

Perceptions of Clinical Research Participation among African American Women

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ABSTRACT

Background: Recruiting minority women into clinical research remains a significant challenge to conducting ethnically representative research. The main objective of this Office on Women's Health, DHHS-funded e-health database evaluation project was to examine African American women's thoughts and perceptions about the clinical research process and about participation in the University of Michigan Women's Health Registry research database.

Methods: Thirty-one African American women were recruited from the community to participate in a total of five 90-minute focus group discussions. All sessions were audiotaped and transcribed *verbatim*. Thematic content analysis was used to identify relevant themes about participation in clinical research and the Women's Health Registry.

Results: Ten common trends were identified. (1) Information about the Women's Health Registry is not reaching the community. (2) Research is perceived as biased to benefit Caucasians. (3) Community involvement by the research team is critical for trust to develop. (4) Research directly relevant to African Americans or their community will encourage participation. (5) Researchers should use existing networks and advertise in appropriate locations. (6) The community needs more information concerning research. (7) Compensation is important. (8) Research that addresses a personal or family medical problem encourages involvement. (9) Minority representation on the research team is a motivator to participation. (10) There is limited time for healthcare-related activities.

Conclusions: Successful recruitment strategies for African American women should feature community-based, culturally appropriate approaches. Online research databases for subject recruitment will likely be successful only if implemented within a broader community-oriented program.

INTRODUCTION

THE RECENT LARGE AND SUCCESSFUL Women's Health Initiative (WHI) trial^{1,2} focused atten-

tion on the special contributions of women to research and emphasized the importance of recruitment methodology.^{3,4} Many factors influence the successful recruitment of women into

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clinical research trials. Recruitment and retention literature identifies three major influences when women are considering participation in health-related research: barriers to entry, incentives, and deterrents.⁵⁻⁸ According to the existing literature, women are motivated to participate in health-related research by the desire to be altruistic, compensation (monetary or nonmonetary) that is associated with participating in a study,^{6,8} and a change in one's daily routine.⁶ Limited opportunities to participate, general reluctance, and individual challenges, such as lack of transportation and child care, are described as barriers for women considering participation in health-related research.^{9,10}

Recruitment of minority women into clinical research trials remains one of the greatest challenges to conducting ethnically representative research and to complying with gender-based analysis requirements for federally funded research.^{11,12} Exclusion of minorities can cause selection bias and reduce the ability to generalize research results even when the study is internally valid.^{13,14} The systematic abuse of people of color has in part created a historically based culture of distrust of the medical profession within minority communities.^{15,16} However, knowledge about successful recruitment and retention techniques for women and ethnic minorities in clinical trials is limited by experience and a dearth of reports on recruitment.^{9,17,18}

The University of Michigan Health System's (UMHS) National Center of Excellence (CoE) in Women's Health operates an e-health database, the Women's Health Registry, designed to link women who are interested in participating in health-related research with institutional review board-approved investigators. In 2001, the UMHS Women's Health Program launched a publicity campaign designed to recruit more African American women into the Women's Health Registry. This campaign featured call to action posters depicting a young African American woman and a large header that read: "Give us some of your time and we'll give it back to future generations." By the end of this campaign, 76 women of color enrolled in the UMHS Women's Health Registry, resulting in a total increase of nonwhite enrollment from 8% to 14.48%.⁵ The campaign was not renewed, however, and during a reevaluation of minority enrollment in the summer of 2003, African American enrollment in the Women's Health Registry

had returned to 8%. This decline highlighted the importance of sustainable, continued partnerships and consistent ongoing communication between the Women's Health Program and the African American community.

In the interest of discovering new uses for e-health databases, the Office on Women's Health (OWH) at the U.S. Department of Health and Human Services (DHHS) funded 12-month projects at CoEs in Women's Health designed to experiment with or evaluate e-health applications in relation to minority women's participation in clinical research. In 2003, the OWH funded a project at the UMHS CoE to assess knowledge and perceptions of the Women's Health Registry among women of color in the local community. More specifically, the objectives of this e-health database evaluation project were to assess and examine African American women's thoughts and perceptions about the clinical research process and to identify barriers and motivators to participating in the Women's Health Registry. The University of Michigan CoE recognized this as a perfect opportunity to redefine its work related to creating a sustainable, continued partnership with the local African American community.

