Assistant Professor
Department of Psychiatry
University of Pennsylvania
Philadelphia, PA

Marjorie Kagawa-Singer, Ph.D., M.N., R.N.
Associate Professor
UCLA School of Public Health & Asian American Studies
Los Angeles, CA

*Judith Kaur, M.D.
Medical Director for Native American Programs
Associate Professor of Oncology
Mayo Clinic College of Medicine
Rochester, MN

Jon Kerner, Ph.D.
Cancer Prevention & Control
National Cancer Institute
U.S. National Institutes of Health
Bethesda, MD

Worta McCaskill-Stevens, Ph.D.
Treatment & Prevention Trials, Minority Physicians and Clinical Trial Accrual
National Cancer Institute
U.S. National Institutes of Health
Bethesda, MD

*Electra D. Paskett, Ph.D.
Division of Epidemiology and Biometrics
The Ohio State University
Columbus, OH

Eliseo Perez-Stable, M.D.
Dept. General Internal Medicine
University of California, San Francisco
San Francisco, CA

*Amelie Ramirez
Associate Director for Community Research
San Antonio Cancer Institute
San Antonio, TX

Vickie Shavers, Ph.D.
Racial/ Ethnic Health Disparities
National Cancer Institute
U.S. National Institutes of Health
Bethesda, MD

* Member of the Special Populations Network (SPN)

Cynthia Vinson
Dissemination and Diffusion
National Cancer Institute
U.S. National Institutes of Health
Bethesda, MD

## Internal Technical Experts

Martin Abeloff, M.D.
Director and Professor
Oncology Administration
Johns Hopkins University School of Medicine

Lawrence Appel, M.D., M.P.H.
Professor
Division of General Internal Medicine
Johns Hopkins University School of Medicine

Steve Goodman, M.D., Ph.D.
Associate Professor Oncology-Clinical Trials and Biometrics
Johns Hopkins University School of Medicine

David Levine, M.D.
Professor
Division of General Internal Medicine
Johns Hopkins University School of Medicine

Jonathan Samet, M.D.
Professor and Chair
Department of Epidemiology
Johns Hopkins University Bloomberg School of Public Health

# EPC Recruitment: Journals Hand Searched

All journals searched January 2003 through June 2004.

## Journal Title

American Journal of Epidemiology
American Journal of Preventive Medicine
American Journal of Public Health
Annals of Epidemiology
Annals of Family Medicine
Archives of Pediatric and Adolescent Medicine
British Medical Journal
CA - A Cancer Journal for Clinicians
Cancer
Cancer Causes and Control
Cancer Epidemiology, Biomarkers and Prevention
Clinical Trials
Controlled Clinical Trials
Ethnicity and Disease
Ethnicity and Health
Gerontologist
Gerontology
Health Services Research
Journal of General Internal Medicine
Journal of Clinical Epidemiology
Journal of Clinical Oncology
Journal of Community Health
Journal of the American Medical Association (JAMA)
Journal of Health Care for the Poor and Underserved
Journal of the National Cancer Institute (JNCI)
Journal of the National Medical Association
Annals of the New York Academy of Science
Journal of School Health
Lancet
New England Journal of Medicine
Pediatrics
Preventive Medicine
Psycho- Oncology
Social Science and Medicine

# EPC Recruitment: Search Strategies

## MEDLINE Strategy

| | |
|---|---|
| (neoplasm[mh] OR cancer[tw] OR carcino*[tiab] OR tumor[tiab] OR oncolog*[tiab]) AND (patient selection[mh] OR recruit*[ti] OR participat*[ti] OR enrol*[ti] OR enlist*[ti]) AND eng[la] NOT (animal[mh] NOT human[mh]) | 3676 |
| *ADD "OR refer*[ti]"*<br>Most of these titles aren't relevant | 6844 |
| Try ((recruitment terms) AND (strategies/methods/etc))<br>*ADD "AND strateg*[tiab] OR method*[tiab]"*<br>Can't use this phrase because the Donovan et al. study doesn't mention strategy or method | 1688 |

## PsychINFO Strategy

| | |
|---|---|
| neoplasm or cancer or carcinogen or tumor or oncolog* | 17106 |
| patient selection or TI recruit* or TI participat* or TI enrol* or TI enlist* or TI refer* | 18396 |
| trial* or stud* | 1186777 |
| And LA english | |
| (neoplasm or cancer or carcinogen or tumor or oncolog*) and (patient selection or TI recruit* or TI participat* or TI enrol* or TI enlist* or TI refer*) and (trial* or stud*) And LA english and human | 152 |

## CINAHL Strategy

| | |
|---|---|
| neoplasm or cancer or carcino* or tumor or oncolog* | 67915 |
| MW patient selection or MW research subject recruitment or TI recruit* or TI participat* or TI enrol* or TI enlist* or TI refer* | 12547 |
| trial* or stud* | 306204 |
| And LA English and | |
| (neoplasm or cancer or carcino* or tumor or oncolog*) and (MW patient selection or MW research subject recruitment or TI recruit* or TI participat* or TI enrol* or TI enlist* or TI refer*) and (trial* or stud*) | 1070 |
| (neoplasm or cancer or carcino* or tumor or oncolog*) and (MW patient selection or MW research subject recruitment or TI recruit* or TI participat* or TI enrol* or TI enlist* or TI refer*) and (trial* or stud*) and LA English and human | 284 |

## Cochrane Database (CENTRAL and Methodology Review) Strategy

| | |
|---|---|
| Neoplasm* | 20087 |
| neoplasm* OR cancer OR carcino* OR tumor* or oncolog* | 39642 |
| (neoplasm* or cancer or carcino* or tumor* or oncolog*) and (patient selection or recruit*:ti or particip*:ti or enrol*:ti or enlist*:ti or refer*:ti) | 436 |
| (neoplasm* or cancer or carcino* or tumor* or oncolog*) and (patient selection or recruit*:ti or particip*:ti or enrol*:ti or enlist*:ti or refer*:ti) and (trial* OR stud*) | 416 |
| (neoplasm* or cancer or carcino* or tumor* or oncolog*) and (patient selection or recruit*:ti or particip*:ti or enrol*:ti or enlist*:ti or refer*:ti) and (trial* OR stud*) NOT (animal NOT human) | 414 |

## C2-SPECTR Strategy

| | |
|---|---|
| All Indexed Fields: {neoplasm} or {cancer} or {carcino} or {tumor} or {oncolog} | 16 |
| All Indexed Fields: {neoplasm} or {cancer} or {carcino} or {tumor} or {oncolog}<br>OR All Non-Indexed Fields: {neoplasm} or {cancer} or {carcino} or {tumor} or {oncolog} | 28 |
| All Indexed Fields: {neoplasm} or {cancer} or {carcino} or {tumor} or {oncolog}<br>OR All Non-Indexed Fields: {neoplasm} or {cancer} or {carcino} or {tumor} or {oncolog}<br>AND All Non-Indexed Fields {patient selection} or {recruit} or {participat} or {enrol} or {enlist} or {refer} | 18 |
| All Indexed Fields: {neoplasm} or {cancer} or {carcino} or {tumor} or {oncolog}<br>OR All Non-Indexed Fields: {neoplasm} or {cancer} or {carcino} or {tumor} or {oncolog}<br>AND All Non-Indexed Fields {patient selection} or {recruit} or {participat} or {enrol} or {enlist} or {refer}<br>AND All Non-Indexed Fields {trial} or {stud} | 15 |
| All Indexed Fields: {neoplasm} or {cancer} or {carcino} or {tumor} or {oncolog}<br>OR All Non-Indexed Fields: {neoplasm} or {cancer} or {carcino} or {tumor} or {oncolog}<br>AND All Non-Indexed Fields {patient selection} or {recruit} or {participat} or {enrol} or {enlist} or {refer}<br>AND All Non-Indexed Fields {trial} or {stud}<br>NOT All Non-Indexed Fields {animal} NOT {human} | 15 |

# EPC Recruitment to Clinical Trials Abstract Review Form

<print date>

**Reviewer: _____**

<Record #>

**Data Entry: _____**

<title>

<abstract>

**Delete article because (check one):**

□ not in English

□ not U.S.-based study

□ does not include human data

□ no original data

□ meeting abstract (no full article for review)

□ does not address cancer treatment or prevention

□ does not report a controlled trial or discuss recruitment to a controlled trial

□ other: (specify) _____

□ **Unclear: get article to decide**

***Do not go on if any item above is checked.***

**Article may address the following questions (check all that apply):**

□ efficacious research methodologies (Q1)
□ measures of success (Q2)
□ participation in treatment trials (Q3)
□ participation in prevention trials (Q4)
□ documented barriers/promoters (Q5)
□ barriers/promoters differ (Q5a)
□ barriers/promoters modified (Q5b)
□ attitudes and perceptions (Q6)

□ This article does not apply to any of the questions

□ Get article for reference regarding:
_____

## Appendix E. EPC Recruitment: Article General Abstraction Form

**JOHNS HOPKINS EVIDENCE-BASED PRACTICE CENTER**

**RECRUITMENT OF MEDICALLY UNDERSERVED TO CANCER TRIALS**

**GENERAL ABSTRACTION FORM**

**Article ID: _____** **First Author:_____**

**Reviewer 1: _____** **Reviewer 2: _____**

---

**Exclusion criteria: (Check one)**

- □ not in English
- □ not U.S.-based study
- □ does not include human data
- □ no original data
- □ meeting abstract (no full article for review)
- □ case report or case series (no denominator)
- □ letter
- □ does not address cancer treatment or prevention
- □ does not report a controlled trial or discuss recruitment to a controlled trial
- □ other: (specify)_____

*****IF ANY OF THE ABOVE IS CHECKED, DO NOT CONTINUE*****

## Appendix E. EPC Recruitment: Article General Abstraction Form (continued)

**1. Key Questions: (Check all that apply)**

□ 1. What **methods** (survey studies, focus groups, etc.) have been used to study strategies to recruit medically underserved populations (the elderly, adolescents, those of low socioeconomic status, those living in rural areas, African Americans, Hispanics/Latinos, Asian-Americans, and American Indians, etc.) in cancer prevention and treatment trials?

□ 2. What **measures** of success (proportional representation relative to the U.S. population; proportional representation relative to incidence of a cancer in a specified population, etc.) have been used to evaluate the efficacy and/or effectiveness of strategies for recruitment of medically underserved populations in cancer prevention and treatment trials?

**NOTE:** All studies eligible for Questions 3 & 4 have been determined to be eligible for Q 1 & 2.
**In addition:**
Descriptive studies, such as studies that describe a recruitment strategy and results of that recruitment strategy, are eligible for Q 1 & 2 even if not for Q 3 & 4.

□ 3. Which recruitment strategies (media appeals, incentives, etc.) have been shown to be efficacious and/or effective in increasing participation of medically underserved populations in cancer **treatment** trials?

□ 4. Which recruitment strategies have been shown to be efficacious and/or effective in increasing participation of medically underserved populations in cancer **prevention** trials?

**NOTE:** Studies will be considered eligible for Questions 3 & 4 as long as two or more recruitment strategies are compared, and may include pre- and post-comparison or historical comparisons.

□ 5. What are the documented **barriers** to (access, knowledge, attitudes, eligibility, fatalism, religiosity/spirituality, exclusions by design, etc.) and **promoters** of (attitudes, role of altruism, advanced disease, financial incentives, no-cost treatment, etc.) participation of underserved populations in cancer prevention and treatment trials?

□ 5a. Do these barriers and promoters differ by age, gender, socioeconomic status, race/ethnicity?

□ 5b. Are these barriers and promoters modified by cultural factors?

□ 6. What effects do the **attitudes and perceptions of health care providers** have on the efficacy/effectiveness of strategies for recruitment of medically underserved populations to cancer prevention and treatment trials?

**NOTE:** Questions 5 & 6 include studies that assess willingness to participate in cancer trials even if they only address hypothetical trials.

□ None of the above: **IF THIS IS CHECKED, STOP HERE.**

**STUDY CHARACTERISTICS**

**2. What design was used to study the recruitment into this trial? (Check one)**

□ Randomized controlled trial

□ Comparison of two or more non-randomized interventions (can include historical comparisons)

□ Case series

□ Survey

□ Qualitative (focus group or in-depth interviews)

□ Other (specify):_____

□ Not applicable

NOTE: Complete the article review forms for Q3 & Q4 only if the study has a comparison group

**3. What was the target population of the recruitment intervention? (Check all that apply)**

□ Patients/participants □ Researchers

□ Physicians □ Organizations

□ Other (specify): _____

**4. Where was the study conducted (study setting) OR where was the population recruited? (Check all that apply)**

□ Community health facility (non-hospital) □ Hospital inpatient

□ Community (residents) □ Hospital outpatient clinic

□ School □ Group practice

□ Faith-based organization □ Solo practice

□ Work site □ Other (specify): _____

□ Other community center (specify): _____

□ Unclear

**5. What were the main objectives of the study on recruitment strategies?**

A. _____

_____

B. _____

_____

C. _____

_____

**6. Enter the characteristics of the main target patient population** (e.g., numbers AND/OR percentages). Use comment box if intervention is targeted at more than one population. Enter "NS" where the number (or percentage) is not specified and "NA" where not applicable. Enter age range only if mean and median not provided.
Note: If the study does not define adolescent and elderly, then adolescent is defined as age between 12 and 21 years and elderly is defined as age older than 65 years.

□ Not applicable

□ No information on targeted patient population

| | **N** | **%** |
|---|---|---|
| Female | | |
| Male | | |
| African American | | |
| American Indian/Alaskan Native | | |
| Asian/Pacific Islander | | |
| Caucasian | | |
| Hispanic | | |
| Adolescent: how defined _____ _____ | | |
| Elderly: how defined _____ _____ | | |
| Low socioeconomic status: how defined _____ _____ | | |
| Rural | | |

| | **Mean** | **Median** | **Range** |
|---|---|---|---|
| Age | | | |
| Years of education | | | |
| Income | | | |
| Other: _____ | | | |

## Recruitment of Medically Underserved to Cancer Clinical Trials
## General Form - Addition

**Comments:participant characteristics not captured in the previous tables:**

**7. What type(s) of cancer was/were the focus of the clinical trial to which the recruitment efforts were directed?_____**

**8. What were the primary outcomes of the clinical trial to which the recruitment efforts were directed? (Check all that apply)**

□ Cancer prevention

- □ Primary
- □ Secondary
- □ Chemoprevention

□ Cancer treatment

- □ Therapeutic
- □ Complementary & alternative medicine (CAM)
- □ Survival
- □ Other _____
- □ Quality of life
- □ Recurrence prevention
- □ Complications

□ Survivorship

- □ Chemoprevention
- □ Complementary & alternative medicine(CAM)
- □ Survival
- □ Other _____
- □ Quality of life
- □ Recurrence prevention
- □ Complications

□ Other: _____

□ Other: _____

**9. Date recruitment started: _____**

**10. Date recruitment ended: _____**

**11. Other comments about the study not already reported:**

_____

_____

_____

**6**.

| | **Mean** | **Median** | **Range** |
|---|---|---|---|
| Age (specify) | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| Years of education (specify) | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| Income (specify) | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| Other (define): | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| Other (define): | | | |
| | | | |
| | | | |
| | | | |
| Other (define): | | | |
| | | | |
| | | | |
| | | | |

JOHNS HOPKINS EVIDENCE-BASED PRACTICE CENTER

# RECRUITMENT OF THE MEDICALLY UNDERSERVED IN CANCER CLINICAL TRIALS

## QUESTION 1 AND 2 - CONTENT REVIEW FORM

**Article ID:** _____ **First Author:** _____

**Reviewer 1:** _____ **Reviewer 2:** _____

---

## GENERAL QUESTIONS

**1. How was recruitment defined?**

- ☐ Willingness to participate
- ☐ Actual participation
- ☐ Other (specify):_____
- ☐ Not defined
- ☐ Not applicable

## RECRUITMENT METHODS

**2. What method was used to design the recruitment plan? (Check all that apply)**

| |
|---|
| ☐ Focus group |
| ☐ Survey |
| ☐ In-person interviews |
| ☐ Literature review |
| ☐ Other (specify): _____ |
| ☐ Not reported |
| ☐ Not applicable |

**3. Describe the recruitment intervention(s):**

A. _____

_____

B. _____

_____

C. _____

_____

D. _____

_____

E. _____

_____

- ☐ F. Not applicable
- ☐ G. Not reported

**MEASURES OF SUCCESS OF RECRUITMENT**

**4. Was a recruitment goal for the underserved group(s) stated *a priori*?**

- ☐ Yes
- ☐ No
- ☐ Not applicable

**If yes, what was the recruitment goal (percentage) for the underserved group(s)_____**

**5. What recruitment success measure was used in this study?**

- ☐ Geographic representation (e.g., % Asian in Baltimore compared to % Asian in study)
- ☐ U.S. proportion of underserved group (e.g., % African-American in U.S. compared to % African-American in study)
- ☐ Disease-specific proportion of underserved (e.g., % Native American with lung cancer compared to % Native American in study)
- ☐ Research institution proportion of underserved (e.g., % underserved in that research institution compared to % in study)
- ☐ Measure of recruitment success set arbitrarily by researchers.
  Specify: _____
- ☐ Other (specify): _____
- ☐ Not reported
- ☐ Not applicable

