Attitudes and Beliefs of African Americans Toward Participation in Medical Research

Giselle Corbie-Smith, MD, Stephen B. Thomas, PhD, Mark V. Williams, MD, Sandra Moody-Ayers, MD

OBJECTIVE: **To describe barriers to participation of African Americans in research.**

DESIGN: **Focus group interviews conducted in 1997.**

PATIENTS: **Thirty-three African-American adults presenting to an urban public hospital for outpatient medical care participated in one of five focus groups.**

MEASUREMENTS AND MAIN RESULTS: **African-American patients' attitudes toward medical research were measured. Mistrust of doctors, scientists, and the government was reported consistently by the participants. Many participants described concerns about the ethical conduct of clinicians and investigators when poor or minority patients are involved and cited examples of exploitation as supporting evidence for their mistrust of the medical establishment. While participants were clear about the violation of human rights in the Tuskegee Syphilis Study, all were misinformed of the historical facts of the study. Few participants understood the concept of informed consent. Participants saw signing the document as relinquishing their autonomy and as a legal protection for physicians. Despite these concerns, participants gave recommendations to improve minority participation in research.**

CONCLUSIONS: **African-American participants in this study described distrust of the medical community as a prominent barrier to participation in clinical research. Participants described real and perceived examples of exploitation to support their distrust of researchers. The goal of the consent process, to inform patients of risks and benefits so as to facilitate self-determination, was misinterpreted by these participants. Understanding the importance of interpersonal trust within the clinical relationship may prove to be a significant factor in enhancing participation in clinical trials.**

KEY WORDS: **African American; research participation; trust; informed consent.**
J GEN INTERN MED 1999;14:537–546.

Received from the Division of General Medicine, Emory University School of Medicine, Atlanta, Ga (GCS, MVW); the Department of Behavioral Sciences and Health Education, Rollins School of Public Health, Emory University, Atlanta, Ga (SBT); and the Division of Geriatrics, Yale University School of Medicine, New Haven, Conn (SMA).

Dr. Moody-Ayers is currently in the Department of Medicine, Geriatrics, University of North Carolina at Chapel Hill.

Presented in part at the Society of General Internal Medicine, 1997 national meeting.

Address correspondence and reprint requests to Dr. Corbie-Smith: Emory University School of Medicine, Division of General Medicine, 69 Butler St. SE, Atlanta, GA 30303.

Recruiting subjects for participation in medical research has proved to be a challenging task. The problem of recruitment is magnified when considering minorities, particularly African Americans. Recent studies highlight lack of participation in clinical trials among African Americans.[1-4] Such lack of participation raises concerns about how well findings from clinical trials can be generalized, as well as how beneficial they can be to African Americans.[5–7] Attempts at increasing participation in clinical studies have been hampered by a paucity of scientific data to guide researchers in design, implementation, and evaluation of recruitment and retention strategies. Patients' attitudes toward research and the researcher, and beliefs about the benefits and risks of involvement in research remain critical factors to be investigated.

Few studies have examined the attitudes of African-American patients regarding perceived barriers to research participation. The available research underscores the importance of patients' attitudes[8–10] and their perception of research[11] in determining participation in clinical trials. However, these studies have been limited by small sample sizes or interviewing only oncology patients.

We undertook this qualitative study as a first step in exploring the reasons for low participation in clinical trials among African Americans. Our primary aims were to identify and contexualize barriers and facilitators to participation in research. We also examined participants' attitudes and beliefs about the informed consent process, specific knowledge about the Tuskegee Syphilis Study and other real or perceived examples of medical abuse, and the perceived benefits and risks of participation in medical research. Finally, we sought recommendations for improving recruitment of African Americans into clinical trials.

METHODS

Design

Given the limited data available to guide researchers in recruitment of African Americans in clinical research, we used focus group interviews in this exploratory study to establish the reasons for low participation. Focus group interviews allow exploration of the issues and themes as lived by the participants.[12] Participants explore and clarify their views in a way that is not accessible through other interviewing methods. This method is particularly useful for exploring participants' knowledge and experiences and why participants might hold a certain belief.[13]

Study Site

Focus group interviews were conducted between December 1996 and February 1997 at Grady Memorial Hospital, an urban public hospital in Atlanta, Ga. The hospital is a teaching affiliate for two university medical schools. Eighty-nine percent of the patients served at this hospital are African American, 53.2% are women, 53.6% are uninsured (another 29.7% are covered under Medicaid), 40% are unemployed, and 75.8% report an income of less than $250 per week.[14]

Participants

We recruited African-American participants from outpatient medical clinics and oncology clinics. After registering with the clerk for their appointment in the clinic, consecutive patients were approached by a research assistant and asked to participate in a discussion about their attitudes and beliefs about medical care and medical research. A screening instrument was administered to potential participants in the waiting time before their scheduled appointment. The instrument included questions on demographics, previous participation in clinical trials, contact telephone numbers, and mailing addresses. The participants were assigned to groups based on the clinic from which they were recruited: oncology or general medicine clinic. Although four group interviews were initially planned, five focus group interviews were conducted to reach theoretical saturation,[15] the point at which no new concepts are elicited during the course of the interview.

Data Collection

An African-American moderator, employed by the consulting firm Macro International Inc., conducted all groups using a written discussion guide. The moderator's guide was divided into the following topic areas (Table 1): introductions and warm-up; introductory questions; general perceptions of medical care; general perceptions of medical providers; general perceptions of medical research. The flow of the guide was intended to create a smooth transition from introduction to the key study questions. Each topic area consisted of open-ended questions followed by a series of probes. For example, in the section on general perceptions of medical research, we asked, "Have any of you ever participated or known someone who has participated in medical research?" (probes: personal experience, family members, friends, or other); "Tell me about these research studies."

