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An Ethno-medical Perspective on Research Participation: A Qualitative Pilot Study

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Abstract

Background: Recruitment of racial/ethnic minorities for clinical research continues to be problematic, yet critical to ensuring that research data will be applicable to diverse populations. There is a paucity of information about culturally appropriate methods for recruiting and retaining racial/ethnic minorities in research.

Objective: To cross-culturally assess perceptions of research participation by African American and immigrant Latinos living in the inner-city community of Watts, Los Angeles, California, using qualitative methods.

Design: Focus groups using ethnically matched moderators were convened with African American and immigrant Latino participants. Discussion was facilitated using a script that focused on perceived "feelings" and "perceptions" about research. Discussions were audiotaped, transcribed, and analyzed using manual and computerized statistically based software (mixed) methods.

Results: African Americans and immigrant Latinos shared several barriers and motivators to research. However, they also reported barriers and motivators to research that were distinct to each group. Latinos were more interested in healthcare and health information, and African Americans were more concerned with issues of trust and quality of care. Most participants said they would participate in research if they were better informed, or if they or a family member had an illness. Improving communication was reported as being important for motivating participation in clinical research. Overall, socioecologically and socioeconomically based domains were shared, whereas historically and/or socioculturally based domains were distinct.

Conclusions: Using an ethno-medical science model, we demonstrated that it is possible to identify shared barriers and motivators to research participation between 2 distinct cultural groups. This approach can be useful in developing targeted community-based strategies to increase minority participation in clinical trials.

Readers are encouraged to respond to George Lundberg, MD, Editor of *MedGenMed*, for the editor's eye only or for possible publication via email: glundberg@medscape.net

Introduction

Ethno-pharmacologic, sociocultural, biobehavioral, and epidemiologic studies support race and ethnicity as predictors of medication efficacy, clinical and health outcomes, and population health status.^[1-7] However, current evidence points to insufficient recruitment and retention of racial/ethnic minorities in medical research despite obvious need, as suggested in National Institutes of Health (NIH) mandates for their inclusion.^[8,9] Evidence accrued from cellular and molecular biology, behavioral and social sciences, and population-based studies aimed at improving prevention, detection, treatment, and management of chronic diseases may therefore be limited in its applicability to racial/ethnic minority populations. Since there has not been optimal application of evidence-based findings, improvement of the quality of

care for racial/ethnic minorities has been hampered.

NIH mandates for inclusion of racial/ethnic minorities have succeeded in encouraging accountability in research design, institutional review board approval, and federal research funding.^[10-12] However, they have not been as successful at helping investigators substantially improve recruitment and retention.^[13-15] These mandates also recommend the recruitment of research participants at the point of healthcare utilization.^[16,17] Examined in the context of this recommendation, persistently poor participation of minorities in research studies may signify that obvious barriers to the optimal utilization of biomedical healthcare facilities have their analogues in continued barriers to research participation, and that the study of the latter should be linked to the study of the former.

Though they share such characteristics as low socioeconomic status, poorer access to biomedical healthcare, poorer quality of care, and health disparities, minority cultural subgroups differ in their perception about healthcare and healthcare utilization and are also likely to differ in their perceptions about research and research participation.^[18-20] Ethno-medical science is the study of how different cultural groups perceive disease (in health and illness), how they align themselves to healthcare (preferences, access), and what kind of social organization the healthcare they choose (biomedical or traditional) fits into.^[21-23] Cross-cultural studies that examine barriers and motivators to utilizing healthcare and research opportunities are needed.^[24] Results from such studies may contribute to an ethno-medical model of research participation that may guide development of culturally appropriate recruitment strategies for multicultural minority populations.