**6. If a measure of success was used, for which underserved group(s) was that measure reported? (Check all that apply)**

- ☐ African American
- ☐ Asian American/Pacific Islander
- ☐ Hispanic
- ☐ Pacific Islander
- ☐ Native American
- ☐ Elderly
- ☐ Adolescent
- ☐ Rural
- ☐ Low socioeconomic status
- ☐ Other (specify): _____
- ☐ Not applicable

**7. Other comments about the study not already reported:**

_____

_____

_____

_____

_____

JOHNS HOPKINS EVIDENCE-BASED PRACTICE CENTER

**RECRUITMENT OF THE MEDICALLY UNDERSERVED IN CANCER CLINICAL TRIALS**

**QUESTION 3 AND 4 - CONTENT REVIEW FORM**

**Article ID:** _____ **First Author:** _____

**Reviewer 1:** _____ **Reviewer 2:** _____

---

**1. Sample size and number of individuals who participated in the study of the recruitment strategy, by target population.** Enter numbers of group(s) that were the target of the intervention(s) for entire study (total for all groups). Enter "NS" where the number of participants is not specified and "NA" where not applicable (e.g., if no participants in study). *"#completed" refers to the number of participants included in **analysis** for the entire study.*

| **Patients** | | | **Providers** | | | **Researchers** | | | **Other** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| # enrolled | # randomized | # completed study | # enrolled | # randomized | # completed study | # enrolled | # randomized | # completed study | # enrolled | # randomized | # completed study |
| | | | | | | | | | | | |

**Comments:**

_____

_____

_____

_____

_____

**2. At what level was the assignment of the recruitment intervention(s) made** (i.e., if the trial was randomized, what was/were the unit(s) of randomization)? **(Check all that apply)**

Patients

Providers

Researchers

Organizations

Other (specify): _____

Not applicable

**3. How many recruitment intervention arms did the study involve? _____**

**Name each group that was compared including control and each intervention group.**

| Group | Name |
|---|---|
| **A** | |
| **B** | |
| **C** | |
| **D** | |
| **E** | |

**Note: Each group listed above needs to have a Question 3 and 4 Supplemental Content Review form filled out.**

**4. Outcomes of recruitment intervention assessed by (check one):**

Clinic

Patients

Providers

Researchers

Combination (specify): _____

Other (specify): _____

**5. Outcomes – Please provide details in boxes for ALL outcomes that are presented in the study.**

| Outcome of Interest | N (Outcome of Interest) | Point Estimate | | | | | | (Check one) ☐ SD ☐ CI ☐ SE | P -value |
|---|---|---|---|---|---|---|---|---|---|
| | | Mean | Median | Risk Ratio | Odds Ratio | Difference | Rate Ratio | | |
| **A.** | | | | | | | | | |
| **B.** | | | | | | | | | |
| **C.** | | | | | | | | | |
| **D.** | | | | | | | | | |



Appendix E. EPC Recruitment: Key Questions 3 and 4 Content Review Form (continued)

**6. Were the study recruitment goals met?**

Yes

No

Unclear

**7. Authors' conclusion/summary (check one):**

Overall improvement in recruitment after intervention

Partial improvement or mixed results

No improvement after intervention

Decrease in recruitment

Unclear

Other (specify): _____

**8. Briefly summarize the authors' main conclusion(s):**

_____

_____

_____

**9. Other comments about the study not already reported:**

_____

_____

_____

JOHNS HOPKINS EVIDENCE-BASED PRACTICE CENTER

## RECRUITMENT OF THE MEDICALLY UNDERSERVED IN CANCER CLINICAL TRIALS

QUESTION 3 AND 4 – QUALITY REVIEW FORM

**Article ID:** _____ **First Author:** _____

**Reviewer 1:** _____ **Reviewer 2:** _____

---

### REPRESENTATIVENESS OF STUDY POPULATIONS

**1. How would you characterize the authors' description of the setting and population from which the study sample was drawn, and the dates of the study?**

| | |
|---|---|
| a. Adequate (setting AND population described AND start and end date specified) | **2** |
| b. Fair (one or more of these NOT reported OR poor description) | **1** |
| c. Inadequate (not specified) | **0** |

**2. The degree to which detailed inclusion/exclusion criteria were provided was:**

| | |
|---|---|
| a. Adequate (detailed description of specific inclusion and exclusion criteria OR statement that all eligible patients enrolled) | **2** |
| b. Fair (some description, but would be difficult to replicate with the information provided) | **1** |
| c. Inadequate (minimal description or none at all) | **0** |

**3. The degree to which information provided on excluded or non-participating patients was:**

| | |
|---|---|
| a. Adequate (all reasons for exclusion AND number excluded OR no exclusions) | **2** |
| b. Fair (only one of above criteria specified or information not sufficient to allow replication) | **1** |
| c. Inadequate (none of the above criteria specified) | **0** |

**4. How well does the study describe key participant characteristics at enrollment?**

***Demographics:*** age, gender, race/ethnicity, education, income, occupation
***Medical characteristics:*** currently diagnosed with cancer (cancer survivor); never diagnosed with cancer; screened for cancer

| | |
|---|---|
| a. Good: Both categories described well (i.e., most items in the category described) | **2** |
| b. Fair: One of the two categories described well | **1** |
| c. Poor: No key patient characteristic categories described well | **0** |

**BIAS AND CONFOUNDING**

**5. The random assignment of participants to study group was:**

| | |
|---|---|
| a. Adequate (investigators could not predict assignment) | **2** |
| b. Partial (date of birth, admission date, hospital record number, or other non-random scheme for assignment OR did not state) | **1** |
| c. Not randomized | **0** |
| d. Unclear | **0** |

**6. Did the participant groups have any important differences in terms of key characteristics?**

***Demographics:*** age, gender, race/ethnicity, education, marital status, occupation, days from index MI to first day of therapy
***Medical characteristics:*** currently diagnosed with cancer (cancer survivor); never diagnosed with cancer; screened for cancer

| | |
|---|---|
| a. Groups equivalent in all factors examined | **2** |
| b. Groups have minor difference in one or two factors | **1.5** |
| c. Groups have an important difference in one or more factors OR a minor difference in more than two factors | **1** |
| d. Analysis not done | **0** |

**7. For the recruitment trial, the blinding of clinician, patient, and/or outcome assessors was:**

| | |
|---|---|
| a. Excellent (all three blinded, including all treatment arms) | **2** |
| b. Good (only two of the three blinded, OR some but not all of the arms) | **1.5** |
| c. Fair (only one of the three blinded) | **1** |
| d. Poor (no blinding OR not stated) | **0** |
| e. Not applicable | **NA** |

## DESCRIPTION OF RECRUITMENT STRATEGY

**8. Did the study describe details of the flow of participants through each stage of the clinical trial? For each group, reporting of the number of participants assigned to intervention, received intended intervention, completed the study protocol, and analyzed for the primary outcome was:**

| | |
|---|---|
| a. Adequate (all of the above described) | **2** |
| b. Fair (one of the above NOT described) | **1** |
| c. Inadequate (more than one of above NOT described) | **0** |

**9. The study description of the details of the recruitment strategy (i.e., methods of accrual, recruitment goals, measures of success) was:**

| | |
|---|---|
| a. Adequate (all of the above described) | **2** |
| b. Fair (one of the above NOT described) | **1** |
| c. Inadequate (more than one of above NOT described) | **0** |

## OUTCOMES AND FOLLOW-UP

**10. How were the outcome measures of recruitment success defined?**

e.g., proportional representation relative to the U.S. population, proportional representation relative to incidence of a cancer in a specified population

| | |
|---|---|
| a. Adequate(clear definitions of each outcome AND exact techniques to assess the outcome) | **2** |
| b. Fair (some description, but information not sufficient to allow replication) | **1** |
| c. Inadequate (no information provided) | **0** |

**11. The description of the measures used to define the recruitment barriers and promoters was:**

***Barrier measures*:** awareness, knowledge, attitudes/beliefs, self-efficacy, organizational environment, health literacy, access, eligibility, provider knowledge, provider attitudes/beliefs, fatalism, religiosity/spirituality, exclusions by design, eligibility, advanced disease
***Promoter measures:*** attitudes, role of altruism, advanced disease, financial incentives, no-cost treatment, etc

| | |
|---|---|
| a. Adequate (clear definitions of each measure AND exact techniques to assess the measure) | **2** |
| b. Fair (some description, but information not sufficient to allow replication) | **1** |
| c. Inadequate (no information provided) | **0** |

**12. Did the study report the numbers of and reasons for withdrawals from the study protocol or patients/participants otherwise lost to follow-up?**

| | |
|---|---|
| a. Numbers and reasons reported (or no withdrawals) | **2** |
| b. Only numbers OR reasons reported | **1** |
| c. Neither given | **0** |

**STATISTICAL QUALITY AND INTERPRETATION**

**13. The statistical analyses used to determine recruitment success were:**

| | |
|---|---|
| a. Adequate (identified for all analyses) | **2** |
| b. Fair (identified for some of the analyses) | **1** |
| c. Inadequate (not identified) | **0** |

**14. Were withdrawals, crossovers, and loss to follow-up handled appropriately in the analysis?**

| | |
|---|---|
| a. Loss to follow-up, withdrawals, or crossovers handled | **2** |
| b. By intention to treat/screen | **2** |
| c. Sensitivity analysis | **1** |
| d. None of the above | **0** |

## CONFLICTS OF INTEREST

**15. The description of study's reporting or identification of the sources of funding was:**

| | |
|---|---|
| a. Adequate (source AND type or degree of involvement OR no funding) | **2** |
| b. Fair (source only) | **1** |
| c. Inadequate (neither) | **0** |

**16. Reflecting on this study as a whole, what is your overall impression of the quality of the study? (Check one)**

Excellent

Very good

Good

Fair

Poor

**Appendix E. EPC Recruitment: Key Questions 3 and 4 Supplemental Content Review Form (continued)**

JOHNS HOPKINS EVIDENCE-BASED PRACTICE CENTER

RECRUITMENT OF THE MEDICALLY UNDERSERVED
IN CANCER CLINICAL TRIALS

QUESTION 3 AND 4 – SUPPLEMENTAL CONTENT REVIEW FORM

**Article ID:** _____ **First Author:** _____

**Reviewer 1:** _____ **Reviewer 2:** _____

---

**Group Name** (From Item 3, p2, Recruitment Content Review Form for Q 3&4)

_____

**[If no patients in study, skip to Item 2S]**

**1S**. **Enter subject characteristics as given**, (e.g., numbers OR percentages) Enter "NS" where the number of participants is not specified and "NA" where not applicable. Enter age range only if mean is not provided.
If the study does not define adolescent and elderly, then adolescent is defined as age between 12 and 21 years and elderly is defined as age older than 65 years.

☐ No patient information

| | **N** | **%** |
|---|---|---|
| Female | | |
| Asian/Pacific Islander | | |
| African American | | |
| Caucasian | | |
| Hispanic | | |
| American Indian/Alaskan Native | | |
| Adolescent: how defined_____ | | |
| Elderly: how defined_____ | | |
| Low socioeconomic status: how defined_____ _____ | | |
| Rural | | |

**Appendix E. EPC Recruitment: Key Questions 3 and 4 Supplemental Content Review Form (continued)**

| | Mean | Median | Range |
|---|---|---|---|
| Age | | | |
| Years of education | | | |
| Income | | | |
| Other | | | |

**2S. Briefly describe the group intervention described on this form. Enter "NS" where number of participants is not specified and "NA" where not applicable.** ***"# completed" refers to total # included in analysis for this group.***

| Column 1 | | | Column 2 |
|---|---|---|---|
| **Patients** # recruited / # completed | **Providers** # recruited / # completed | **Clinics** # recruited / # completed | Indicate group type and provide brief group description (e.g., providers given computer reminders; patients given written material) |
| | | | ☐ No intervention/usual care |
| | | | ☐ Provider intervention |
| | | | ☐ Patient intervention |
| | | | ☐ Researcher intervention |
| | | | ☐ Other _____ |

**3S. Describe this trial group (intervention or control).**

_____

_____

_____

_____

## Appendix E. EPC Recruitment: Key Questions 3 and 4 Supplemental Content Review Form (continued)

**4S. What recruitment methods were used in the intervention? (Check all that apply)**

Written material

- Book
- Pamphlet
- Flyer
- Poster
- Journal
- Article

Audio-Visual (AV) material

- Audiotape
- Videotape
- DVD

Case studies

Computer-based material

- Website tutorial (w/URL)
- E-mail
- CD-ROM
- DVD

Lecture/workshop

Self-study

Small group

Simulated patients/participants

Media

Newspaper

Radio

- ☐ Public service announcements (PSAs)
- ☐ Paid ads

Television

- ☐ Public service announcements (PSAs)
- ☐ Paid ads

Other: _____

**5S. Number of training sessions for recruitment intervention?**

_____sessions

Not specified

Not applicable

## Appendix E. EPC Recruitment: Key Questions 3 and 4 Supplemental Content Review Form (continued)

**6S. What was the total duration for *the most intensive* training session for the recruitment intervention?**

< 1 hours

1 – 2 hours

3 – 4 hours

5 – 6 hours

Not specified

Not applicable

**7S. What was the total amount of training for the recruitment intervention?**

< 2 hrs

2 – 10 hrs

11 – 20 hrs

> 20 hrs

Not specified

Not applicable

**8S. How often were the training sessions held for the recruitment intervention?**

Once only

Weekly

Monthly

Other: _____

Not specified

Not applicable

**9S. What was the total number of training sessions held for the recruitment intervention?**

0

1

2

3 – 4

5 or more

**10S. How much time elapsed from the beginning to the end of the intervention?**

< 1 day

1 – 29 days

1 – 3 months

4 – 6 months

7 – 12 months

> 1 year

Not specified

**11S. Was recruitment of medically underserved populations a primary outcome of this study?**

Yes

No

**12S. Comments about the intervention if not captured by the previous questions (i.e., brief description of the intervention, including duration and frequency).**

_____

_____

_____

_____

JOHNS HOPKINS EVIDENCE-BASED PRACTICE CENTER

## RECRUITMENT OF THE MEDICALLY UNDERSERVED IN CANCER CLINICAL TRIALS

### QUESTION 5 AND 6 - CONTENT REVIEW FORM

**Article ID:** _____ **First Author:** _____

**Reviewer 1:** _____ **Reviewer 2:** _____

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**1. What types of barriers or promoters for recruitment of the medically underserved to cancer prevention/treatment trials did this study address? (Check all that apply)**

Provider

Patient

Study design (e.g., restrictive inclusion and exclusion criteria)

Healthcare system (e.g., lack of clinical trials opened at a particular institution)

Other (specify): _____

Not Applicable

**2. What patient barriers/promoters were associated with decreased or increased enrollment into cancer treatment/prevention trials? (Check one box in each row)**

| | No | Statistically Significant Decrease | Statistically Significant Increase | Reported Qualitatively Important Decrease* | Reported Qualitatively Important Increase* | Unclear | Not Addressed |
|---|---|---|---|---|---|---|---|
| Mistrust of research and medical system | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Fear | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Lack of knowledge about origins of cancer | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Embarrassment | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Transportation | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Time commitment | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Family considerations | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Leaving care of physicians to participate in trial | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Patient satisfaction with primary care doctor | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Language barriers | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Cultural barriers | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Job issues | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Indirect costs (e.g., income loss) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Lack of or inadequate health insurance | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

***** As reported based on qualitative methods

**What patient barriers/promoters were associated with decreased or increased enrollment into cancer treatment /prevention trials? (Check one box in each row)**

| | No | Statistically Significant Decrease | Statistically Significant Increase | Reported Qualitatively Important Decrease* | Reported Qualitatively Important Increase* | Unclear | Not Addressed |
|---|---|---|---|---|---|---|---|
| Religious/spiritual beliefs | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Lack of education about clinical trials | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Incentives (financial or other) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| No-cost treatment | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Lodging | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Culturally relevant education about clinical trials | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Perceived benefits/harms of clinical trial participation | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Other (specify): _____ __ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Other (specify): _____ __ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

* As reported based on qualitative methods

**3. What provider barriers/promoters were associated with decreased or increased enrollment into cancer treatment /prevention trials? (Check one box in each row)**

| | No | Statistically Significant Decrease | Statistically Significant Increase | Reported Qualitatively Important Decrease* | Reported Qualitatively Important Increase* | Unclear | Not Addressed |
|---|---|---|---|---|---|---|---|
| Mistrust of researchers (e.g., loss of clientele) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Cultural competence training | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Training in communicating with patients | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Provider race/ethnicity | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Medical staff race/ethnicity | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Provider attitudes | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Incentive (financial or other) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Communication/ method of presentation | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Ability to speak patient's language | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Other (specify): _____ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Other (specify): _____ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

***** As reported based on qualitative methods

**4. What study design barriers/promoters were associated with decreased or increased enrollment into cancer treatment /prevention trials? (Check one box in each row)**

| | No | Statistically Significant Decrease | Statistically Significant Increase | Reported Qualitatively Important Decrease | Reported Qualitatively Important Increase | Unclear | Not Addressed |
|---|---|---|---|---|---|---|---|
| Comorbidity exclusion | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Age exclusion | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Medication exclusion | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Functional status | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Length of study/visit structure (e.g., interference with work hours) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Diagnostic test result cut-off | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Other (specify): _____ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Other (specify): _____ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