Table 1. Examples of Questions and Topic Areas from the Focus Group Moderator's Guide

Introductions and warm-up
Review and collect informed consent
Introductory questions
Tell me a little about your health.
How long have you been coming to Grady for your medical care?
General perceptions of medical care
How would you rate the quality of your medical care?
Overall, how satisfied are you with your medical care?
General perceptions of medical research
What comes to mind when you hear the term medical research?
What does the term "medical research" mean to you?
How does this compare with "medical care/treatment"?
What are your general feelings about medical research?
Have any of you ever participated or known anyone who has participated in medical research?
If anyone participated in medical research: Tell me about these research studies.
Has anyone ever been asked to participate in a research study that involved more than a personal interview or discussion group?
What are the reasons why you might participate (or have participated) in medical research?
What do you see as real or potential benefits of medical research?
What are reasons why you would not/might not participate in medical research?
How many of you are familiar with the Tuskegee Syphilis Study?
Can you tell me what you know about it?
Have you heard about other experiments like Tuskegee?
Are you aware of legal protections for participants in medical research? Can you describe the protections you know?
Probe: Informed consent, critical elements of
a. adequate disclosure of information,
b. patient ability to understand the information, and
c. voluntary choice
What recommendations do you have for researchers to improve African-American participation in research?

All interviews were audiotaped and transcribed for content analysis. A notetaker was also present at each session to record verbal and nonverbal cues. Immediately after each interview, one of the investigators (GCS) met with the moderator and notetaker to capture first impressions and to highlight and contrast findings with those of earlier sessions. Informed consent was obtained at the beginning of each group interview, and participants received a written copy of the consent form and an honorarium of $25 at the conclusion of the interview. The Human Investigations Committee approved the consent form and project.

Data Analysis

These data were analyzed using grounded theory, or the constant comparative method.[15,16] In this approach to the analysis of qualitative data, the theory is generated from the data, or if existing theories seem appropriate, then these may be elaborated and modified as incoming data are compared against them.[16] Researchers can also carry into current studies any theory based on their previous research, being careful to constantly match their a priori theories against the incoming data.

During the course of the study, each transcript was reviewed with the audiotaped interviews for accuracy. Consistent with the constant comparative method, two investigators (GCS, SBT) reviewed the transcripts after each interview to identify emerging themes and concepts. The identified concepts were used to add to or modify the probes used in the subsequent interviews. Each transcript was reviewed and compared against prior and subsequent interviews to refine the content areas. Research team meetings were used to refine the meaning of each content area, discuss alternative interpretations, and reach agreement on the represented quotations for each category. Based on the results of these meetings, we sorted participants' comments into one or more of five content areas: (1) reasons for nonparticipation; (2) perceived benefits; (3) informed consent; (4) knowledge of the Tuskegee Syphilis Study; and (5) strategies to increase the involvement of African Americans in research. When comments seemed to be polarized by age, patients at least 60 years of age are described as older; those under 60 years, as younger.

RESULTS

Sixty-three patients completed the screening instrument and 55 were invited for interviews (8 patients were excluded because they met at least one of the following exclusion criteria: not fluent in English, not African American, prisoner, or intoxicated at time of screening). Thirty-three patients participated in the focus groups. Seventy percent of the participants were women. The participants ranged in age from 20 to 78 years. Specific group and participant information is provided in Table 2. The most common reasons given for not being able to participate were schedule conflicts and illness from chemotherapy. We did not find any substantive difference in the comments of oncology patients versus general medicine patients.

Six participants responded "yes" to the question, "Have you ever participated in medical research?" Examples of the previous research included drug studies (nonsteroidal anti-inflammatory drugs, drug therapy for asthma and diabetes, and antidepressant therapy), an oncology clinical trial, and testing a home blood pressure monitor. Two participants stated they were asked to participate in a clinical research study but refused.

Participants expressed a mixed set of positive and negative responses to the question, "What comes to mind when you hear the term medical research?" (Table 3). Although there were more negative terms than positive terms, older participants described the balance of benefits and risks associated with medical research more than younger adults, who primarily perceived risk.

Reasons for Nonparticipation

One participant stated he knew of many people who participated in testing experimental medications in exchange for money. When asked if he would participate in such studies, he said, "No, why would you bring something in your body that can start a virus?" Another participant was invited to join a drug study for hepatitis but refused even though he was symptomatic: "It seemed too much like an experiment. People were getting rashes from the needles and I didn't want to be no guinea pig," he said.

