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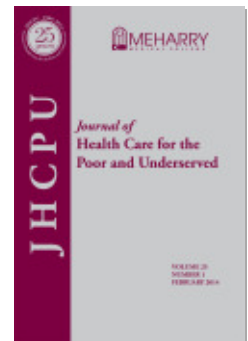
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More than Tuskegee: Understanding Mistrust about Research Participation

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Abstract: This paper describes results of a qualitative study that explored barriers to research participation among African American adults. A purposive sampling strategy was used to identify African American adults with and without previous research experience. A total of 11 focus groups were conducted. Groups ranged in size from 4–10 participants (N=70). Mistrust of the health care system emerged as a primary barrier to participation in medical research among participants in our study. Mistrust stems from historical events including the Tuskegee syphilis study and is reinforced by health system issues and discriminatory events that continue to this day. Mistrust was an important barrier expressed across all groups regardless of prior research participation or socioeconomic status. This study illustrates the multifaceted nature of mistrust, and suggests that mistrust remains an important barrier to research participation. Researchers should incorporate strategies to reduce mistrust and thereby increase participation among African Americans.

Key words: Research participation, mistrust, African Americans, recruitment.

Despite mandates by the federal government to ensure inclusion of women and minorities in all federally funded research,¹ African Americans continue to participate less frequently than Whites. Lower participation rates among African Americans have been reported across various study types (e.g., controlled clinical treatment trials,^{2,3} intervention trials,^{4,5} as well as studies on various disease conditions, including AIDS,^{6–8} Alzheimer's disease,⁹ prostate cancer and other malignancies,^{10–14} stroke,¹⁵ and cardiovascular disease¹⁶).

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Several factors that affect the participation of African Americans in studies have been identified^{17,18} including elements of study design,^{19–21} logistical problems, low levels of health literacy, sociocultural factors, and specific attitudes that hinder research participation.¹⁷ Mistrust of academic and research institutions and investigators is the most significant attitudinal barrier to research participation reported by African Americans.^{8,17,22–29} Its etiology stems from historic events, but is also exacerbated by more current actions,^{30–34} including socioeconomic and healthcare system inequities.^{35,36}

From a historical perspective, the Tuskegee syphilis study is widely recognized as a reason for mistrust because of the extent and duration of deception and mistreatment and the study's impact on human subject review and approval.^{37–39} However, the history of medical and research abuse of African Americans goes well beyond Tuskegee. Harriet Washington eloquently describes the history of medical experimentation and abuse,⁴⁰ demonstrating that mistrust of medical research and the health care infrastructure is extensive and persistent among African Americans and illustrating that more than four centuries of a biomedical enterprise designed to exploit African Americans is a principal contributor to current mistrust. As recently as the 1990s, unethical medical research involving African Americans has been conducted by highly esteemed academic institutions. For example, researchers at a prestigious U.S. university recruited African American boys into a study that hypothesized a genetic etiology of aggressive behavior. Through the use of monetary incentives, they were able to convince parents to enroll their sons in a study that included withdrawal from all medications (including asthma medications), ingesting a mono-amine (low protein) diet, an overnight stay (without parents), withholding of water, hourly blood draws, and the administration of fenfluramine, a drug known to increase serotonin levels and suspected to be associated with aggressive behaviors. In addition to these methods, several other significant human subject violations were cited, including restricting the recruitment to Black children.⁴⁰ It is fair to ask whether mistreatment of African Americans that has occurred more recently than the Tuskegee syphilis study is exacerbating mistrust today.

Attitudinal studies suggest that mistrust of clinical investigators is strongly influenced by sustained racial disparities in health, limited access to health care, and negative encounters with health care providers.^{41–43} Beliefs about physician mistrust among African American patients are reinforced through differential treatment in comparison with Whites. Moreover, previous research indicates that a lack of cultural diversity and competence among physicians is a major contributor to African American mistrust of physicians.^{36,44,45} Ethnic minority patients receive less information, empathy, and attention from their physicians regarding their medical care than their White counterparts.⁴⁶ Lack of information results in limited awareness, knowledge or understanding of the availability or value of medical research.³⁴ Further, studies have illustrated that African American patients are less likely to receive medical services than White patients with similar complaints and symptoms.³⁶