***** As reported based on qualitative methods

**5. What health care system barriers/promoters were associated with decreased or increased enrollment into cancer treatment /prevention trials? (Check one box in each row)**

| | No | Statistically Significant Decrease | Statistically Significant Increase | Reported Qualitatively Important Decrease* | Reported Qualitatively Important Increase* | Unclear | Not Addressed |
|---|---|---|---|---|---|---|---|
| Lack of minority doctors | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Lack of other minority personnel | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Lack of cultural competence among providers and/or staff | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Lack of dissemination of study opportunities to provider/patient | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Lack of language services | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Other (specify): _____ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Other (specify): _____ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

***** As reported based on qualitative methods

**6. Did this study report any information about how barriers and promoters are modified by cultural factors?**

Yes, describe briefly: _____

No

**7. Other comments about the study not already reported:**

_____

_____

JOHNS HOPKINS EVIDENCE-BASED PRACTICE CENTER

## RECRUITMENT OF THE MEDICALLY UNDERSERVED IN CANCER CLINICAL TRIALS

### QUESTION 5 AND 6 – QUALITY REVIEW FORM

**Article ID:** _____ **First Author:** _____

**Reviewer 1:** _____ **Reviewer 2:** _____

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### REPRESENTATIVENESS OF STUDY POPULATIONS

**1. How would you characterize the authors' description of the setting and population from which the study sample was drawn, and the dates of the study?**

| | |
|---|---|
| a. Adequate (setting AND population described AND start and end date specified) | **2** |
| b. Fair (one or more of these NOT reported OR poor description) | **1** |
| c. Inadequate (not specified) | **0** |

**2. The degree to which detailed inclusion/exclusion criteria were provided was:**

| | |
|---|---|
| a. Adequate (detailed description of specific inclusion and exclusion criteria OR statement that all eligible patients enrolled) | **2** |
| b. Fair (some description, but would be difficult to replicate with the information provided) | **1** |
| c. Inadequate (minimal description or none at all) | **0** |

**3. The degree to which information provided on excluded or non-participating patients was:**

| | |
|---|---|
| a. Adequate (all reasons for exclusion AND number excluded OR no exclusions) | **2** |
| b. Fair (only one of above criteria specified or information not sufficient to allow replication) | **1** |
| c. Inadequate (none of the above criteria specified) | **0** |

**4. How well does the study describe key participant characteristics at enrollment?**

***Demographics:*** age, gender, race/ethnicity, education, income, occupation
***Medical characteristics:*** currently diagnosed with cancer (cancer survivor); never diagnosed with cancer; screened for cancer; cancer survivor

| | |
|---|---|
| a. Good: both categories described well (i.e., most items in the category described) | **2** |
| b. Fair: one of two categories described well | **1** |
| c. Poor: neither category described well | **0** |

**5. Was the design of the study based on a conceptual model of the reported research?**

| | |
|---|---|
| a. Yes | **2** |
| b. No | **0** |
| c. Unclear | **0** |

**QUALITY REVIEW OF SURVEYS**

**[IF THIS IS NOT A SURVEY SKIP TO Q16]**

**6. What data collection methods were used in the study? (Check all that apply)**

Self-administered questionnaire

By mail

Group-administered setting

Face-to-face interviews

Telephone interviews

Computer or computer assisted device (CAD)

Other _____

**7. What was the response rate or the proportion of eligible people that actually completed the questionnaire?**

| | |
|---|---|
| a. 80 – 100 % | **2** |
| b. 60 – 79 % | **1.5** |
| c. 40 – 59 % | **1** |
| d. 20 – 39 % | **0.5** |
| e. < 20 % | **0** |
| f. Unclear | **0** |

**8. What was the intra-rater reliability of the survey instrument?**

| | |
|---|---|
| a. 80 – 100 % | **2** |
| b. 60 – 79 % | **1.5** |
| c. 40 – 59 % | **1** |
| d. 20 – 39 % | **0.5** |
| e. < 20 % | **0** |
| f. Unclear/Not reported | **0** |
| g. Not applicable | **N/A** |

**9. What was the inter-rater reliability of the survey instrument?**

| | |
|---|---|
| a. 80 – 100 % | **2** |
| b. 60 – 79 % | **1.5** |
| c. 40 – 59 % | **1** |
| d. 20 – 39 % | **0.5** |
| e. < 20 % | **0** |
| f. Unclear/Not reported | **0** |
| g. Not applicable | **N/A** |

**10. Was the survey instrument validated in terms of face, construct, and/or criteria validity?**

***Face validity:*** The extent to which the instrument appears to be measuring what it is supposed to measure.
***Construct validity:*** The extent to which the measure of concern correlates with other measures in predicted ways, but for which no true criterion exists.
***Criterion validity:*** The extent to which an instrument correlates with another more accurate (and usually more expensive) instrument (criterion).

| | |
|---|---|
| a. Adequate: two or three of above types of validity | **2** |
| b. Fair: One of the above types of validity | **1** |
| c. Inadequate: None of the above type of validity | **0** |

**11. Was the study planned to have adequate power to detect differences between groups?**

| | |
|---|---|
| a. Yes | **2** |
| b. No | **1** |
| c. Unclear | **0** |
| d. Not applicable | **N/A** |

**12. Was the study planned to have adequate power to detect changes within groups?**

| | |
|---|---|
| a. Yes | **2** |
| b. No | **1** |
| c. Unclear | **0** |
| d. Not applicable | **N/A** |

**13. How well was the research question and objective(s) stated?**

| | |
|---|---|
| a. Adequate (research questions clear and objectives presented in specific terms) | **2** |
| b. Fair (research question and objectives presented but not in specific terms) | **1** |
| c. Inadequate (research question unclear AND/OR objectives not presented) | **0** |

**14. How were the study participants selected?**

| | |
|---|---|
| a. Consecutive selection | **2** |
| b. Random sampling | **2** |
| c. Other purposive sampling | **1** |
| d. Convenience sample | **0** |
| e. Unclear | **0** |

**15. Did the authors adequately justify the target population(s)?**

| | |
|---|---|
| a. Yes | **2** |
| b. Not specified | **0** |
| c. Unclear | **0** |

**QUALITY REVIEW OF QUALITATIVE STUDIES**

**16. How were the data generated? (Check all that apply)**

- □ Field observation/participant observation
- □ In-depth interviews
- □ Focus groups
- □ Document analysis
- □ Other _____
- □ Not specified

**17. Did the study use multiple methods of data collection?**

| | |
|---|---|
| a. Adequate (three or more methods were used) | **2** |
| b. Fair (two methods were used) | **1** |
| c. Inadequate (one method OR unclear) | **0** |

**18. Did the authors justify the method(s) of data generation?**

| | |
|---|---|
| a. Yes | **2** |
| b. No | **0** |
| c. Unclear | **0** |

**19. How were the study participants selected?**

| | |
|---|---|
| a. Random sampling | **2** |
| b. Other systematic sampling (e.g., consecutive selection) | **2** |
| c. Convenience sampling | **1** |
| d. Other | **0** |
| e. Unclear | **0** |

**20. How many times were study participants interviewed?**

**[If the study used an in-depth interview method, circle "not applicable"]**

| | |
|---|---|
| a. Two or more times (adequate) | **2** |
| b. Once (fair) | **1** |
| c. Never OR unclear (inadequate) | **0** |
| d. Not applicable | **N/A** |

**21. How were the data captured?**

| | |
|---|---|
| a. Adequate ( both recorded AND transcribed) | **2** |
| b. Fair (recorded but not transcribed OR note taking only) | **1** |
| c. Inadequate (not recorded OR unclear) | **0** |
| d. Not applicable | **N/A** |

**22. How would you rate the overall quality of this study?**

**[Answer Q 22 for ALL studies]**

Excellent (excellent depth and breadth of study participant selection and data collection/analysis)

Good

Fair

Poor

## Appendix F. Evidence Tables

**Evidence Table 1-1. Characteristics of Studies About Methods Used to Study Strategies to Recruit Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 1).**

| Author, Year | U.S. or non-U.S. | Study Setting | Target Population | Study Design | Type of Cancer Studied | Recruitment Dates | Study Objective(s) |
|---|---|---|---|---|---|---|---|
| Advani, 2003 | U.S. | Hospital outpatient | Patients/ Participants | Case-control | Solid or hematologic malignancy (excluding melanoma) | NR | A. Determine if African-American oncology patients are less willing to participate in clinical trials.<br>B. Better delineate existing barriers to recruitment in African Americans.<br>C. Compare attitudes of oncology patients who were treated in rural areas compared to a major medical center. |
| Berman, 1998 | U.S. | Community, school district | Patients/ Participants | Quasi-experimental | Smoking cessation | 1990-1992 | Determine whether there are race & ethnic differences in recruitment. |
| Brewster, 2002 | U.S. | Community; Hospital outpatient | Patients/ Participants | CCT | Cervical | 1999-2000 | Review and compare the recruitment strategies associated with recruiting Latinas into cancer prevention trials. |
| Ford, 2004 | U.S. | Community | Patients/ Participants | RCT | Prostate, lung, and colorectal | 1996-2001 | Evaluate the outcomes of a randomized trial designed to recruit African American men aged 55-74 years to a PLOC screening trial. |
| Kaluzny, 1993 | U.S. | Community; Hospital outpatient; Group practice | Patients/ Participants; Physicians | Descriptive; Qualitative | All | 1990-1992 | Describe the early implementation of the MBCCOP and identify the challenges that have emerged in developing a network aimed at increasing the participation of minority populations in clinical trials. |
| Linnan, 2002 | U.S. | Work site; Workers homes | Patients/ Participants | RCT | Lung | NR | A. Describe organizational factors associated with each employee recruitment method.<br>B. Investigate differences in employee enrollment and attrition based on elected recruitment method.<br>C. Compare self-reported health behaviors and motivational readiness to change among employees enrolled in home-based intervention study by recruitment method. |

**Evidence Table 1-1. Characteristics of Studies About Methods Used to Study Strategies to Recruit Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 1). (Continued)**

| Author, Year | U.S. or non-U.S. | Study Setting | Target Population | Study Design | Type of Cancer Studied | Recruitment Dates | Study Objective(s) |
|---|---|---|---|---|---|---|---|
| Maurer, 2001 | U.S. | Hospital inpatient | Patients/ Participants | Case series | Breast, colon, rectum, lung, prostate | 1993-1997 | Determine whether participation in clinical trials would lead to generalizable changes in patterns of care from before to after implementation. |
| Paskett, 1995 | U.S. | Community | Physicians | Community physicians | Colorectal Cancer | 1991-present | Get community physicians involved in clinical trial research. |
| Paskett, 2002 | U.S. | Community | Physicians | CCT | Breast and colorectal | 1993-1996 | A. Evaluate a rural cancer care Intervention.<br>B. Assess rural-based primary care.<br>C. Assess physician knowledge and attitudes/beliefs about patient and physician barriers to cancer clinical trials and accrual to clinical treatment trials. |
| Randall-David, 2001 | U.S. | Unclear | Patients/ Participants | Qualitative | All | NR | Use focus groups to elicit perceptions of urban and rural adults regarding participation in cancer clinical trial. |
| Sears, 2003 | U.S. | Community | Patients/ Participants | Descriptive; Retrospective | Breast | 1999-2000 | Examine recruitment, retention, and predictors of participation. |
| Thornquist, 1991 | U.S. | Community | Patients/ Participants | Descriptive; Retrospective | Lung cancer prevention | 1985-1988 | Describe any differences in accrual and adherence to trial by age group--relevant to overall study power calculation |
| Zhu, 2000 | U.S. | Community | Physicians | Descriptive; Qualitative | Breast Cancer | NR | Present the strategy and outcome of a strategy to recruit elderly African American women into cancer prevention and control studies. |

CARET = Beta-carotene and Retinol Efficacy Trial
CCT = Concurrent controlled trial
MBCCOP = Minority-based Community Clinical Oncology Program
NR = Not Reported
PLOC =Prostate, Lung, Ovarian and Colorectal Cancer
RCT = Randomized controlled trial

**Evidence Table 1-2. Target Population Characteristics of Studies About Methods Used to Evaluate Strategies to Recruit Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 1).**

| Author, Year | U.S. or non-U.S. | Mean Age, y | Age, Range | % Male | % Underrepresented | Study Setting | Target Population | Study Design | Type of Cancer Studied | Recruitment Dates |
|---|---|---|---|---|---|---|---|---|---|---|
| Advani, 2003 | U.S. | NR | NR | NR | 33% AIAN; 64% rural | Hospital outpatient | Patients/ Participants | Case-control | Solid or hematologic malignancy (excluding melanoma) | NR |
| Berman, 1998 | U.S. | NR | NR | 0 | 15% AA; 85% Latino/Hispanic | Community | Patients/ Participants | Quasi experimental | Smoking cessation | 1990-1992 |
| Brewster, 2002 | U.S. | 43 | 17-78 | 0 | 78% Latino/Hispanic; 39% with <$10,000/y income | Community; Hospital outpatient | Patients/ Participants | CCT | Cervical | 1999-2000 |
| Ford et al, 2004 | U.S. | 62 | 55-74 | 100 | 100% AA; 100% elderly; 35% low SES | Community | Patients/ Participants | RCT | Prostate, lung, and colorectal | 1996-2001 |
| Kaluzny, 1993 | U.S. | NR | NR | NR | NR | Community; Hospital outpatient; Group practice | Patients/ Participants; Physicians | Descriptive; Qualitative | All | 1990-1992 |
| Linnan, 2002 | U.S. | 43 | NR | 53 | 6% Latino/Hispanic; 27% with <29,999/ yr income | Work site; Workers' homes | Patients/ Participants | RCT | Lung | NR |
| Maurer, 2001 | U.S. | NR | NR | NR | 100% rural | Hospital inpatient | Patients/ Participants | Case series | Breast, colon, rectum, lung, prostate | 1993-1997 |
| Paskett, 1995 | U.S. | NR | NR | NR | NR | Community | Physicians | Community physicians | Colorectal | 1991-present |

**Evidence Table 1-2. Target Population Characteristics of Studies About Methods Used to Evaluate Strategies to Recruit Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 1). (continued)**

| Author, Year | U.S. or non-U.S. | Mean Age, y | Age, Range | % Male | % Underrepresented | Study Setting | Target Population | Study Design | Type of Cancer Studied | Recruitment Dates |
|---|---|---|---|---|---|---|---|---|---|---|
| Paskett, 2002 | U.S. | 47 | NR | 84 | 100% rural | Community | Physicians | CCT | Breast, colorectal | 1993-1996 |
| Randall-Davi2, 2001 | U.S. | 55 | 18-72 | 0 | 100% rural | Unclear | Patients/ Participants | Qualitative | All | NR |
| Sears, 2003 | U.S. | 56 | NR | NR | 6% AA; 9% Asian/PI | Community | Patients/ Participants | RCT; Retrospective | Breast | 1999-2000 |
| Thornquist et al, 1991 | U.S. | NR | 45-74 | 53 | 23% elderly | Community | Patients/ Participants | Descriptive; Retrospective | Lung | 1985-1988 |
| Zhu, 2000 | U.S. | NR | 65-85 | 0 | 100% AA; 100% elderly; 91% with <$15,000/ y income | Community | Physicians | Descriptive; Qualitative | Breast | NR |



AA = African American
AIAN =American Indian/ Alaskan Native
CCT = Concurrent controlled trial
NR = Not reported
PI = Pacific Islander
RCT = Randomized controlled trial
SES = Socioeconomic status

**Evidence Table 1-3. Methods That Have Been Used to Study Strategies to Recruit Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 1).**

| Author, Year | Recruitment definition | Method(s) to design recruitment | Primary Outcomes | Recruitment Intervention(s) |
|---|---|---|---|---|
| Advani, 2003 | Willingness to participate | Survey | Therapeutic treatment; Willingness to participate | NR |
| Berman, 1998 | Actual participation | NR | Primary prevention | A. Individuals interested in participating in a smoking-cessation program were invited via telephone to participate.<br>B. Tailored.<br>C. Opportunistic.<br>D. General publicity presentations, media, distribution of flyers. |
| Brewster, 2002 | Actual participation | Literature Review; Assumed based on introduction but not reported specifically by author | Secondary prevention | A. First 6 months, bilingual letters of introduction mailed with return postcards. Bilingual research personnel made 3 attempts to contact patients (only individuals who attended that particular clinic).<br>B. Second 6 months, media recruitment (study advertised weekly in community and regional newspapers in English or Spanish). Fliers placed in local businesses, community organizations, churches, mental health and free clinics, and 2 Spanish language TV stations. |
| Ford, 2004 | Actual Participation | Addressed barriers to recruitment of minority group members | Primary Prevention | A & B. Eligibility screening telephone call conducted; baseline information gathered via mailed packet; telephone and mailed reminder to return baseline information.<br>C. Eligibility screening telephone call conducted; church-based project sessions -study site collection of baseline information took place at church, transportation was provided to the churches<br>D. Standard recruitment letter and mailing process, eligibility screening via telephone by Caucasians or African Americans, telephone and mailed reminder to return baseline information. |
| Kaluzny, 1993 | Actual participation | NR | Treatment | A. Modification and translation of protocol consent forms and educational materials to reach low literacy and non-English speakers.<br>B. Promotional and educational materials to increase awareness of trials among physicians practicing in minority communities.<br>C. Design of interdisciplinary teams to aid with protocol recruitment and assure compliance follow-up.<br>D. Targeting younger physicians (interns, residents, fellows) and emphasizing the special needs of minority populations to them.<br>E. Development of data management systems to track and evaluate the provision of services in large minority populations |
| Linnan, 2002 | Actual participation | NR | Primary prevention | A. Letter from CEO to workers. B. Recruitment events at work with free food and giveaways. C. Flyers, posters, and notices at work. D. Passive vs. active recruitment. |

