# RETENTION OF UNDER-SERVED WOMEN IN CLINICAL TRIALS: A FOCUS GROUP STUDY

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More information is needed to understand how women view their participation in clinical trials. As part of the formative evaluation phase of a 4-year National Cancer Institute funded study, researchers associated with the ''Community Retention Intervention Study'' (CRIS) conducted focus groups to identify additional data on the underlying issues regarding the retention and compliance of under-served women in clinical trials. Six focus groups were conducted: 3 were age-based, and 3 involved participants of the Women's Health Initiative (WHI) clinical trial component in Birmingham, Alabama. A total of 62 women, between 18 and 87 years of age, participated in the sessions: 79% were African-American and 52% reported incomes below $20,000. The qualitative data analysis revealed that women were more inclined to participate in a clinical trial if they, or a family member, would benefit. Noncompliance with study protocols was generally a result of complications or unwanted side effects of treatments. Focus group data were used to develop retention and compliance strategies for the CRIS study. Findings suggest that focus group data can be used effectively to develop retention and compliance strategies specific to under-served women. (*Ethn Dis*. 2003;13:268–278)

**Key Words:** African-American Women, Clinical Trials, Low Income Women, Minority Women, Research Trials, Retention in Clinical Trials, Retention in Research Trials, Underserved Women, Women

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## INTRODUCTION

Federal recommendations highlight the need to include special population groups in clinical research,[1] yet few studies provide researchers with the assistance necessary to meet the recruitment and retention challenges posed by these groups.[2] The retention of special populations throughout the duration of clinical research trials remains a major challenge, and requires special efforts from the research team. Furthermore, tracking non-compliant participants can be very costly, especially in long-term studies.[3,4]

General studies of retention and compliance have found the characteristics associated with non-compliance and withdrawal to include: losing interest in the study, not being assigned to the desired treatment, being of older age, having a lower educational level, being unemployed, being a smoker, being female, being an ethnic/racial minority, and having difficulties with transportation and child care.[5,6] These studies, however, were conducted with general populations and were not minority- and gender-specific. These associations, while perhaps applicable to minority or female populations, may not be the most prohibitive of the everyday difficulties many low income and minority women face. One investigation that focused on women noted that the timing of withdrawal suggested that the complexity of study tasks was related to dropout rates.[7] A study on minority women reported that the factors contributing to dropouts in the intervention group were socioeconomic status and educational level. Those who stayed with the study tended to be wealthier, better educated, married, and employed.[8]

Studies addressing barriers to participation have typically focused on recruitment issues. To the extent that recruitment and retention are inextricably linked, barriers to recruitment have been viewed as retention barriers as well. It is not clear how barriers related to retention (remaining in the study), compliance (keeping study protocols), and recruitment are related. In their review of "the state of the art in recruiting" for clinical trials, Swanson and Ward reported that the major criticism of recruitment scholarship has been its descriptive nature and lack of detailed information on how to increase diverse population participation.[2] Although there has been a lack of data that systematically studied the barriers and the strategies used to increase overall participation of special populations, Swanson and Ward identified 3 general categories of barriers (eg, time and hassle, negative personal and family attitudes, and inadequate evidence of benefits), and additional barriers specific to minorities (eg, knowledge of the Tuskegee Experiment, mistrust, and economics).[2] Based on the results of recruitment studies, strategies for retaining these special populations have to be developed. Although a loose configuration of designs, including community, healthcare provider and system, and individual and family models, have been moderately successful, much remains unknown.[9–14] According to Swanson and Ward, the problem is that researchers are not sure how and why these designs work. Many of these studies lack the detail and documenta-

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tion necessary to replicate research efforts.[2]

This paper reports the focus group findings of the Community Retention Intervention Study (CRIS). The CRIS project was funded by a grant from the National Cancer Institute and included a multidisciplinary and diverse research team that included specialists in obstetrics and gynecology, preventive medicine, public health, health promotion, nursing, social psychology, and sociology. As part of the formative phase of the 4-year study, focus groups were used to address the lack of detailed information about retention and compliance in clinical research trials. Over the last 10 years, the advantages of using focus group data in theory and practice of health education have been reported in the literature.[15,16]

The objective of CRIS was to evaluate the efficacy of a community-based intervention strategy that was designed to enhance low-income and minority women's retention and compliance in cancer prevention trials. First, focus groups were held to assess community women's attitudes, health beliefs, and knowledge about clinical research. Second, a collaborative relationship was established with community leaders. A peer support intervention program was designed based on the Lay Health Advisors (LHAs) and Community Health Advisor Network (CHAN) models to enhance the retention and compliance of women targeted to participate in clinical research trials. The focus groups provided insights on how to retain the CRIS target population: women participating in the Randomized Trial on the Clinical Management of Atypical Squamous Cells of Undetermined Significance (ASCUS), Low-grade Squamous Intraepithelial Lesions (LSIL) of the Uterine Cervix Trial at Birmingham Clinical Center, and the ASCUS LSIL Triage Study (ALTS).