Attitudes of mistrust reflect perceptions about interpersonal and technical incompetence, physician focus on profit, and expectations of experimentation.⁴⁴ Several investigators have found that African Americans are more likely than age-, education-, and gender-matched Whites to believe that research findings will be used to reinforce negative stereotypes about their ethnic group⁴⁷ or will expose them to unnecessary

risks.^{25,48} Two separate studies examining barriers to African American participation in genetics research found that African American participants worried about the use of DNA data collected in biomedical research in later criminal investigations to implicate innocent people.^{49,50} Moreover, the literature demonstrates that African Americans report concern that the findings associated with their participation will not benefit the African American community.²⁴ Finally, several studies suggest that investigators themselves often limit minority participation because they are less likely to ask minority patients to consider enrolling in clinical trials.^{6,11,15,46} Despite these concerns, other research has shown that African Americans recognize the value and importance of clinical research and the possibility of new and better treatments emerging from it for themselves and the African American community.¹⁷

This exploratory, qualitative study was undertaken to attempt to understand the barriers to research participation particular to African American adults who reside in a mid-size urban area. This study was designed to gain an in-depth understanding of the factors associated with participation/lack of participation in research studies, including more invasive biomarker and clinical treatment trials sponsored by Washington University and Siteman Cancer Center. Both had been successful in recruitment of African Americans for surveys and screening studies, but had experienced less success in recruitment for invasive studies or clinical trials. The goal was to identify barriers to research participation, including more complex studies, and then use the findings to develop interventions to improve participation in both cancer and Alzheimer's-related trials.

Methods

Participants and sampling. A purposive sample of African American adults was generated for participation in one of 11 focus groups (N=70). The focus groups were designed to be homogeneous on at least one of three characteristics: previous or current participation in research (*Yes/No*), age category (18–35, 36–55, older than 55 years) and gender and to represent a range of socioeconomic categories. We recruited individuals with and without previous research experience because previous studies have found differences by previous participation^{51,52} and the researchers in the study groups had intentionally implemented strategies to enhance participation. Participants were recruited in four ways: 1) letters sent and phone calls made to participants enrolled in studies at the Alzheimer's Disease Research Center at Washington University School of Medicine; 2) coordination with community members and leaders to identify potential participants; 3) advertisements placed in the local African American newspaper; and 4) recruitment flyers posted at a community health center.

Interview. The content of the focus group interview was generated by the project investigators, and questions were adapted by the moderator to be conversational. The flow of the questions followed a traditional focus group question format (i.e., introductory, key, ending, and summary) to ensure maximum participation by focus group attendees.⁵³ Probes or follow-up/clarification questions succeeded each of the three main-topic questions (barriers, facilitators, and suggestions to increase participation). Additionally, participants were probed about specific topics that were not always

spontaneously generated by them (e.g., *Does the recruiter need to be your doctor or African American?*).

Data collection. Each focus group lasted one and a half hours and was audio-taped. Recordings were transcribed by a professional transcriptionist. Moderators created an informal atmosphere so that participants felt comfortable sharing both positive and negative perceptions. The co-moderator took notes that reflected the tone and processes of each group, noting characteristics of the groups' conversation (such as participation, signs of emotion, and non-verbal responses). Each participant received a \$25 voucher to a local grocery store. A debriefing between moderators was conducted at the end of each group.

Data analysis. A grounded theory design guided data collection and analysis. Grounded theory is an inductive approach, meaning that there is no preconceived theory (about barriers to research participation, for example) that drives data collection, and the theory evolves from the data.⁵⁴ Theory emerges from systematic data collection and the observation of the interrelationships of categories of information.^{55,56}

As an initial step in the analysis, each of the analysis team members independently reviewed the focus group transcripts using a whole-text analysis, open-coding method⁵⁷ to identify themes around barriers and facilitators of research participation. Using the debriefing and the co-moderators' notes, a summary of the group themes, dynamics, and demographic characteristics was then developed. The codes were developed from the major themes that emerged from the first phase of analysis, along with the original focus group guides. The list of theme-generated codes was compared with the original focus group interview guide and items that were not identified by the themes were added as codes. The co-moderator's notes and debriefing notes were also used as validation of the codes. Additional codes were developed from the notes that were not reflected in the existing list.

In the next step of analysis, independent focused coding⁵⁸ occurred and inter-rater reliability was established. Where inconsistencies in the coding occurred, the raters came to consensus on discrepancies. Next, the coded transcripts were reviewed by the senior team member to ensure that the final list of codes adequately reflected the data. New codes were developed to capture new themes or ideas. QSR N6 qualitative software was used to code, retrieve, merge, and analyze chunks of data and annotate data about group dynamics (QSR International, Melbourne, Australia). Coded data were then reorganized into logical categories for presentation.