The majority of focus group participants tended to be in favor of medical research, as long as they were not

Table 2. Focus Group Participants by Gender, Age, and Recruitment Location

			Participant Demographics		
Group Number	*n*	Group Type	Female, *n* (%)	Male, *n* (%)	Mean Age, Years
1	10	General medical clinic patients	7 (70)	3 (30)	41.8
2	9	General medical clinic patients	5 (56)	4 (44)	37.7
3	4	Oncology clinic patients	3 (75)	1 (25)	48.5
4	4	Oncology clinic patients	3 (75)	1 (25)	53.75
5	6	General medical clinic patients	5 (83)	1 (17)	68.18
Total	**33**		**23 (70)**	**10 (30)**	**50.0**

Table 3. Grouped Responses to the Question "What Comes to Mind When You Hear the Term Medical Research?" Sorted by Content Area

Trust
Being lied to
Corruption
Deception
Negligence
Using people
Harm
Sacrifice
Cruelty
Science/Research
Experiment
Trial and error
Searching for more knowledge
Progress
Learning how to treat problems
Finding a cure
Belief
Guinea pig
Necessary

"guinea pigs." As one participant stated, "they always use our race as guinea pigs." Expressed concerns about participation in medical research included, but were not limited to: (1) inconvenience—interfering with work schedules, restriction of normal behavior; (2) too much risk, particularly infection with unknown viral agents; (3) fear of injections and needles; (4) concerns about whether physicians would be fully honest with them about risks and procedures; (5) failure to see any need, given current good health, and (6) concern that even if something good came out of the research, African Americans would not necessarily benefit from the advancements in scientific knowledge because of racial discrimination and poverty.

Several participants drew parallels between the medical care they received and clinical research. For example, inexperience of young physicians and interns was described as "being experimented on." As one participant stated, "They treat us like guinea pigs. They are trying stuff out on us—stuff they learned in school."

Most participants also feared procedures involved in research could expose them to infection with viruses such as HIV, or to harmful chemicals such as Agent Orange. There was some willingness expressed to donate blood for studies of health status, but generally there was strong disapproval of any regular use of injections or surgical procedures. Studies designed to examine health behaviors and their relation to illness were described more positively than controlled clinical trials. The most common perceived risk of participation in research was the belief that participation may actually worsen health status. Healthy participants were concerned that they might become ill, perhaps permanently or terminally, if something went wrong. Specific and general concern about being infected with an "unknown virus," similar to AIDS, recurred frequently.

Perceived Benefit

In response to the questions, "What are the reasons you might participate in medical research?" and "What do you see as the real or potential benefits of medical research?" the discussion polarized around research that benefits the individual participant versus research that benefits the broader society. Young participants described their desire to access state-of-the-art medical care, obtain free medications, and discover alternatives to standard therapy. Older participants described the benefits of research for their extended family and the broader society. Many participants articulated concern about the actual benefit of research for the broader African-American community. As one participant stated, "If I do all of this and it benefits society and everything, given the way brothers [blacks] are treated, how is it going to help me?"

All participants, regardless of age, expressed suspicion about the motives of investigators conducting the research. The discussion focused on how the scientific knowledge to be gained by researchers was actually motivated by their drive for money, status, and prestige.

> *Knowledge [is a benefit of research] but at the same time you have to face reality. He gets more money and more prestige by being in front with the knowledge . . . they have their ulterior motives.*

Informed Consent

All participants had limited understanding of the informed consent process even though written informed consent is required to receive medical treatment. In general, participants believed the purpose of the consent document was to protect hospitals and doctors from any legal responsibility. As one participant stated,

> *If you give consent, then you don't have any legal rights. When you sign that paper, you sign all of your rights away because they have disclaimers all neatly typed up, reviewed by their lawyers to protect themselves from being sued.*

None of the participants was aware of any legal protection for people participating in medical research. When probed about suing for compensation if they were treated inappropriately, they concluded there was little assurance of successful litigation after signing a consent form. More importantly, participants' perception of potential collusion between lawyers and doctors made seeking legal redress impossible. As one participant stated,

> *. . . if you don't have any money, whatever happens to you, you can't prove it. You have to have a lawyer and that costs money. And some of them lawyers and doctors stick together anyway.*

Many participants also described how the difficulty of giving informed consent was related to not understanding

technical medical and legal terminology. In addition, there was concern expressed about understanding the full scope of research protocols. For example, there were specific concerns about exactly what would be done to them, what would be expected from them as participants, the duration of the project, and what were the expected risks and benefits of the research. One participant characterized the problem as the difference between "knowing" and "understanding": "When you sign this, they say you should know what you are doing—but that doesn't mean you fully understand."

Finally, several participants believed that a fundamental lack of trust between the researcher and the participant undermined the entire meaning and spirit of the informed consent process. Participants expressed fear that doctors could and would make statements to persuade people to participate in the research, but there was little assurance that the doctors would actually keep their word.

Knowledge of the Tuskegee Syphilis Study

Throughout the focus group interviews (before and after the moderator introduced the topic), participants made reference to the Tuskegee Syphilis Study. Yet, when probed about historical facts, their knowledge was limited. Everyone reported having some knowledge about the Tuskegee Syphilis Study, but few could describe specific details. For example, while the Tuskegee Syphilis Study involved approximately 400 black men in Macon County, Alabama, a few focus group participants estimated that only 20 to 40 men were in the study. Other participants believed that men in the study were, in fact, injected with syphilis. Another participant stated that the original intent of the study was not to inject the men with syphilis, but that the "scientists got carried away."