## METHODS

Six focus group sessions were conducted during the formative stage of the project. This method required selecting a purposive sample that would generate the most productive discussions on retention and compliance.[17] Targeted women were invited by letter to attend one of the 6 focus groups. The letter explained the purpose of the study, the focus group format, and that participants would receive a $15 gift certificate as compensation for their time and travel. Those who responded to the invitation and agreed to participate in the focus group were sent a confirmation letter with the time and a map providing directions to the focus group meeting place. Focus groups were held in a variety of settings. The first 3 sessions were held at enclosed rooms at 3 community centers. The final 3 sessions were held in conference rooms at a healthcare facility. Light refreshments were served at each of the 6 sessions, helping to create a social atmosphere in which the women had the opportunity to mingle and get acquainted.

### Recruitment

Our Program Coordinator contacted community agency representatives in the target area and asked if they would be willing to refer women to participate in the focus groups. Our Coordinator had extensive outreach experience with community agencies in the area, and had experience recruiting minority populations in research projects. Of the 50 women who were referred from local agencies and invited to take part in the focus groups, 34 participated (68% response rate). These women were recruited based on the similarity of their demographic characteristics to those of the clinical trial participants (CTPs) targeted for the CRIS project. Focus group participants were low-income women from the large urban area of southeastern Birmingham, Alabama, and surrounding counties. Each focus group reflected one of the 3 age cohorts of the ALTS trial. Focus group 1 included 10 women between 35 and 55 years of age, with a mean age of 40; the 11 women in focus group 2 were between 18 and 34 years of age, with a mean age of 24 years; and focus group 3 included 13 women over the age of 55, with a mean age of 73. The 34 women ranged from 18 to 87, with a mean age of 48 years. Educational backgrounds varied: 27% had not completed high school; 27% had completed high school, and 46% had gone on to receive further educational training. Most of the women (73%) had children, were not currently married (62%), were not employed (70%), and had an income under $20,000 (92%). All focus group participants were African-American.

Data gained from the first 3 focus groups indicated that more detailed information about retention and compliance was needed. It was decided that women with clinical trial experience would be the best ones to provide this type of information. Therefore, 3 additional focus groups were conducted with women who were CTPs. The CTPs were recruited from the longitudinal randomized controlled trial from the Birmingham clinical center of the Women's Health Initiative (WHI) study. The WHI is designed to examine the major causes of death and disability in women, focusing on cardiovascular disease, cancer, and osteoporosis.[18] The focus groups with WHI participants were arranged so the women assigned to

treatment and compliant ($N$=25), treatment and non-compliant ($N$=25), and control conditions ($N$=25) would not be in the same focus group.

Of the 75 WHI women invited to the focus group sessions, 28 participated (37% response rate); these participants included 8 (32%) women from the compliant group, 7 (28%) from the non-compliant group, and 13 (52%) from the control group. The CTPs were between the ages of 53 and 81, with a mean of 65 years. Educational backgrounds varied: 25% had not completed high school; 21% had completed high school; and 54% had more than a high school education. Most of the women (79%) had children, were currently married (61%), were not employed (74%), and had incomes greater than $20,000 (60%). Sixty-one percent (61%) of the CTPs were African-American.

## Focus Group Procedures

Prior to participation in the sessions, women were given program materials describing the purpose of their involvement in the focus group. Consent forms were explained and signed by the participants before continuing. Those who signed the consent form were asked to complete a demographic data form before beginning the actual focus group session. Any woman who asked for, or appeared to need, assistance was helped by one of the research assistants or project investigators. After signing the informed consent form and completing the demographic data sheet, participants were given a $15 gift certificate, which marked the beginning of the discussion session.

At each focus group meeting, participants and members of the research team sat around a rectangular table. The facilitator began each session by describing the purpose of the study and discussing the basic ground rules (eg, that all members' comments were important and that there were no right or wrong answers to the questions) for the sessions. Participants were informed that they did not have to answer questions they felt were not appropriate. They were reminded of the confidentiality of the study, and were also informed that no names would appear in the transcripts of the sessions.

Sessions were recorded using an audio recorder and a directional microphone placed in the center of the table. Research assistants were present to observe the sessions, take notes, and handle technical difficulties. Two of the investigators of the research project, trained in the use of focus group techniques and protocols, facilitated the sessions. Facilitators also took notes at each session. It should be noted that although facilitators were provided information about the WHI, they were not involved in any way with the study. Since it was anticipated that the focus groups would include women from diverse racial and ethnic backgrounds, members of the research team present at all focus group meetings included both African-American and White investigators.

