Strategies for Increasing Minority Patient Participation in Clinical Research Programs in the United States

By

Michelle Leavy

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Advisor signature/printed name

Second Reader Signature/printed name

Date
STRATEGIES FOR INCREASING MINORITY PATIENT PARTICIPATION IN CLINICAL RESEARCH PROGRAMS IN THE UNITED STATES

Master's Paper

Michelle Leavy

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ABSTRACT

Cardiovascular disease (CVD) is the leading cause of death in minority populations in the United States, yet minority patients tend to be under-represented in cardiovascular disease research. The under-representation of minorities in clinical research raises two major issues. First, low minority participation levels mean that study findings are not applicable or able to be generalized to minority patients. Second, social justice and research ethics require that the benefits and burdens of clinical research be shared equally among the potential beneficiaries of the research; by not participating in research, minority patients may not benefit from access to new treatments or prevention programs.

Many studies have identified barriers to minority patient participation in clinical research, including distrust of medical researchers and fear of harm; lack of knowledge; lack of transportation; interference with work or family responsibilities; burden of participation; financial costs; language or literacy issues; and restrictive study designs. Much has been written about strategies for overcoming these barriers and increasing minority patient participation in cancer and HIV/AIDS research. This paper examines potential strategies for increasing minority patient participation in cardiovascular disease research. Specifically, this paper addresses five questions: What strategies have been documented for increasing the participation of minority patients in cardiovascular disease research in the United States? What strategies have been documented for increasing the participation of minority patients in research in other disease areas or in clinical research generally (e.g., not in a specific disease area)? Are these strategies adaptable for cardiovascular disease? Has the effectiveness (and possibly relevant effectiveness) of the strategies been assessed? Are there opportunities for collaboration between the clinical
research and public health sectors to implement new strategies and/or to implement existing strategies more efficiently?

The primary source of information for this paper was a literature review. The literature review identified few strategies specifically designed to increase minority participation in CVD research. Strategies designed for other disease areas or for clinical research generally may be adapted for CVD research, but assessments of the effectiveness of these strategies are necessary before they are widely implemented. Few assessments of strategy effectiveness are available for any disease area.

New research should be conducted to develop and test effective strategies for CVD research. New strategies and approaches are needed at both the individual study level and the broader systems level. Addressing the issue from a public health leadership standpoint may be particularly useful for developing new systems level strategies. Researchers should also investigate the potential for partnerships with public health organizations that are already investing in education, prevention, and treatment campaigns for CVD.
INTRODUCTION

Cardiovascular disease is the leading cause of death in minority populations in the United States, yet minority patients tend to be under-represented in cardiovascular disease research. This has important implications for prevention and treatment of CVD in these populations, as there may be biological differences in risk factors and response to treatment. Much has been written about strategies for increasing minority patient participation in cancer and HIV/AIDS research. This paper examines potential strategies for increasing minority patient participation in cardiovascular disease research. The paper includes a summary of the issue, a description of the methods and findings of a literature review on this topic, and a discussion of future research and policy needs.

PREVALENCE OF CARDIOVASCULAR DISEASE (CVD)

Cardiovascular disease (CVD) refers to a broad set of clinical conditions that affect the heart and circulatory system. The four most common forms of CVD are coronary heart disease, stroke, hypertension, and heart failure. As of 2006, more than 80 million Americans (nearly one third of the population) had a history of some form of CVD. CVD of all forms is the leading cause of death in the United States, accounting for nearly 35 percent of all deaths in 2006. CVD also results in significant health care expenditures in the United States, with estimated direct and indirect costs for 2010 of $503.2 billion.

CVD is particularly problematic in minority populations in the United States. For the purposes of clinical research, the National Institutes of Health (NIH) uses race and ethnicity classifications. The races are American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. The ethnicities are Hispanic or Latino and not Hispanic or Latino. Non-Hispanic Whites are considered the majority group in
the United States; the remaining races and ethnicity are considered minority populations. African American men face a 30 percent higher risk of dying from CVD than non-Hispanic white men. African Americans are also more likely to have hypertension, a major risk factor for CVD, than non-Hispanic whites (32 percent compared to 22.5 percent). American Indians and Alaska Natives have the highest percentage of premature deaths from CVD, while whites have the lowest percentage. Hispanic/Latinos are more likely to be overweight or obese, a major risk factors for CVD, than non-Hispanic whites; over 70 percent of Hispanic/Latino adults are overweight or obese. Diabetes is another major risk factor for CVD that disproportionately affects minority populations. Over 10 percent of African Americans and Hispanic/Latinos and over 9 percent of American Indians have diabetes, compared with only 6.2 percent of non-Hispanic whites.

**CLINICAL RESEARCH IN CVD**

Due to its prevalence and high mortality rates, CVD is the focus of large amounts of clinical research on its risk factors, prevention, and treatment. A simple search of ClinicalTrials.gov identified over 11,000 research studies in the area of CVD. The NIH spends approximately 7 percent of its budget on research related to cardiovascular disease. The federal government also supports CVD research through agencies such as the Centers for Disease Control and Prevention and the Agency for Healthcare Research and Quality. In the private sector, non-profit organizations, such as the American Heart Association, and academic centers fund large amounts of research. Pharmaceutical and device manufacturers are also very active in CVD research.

**MINORITY PATIENT PARTICIPATION IN CVD RESEARCH**
CVD is a significant health problem in minority populations. Concurrently, a large amount of CVD research is being conducted. Despite these two facts, minority groups tend to be under-represented in CVD research. A systematic review on this topic examined whether major cardiovascular cohort studies in North America and Europe included or excluded ethnic minority populations. Of the 72 studies included in the review, only 10 were designed to compare white and minority populations, and only five studies specifically focused on one minority group. All 15 of these studies were conducted in the United States. The authors concluded that there is a lack of data from CVD cohort studies on minority patient populations.11

A second systematic review assessed participation in CVD research. In this case, the authors examined the literature to assess the participation of minority groups in clinical trials of antihypertensive drug therapy and to identify any differences in efficacy for these therapies. Twenty-eight studies were included in the review. Of these, 12 did not report any information on participants’ race/ethnicity, and eight studies reported information on participants’ race/ethnicity, but did not examine outcomes by race/ethnicity. Only eight studies reported on outcomes by minority subgroup.12

In fact, minority populations are under-represented in clinical research generally. A 2007 article in the Journal of Clinical Endocrinology & Metabolism summarized the problem, stating, “The underrepresentation of minorities occurs in all types of clinical research and all therapeutic areas, including those diseases that predominantly affect ethnic minorities.”13(p3) Low participation rates have been particularly well documented in cancer research. For example, a review of cancer drugs approved by the U.S. Food and Drug Administration between 1995 and 1999 found that minority groups (collectively African Americans, Asian/Pacific Islanders, Hispanics/Latinos, and Native Americans) represented less than 10 percent of trial participants.
The National Cancer Institute (NCI), which sponsors a large volume of cancer research, has also reported low minority participation rates. Between 1998 and 2001, NCI reported an increase of 22 percent in trial enrollment; however, during the same time frame, the number of minority patients enrolling in trials remained the same. The result was a decrease in the overall percentage of minorities in enrolling in trials.\textsuperscript{14} Graph 1 below summarizes the minority patient participation issue in cancer research; the graph depicts enrollment in cancer clinical trials between January 2003 and June 2005.