The final phase of analysis involved identifying significant themes from the data. Themes were considered significant if any of the following characteristics were observed: the theme was discussed frequently, extensive comments around the theme were made, intensity or passion around the theme became evident, and/or stories were used to specify the theme or indicate its relevance to the focus group participant.

Results

Sample characteristics. Table 1 reports the demographic characteristics of focus group participants. All participants were African American adults residing in a mid-size urban area (population: 347,000⁵⁹). In groups one through four and seven, all participants had

previous experience with research participation. Five of the nine groups were made up of women only. We were unable to create groups based on all of the pre-defined age categories. However, groups one to three mostly comprised older individuals and group 11 comprised individuals who were all under 30 years of age. Focus groups seven and eleven comprised individuals who had at least a bachelor's degree and earned more than \$30,000 per year. Groups five, nine, and ten comprised individuals who earned \$30,000 or less each year. The Washington University Human Studies Committee approved all procedures. Informed consent was obtained from participants after the study was fully described.

Themes. A number of *barrier* themes were identified in the study, including mistrust of researchers and the health care system, fear related to research participation, inadequate information about research and opportunities to participate, inconvenience, questionable reputation of the researcher or research institution, and logistical concerns. The themes related to mistrust surfaced as significant in frequency, intensity, extensiveness, and specificity. However, we focus here on mistrust, fear, and inadequate information, and their effects on research participation and their relationships to each other. (Other barrier themes and facilitators such as relevance to individuals and benefit to the African American community are fully discussed in a soon-to-be-published manuscript.⁶⁰) The findings are presented in the aggregate because there were no clear differences about mistrust that emerged by the types of groups, i.e., there were no differences in mistrust, fear, and inadequate information by gender, education, income, or by prior participation in research.

In general, participants understood that medical research usually occurs within the context of the health care system, and it appeared that participants' beliefs about one frequently informed their beliefs about the other. Focus group discussions about medical research regularly turned back to discussions about their experiences with the health care system. When this occurred, the moderator confirmed with participants the transferability of their beliefs about the health care system to beliefs about medical research. Additionally, overall, participants recognized that research is both important and necessary for scientists to learn better ways to treat and prevent disease. However, they gave strong voice to a number of barriers that prevent them from participation.

Mistrust. Participants associate the term "medical research" with terms that represent the negative connotations of research, such as experimentation, rats, and test tubes. Experimentation, it was said, is viewed in a particularly negative light, given the history of research in the African American community. More specifically, participants in every focus group suggested that medical research conjures up the term "guinea pig." Many endorsed the view that this term applied specifically to African Americans (as opposed to other racial or ethnic groups) being used to test medications or procedures. A participant said,

One of the reasons most Black people are reluctant to get involved is suspicion. We've been kind of brainwashed, and we're guinea pigs.

Mistrust of the health care system among African Americans in our sample is deeply ingrained and appears to cross socioeconomic lines, in that mistrust was identified as

Table 1.

DEMOGRAPHIC CHARACTERISTICS OF FOCUS GROUP PARTICIPANTS

Focus group	1 ^a N=6	2 ^a N=4	3 ^a N=5	4 ^a N=9	5 N=8	6 N=6	7 ^a N=6	8 N=10	9 N=6	10 N=4	11 N=6
Mean age	67	69	69.6	51	53.9	52.4	58.8	47.5	45.1	44.2	28.3
± SD	± 8.12	± 8.04	± 12.99	± 11.92	± 8.17	± 8.16	± 13.8	± 14.4	± 8.08	± 15.78	± 3.14
(range)	(57-79)	(57-74)	(53-79)	(29-70)	(42-65)	(38-60)	(33-69)	(21-76)	(32-57)	(21-55)	(24-32)
% Female	100	100	100	78	50	68	100	70	100	0	33
Marital status (%)											
Single	17	25	20	33	63	67	17	70	83	50	33
Married	33	50	20	57	—	33	67	—	17	50	67
Divorced	50	25	60	11	37	—	17	—	—	—	—
Education (%)											
< HS	—	—	20	—	—	—	—	20	33	25	—
HS	—	—	—	11	—	17	—	20	50	50	—
Some college	33	25	80	44	75	33	—	40	17	25	—
Bachelors or >	67	75	—	44	25	50	100	20	—	—	100
Income (%)											
<\$10K	17	—	40	44	29	17	—	60	83	50	—
>10-≤20K	13	—	—	—	57	17	—	20	17	50	—
>20-≤40K	17	50	60	33	14	—	—	10	—	—	33
>40K	33.	50	—	22	—	67	100	10	—	—	50
Participated in research studies	Yes	Yes	Yes	Yes	No	No	Yes	No	No	No	No