The protocols and questions used in the sessions were developed using the methods outlined by Morgan[17] and Krueger.[19,20] Items were developed to elicit participants' views without superimposing the cultural biases of the facilitators. Questions were open-ended and kept as simple as possible. Care was taken to word questions so they would not create a bias. In order to establish the clarity and utility of the items, the initial set of focus group questions was pilot tested on five women selected from the community, with modifications made according to suggestions. Throughout each of the six sessions, the facilitators used comprehensive probes to fully explore the meaning of the responses. In addition to probes, participants were asked to tell how they felt about specific terms, as well as to provide detailed information about their attitudes, beliefs, and actual experiences.

Focus group sessions began with a general question regarding participants' perceptions of the word, "research." Subsequent inquiries were made about clinical research trials, advantages and disadvantages of participation in a clinical trial, factors that might serve to deter or promote participation, and whether participants would seek advice about participation in trials. One of the questions dealt with the Tuskegee Study. Additional questions and statements were added to clarify participants' responses. For example, a definition for randomization was added to help women better understand questions about randomization. Table 1 provides a list of questions utilized to elicit responses from focus group participants. Questions 11 through 17 were additional inquiries only asked of women participating in clinical trials to further clarify retention and compliance issues. Table 1 also includes definitions of clinical trials and randomization[21] provided to the women.

## Data Analysis

Qualitative data were analyzed using the methodology described by Miles and Huberman, with the participants' responses being transcribed and coded independently by 2 researchers.[22] After the initial coding, the researchers identified patterns jointly. These were analyzed further and categorized into patterns of responses. Throughout the analysis, data were organized using QSR NUD.IST, a computer program that facilitates qualitative data analysis and allows the investigators to explore the data documents and record information about them.[23]

Data analysis was an ongoing group effort by the investigators and data collectors, who met at regular monthly meetings. Transcriptions of sessions were reviewed by the facilitators and revised to coincide with their notes. In cases where it was difficult to determine what was said on the tapes, team members were consulted. If a reasonable reconstruction of the comments could not

**Table 1. Focus group questions and selected definitions used to elicit participants' responses**

| Questions |
|---|
| 1. Tell me what comes to mind when you hear each word: clinical research trial and randomization. |
| 2. Would you be willing/interested to participate in a research study? |
| 3. Would you be willing to participate in a clinical research trial? |
| 4. What would make women like you feel comfortable about participating in a clinical research trial? |
| 5. What barriers do you think would keep women like you from participating in a clinical research trial? |
| 6. What would make women like you feel that you must stay with a clinical trial once it began? |
| 7. What barriers to you feel would keep women like you from staying with a clinical trial once it began? |
| 8. What are some of the ways we could get more women to participate in and complete clinical research trials? |
| 9. Who would you talk to before you decided to be in a clinical trial? |
| 10. Have you ever heard of the Tuskegee Study or Experiment? |
| 11. How did you find out about the Women's Health Initiative (WHI) study? |
| 12. What has it been like to be in the study? |
| 13. What do you like best about taking part in the study? |
| 14. What do you like least about taking part in the study? |
| 15. Would you be willing to participate in a study similar to this one in the future? |
| 16. What would be some reasons for stopping or dropping out of a study? |
| 17. What would you say are one or two things that would improve the study? |

Note: Questions 11 through 17 were additional items asked of WHI participants referred to as clinical trial participants (CTPs).

Clinical research trial: refers to studies that evaluate different ways to prevent or treat a disease, such as heart disease or cancer. These are studies in which patients with similar traits, for example the same type of cancer, are selected by chance, to be placed in separate groups that are comparing treatments.[21]

Randomization: being chosen or selected by chance to be placed in separate groups that are comparing different treatments.[21]

be made, then the statement was left blank. The investigators had in-depth knowledge of the data, since they collected it.

Each transcript was read in its entirety to get a sense of the whole. Individual units in the form of responses to questions or themes from each transcript were identified and coded, using the participants' own words whenever possible. Similar codes were clustered and given an initial category label. Data collection and analysis took place in concert, and, as additional data was analyzed, comparisons resulted in the revision of codes and categories. Through ongoing analysis, the concrete language of the codes was transformed into more conceptual terms. After analysis of the total data set, larger themes encompassing the categories were identified and described.

### Limitations

As with much research utilizing focus groups, this study had shortcomings. The major limitation centers around the sampling procedure. Recruitment of the women for the focus groups was based on a written invitation, rather than on personal contact. Personal contact with potential focus group participants could have identified and reduced potential barriers and logistical problems (eg, transportation, child care needs, and location), and clarified any questions community women may have had, thereby increasing participation. A second limitation of the sampling procedure utilized concerns the final group of women who actually attended the focus group sessions. Background characteristics of the 2 groups of women were quite different. Overall, age based participants (ABPs) were about 15 to 20 years younger than CTPs, but were similar to the target population of the CRIS project. The ABPs were more likely than CTPs to have young children; fewer ABPs had completed college; ABPs reported lower family incomes, and were more likely to be working than CTPs; and CTPs were 2 times more likely than ABPs to be married. Although characteristics of the CTPs were consistent with women who generally remain in clinical trials,[8] characteristics of the ABPs were consistent with women who typically are non-compliant and tend to withdraw from trials.[5,6,8] These sampling issues, therefore, need to be considered when interpreting the findings, especially since the compliant and non-compliant groups were both under-represented in the focus group sessions. Nonetheless, the 6 focus groups provided a unique opportunity to look at issues of retention and compliance from the perspective of women whose clinical trial experiences ranged from some level of involvement to none.