**Evidence Table 1-3. Methods That Have Been Used to Study Strategies to Recruit Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 1). (continued)**

| Author, Year | Recruitment definition | Method(s) to design recruitment | Primary Outcomes | Recruitment Intervention(s) |
|---|---|---|---|---|
| Maurer, 2001 | Actual participation | NR | Treatment | NR |
| Paskett, 1995 | Actual participation | Lead oncologist model | Survivorship; Recurrence prevention | A. Medical oncologists as community leaders carry out activities in community hospitals and clinics. B. Lead oncologist meets with community physicians. C. Community physicians meet at yearly meetings. |
| Paskett, 2002 | Actual participation | NR | Treatment | A. Tumor reporting - for state cancer registry.<br>B. Nurse facilitator to inform physicians on available trails.<br>C. Quarterly newsletter to physicians about cancer treatment and clinical trials.<br>D. Health educator for community about cancer screening and treatment |
| Randall-David, 2001 | Not defined | Focus group used to assess beliefs which subsequently were used to establish an awareness campaign | No particular trial, no recruitment attempted. | NA |
| Sears, 2003 | Actual participation | NR | Therapeutic CAM | A. Provide contact information on all eligible patients within 5 weeks of surgery.<br>B. Mail introductory letter to patient 1 to 5 weeks after surgery.<br>C. Called patient 2 to 6 weeks after surgery; 3 calls without response = passive refusal. |
| Thornquist, 1991 | Actual participation | NR | Chemo-prevention | A. Mailings to all insurers of Seattle-based King County Medical Blue Shield—one arm |
| Zhu, 2000 | Actual participation | In-person interview | Primary prevention | A. Use of in-person communications by door-to-door canvassing.<br>B. Use of local spokesperson to establish trust and increase credibility.<br>C. Representation of African-Americans among research staff and use of African Americans women in direct contact with potential subjects.<br>D. Provisions of monetary and/or material incentives. |

CAM = complimentary alternative medicine
CEO = Chief Executive Officer
MBCCOP = Minority-based Community Clinical Oncology Program
NCI = National Cancer Institutes
NR = Not reported
NA = Not applicable

## Appendix F. Evidence Tables (continued)

**Evidence Table 2-1. Characteristics of Studies about Measures of Success Used to Evaluate the Efficacy or Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2).**

| Author, Year | Country | Study Setting | Target Population | Study Design | Type of Cancer Studied | Recruitment Dates |
|---|---|---|---|---|---|---|
| Alexander, 2000 | U.S. | All NCI-sponsored trials from 1994 to 1998 | Patients/Participants | Cross-sectional; Descriptive; Retrospective | All | 1994-1995 |
| Benson, 1991 | U.S. | Clinical Trials Cooperative Group (1839 hospitals, 194 universities) | Patients/Participants | Cross-sectional; Descriptive; Retrospective | All | 1991-1994 |
| Berman, 1998 | U.S. | Community | Patients/Participants | Quasi-experimental | Smoking cessation | 1990-1992 |
| Brewster, 2002 | U.S. | Community; Hospital outpatient | Patients/Participants | CCT | Cervical | 1999-2000 |
| Ford, 2004 | U.S. | Community | Patients/Participants | RCT | Prostate, lung, colorectal | 1996-2001 |
| Goodwin, 1988 | U.S. | SWOG | Patients/Participants | Cross-sectional; Descriptive; Retrospective | All | 1959-1982 |
| Hunter, 1987 | U.S. | Hospital inpatient; Hospital outpatient; | Patients/Participants | Cross-sectional; Descriptive; Retrospective | All | 1984-1985 |
| Kaluzny, 1993 | U.S. | Community; Hospital outpatient; Group practice | Patients/Participants; Physicians | Descriptive | All | 1990-1992 |
| Kemeny, 2003 | U.S. | Community | Patients/Participants | Case-control | Breast | NR |
| Kladbunde, 1999 | U.S. | CCOP, Hospitial inpatient | Patients/Participants | Retrospective | All | 1997-1998 |
| Krailo, 1993 | U.S. | Hospital inpatient; Hospital outpatient | Patients/Participants | Cross-sectional; Descriptive; Retrospective | All | 1980-1987 |
| Lewis, 2003 | U.S. | NCI cooperative groups | Patients/Participants | Cross-sectional; Descriptive; Retrospective | All | 1997-2000 |
| Linnan, 2002 | U.S. | Work site; Workers homes | Patients/Participants | RCT | Lung | NR |
| Maurer, 2001 | U.S. | Hospital inpatient | Patients/Participants | Case series | Breast, colon, rectum, lung, prostate | 1993-1997 |
| Moinpour, 2000 | U.S. | Hospital outpatient; NCI Comprehensive Cancer Center | Patients/Participants; Researchers | Descriptive | Prostate | 1993-1997 |

## Appendix F. Evidence Tables (continued)

**Evidence Table 2-1. Characteristics of Studies about Measures of Success Used to Evaluate the Efficacy or Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2). (continued)**

| Author, Year | Country | Study Setting | Target Population | Study Design | Type of Cancer Studied | Recruitment Dates |
|---|---|---|---|---|---|---|
| Murthy, 2004 | U.S. | Hospital inpatient; Hospital outpatient | Patients/Participants | Cross-sectional; Descriptive; Retrospective | Breast, colorectal, lung, prostate | 1996-2002 |
| Paskett, 2002 | U.S. | Community | Physicians | CCT | Breast, colorectal | 1993-1996 |
| Schiffman, 2000 | U.S. | Community; Group practice | Patients/Participants | Descriptive | Cervical | 1997-1998 |
| Simon, 2004 | U.S. | NCI Comprehensive Cancer Center | Patients/Participants | Descriptive | Breast | 1996-1997 |
| Thornquist, 1991 | U.S. | Community | Patients/Participants | Descriptive; Retrospective | Lung | 1985-1988 |
| Trimble, 1994 | U.S. | All NCI trials in 1992 | Patients/participants | Retrospective review of NCI trials in 1992 | All | 1992-1993 |
| Yee, 2003 | Canada | Canada NCIC CTG treatment trials & U.S. SWOG treatment trials | Patients/Participants | Cross-sectional; Descriptive; Retrospective | All | 1993-1996 |
| Zhu, 2000 | U.S. | Community | Physicians | Descriptive; Qualitative | Breast | NR |

CCOP = Community clinical oncology program
CCT = Concurrent controlled trial
CTEP = Cancer Therapy Evaluation Program
NCI = National Cancer Institute
NCI = National Cancer Institutes
NCIC CTG = National Cancer Institute of Canada Clinical Trials Group
NR = Not reported
RCT = Randomized controlled trial
SWOG = Southwest Oncology group

**Evidence Table 2-2. Characteristics of Studies about Measures of Success Used to Evaluate the Efficacy or Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2).**

| Author/ year | Country | Mean Age, y | Age Range, y | % High School or Less | % Male | % White | % Under-represented | Study Setting | Target Population | Study Design | Type of Cancer Studied | Recruitment Dates |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Alexander, 2000 | U.S. | NR | NR | NR | 41 | NR | NR | NCI-sponsored trials from 1994 to 1998 | Patients/ Participants | Cross-sectional; Descriptive; Retrospective | All | 1994-1995 |
| Benson, 1991 | U.S. | NR | NR | NR | | 85 | 10% AA; 6% LH; 51% elderly | Clinical Trials Cooperative Group (1,839 hospitals, 194 universities) | Patients/ Participants | Cross-sectional; Descriptive; Retrospective | All | 1991-1994 |
| Berman, 1998 | U.S. | NR | NR | 84 | 49 | | 85% Hispanic; 15% AA | Community | Patients/ Participants | Quasi-experimental | Smoking cessation | 1990-1992 |
| Brewster, 2002 | U.S. | 43 | 17-78 | NR | 0 | 22 | 78% LH; 39% low annual income | Community; Hospital outpatient | Patients/ Participants | CCT | Cervical | 1999-2000 |
| Ford, 2004 | U.S. | 63 | (55-74) | NR | 100 | 0 | 100% AA; 100% elderly; 38% low SES | Community | Patients/ Participants | RCT | Prostate, lung cololrectal | 1996-2001 |
| Goodwin, 1988 | U.S. | 53 | NR | NR | NR | NR | 15% elderly | SWOG | Patients/ Participants | Cross-sectional; Descriptive; Retrospective | All | 1959-1982 |
| Hunter, 1987 | U.S. | NR | NR | NR | 43 | 93 | 4% AA; 3% LH | Hospital inpatient; Hospital outpatient; | Patients/ Participants | Cross-sectional; Descriptive; Retrospective | All | 1984-1985 |
| Kaluzny, 1993 | U.S. | NR | NR | NR | NR | NR | NR | Community; Hospital outpatient; Group practice | Patients/ Participants; Physicians | Descriptive | All | 1990-1992 |

**Evidence Table 2-2. Characteristics of Studies about Measures of Success Used to Evaluate the Efficacy or Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2). (continued)**

| Author/ year | Country | Mean Age, y | Age Range, y | % High School or Less | % Male | % White | % Under-represented | Study Setting | Target Population | Study Design | Type of Cancer Studied | Recruitment Dates |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kemeny, 2003 | U.S. | 48 (young group), 74 (older group) | NR | 45 | 0 | NR | 50% elderly | Community | Patients/ Participants | Case-control | Breast | NR |
| Kladbunde, 1999 | U.S. | NR | NR | NR | 0 | 30 | NR | CCOP, Hospital inpatient | Patients/ Participants | Retrospective | All | 1997-1998 |
| Krailo, 1993 | U.S. | NR | 0-19 | NR | NR | NR | NR | Hospital inpatient; Hospital outpatient | Patients/ Participants | Cross-sectional; Descriptive; Retrospective | All | 1980-1987 |
| Lewis, 2003 | U.S. | NR | NR | NR | NR | NR | 32% elderly | NCI cooperative groups | Patients/ Participants | Cross-sectional; Descriptive; Retrospective | All | 1997-2000 |
| Linnan, 2002 | U.S. | 43 | NR | 50 | 53 | 91 | 6% LH; 27% low income | Work site; Workers homes | Patients/ Participants | RCT | Lung | NR |
| Maurer, 2001 | U.S. | NR | NR | NR | NR | NR | 100% rural | Hospital inpatient | Patients/ Participants | Case series | Breast, colon, rectum, lung, prostate | 1993-1997 |
| Moinpour, 2000 | U.S. | NR | 51-91 | 25 | 100 | 91 | NR | Hospital outpatient; NCI Comprehensive Cancer Center | Patients/ Participants; Researchers | Descriptive | Prostate | 1993-1997 |
| Murthy, 2004 | U.S. | NR | 30-75 | NR | 32 | 86 | 9% AA; 2% Asian/PI; 3% LH; 32% elderly | Hospital inpatient; Hospital outpatient | Patients/ Participants | Cross-sectional; Descriptive; Retrospective | Breast, colorectal, lung, prostate | 1996-2002 |
| Paskett, 2002 | U.S. | 47 | NR | NR | 87 | NR | 100% rural | Community | Physicians | CCT | Breast, colorectal | 1993-1996 |

**Evidence Table 2-2. Characteristics of Studies about Measures of Success Used to Evaluate the Efficacy or Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2). (continued)**

| Author/ year | Country | Mean Age, y | Age Range, y | % High School or Less | % Male | % White | % Under-represented | Study Setting | Target Population | Study Design | Type of Cancer Studied | Recruitment Dates |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Schiffman, 2000 | U.S. | 27 | 18-81 | 31 | NR | 64 | 31% AA; 2% AIAN; 3% Asian/PI; 5% LH | Community; Group practice | Patients/ Participants | Descriptive | Cervical | 1997-1998 |
| Simon, 2004 | U.S. | 55 | NR | NR | 0 | 57 | 32% AA | NCI Comprehensive Cancer Center | Patients/ Participants | Descriptive | Breast | 1996-1997 |
| Thornquist, 1991 | U.S. | NR | 45-74 | | 53 | | 23% elderly | Community | Patients/ Participants | Descriptive; Retrospective | Lung | 1985-1988 |
| Trimble, 1994 | U.S. | NR | NR | NR | NR | NR | 100% elderly | NCI cancer trials | Patients/ Participants | Descriptive; retrospective | Lung, prostate, colorectal, pancreas, leukemia, ovarian, breast | 1992-2993 |
| Yee, 2003 | Can | NR | NR | NR | NR | NR | 22% elderly | Canada NCIC CTG treatment trials & U.S. SWOG treatment trials | Patients/ Participants | Cross-sectional; Descriptive; Retrospective | All | 1993-1996 |
| Zhu, 2000 | U.S. | NR | 65-85+ | 88 | 0 | | 100% AA; 100% elderly; 91% low income | Community | Physicians | Descriptive; Qualitative | Breast | NR |

**Evidence Table 2-2. Characteristics of Studies about Measures of Success Used to Evaluate the Efficacy or Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2). (continued)**

AA = African American
AIAN = American Indian/Alaska Native
Can = Canada
CCOP = Community Cooperative Oncology Program
CCT = Concurrent controlled trial
CTG = Clinical trials group
LH = Latino/Hispanic
NCIC =National Cancer Institute of Canada
NR = Not reported
PI = Pacific Islander
RCT = randomized controlled trial
SES = Socioeconomic status
SWOG = Southwest Oncology Group

**Evidence Table 2-3. Studies about Measures of Success Used to Evaluate the Efficacy or Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2).**

| Author, Year | Recruitment Definition | Primary Outcomes of Trial | Was Recruitment Goal Stated a priori (Y/N). If yes, what was goal (in %)? | Recruitment Success Measure | For Which Underserved Group was the Measure of Success Used? |
|---|---|---|---|---|---|
| Alexander, 2000 | Actual participation | Primary and secondary prevention; Treatment for NCI supported trials | NA | Disease-specific proportion in U.S. for Asian/PI; Researcher set for elderly: proportion younger Asian/PIs in the NCI-supported treatment trials | Asian/ PI; elderly |
| Benson, 1991 | Actual participation | Treatment | NA | Disease-specific proportion in U.S. | African American; Latino/Hispanic |
| Berman, 1998 | Actual participation | Primary prevention | No | Geographic representation: proportion underserved group in school district. | Latino/Hispanic, African American |
| Brewster, 2002 | Actual participation | Secondary prevention | No | Researcher set: Proportion underserved that agreed to participate in study | Latino/Hispanic |
| Ford, 2004 | Actual participation | Primary prevention | No | Measurement of enrollment of increasingly intensive intervention strategies compared to the control arm | African American men |
| Goodwin, 1988 | Actual participation | Treatment | NA | Researcher set: New Mexico non-SWOG cancer trials proportion of underserved groups | Elderly |
| Hunter, 1987 | Actual participation | Treatment; Phase I, II, III trials | NA | Disease-specific proportion in U.S.: Compared CCOP participation to SEER data from 1973-1977 | African American; Elderly |
| Kaluzny, 1993 | Actual participation | Treatment | NA | Researcher set: Proportion of minority-based CCOP eligible patients compared to annual proportion of CCOP eligible patients who entered trials from 1985-89 | African American; Latino/Hispanic |
| Kemeny, 2003 | Actual participation | Treatment | NA | Researcher set: Proportion underserved offered a cancer trial | Elderly |
| Kladbunde, 1999 | Actual participation | Treatment | NA | Research Institution proportion | African American |
| Krailo, 1993 | Actual participation | Prevention and treatment | NA | Disease-specific proportion in county: proportion underserved with cancer in county | Adolescents |
| Lewis, 2003 | Actual participation | Treatment | NA | Disease-specific proportion in U.S. | Elderly |
| Linnan, 2002 | Actual participation | Primary prevention | NA | Researcher set: Proportion underserved eligible for trial | Low SES; persons with high school education or less |