MATERIALS AND METHODS

University of Michigan Institutional Review Board approval was obtained for this project. With the long-term objective to improve the enrollment and retention of African American women in the Women's Health Registry, this project was designed to generate dialogue with local African American women between the ages of 30 and 60 through semistructured focus group discussions, facilitated by an African American female team member at the UMHS CoE. Each session addressed the following categories of interest: (1) perceptions of health-related research in general, (2) perceptions of health-related research done at the University of Michigan, (3) identification of culturally competent recruitment/retention strategies, and (4) identification of barriers and motivators to participation in research or Registry database projects. Details of the focus group strategy are presented in Table 1.

Focus group participants were recruited at local hair salons, churches, beauty supply vendors, social organizations, professional/civic organizations, and social support agencies within the

TABLE 1. FOCUS GROUP STRATEGY

1. Introduction	Convey the purpose of the focus group Personal introductions (first name) Reasons for interest in participating
2. Present major topics and ask participants to write down their thoughts and perceptions concerning these topics	Health (cardiovascular disease and breast cancer) Research Women's Health Program
3. Group discussion concerning responses to these topics	General healthcare discussion concerning breast cancer and heart disease Protecting against misinformation and misconceptions Thoughts about research in general, research knowledge, motivators, and barriers Strategies to increase awareness of research in the African American community Awareness of the Women's Health Program and Women's Health Registry Strategies to increase awareness in the African American community of the Women's Health Program and Women's Health Registry

greater Washtenaw County (MI) community through word-of-mouth discussions, telephone calls, and posting of fliers. Criteria for inclusion were age (30–60 years), ethnicity (self-identified African American), female sex, and location of residence in Washtenaw County. Upon meeting the selection criteria, focus group participants were sorted by age, with two groups of women aged 30–45 years and two groups aged 46–60 years.

This project initially was intended to accommodate four 90-minute focus group discussions that we anticipated would include nine different African American women at each session. A fifth group was convened following the original four groups, composed of one representative from each of the four focus groups and five additional African American women between the ages of 30–60 who held business or community leadership roles throughout Washtenaw County. The purpose of the fifth focus group was to share the trends identified in each of the focus group discussions and discuss how this information could best be shared with the community.

All sessions were audiotaped and professionally transcribed *verbatim*. The focus group transcripts were compiled, and thematic content analysis was used to organize the information and flag relevant themes.¹⁹ During the review of

the transcripts, themes were deciphered that encompassed the majority of the participants' discussions. Themes were allowed to emerge from the analysis and were not identified beforehand. The analysis was validated by a second investigator who also reviewed the transcripts in their entirety to obtain consensus. In areas where disagreement occurred about interpretation, a third investigator reviewed the transcript.

RESULTS

A total of 31 women participated in this project through the five focus groups: 13 in the younger age range (5 in the first and 8 in the second focus groups) and 13 in the older age range (6 in the first and 7 in the second focus groups), and 5 additional community leaders who attended the fifth focus group.

Ten clear and common trends emerged in the focus group discussions. These are described, with quotes from the participants.

1. Information about the Women's Health Registry (and UMHS research efforts in general) is not reaching the African American community in a form that is recognizable.
 - I never knew about the database that you were talking about. I would love to be a part of that, but I never heard of the registry. I never even knew it existed.
 - I thought it [the Women's Health Registry] was for white women.
2. There was a general perception that research is biased to benefit white people, resulting in a lack of trust.
 - Well, you know personally for me, looking at the big picture, the society that you live in is racist, and this organization is like a pea compared to what we see, what we face, what we deal with in the world. So it's going to be extremely difficult to build trust in this particular group.
 - For me it's just, it's unknown. Literally you just don't know. I mean we cannot close our eyes to what happened with the Tuskegee experiment. I'm just telling you that it's imprinted in our community, and we will not forget it, frankly. And so it's getting over