## RESULTS

### Age Based Focus Groups

Table 2 presents the age-based focus group participants' responses to questions concerning their attitudes about participation in research and clinical trials. Overall, a majority of the women indicated that they were aware of research studies, but unable to differentiate between clinical trials and other types of research studies. Several women knew the names of particular studies, and a few reported participating in a study. None of the women reported participation in a clinical trial. A larger proportion of the elderly women (85%), compared to the middle-aged (60%) and younger (55%) women, were aware of research/clinical studies.

When asked if they would be willing to participate in a clinical trial, about 80% of the women said they would not.

**Table 2. Comparison of women's responses to directed questions among age-based focus group participants**

| Responses | Young (M=24 years) % | Middle-aged (M=40 years) % | Elderly (M=72 years) % |
|---|---|---|---|
| Aware of clinical trials | (*N*=11) 55 | (*N*=10) 60 | (*N*=13) 85 |
| Favorable to clinical trial participation in general | (*N*=11) 36 | (*N*=10) 30 | (*N*=13) 0 |
| Favorable to clinical trial participation under certain conditions (ie, must receive the treatment not the placebo, have the disease under study, be provided all valid information about the study, not be pregnant) | (*N*=11) 82 | (*N*=10) 60 | (*N*=13) 92 |
| Most important person giving advice | (*N*=10) | (*N*=4) | (*N*=12) |
| God/prayer | 10 | 0 | 50 |
| Family member | 50 | 50 | 17 |
| Health provider | 10 | 25 | 17 |
| Faith based provider | 0 | 0 | 17 |
| Attorney/lawyer | 0 | 25 | 0 |
| Trial participant | 10 | 0 | 0 |
| Researchers/information | 20 | 0 | 0 |
| Benefits of clinical trial participation | (*N*r=11) | (*N*r=9) | (*N*r=13) |
| Cure of treatment of disease | 36 | 67 | 38 |
| Information to pass on | 36 | 22 | 15 |
| Free medication | 9 | 11 | 23 |
| Other incentives (ie, money, gifts, childcare, transportation) | 18 | 0 | 23 |
| Barriers to clinical trial participation | (*N*r=14) | (*N*r=10) | (*N*r=11) |
| Harmful or dangerous procedures | 43 | 40 | 27 |
| Negative actions and/or impressions of research or health team | 0 | 50 | 45 |
| Boring and time consuming tasks | 14 | 10 | 27 |
| Lack of incentives | 43 | 0 | 0 |

*N*=number of women; *N*r=number of responses given.

The women were quick, however, to clarify their responses. The vast majority in each age group indicated that they would be willing to participate in a clinical trial under certain conditions. Surprisingly, 92% of the elderly women stated that they would participate if the conditions were right. Key to participation for the middle-aged and elderly was their either having a family history of the disease in question, or having the disease themselves. In either of these situations, they considered that they had a vested interest in participation. They also noted, however, that even if they had the disease, they did not want to be a "guinea pig"; rather, they wanted to know that they were receiving the treatment and not the placebo. In addition, they wanted to make sure that they had all the information concerning the risks and potential side effects associated with their involvement in the study. The young women were more concerned about risky treatments and side effects, because they were in their childbearing years and feared treatments if they were pregnant.

When asked, "What would make women like you feel comfortable about participating in a clinical research trial?" focus group members stated that they would seek guidance from a variety of sources before deciding whether they would participate. Fifty percent of the elderly reported that they would consult God and pray for guidance. The advice of family, health providers, and faith-based providers was also reported to be important. Fifty percent of the young and middle-aged women indicated that they would consult a family member regarding their involvement.

Benefits and barriers also affected participation. The women reported receiving "a cure or treatment for disease" as the most important reason for participating, with 67% of the middle-aged group reporting this as a major benefit. Although the women reported that while receiving free tests, screenings, and incentives was important, the ability to have "information to pass on" was also very important. If we used the amount of time the women devoted to discussion of each variable as a measure of its importance to their participation, the most important factor in clinical trial participation for this group of women would be the quest for information. Most of the self-directed or non-questioning related responses of the women centered on acquiring information and knowledge about health. The women felt that their health providers simply did not provide enough information. The women were anxious for more knowledge and information.