An ethno-medical model of research participation posits that culturally based perceptions about health and illness influence the utilization of research opportunities through the mediating effects of cultural understandings, preferences, access to and utilization of biomedical healthcare in all its tiers, as well as obvious political economic constraints. Although it is known that use of traditional healthcare may be a barrier to utilization of biomedical care, this model posits that, for some illnesses, utilization of biomedical care may be inevitable with worsening health, and that dissatisfaction with biomedical care (eg, poor communication and understanding) may motivate patients to continue to seek traditional healthcare. The model emphasizes the likelihood of minority research participants being drawn from those who access biomedical healthcare, leaving beyond the umbrella of participation those who, for lack of understanding or any number of socioeconomic and/or culturally based reasons, fail to utilize it (Figure 1). An ethno-medical science model applied to research participation may help to unravel the complex set of factors that limit full application of current evidence-based medicine to racial/ethnic minority groups.

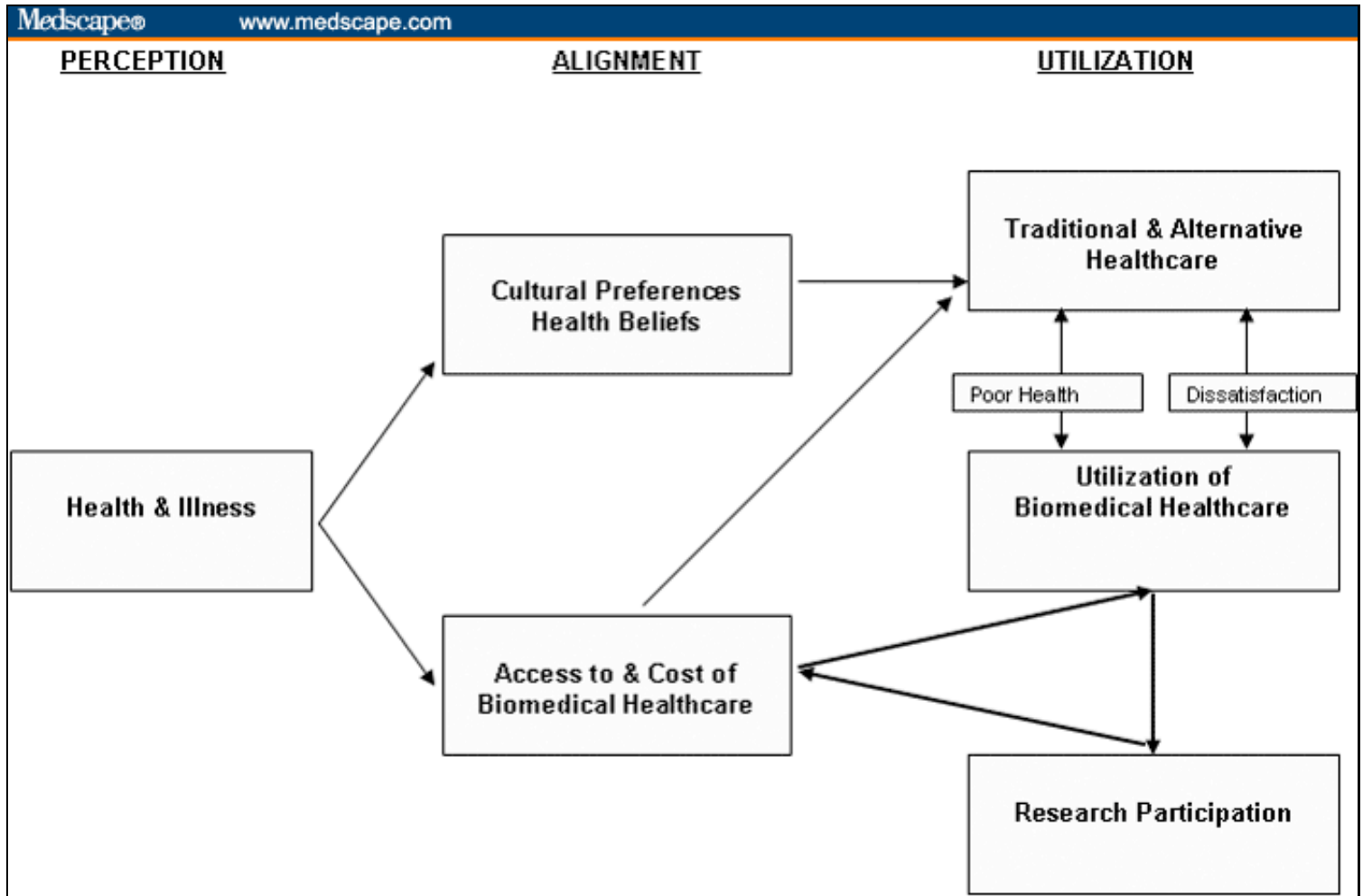


Figure 1.