When the focus group moderator provided historically accurate information about the Tuskegee Syphilis Study, many participants aggressively challenged her, questioning the information source and the historical accuracy of the facts. One participant adamantly stated,

> *I'm not saying you are lying or anything, but just like you are telling me one side, there could be a lot of different sides. You may have been misled as to the facts.*

Several participants believed other related "experiments" and "conspiracies" validated their concerns about the Tuskegee Syphilis Study. These conspiracies were related to Agent Orange, manmade creation of the AIDS virus, the distribution of crack cocaine in the inner city by the Central Intelligence Agency, and target marketing of cigarettes to African Americans. The following quotation captures the logic linking such events:

> *This is my own theory [about the AIDS virus]. If it is transported by needles, they knew people share needles. They could somehow put it in the needles. And with gay white men. It hit San Francisco and New York at the same time, just like crack. How did it get there unless somebody put it there.*

One participant stated that she had not heard of any other examples of research abuse like the Tuskegee Syphilis Study and did not expect public exposure of such events. She said,

> *. . . just like Tuskegee. We heard about that years later. Why would they tell us now? If they let me know they are experimenting and it was going to kill me, I wouldn't try it.*

Several participants considered the Tuskegee Syphilis Study validation of their belief that "doctors value your life less than their own" and that African Americans still need to be suspicious when dealing with the medical research establishment and the government. One participant described government responsibility for the Tuskegee Syphilis Study and how the government's involvement in creation of the AIDS virus was an experiment on the gay community "gone wrong." She stated, "I don't put it beyond the government to do something like that. Just like this cancer [that I have]. . . . The government is tricky," implying that the government may be responsible for her cancer. When probed as to why the government might do such studies, another participant stated,

> *Well, this is just my opinion. The population is growing. People are dying at slower rates. So they said, let's see what happens if we inject this [HIV] out there. A lot of this is from movies but movies have some truth to them.*

The Tuskegee Syphilis Study also emerged as justification by the participants to expect dishonesty and nondisclosure of research risk from investigators. As one female participant stated, "Even if you give informed consent, like the Tuskegee thing—those men were told they would be treated but they weren't."

Strategies to Increase the Involvement of African Americans in Research

Despite an overwhelmingly negative and conspiratorial view toward medical research, participants offered suggestions on how to increase their involvement. When asked how participation in research might be improved, participants expressed the need for more honest and respectful communication from physicians and other research personnel, and the importance of providing complete information about risk and benefits of research.

Although money and other incentives were also mentioned, the main discussion consisted of strategies to ensure potential research participants had full knowledge about what they were being asked to do and were given sufficient time to consider their options. There was a strong desire to receive information from multiple points of view, including time to go to the library on their own and to talk with friends or family members. One participant described a video presentation about a medical procedure that mirrored the information in the consent form,

There should be more ways for the patient to get information other than from one source. If you can get the same thing from different people, you are apt to feel trust. When I signed [my consent form], they showed me a video explaining the risks, and then the same thing was given to me in written form on the consent form. It made me feel more comfortable.

Participants also recommended that information materials be improved and that copies of all signed documents related to their involvement in the research be distributed to them. In addition, they requested assurance that the doctors who conduct the research be available for any questions for the duration of the study:

The doctor would have to walk me through it. I would have to know I could call them whenever I felt like it.

One participant recommended a focus on better education in elementary and secondary schools so people would have a more informed understanding of why research is important and how science is conducted. Early education was described as a key factor needed to dispel myths and misconceptions about research involving human subjects.

Let people know the benefits of medical research along with the curriculum in public school. The myths about it should be dispelled.

Finally, in order to increase the involvement of African Americans, many participants believed that more must be done to promote and raise awareness about the purpose of research and opportunities to participate. When probed to discuss ways to improve the actual research process, the need for maintaining honest communication, access to complete information, and trust in the physicians conducting the research emerged as dominant themes.

[I want an] explanation by a person who is comfortable to talk to and who is comfortable talking with me. You have to have a level of trust.

Several participants expressed specific interest in understanding the research hypotheses and learning more about the expectations of the research team, especially with regard to what could go wrong. They requested information about related research that had already been conducted in order to assess the potential risks and benefits of the proposed study. One participant expressed worry about people in a study who received placebos, believing those individuals might not fully benefit from participation.

DISCUSSION

Historically, nonparticipation of African Americans in research has been linked to the history of racism in medical research.[4,17–22] The most powerful example of this is the Tuskegee Syphilis Study. "For many blacks, the Tuskegee study became a symbol of their mistreatment by the medical establishment, a metaphor for deceit, conspiracy, malpractice, and neglect, if not outright racial genocide."[23] In the wake of the Nazi experiments and later the Tuskegee Syphilis Study, biomedical research emphasized the protection of the individual patient.[1] This concern for the protection of human subjects was formally codified in the Nuremberg Code in 1949,[24] which was the beginning of a cascade of regulations emphasizing the protection of human subjects. Some of the most prominent events include the following: The Declaration of Helsinki in 1964,[25] the establishment and strengthening of the institutional review board, exclusion of women of childbearing potential from early phases of drug trials,[26] and the publication of the Belmont Report by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.[27] As a consequence of many of these regulations designed to protect vulnerable populations from potential abuse, minorities were sometimes seen as a vulnerable population and excluded from participating in clinical trials.

More recently, however, the scientific community began questioning exclusion of certain groups. First, the bioethical principle of justice requires that the burdens and benefits associated with participating in research be distributed within a society. In addition, generalizing and applying research findings from a homogeneous study sample to racially and ethnically diverse populations may not be appropriate. These and other concerns led to the creation of the National Institutes of Health (NIH) Office of Research on Women's Health in 1990[28] and culminated in the passage of the NIH Revitalization Act by Congress in 1993.[29]

The NIH Revitalization Act of 1993, which mandates inclusion of women and minorities as subjects in clinical research, makes it incumbent on investigators to understand and respond to the attitudes and beliefs of potential research participants. Results from this study identify important issues to consider before attempting to recruit African Americans into research studies. While previous studies addressing the concerns of minority populations involved participants from cancer trials[8,11] and cancer prevention studies,[9,30] this study also sampled patients presenting for health care not usually associated with research. These participants' comments echo the lack of trust in the medical community[9] and concerns about ethical misconduct[11,30] found in previous studies.