Specific barriers to clinical trial participation were also identified. The middle-aged and elderly women were more likely to not participate because of negative actions or impressions they had of the investigators. Risky medical procedures and side effects were deterrents for both young and middle-aged women, while a lack of incentives was also a consideration for young women. Women in all age groups mentioned that boring and time-consuming tasks would also be a barrier to their participation.

## Clinical Trial Focus Groups

Table 3 presents responses to questions directed toward the CTPs. Women who participated in the focus group sessions included women from treatment (compliant and non-compliant) and

control conditions. Clinical trial participants (CTPs) had a better understanding of research, but they were also not sure of the distinctions between clinical trials and other types of research studies.

Women in the compliant and control focus groups rated their clinical trial experience as positive, and had more positive comments about their experiences than did women in the non-compliant group, who expressed mixed feelings. More non-compliant than compliant women reported having complications and treatment side effects. Although boring tasks, such as keeping diaries, and study design issues and concerns about receiving the treatment did affect compliance with study protocols, women who were non-compliant stated several times that complications and treatment side effects were the primary reasons for their non-compliance with study protocols, or their non-retention in studies. Women's responses suggest that retention of participants in clinical trials is based on investigators providing the participants with more positive than negative experiences. Women in the control group seemed to have the most positive comments about their experiences. The women who were non-compliant had more complications and side effects than did women in the compliant or control groups, and refused to continue taking treatments that made them sick or uncomfortable. Although compliance appears to be less in the control of the research team, arming participants with more information about participation, as well as about potential side effects of treatment, appears to be the best way to keep the women compliant with clinical trial protocols.

**Table 3. Comparison of women's responses to directed questions among clinical trial focus group participants**

| Responses | Treatment Compliant (M=64 years) % | Treatment Non-compliant (M=68 years) % | Control (M=65 years) % |
|---|---|---|---|
| General overall clinical trial experience | (*N*=8) (*Nr*=10) Positive | (*N*=7) (*Nr*=7) Mixed | (*N*=13) (*Nr*=19) Positive |
| Benefits of clinical trial participation | (*N*=10) | (*N*=7) | (*N*=19) |
| Positive medical and health outcomes (ie, weight loss, better health) | 20 | 29 | 37 |
| Free drugs, tests, and screenings | 20 | 43 | 5 |
| Free medical diagnoses and advice | 10 | 0 | 0 |
| Health, medical, and nutrition information | 20 | 29 | 26 |
| Positive group interactions with other women | 20 | 0 | 11 |
| Helpful and courteous research/medical team | 10 | 0 | 11 |
| Incentives (ie, gifts, transportation) | 10 | 0 | 11 |
| Barriers with clinical trial participation | (*Nr*=3) | (*Nr*=7) | (*Nr*=5) |
| Complications and treatment side effects (ie, nausea/vomiting, breast swelling and tenderness, menstrual bleeding/pain, growing unwanted hair, weight gain) | 33 | 72 | 40 |
| Keeping diaries | 0 | 0 | 20 |
| Incentives (ie, transportation) | 33 | 14 | 20 |
| Study design issues and concerns (ie, whether receiving treatment or placebo) | 33 | 14 | 20 |

*N*=number of women; *Nr*=number of responses given.

## Compliance and Retention Themes

Qualitative analysis of the focus group data identified 3 major themes related to retention and compliance, including knowledge about research in general, and benefits and barriers to clinical trial participation. Table 4 includes CTPs' and age-based participants' (ABPs) responses to illustrate the data.

## Knowledge

The questions on knowledge described the women's familiarity with research in general, clinical trials, randomization, treatment, and the Tuskegee Study. All participants had basic information about the purpose of research; however, the CTPs were able to give more detailed information. Neither group (CTPs or ABPs) had a clear understanding of the differences between clinical trials and basic research studies. The CTPs reported that they knew that the randomization process of studies was "fair" (unbiased) because the computer was used to assign participants to treatment and control conditions.

The vast majority of women reported that they had heard of the Tuskegee Syphilis Study, though not necessarily as the Tuskegee Study, but as a study of Black men in Alabama. One participant put it this way, "Well, I would like to clear this up. I am not sure that it was necessarily because they were Black, but I think it would definitely be because people were poor and could not do better and did not know. They were less educated." Although most CTPs and ABPs shared the belief that there were safeguards in place to prevent a recurrence of the Tuskegee Study, a few women openly expressed their opinion that this "tragic human experiment" could occur again.