^aAll participants had participated in research.

a barrier to participation in research in every group. In fact, most of the participants in Group 11 (all professionals of high socioeconomic status) discussed recent events that they directly or indirectly experienced in health care or research situations that exacerbated mistrust. For example, one participant described his experience with attempting to enter a study that was evaluating a treatment for razor burn. He asked several questions of the researchers as a way to determine whether to participate. The researchers, he explained, were surprised by the extent of the questions he posed. Additionally, when he informed the researchers that he used clippers to remove whiskers, the researchers were unfamiliar with this method and asked him to describe it. The gentleman decided not to participate: he saw that the researchers were unfamiliar with a technique for hair removal common in the African American community (and relevant for the study) and, consequently, concluded that they were unprepared for African American participants in the study.

Impact of Tuskegee. Participants explained that the lack of trust regarding the health care system among African Americans has historical roots: the Tuskegee syphilis study and others were either explicitly or implicitly referred to in every group. The impact of this event carries on throughout the generations, as this participant explained:

Just that awareness [about Tuskegee] is enough to stand up generation after generation.

Although most understood that men were *not treated* for syphilis in the Tuskegee study, many believe that men were both *injected* with the disease and *not treated*. One participant said,

Most people have gained information on the Tuskegee experiments where they injected these men with the syphilis virus.

This belief remains active within the Black community, regardless of age or socioeconomic status. For example, a young professional understood on the one hand that the government did not infect men with syphilis but believed otherwise given what was heard in the community.

And I think that over time the legend of Tuskegee is more palpable than what people know about what went down. I think I've always known. But I've always known that the government gave people syphilis, and this is not true.

Much of the mistrust expressed by participants is focused on the federal government as they recognize their role in the support of research studies such as the Tuskegee syphilis study. One participant said,

I think you have a lot of people who mistrust the government. You start looking at a lot of medical centers, there's always going to be some link up the chain to some government entity.

Participants discussed how the government is supposed to have the best interest of its citizens in mind but has proven on a number of occasions that it does not:

You don't know what they are giving you and what they're experimenting on you. They are very secretive. They say one thing and might do another.

In fact, some participants believe that the government only stands to make money through research, especially research performed on underserved individuals.

Participants explained that the result of the Tuskegee syphilis study and other negative historical events have both a rational and emotional component. They argued that after the number of years during which African Americans have been deceived, it makes sense that they do not trust researchers and are not willing to participate in medical research:

It [Tuskegee] becomes a symbol of these two portions of my existence and it becomes a way for me to answer the question, why. So me participating in something else that might be like that, why would I do that to myself?

From an emotional perspective, participants described how the impact of historical and current events effect other decisions they make. One participant used a story to illustrate the depth of the emotion.

I sat in the driver's license bureau for about 45 minutes and every Black person that was in there, they'd be like, "Would you like to be an organ donor?" And every Black person said no. And every person of another race they asked was like, "Yeah, no problem." And I immediately said no. And this thing in my head was telling me they will misuse my organs. I don't even know why I was so emotional.

The emotional toll that history plays on many African Americans was evident in many of the focus group discussions. Participants discussed the Tuskegee syphilis study with passion and provided examples illustrating how it (and other historical events) plays a role in who they are today.

It's [Tuskegee] part of the sociological and theological question: who are we and why are we in this position?

One woman described being in Tuskegee when President Clinton officially apologized for the experiments on behalf of the U.S. government. She talked about the fact that the university received a large sum of money in reparation, but that no amount of money could ever take away the hurt she saw first-hand from residents of the Tuskegee area.

I was actually there [Tuskegee] for the satellite telecast of the apology. I got to see some of the participants and it was pretty profound hearing what some of them had to go through. I know now the university has a whole new medical center and they got a lot of money, but that can't make up for it. And you can't go back and change what happened. I can't speak for other people but that was a huge emotional experience for me.