Concerns about participating in research dominated discussions. Participants believed medical research was most beneficial to investigators and gave clear examples of how they might personally suffer from involvement in clinical research. They also expressed concern that African Americans would be least likely to benefit from research findings because of racism or inability to pay for services. In addition, the analogy of being used as a guinea pig was extended not only to research participation but also to medical care at teaching hospitals. Because academic medical centers are often an important location for recruiting study participants, the guinea pig analogy must be taken seriously and addressed by members of the research team.

Since the Tuskegee Syphilis Study is seen as a metaphor for research subject abuses, we felt it important to explore the perception in this community. Other authors have described knowledge of the Tuskegee Syphilis Study to be an important deterrent to participation in health promotion and research.[18,31–36] In this study, the majority of participants were misinformed about many of the historical facts of the Tuskegee Syphilis Study. When the moderator presented facts about the study, participants challenged her, exhibiting a global suspicion of information from any source they could not personally check for authenticity. We suggest that historical accuracy may be less salient than strength of belief. And as indicated in the discussions about what really happened at Tuskegee, it is clear that any attempt to simply present "the facts" as though unquestionable and self-evident may be challenged. It is important to note that all focus group interviews were completed before national media attention focused on the February release of the Home Box Office special "Miss Evers' Boys" and the Presidential apology for the Tuskegee Syphilis Study on May 16, 1997. Current interviews may reveal a higher level of awareness of the Tuskegee Syphilis Study, but misinformation may persist.

Of note, the participants in this study didn't limit their justification of mistrust to the Tuskegee Syphilis Study. In their opinion, "creation" of HIV and military experiments with Agent Orange were among the more recent examples of experimentation. Regardless of whether the instances participants provided as explanations are historically accurate, every instance is perceived as "real" in their minds. The fact that participants drew on historical evidence of exploitation of African Americans in medical research to validate their fear of ethical misconduct is important regardless of historical accuracy. In fact, as Dula[37] and Gamble[17,38] suggest, mistrust of the medical community can be justified by a long history of exploitation in the name of research that dates back to slavery and continues to the present day. From experimentation during slavery to public health efforts gone awry in sickle cell screening and involuntary sterilization, the authors argue that conspiracy theories cannot be simply written off as paranoia or hypersensitivity.

One of the most significant findings of this study was the interpretation of the consent process. Participants in the study described the consent document as legal protection for researchers and funding institutions rather than describing its use as a method of increasing their understanding during the consent process. As these participants so eloquently point out, achieving a balance between the legal rationale and moral justification of informed consent may not be recognized as a goal by the patient or physician. More often, physicians consider the informed consent process as a legal requirement, rather than an opportunity for facilitating patient autonomy,[39,40] and view the consent process as having a negative impact on patient care.[41] The extent to which attitudes of potential participants in research have been shaped by the attitudes of physician-researchers clearly requires further investigation.

Making sure that participants entering a clinical trial are fully informed before they agree to participate in clinical research has been and continues to be a tremendous challenge. The difficulty of informed consent is magnified when cultural differences exist between the study team and the participant.[42] The method currently used to inform the patient may be a major hindrance to obtaining fully informed consent.[43,44] In patients from varying ethnic backgrounds, with different levels of English fluency or limited formal education, written documents often outstrip their comprehension of the intended content.[45] In addition to literacy, cultural and linguistic barriers may complicate comprehension of written materials.[46] Novel methods of transmitting information such as an instructional video alone, or in combination with the written form, have been shown to be preferred by patients,[47] and may increase understanding of the information to be delivered.[48] The results of this study support the available literature on patient preferences in the use of other media instead of or in addition to standard written consent.[49–51] However, more systematic research is needed to address the problems of obtaining consent in populations of varied socioeconomic status and cultural backgrounds.

Most recently, the question has been raised of waiving consent for some areas of clinical investigation.[52–54] We advocate extreme caution in populations such as the African-American community that are particularly sensitive to the implications of being involved in research without their consent. Although the authors advocating these changes in informed consent have described explicit and ethically sound guidelines for waiver of informed consent for specific protocols, we would strongly suggest that institutional review boards reviewing these protocols not only take into consideration the scientific integrity of the proposed research but also put particular emphasis on the history of medical experimentation of the intended research subjects.

Despite the general negative attitude toward participation in medical research, participants did identify benefits of research. All participants expressed a greater willingness to volunteer for research if there were clear benefits to themselves or their families. Although all participants could discuss the theoretical benefits of medical research, they were less likely to perceive a direct link between these benefits and their own lives. Other investigators have shown that participants expect to obtain personal benefit while contributing knowledge to medical science for the good of society.[8,55,56] In other studies of perceived benefits of trial participation, medical monitoring and treatment,[57–61] altruism,[59,60] and financial compensation[59,62] were described by participants as important. In the few studies that have looked at reasons for nonparticipation, however, patients described treatment-related concerns.[63] Unfortunately, few of these studies reported the race of the respondents, and none stratified responses according to race or ethnicity.

Participants also provided a wide range of strategies for improving recruitment of African Americans into clinical studies. Many participants tended to filter all information through their personal networks and to engage in a communal process of decision making. This appears to apply not only to possible research participation but also to medical treatment options and recommendations. The majority of participants requested broader education about the importance of and opportunities for participation in medical research. The suggestion to increase awareness of research may be taken as a call for a more open and frank dialogue about medical research with the African-American community. Addressing the myths and acknowledging the abuses surrounding medical research held by many in the African-American community could create an opportunity for dialogue to heal the breached trust represented by Tuskegee but personalized by these participants in other events.