\textbf{Graph 1: Cancer Clinical Trials: Enrollment by Race and Ethnicity}\textsuperscript{15}

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\begin{figure}
\includegraphics[width=\textwidth]{chart.png}
\caption{Cancer Clinical Trials: Enrollment by Race and Ethnicity}
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\textbf{Source: National Cancer Institute. Data from January 2003 to June 2005.}

\textbf{BARRIERS TO MINORITY PATIENT PARTICIPATION IN CVD RESEARCH}

In response to the well-documented low rates of minority patient participation in clinical research, several studies have attempted to identify the barriers to minority participation. Only one of these studies examined the question specifically for CVD. In that study, the researchers
used a survey to assess willingness to participate in a hypothetical cardiovascular drug trial among African Americans. The authors found that African Americans were less likely to express a willingness to participate than whites (27 percent vs. 39 percent). African American participants also expressed more concern about potential harm from participating in the trial and more distrust of the medical researchers than white participants. The authors concluded that these factors are significant barriers to recruiting African Americans to participate in clinical research.  

Several other studies and reports have described general barriers to participation. Socioeconomic factors influence a number of the obstacles to participation in clinical research. Financial incentives to participate may offset costs incurred from participation or compensate patients for time spent on study-related activities. However, it considered unethical to use financial compensation to incentivize participation in clinical research. In 2002, the NIH published an “Outreach Notebook For the Inclusion, Recruitment and Retention of Women and Minority Subjects in Clinical Research” as part of its efforts to increase the participation of women and minorities in clinical trials. The guide discusses the following six major barriers to clinical trial participation: distrust of medical researchers and fear of harm; lack of knowledge; lack of transportation; interference with work or family responsibilities; burden of participation; and financial costs. These barriers are described below.

**Distrust of Medical Researchers and Fear of Harm**

Distrust of medical researchers and fear of harm from participating in clinical studies are often linked to historical events, such as the Nuremberg trial in 1949 and the Tuskegee syphilis study. At the Nuremberg trial, Nazi scientists were prosecuted for conducting unethical and inhumane experiments on human subjects. The Tuskegee syphilis study is an infamous
example of unethical treatment of research subjects. In this study, run by an agency of the U.S. government, African American males with syphilis were denied treatment for their condition. Fears of research participant abuse led to efforts, such as the Declaration of Helsinki and the Good Clinical Practice Guidelines, to prevent such unethical behavior. These guidelines for ethical research practices have been widely adopted by researchers, and many regulatory or funding agencies also require compliance with all or part of the guidelines.

Despite these efforts to prevent abuse, mistrust of research lingers, particularly among minority groups. A 2002 study documented the strong belief among minority patients that participation in clinical research may harm one's health. In 2005, an Evidence Report from the Agency for Healthcare Research and Quality also documented distrust of medical researchers as a major barrier to minority patient participation in clinical trials. Several other studies have also examined barriers to participation among minority patients in relation to clinical research generally and found distrust of medical researchers to be a significant issue.

Distrust of researchers may also be affected by stories of questionable research projects that are widely reported in the media. For example, in 2000, the Washington Post published an investigative series revealing research misconduct by Pfizer, a major American pharmaceutical company. The articles described a study that Pfizer conducted in Nigeria in 1996 to test a vaccine in children. Pfizer did not obtain informed consent before enrolling and treating the children, and the study used a falsified ethics approval letter. Eleven children died during the study, and many others were injured. In 2001, several of the Nigerian families involved in the study sued Pfizer, alleging that the company did not explain that the drug was experimental, offer other treatment choices, or obtain proper consent. Pfizer disputed the claims, but agreed to a $75 million settlement in 2009 after the Nigerian government filed criminal charges against
Pfizer staff. Another example, from 1999, involves a gene therapy trial at the University of Pennsylvania, where an 18-year old participant died from an adverse reaction to an experimental treatment. Investigations into the patient’s death revealed that researchers had not disclosed all of the risks of participating in the study and that the lead researcher had a significant financial stake in the outcome of the study. The U.S. Food and Drug Administration (FDA) sanctioned the researchers, and the patient’s family sued the researchers and the university, leading to an out-of-court settlement. Both of these incidents, as well as other examples of research misconduct, have received significant media coverage in the United States. Stories such as this are likely to increase patients’ distrust of medical research.

**Lack of Knowledge**

Minority patients may not participate in clinical research because they are not aware of opportunities. In 2003, a national survey of cancer patients found that 85 percent of patients were not aware of clinical trials as a treatment option for their condition. Physicians are often responsible for informing patients of clinical trials opportunities. If physicians, particularly primary care physicians, are not informed of research opportunities, patients are unlikely to learn of these opportunities. In some cases, physicians may not be aware of research opportunities. Minority patients are also more likely to see minority physicians, who in turn are less likely to participate in clinical research. In a 2006 study, researchers reviewed the enrollment records for several health research studies and concluded that minority patients were less likely to be asked to participate in the study, compared to non-Hispanic whites. Even when physicians discuss clinical research opportunities with patients, patients may lack knowledge of clinical research protections and the informed consent process. The NIH guide notes that “some would-be research participants believe that the informed consent document protects the research
institution and its staff while abridging the rights of the individual research participant. Another possibility for lack of knowledge of clinical research among minority patients may be systematic differences in how these patients access care. For example, these patients may be more likely to receive treatment at urgent care clinics or emergency rooms, rather than in office visit settings. This type of difference could have a significant impact on minority patients' access to research opportunities. This issue was not discussed as a potential barrier to research participation in the literature reviewed for this paper, but it warrants further study.

**Lack of Transportation**

Many clinical research studies are conducted at specialized clinics or at academic teaching hospitals. These locations are not readily accessible to all potential research participants. For some potential participants, lack of transportation may pose a significant barrier to participation. This is a particular issue in rural areas and in underserved areas. In rural areas, the research site may be located a significant geographic distance from patient homes. For other patients, research sites may be located within the same general geographic area, but may be difficult to access for patients who do not own a car or do not drive. Research sites may be accessible by public transportation in some cases, but patients may find it too inconvenient or expensive to travel to the site.