**Evidence Table 2-3. Studies about Measures of Success Used to Evaluate the Efficacy or Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2). (continued)**

| Author, Year | Recruitment Definition | Primary Outcomes of Trial | Was Recruitment Goal Stated a priori (Y/N). If yes, what was goal (in %)? | Recruitment Success Measure | For Which Underserved Group was the Measure of Success Used? |
|---|---|---|---|---|---|
| Maurer, 2001 | Actual participation | Treatment | No elderly goal, Yes-rural goal; 40% of incident cancer cases & 54% would be eligible | Researcher set: proportion underserved based upon elements from another study for rural and proportion underserved participated in trial for elderly | Elderly, rural |
| Moinpour, 2000 | Actual participation | Treatment | Yes; 8% African American | Geographic representation: U.S. proportion underserved | African American |
| Murthy, 2004 | Actual participation | Treatment | NA | Disease-specific proportion in U.S. | African American; Asian/ PIs; Latino/Hispanic; Elderly |
| Paskett, 2002 | Actual participation | Treatment | No | Researcher set: Proportion underserved enrolled pre and post intervention | Rural |
| Schiffman, 2000 | Actual participation | Secondary prevention | No | Researcher set: Proportion underserved enrolled in the trial | African American |
| Simon, 2004 | Actual participation | All treatment trials except one diet intervention | No | Disease-specific proportion: proportion underserved group with cancer(taken from the SEER database) in Detroit | African American; Elderly |
| Thornquist, 1991 | Actual participation | Primary prevention/ Chemoprevention | No | Researcher set: Wanted enough elderly participants to evaluate them in study. Also wanted equal participation in 5-year age groups. | Elderly |
| Trimble, 1994 | Actual participation | Cancer treatment; phase II and III trials | NA | Disease-specific proportion in the U.S. | Elderly |
| Yee, 2003 | Actual participation | Treatment | NA | 1) Disease-specific proportion in Canada. 2) Researcher set: proportion underserved compared to U.S SWOG cancer treatment trial rates. | Elderly |
| Zhu, 2000 | Actual participation | Primary prevention | No | Researcher set for African-American elderly women: Authors noted participation rates were high, compared to other study with participation rate ranging from 20-48% | African American; Elderly |

**Evidence Table 2-3. Studies about Measures of Success Used to Evaluate the Efficacy or Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 2). (continued)**

CCOP = Community Cooperative Oncology Program
NA = Not applicable
NCI = National Cancer Institute
PI = Pacific Islander
SEER = Surveillance, Epidemiology, and End Results Program
SES = Socioeconomic status
SWOG = Southwest Oncology Group

**Evidence Table 3/4-1. Characteristics of Studies on the Efficacy or Effectiveness of Recruitment Strategies for Increasing Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Questions 3 and 4).**

| Author, Year | Study setting | Target population | Study Design | Type of Cancer studied | Recruitment Dates | Study Objective(s) |
|---|---|---|---|---|---|---|
| Brewster, 2002 | Community; Outpatient hospital | Participants | CCT | Cervical | 1999-2000 | Review and compare the recruitment strategies associated with recruiting Latinas into cancer prevention trials |
| Ford, 2004 | Community; Faith-based organization | Participants | RCT | Prostate, Lung, Colorectal | 1996-2001 | Test effectiveness of three increasingly intensive recruitment strategies in recruiting African-American men to the PLCO Cancer Screening Trial |
| Linnan, 2002 | Community | Participants | RCT | Lung | NR | 1) Describe organizational factors associated with each selected employee recruitment method.<br>2) Investigate differences in employee reaction, enrollment, and attrition based on selected recruitment methods.<br>3) Compare self-reported health behaviors and motivational readiness to change among employees enrolled in home-based intervention study by recruitment method. |
| Moinpour, 2000 | Outpatient hospital | Participants; Researchers | RCT | Prostate | 1993-1997 | Summarize the challenges of enrolling and randomizing African Americans and other minorities in the prostate cancer prevention trial (PCPT). |
| Paskett, 2002 | Community | Physicians | CCT | Breast, Colorectal | 1992-1996 | 1) Evaluate a rural cancer care intervention.<br>2) Assess rural-based primary care physician knowledge and attitudes/beliefs about patient and physician barriers to research.<br>3) To study cancer clinical trials and accrual to clinical treatment trials. |

CCT = Concurrent controlled trial
PLCO = Prostate, Lung, Cervical, Ovarian
RCT = Randomized controlled trial

**Evidence Table 3/4-2. Target Population Characteristics of Studies on the Efficacy or Effectiveness of Recruitment Strategies for Increasing Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Questions 3 and 4).**

| Author, Year | Target Population | Study Subgroup | Sample size | Mean Age, y | Mean Education | Mean Income (per year) | % Male | % AA | % Cauc | % Lat/Hisp | Study Setting |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Brewster, 2002 | Participants | Clinic registry | 405 | 44 | < HS graduate (55%) | ≤ $10,000 (41%) > $10,000 (59%) | 0 | 0 | 27 | 73 | Urban |
| | | Media campaign | 535 | 42 | < HS graduate (49%) | ≤ $10,000 (38%) > $10,000 (62%) | 0 | 0 | 17 | 83 | |
| Ford, 2004 | Participants | AA, Arm A | 3,079 | NR | NR | NR | 100 | 100 | 0 | 0 | Urban |
| | | AA, Arm B | 3,075 | | | | | | | | |
| | | AA, Arm C | 2,949 | | | | | | | | |
| | | AA, Arm D | 3,297 | | | | | | | | |
| Linnan, 2002 | Participants | Passive employee contact | 891 | 41 | ≤ HS graduate (50.4%) | < $29,999 (24%) | 53 | NR | 90 | 5 | Urban |
| | | Active employee contact | 1,015 | 44 | ≤ HS graduate (39.5%) | < $29,999 (14%) | 53 | NR | 95 | 2 | Urban |
| Moinpour, 2000 | Participants; Researchers | AA, Site A, 1995 | NR | NR | NR | NR | 100 | NR | 0 | NR | Urban |
| | | AA, Site A, 1996 | | | | | | | | | |
| | | AA, Site B, 1995 | | | | | | | | | |
| | | AA, Site B, 1996 | | | | | | | | | |
| | | AA, Site C, 1995 | | | | | | | | | |
| | | AA, Site C, 1996 | | | | | | | | | |
| | | AA, Site D, 1995 | | | | | | | | | |
| | | AA, Site D, 1996 | | | | | | | | | |
| | | Lat/Hisp, Site E, 1995 | | | | | | | | | |
| | | Lat/Hisp, Site E, 1996 | | | | | | | | | |
| Paskett, 2002 | Providers (physicians) | South Carolina 1993 | 72 | 44 | NR | NR | 92 | NR | NR | NR | Rural |
| | | North Carolina 1993 | 124 | 49 | NR | NR | 84 | NR | NR | NR | |
| | | South Carolina 1996 | 62 | 45 | NR | NR | 85 | NR | NR | NR | |
| | | North Carolina 1996 | 102 | 49 | NR | NR | 87 | NR | NR | NR | |

AA = African American
Cauc. = Caucasian
HS = High School
Lat/Hisp = Latino/Hispanic
NR = not reported

**Evidence Table 3/4-3. Interventions Used in Studies on the Efficacy or Effectiveneses of Strategies for Increasing Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Questions 3 and 4).**

| Author, Year | Target Population | Intervention Group | Elapsed Duration of Interventions | Underrepresented Recruitment Primary Outcome | Study Design |
|---|---|---|---|---|---|
| Brewster, 2002 | Clinic registry | Women were identified from clinic registry and contacted to participate. | 1 year | Yes: objective was to review recruitment strategies associated with recruiting Latinas into prevention trials. | CCT |
| | Media campaign | The study advertised using several media strategies (flyers, newspapers). Women responded to these advertisements. | | | |
| Ford, 2004 | AA, Arm A | Enhanced mailing process; eligibility screening conducted by AA interviewers; baseline information gathered via mailed packet. | NR | Yes: enrollment of AA men to cancer screening trial. | RCT |
| | AA, Arm B | Enhanced mailing process; eligibility screening conducted by AA interviewers; baseline information gathered via telephone interviews. | NR | | |
| | AA, Arm C | Enhanced mailing process; eligibility screening and church project sessions conducted by AA; baseline information gathered at church sessions; letters and telephone call reminders for church session | NR | | |
| | AA, Arm D | Control group: standard PLCO trial recruitment procedures; eligibility screening conducted by AA or Caucasian interviewers; baseline information gathered via mailed packets | NR | | |
| Linnan, 2002 | Passive employee contact | Companies provided list of employee names and home telephone numbers to research team and employees (target population) were contacted by research team to participate in study. | NA | No, target population was worksite employees but population included persons with less than high school education and relatively lower income. | RCT |
| | Active employee contact | Companies did not provide employee list to research team. Instead, employees (target population) actively contacted research team to partcipate in the study. | NA | | |
| Moinpour, 2000 | AA, Site A, 1995 | No specific details of intervention for each of the five sites were given. | 3.5 years | No, but the successes and failures in increasing minority participation in cancer prevention trial were presented. | RCT |
| | AA, Site A, 1996 | | | | |
| | AA, Site B, 1995 | | | | |
| | AA, Site B, 1996 | | | | |
| | AA, Site C, 1995 | | | | |
| | AA, Site C, 1996 | | | | |
| | AA, Site D, 1995 | | | | |
| | AA, Site D, 1996 | | | | |
| | Lat/Hisp, Site E, 1995 | | | | |
| | Lat/Hisp, Site E, 1996 | | | | |

**Evidence Table 3/4-3. Interventions Used in Studies on the Efficacy or Effectiveneses of Strategies for Increasing Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Questions 3 and 4). (continued)**

| Author, Year | Target Population | Intervention Group | Elapsed Duration of Interventions | Underrepresented Recruitment Primary Outcome | Study Design |
|---|---|---|---|---|---|
| Paskett, 2002 | Physicians in North Carolina, 1993 | Interventions included tumor-reporting system to expedite receipt of data on cancer patients to physicians, nurse facilitator and quarterly newspapers to inform physicians of cancer treatment and clinical trials, and health educators to provide community-based cancer education about cancer screening, treatment, and clinical trials. | 4 years | Yes: enrollment of rural patients to controlled trials | CCT |
| | Physicians in North Carolina, 1996 | | | | |
| | Physicians in South Carolina, 1993 | Control group (usual medical care in South Carolina counties) | NA | | |
| | Physicians in South Carolina, 1996 | | | | |

AA = African American
CCT = Concurrent controlled trial
Lat/Hisp = Latino/Hispanic
NA = Not applicable
NR = Not reported
PLCO = Prostate, Lung, Cervical, Ovarian
RCT = Randomized controlled trial

**Evidence Table 3/4-4. Quality of Studies on the Efficacy or Effectiveness of Strategies for Increasing Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Questions 3 and 4).**

| Author/ Year | Represent-ativeness[a] | Bias and confounding[b] | Recruit-ment Descrip-tion[c] | Outcomes and Follow-Up[d] | Statistical Quality and Interpretation[e] | Conflict of Interest Mean[f] |
|---|---|---|---|---|---|---|
| Linnan, 2002 | ◒ | ○ | ◒ | ○ | ◒ | ◒ |
| Brewster, 2002 | ● | ◒ | ◒ | ◒ | ● | ○ |
| Paskett, 2002 | ◒ | ○ | ○ | ◒ | ○ | ● |
| Moinpour, 2000 | NA | NA | NA | NA | NA | NA |
| Ford, 2004 | ◒ | ○ | ● | ● | ● | ◒ |

● Excellent: > 75% quality score

◒ Good: 50-74% quality score

◒ Fair: 25-49% quality score

○ Poor: <25% quality score

NA Not applicable

[a] Representativeness: Score was based on a total maximum score of 8 points. This included the authors' description of setting and population (2 points), detail on provided inclusion and exclusion criteria (2 points), information provided on non-participants (2 points), and description of key participant characteristics (2 points).
[b] Bias and Confounding: Score was based on a total maximum score of 6 points. This included random assignment of participants to a study group (2 points), differenced of participants between groups (2 points), and details on the recruitment trial, blinding of the clinician, patient and/or outcome assors (2 points).
[c] Recruitment description: Score was based on a total maximum score of 4 points. This included details on the flow of participants through each stage of the clinical trial (2 points), and description of the details of the recruitment strategy (2 points).
[d] Outcomes and Follow-up: Percentage score was based on a total maximum score of 6 points. This included how the recruitment success outcomes were defined (2 points), description of the measures used to define the recruitment barriers and promoters (2 points), and whether the study reported the numbers and reasons for withdrawals from the study protocol (2 points).
[e] Statistical Quality and Interpretation: Percentage score was based on a total maximum score of 4 points. This included the statistical analyses used to determine recruitment success (2 points), and whether withdrawals, crossovers, and loss to follow-up were handled appropriately (2 points).
[f] Conflict of Interest: Percentage score was based on a total maximum score of 2 points. Did the study report it's source of funding (2 points)

**Evidence Table 3/4-5. Outcome Point Estimates on the Efficacy or Effectiveness of Recruitment Strategies for Increasing Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Questions 3 and 4).**

| Author, Year | Descriptor of Point Estimate (%, OR, difference) | Point Estimate (value) | Measure of Spread / Significance (CI, P value) | Author Conclusion |
|---|---|---|---|---|
| Brewster, 2002 | OR of women presenting to clinic (media campaign vs. clinic registry) | 3.0 | 2.38 - 3.78 | Media campaign recruitment yielded better recruitment results compared to the clinic registry recruitment strategy. |
| | OR of women screened by telephone (media campaign vs. clinic registry) | 3.0 | 2.52 - 3.51 | |
| Ford, 2004 | Difference of enrollment between Arm C vs. Arm D<br>Arm C = intervention included enhanced mailing process and church-based sessions<br>Arm D = control group which received standard recruitment procedures | 1.0 | P = .02 | Arm C, the most intensive of the arm interventions, yielded higher enrollment compared to the control (Arm D) and other intervention arms (Arms A and B). |
| Linnan, 2002 | Difference of enrollment between passive employee contact and active employee contact (%) | 36.6 | P < .0001 | Active recruitment had lesser reach, higher enrollment, and smaller attrition rate. Passive recruitment had wider ethnic and financial diversity. No significant differences in organizational factors comparing active and passive recruitment. |
| Moinpour, 2000 | Change in Site A enrollment from 1995 to 1996 (%) | 0.3 | NR | It was difficult to evaluate effectiveness of minority recruitment strategies since the strategies were used at the final period of accrual. |
| | Change in Site B enrollment from 1995 to 1996 (%) | 0.5 | NR | |
| | Change in Site C enrollment from 1995 to 1996 (%) | 2.8 | NR | |
| | Change in Site D enrollment from 1995 to 1996 (%) | 0.6 | NR | |
| | Change in Site E enrollment from 1995 to 1996 (%) | 0.5 | NR | |
| Paskett, 2002 | Change in enrollment of breast cancer patients from 1991 to 1996, North Carolina (%) | 9 | NR | No improvement in enrollment of cancer patients into cancer clinical trials was observed after intervention. |
| | Change in enrollment of colorectal cancer patients from 1991 to 1996, North Carolina (%) | 1 | NR | |
| | Change in enrollment of breast cancer patients from 1991 to 1996, South Carolina (%) | 44 | NR | |
| | Change in enrollment of colorectal cancer patients from 1991 to 1996, South Carolina (%) | 5 | NR | |

CI = Confidence interval
OR = Odds ratio

**Evidence Table 5-1. Characteristics of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5).**

| Author, Year | Study Setting | Target Population | Targeted Under-represented Population | Study Design | How Measured | Type of Cancer Studied | Study Objective(s) | Type of Cancer Trial into Which Recruiting |
|---|---|---|---|---|---|---|---|---|
| Adams-Campbell, 2004 | Hospital inpatient; Hospital outpatient | Patients/ Participants; Physicians | AA | Tumor registry review | Enrollment NR | Breast, colorectal, head and neck, lung, prostate | Determine AA barriers to enrollment in trials. | Treatment |
| Advani, 2003 | Hospital outpatient | Patients/ Participants | AA | Case-control | Surveys, phone interview | Solid or hematologic malignancy (excluding melanoma) | A. Determine if AA oncology patients are less willing to participate in trials. B. Better delineate existing barriers to recruitment in AAs. C. Compare attitudes of oncology patients who were treated in rural areas compared to a major medical center. | Treatment |
| Barofsky, 1979 | Community; Hospital inpatient | Patients/ Participants | AA | Qualitative | Semi-structured Interview | Histologically confirmed soft-tissue or osteosarcoma | Determine the extent and nature of patient nonparticipation in the soft tissue and osteosarcoma protocols at NCI. | Treatment |
| Berman, 1998 | Community | Patients/ Participants | Lat/Hisp, AA | Quasi experimental. | Survey; Enrollment | Smoking cessation | Determine whether there are race & ethnic differences in recruitment. | Prevention |

**Evidence Table 5-1. Characteristics of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Study Setting | Target Population | Targeted Under-represented Population | Study Design | How Measured | Type of Cancer Studied | Study Objective(s) | Type of Cancer Trial into Which Recruiting |
|---|---|---|---|---|---|---|---|---|
| Bieniasz, 2003 | Community | Patients/ Participants | AA women | Qualitative | Semi-structured interview | Cervical (dysplasia) | A. Explore women's intention to participate in a chemoprevention trial for cervical dysplasia. B. Identify women's attitudes to certain outcomes from participation in trials. C. Determine who women would consult regarding participation. | Prevention |
| Brewster, 2002 | Community; Hospital outpatient | Patients/ Participants | Latino / Hispanic women | CCT | Enrollment | Cervical | Review and compare the recruitment strategies associated with recruiting Latinas into cancer prevention trials. | Prevention |
| Broome, 2003 | Hospital inpatient; | Patients/ Participants | Children; Adolescents | Qualitative | Semi-structured interview | Ewing's sarcoma, acute lymphatic leukemia or hematological malignancy | How childrens' relationships with parents and clinicians influence participation in the study. | Treatment |
| Broome, 2001 | Community; Hospital inpatient; Hospital outpatient | Patients/ Participants | Children; Adolescents | Qualitative | Interview | Hematological malignancy or solid tumors | Assess childrens' and adolescents' understanding about research and their involvement in the decision to participate in trials. | Treatment |

