

WHY AFRICAN AMERICANS MAY NOT BE PARTICIPATING IN CLINICAL TRIALS

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African Americans have been underrepresented in clinical trials. This study was designed to determine factors that may help explain the low participation rate of African Americans in clinical trials. A historical review documented past medical experimentation and other practices on blacks that were often brutal and unethical. These experiences may have served to fortify the legacy of African-American mistrust in the medical system and culminated in the infamous Tuskegee Syphilis Study. Four major barriers to participation in clinical trials were identified: lack of awareness about trials, economic factors, communication issues, and mistrust. These barriers, as well as others, can be surmounted with proper pretrial planning, patient education, genuine commitment and concern by study staff, and hard work to overcome deficiencies. (*J Natl Med Assoc.* 1996;88:630-634.)

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African Americans have a substantial survival disadvantage. In almost every major category of mortality,

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African Americans are disproportionately affected.¹ For the three major causes of death (heart disease, cancer, and stroke), the ratio of black to white mortality exceeds one and is most pronounced for stroke with a ratio of 1.9.² Not only are black men and women almost twice as likely to die of stroke, they also are almost twice as likely to experience stroke.^{3,4} The mortality and incidence statistics are especially striking in that African Americans have disproportionate stroke burden in middle-age as compared to white Americans.^{3,4} Other major causes of mortality such as heart disease and cancer may affect African Americans earlier in life and may be associated with premature mortality.⁵

Historically, African Americans, other minorities, and women have been underrepresented in clinical trials.⁶⁻⁹ For African Americans, this trend parallels other health-care trends that indicate a general lack of access to care and use of preventive and palliative medical diagnostic and treatment services.^{1,3,10,11} As clinical trials play a dominant role in the development of safe and effective treatments to reduce the societal burden of disease, participation by minorities and women is crucial to assure sufficient scientific information to assess the safety and efficacy of new treatments. Underrepresentation of minorities and women in clinical research has led to a change in federal policy to mandate such inclusion in clinical trial proposals.¹²

The study described in this article was designed to identify barriers to African-American participation in clinical trials and to propose solutions to overcome these barriers. Both original data and a brief historical review are used to demonstrate salient points.

HISTORICAL REVIEW

The historical background of African Americans as research subjects illustrates how their attitudes, fears, and

mistrust of the medical profession and health institutions were shaped. The history of abuse in the name of research has created real and well-founded fear and skepticism in the African-American community.⁷ African Americans have been subjected to medical demonstration and experimentation that, at times, has been painful and unethical.¹³ In the antebellum South, by reason of their slave status, blacks were forced to participate in medical research and demonstration. During this period, the poor and enslaved were used to fill hospital beds to help doctors practice and perfect their craft. Southern blacks, helpless and in a lower position in society, became a prime source for medical school dissection experiments and autopsy specimens. Fearful of this practice, some expressed the hope to die in the summer months when dissection classes were not in session. This practice continued in the postbellum South in the form of "night-doctors" who stole and dissected bodies of blacks. Given these accounts, it is not surprising that the autopsy rate for some major causes of mortality is low among African Americans.^{14,15}

Blacks were used to test new techniques and remedies in the name of medical progress. Such experimentation was often brutal. This is exemplified by the experimentation to test remedies for heatstroke on a slave named Fed.¹³ Fed was secured in an open pit in the ground that was then covered and heated to test which medication enabled him to withstand heat. Each session ended when Fed finally succumbed to the heat and fainted. In another type of experiment, black slave women in Montgomery, Alabama, were used to search for a cure for vesicovaginal fistula.^{7,16} In this time period, prior to the advent of anesthetics for this type of operation, the pain and agony of the surgical experiments were extreme. As the state considered the slaves "property," they were denied the right to refuse to participate.

The legacy of mistrust continued into the 1920s as the prevailing feeling among many blacks was that they would be experimented on if they entered hospitals.¹⁶ This fear was fueled further by the Tuskegee Syphilis Study initiated in the 1930s.^{17,18} The subjects included poor black sharecroppers from Macon County, Alabama. Sharecroppers with syphilis were matched with controls. The study was designed to document the natural history of syphilis. Penicillin was not in use as a standard treatment for syphilis in the 1930s. However, it became widely available in the 1940s and later became a standard treatment for syphilis. The participants in the program were not made aware of or given the treatment. Then, in the early 1970s, the lay press ran lead stories about the study and it was eventually terminated.

The Tuskegee Syphilis Study has been referred to as the longest running nontherapeutic experiment on humans and one of the most notorious cases of prolonged and knowing violation of human subjects.¹⁷ The negative aftereffects of this study on black attitudes toward the medical establishment are believed to be substantial. The "folklore" effect stemming from the events also is believed to have led to considerable mistrust. Although modern-day safeguards are in place to prevent this type of abuse, the effect of institutional racism does not dissipate quickly.⁶

METHODS AND MATERIALS

Study Subjects and Interview Instrument

In preparation for our stroke prevention trial, the African-American Antiplatelet Stroke Prevention Study (AAASPS), a questionnaire was designed to identify factors that might contribute to the lack of participation of African Americans in clinical trials. Nineteen consecutive caregivers or subjects from our ongoing National Institute on Aging funded project were interviewed to determine risk factors for vascular dementia. The questionnaire consisted of 21 questions, 5 of which were open-ended. The questionnaire provided information about participants' medical history, demographics, attitudes, knowledge, and prior participation in clinical trials, as well as possible benefits of participation. The questionnaire was pretested and administered by a trained African-American field representative.