**Inference with Work or Family Responsibilities**

Participation in clinical research may require a significant time commitment from patients to attend additional doctor appointments, undergo laboratory tests, or complete study diaries or surveys. Some patients may find these activities too difficult to fit into busy or unpredictable work schedules; others may be overwhelmed with caring for immediate and extended family members. Some patients may not be able to take time off from work to attend
additional doctor appointments. These barriers may be particularly significant for conditions that are not life-threatening and preventive studies.

**Burden of Participation**

Participation in clinical research may become more burdensome as researchers attempt to assess additional outcomes, such as genetic links to a disease or patient's perceptions of quality of life. Significant burden, either in terms of time or in terms of the types of procedures required, may reduce patients' willingness to participate in clinical research. This barrier exists for all potential research participants – minority and otherwise.

**Financial Costs**

Some patients with limited financial resources may participate in a trial to gain access to a new and expensive medication. However, other patients with limited financial resources may be less likely to participate in clinical research due to worries about the financial cost of participating. This may be particularly true for studies of risk factors or preventive measures that do not involve new medications. Patients with limited financial resources may not be able to afford to take time off from work, or they may worry about incurring additional expenses, such as insurance co-pays, childcare costs, or transportation expenses.

Patients with limited financial resources and no insurance coverage may be even more hesitant to participate due to financial concerns. Clinical trial sponsors typically rely on insurers to cover the costs of the patient’s usual care, such as office visits, laboratory tests, and surgical procedures. The trial sponsors usually only pay for additional procedures or tests that are done solely for research purposes. Patients without insurance may be hesitant to take part in a study that will require a certain number of office visits or laboratory tests, for which they will have to pay out-of-pocket. In a 2002 review of cancer treatment trials sponsored by the NCI, uninsured
patients represented only 5.4 percent of participants. The authors concluded that uninsured patients diagnosed with cancer tend to have more advanced disease, which may make them ineligible for some trials; in addition, these patients may be less likely to see cancer specialists who are involved in clinical trials. Lack of insurance coverage may be an important barrier for minority patients, as these patients are less likely to be insured than other patients. In 2008, 19.1 percent of African Americans, 17.6 percent of Asians, 31.7 percent of American Indians or Alaska Natives, and 18.5 percent of Native Hawaiians and Other Pacific Islanders were uninsured. Among Hispanic or Latinos, 30.7 percent were uninsured. In comparison, only 10.8 percent of non-Hispanic whites were uninsured.

**Other Barriers**

In addition to the barriers identified by the NIH, other groups have identified language and literacy as major barriers specifically for minority groups in the United States. For example, many studies in the United States require patients to be proficient in English; this may be a major barrier for Hispanic/Latino and Asian patients. Even patients who are proficient in English may not be able to read and understand complex documents, such as informed consent forms and other materials related to the clinical study. Patients may decline to participate in the study due to lack of understanding of the research study procedures and goals.

Study design is another significant barrier, particularly among minority patients. Randomized clinical trials generally have strict inclusion and exclusion criteria. The goal of these criteria is to make the patients within the trial as similar as possible, to minimize the potential for other factors (e.g., other medications, other conditions) to influence the study results. However, the strict criteria can make many patients ineligible for the study; this is an important issue, since minority patient populations have high rates of certain co-morbidities (e.g.,
hypertension). For example, in one study, researchers examined barriers to participation in cancer clinical trials at Howard University Cancer Center. The authors found that, as a result of strict inclusion/exclusion criteria, only 8.3 percent of African American cancer patients were eligible for clinical trial participation. Another study also documented study design factors as a barrier to minority patient enrollment in cancer clinical trials.

Lastly, some studies have suggested that the low number of minority physicians may be related to low participation rates among minority patients. In 2001, the American Medical Association reported that only 2.7 percent of internal medicine physicians were African American, and only 3.3 percent were Hispanic. The percentages were similar for cardiologists. Two percent of cardiologists were African American, 3.8 percent were Hispanic, and 12.7 percent were Asian. In 2007, a report from The Endocrine Society noted that African Americans, Hispanics/Latinos, and Native Americans, taken together, make up only 6.4 percent of physicians graduating from medical schools. The report acknowledges that there is a lack of data on the participation of minority physicians in clinical research.

Other studies have found that minority patients are more willing to participate in research when invited by their own physician. Since minority patients tend to choose minority physicians, the authors of these studies conclude that increasing minority physician participation in research may increase minority patient participation in clinical studies. One study in particular found that distrust of medical researchers was less of a factor in minority patient participation than the lack of invitations to participate from their own physicians.

**Significance of Low Minority Patient Participation Rates**

As established above, minority patient populations are under-represented in clinical research, including in CVD research. Before examining specific strategies for increasing
minority patient participation in clinical research, the rationale for increasing participation must be examined. The major reasons for increasing participation fall into two categories: enhancing the applicability of study results, and improving access to research program and benefits.

**APPLICABILITY OF STUDY RESULTS**

The goal of clinical research, generally, is to examine the effects of an intervention among patients who are similar to the patients who will ultimately use the intervention. For example, a new medication for hypertension would, ideally, be tested in a population that is representative of the general population of people with hypertension, in terms of age, gender, race, co-morbidities, and use of other medications. The purpose of using a representative patient population in clinical research is to allow the study results to be generalized from the small patient population in the trial to the much larger patient population in the general public.

However, the ability to generalize the study results is limited when minority patient populations are under-represented in the studies. Several studies that have included minority patients have found differences in outcomes based on race/ethnicity. One systematic review identified multiple studies where differences in efficacy among minority subgroups were reported. For example, the ALLHAT study found a greater beneficial effect for blacks taking a diuretic therapy than for non-blacks. Another study, the LIFE trial, reported worse outcomes among blacks using angiotensin-receptor blockers than among non-blacks. Two studies reported similar outcomes for Asians and non-Asians. Notably, no studies examined outcomes specifically for Native Americans.53

Other studies have identified differences in disease-specific risk factors among minority groups. For example, a 1998 study examined CVD risk factors among minority women and found that CVD risk factors are higher among minority women and among those of lower
socioeconomic status in the United States. Minority women were also more likely to be of lower socioeconomic status. The authors expected to find that socioeconomic status would substantially explain the higher rates of CVD risk factors among minority women, but the study data did not confirm the authors’ hypothesis. Instead, the authors concluded that both race and socioeconomic status have independent associations with CVD risk factors, including systolic blood pressure and body mass index. This finding is particularly important, given that risk prediction models for CVD have largely been developed using data from non-Hispanic white populations. The problem of distinguishing the effects of socioeconomic status and race on treatment response and risk factors also exists in cancer. One study noted that, without increased participation of minorities in cancer research, drawing out these distinctions will be impossible.