Ethno-medical model of research participation.

Current knowledge of attitudes and beliefs about research participation by racial/ethnic minority populations is mainly derived from studies with African Americans.^[25-29] Fewer studies have reported Latino perceptions of participation in research (the largest minority group).^[30,31] Even less information is reported about Asian subgroup perceptions, and virtually no information is available on Pacific Islander perceptions about research (the fastest-growing minority groups).^[32,33] Moreover, little is known about cues to action that may encourage or discourage diverse racial/ethnic minorities to participate in research.

The purpose of this paper is to report the results of a qualitative pilot study that used an ethno-medical science framework to examine research participation among African Americans and immigrant Latinos from Watts, South Los Angeles, California. This pilot was not intended to report the full richness of text that results from qualitative data but rather to apply an ethno-medical science model to the investigation of perceptions, barriers, motivators, and values surrounding research participation among culturally diverse groups. Results from this study were the basis for a larger, NIH-funded, multi-institutional, multicultural, multigeographic, qualitative study on racial/ethnic minority group research participation that is ongoing.

Study Design and Methods

This pilot study was phase 1 for the larger collaborative research initiative, "*Minority Involvement in Clinical Research Opportunities Project*" (Project MICRO). The overarching objective of Project MICRO is to use an ethno-medical

science model to study perceptions of (including cultural health beliefs), alignment toward (barriers and motivators), and utilization of clinical research opportunities across several cultural groups. Project MICRO is a Research Centers in Minority Institutions Translational Research Network (RTRN)-initiated, National Center for Research Resources, NIH-funded, multi-institutional (*Drew University, Meharry College, Morehouse University, UCLA, University of Hawaii, University of Puerto Rico*), multicultural (*African Americans, Central American immigrants, Filipinos, Hawaiians, Mexican Americans, Mexican immigrants, Puerto Rican Islanders, Samoans, whites living in poverty*), and multilingual study (*English, Hawaiian, Ilocano, Spanish, and Tagalog*).

Phase 2 of the study calls for convening 40 focus groups with up to 400 participants across 5 geographic sites; Atlanta, Los Angeles, Nashville, Oahu, and San Juan. Results from this study may lend insight into factors that impede or enhance research participation across diverse racial/ethnic minority groups and may allow us to develop an ethno-medical science-based theory of research participation.

Design

Phase 1 was implemented at the King/Drew Medical Center (KDMC), a public safety net hospital that is the primary healthcare provider for many of the 1.5 million residents of South Los Angeles. This service area has the highest concentration of minorities (65% Latino and 30% African American), the poorest health status, highest poverty rate, lowest educational attainment, and one of the highest rates of limited English proficiency in Los Angeles County.^[34-37]

The KDMC Institutional Review Board approved this study. Four exploratory focus groups homogenized by gender and race/ethnicity (immigrant Latino and African American) were convened for this study. Focus groups are unique as discussion groups in that they represent a type of structured interview that generates qualitative data using predetermined questions.^[38] Focus groups have been used successfully to assess African Americans' and Latinos' perceptions of and attitudes toward chronic disease.^[39-42]

Methods

Proactive (face-to-face) and reactive (response to flyer) recruitment methods were used at community-based clinics and at KDMC.^[43] Informed consent was obtained from study participants prior to each focus group and read aloud in English and/or Spanish to ensure comprehension given widespread limited literacy in South Los Angeles. A short demographic survey was administered at the end of focus group discussions. Each participant was remunerated \$40 for their time and travel, and a small meal was served before convening the group. An ethnically matched moderator led each group, and discussions generally lasted about 2 hours. All sessions were audiotaped and transcribed for data analysis.