The issue of trust was a recurrent theme throughout the entire discussion of participation in research. Although participants expressed concerns about the ethical conduct of researchers in general, they also noted that a trusting relationship was important for them to feel comfortable as participants in clinical studies. Other authors have suggested that trust developed between a primary care provider and a patient is the only way fear of exploitation in research can be overcome[64] and that lack of trust in the researcher is the primary barrier to African-American participation in clinical trials.[30] The possibility remains, however, that interpersonal trust, when it exists, may override a truly informed and carefully deliberate decision. More research is needed to examine the duality of trust within the doctor-patient relationship and its impact on medical decision making, with emphasis on the influence of managed care on the time needed to establish and maintain interpersonal trust within the physician-patient relationship. As fewer patients are able to use their social network to choose a provider, and as time constraints increasingly limit the clinical interaction, a trusting relationship may take longer to develop if it develops at all. In fact, other authors have documented that physicians practicing in a managed care environment were concerned about their ability to respect patient autonomy.[65] The implications for clinical decision making and enrollment into clinical trials have yet to be delineated.

As in all studies, there are limitations. First, although the focus group interview is an important tool to explore participants' experiences, attitudes, and beliefs, this qualitative research methodology is used primarily to generate, rather than test, hypotheses. The results presented here should be validated through quantitative research. Cross-sectional studies of a nationally representative sample would help describe the impact of socioeconomic status and other demographic variables on willingness to participate in research. Second, participants were interviewed at only one site with a fairly homogeneous socioeconomic profile. The attitudes and beliefs expressed in this cohort may not be representative of African Americans in other geographic areas or from other socioeconomic strata. In particular, Atlanta, Ga, may represent a special geographic area in its proximity to Tuskegee, Ala, location of the Centers for Disease Control and Prevention, the last administrative home of the Tuskegee Syphilis Study, and staged productions of "Miss Evers' Boys" in the early 1990s. For these and other reasons, participants in this geographic region may be more acutely aware of the Tuskegee Syphilis Study. In addition, caution should be exercised in extending these results to other racial and ethnic minorities. Interviews with other populations would be important to describe the extent that these opinions are held by other sociodemographic groups.

Despite these limitations, this qualitative study gives voice to African-American mistrust of the medical community in general and medical research in particular. The absence of trust has emerged as a stumbling block in efforts to include African Americans in clinical research. Although the Tuskegee Syphilis Study has come to symbolize exploitation of minorities, participants also believed HIV infection, Agent Orange exposure, and Central Intelligence Agency distribution of crack cocaine in black communities were contemporary evidence that the legacy of abuse continues in this population.

In addition, the informed consent process seems to hinge on the presence or absence of interpersonal trust, rather than the intended careful deliberation of benefits and risks. Further research is necessary to understand the factors that contribute to the development of interpersonal trust between investigator and participants and the impact of trust on decision making around research participation.

Recently, the AIDS epidemic and clinical trial participation have created a new dilemma in research participation. African Americans are disproportionately affected by HIV/AIDS, yet they continue to be underrepresented in clinical trials.[35,64,66,67] This may be partly due to distrust of the medical establishment among African Americans.[18,35,68] Conversely, the AIDS epidemic has also changed people's perceptions of biomedical research such that certain populations are demanding access to clinical trials and experimental drugs rather than protection.[69] AIDS research may involve a unique subgroup of clinical trials. The range of attitudes and beliefs of participants in AIDS research and how they may differ from participants in other clinical trials deserves further inquiry.

Investigators would do well to solicit and incorporate the suggestions of African-American community members and potential participants in designing research protocols and recruitment strategies. The model of community consent and a collaborative relationship with the population under investigation is not new, and its use has been described in the United States[70–73] as well as international communities.[74] However, finding ways to effectively implement community consent, as a complement to individual consent, may be particularly important in African-

American and other ethnic minority populations in which the collective community can be valued as highly as the individual. Not only might this inclusive approach lead to fewer failed efforts, it could help forge strong community partnerships thereby transcending the devastating effects of societal mistrust. Finally, in our opinion, the Presidential apology on May 16, 1997, for the Tuskegee Syphilis Study may represent the greatest opportunity for a new era of respect, partnership, and trust between African Americans and the biomedical research community.

The authors thank Anna Dixon, Michele Revels, and Eric Zook, PhD, of Macro International for their expertise in organizing and executing the focus group interviews. They also thank Dr. William T. Branch for his unwavering support and encouragement throughout this project. This research was supported by an intramural grant from The Emory Medical Care Foundation.