Some researchers have suggested that differences in outcomes and risk factors may be related to biological differences between racial/ethnic groups. Studies have found differences among racial/ethnic groups in the pharmacokinetics of some drugs and in the biologic course of some diseases. These differences may alter the effectiveness of some medications. The most well known of these examples is the drug BiDil® (isosorbide dinitrate/hydralazine), which was approved by the FDA specifically for the treatment of heart failure in African Americans. The initial trial for the drug enrolled men of various races, but the results were not statistically significant. Further analyses of the data showed that results were statistically significant among African American men. Researchers conducted a new placebo-controlled trial, enrolling only self-identified African American men and women. The results of the second trial were statistically significant and were used to obtain FDA approval of the drug in 2005. The drug is not indicated for use in non-African American patients.
The potential racial and ethnic variations in the biologic course of disease and in the response to medications heighten the need for increased representation of minority groups in clinical research. Without increased representation, it will be difficult, if not impossible, to generalize study findings to minority groups.

**EQUAL ACCESS TO RESEARCH AND RESEARCH PROGRAM BENEFITS**

The second major reason for increasing minority patient participation in clinical research concerns social justice and ethics. As an issue of social justice, medical interventions must be tested in the populations that will ultimately use them. Findings from research studies are most likely to be useful to patients who are similar to the study participants. Therefore, medical research, much of which is supported by public funding, must provide information on risk factors and prevention strategies that is useful to all racial and ethnic groups in the United States, not just the majority group. Increasing minority participation in research may also help address another major social justice issue – health care disparities in the United States. As an issue of ethics, balancing the burden and benefits of research across all patient groups is critical; the majority group should not bear the entire burden of participating in research, nor reap all of the benefits of participation.

Related to the ethics argument is the concept of equal access to research program benefits. As noted in a General Accounting Office report to Congress, clinical trials can be “especially important for patients with serious or life-threatening conditions that have limited treatment options. For those patients, participation in a clinical trial ... may offer the best chance of finding an effective treatment.” In addition to potentially effective treatments, research programs may offer patients other benefits, such as access to new screening tools for some diseases or opportunities to participate in structured risk reduction programs (e.g., smoking
cessation or weight loss intervention studies). These programs could have a beneficial impact on the patient's health.

**Efforts to Increase Minority Patient Participation in Research**

The problem of under-representation of minority groups in clinical research has received significant attention in recent years. Most notably, Congress acted in 1993 to increase minority patient participation in NIH-funded research. In response to the passage of the NIH Revitalization Act of 1993, the NIH revised its policies to require that women and minorities be included in all of its clinical research studies. The new policies require Phase III trial to include women and minorities in sufficient numbers to permit analyses of differences in treatment effect. The law specifically states that cost is not a valid reason to exclude minority patients. The law also required the NIH to develop programs and support for outreach efforts to recruit women and minority patients into clinical research programs. All studies that the NIH considers for funding must include specific plans for recruiting and retaining women and minority groups.67

The NIH also promotes increased minority patient participation in cancer research through the NCI's Community Clinical Oncology Program. This program connects community physicians with academic research centers to facilitate participation in cancer prevention and treatment research. Community hospitals and physicians organize themselves into groups that enter into cooperative agreements to participate in cancer clinical trials. Research centers who are conducting the studies then have direct access to community physicians who are interested in research opportunities. The program also includes minority-based groups, defined as groups with 40 percent or more of new patients coming from minority populations. Minority-based groups provide cancer researchers with direct access to minority patient populations.68
The FDA has not followed the NIH's example in requiring the inclusion of minority groups in clinical trials. The FDA recommends that these groups be included and makes recommendations for how to categorize minority patients. However, the agency does not require inclusion of minority groups; instead, individual companies developing and testing new interventions decide if and when to include minority groups in their research.\textsuperscript{69}

Outside the federal government, several groups have developed programs to increase minority participation in research. For example, the National Medical Association supports Project IMPACT: Increasing Minority Participation and Awareness of Clinical Trials. This program provides training in research methods to minority physicians and offers educational resources for minority patients. The program also collaborates with community organizations and other groups to increase awareness of clinical research opportunities.\textsuperscript{70} To facilitate involvement of minority physicians in clinical research, the program maintains a database of minority physicians interested in participating in clinical studies; study sponsors may submit trial information to the program to be shared with interested investigators.\textsuperscript{71} Another example is the Center for Innovation in Health Disparities Research, which aims to increase the number of minority nurse researchers. The Center provides mentoring and internships to minority undergraduate and master's nursing students and provides funding for new research. The Center is the result of a partnership between the Department of Nursing at Winston-Salem State University and North Carolina Central University and the School of Nursing at The University of North Carolina at Chapel Hill.\textsuperscript{72} Pharmaceutical companies, such as GlaxoSmithKline and AstraZeneca, also sponsor research training and physician engagement programs aimed at increasing the participation of minority physicians – and hopefully minority patients – in clinical research.\textsuperscript{73,74}
STUDY QUESTIONS AND OBJECTIVES

In spite of the efforts to increase minority participation in clinical research, minority groups remain under-represented in CVD research. The goal of this paper is to identify and recommend potential strategies for increasing minority patient participation in CVD research. The paper describes documented strategies for increasing patient participation in CVD research and attempts to examine the relative effectiveness of the strategies. Specifically, this paper addresses five questions: What strategies have been documented for increasing the participation of minority patients in cardiovascular disease research in the United States? What strategies have been documented for increasing the participation of minority patients in research in other disease areas or in clinical research generally (e.g., not in a specific disease area)? Are these strategies adaptable for cardiovascular disease? Has the effectiveness (and possibly relevant effectiveness) of the strategies been assessed? Are there opportunities for collaboration between the clinical research and public health sectors to implement new strategies and/or to implement existing strategies more efficiently?

This paper does not address barriers to participation or strategies for increasing participation in genomic research into CVD causes or risk factors. Some research has documented unique barriers to genomics research, both among majority and minority participants. A full review of these unique barriers to genomics research is beyond the scope of this paper.

METHODS

The primary sources of information for this paper were articles published in peer-reviewed journals, policy or research papers published by government agencies or non-profit associations, and media reports (e.g., newspaper or magazine articles). In January 2010,
searches of PubMed, Google Scholar, and Google were conducted to identify relevant literature. PubMed and Google Scholar were used to identify publications in peer-reviewed medical literature, while Google was used to identify other publications, such as government policy papers, news reports, and magazine articles. The following MeSH term combinations were used to search for articles in PubMed:

- Willingness to Participate AND Minority Groups
- Patient Participation AND Minority Groups AND Cardiovascular Diseases
- Patient Participation AND Minority Groups AND Strategy
- Patient Selection AND Minority Groups AND Cardiovascular Diseases
- Patient Selection AND Minority Groups AND Strategy

The phrases, "minority patient participation in clinical research" and "minority patient participation in cardiovascular disease research," were used to search for relevant publications on Google Scholar and Google. Focused searches of relevant websites, including websites for the NIH, Centers for Disease Control and Prevention, American Medical Association, FDA, American College of Cardiology, and American Heart Association were also conducted. Lastly, the reference lists of included publications were reviewed to identify any additional relevant citations.