No benefit to African American community. Participants indicated that their relationships with White America have historically been one-sided. They recounted stories in which they gave to White America and received nothing in return.

We were . . . a lot of Black people don't ever encounter White people. Whenever I encounter White people, they're coming to take. The only White person in my neighborhood is the insurance man, and he only takes my money.

In fact, participants indicated that research findings rarely benefit the African American community because they do not see the results of studies. They contend that research usually is conducted for the benefit of others, specifically, Whites.

I think the deception is when we read studies, they don't relate to us. They don't . . . I mean, they're about another nationality. They're not really for African Americans. And they don't apply to us.

Additionally, many expressed that they have not seen *any* positive results from the research conducted in their community and, therefore, have no expectations:

And it goes back, if you find something, are we ever going to see it? So truly, why does my participation really matter for anything? If it's not going to produce a product that I'm going to see, why should I be one of the study participants?

Some participants question the motives and practices of the researchers:

I guess it all ties in with the motives and the integrity of those doing the research. Are they doing it because of race, is it class, or is it a combination of both?

Many wondered how information is used by researchers:

How are you going to use this? It still comes back, to me, to that question, how much feeling, how much thought of life and value of life are they putting into this research?

Recent examples of racism or discrimination. Many participants described recent stories about the use of the health care system in which they or someone they know received poor quality health care or were treated disrespectfully. They emphasized that this type of mistreatment still occurs today:

I'm not going to go into details. But he wasn't treated properly, given the proper tests at this hospital. He's in a coma to this day. And I guess because he's a Black man. Like I said, I just haven't seen it happen to White patients.

Such experiences create a lack of respect for health care providers that appears to be fairly prevalent in the community:

I think life experience. Working in the hospital, I have a great deal less respect for doctors and nurses.

Inadequate information. Participants explained that the deception experienced by the men in the Tuskegee syphilis study continues to be a factor for many African Americans today, especially men. Many expressed the belief that, just as the Tuskegee study participants were not informed, they too are not informed by health care providers today. Inadequate information exacerbates mistrust and creates the perception that there is something to hide. Many suggested that health care providers are dishonest, either by leaving out important information when obtaining consent or by misinforming them:

I know as a Black American that we are not told all the time the correct truth.

Participants suggested that misinformation (or lack of information) has resulted in African Americans being enrolled in research studies without a full understanding of what their participation meant. They argued that researchers often target vulnerable individuals as study participants because they believe that these individuals are less likely to question them. For example, they talked about the fact that researchers often reach out to the homeless, prisoners, children, elderly, and impoverished when recruiting for studies. Using money as an incentive ensures that marginalized individuals will volunteer to participate in research studies.

I do know that when they offer money for research, they are trying to get probably a different clientele of people. If people are going to be paid a large amount of money, people who need money may be more likely to involve themselves in that

Overall, many participants believe that confusion about research and medical care stems from the lack of education and dissemination to the public. When information is presented, it is rarely done in way that is understandable, and therefore its use is limited.

Additionally, participants suggested that doctors, researchers, and others in health care do not always present information in a way that is respectful and understandable.

The words are important but it's also the way you present those words, because they can say a lot of words but if it's not presented correctly or with some kind of feeling that you have concern . . . just don't talk to me.

Impact of mistrust. In view of widespread mistrust and suspicion in their community, African Americans in our study indicated that they tend to be reluctant to provide information about themselves. Many discussed the fear that personal information may be used against them at some later date. This belief has a historical etiology that has been sustained throughout the generations.

People are reluctant to go open up because of what's happened to them. It's just a fear that they don't want anyone to know their business.

The *deep* beliefs described by participants have a major impact on willingness to participate in medical research, as illustrated by the following:

Normally, African Americans are, as you said before, suspicious. They have that first in their mind, well, what are these experimental drugs they're using, because of the things that have happened in the past.

Discussion

This study used qualitative methods to explore barriers to participation in research among African American adults who reside in a mid-size urban city. Mistrust was the primary concern voiced by study participants. Literature that describes and explores the role of mistrust among African Americans dates back to the early 1970s, just after the Tuskegee syphilis study became public and uses both quantitative^{17,24,25,29,42,48} and qualitative^{17,22,26,27} approaches to describe mistrust and understand its relationship to research participation. Our data support existing literature and deepen the understanding of how multifaceted this mistrust is, how it influences many parts of people's lives, and how it creates a significant emotional burden. Indeed, our data remind us that ongoing experiences with the health care system perpetuate feelings of mistrust. This continues to reduce our ability to recruit African Americans into research studies and limiting the generalizability of current research findings.