**Evidence Table 5-1. Characteristics of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Study Setting | Target Population | Targeted Under-represented Population | Study Design | How Measured | Type of Cancer Studied | Study Objective(s) | Type of Cancer Trial into Which Recruiting |
|---|---|---|---|---|---|---|---|---|
| Brown, 2000 | Hospital outpatient | Patients/ Participants | AA and Hispanic women | Descriptive | Survey; Interview; Enrollment | Breast, cervical | A. Determine factors related to intention to participate in a chemo-prevention trial for cervical neoplasia. B. Address differences in AA and Caucasians in factors affecting clinical trial accessibility and participation. | Prevention |
| Brown, 2003 | Community | Patients/ Participants | AA | Cross-sectional; Descriptive | Telephone surveys | NR | Analysis on factors affecting willingness of older AAs and whites to participate in clinical treatment study. | Treatment |
| Chen, 2000 | Hospital inpatient | Patients/ Participants | Elderly | Hospital registry review; Retrospective | Enrollment NR | Aggressive histology lymphoma | Compare baseline patient characteristics, treatments, and outcomes of elderly patients who were entered or not entered into a randomized phase I trial. | Treatment |
| Comis, 2003 | Community | Patients/ Participants | Elderly (by sub-group analysis) | Cross-sectional; Descriptive | Telephone interview | NR | Examine attitudes regarding participation in cancer trials. | Treatment |
| Diener-West, 2001. | Hospital inpatient; Hospital outpatient; Group practice; Solo practice | Patients/ Participants | Elderly (by sub-group analysis) | RCT | Enrollment; Face-to-face interview | Eye | Study and compare predictors of patient participation in 2 related multicenter trials conducted concurrently in the U.S. and Canada. | Treatment |

**Evidence Table 5-1. Characteristics of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Study Setting | Target Population | Targeted Under-represented Population | Study Design | How Measured | Type of Cancer Studied | Study Objective(s) | Type of Cancer Trial into Which Recruiting |
|---|---|---|---|---|---|---|---|---|
| Ford, 2003 | Community | Patients/ Participants | AA men | RCT | Enrollment NR | Prostate, lung, colorectal | A. Demonstrate that low-income and moderate to high income older AA men can be recruited into a cancer trial.<br>B. Identify a method for increased participation of older AA men in cancer screening trials. | Prevention |
| Fouad, 2000 | Community | Patients/ Participants; Physicians | AA | Qualitative | Focus groups / key informant interview | NR | A. Determine the perceptions of AA residents regarding participation in research.<br>B. Determine health care providers perceptions of barriers to participation of AAs in trials. | NR |
| Fouad, 2001 | Community | Patients/ Participants; Physicians | AA | Qualitative | Focus groups / key informant interview | NR | Ascertain the community's perspective of participating in trials. | NA |
| Green, 2000 | Community | Patients/ Participants | AA | Qualitative | Focus group | NR | Identify important issues regarding AAs' perceptions/ attitudes toward trials and to plan a conference. | NR |
| Grunfeld, 2002 | Hospital inpatient | Researchers | Clinical research associates | Qualitative | Semi-structured interview | NR | Get the views of clinical research associates on barriers and facilitators to accrual. | Treatment |

**Evidence Table 5-1. Characteristics of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Study Setting | Target Population | Targeted Under-represented Population | Study Design | How Measured | Type of Cancer Studied | Study Objective(s) | Type of Cancer Trial into Which Recruiting |
|---|---|---|---|---|---|---|---|---|
| Hunter, 1987 | Group practice; Hospital inpatient | Patients/ Participants | AA | Descriptive; Qualitative; Retrospective | Secondary analysis of program data | All | A. Provide characteristics of the cancer patient population from which patients entered in trials are derived.<br>B. Describe the process by which patients are recruited and selected from trials as determined from the CCOP physicians' patient log. | Treatment |
| Kaluzny, 1993 | Community; Hospital outpatient; Group practice | Patients/ Participants; Physicians | NR | Descriptive; Qualitative | Secondary analysis of NCI patient log data; Interviews from site visits | NR | Describe the early implementation of the MBCCOP and identify the challenges that have emerged in developing a network aimed at increasing the participation of minority populations in trials. | Treatment |
| Kemeny, 2003 | Community | Patients/ Participants; Physicians | Elderly | Case-control | Patient interviews; Self-administered written questionnaires for physicians | Breast | A. Were patients older than 65 years offered trial more often than younger patients ?<br>B. Assess reasons why oncologists choose not to offer a trial to their older patients and why patients chose to, or refused to participate. | Treatment |

**Evidence Table 5-1. Characteristics of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Study Setting | Target Population | Targeted Under-represented Population | Study Design | How Measured | Type of Cancer Studied | Study Objective(s) | Type of Cancer Trial into Which Recruiting |
|---|---|---|---|---|---|---|---|---|
| Kemp, 1984 | Community | Patients/ Participants | Elderly (by sub-group analysis) | Descriptive; Cross-sectional | Face-to-face interview; Survey | Breast, bone | A. Assess whether people were prepared to participate in randomized trials or whether they wanted to choose their own treatment.<br>B. Assess whether or not people wanted their doctor to provide information about their treatment and the system of allocation. | Treatment |
| Kornblith, 2002 | Hospital inpatient | Physicians | Elderly | Cross-sectional; Descriptive | Questionnaire | Breast | Test the magnitude of barriers to recruitment among elderly breast cancer patients from physician perspective. | Treatment |
| Krailo, 1993 | Hospital inpatient; Hospital outpatient | Patients/ Participants | Children; Adolescents | Hospital registry review, Qualitative | Enrollment NR | All | Assess the proportion of children diagnosed with cancer who are enrolled in cancer studies. | Treatment |
| Lee, 1999 | Hospital inpatient | Patients/ Participants | AA men | Descriptive; Cross-sectional | Survey | Prostate | Assess factors affecting interest in participation in a prostate cancer chemoprevention trial. | Prevention |

**Evidence Table 5-1. Characteristics of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Study Setting | Target Population | Targeted Under-represented Population | Study Design | How Measured | Type of Cancer Studied | Study Objective(s) | Type of Cancer Trial into Which Recruiting |
|---|---|---|---|---|---|---|---|---|
| Lerman, 1994 | Community | Patients/ Participants | AA women | Descriptive; Cross-sectional | Structured telephone interview | Breast | Identify factors, especially sociodemographic, psychological, historic and risk factors of breast cancer patients associated with their decision to participate in a randomized trial. | Prevention |
| Lewis, 2003 | NCI cooperative groups | Patients/ Participants | Elderly | Cross-sectional; Descriptive; Retrospective | Secondary analysis of national database (NCI, CTEP, PDQ, SEER) | NR | Determine the proportion of elderly participants in NCI-sponsored cancer treatment trials from 1997-2000. | Treatment |
| Ling, 2000 | Hospital inpatient; Hospital outpatient | Patients/ Participants | Elderly (by sub-group analysis) | Qualitative | Survey | NR | Describe recruitment experiences into RCTs of a Palliative Care Center. | Treatment |
| McCaskill-Stevens, 1999 | Community | Physicians | AA | Qualitative | Workshops with discussions and questionnaires | All | Identify barriers and solutions to AA accrual to cancer trials. | Prevention; Treatment |

**Evidence Table 5-1. Characteristics of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Study Setting | Target Population | Targeted Under-represented Population | Study Design | How Measured | Type of Cancer Studied | Study Objective(s) | Type of Cancer Trial into Which Recruiting |
|---|---|---|---|---|---|---|---|---|
| Millon-Underwood, 1993 | Community | Patients/ Participants | AA | Descriptive; Cross-sectional | Survey | NR | A. Assess perceptions/attitudes and beliefs of AAs regarding participation in cancer studies.<br>B. Evaluate effect of perception/attitudes belief on willingness.<br>C. Evaluate role of perceived risk, personal experience, perceived efficacy, economics status on willingness to participate. | Prevention; Treatment |
| Moinpour, 2000 | Hospital outpatient; NCI Comprehensive Cancer Center | Patients/ Participants; Researchers | AA and Hispanic men | RCT | Enrollment NR | Prostate | Summarize challenges of enrolling and randomizing AAs/other minorities in the PCPT. | Prevention |
| Mouton,, 1997 | Community | Patients/ Participants | AA women | Descriptive; Cross-sectional | Telephone survey | Breast,colorectal | A. Compare attitudes toward participation in cancer trials and attitudes toward cancer screening and prevention for black and white subjects.<br>B. Discover why black women decide to participate in cancer trials.<br>C. Assess whether blacks are more likely to participate in research that is conducted by black researchers. | Prevention |

**Evidence Table 5-1. Characteristics of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Study Setting | Target Population | Targeted Under-represented Population | Study Design | How Measured | Type of Cancer Studied | Study Objective(s) | Type of Cancer Trial into Which Recruiting |
|---|---|---|---|---|---|---|---|---|
| Outlaw, 2000 | Hospital inpatient | Physicians; Data managers | AA | Qualitative | Survey | NR | Identify factors related to AAs participation in trials. | NR |
| Paskett, 2002 | Community | Physicians | Rural | CCT | Survey, Enrollment NR | Breast, colorectal | A. Evaluate a Rural Cancer Care Intervention.<br>B. Assess rural-based primary care physician knowledge, attitudes, and beliefs about patient and physician barriers to cancer trials and accrual to clinical treatment trials. | Treatment |
| Pinto, 2000 | Community | Physicians | AA | Qualitative | Focus groups | NR | Identify barriers to accrual of minority patients and develop solutions to these barriers from physicians perspective | Prevention; Treatment |
| Randall-Davis, 2001 | Community | Patients/ Participants | Rural | Qualitative | Focus groups | All | To elicit perceptions of urban and rural adults regarding participation in cancer trial. | Treatment |
| Roberson, 1994 | Community | Patients/ Participants | AA, American Indian or Alaskan Native, Lat/Hisp | Qualitative | Telephone survey | NR | Discuss racial/ethnic minority groups views and opinions about clinical trial participation. | Treatment |
| Robinson, 1996 | Community | Patients/ Participants | AA men | Qualitative | Focus groups | Prostate | Identify attitudes among AAs associated with participation in prostate cancer trials. | Treatment |

**Evidence Table 5-1. Characteristics of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Study Setting | Target Population | Targeted Under-represented Population | Study Design | How Measured | Type of Cancer Studied | Study Objective(s) | Type of Cancer Trial into Which Recruiting |
|---|---|---|---|---|---|---|---|---|
| Sateren, 2002 | All patients from NCI-funded trials between April 1998-April 1999 | Patients/ Participants | AA | Cross-sectional; Descriptive; Retrospective | Secondary analysis of national database (US Census, SEER) | All | Examine the impact of socioeconomic factors on accrual to to NCI-sponsored cancer treatment trials | Treatment |
| Sears, 2003 | Community | Patients/ Participants | AA women | RCT; Retrospective | Enrollment NR | Breast | Examine recruitment, retention, and predictors of participation. | Treatment |
| Simon, 2004 | Hospital inpatient | Patients/ Participants | AA | Descriptive | Survey | Breast | Better understand factors associated with accrual to breast cancer trials. | Treatment |
| Spaight, 1984 | Hospital inpatient | Physicians | Elderly | Qualitative | Structured interview | NR | Assess factors influencing trials participation from the perspective of medical oncologists and hematologists | Treatment |
| Thornquist, 1991 | Community | Patients/ Participants | Elderly (by sub-group analysis) | Cohort; Prospective | Enrollment NR | Lung | Describe any differences in accrual and adherence to trial by age group or by gender. | Prevention |
| Twelves, 1998 | Hospital inpatient; Hospital outpatient; Solo practice | Patients/ Participants | Elderly women (by sub-group analysis) | Retrospective; Tumor registry review | Enrollment NR | Breast | Identify factors influencing enrollment into invasive breast cancer trials. | Treatment |

**Evidence Table 5-1. Characteristics of Studies Investigating the Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Study Setting | Target Population | Targeted Under-represented Population | Study Design | How Measured | Type of Cancer Studied | Study Objective(s) | Type of Cancer Trial into Which Recruiting |
|---|---|---|---|---|---|---|---|---|
| Woods, 2002 | Hospital outpatient | Patients/ Participants | AA | Qualitative | Focus groups / interview | NR | A. Identify characteristics of those who chose not to participate in a trial. B. To understand why some eligible participants did not return for enrollment. C. To see what strategies might make participation more likely. | Prevention; Treatment |

AA = African American
CCOP = Community Clinical Oncology Program
CCT = Concurrent controlled trials
CTEP = Cancer Therapy Evaluation Program
ECOG = Eastern Cooperative Oncology Group
Lat/Hisp = Latino/Hispanic
MBCCOP = Minority-based Community Clinical Oncology Program
NCI = National Cancer Institute
PCPT = Prostate Cancer Prevention Trial
PDQ = Physician Data Query
PLCO = Prostate, Lung, Colorectal, and Ovarian Cancer Trial
RCT = Randomized controlled trial
SEER = Surveilance, Epidemiology, and End Results Program
SES = Socioeconomic status

**Evidence Table 5-2. Target Population Characteristics of Studies Investigating the Documented Barriers and Promoters of Participation of Medically Underserved Populations in Cancer Prevention and Treatment Trials (Key Question 5).**

| Author, Year | U.S.or Non-U.S. | Sample Size | Mean Age, y | Age Range, y | Mean Income ($) | Income range ($) | % Male | % AA | % AIAN | % Asian /PI | % White | % Lat/ Hisp | % Adol | % Elderly | % Low SES | % Rural |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adams-Campbell, 2004 | U.S. | 235 | NR | 22-97 | NR | NR | 30 | 100 | 0 | 0 | 0 | 0 | NR | NR | NR | NR |
| Advani, 2003 | U.S. | 218 | NR | NR | NR | <15,000->35,000 | NR | 33 | NR | NR | 67 | NR | NR | NR | NR | NR |
| Barofsky, 1979 | U.S. | 103 | NR | ≤19-≥50 | NR | NR | 65 | 16 | 0 | 0 | 84 | 0 | NR | NR | NR | NR |
| Berman, 1998 | U.S. | 435 | 37 | NR | NR | NR | 49 | 15 | 0 | 0 | 0 | 85 | NR | NR | NR | NR |
| Bieniasz, 2003 | U.S. | 66 | 37 | 18-81 | 28,045 | NR | 0 | 64 | NR | NR | 27 | NR | NR | NR | NR | NR |
| Brewster, 2002 | U.S. | 545 | 43 | 17-78 | NR | <10,000-≥10,000 | 0 | 0 | 0 | 0 | 22 | 78 | NR | NR | NR | NR |
| Broome,2003 | U.S. | 34 | 14 | 8-22 | NR | NR | NR | 9 | 3 | 3 | 73 | 12 | 100 | NR | NR | NR |
| Broome, 2001 | U.S. | 34 | NR | 8-22 | NR | NR | NR | 9 | 3 | 3 | 74 | 11 | 100 | NR | NR | NR |
| Brown, 2000 | U.S. | 434 | Study 1 = 32; Study 2 = NR | NR | NR | NR | 0 | 29 | NR | NR | 54 | 17 | NR | NR | NR | NR |
| Brown, 2003 | U.S. | 438 | NR | 50->75 | NR | <25,000->40,000 | 33 | 49 | 0 | 0 | 51 | 0 | NR | 100 | NR | NR |
| Chen, 2000 | Non-U.S. | 68 | NR | 65-89 | NR | NR | 50 | NR | NR | NR | NR | NR | NR | 100 | NR | NR |

**Evidence Table 5-2. Target Population Characteristics of Studies Investigating the Documented Barriers and Promoters of Participation of Medically Underserved Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | U.S.or Non-U.S. | Sample Size | Mean Age, y | Age Range, y | Mean Income ($) | Income range ($) | % Male | % AA | % AIAN | % Asian /PI | % White | % Lat/ Hisp | % Adol | % Elderly | % Low SES | % Rural |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Comis, 2003 | U.S. | 887 | NR | 18->65 | NR | NR | 51 | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Diener-West, 2001 | U.S. | 4,191 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Ford, 2003 | U.S. | 34,376 | 63 | 55-74 | NR | NR | 100 | 100 | 0 | 0 | 0 | 0 | 0 | 100 | 38 | NR |
| Fouad, 2000 | U.S. | 103 | 51 | NR | NR | NR | 31 | 100 | NR | NR | NR | NR | NR | NR | NR | NR |
| Fouad, 2001 | U.S. | 103 | NR | NR | NR | NR | 31 | 100 | NR | NR | NR | NR | NR | NR | NR | NR |
| Green, 2000 | U.S. | 103 | 50.8 | NR | NR | NR | 30 | 100 | NR | NR | NR | NR | NR | NR | NR | NR |
| Grunfeld, 2002 | Non-U.S. | 29 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Hunter, 1987 | U.S. | 17,773 | NR | NR | NR | NR | 43 | 4 | NR | NR | 93 | NR | NR | NR | NR | NR |
| Kaluzny, 1993 | U.S. | NR | NR | 51->71 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Kemeny, 2003 | U.S. | 154 | 61 | NR | NR | NR | 0 | NR* | 0 | 0 | 77 | NR* | NR | 50 | NR | NR |
| Kemp, 1984 | Non-U.S. | 1,022 | NR | 16-70 | NR | NR | 49 | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Kornblith, 2002 | U.S. | 156 | NR | 29-74 | NR | NR | 69 | 3 | 3 | NR | 87 | NR | NR | 7 | NR | NR |
| Krailo, 1993 | U.S. | 2,788 | NR | 0-19 | NR | NR | NR | NR | NR | NR | NR | NR | 33 | NR | NR | NR |
| Lee, 1999 | U.S. | 165 | NR | NR | NR | NR | 59 | 67 | NR | NR | 33 | NR | NR | NR | NR | NR |
| Lerman, 1994 | U.S. | 271 | NR | 35->50 | NR | NR | 0 | NR | NR | NR | 100 | NR | NR | NR | NR | NR |
| Lewis, 2003 | U.S. | 59,300 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | 32 | NR | NR |
| Ling, 2000 | Non-U.S. | 1,206 | NR | 18-95 | NR | NR | 35 | NR | NR | NR | NR | NR | NR | 51 | NR | NR |