We constructed a focus group script with introductory, transition, key, closing, and summary questions to foment discussion (Table 1). Introductory and transition questions generated discussion about knowledge and perception of medical research, key questions generated discussion about barriers and motivators to research participation, and closing questions generated discussion about the value placed on medical research by the participants and their willingness to participate. Summary questions generated open-ended commentary and wrapped up the session. This format was adopted as a template for scripts used in the qualitative, multicultural, multi-institutional phase 2 of Project MICRO.

The script was adjusted to less than 6th-grade level readability (considered very easy to read) using the Flesch-Kincaid readability formula and Flesh Reading Ease Index available on the Microsoft Word 2000 program.^[44,45] It was translated into Spanish using forward translation, independent back-translation, 4 independent conceptual and semantic equivalence ratings, and a final translation after modification of the original English version based on conceptual and semantic equivalence rating.^[46-48] In all, 3 independent translations were used. Cultural adaptation for use among diverse Latino subgroups was accomplished by committee review and consensus agreement by 4 fully bilingual Latino nurses from the Drew clinical trials Unit representing 4 subgroups (Colombian, Cuban, Mexican, Puerto Rican).^[49,50]

Data Analysis

Full transcripts were generated from audiotapes of the group discussions. Analyzed text consisted of participant

responses to focus group questions, moderator probes, and retorts to responses by other participants. Discussion generated by focus group questions that are categorized within a script form unique sections of text that in our experience facilitate content and inductive analysis of focus group data.

Manual and computerized methods (mixed) were used to analyze the qualitative data based on a grounded theory approach. Grounded theory is an inductive method of qualitative data analysis that generates theory using a variety of strategies.^[51] Manually, we used constant comparison to code and merge data within cultural groups (Latino or African American) and then categorized and merged data across groups to seek similarities and differences in perception and attitude toward research participation. Computerized analysis was accomplished using the Atlas.ti qualitative software program. This program has code-and-retrieve capability that allows coding of phrases and sections of text for later retrieval, merging, and analysis. For computerized analysis, we used the grounded theory approaches of theoretical sensitivity, theoretical sampling, and discovery of core variables to identify basic social processes that may influence perceptions, alignment to, and utilization of clinical research opportunities among Latinos and African Americans. An advantage of the Atlas.ti program is its code-based theory building capability, which allows the analyst to write, code, retrieve, merge, and analyze memos and comments made about phrases or sections of text. And finally, we triangulated data derived from 3 independent applications of the Atlas.ti software and 1 manual analysis of the text.

Results

The study cohort comprised 20 men and 12 women; 16 were Latino and 16 were African American. The age of Latino men ranged from 28 to 73 years (median, 40) and that of African American men from 27 to 70 years (median, 50). The age of Latino women ranged from 42 to 63 years (median, 50) and that of African American women from 36 to 54 years (median, 47). The median educational attainment was grade 11.5 (range, 8-13) for African Americans and grade 6 (range, 0-12) for Latinos. Unemployment and unmarried status were more prevalent among African American participants (11/16 and 10/16, respectively) compared with Latino participants (6/12 and 1/12, respectively). Of the 16 Latino participants, 14 were born in Mexico/Central America and had immigrated to the United States within the last 10 years.

Knowledge and Perception of Research

African American women (n = 8) participants had greater knowledge of research, followed by Latino men (n = 12), African American men (n = 8), and Latino women (n = 4), as measured by the extent and content of discussion about advertisements (TV, newspaper, magazines), recruitment efforts (proactive and reactive), personally knowing someone who participated in research, and personal experience with research that was facilitated by probing (eg, moderator queries supporting and expounding on predetermined questions in the script as needed).

There was good participation and vigorous discussion in both African American focus groups. There was consensus among the African American women that they had seen recruitment flyers posted in clinics at KDMC and had seen advertisements for research in public places and on television. All African American women participants had seen Dionne Warwick's television infomercial on breast cancer (a Grammy award-winning African American singer who lost 3 sisters to this disease). One African American woman had a friend who participated in schizophrenia research and admitted that her friend was motivated by the money offered. Three African American women were approached about participating in medical research, but only 1 had personal experience as a research participant. This woman claimed her participation saved her life since she was homeless at the time, and participation gave her access to social services and healthcare.