## Benefits

Benefits included the positive aspects of being in a study. Many participants described the benefits of learning more about their health, and being able to help others through their participation. Women in clinical trials described

**Table 4. Focus group themes addressing retention and compliance of non-clinical trial participants (ABPs) and clinical trial participants (CTPs)**

| Themes | ABPs | CTPs |
|---|---|---|
| Research knowledge | Ideas, coming together to find a cure<br>Finding cures<br>Trying to help with a cure<br>Solutions to problems<br>Finding solutions to problems<br>Like a background check-up<br>Studies and searching for something<br>To help us with information going on in our lives | One group gets the treatment and the other does not<br>Clinical trials involve gathering data randomly<br>Randomization is fair<br>Study's purpose is to obtain information |
| Benefits | If I have a history of the disease and need to learn about it<br>Getting medication free<br>If the study would benefit someone else<br>If it is very interesting I would stay in<br>Money or a gift certificate<br>Doctors that make you feel comfortable<br>Provide transportation | Learning experiences<br>It helps me and my family<br>It is motivational<br>Helps to change your eating habits<br>The group reminds you to have your annual exams<br>It was kept interesting<br>The research staff came to our city<br>Courteous staff<br>Staff were personally involved<br>My cholesterol was real high before I joined the study<br>Because of the food study groups I dropped my cholesterol to 195 |
| Barriers | Know it would not harm me<br>Confidentiality<br>Being used as guinea pigs<br>They will tell you anything to keep you in the study<br>Lack of information<br>A lot of shots<br>Too many visits, where you have to take a lot of time off work<br>No childcare<br>No transportation | How many times I would have to come<br>Did not want it to tie me down like a job<br>Safety of the study<br>Types of procedures<br>Not keeping my doctor informed<br>Docs all around watching while you are on a machine<br>Having to write down everything you eat<br>Remembering to take pills<br>Keeping the diary was stressful<br>All the side effects and complications<br>Complications |

additional benefits specific to their study, such as weight loss, and getting free screening tests. In addition, many women found it beneficial to know that others had similar health problems.

Other benefits mentioned were also factors that would allow the study to retain participants. The CTPs and ABPs reported that the staff and investigators were important components in retention. Of particular importance was having an investigative team that was courteous, respectful, and genuinely concerned about them, not just as study participants, but as people. For the ABPs, retention was associated with benefits to self and others, as well as being part of an interesting study. ABPs also mentioned that incentives, such as money, were important features. For the CTPs, retention was based on their being kept informed of the outcomes, and on whether they continued to find participation to be interesting. In addition, CTPs indicated that retention in a clinical trial would be enhanced if the trials focused on health-related issues, such as weight reduction programs, and cancer detection programs. They further stated that they would remain in the study as long as benefits or improvements continued. The CTPs expressed that learning ways to improve their personal and family health was an important aspect of retention.

### *Barriers*

Several barriers were identified. Ethical and commitment concerns reflected the women's fears about clinical trial participation, from recruitment through retention. Spoken fears and concerns included questions about their personal safety, time commitment, and confidentiality. Participants of childbearing age, mainly young ABPs, had concerns about the effect that clinical trials might have on unborn babies, if they were pregnant. Many of the older participants wanted to ensure that their personal physician would receive reports about their health status from the study physicians. Both the CTPs and ABPs reported that they were willing to ask investigators to address these fears and concerns.

Middle-aged and older women in focus groups would not direct all of their questions to the investigative team. Most of these concerns revolved around

ethical issues related to research and the integrity of the investigative team. One of the most prevalent concerns was that women did not want to be used as "guinea pigs." Age-based participants (ABPs) were concerned about painful procedures, such as injections. Other concerns reflected their fears of contracting a disease, such as AIDS, through injections with blood. The CTPs were concerned about the possibility that, in order to retain them in the study, investigators would withhold negative information from participants, such as the discovery that a participant had contracted a disease and should discontinue treatment. Yet, some CTPs praised the investigative team for alerting them to health problems, such as an abnormal mammogram, and assisting them in pursuing follow-up treatments.

To discuss the ethical concerns, participants stated that they would go to individuals other than members of the investigative team, such as a family member, or another health professional not associated with the study. For example, the ABPs expressed a concern about being randomized to the control group because they would not be given the "drug/medication" and would have preferred to receive the "drug treatment." Interestingly, one of the non-compliant CTPs reported that some participants had their "pill" checked by a pharmacist to see if they were getting the "sugar pill" or the "real medication." Many of the older ABPs talked about going to God in prayer before they made their decision about participating in a study. As one participant described it, "Yes, I'd go to God first. He's going to be your sign. He is going to let you know." Younger and middle-aged ABPs stated that they would talk to a person who had already been through the clinical trial, in order to find out what was going on. One middle-aged ABP expressed it this way, "Because sometimes doctors will tell you anything to get you to participate. I'm serious."

Other barriers focused on the negative aspects of being in a study. The most commonly reported barrier by the CTPs was that of risks, such as those related to side effects from medications, or participants not being told that they have a disease. Another barrier reported was having family members who discouraged participation (particularly at the time of recruitment). For the CTPs, a common negative aspect of being in a clinical trial was expressed as "tasks related to the study," such as having to keep a written diary. In addition, a few of the CTPs mentioned inconveniences, including multiple trips to the research site and lack of convenient transportation.