Of particular interest is that the data indicate that barriers are common across multiple subgroups including those who had and had not previously participated in research studies, suggesting that merely participating in research is not enough to lessen mistrust. We intentionally created groups that consisted of individuals who had participated in research (from one of our centers), as there is some work that suggests that prior research participation increases the likelihood of participation.^{51,52} Additionally, researchers in the study centers had developed multiple strategies to improve low participation among minorities. The primary strategies were to develop long-term partnerships and improve access to quality care. The specific activities included (1) creating community advisory boards (2) delivering culturally targeted education programs (3) partnering with community-based organizations serving the African American community and (4) improving access to clinical care and support services. These findings suggest that previous participation in low risk research, such as survey or focus group studies, will not in and of itself increase participation in more invasive and higher risk studies.

Participants emphasized that historical events such as the Tuskegee syphilis study remain in the minds of many African Americans and often attributed mistrust to this history. History was discussed in every group and across socioeconomic statuses. Many described their beliefs that the federal government, responsible for the Tuskegee study, both injected syphilis into and withheld treatment from study participants beliefs learned from parents and grandparents. Even the more educated participants relate to this history and, although they recognize that Tuskegee participants were not injected, expressed continuing mistrust related to these past events. In fact, the emotional side of mistrust was particularly evident in groups constituted of higher-educated participants. This may reflect the fact that better-educated individuals have greater access to information, in general, and can therefore learn about specific events in more detail. This finding is illuminating because the research is mixed regarding the impact of education on mistrust,⁶¹⁻⁶³ and we could identify no other studies that clearly demonstrate that mistrust is similar across socioeconomic groups.

Although historical events such as Tuskegee foster mistrust, participants stressed that disrespect and discrimination towards African Americans continues to occur. Recent literature supports the view that current occasions of perceived or real racism or discrimination exacerbate mistrust.⁶⁴ The Institute of Medicine report on disparities of treatment by race suggests that much disparate care is due to discrimination, both conscious and unconscious.³⁶ VanRyn and colleagues describe the complex process of decision making that medical providers go through and suggest that perhaps false beliefs about individuals may result in disparate treatment.⁶⁵ Some studies, however, argue that participation in research increases discrimination by allowing investigators to highlight problems in the community (i.e., to emphasize negative traits of Black individuals and their communities). In fact, Nicholson and colleagues found that African Americans respond negatively to cancer disparity information and positively to messages of hope.⁶⁶

Perhaps the most disturbing instance of mistrust that participants described is the belief that information about research studies and their participation is withheld by researchers, which may be one factor that perpetuates feelings of mistrust. In particular, focus group participants indicated they are provided limited or inadequate information about their participation in research. Indeed, this may be one of the most enduring negative fallouts from the Tuskegee syphilis study and other unethical studies. However, these beliefs cannot just be attributed to historic events. For example, a recent study reported that over 50% of physicians prescribe placebos without thoroughly informing patients, suggesting that these beliefs may have merit.⁶⁷ As researchers continue to behave in a way that exacerbates mistrust, so will the fear about research among the African American community continue. In turn, there will continue to be low participation rates, resulting in studies that can only be generalized to the White majority. The resulting inability truly to understand the biological and social determinants of disease etiology and progression among minority populations will only deepen the existing disparities in health.

This study has limitations. Qualitative data are descriptive and are not meant to generalize to any broader population. Our goal in this study was to gain in-depth understanding about research participation from individuals who could speak from life experiences about the issue, therefore creating productive conversation.⁵³ Our data suggest the importance of working with and in the community as a way to understand perceptions specific to a particular community.

As is appropriate with focus group methodology, we developed and used a purposive sampling strategy.⁵³ We segmented groups by previous research participation, gender, and socioeconomic status. Our findings did not identify differences by segments, suggesting that previous research experience and/or higher socioeconomic status were not enough to change deep-seated beliefs. We were able to recruit a large number of groups, which allowed us to reach saturation (or, repetition) of themes.⁵⁵