- that hurdle, and one of the ways you get over that hurdle is with education.
3. Trust from the community (toward research and researchers) will come only through consistent community involvement on the part of the researcher (or research team).
 - We need some programs that are safe to go to, that it's okay for us to go to, black women's health seminars, whatever, something free, too, free and close.
 - Just talking about the University of Michigan, there is a lot of research that's going on, but it just doesn't reach the majority of the people. . . . If you're trying to reach outside University of Michigan hospital itself to get research participants, you've got to be able to put it out there in the community.
 4. Most participants will become involved only in research that they perceive can help their community or other people of color or both.
 - I'm saying, well, this will help some woman somewhere, but what about my community? Is it helping my community?
 - You're going to have to show tangibly how it's going to benefit our community and benefit us.
 5. Researchers should use existing networks and advertise health research, programs, or educational opportunities in venues or periodicals that cater to African American audiences.
 - We've got to find some ways, some nontraditional ways, to get the information to each other in shops or going to places where women gather. . . . so maybe the information is not getting to where it needs to.
 - I mean if you advertise on 92.3 (FM radio) that people listen to, I think that you would be just overwhelmed with responses.
 - Maybe sometimes the pastor can make an announcement, you know, it can be in the program. Maybe something in the bulletin board at church . . . Give it to my hairdresser.
 6. The community needs more information about what research is and why it is important.
 - I think that there has been a lack of research within the black community, within any minority group, so . . . we're not educated on it. It doesn't happen. It doesn't come to us in a form that we can recognize or feel safe doing.
 - So I hate the onus to be put on us. Why aren't you participating? Well, why aren't you making me aware that I can participate?
 7. Compensation is an important motivator to participation in research.
 - The bottom line is the money is a great incentive. It is a great incentive.
 - And so that's what you're going to have to invest in, you know, the money.
 - Compensation for black people really helps. It may not just be monetary. It may be some type of free something.
 8. African American women are more likely to participate in research that addresses a personal medical problem or a medical illness in their family.
 - When you're faced with a deadly disease, then it's a little easier to say, "I don't have anything to lose," you know, "I don't have anything to lose. I have a shot in the dark that might work. So why not?"
 - I think when you have something that touches you, you're more prone [to participate in research]. If you know your mother is suffering with breast cancer, you're going to likely help that cause because you know what your mother went through.
 9. Minority representation on the research team is a motivator to participation.
 - If you have a group of researchers that are not the same color of people that you're researching, you may be missing something, you may be missing something that a black person would see a correlation in, just because of their sensitivity to the culture of the people that are being studied.
 - You know, what I was thinking and what would discourage me is if I didn't see other black women involved, as far as being in charge. . . . But, if it's just white women

coming to me and saying, "Come and be involved," see I wouldn't.

- Let blacks just actually be the ones to take it to the community.

10. There is limited time for healthcare-related activities.

- I think so many other things are going on in the black community that health is often at the bottom of the list. I mean, you're trying to make ends meet, and you're trying to raise the family, sometimes single-handedly, and you're just trying to lay down at night and rest and sleep. Often health is just at the bottom of the list.
- I think our health is not a priority. We think of our families. We think finances, jobs, and other things are always more important than our health. And I think that even causes a lot of women not to go to the doctor.

DISCUSSION

Low recruitment rates of African American women into health-related research are a great challenge faced by many medical researchers. The Women's Health Registry was designed to reduce the investigator's subject recruitment burden but has experienced modest success in recruiting minority participants. This study identified, through focus group discussions, several themes, including motivators, barriers, and strategies for African American women to participate in health-related research.

The focus group approach was chosen to promote interactive dialogue and allow researchers access to social dynamics that reveal insights, memories, positions, and desires among African American women in regard to health research participation.²⁰ Perhaps one of the most difficult to address barriers identified was the overall lack of trust in healthcare systems and researchers. This was simply and eloquently relayed in a statement by one of the participants: "We have our guard up all day, so why would you drop it for research?"

The importance of community involvement of the researcher and research team, use of existing community networks for advertising, and relevance to the African American community of the health issue under study were empha-

sized by participants and perhaps offer an opportunity to increase trust within the community. This suggests that typical recruitment campaigns of newspaper advertisements and distribution of fliers would be less successful for recruiting African American women into health-related research.

The focus groups also identified that researchers are not reaching the African American community in terms of education about research or recruitment in appropriate locations. Indeed, a recent report concerning recruitment of African American women into a breast cancer genetic counseling program attributed part of their enrollment success to working within social networks, such as churches and community centers.²¹ These findings emphasize the importance of engaging the community with versatile, dynamic, and culturally appropriate approaches to participant recruitment.

Investigators interested in women's health research face the common process barriers of publicity, initial contact, and inclusion screening that are costly and complicate subject recruitment.^{18,22,23} In parallel, women, interested in research participation are challenged by an inability to readily access enrollment information for active clinical research trials. For minority women, this may be an even more significant barrier, as physicians may fail to refer minorities to clinical trials more frequently.¹⁰ The University of Michigan Women's Health Registry was designed to reduce these barriers, with the goal of linking women from all races and ethnicities with researchers. This opportunity to evaluate our e-health database, the Women's Health Registry, identified that our low minority participation was in part due to our lack of success in making the community aware of the existence of this registry and also provided insight into appropriate strategies to increase enrollment.

The results of this study indicate that successful recruitment strategies for African American women will feature community-based, culturally appropriate approaches and that an emphasis on technology solutions, such as online databases, will be successful only if implemented as part of this broader community-oriented approach. Data gathered in this study are being used to develop effective educational campaigns, outreach events, and marketing materials for African American health research participation.

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