REFERENCES

1. Chavkin W. Women and clinical research. J Am Med Women's Assoc. 1994;49:99–100.
2. Allen M. The dilemma for women of color in clinical trials. JAMA. 1994;49:105–9.
3. Mohiuddin SM, Hilleman DE. Gender and racial bias in clinical pharmacology trials. Ann Pharmacother. 1993;27:972–3.
4. Swanson GM, Ward AJ. Recruiting minorities into clinical trials: toward a participant-friendly system. J Natl Cancer Inst. 1995;87: 1747–59.
5. Wermeling D, Selwitz A. Current issues surrounding women and minorities in drug trials. Ann Pharmacother. 1993;27:904–11.
6. Cotton P. Is there still too much extrapolation from data on middle aged white men? JAMA. 1990;263:1049–50.
7. Dresser R. Wanted: single, white male for medical research. Hastings Cent Rep. 1992;22:24–9.
8. Robinson SB, Ashley M, Haynes MA. Attitudes of African-Americans regarding prostate cancer clinical trials. J Commun Health. 1996;21:77–87.
9. Roberson NL. Clinical trial participation: viewpoints from racial/ethnic groups. Cancer. 1994;74:2687–91.
10. Harris Y, Gorelick PB, Samuels P, Bempong I. Why African Americans may not be participating in clinical trials. J Natl Med Assoc. 1996;88:630–4.
11. Million-Underwood S, Sanders E, Davis M. Determinants of participation in state-of-the-art cancer prevention, early detection, screening, and treatment trials among African-Americans. Cancer Nurs. 1993;16:25–33.
12. Krueger RA. Focus Groups: A Practical Guide for Applied Research. 2nd ed. Thousand Oaks, Calif: Sage Publications; 1994:255.
13. Kitzinger J. Qualitative research: introducing focus groups. BMJ. 1995;311:299–302.
14. Rask K, Williams M, Parker R, McNagny S. Obstacles predicting lack of a regular provider and delays in seeking care for patients at an urban public hospital. JAMA. 1994;271:1931–3.
15. Glaser BG, Strauss AL. The constant comparative method of qualitative analysis. In: The Discovery of Grounded Theory: Strategies for Qualitative Research. Chicago, Ill: Aldine Publishing Co.; 1967: 101–15.
16. Denzin NK, Lincoln YS. Handbook of Qualitative Research. Thousand Oaks, Calif: Sage Publications; 1994:643.
17. Gamble VN. Under the shadow of Tuskegee: African Americans and health care. Am J Public Health. 1997;87:1773–8.
18. Thomas SB, Quinn SC. The Tuskegee syphilis study, 1932 to 1972: implications for HIV education and AIDS risk education in the black community. Am J Public Health. 1991;81:1498–1505.
19. Brandt AM. Racism and research: the case of the Tuskegee Syphilis Study. Hastings Cent Rep. December 1987.
20. Caplan AL. When evil intrudes. Hastings Cent Rep. 1992;22:29–32.
21. Edgar H. Outside the community. Hastings Cent Rep. 1992;22:32–5.
22. King P. The dangers of difference. Hastings Cent Rep. 1992;22:35–8.
23. Jones J. Bad Blood: The Tuskegee Syphilis Experiment. New York, NY: Macmillan; 1993.
24. Nuremberg Code: Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law; 1949:2:181–2.
25. World Medical Association. Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects (1975 revision of original 1964 version). MIT Press; Cambridge, Mass: 1964:328–9.
26. Department of Health and Human Services, 40 FR 33528. August 8, 1975.
27. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Washington, DC: Department of Health, Education and Welfare; 1979. DHEW publications (OS) 78-0013 and (OS) 78-0014.
28. Pinn VW. The role of the NIH's Office of Research on Women's Health. Acad Med. 1994;69:698–702.
29. NIH guidelines on the inclusion of women and minorities as subjects in clinical research; notice. Fed Reg. 1994;54:14508–13.
30. Mouton CP, Harris S, Rovi S, Solorzano P, Johnson MS. Barriers to black women's participation in clinical trials. J Natl Med Assoc. 1997;89:721–7.
31. Green BL, Maisiak R, Wang MQ, Britt MF, Ebeling N. Participation in health education, health promotion, and health research by African Americans: effects of the Tuskegee Syphilis Experiment. J Health Educ. 1997;28:196–201.
32. Des Jarlais DC, Stepherson B. History, ethics, and politics in AIDS prevention research. Am J Public Health. 1991;81:1393–4.
33. Cox J. Paternalism, informed consent and Tuskegee. Int J Radiat Oncol, Biol, Phys. 1998;40:1–2. Editorial; comments.
34. Wolinsky H. Steps still being taken to undo damage of "American's Nuremberg." Ann Intern Med. 1997;127:143–5.
35. Guinan M. Black communities' belief in "AIDS as genocide": a barrier to overcome for HIV prevention. Ann Epidemiol. 1993;3:193–5.
36. Thomas SB, Curran JW. Tuskegee: from science to conspiracy to metaphor. Am J Med Sci. 1999;317:1–4.
37. Dula A. African American suspicion of the healthcare system is justified: what do we do about it? Camb Q Healthc Ethics. 1994;3:347–57.
38. Gamble V. A legacy of distrust: African Americans and medical research. Am J Prev Med. 1993;9:35–8.
39. Lidz CW, Meisel A, Osterweis M, Holden JL, Marx JH, Munetz MR. Barriers to informed consent. Ann Intern Med. 1993;99:539–43.
40. Lantos J. Informed consent: the whole truth for patients? Cancer. 1993;72:2811–5.
41. Taylor KM, Kelner M. Informed consent: the physicians' perspective. Soc Sci Med. 1987;24:135–43.
42. Corbie-Smith G. The continuing legacy of the Tuskegee Syphilis Study: considerations for clinical investigation. Am J Med Sci. 1999;317:5–8.
43. Williams MV, Parker RM, Baker DW, et al. Inadequate functional health literacy among patients at two public hospitals. JAMA. 1995;274:1677–82.
44. Taylor K, Bezjak A, Fraser H. Informed consent for clinical trials: is simpler better? J Nat Cancer Inst. 1998;90:644–5.
45. Davis T, Holcombe R, Berkel H, Prammanik S, Divers S. Informed consent for clinical trials: a comparative study of standard versus simplified forms. J Natl Cancer Inst. 1998;90:668–74.
46. Smith R. Deception in research, and racial discrimination in medicine. BMJ. 1993;396:668–9.