Publications that discussed strategies for increasing minority patient participation in clinical research (including cardiovascular disease, other disease areas, and clinical research generally) in the United States were included. Publications that only discussed clinical research participation issues among minority physicians were excluded, as were publications that were not available in English, not publically available, or not accessible online in the University of North Carolina (UNC) library system.
Included publications were organized into two categories:

1. **Strategy Descriptions**: descriptive discussions of barriers to minority patient participation and strategies for increasing participation, without quantitative assessments of strategy effectiveness.

2. **Strategy Assessments**: quantitative assessments of the effectiveness of various strategies to increase patient participation in clinical research.

Publications from the Strategy Descriptions group were used to describe the currently available strategies for cardiovascular disease, for other disease areas, and for clinical research generally. Publications from the Strategy Assessments groups were used to discuss the effectiveness of currently available strategies. Publications from both groups were used to describe collaboration approaches.

**LITERATURE REVIEW**

Using the search methods described above, 73 articles were retrieved from PubMed, although the number included in the review was less than 73 due to duplicate publications. An additional 18 publications were identified through searches of Google Scholar and Google, and 11 publications were identified by review of article citations. Not all of the identified publications were included in the review; publications were excluded primarily because they reported low minority recruitment levels for a specific study, without discussions of barriers to recruitment or strategies for improving recruitment. The literature review findings are summarized below; the findings are organized into strategies specifically designed for CVD, general strategies or strategies designed for other disease areas, strategies that discuss collaboration across health care sectors, and assessments of strategy effectiveness.
STRATEGIES SPECIFICALLY DESIGNED FOR CARDIOVASCULAR DISEASE

Only two publications described recruitment strategies specifically designed for CVD research. First, a 2009 study reported on the use of an ecological systems model to recruit minority women at risk for CVD for a study on interventions to increase physical activity. An ecological systems model examines individuals’ interaction with their environment on four levels. The first level is the immediate environment in which the person lives (e.g., family and friends). The second level is the broader environment in which the person operates (e.g., employment, larger social network). This level is followed by the community in which the person resides. The fourth level is the larger society/culture/political group to which the person belongs. Each level of the environment has its own roles, culture, behaviors, and norms, which in turn influence multiple aspects of the individuals’ lives. In this study, the researchers attempted to understand how factors at each level might influence patient enrollment. The researchers assembled a team that included a co-investigator, an African American nurse who was familiar with the target population, and two women who were long-time residents in the community. The recruitment team identified likely locations for recruitment (e.g., community centers) and observed the locations to determine if the target population frequented them. The team also observed general community activity over a number of days to determine the most promising locations for recruitment activities. Using these techniques, the researchers conducted targeted outreach activities and successfully recruited a study population that was over 70 percent African American. The authors concluded that “culturally competent approaches [to recruitment] must include an understanding of the characteristics, experiences, norms, values, beliefs, behavioral patterns, social, and environmental forces of the population of focus.”

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The second strategy designed for CVD involved a community-wide collaboration. The Cherishing Our Hearts and Souls Coalition (COHS) is a community-based initiative that aims to reduce CVD and other chronic health issues among minority groups (particularly African Americans) living in Roxbury, Massachusetts. The Roxbury area of Boston has a large minority population (less than 15 percent of the residents are white) and significant health issues. The Harvard School of Public Health is the coordinating organization for the program; other participants include neighborhood health centers, local hospitals, community groups, public schools, and local health departments. The group meets several times per year and has several active programs related to improving access to care and encouraging healthy behaviors. In addition, the program has a specific sub-group that works to improve access to community-based research opportunities. The subgroup helped to establish the Roxbury Community Research Advisory Board (CRAB), which includes community leaders and residents. The board’s goal is to improve residents’ understanding of and willingness to participate in community-based and clinical research; a major function of CRAB is the organization and presentation of training sessions that discuss social justice, research ethics and protections, and the ways in which increased participation in research may reduce health disparities. COHS has been an important partner in minority recruitment efforts for CVD studies in the Boston area.\textsuperscript{77,78}

**STRATEGIES DESIGNED FOR OTHER DISEASE AREAS OR CLINICAL RESEARCH GENERALLY**

Several publications describe strategies for recruitment in disease areas other than CVD or for recruitment of minority patients generally. Some of these strategies directly address barriers noted above, while others discuss general approaches to recruitment.
INCREASE PATIENT KNOWLEDGE

A study published in 2009 surveyed HIV-infected patients at primary care clinics in Chicago to assess reasons for low participation rates in HIV research. The authors found that “although less than a third of patients had ever been asked to participate in research, being asked by their primary provider was the most important predictor of research participation.” The authors concluded that busy primary care practices must find new, innovative ways to remind physicians about the currently available studies and encourage them to ask patients to participate. Strategies for overcoming this barrier may include verbal or electronic reminders about studies and the use of other research staff to pre-screen patients and inform physicians about a patient’s eligibility for trials.

In an example from cancer research, a study examined whether Internet-based tools are useful for identifying minority patients that are interested in participating in cancer clinical trials. The authors examined data from an Internet-based decision support program designed to provide cancer patients with evidence-based information on treatment options for their specific disease. Patients using the tool are asked to provide race/ethnicity data early in the questionnaire and are later asked if they are interested in learning more about clinical trials. The authors found that minority patients were more likely to express interest in clinical trials than white patients. For example, 67 percent of white patients indicated interest in clinical trials, while 73 percent of African Americans, 74 percent of Hispanics, and 72 percent of Asians indicated interest. The authors concluded that Internet-based recruitment tools may be an effective strategy for reaching minority patients who are interested in participating in clinical studies. Another cancer study disputed this finding, however, suggesting that Internet-based recruitment tools may lead to enrollment bias. The authors in this study argue that Internet-based strategies may exclude those
of low socioeconomic status (predominantly minorities) may not have reliable access to the Internet.\textsuperscript{82}

A systematic review from 2006 attempted to identify major barriers to minority patient participation and strategies to overcome these barriers. The authors note that many patients view randomized studies that use placebos or double-blind assessments negatively. The authors suggest three strategies to address this barrier: education about the advantages of randomization, study designs that offer delayed or alternative interventions to the control group, and reassurances that control group patients still receive a minimum standard of care.\textsuperscript{83}

Lastly, in another example from cancer research, a 2007 study used a social ecological framework to assess barriers to participation in cancer clinical trials and recommend strategies to improve participation. A social ecological framework describes how individuals' interact with multiple levels of their environment; the framework is similar to the ecological systems model discussed earlier. In this study, the authors used the model to identify barriers to trial participation at six levels: intrapersonal, interpersonal, environmental, socio-cultural, community, and institutional/societal. The authors suggest that social workers may play a key role in connecting patients with research opportunities. Specifically, they suggest placing clinical social workers in health care settings where they can be part of the patient's medical team; in that role, social workers can help to educate patients about trials and address concerns about the process (e.g., informed consent, procedures).\textsuperscript{84}