A few of the African American men had seen medical research recruitment information in the hospital, but none had been approached to participate. One African American man described research he had heard about. When asked where he had heard of a study on shark brains that was to be applied to human brains, he responded with the name of a popular movie, *Deep Blue Sea*. The African American groups were probed about the Tuskegee Research Study involving African American men. Only 1 female participant had knowledge of this well-known syphilis study, and 1 African American man claimed to have heard of the study. The latter cited *Tuskegee Airmen*, a popular cable television-produced movie and true story of African American fighter pilots who were discriminated against during World War II, as his source of information. This probe was not presented to the Latino focus groups, as it was deemed culturally inappropriate to ask a question about an event in American history and biomedicine to participants that were likely not to know given their country of origin, socioeconomic status, and cultural distinction.

Men in the African American focus group did not know anyone who had participated in research, but one participant claimed he attempted to enter an AIDS study but was turned down because of his health status. With the exception of the African American woman who had participated in research, there was consensus in both African American focus groups that medical research treats people as "guinea pigs" and that they "feared experimentation," especially without their knowledge. There was consensus in the African American groups that African Americans are probably experimented on without their knowledge. One man claimed he was experimented on during a hospitalization for surgery; he underwent 3 procedures that weren't explained to him.

Though they apparently had less knowledge than African American women, the Latino men's focus group was the most vigorous in their discussion of medical research, as measured by spontaneity of discussion and less need for probing on this issue. All the men in this group had heard of medical research and experimentation in their country of origin. Two Latino men had heard of research recruitment locally, but none recalled where they heard the information or knew details of specific research studies. None were approached to participate in research until this study. The 9 Latino men who were of Mexican origin heard of the deaths of women who were part of a research study conducted in Mexico on TV news, but none knew details about the type of research. The other 3 participants were Central American and had not heard of research on women conducted in Mexico.

The Latino women's focus group was the least vigorous of all, and Latino women were less outspoken, more difficult to engage, and needed more frequent probing to foment discussion. When asked questions about research, they tended to digress from the topic it represented. Of note is that, when asked "what medical research do you think is needed in your community?" Latino women did not respond until asked a third time. Furthermore, responses were digressions to their need for free healthcare and health information in Spanish. However, there was consensus in the Latino women's group that they had heard of research opportunities on Spanish television. None had been approached to participate and none knew someone who had been approached before participating in this study.

Barriers to Research Participation

Eighteen barriers to research participation were identified in this study; 7 were shared by African Americans and Latinos, and 11 were distinct to one or the other group (Table 2). It is notable that 5 of the 7 barriers shared by African Americans and Latinos in this study are socioecologically and socioeconomically relevant to people living in urban poverty (eg, lack of transportation; number of visits required; limited financial resources; lack of childcare; time conflicts). Of the 11 distinct barriers to research participation, 7 had sociocultural and political characteristics germane to the experiences of immigrant Latinos living in a dominant society (eg, communication barriers, immigration status) and 4 had historical and political characteristics germane to the experiences of African Americans in American society (eg, mistrust of medical institutions and institutional racism).

Motivators to Research Participation

Fifteen motivators to research participation were identified in this study; 6 were shared by African Americans and Latinos and 9 were distinct to one group or the other (Table 3). It is notable that the 6 motivators shared by these groups related to personal and family health status and socioeconomic factors, and that the latter were motivators directly related to overcoming socioeconomic barriers to research participation. Of the 9 distinct motivators to research participation, the 7 that were cited by Latinos included burden of disease in family, burden of disease in community, susceptibility to disease, access to healthcare, access to medicines, access to health information in Spanish, and access to Spanish-speaking staff.

The 2 motivators cited by African Americans included personal health status and remuneration. One notable contrast between the groups was that burden of disease in family and burden of disease in community are important motivators for immigrant Latinos, whereas personal burden of disease is an important motivator for African Americans. However, there was consensus within both Latino and African American groups that helping a family member with disease would motivate research participation.