## DISCUSSION

The purpose of this focus group study was to describe women's views of retention and compliance in clinical trials. Views were elicited from a purposive sample of predominantly minority and low-to-middle income women, between the ages 18 and 87, who resided in or near a large urban area in the southeastern United States. Therefore, implications must be limited to a population with these characteristics.

Strengths of this study include: 1) a sample that included women from the community (3 age cohorts), and women whose clinical trial experiences ranged from none, to compliant, or non-compliant involvement; 2) a diverse and multidisciplinary investigative team; 3) the expertise of the community outreach coordinator with established ties to the communities; 4) the support from the WHI investigators to facilitate involvement of the CTPs; and 5) the use of focus groups as a data collection methodology to assess the culture under study.

Discussions with the women in the CTP and ABP groups revealed similar themes associated with concerns related to the retention and compliance of women in clinical trials; however, they used very different language to express these concerns. The CTPs were more likely than ABPs to use the terminology of the investigators. For example, CTPs would say "gather data, the study's purpose, type of procedures, annual exams, and side effects," whereas the ABPs would say "finding cures, solutions to problems, harm me, getting medicine free, a lot of shots, and a lack of information." Although the CTPs may not have completely understood the meaning of the term "randomization," they knew that it made the assignment of individuals to treatment groups "fair."

Overall, the vast majority of women in the study were knowledgeable about the purpose of research. Women in clinical trials provided more detailed information about the research process, and were able to understand and describe how participation in a study might affect their own health. Findings related to the Tuskegee Experiment were important, too. Although most of the women in the focus groups believed that safeguards were currently present to prevent the repeat of such tragedies, some remained uncertain; this uncertainty may be reflected as a lack of trust in the study investigators.

Clinical trial participants (CTPs) had more information and experience with clinical research trials. This experience was reflected by their use of 'research jargon'; they were more willing to discuss their concerns in greater detail. This group of women was more likely to have clinical trial-specific concerns, such as the strenuous task of keeping a diary, or remembering to take pills. The ABPs reflected concerns that were raised in the literature; they were more likely to mistrust investigators, and to have monetary and childcare issues.

A new finding expressed by women participating in clinical trials was the beneficial value of the group to support and motivate study participants. Women found it helpful to be able to share their health concerns with others who had similar problems. In addition, they

found that group discussions were important for helping them follow the clinical protocols. Another potential barrier to women's continued participation in clinical trials that was raised, but did not seem to affect this group of women, was that of a family's positive or negative comments regarding participation in a trial these comments could either help or hinder a participant's initial recruitment and continued involvement and retention in a study. The family's opinions and support could be very important to the woman remaining in a study, especially when she had questions and did not feel comfortable talking with the investigators or program staff. The family's perspective is critical to the decisions made with respect to the participant's ethical fears and concerns. This factor is worth mentioning because it would probably not be a barrier apparent to the investigative team.

Several inferences can be made from these findings, and may have a direct impact on retention. These women wanted to be a part of an interesting study, especially if they could continue to learn about their health and to pass this information to others. If the study includes time-consuming and boring tasks, then the participants need to understand the importance of these tasks. The participants wanted to feel that researchers valued them and the time that they devoted to the study. If the women felt that they were not valued, they were less likely to comply with study protocols and were more likely to drop out completely. Economics seemed to be a factor in retaining participants, since 60% of those retained had incomes greater than $20,000. Clinical trial participants (CTPs) did not feel that monetary incentives were a key factor for retention; they appreciated that travel and other financial concerns (eg, paying for screening, doctor visits) were taken care of by the project, and these considerations seemed to lead to more satisfactory feelings about the project staff. However, the non-clinical trial participants felt that monetary incentives would be important to keep them in a study.

An additional finding was that of the critical role the investigative team plays in retention efforts. Foremost are the interpersonal skills of the team in developing long-term trusting relationships with study participants. These relationships begin with recruitment and continue through the conclusion of the study. Providing participants with honest information, especially about the study's risks and benefits, as well as about safeguards addressing these risks, was essential to retention and compliance. Based on this study's findings, participants wanted to be informed of the study outcomes. They indicated that they wanted a partnership with the researchers (and certainly did not want to be "guinea pigs").

In general, results were comparable to those of other studies related to retention and compliance. Our findings, however, suggest that under-served women may be more knowledgeable about potential risks involved in clinical trials than was previously thought. These women wanted to know exactly what risks were involved, that their participation would be beneficial, and that they would experience more positive than negative outcomes. In addition, these women were interested in maintaining their health. They tended to trust the healthcare system and study investigators when they were treated courteously and with respect. When they had fears and concerns, however, the women tended to request advice from people they knew well, and to turn to their own spirituality for answers, rather than seeking advice or answers from the investigative team.