**Evidence Table 5-2. Target Population Characteristics of Studies Investigating the Documented Barriers and Promoters of Participation of Medically Underserved Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | U.S.or Non-U.S. | Sample Size | Mean Age, y | Age Range, y | Mean Income ($) | Income range ($) | % Male | % AA | % AIAN | % Asian /PI | % White | % Lat/ Hisp | % Adol | % Elderly | % Low SES | % Rural |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| McCaskill-Stevens, 1999 | U.S. | 89 | NR | NR | NR | NR | NR | 56 | 0 | 0 | 0 | 0 | NR | NR | NR | NR |
| Millon-Underwood, 1993 | U.S. | 220 | 27 | 18-47 | 30,626 | 13,915-46,138 | 56 | 100 | NR | NR | NR | NR | NR | NR | NR | NR |
| Moinpour, 2000 | U.S. | NR | NR | NR | NR | NR | 100 | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Mouton, 1997 | U.S. | 80 | NR | <56->72 | NR | <25,000-≥25,000 | 0 | 36 | 0 | 0 | 64 | 0 | NR | NR | NR | NR |
| Outlaw, 2000 | U.S. | 52 | NR | <40->61 | NR | NR | NR | 2 | 0 | 2 | 96 | 0 | NR | NR | NR | NR |
| Paskett, 2002 | U.S. | 360 | 47 | NR | NR | NR | 84 | NR | NR | NR | NR | NR | NR | NR | NR | 100 |
| Pinto, 2000 | U.S. | 73 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Randall-David, 2001 | U.S. | 37 | 55 | 18-72 | NR | NR | 8 | 31 | 6 | NR | 58 | 3 | NR | NR | NR | 73 |
| Roberson, 1994 | U.S. | 28 | NR | NR | NR | NR | 12 | 29 | 36 | 0 | 0 | 36 | NR | NR | NR | NR |
| Robinson, 1996 | U.S. | 46 | NR | NR | NR | NR | 100 | 100 | NR | NR | NR | NR | NR | NR | NR | NR |
| Sateren, 2002 | U.S. | 24,332 | NR | 0->80 | NR | NR | 44 | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Sears, 2003 | U.S. | 558 | 57 | NR | NR | NR | 0 | 6 | NR | NR | 85 | NR | NR | NR | NR | NR |
| Simon, 2004 | U.S. | 319 | 55 | NR | NR | NR | 0 | 32 | NR | NR | 57 | NR | NR | NR | NR | NR |
| Spaight, 1984 | U.S. | 23 | NR | 33-65 | NR | NR | 87 | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Thornquist, 1991 | U.S. | 1,284 | NR | 45-74 | NR | NR | 52 | NR | NR | NR | NR | NR | NR | 35 | NR | NR |

**Evidence Table 5-2. Target Population Characteristics of Studies Investigating the Documented Barriers and Promoters of Participation of Medically Underserved Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | U.S.or Non-U.S. | Sample Size | Mean Age, y | Age Range, y | Mean Income ($) | Income range ($) | % Male | % AA | % AIAN | % Asian /PI | % White | % Lat/ Hisp | % Adol | % Elderly | % Low SES | % Rural |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Twelves, 1998 | Non-U.S. | 4,688 | NR | <50-≥80 | NR | NR | 0 | NR | NR | NR | NR | NR | NR | 9 | NR | NR |
| Woods, 2002 | U.S. | 120 | 41 | NR | NR | NR | 27 | 100 | NR | NR | NR | NR | NR | NR | NR | NR |

*Kemeny, 2003 reports that 23% were Latino/Hispanic or African American.
AA = African American
Adol = Adolescent
AIAN = American Indian/Alaska Native
Lat/Hisp = Latino/Hispanic
NR = Not reported
PI = Pacific Islander
SES = Socioeconomic status

## Appendix F. Evidence Tables (continued)

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5).**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Adams-Campbell, 2004 | Study design | NR | NR | NR | NR | Comorbidity exclusion; Functional status; Diagnostic test result cut-off; Lack of available protocols | NR | NR | NR | No |
| Advani, 2003 | Patient | Lack of education about clinical trials*; Perceived harms of clinical trial participa-tion*; Chance of side effects*; Distance to clinic* | Younger age*; Altruism*; Perceived benefits of clinical trial participation | NR | NR | NR | NR | NR | NR | No |
| Barofsky, 1979 | Patient | NR | Being male* | NR | NR | NR | NR | NR | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Berman, 1998 | Patient; Provider | NR | Lack/ inadequate health insurance for Latinos; Opportunistic strategies for Latinos | NR | Communica-tion/ Method of presentation for Latinos and AAs | NR | NR | NR | NR | Yes: Difference between Latinos and AAs regarding reasons for participa-tion |
| Bieniasz, 2003 | Patient | Intervention character-ristics* | NR | NR | NR | NR | NR | NR | NR | No |
| Brewster, 2002 | Patient | Did not wish to participate in study; Family consider-ations (childcare problems); Work conflict; No time; Modesty / embarrass-ment; Un-comfortable with test; Transporta-tion; Other insurance / physician / clinic | NR | NR | NR | NR | NR | NR | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Broome, 2001 | Patient | NR | Chance for better treatment; altruism | NR | NR | NR | NR | NR | NR | No |
| Broome, 2003 | Patient | NR | Family considera-tions; Trust, communica-tion, and love of parents | NR | NR | NR | NR | NR | NR | No |
| Brown, 2000 | Patient | Fear; Transporta-tion; Family considera-tions; Taste of Drug; Mistrust of research and medical system; Lack of health insurance / inadequate health insurance; Lack of education about clinical trials | NR | NR | NR | NR | NR | NR | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Brown, 2003 | Patient | AA older age*; Lower income* | Male gender* | NR | NR | NR | NR | NR | NR | Yes |
| Chen, 2000 | Patient; Provider; Study design | Patient refusal | NR | Physician choice | NR | Comorbidity exclusion; Functional status; Previous cancer | NR | NR | NR | No |
| Comis, 2003 | Patient | Age | NR | NR | NR | NR | NR | NR | NR | No |
| Diener-West | Patient; Study design | Age*; Living near treatment center* | NR | NR | NR | NR | Large tumor size* | NR | NR | No |
| Ford, 2004 | Patient; Study design | Unlisted telephone number*; Age* | Low income level* | NR | NR | NR | NR | NR | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Fouad, 2000 | Patient; Provider; Study design | Mistrust of research and medical system; Time commit-ment; Indirect costs; Lack/inade-quate health insurance; Lack of education about trials; Blood draw; Radiation involve-ment; Past experiences | Benefit to family; Benefit to church | Provider attitudes; Skepticism about low-income patients' ability to participate; Concern that their patients would be randomized | Education programs for community physicians; Involvement of providers in prevention trials | Length of study/visit structure; Complexity of forms | Easy to read consent forms; Using recruiters who are known to community | NR | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Fouad, 2001 | Patient | Mistrust of research and medical system; Cultural barriers; Job issues; Indirect costs; Lack of education about trials; Lack of knowledge about origins of cancer; Culturally relevant education about clinical trials; Perceived harms of trial participation | Provide transporta-tion; Flexible scheduling; Provide childcare; Incentives (free meals); Adequate knowledge about the study; Workshops on trials; Trust | NR | NR | NR | NR | NR | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Green, 2000 | Patient | Mistrust of research and medical system; Time commitment; Family considera-tions; Perceived harms of trial participa-tion; Radiation involved in treatment | Altruism*; Incentives*; No cost treatment* | NR | NR | NR | NR | NR | NR | No |
| Grunfeld, 2002 | Patient; Provider; Study Design | Mistrust of researcher and medical system; Transportation; Language barrier; Perceived harms of clinical trial participation; Physician expertise; Physician discourage ment | Incentives (financial or other); Trial beneficial to them; Hope for care; Receive extra care; Benefit future generations | Provider attitudes; Communica-tion / method of presentation; Physician beliefs about patient preference | NR | Excessive requirements of study | NR | NR | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Hunter, 1987 | Patient; Provider; Study Design | Experi-mentation; Treatment toxicity; Costs | NR | Physician's preference for a specific treatment or alternative therapy | NR | Comorbidity exclusion; Age exclusion; Functional status /Poor performance | NR | NR | NR | No |
| Kaluzny, 1993 | Patient; Provider; Study design; Healthcare system | Mistrust of research and medical system; Fear; Transporta-tion; Family considera-tions; Language barrier; Job issues; Indirect costs; Limited education or low literacy; Socio-economic conditions of inner-city commun-ities | NR | Mistrust of researchers; Provider attitudes; Little time available per patient; Lack of interest in protocol studies (unless money); Lack of support staff | Incentive | Comorbidity exclusion; Length of study/visit structure; Late stage disease | NR | Lack of dissemination of study opportunities to provider/ patient; Lack of language services; lack of support staff to facilitate protocol activity | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Kemeny, 2003 | Patient; Provider | Age*; Disease stage*; Number of comorbid-ities* | NR | Toxicity of treatment; Thought patient ineligible; Patient comorbid conditions | NR | NR | NR | NR | NR | No |
| Kemp, 1984 | Patient | NR | Less control over health decisions | NR | NR | NR | NR | NR | NR | No |
| Kornblith, 2002 | Patient; Provider; Study design | Transporta-tion; Lack/ inadequate health insurance; Toxicity of treatment; Co-morbidity; Patient unable to understand trial | NR | NR | Provider attitudes; Communica-tion/ method of presentation | Comorbidity exclusion; Life expectancy | NR | NR | NR | No |
| Krailo, 1993 | Study design | NR | NR | NR | NR | Age exclusion; Treatment policies; Lack of available protocols | NR | NR | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Lee, 1999 | Patient | NR | Willingness to take pills | NR | NR | NR | NR | NR | NR | No |
| Lerman, 1994 | Patient | NR | Impact of diagnosis on risk perception*; >HS education; if > HS education: marriage, unemploy-ment, # of affected relatives; ≤HS education: age, employment; Age* | NR | NR | NR | NR | NR | NR | No |
| Lewis, 2003 | Patient | Protocol exclusions | NR | NR | NR | Comorbidity exclusion; Functional status; Diagnostic test cut-off | Life expectancy | NR | NR | No |
| Ling, 2000 | Study design | NR | NR | NR | NR | Entry criteria | NR | NR | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| McCaskill-Stevens, 1999 | Patient; Provider; Study design; Healthcare system | Mistrust of research and medical system; Fear; Cultural barriers; Poverty / cost to patient | Culturally relevant education about clinical trials | Mistrust of researchers; Lack of physician awareness of trials; Insufficient resources; Lack of proven therapy | NR | Length of study/visit structure | NR | Lack of minority personnel; Lack of minority investigators; Lack of dissemination of study opportunities to provider/ patient | NR | No |
| Millon-Underwood, 1993 | Patient | Mistrust of medical research; Perceived harms of clinical trial participation | Hope; Altruism; Perceived efficacy | NR | NR | NR | NR | NR | NR | No |
| Moinpour, 2000 | Patient; Study design | Mistrust of research | NR | NR | NR | Lack of time to establish presence in communities | NR | NR | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Mouton, 1997 | Patient | Mistrust of research and medical system*; Perception of researchers not caring about patient | Preference for study's Principal Investigator to be Black; Perception that it is better to be treated by research doctors | NR | NR | NR | NR | NR | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Outlaw, 2000 | Patient; Provider; Study design | Mistrust of medical research; Fear; Language barriers; cultural barriers; Indirect costs; Religious/ spiritual beliefs; Lack of education (culturally relevant) about clinical trials; Perceived harms of trial participa-tion; Lack of comfort with technology care; Lack of family support; Perceived discrimina-tion; Lack of access to health care | NR | Mistrust of researchers; Provider attitudes; Lack of minority providers; Lack of support staff; Additional time required; concern in patient age frailty; Discomfort | NR | Complexity of clinical trials; Late stage disease | NR | NR | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Paskett, 2002 | Patient; Provider; Study design | Mistrust of research & medical system; Discomfort; Transporta-tion; Unfamiliar physician; Costs; Lack /inadequate health insurance; Lack of education about trials; Perceived harms of participation | NR | Logistical burden; Cost to patient; Perceived treatment risk; Established referral patterns | NR | Eligibility | NR | NR | NR | No |
| Pinto, 2000 | Patient; Provider; Study design; Healthca re system | Mistrust of medical research; Fear;Cultural barriers; Lack of education about trials; Perceived harms of participation; Physicians do not offer trials; Cost | Culturally relevant education about clinical trials | Provider attitudes; Mistrust of researchers; Cultural barriers; Lack of provider awareness about trial; Lack of time; Racial bias | Incentive (financial or other) | Comorbidity exclusion; Length of study/visit structure; Protocols too complex; Randomization | NR | Lack of cultural competence among provider/staff; Lack of dissemination of study opportunities to provider/ patient; Lack of access to institution | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Randall-David, 2001 | Patient; Provider; Healthcare system | Mistrust of medical research; Fear; Lack of knowledge about origins of cancer; Transport-ation; Time commit-ment; Family considera-tions; Religious/ spiritual beliefs; Lack of education about trials; Perceived harms of trial participation | Altruism; Incentives (reimburse-ment); Perceived benefit of trial participation | Mistrust of researcher; Communica-tion / method of presentation | NR | NR | NR | Lack of dissemination of study opportunities to provider/ patient | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Roberson, 1994 | Patient | Mistrust of medical research; Fear; Access to information; Time commit-ment; Language barriers; Cultural barriers; Lack of education about trials; Do not like to get involved; Lack of information / awareness | Incentives; Culturally relevant education about trials; Perceived benefits of trial participation | NR | NR | NR | NR | NR | NR | Yes: Among Latino / Hispanic partici-pants |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Robinson, 1996 | Patient; Provider; Healthcare system | Mistrust of research/ medical system; Fear; Lack of knowledge about origins of cancer; Lack of education about trials; Perceived harms of trial participation; Concerns about randomization | Incentives; Culturally relevant education about trials; Perceived benefits of trial participation | Mistrust of researchers; Provider attitudes; Communication/ method of presentation | Competent/ experienced physician/ researcher; Compassionate provider | NR | NR | Lack of dissemination of study opportunities to provider/ patient | Reputation of medical facility | No |
| Sateren, 2002 | Patient; Provider; Healthcare system | Lack/inadequate health insurance*; Being Black male aged 30-59 years*; Asian adults / Latino / Hispanic adults* | Living in suburban area; Higher SES | NR | Higher number of oncology specialists | NR | NR | NR | Presence of cancer programs | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Sears, 2003 | Patient; Study design | Time commit-ment; Willingness to travel, Stress; ≥ 65 years old; minority; Not married | NR | NR | NR | Medication exclusion; Metastatic disease | NR | NR | NR | No |
| Simon, 2004 | Patient; Provider; Study design | Leaving care of physician to participate in trial; Lack/ inadequate health insurance* | NR | Patient likely to be non-compliant; No protocol available for disease stage | NR | Age exclusion; Medication exclusion | NR | NR | NR | No |
| Spaight, 1984 | Patient; Provider; Study design | Age; Transporta-tion; Inability to understand protocol; Patient resistance or potential noncompli-ance; Cost | NR | NR | Advancement of cancer field | Participation requires too much travel; Failure to use most effective drug; Too many lab tests | NR | NR | NR | No |
| Thornquist, 1991 | Patient | Age (50-54; 65-69)* | Age (60-64; 55-59)* | NR | NR | NR | NR | NR | NR | No |