African Americans and Latinos shared perceptions about medical research in citing that research is important and necessary. However, there was agreement in all groups that they would not participate in research to find new treatment for diseases with available treatments. There was also agreement that fear of being used for experimental purposes may prevent them from participating in medical research.

Though both groups cited fear of experimentation as a barrier to research participation, inductive data analysis revealed important differences in the perceptions of African American and Latino men in this regard. The Latino men's group vigorously discussed experimentation, and there was agreement within this group that in their countries of origin, most people believed they may be part of a medical experiment when accessing healthcare. By contrast, there was agreement among African American men that the racism and differential treatment they experience when accessing healthcare would likely occur if they participated in research. For Latino men, access to treatment and medicines outweighed fear of experimentation. For African American men, fear of experimentation outweighed access to treatment and medicines.

With the exception of perceived barriers and motivators that were shared by both groups and the greater importance attached to childcare by the women from both groups, there were important contrasts between men and between women across groups in how they perceived research participation. African Americans in this study placed more value on remuneration, whereas Latinos placed more value on access to healthcare and health information. Furthermore, content and inductive data analysis revealed that African American women and Latino men were more likely to participate in medical research, whereas African American men and Latino women were less likely to do so.

Discussion

We applied an ethno-medical science model (Figure 1) to elicit, clarify, and help formulate a realistic and valid representation of the understandings and perceptions of research and research participation of 2 culturally diverse groups. We sought to compare African Americans and immigrant Latinos in terms of their thought worlds and habit patterns in the area of healthcare utilization and participation in research protocols. The model was based on cultural knowledge in the field of comparative studies of medicine. It involved comparisons of perceptions about health, healthcare access, and utilization. An explicit focus and aim was to clarify needs and consumer understandings of biomedical tenets and of the research enterprise as exemplified in minority subjects, particularly barriers to their participation in programs of biomedical research. Using this model in this study revealed that barriers and motivators to research participation shared by African Americans and Latinos are based on socio-economic factors. In addition, barriers and motivators that were distinct to one or the other group were based on historical and sociocultural factors.

Reports from studies that have investigated barriers to successfully including minorities in clinical research are mostly based on African American populations and cite issues related to mistrust of scientists, Caucasian researchers, and the medical establishment, as well as historical events that have contributed to this mistrust (particularly the Tuskegee Syphilis Study of African American men), as recurring themes.^[52-54] Our study confirms this mistrust of research among African Americans. However, it is notable that this mistrust had no basis in knowledge of historical tragedies such as the Tuskegee study, but rather is based on experience with institutional racism in healthcare, which may dissuade African Americans from participating in research. This is in keeping with a recent meta-analysis of 28 large clinical trials that reported severe under-representation of African Americans in overall completed clinical trials (0%-8%) and diabetes clinical trials, and the need for oversampling in clinical trials on hypertension.^[55]

Immigrant Latinos in this study reported difficulty communicating in the healthcare setting, which is not new knowledge. However, that they perceived difficulty obtaining health information and lack of free or affordable healthcare as significant barriers to participation in medical research is new information. Furthermore, they reported that communicating in Spanish in the healthcare setting regardless of the provider's race/ethnicity, access to health information that is usable, and access to free or affordable healthcare are key motivators to research participation. Further studies that examine Latino perceptions about barriers and motivators to research participation are needed.

Though there is much concern about culturally appropriate recruitment, little has been reported about specific barriers and motivators or about perceptions of research participation across diverse racial/ethnic populations. Enhanced recruitment and retention of diverse racial/ethnic minority groups in clinical research has been reported through trust-building activities such as applying university resources during times of critical need, participating in the political process regarding health concerns, employing researchers and staff reflective of the community, using participatory approaches to research, and communicating research outcomes to study communities.^[56] However, other reports cite considerable difficulty recruiting minority group participants despite committing considerable time, effort, and money to meet their recruitment goals, including involvement of a community-based advisory committee, school district, and the hiring of local staff.^[57]