\textbf{ENGAGE THE COMMUNITY}

Four studies discuss community engagement strategies as a way to increase clinical research participation. In an example from HIV research, a 2006 study described a community-academic partnership for recruiting HIV infected African American and Hispanic women into a
research study. In developing the partnership, the authors identified three types of relationships: 1) researchers ask the community to help them identify potential participants; 2) the community and research team develop a collaborative relationship; and 3) the community initiates the research project and asks the academic researchers for support. In their study, the authors primarily used the first two approaches. The researchers contacted community organizations (e.g., substance abuse centers, counseling centers, clinics), explained the nature of the study, and asked for help in recruiting patients. In a few instances, the researchers found opportunities to develop a more collaborative relationship with an organization (e.g., finding speakers for lunch sessions). Overall, the researchers found that engaging community organizations was an effective tool for recruiting patients from a sensitive population. In particular, the authors emphasized the importance of establishing personal relationships with supervisors and staff at the organization, explaining how the results of the study could benefit their clients, developing a plan to help the organization achieve some of its goals, and maintaining a strong presence at the organization throughout the life of the study. In terms of actual recruitment efforts, the authors emphasize the importance of using culturally matched research staff. A systematic review published in 2006 identified similar strategies. The authors of this review recommend the use of lay outreach workers, inclusion of minority investigators, and working through community-based organizations (e.g., churches) as useful strategies.

A report on recruiting Latino patients describes similar recruitment strategies for cancer studies. In one example, a cancer screening trial initially had poor enrollment among Latinos. In the first five years of the trial, only 232 Latinos had enrolled. The researchers developed a campaign to increase participation among Latinos. The campaign included targeted media announcements and mailings, community recruiters, and partnerships with other community and
medical institutions. During the campaign, 1,046 additional Latinos enrolled in the study. In
another example, the Study of Tamoxifen and Raloxifene (STAR) trial, researchers built
relationships with professional Latino organizations (e.g., nurses associations, teachers groups)
to reach their target population of acculturated Latinas. The researchers used these relationships
to give educational sessions about the study and clinical research generally.\(^{87}\)

In contrast to these studies, a 2008 report on experiences with recruiting minority women
into clinical trials related to reproductive health issues found that print marketing was more
effective than community engagement. The researchers used a combination of print marketing
materials (e.g., brochures, flyers) placed in high-traffic locations for potential participants and
outreach to community organizations (e.g., churches, health fairs, public housing units). The
authors reported successful enrollment of African American women in the study, largely in
response to the print media outreach. They also noted that the community outreach, while useful
in that it improved ties between the academic medical centers and the community, did not
substantially contribute to enrollment success.\(^{88}\)

**CONSIDER MINORITY PATIENTS IN STUDY DESIGN PHASES**

Two articles discussed study design issues in relation to minority patient participation.
One study evaluated barriers to cancer clinical trial participation at Howard University Cancer
Center and found that many African American patients were not eligible due to the presence of
other co-morbidities (e.g., hypertension, hyperlipidemia). The authors concluded, “It is evident
that the African American population has a disproportionate burden of co-morbidities that
exclude patients from clinical trials.”\(^{89}(p733)\) The authors recommended adjusting inclusion and
exclusion criteria to allow for the enrollment of more African American patients.\(^{90}\)
The second study used a concept-mapping approach to identify perceived barriers to participating in clinical research among minority patients. The authors compared barriers identified by community members with barriers perceived by investigators and concluded that the actual and perceived barriers are not always the same. The authors recommended that researchers include minority patient representatives in the design and implementation of research studies as a strategy to overcome actual barriers and increase participation.91

**INCREASE PARTICIPATION AMONG MINORITY PHYSICIANS**

Two publications discussed outreach to minority physicians as a strategy for increasing minority patient participation. First, in a report on barriers to minority participation, the authors recommended that researchers identify a diverse pool of investigators for studies and use these physicians to recruit minority patients.92 The second publication examined attitudes toward clinical research and found that minority physicians and physicians with large numbers of minority patients were more likely to express their distrust of medical research and less likely to refer patients to clinical trials. This study suggests that efforts to overcome distrust of medical research through education about the research process and ethics must include physicians as well as patients.93

**STRATEGIES WITH COLLABORATION ACROSS HEALTH CARE SECTORS**

Many health care sectors (e.g., primary care and specialist providers, hospitals, clinics, public health departments, academic research centers, pharmaceutical companies and medical device manufacturers, non-profit associations, and government agencies) are involved in the prevention and treatment of CVD. An objective of this paper is to identify strategies that involve collaboration across these sectors. Three publications described strategies that engaged other sectors of the health care community active in CVD treatment and prevention.
The first study describes a strategy to recruit minority patients for a trial of a telemedicine-based diabetes self-management intervention. The trial was designed and run by an academic medical center, but conducted within rural community health centers. The authors reported successful enrollment of a representative portion of minority patients using a strategy that connected academic researchers with community health care providers. By engaging community health care providers, the researchers were able to prospectively identify many potential barriers to participation, including distrust of researchers, lack of transportation, and time burden. For example, the researchers helped participating health care providers identify eligible patients, but the invitation to the patient came directly from the health care provider. This was done to help establish trust in the research study. To avoid transportation issues, the study provided free transportation to and from the study site for any necessary study visits. Patients also received gift cards and other items (e.g., tote bags, t-shirts) as compensation for their time spent participating in the study. The authors concluded that “collaboration between the academic institution and the community health center during the planning phase to gain input on the development of research practices and continued input by the community health center during the Diabetes TeleCare Study facilitated the successful recruitment and retention of an ethnically diverse sample, which included a preponderance of females.”

The second study describes a similar strategy for cancer trials. The authors recommend that academic research centers and other organizations designing cancer clinical trials engage community-based oncology practices to increase participation of minority patients in cancer clinical trials. The authors outlined the following steps that community-based practitioners could follow to recruit minority patients more effectively:
• Encourage open discussion between the patient and physician about participation concerns;
• Clearly address/discuss costs of participating;
• Include the patient’s family in the discussion about participation;
• Involve the entire staff in recruitment efforts;
• Hire an ethnically diverse staff with bilingual capabilities;
• Network with primary care physicians in the community;
• Develop relationships and network with community organizations/leaders;
• Build partnerships with local/community-based organizations;
• Educate the community about research by giving presentations or informal talks;
• Continue to network with the community after recruitment, and share results from research project with the community.\(^9^5\)

The Cherishing Our Hearts and Souls Coalition (COHS) described earlier is a particularly relevant example for CVD. This initiative connects local health departments, academic researchers, and local providers (clinics and hospitals) to encourage participation in research.