Although researchers are adept at providing incentives and recruiting from community venues to enhance African Americans participation in studies, it is important to understand that these efforts are not enough to facilitate recruitment into many more involved clinical studies or trials. It is imperative that we understand and act specifically upon mistrust that this and other studies have reported. Several reports outline

ways in which researchers and health care providers can gain the trust of community members.^{4,18,24,68–70} For example, community-based participatory research (CBPR) models claim to improve community-research relationships^{71–73} although they are still not widely used.⁷⁴ CBPR is a collaborative approach to research that equitably involves all partners in the research process, recognizing the unique strengths that each brings.⁷³ It stipulates that long term relationships develop and that knowledge is gained by both parties, which is used to improve health.^{71,75} Cook recently conducted a review of CBPR projects that addressed health disparities.⁷⁶ In two-thirds of the studies, CBPR led to community actions to improve health. Studies that used qualitative methods were more acceptable to the community. In fact, community partners felt that the randomized controlled trials were too complex and were concerned that they withheld valuable interventions from the control group.

Principles of CBPR have been used by investigators to increase African American participation. One tool that has been used successfully is a community advisor board (CAB), which provides a window into the context in which many participants live, helps define the consent process, and creates relationships.⁷⁵ Several large research centers (Harvard, University of Pittsburg, Mayo Clinic) have created Community Research Advisory Boards (CRABs) to provide review and advice to investigators initiating more invasive studies and clinical trials. These boards review the project design and procedures to identify and address modifiable community-specific barriers to participation. Additionally, community boards and other groups promote regular, honest, and thorough dissemination of information about the research process. Studies also suggest that short and long-term outcomes must be communicated back to the community in order to gain and maintain trust.^{25,77} Participants in our study confirmed this desire. Finally, it is strongly recommended that potential participants be given adequate time to make decisions about research participation.²⁵

Other ways to increase African American participants in research should also be considered. For example, in both this project and much of our other work, community members express the desire for researchers to have a presence in the community. Participants indicate that small group information sessions, co-led by researchers and community members, would be welcome. In some of our other work, we employ community members to help us carry out the research. Finally, as recommended by the Institute of Medicine and the Dept. of Health and Human Services, we must be diligent about encouraging African American (and other minority) students to continue their education to become scientists, thus increasing the proportion of underrepresented minorities in research positions.^{36,78}

In the early 1970s, the National Heart, Lung and Blood Institute established a program designed to increase minority participation. The most important strategy suggested by the report was soliciting contributions from community opinion leaders.⁷⁹ Why are researchers *not* implementing some of these strategies? Perhaps they have difficulty seeing the applicability of CBPR principles to clinical trials, as it has traditionally been used in public health and prevention studies. It is reasonable, however, to believe that researchers who conduct clinical trials can incorporate some of the CBPR assumptions and principles into their work. For example, researchers can attempt to understand the community and its “local theories,” or beliefs about determinants and solutions to

problems.⁸⁰ Communication of study findings has also been shown to positively influence attitudes about participation and willingness to consider participation in future trials, even when the results are negative or inconclusive.⁸¹ Participants in our study emphasized that when study findings are communicated back to the community, they should be presented in an understandable way, and also from a sense of interest and concern about the community. Teal and colleagues describe a framework for culturally competent communication, which includes communication repertoire, situational awareness, adaptability, and knowledge about core cultural issues.⁸² Researchers should indicate how studies can potentially benefit the African American community. To close the loop, investigators can work to ensure that minority communities reap benefits from new research findings.

Investigators will continue to be limited in their ability to recruit study participants until they (the investigators) understand the depth of mistrust among many African Americans and its impact on access to health care, medical treatment, and research participation. Perhaps researchers are not as culturally competent as is necessary and continue to make decisions unconsciously based on race.³⁶ Our study suggests that the racism that was a community norm during the time Tuskegee syphilis study⁸³ persists, a position validated by the report issued by *the Institute of Medicine*.³⁶ This study reminds us that mistrust among African Americans, regardless of prior participation or socioeconomic status, continues and illuminates its multifaceted nature. Because of the recent and continued acknowledgement of health disparities that exist in African Americans, it is incumbent upon us to continue to explore and report the continuation of mistrust among African Americans related to research participation and to develop new and use existing strategies to enhance the trustworthiness of researchers and health care institutions. This study is a reminder about the significance of mistrust on research participation. It helps assure that investigators consider all of the issues related to mistrust as they embark upon studies, including informing community members about the potential impact of study findings on health disparities as part of outreach and recruitment. Unless researchers and practitioners acknowledge their roles in the development and continuation of disparities and create mechanisms to reduce mistrust, health disparities and limited research participation will continue.

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