47. Agre P, McKee K, Gargon N, Kurtz R. Patient satisfaction with an informed consent process. Cancer Pract. 1997;5:162–7.
48. Onel E, Hamond C, Wasson J, et al. Assessment of the feasibility and impact of shared decision making in prostate cancer. Urology. 1998;51:63–6.
49. Aaronson N, Zittoun R. Informed consent and cancer clinical trials. In: Psychological Aspects of Oncology. Berlin, Germany: Springer; 1990.
50. Krynski M, Tymchuk A, Ouslander J. How informed can consent be? New light on comprehension among elderly people making decisions about enteral tube feeding. Gerontologist. 1994;34:36–43.
51. Rikkert M, van den Bercken JH, ten Have HA, Hoefnagels WH. Experienced consent in geriatrics research: a new method to optimize the capacity to consent in frail elderly subjects. J Med Ethics. 1997;23:271–6.
52. Biros M, Lewis J, Olson CM, Runge J, Cummins R, Fost N. Informed consent in emergency research: consensus statement from the Coalition Conference of Acute Resuscitation and Critical Care Researchers. JAMA. 1995;273:1283–7. Special Communication.
53. Truog R, Robinson W, Randolph A, Morris A. Is informed consent always necessary for randomized, controlled trials? N Engl J Med. 1999;340:804–7.
54. Brody B, Katz J, Dula A. In case of emergency: no need for consent. Hastings Cent Rep. 1997;27:7; discussion 7–12.
55. Mattson ME, Curb D, McArdle R, AMIS and BHAT Research Groups. Participation in a clinical trial: the patient's point of view. Control Clin Trials. 1985;6:156–67.
56. Blumenthal DS, Sung J, Coates R, Williams J, Liff J. Mounting research addressing issues of race/ethnicity in health care: recruitment and retention of subjects for a longitudinal cancer prevention study in an inner-city black community. Health Serv Res. 1995;30:197–205.
57. Wilcox M, Schroer S. The perspective of patients with vascular disease on participation in clinical trials. J Vasc Nurs. 1994;12:112–6.
58. Tangrea JA, Adrianza ME, Helsel WE. Patients' perceptions on participation in a cancer chemoprevention trial. Cancer Epidemiol Biomarkers Prev. 1992;1:325–30.
59. Cunny KA, Miller HW. Participation in clinical drug studies: motivations and barriers. Clin Ther. 1994;16:273–82.
60. Aby JS, Pheley AM, Steinberg P. Motivation for participation in clinical trials of drugs for the treatment of asthma, seasonal allergic rhinitis, and perennial nonallergic rhinitis. Ann Allergy Asthma Immunol. 1996;76:348–54.
61. Daughtery C, Ratain M, Grochoowski E, et al. Perceptions of cancer patients and their physicians involved in phase I trials. J Clin Oncol. 1995;13:1062–72.
62. Bigorra J, Banos JE. Weight of financial reward in the decision by medical students and experienced healthy volunteers to participate in clinical trials. Eur J Clin Pharmacol. 1990;38:443–6.
63. Barofsky I, Sugarbaker P. Determinants of patient nonparticipation in randomized clinical trials for the treatment of sarcomas. Cancer Clin Trials. 1979;2:237–46.
64. El-Sadr W, Capps L. The challenge of minority recruitment in clinical trials for AIDS. JAMA. 1992;267:954–7.
65. Feldman D, Novack D, Gracely E. Effects of managed care of physician-patient relationships, quality of care, and the ethical practice of medicine: a physician survey. Arch Intern Med. 1998; 158:1626–32.
66. Diaz T, Chu SY, Sorvillo F, et al. Differences in participation in experimental drug trials among persons with AIDS. J Acquir Immune Defic Syndr Hum Retrovirol. 1995;10:562–8.
67. Stone VE, Mauch MY, Steger K, Janas SF, Craven DE. Race, gender, drug use, and participation in AIDS clinical trials. J Gen Intern Med. 1997;12:150–7.
68. Quinn SC. AIDS and the African American woman: the triple burden of race, class, and gender. Health Educ Q. 1993;20:305–20.
69. Levine DM, Becker DM, Bone LR, Hill MN, Tuggle MB II, Zeger SL. Community–academic health center partnerships for underserved minority populations. JAMA. 1994;272:309–11.
70. Foster MW, Bernsten D, Carter TH. A model agreement for genetic research in socially identifiable populations. Am J Hum Genet. 1998;63:696–702.
71. Freeman HP. The impact of clinical trial protocols on patient care systems in a large city hospital: access for the socially disadvantaged. Cancer. 1993;72:2834–8.
72. Kaluzny A, Brawley O, Garson-Angert D, et al. Assuring access to state-of-the-art care for U.S. minority populations: the first 2 years of the minority-based community clinical oncology program. J Natl Cancer Inst. 1993;85:1945–50.
73. Gorelick PB, Richardson D, Hudson E, et al. Establishing a community network for recruitment of African Americans into a clinical trial: the African-American Antiplatelet Stroke Prevention Study (AAASPS) experience. J Natl Med Assoc. 1996;88:701–4.
74. Barry M. Ethical considerations of human investigation in developing countries: the AIDS Dilemma. N Engl J Med. 1988;319: 1083–5.