Statistical Analysis

Data were analyzed using the Epi-Info statistical package to determine the mean, standard deviation, and percentage as applicable.

RESULTS

All of our study participants were African-American (Tables 1 and 2). The mean age was 59.3 years, and most of the participants were women (68.4%), married (47.4%), lived with their spouse or some other family member (68.5%), and had at least a high school education (58%). Furthermore, there was a relative high frequency of hypertension (57.9%), diabetes mellitus (31.6%), heart disease (10.5%), and stroke (21.1%). Most had a primary care physician (68.4%); the mean number of visits to the doctor in the past 12 months was 4.2.

Few were familiar with terms used to refer to clinical trials (Table 2). Furthermore, few had ever participated in a clinical trial (5.4%), had ever been asked to participate (15.8%), or knew of family or friends who

TABLE 1. PATIENT CHARACTERISTICS

Characteristic	No. (%)*
Demographics	
Age (mean years±SD)	59.3±9.2
Women	13 (68.4)
African Americans	19 (100)
Marital Status	
Married	9 (47.4)
Widowed	5 (26.3)
Separated/divorced	2 (10.5)
Never married	3 (15.8)
Living Arrangement	
Alone	2 (10.5)
With husband/wife only	4 (21.1)
With husband/wife and other	3 (15.8)
Family, no husband/wife	6 (31.5)
Other	4 (21.1)
Years of Formal Education†	
Grade school	5 (26.3)
Some high school	3 (15.8)
Graduated high school	6 (31.5)
Some college	4 (21.1)
Graduated college	0 (0)
Postgraduate	1 (5.3)
Annual Income	
\$0 to \$5999	5 (26.3)
\$6000 to \$19,999	8 (42.0)
\$20,000 to \$29,999	3 (15.8)
\$30,000 to \$39,999	1 (5.3)
\$40,000 to \$49,999	1 (5.3)
≥\$50,000	1 (5.3)

*N=19.

†Respondents were asked to choose one category only.

had ever participated (10.5%). Sixty-eight percent responded that they might participate if asked to, with the rationale being to save lives, benefit themselves or others, and obtain free health care and medication.

However, responses to the open-ended questions indicated that the patients feared clinical trials, did not want to be treated like “guinea pigs” (which they associated with trials), lacked trust in the medical system, and felt blacks were not being approached for enrollment in a proper manner. These responses were elicited after the participants were educated in layman’s terms about the nature of clinical trials.

DISCUSSION

African Americans traditionally have been under-represented in clinical trials.^{5,6,8,18} The major impetus for this study was to obtain information on African-Americans’ attitudes toward clinical trials in prepara-

TABLE 2. PATIENTS’ KNOWLEDGE OF MEDICAL AND CLINICAL DRUG STUDIES INFORMATION

Variable	No. (%)*
Medical Factors	
No. doctor visits in past 12 months (mean±SD)	4.2±3.18
Primary care physician	
Yes	13 (68.4)
No	6 (31.6)
History of:	
Hypertension	11 (57.9)
Diabetes mellitus	6 (31.6)
Heart disease	2 (10.5)
Stroke	4 (21.1)
Clinical Drug Studies Information	
Term most familiar with:	
Clinical drug studies	6 (31.5)
Experimental studies	4 (21.1)
Human experiments	1 (5.3)
Drug studies	5 (26.3)
Medical research	1 (5.3)
Research studies	2 (10.5)
Ever participated in a clinical trial	
Yes	1 (5.3)
No	18 (94.7)
Ever asked to participate	
Yes	3 (15.8)
No	16 (84.2)
Would you ever participate	
Yes	13 (68.4)
No	6 (31.6)
Ever have family/friends who participated	
Yes	2 (10.5)
No	17 (89.5)

*N=19.

tion for our own stroke prevention trial, AAASPS. A secondary stroke prevention program, AAASPS targets African Americans with acute ischemic stroke within 90 days for treatment with either ticlopidine (500 mg/day) or aspirin (650 mg/day). The trial will enroll 1800 patients. Such a focused stroke prevention initiative is long overdue in view of the disproportionate stroke morbidity and mortality in the African-American community and underrepresentation in secondary stroke prevention studies (Table 3).

Our questionnaire and a literature review identified four major barriers to participation in clinical trials for African Americans:

- a general lack of awareness of trials,
- mistrust of the medical system,
- economic factors, and
- communication gaps (Figure).