**Evidence Table 5-3: Results of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Type of Barrier/ Promoter | Patient Barrier Associated with Decrease in Reported Enrollment | Patient Promoter Associated with Increase in Reported Enrollment | Provider Barrier Associated with Decrease in Reported Enrollment | Provider Promoter Associated with Increase in Reported Enrollment | Study Design Barrier Associated with Decrease in Reported Enrollment | Study Design Promoter Associated with Increase in Reported Enrollment | Healthcare System Barrier Associated with Decrease in Reported Enrollment | Healthcare System Promoter Associated with Increase in Reported Enrollment | Barriers/ Promoters Modified by Cultural Factors? |
|---|---|---|---|---|---|---|---|---|---|---|
| Twelves, 1998 | Patient; Provider | Age* | Place of initial treatment* | NR | Surgeons with high case load*; Referral to an oncologist* | NR | NR | NR | NR | No |
| Woods, 2002 | Patient; Provider; Study design | Mistrust of medical research; Job issues; Transportation problems; Time commitment; Family considerations; Perceived harms of trial participation; Not ready to quit smoking | Transportation support; Incentives; Perceived benefit of trial participation; Support/ encouragements/ prayer; Certainty of receiving actual medication | Training in communicating with patients; Communication/ method of presentation | NR | NR | Length of study/visit structure; Reminder phone calls | NR | NR | No |

* Statistically significant
HS = High school
NR = Not reported
PSA = Prostate specific antigen test
SES = Socioeconomic status

**Evidence Table 5-4. Quality of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5).**

| Author, Year | Representative-ness[a] | Justification[b] | Bias[c] | Reliability & Validity[d] | Analysis[e] |
|---|---|---|---|---|---|
| Adams-Campbell, 2004 | ◒ | ● | ○ | ◒ | NA |
| Advani, 2003 | ● | ◒ | ○ | ● | ○ |
| Barofsky, 1979 | ● | ◒ | ● | ◒ | ◒ |
| Berman, 1998 | ◒ | ◒ | ○ | ○ | ○ |
| Bieniasz, 2003 | ◒ | ○ | ◒ | ◒ | NA |
| Brewster, 2002 | ● | ◒ | ◒ | ○ | ◒ |
| Broome, 2001 | ◒ | ◒ | ◒ | ◒ | NA |
| Broome,2003 | ◒ | ◒ | ◒ | ◒ | NA |
| Brown, 2000 | ◒ | ◒ | ◒ | ○ | ◒ |
| Brown, 2003 | ◒ | ● | ◒ | ○ | ○ |
| Chen, 2000 | ● | ○ | NA | NA | NA |
| Comis, 2003 | ● | ◒ | ○ | ◒ | ○ |
| Diener-West | ● | ○ | NA | NA | NA |
| Ford, 1998 | ◒ | ○ | NA | NA | NA |
| Ford, 2003 | ◒ | ● | ○ | ● | ● |
| Fouad, 2000 | ◒ | ● | ◒ | ◒ | NA |

**Evidence Table 5-4. Quality of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Representative-ness[a] | Justification[b] | Bias[c] | Reliability & Validity[d] | Analysis[e] |
|---|---|---|---|---|---|
| Fouad, 2001 | ◓ | ◓ | ◓ | ◓ | NA |
| Green, 2000 | ◓ | ◓ | ◓ | ◓ | NA |
| Grunfeld, 2002 | ○ | ○ | ◓ | ◓ | NA |
| Hunter, 1987 | ◓ | ◓ | ● | ◓ | NA |
| Kaluzny, 1993 | ◓ | ○ | NA | NA | NA |
| Kemeny, 2003 | ◓ | ◓ | ◓ | ○ | ○ |
| Kemp, 1984 | ◓ | ◓ | ◓ | ○ | ○ |
| Kornblith, 2002 | ◓ | ● | ○ | ○ | ○ |
| Krailo, 1993 | ● | ◓ | NA | NA | NA |
| Lee, 1999 | ◓ | ◓ | ◓ | ○ | ○ |
| Lerman, 1994 | ● | ◓ | ● | ○ | ○ |
| Lewis, 2003 | ◓ | ○ | NA | NA | NA |
| Ling, 2000 | ○ | ◓ | ● | ○ | ○ |
| McCaskill-Stevens, 1999 | ◓ | ◓ | ◓ | ○ | NA |
| Millon-Underwood, 1993 | ◓ | ◓ | ◓ | ◓ | ○ |
| Moinpour, 2000 | ○ | ○ | NA | NA | NA |

**Evidence Table 5-4. Quality of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

| Author, Year | Representative-ness[a] | Justification[b] | Bias[c] | Reliability & Validity[d] | Analysis[e] |
|---|---|---|---|---|---|
| Mouton, 1997 | ◒ | ◒ | ◒ | ○ | ● |
| Outlaw, 2000 | ◒ | ◒ | ◒ | ○ | ○ |
| Paskett, 2002 | ◒ | ◒ | ◒ | ○ | ◒ |
| Pinto, 2000 | ○ | ◒ | ◒ | ◒ | NA |
| Randall-David, 2001 | ◒ | ○ | ○ | ● | NA |
| Roberson, 1994 | ◒ | ● | ◒ | ○ | ◒ |
| Robinson, 1996 | ○ | ○ | ○ | ○ | NA |
| Sateren, 2002 | ◒ | ○ | NA | NA | NA |
| Sears, 2003 | ● | ◒ | ◒ | ◒ | NA |
| Simon, 2004 | ● | ◒ | ○ | ○ | ○ |
| Spaight, 1984 | ◒ | ○ | NA | ○ | NA |
| Thornquist, 1991 | ◒ | ◒ | ◒ | ○ | ● |
| Twelves, 1998 | ◒ | ○ | NA | NA | NA |
| Woods, 2002 | ◒ | ◒ | ◒ | ◒ | NA |

**Evidence Table 5-4. Quality of Studies Investigating the Documented Barriers and Promoters of Participation of Underrepresented Populations in Cancer Prevention and Treatment Trials (Key Question 5). (continued)**

● Excellent: > 75% quality score

◒ Good: 50-74% quality score

◒ Fair: 25-49% quality score

○ Poor: <25% quality score

NA = Not applicable

[a] Representativeness: Score was based on a total maximum score of 8 points. This included assessment of how well the study described the study setting and population (2 points), inclusion/exclusion criteria (2 points), non-participating patients (2 points), and patient characteristics at enrollment (2 patients).
[b] Justification : Percentage score was based on a total maximum score of 6 points. This included whether the study design was based on a conceptual model (2 points), whether the research question and objectives were stated (2 points), and whether the target population was adequately justified (2 points).
[c] Bias: Percentage score was based on a total maximum score of 4 points. This included the response rate or proportion of eligible people that actually completed the questionnaire (2 points), and the description of how study participants were selected (2 points).
[d] Reliability and Validity: Percentage score was based on a total maximum score of 6 points. This included intra-rater reliability (2 points), inter-rater reliability (2 points), and validation of the survey instrument (2 points)
[e] Analysis: Percentage score was based on a total maximum score of 4 points. This included assessment of whether the study was planned to have adequate power to detect differences within groups (2 points), and whether the study was planned to have adequate power to detect changes within groups.

**Evidence Table 6-1. Characteristics of Studies on the Effects of Attitudes and Perceptions of Healthcare Providers on the Efficacy or Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 6).**

| Author, Year | Sample Size | Study Setting | Target Population of Study | Targeted Under-represented Population | Study Design | How Measured | Type of Cancer Studied | Study Objective(s) | Type of Cancer Trial |
|---|---|---|---|---|---|---|---|---|---|
| Benson, 1991 | 252 | Community | Physicians | NR | Descriptive | Mailed survey | NR | Investigate the reasons physicians do not place patients in clinical trials. | Treatment |
| Fallowfield, 1997 | 357 | Community | Physicians | NR | Descriptive | Mailed survey | All | Compare results of physician orientation profile used in the ECOG study with that obtained from surveying British oncologists. | Treatment |
| Kemeny, 2003 | 154 | Hospital inpatient | Patients; Participants | Elderly | Case-control | Telephone survey; Interview | Breast | A. Test the extent to which eligible breast cancer patients older than 65 years were offered trials compared to younger patients.<br>B. Assess reasons why oncologists chose not to offer a trial to their older patients and why patients chose to, or refused to participate. | Treatment |
| Kornblith, 2002 | 156 | Hospital inpatient | Physicians | Elderly | Descriptive | Mailed survey | Breast | Test the magnitude of barriers to recruitment among elderly breast cancer patients from physician perspective. | Treatment |
| McCaskill-Stevens, 1999 | 90 | Community | Physicians | Minorities | Descriptive/ Qualitative | Open-ended questionnaire | Breast, Colorectal, Lung, Prostate | Identify barriers and solutions to African American accrual to cancer trials. | Treatment / Prevention |
| Paskett, 2002 | 196 (in 1993); 168 (in 1996) | Community | Physicians | Rural | CCT | Mailed survey | Breast, colorectal | A. Evaluate a Rural Cancer Care Intervention.<br>B. Assess rural-based primary care physician knowledge, attitudes, and beliefs about patient and physician barriers to accrual to cancer treatment trials. | Treatment |

**Evidence Table 6-1. Characteristics of Studies on the Effects of Attitudes and Perceptions of Healthcare Providers on the Efficacy or Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 6). (continued)**

| Author, Year | Sample Size | Study Setting | Target Population of Study | Targeted Under-represented Population | Study Design | How Measured | Type of Cancer Studied | Study Objective(s) | Type of Cancer Trial |
|---|---|---|---|---|---|---|---|---|---|
| Pinto, 2000 | 73 | Community | Physicians; Investigators | Minorities | Descriptive/ Qualitative | Focus groups | All | Identify barriers to accrual of minority patients & develop solutions to these barriers from physician's perspective. | Treatment / Prevention |
| Richardson, 1986 | 59 | Community | Physicians | NR | Descriptive | Mailed survey | NR | Assess attitudes and perceptions of medical oncologists regarding cancer trial participation. | Treatment |
| Simon, 2004 | 319 | Hospital inpatient | Patients; Participants | African Americans | Descriptive | Survey | Breast | Understand factors associated with accrual to breast cancer clinical trials. | Treatment / Prevention |
| Spaight, 1984 | 23 | Community | Physicians | NR | Descriptive/ Qualitative | Face-to-face interview | NR | Assess factors influencing clinical trials participation from the perspective of medical oncologists and hematologists. | Treatment |



CCT = Concurrent controlled trial
ECOG = Eastern Cooperative Oncology Group
NR = Not reported

**Evidence Table 6-2. Target Population Characteristics of Healthcare Providers Discussed in Studies on the Efficacy or Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 6).**

| Author, Year | U.S.or Non-U.S. Study | Mean Age, y | Age Range, y | % Male | % AA | % AIAN | % Cauc | % Elderly |
|---|---|---|---|---|---|---|---|---|
| Benson, 1991 | U.S. | NR | NR | NR | NR | NR | NR | NR |
| Brown, 2003 | U.S. | NR | NR | 33 | 49 | NR | 51 | 100 |
| Fallowfield, 1997 | U.S. | NR | NR | NR | NR | NR | NR | NR |
| Kemeny et al, 2003 | U.S. | NR | 48 to 74 | NR | NR | NR | NR | 50 |
| Kornblith, 2002 | U.S. | NR | NR | 69 | 3 | 3 | 87 | 7 |
| McCaskill-Stevens, 1999 | U.S. | NR | NR | NR | 1 | 0 | 0 | NR |
| Paskett, 2002 | U.S. | 49 | NR | 84 | NR | NR | NR | NR |
| Pinto, 2000 | U.S. | NR | NR | NR | NR | NR | NR | NR |
| Richardson, 1986 | U.S. | NR | NR | 1 | NR | NR | NR | NR |
| Simon, 2004 | U.S. | 55 | NR | NR | 32 | NR | 57 | NR |
| Spaight, 1984 | U.S. | NR | 33 to 65 | 1 | NR | NR | NR | NR |

AA = African American
AIAN = American Indian/Alaska Native
Cauc = Caucasian
NR = Not reported

**Evidence Table 6-3. Quality of Studies on the Effects of Attitudes and Perceptions of Healthcare Providers on the Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 6).**

| Author, Year | Representativeness[a] | Justification[b] | Bias[c] | Reliability & Validity[d] | Analysis[e] |
|---|---|---|---|---|---|
| Benson, 1991 | ◒ | ◒ | ◒ | ○ | ○ |
| Fallowfield, 1997 | ◒ | ◒ | ● | ○ | ○ |
| Kemeny, 2003 | ● | ◒ | ◒ | ○ | ○ |
| Kornblith, 2002 | ◒ | ● | ○ | ○ | ○ |
| McCaskill-Stevens et al., 1999 | ◒ | ◒ | ◒ | ○ | N/A |
| Paskett, 2002 | ◒ | ◒ | ◒ | ○ | ◒ |
| Pinto, 2000 | ○ | ◒ | ◒ | ◒ | N/A |
| Richardson 1986 | ○ | ○ | ◒ | ○ | ○ |
| Simon, 2004 | ● | ◒ | ○ | ○ | ○ |
| Spaight, 1984 | ◒ | ○ | ◒ | ○ | N/A |

N/A= Not Applicable

● Excellent: 75-100% quality score

◒ Good: 50-74% quality score

◒ Fair: 25-49% quality score

○ Poor: <25% quality score

**Evidence Table 6-3. Quality of Studies on the Effects of Attitudes and Perceptions of Healthcare Providers on the Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 6). (continued)**

a - Representativeness: Score was based on a total maximum score of 8 points. This included assessment of how well the study described the study setting and population (2 points), inclusion/exclusion criteria (2 points), non-participating patients (2 points) and patient characteristics at enrollment (2 patients).
b - Justification : Percentage score was based on a total maximum score of 6 points. This included whether the study design was based on a conceptual model (2 points), whether the research question and objectives were stated (2 points), and whether the target population was adequately justified (2 points).
c - Bias: Percentage score was based on a total maximum score of 4 points. This included the response rate or proportion of eligible
people that actually completed the questionnaire (2 points), and the description of how study participants were selected (2 points).
d -Reliability and Validity: Percentage score was based on a total maximum score of 6 points. This included intra-rater reliability (2 points), inter-rater reliability (2 points), and validation of the survey instrument (2 points)
e - Analysis: Percentage score was based on a total maximum score of 4 points. This included assessment of whether the study was planned to have adequate power to detect differences within groups (2 points), and whether the study was planned to have adequate power to detect changes within groups.

**Evidence Table 6-4. Provider Barriers/Promoters on the Efficacy or Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 6).**

| Author, Year | Type of Barrier/ Promoter | Provider Barrier/ Promoter Associated with Decrease in Enrollment | Provider Barrier/ Promoter Associated with Increase in Enrollment | Study Design Barrier/ Promoter Associated with Decrease in Enrollment | Healthcare System Barrier/ Promoter Associated with Decrease in Enrollment |
|---|---|---|---|---|---|
| Benson, 1991 | Provider | Communication/ method of presentation; Need to obtain informed consent; Follow-up time; Insufficient resources | | Age exclusion; Strict protocols | |
| Fallowfield, 1997 | Provider | Provider attitudes; Communicating/ method of presentation; Perceived patient intelligence as low | Social class (i.e., working class easier to approach) | Disease stage or location | |
| Kemeny, 2003 | Provider; Patient | Patient age*; Disease stage (Stage II)*; Comorbidity*; Provider attitudes; Toxicity of treatment; Ineligibility | | | |
| Kornblith, 2002 | Provider; Patient; Study design | | Provider attitudes; Communication/ method of presentation | Comorbidity exclusion; Life expectancy | |
| McCaskill-Stevens, 1999 | Provider; Patient; Study design; Healthcare system | Mistrust of researchers; Lack of provider awareness of trials; Insufficient resources; Lack of proven therapy | | Length of study/visit structure | Lack of minority investigators; Lack of other minority personnel; Lack of dissemination of study opportunities to provider |
| Paskett, 2002 | Provider; Patient | Provider attitudes; Logistics; Cost; Referral patterns; Treatment risk; | | Eligibility | |
| Pinto, 2000 | Provider; Patient; Study design; Healthcare system | Provider attitudes; Mistrust of researchers; Cultural barriers; Lack of provider awareness about trial; Lack of time; Racial bias | Incentive (financial or other) | Comorbidity exclusion; Length of study/visit structure; Protocols too complex; Randomization | Lack of cultural competence among providers and/or staff; Lack of dissemination of study opportunities to provider/ patient; Lack of access to institution conducting cancer trial |
| Richardson, 1986 | Provider | Patient age | Patients with regionalized disease*; Physician training*; Institutional affiliation* | | |

**Evidence Table 6-4. Provider Barriers/Promoters on the Efficacy or Effectiveness of Strategies for Recruitment of Underrepresented Populations into Cancer Prevention and Treatment Trials (Key Question 6). (continued)**

| Author, Year | Type of Barrier/ Promoter | Provider Barrier/ Promoter Associated with Decrease in Enrollment | Provider Barrier/ Promoter Associated with Increase in Enrollment | Study Design Barrier/ Promoter Associated with Decrease in Enrollment | Healthcare System Barrier/ Promoter Associated with Decrease in Enrollment |
|---|---|---|---|---|---|
| Simon, 2004 | Provider; Patient | Potential patient non-compliance; No protocol available for disease stage | | Age exclusion*; Medication exclusion* | |
| Spaight, 1984 | Provider; Patient; Study design | Patient age; Cost; Potential patient non-compliance; Lack of patient understanding about trial; Comorbidity | Advancement of cancer medicine | Toxicity and side effects; Protocol (i.e., requires too much travel; failure to use most effective drug; too many lab tests) | |

*Statistically significant