### *Recommendations*

The literature on retention of minority and low-income women in clinical trials is limited.[2] First and foremost, focus groups are useful in the cultural assessment of the community's knowledge, attitudes, and beliefs related to clinical trials. The focus group format allowed us to gain insight and understanding by hearing the fears of the women; however, it is not clear whether these fears will be the same for each community. Time and funds must be devoted to the assessment and development of culturally appropriate recruitment and retention strategies. Recruitment, compliance, and retention issues must be taken into account at the time a grant proposal is submitted for funding. These issues cannot be an afterthought when the project runs into retention problems. Federal agencies should consider participant cost issues when funding research. Traditionally, funds have not been available to recruit and retain minority and low-income populations.

Other recommendations relate to the investigative team's early establishment of trusting relationships with the study participants. A key element to a trusting relationship is open communication. The investigative team must provide clear, honest information about the study's risks and benefits. The women were quite emphatic that non-compliance with study protocols was generally a result of complications or unwanted side effects of treatments that made them sick or uncomfortable. The study's safeguards should be explained and reinforced periodically to allow an honest exchange regarding the participants' treatment experiences. It should be noted that the investigative team will also be evaluated. The women studied were perceptive and observed how the investigators treated each other. Participants cannot be fooled by the pretense of good will. The interpersonal skills of the team members are just as important as their research skills.

Also, communication must include the participant's family from the earliest phase to the conclusion of the study. For example, special sessions should be conducted for families to address concerns about the clinical trials. Throughout the

study, investigators should disseminate information to the participants and their families about the study and its progress. In addition, they should incorporate ongoing focus groups, facilitated by an external team, to identify the participants' concerns.

It is also recommended that studies be interesting to the participants. Staff members are crucial to maintaining participants' interest in a study by making each visit special and interesting. These women reported that they were motivated to stay with the study if they received culturally appropriate materials, as well as incentives, such as transportation vouchers and gift certificates. Interest can also be maintained if the investigative team demonstrates an ongoing appreciation of the participants' efforts. This appreciation may take many forms, but must include expressions of thanks for their "faithfulness" and compliance on behalf of the study.

## The CRIS Project Retention and Compliance Strategies

Based on the focus group sessions about the clinical trial participation of under-served women, 3 major findings were used as the foundation for an 8-week training session for the investigative team. First, the women were not likely to speak to the investigative team about a problem or a concern, tending to address their concerns to other participants. Second, they were willing to remain in the study and comply with protocols if they perceived some personal benefit from their participation. However, most of the women with clinical trial experience had trouble understanding the benefits of participation if they did not receive the treatment. Third, the women were likely to remain in the study and follow protocols if they had a positive relationship with the investigative team, and assessed them highly in terms of trust and integrity.

In keeping with our findings and recommendations to address retention and compliance barriers, a strategy was developed to recruit and train community women (volunteers) as a part of the investigative team. The training included learning how to translate clinical trial information to participants. The investigative team was taught how to anticipate and deal with problems or concerns even before they occurred. The team also had to learn to devise ways to help CRIS participants understand the benefits of being part of a control group. A more detailed description of the training program will be reported in another publication.

*The study's findings suggest that investigators appear to be improving their image within the community by educating women and minorities about the need for research.*

## SUMMARY

Women in these focus groups were interested in research that would provide them with good information that they could use to improve their health, prevent disease, and help their daughters and generations to come. In addition, non-compliance among this group of women was primarily a result of complications and unwanted side effects of the treatment. The study's findings suggest that investigators appear to be improving their image within the community by educating women and minorities about the need for research. Based on these findings, specific retention and compliance strategies were incorporated into the CRIS project.

In general, when attempting to retain young women in any clinical trial, researchers should consider including parents and significant others in all relevant discussions. They must also provide the young women and family members with complete and honest information about all possible risks associated with the study. The research team should offer gift certificates, child care, or transportation to young women, in an attempt to improve their retention and compliance with the study protocol.

To enhance the retention and compliance of middle-aged and older women, special attention needs to be given to how the investigative team members interact with participants and each other. Researchers need to emphasize the potential study risks and translate this to participants so they have a better understanding of how their participation may enhance their own health, or that of other family members.

We found that focus group sessions were an effective method to assist investigators in addressing participants' concerns. Focus group findings were instrumental in the development of retention and compliance strategies for the CRIS Project. These findings suggest ways that under-served women can be retained in clinical trials and may be better able to comply with clinical protocols. There is still much work to be done to succeed in retention efforts. To be successful, clinical trials must retain the participants that are recruited.

### ACKNOWLEDGMENTS

Supported in part by grant #1R01 CA73364-01 to the University of Alabama at Birmingham from the National Cancer Institute (NCI), Bethesda, Maryland. The authors acknowledge the commitment, hard work, and dedication of the CRIS research team. Special thanks are extended to Martha Williams and Trinita Ashford for administrative support; Joanice Thompson for community outreach and recruitment of focus group participants; and Daane Logsdon and Cornelia White for organizing and assisting with the focus group sessions.

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