Given the continued suboptimal recruitment of ethnic minorities and their reticence to participate in medical research, multicultural, multilingual, population-based research that accrues detailed information about the political, social, cultural and socioeconomic factors influencing research participation are needed. Moreover, an ethno-medical perspective has been suggested as necessary for developing culturally and linguistically appropriate health communication for multicultural populations and has relevance to developing similar approaches to appropriately inform and enhance research participation by racial/ethnic minorities.^[58,59]

Study limitations include those relevant to the use of qualitative focus group research. The small number of groups and the qualitative nature of the study mean that results may not generalize to a broader population of African Americans. However, the intent of this pilot study was to assess the feasibility of using an ethno-medical science model as a framework for designing a larger research study, the findings of which may be generalized to the larger populations of racial/ethnic minorities. Another limitation is the use of only Spanish-speaking Latino groups. Though the intent was to pick groups that had differences that were obvious, the addition of English-speaking or nonimmigrant Latino groups may have added another dimension in our understanding of how acculturative factors influence research participation. Of importance, our findings contribute a framework for developing a cross-cultural understanding of shared and distinct barriers and motivators to research participation that may help investigators in recruiting participants from culturally diverse populations.

That there were more culturally distinct than shared barriers and motivators reported in this study and that they relate to healthcare utilization may mean that investigators should pay closer attention to differing cultural perceptions about healthcare utilization when aiming to recruit participants into research studies from culturally diverse communities. Moreover, African Americans and Latinos in this study reported motivators to research participation that were shared by or distinct to them. An understanding of shared barriers and motivators for diverse racial/ethnic groups may contribute to the development of recruitment strategies that are cross-culturally valid. Notably, an ethno-medical science model for assessing research participation in diverse cultural groups may contribute to developing an ethno-medical theory of research participation that is cross-culturally applicable. Research recruitment and retention strategies based on an ethno-medical perspective on research participation may be one way to address the ongoing challenge of poor research participation by minority populations.

Table 1. Focus Group Script

I.	Introductory Questions What is medical research?
II.	Transition When you hear about research, what comes to mind? Do you think medical research is needed? Why or why not? What research have you heard about? Where did you hear about this research?
III.	Key Questions Have you been asked to be in medical research? What would stop you from taking part in medical research? What would encourage you to take part in medical research? How do you feel about patients being in medical research?
IV.	Closing Questions Is medical research important to your health? Is medical research important to your family? Can medical research help your community?

	What research is needed in your community?
V.	<p>Summary Questions</p> <p>Moderator summarizes the discussion and seeks respondent validation.</p> <p>a. Did this summary cover what we talked about?</p> <p>b. What would you add to our talk?</p> <p>c. Would you do Focus Group research again?</p> <p>Thank you for your time today. Your opinions are very important to us.</p> <p>This script has a reading grade level of 5.6 and is considered very easy to read as measured by the Flesch-Kincaid readability formula and the Flesch Reading Ease Index, respectively.</p>

Table 2. Shared and Distinct Barriers to Research Participation

Shared Barriers	
Fear of experimentation/harm	
Research for disease with current Rx	
Transportation	
Lack of financial resources	
Time conflicts (work, family)	
Need for childcare	
Number of visits required	
Distinct Barriers	
Immigrant Latinos	African Americans
Fear of deportation	Racism in healthcare
Lack of information about free care	Mistrust of healthcare systems
Lack of information about health	Mistrust of medical research
Lack of information about research	Differential treatment because of race
Poor communication	
Language barriers	
Need for healthcare	

Table 3. Shared and Distinct Motivators to Research Participation for Latinos and African Americans

Shared Motivators

Having a disease without a cure	
Helping a close family member with disease	
Finding new cures for disease	
Staff from same racial/ethnic group	
Childcare provided	
Transportation provided	
Limited number of visits required	
Distinct Motivators	
Immigrant Latinos	African Americans
Burden of disease in family	Adequate remuneration
Burden of disease in community	Self having disease at a severe stage
Susceptibility to a disease	
Access to healthcare	
Access to medicines	
Access to health information	
Spanish-speaking research staff	

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