**ASSESSMENTS OF STRATEGY EFFECTIVENESS**

Few publications described systemic assessments of strategy effectiveness, and even fewer publications compared the effectiveness of multiple strategies. Only two individual studies reported on effectiveness. The first study reported on the effectiveness and cost of recruitment strategies for a randomized trial of a smoking cessation program. The authors found that active recruitment strategies (e.g., in-person visits by the study staff) were less effective than passive strategies (e.g., media outreach and other print dissemination activities). Passive
strategies produced 89 percent of the enrollees in the study and cost only $22 per enrollee, whereas active strategies cost $159 per enrollee.\textsuperscript{96}

A second study conducted a formal assessment of the effectiveness of its recruitment strategy. This study, which was described earlier, developed a community-academic partnership for recruiting HIV infected African American and Hispanic women. The researchers created a recruitment success factor (RSF) score and used it to compare recruitment success across different organizations. The quantitative aspect of the study was helpful in determining which types of community organizations were most useful for recruiting patients into an HIV research study. However, the effectiveness of the strategy itself (community-academic partnership) was not compared to the effectiveness of other strategies (e.g., engaging primary care providers).\textsuperscript{97}

Two systematic reviews also reported on effectiveness. First, a systematic review published in 2006 identified and examined studies that assessed the effectiveness of recruitment strategies aimed at increasing minority patient participation in cancer clinical trials. The authors identified only five studies that examined the effectiveness of recruitment strategies. The other nine studies were descriptive in nature. Of the five studies that assessed effectiveness, three reported that the recruitment strategies under study increased minority patient enrollment. These strategies included media campaigns and a church-based project. The authors conclude that the "the small number of studies, their heterogeneity, the lack of consistency in the results, and the quality of the evidence suggest that further studies are needed to evaluate the efficacy and/or effectiveness of strategies to increase enrollment in cancer-related trials."\textsuperscript{98(p139)}

The second systematic review concluded that mass mailings are an effective means of recruitment for African Americans, particularly for those of middle or higher socioeconomic status. The authors also noted that passive strategies are more effective for studies with large
numbers of eligible participants. For studies where eligibility is relatively rare, active strategies are more effective. The systematic review did not find sufficient evidence on the effectiveness of culturally adapted recruitment materials, and the authors concluded that more study was needed. The authors also suggested that more work needs to be done to examine retention strategies for minority patients.99

RESULTS FROM LITERATURE REVIEW

RESULTS RELATED TO STUDY QUESTIONS

The goal of the literature review was to identify and recommend potential strategies for increasing minority patient participation in CVD research. However, the literature review identified few such strategies. Only two documented strategies specifically designed to increase participation in CVD research were identified. In both cases, the researchers reported success using the strategy, but, since neither strategy was compared to other means of recruitment, no objective data exists to support the researchers’ views. Without objective data on the effectiveness of the strategies, recommending them for use in other studies is difficult.

Several strategies that were designed for other disease areas or for clinical research generally could be adapted for CVD research. For example, strategies to increase patient and physician knowledge about clinical research opportunities would be beneficial for CVD research. Community engagement strategies may also be useful for CVD research. Study design issues may be a barrier in CVD research, but little evidence of this is available in the current literature. More research is needed to determine if multiple co-morbidities or other design issues are resulting in low eligibility among minority patients for CVD research.

Limitations to adapting strategies designed for other disease areas to CVD research exist, particularly when the diseases are very different in nature from CVD. For example, minority
populations with diseases such as HIV/AIDS may be particularly difficult to recruit due to the social stigma surrounding the disease. Researchers must consider this factor when designing recruitment strategies for this population. CVD, on the other hand, is common in non-minority groups and occurs across socioeconomic lines; as a result, social stigma is not likely to be an issue in recruiting patients for CVD research. The imminently life-threatening nature of HIV/AIDS and cancer also may alter patients’ willingness to participate in clinical research. For CVD, patients may not feel that they are in immediate danger of dying, and therefore may decide not to participate. This factor could make it particularly difficult to recruit patients for preventive CVD studies.

The available literature describes few collaboration approaches that are specifically relevant to CVD. The COHS model noted above is one relevant approach. The strategy of building connections between academic research centers and community-based hospitals or physicians is also useful for CVD research, since many CVD patients receive care from their primary care physician, in their local community. Additional research to develop new collaboration approaches and to assess the effectiveness of existing approaches is needed. This research may build on the efforts of the cancer community to increase participation in clinical trials by linking academic research centers with community-based physicians and with cancer advocacy organizations (e.g., the American Cancer Association).

Lastly, the literature review found very limited evidence on the effectiveness of recruitment strategies. The literature primarily described different strategies, without providing any quantitative analysis of the strategy effectiveness. The available assessments generally report only on effectiveness of a single strategy for a specific study. Few assessments compare multiple approaches to recruitment for a single study, and even fewer studies compare
recruitment strategies across minority populations (e.g., African American vs. Hispanic). More research is needed in this area to understand the effectiveness of various strategies, both generally and in specific sub-populations. The conclusions of one systematic review hold true for CVD as well as cancer. The authors of that review recommended that “researchers design and evaluate the efficacy and/or effectiveness of recruitment strategies tailored to specific underrepresented groups.”

GAPS IN EXISTING LITERATURE

Overall, the literature review revealed a startling lack of evidence on which recruitment strategies would be effective for increasing minority patient participation in CVD research. In addition, the review identified several other major gaps in research and strategy development in this area. Specifically, the review found little to no information on how the nature of the organization conducting the research affects patient trust and participation, on what motivates researchers to recruit minority populations, and on how the problem could be addressed from a broader, public health leadership perspective.

ORGANIZATION TYPE AND PATIENT TRUST

Clinical research in the United States is generally conducted by one of three groups: government, academia, and industry. Each group has different motivations for conducting research. Patients who are approached about participating in a study receive information on the study sponsor. The study sponsor may influence the patients’ willingness to participate in the study. For example, patients may be more distrustful of research sponsored by pharmaceutical companies, for fear that the sponsor is motivated by financial concerns and not concerns about the patients’ health. Alternately, minority patients may be more distrustful of government-sponsored studies, given the history of the Tuskegee syphilis study. None of the identified...
literature explored whether the type of organization sponsoring the research influenced patient participation. More research is needed in this area to identify if this is a barrier to research and, if so, to develop appropriate strategies to overcome this obstacle.