While other barriers may exist,¹⁹ these four barriers

TABLE 3. REPRESENTATION OF NONWHITES IN RECENT RECURRENT STROKE PREVENTION STUDIES IN THE UNITED STATES AND CANADA

Study	Year	No. Subjects	Race (%)		
			White	Nonwhite	Black
Canadian Cooperative	1978	585	*	*	*
American-Canadian Cooperative	1985	890	91	9	*
Canadian Aspirin-Ticlopidine Study (CATS)	1989	1053	71	29	29
Ticlopidine Aspirin Stroke Study (TASS)	1989	3069	80	20	16
CAPRIE	Ongoing	432	89	*	*
Stroke Prevention in Atrial Fibrillation (SPAF)	1990	1244	*	*	*
Boston Area Anticoagulation Trial for Atrial Fibrillation (BAATAF)	1990	420	*	*	*
Veterans Administration Hospital VAH Cooperative	1992	571	*	*	*
North American Symptomatic Carotid Endarterectomy Trial (NASCET)	1991	659	91	9	3
Veterans Administration Hospital (VAH) Cooperative	1993	444	87	13	7

*Not listed.

†CAPRIE=clopidogrel versus aspirin in patients at risk of ischemic events.

offer significant insight into why African Americans do not participate in clinical trials. Furthermore, these four barriers can be overcome by proper pretrial planning. Table 4 provides a summary of proposed solutions to these barriers.

CONCLUSION

A well-conceived clinical trial for the African-American community must establish:

- *A community awareness mechanism to inform and educate community members about the study.* This may be accomplished through a community-based speaker's bureau, participation in church and community health fairs, dissemination of information about the program to community physicians via newsletters, educational messages via the mass media, and word-of-mouth. A community advisory panel should be developed to facilitate this process.
- *Reimbursement for travel to and from the program site, program site accessibility, convenient hours for program patients especially those who work, and home visits for disabled patients or shut-ins.* These clinical trial provisions are geared to alleviate possible economic hardship factors.
- *A communications system centered in the community with the support of the community and trusted individuals.* By organizing communications around community churches, physician groups and key organizations, communication can be successfully accomplished and the program can achieve credibility.
- *Sincere commitment and honesty by program staff, and*

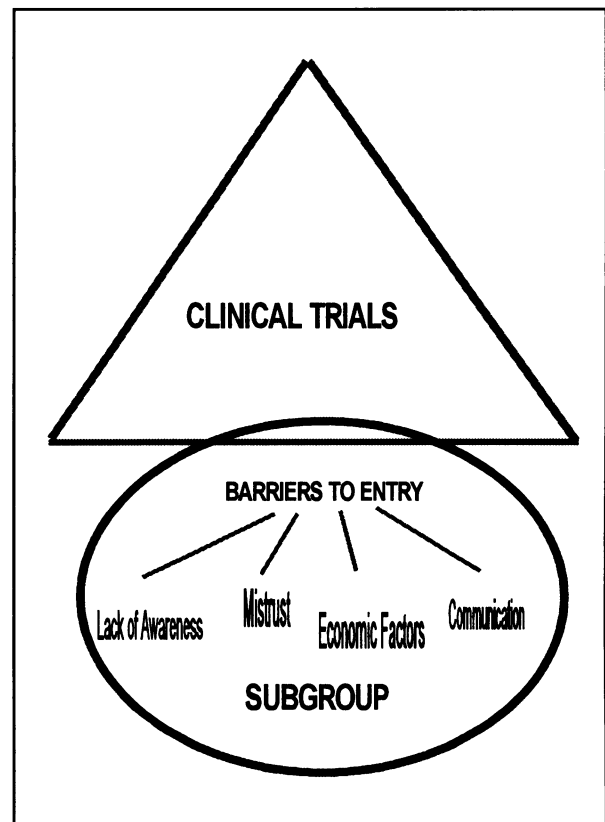


Figure. Model of clinical trial participation with barriers. (Adapted and modified from Roberson N. Clinical trial participation: viewpoints from racial/ethnic groups. *Cancer*. 1994;74:2687-2691.)

TABLE 4. BARRIERS TO ENTRY OF AFRICAN AMERICANS INTO CLINICAL TRIALS

Barriers	Solutions
Lack of awareness	Patient education, which can be accomplished by: <ul style="list-style-type: none"> ● Speaker's bureau for churches and community organizations ● Community-based health fairs ● Church screenings ● Letters to private physicians ● Mass media ● Word-of-mouth
Mistrust	Hire African-American staff Increase involvement of African-American community representatives Show commitment, honesty, and patience
Economic factors	Reimbursement for travel to and from the study site Make study site location accessible or convenient for the patient Offer extended office hours
Communications	Community-based approach: <ul style="list-style-type: none"> ● Use a community-based information system ● Involve members of the community ● Disseminate information to community institutions and individuals of trust

involvement of culturally sensitive staff and representatives, especially those from the African-American community. Dedicated African-American program staff can help overcome patients' mistrust and fear of clinical trials.

Finally, patients with higher educational attainment are more likely to participate in clinical trials. Those with lower educational attainment may require additional counseling about a study. The establishment of a community awareness coordinator or counselor may be useful to help educate patients who may be skeptical about the program or hesitant to participate. Patience and hard work are the watch words that will help to dismantle the barriers.

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