**Motivations for Researchers to Recruit Minority Patients**

Another critical issue that was not addressed in the literature review is how to motivate researchers to include minority patients in their studies. Most publications discussed the broad reasons, such as reducing health care disparities and providing equal access to research benefits, for including minority patients in their studies. However, the authors did not address how to motivate researchers to make a substantial effort to improve participation rates. This is a significant issue. The NIH mandates enrollment goals and plans for recruiting minority patients, but studies may still be unsuccessful in meeting their goals. The FDA does not require inclusion of minority groups in clinical research. The literature review shows that recruitment of representative minority populations generally requires substantial effort, time, and money. Because of the lack of mandate, researchers may make a good faith effort to enroll minority patients, but they may limit their activities to avoid going over budget or missing enrollment deadlines. Researchers may understand the importance of including minority populations, but may not do so in practice due to the logistical difficulties. More research is needed to understand why some researchers make a substantial effort to include minority patients, and why other studies fail to do so. Research is also needed to better understand what would motivate researchers to make a stronger effort to recruit minority patients.

**Public Health Leadership Perspective**

A surprising finding of the literature review was the lack of high-level strategies for addressing the issue of minority participation rates. Almost all of the literature identified here
focused on strategies for specific types of studies, in specific disease areas. The strategies described in these publications are intended for individual research teams. Only one of the reviewed publications, from the Endocrine Society, discussed the issue from the perspective of the public health leadership framework. The public health leadership framework includes competencies related to effective change, political processes, negotiation and mediation, ethics, organizational capacity, and team building. The authors of this publication assessed the issue from several perspectives and identified the need for transformational change. The authors then examined trans-organizational capacity and identified the major stakeholders for this issue, including the NIH, FDA, pharmaceutical companies, academic institutions, health care providers, community organizations, and patient groups. Next, the authors recommended a team-building approach and suggested creating collaborative centers between the NIH, researchers, and other stakeholders. These centers would develop and test recruitment strategies and assist with recruitment efforts. From a political standpoint, the authors recommended passing new federal laws to require research to include minority patients, providing tax breaks or other incentives to offset increased costs of recruitment, and requiring minority participation in trials for FDA approval.104

While the strategies put forth in this paper are interesting and potentially useful for addressing the issue of minority patient participation, further analysis of the problem from a public health leadership standpoint is needed. Given the scope of the problem and the lack of success in improving participation rates to date, solutions that tackle the issue from a systems level are needed.
CONCLUSIONS AND RECOMMENDATIONS

The health care community generally agrees that clinical research should be more representative of minority populations in the United States. Many barriers to minority patient participation have been identified, and some strategies have been suggested to improve participation. However, few strategies have been designed specifically for CVD research, and more research is needed to determine whether strategies documented for CVD and those documented for other disease areas are effective in CVD. As noted above, costs vary dramatically between strategy types. In order to make the best use of limited research resources, it will be important to understand what strategies are most effective and most cost-efficient. This may vary by study type (interventional vs. observational), by the area of study (treatment vs. prevention), by the geographic location of the study (rural vs. urban), and by the characteristics of the target population (elderly vs. young, African American vs. Hispanic, men vs. women).

The lack of documented, effective strategies for increasing participation in CVD research clearly points to a need for new research to develop and test strategies. Researchers undertaking new studies may find it useful to undertake a small feasibility study to assess barriers to recruitment and strategies to overcome those barriers. The feasibility study could include surveys or other interviews with potential participants. This will allow the researchers to design the study in a manner that avoids some of the key barriers for that population. For example, researchers may learn that transportation, and not language or cultural issues, are the key barrier for a particular group. Rather than spending the recruitment budget on translating materials and hiring culturally appropriate staff, the researchers may arrange for alternate locations or pay for transportation services. Prospective identification of barriers will be a critical factor in developing a cost-effective approach to engaging minority populations.
Secondly, new analyses of the problem from the public health leadership standpoint are critical for the development of systems level strategies to address this issue. The currently documented strategies are intended for addressing barriers at the individual study level. However, broader strategies are needed to address systems level issues, such as the lack of motivation for researchers to recruit minorities for clinical research studies. The use of political processes, including new laws and requirements for FDA approval, may be particularly useful for addressing the motivation issue. Team-building approaches may help to improve knowledge sharing and reduce the logistical difficulties around recruiting minority patients. Transformational change to existing organizations and systems may be necessary to increase the number of minority physicians and to eliminate the barriers of insurance coverage and access to care. Most importantly, perhaps, the public health community needs to develop and articulate a clear mission to address this issue, across disease areas.

A potential barrier to successful public health leadership on this issue is the lack of a clear primary stakeholder. No organization is currently empowered with this mission, and so it becomes a lower-tier priority at many groups, such as the NIH and FDA. A potential solution is to empower an agency (with funding and authority), such as the Office of Minority Health at the Department of Health and Human Services, to take charge of addressing this issue.

Placing this issue in the charge of a single agency may help to promote collaboration between health care sectors. This paper identified few examples of strategies that attempted to bridge the gap between academic or industry-funded research and public health organizations. As part of the Healthy People 2010 initiative, public health organizations across the country are working to reduce health care disparities and improve prevention and treatment for major disease areas, including CVD. Many public health organizations have campaigns to raise awareness or
to prevent the disease by reducing risk factors. Others attempt to provide higher quality care for patients with acute CVD. As an example, the American Heart Association organizes campaigns to raise awareness of CVD and to reduce risk factors, such as smoking, obesity, high blood pressure, and high cholesterol. The organization also works with hospitals to improve the quality of care for patients with the disease. Many of these programs are conducted in partnership with public health agencies, at the local, state, and federal levels.

Despite the high level of activity related to CVD in public health organizations, few documented attempts to connect public health activities to clinical research exist. Public health organizations may be reluctant to promote specific studies in CVD, either due to lack of resources or to the perception of a conflict of interest. For example, it would likely be inappropriate for the Centers for Disease Control and Prevention to specifically support recruitment activities for a clinical trial of a new antihypertensive. However, the above discussion of barriers and strategies points to several areas where public health organizations could contribute to improving minority participation in research. Collaboration on education would be particularly useful; for example, as part of efforts to increase awareness of CVD and risk factors, public health agencies could add a component on clinical research to their education programs. This component could focus on research generally; it could explain the importance of research participation, the concept of randomization, the benefits and potential risks of participating in research, and the informed consent process. Educating minority groups about clinical research generally would help potential study participants to make a more informed decision about enrolling in a clinical study.

In conclusion, this literature review identified few strategies specifically designed to increase minority participation in CVD research. Other existing strategies may be adapted for
CVD research, but assessments of the effectiveness of these strategies are necessary before they are widely implemented. New research should be conducted to develop and test effective strategies for CVD research. New strategies and approaches to addressing this issue are needed, both at the individual study level and at the broader systems level. Addressing the issue from a public health leadership standpoint may be particularly useful for developing new, systems level strategies. Researchers should also investigate the potential for partnerships with public health organizations that are already investing in education, prevention, and treatment campaigns for CVD. Increasing minority participation in CVD research is a critical step in reducing the burden of CVD among minority populations and eliminating health care disparities in the United States.
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