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The influence of race and ethnicity on becoming a human subject: Factors associated with participation in research

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ABSTRACT

Introduction: The purpose of this study was to explore factors associated with willingness of African Americans and Latinos to participate in biomedical and public health research and to delineate factors that influence the decision to become a human subject.

Methods: We present results from a 2010 random digit-dial telephone survey of 2,455 African American (N = 1191) and Latino (N = 1264) adults. We used standard measures to assess knowledge of research, terminology, informed consent procedures, previous participation in research, health care experiences, social support, risk perception, religiousness, and trust.

Results: Over 60% of both African Americans and Latinos reported they believed people in medical research are pressured into participating. Over 50% said that it was not at all important to have someone of the same race/ethnicity ask them to participate. In a sub-sample of 322 African Americans and 190 Latinos who had previously been asked to participate in a research study, 63% of African Americans and 65% of Latinos consented to participate in a study. Finally, both African Americans (57%) and Latinos (68%) reported willingness to participate in future research. Overall, the multivariate analysis explained 29% of the variability in willingness to participate in future research.

Conclusions: Results suggest that African Americans and Latinos have no automatic predisposition to decline participation in research studies. These results can inform culturally tailored interventions for ethical recruitment of minorities into research and clinical trials.

1. Introduction

Including racial and ethnic minorities in research is critical for generalizability of results and for providing equal opportunities to all people who may benefit from participation in research. Despite one article that suggests that minorities are overrepresented in Phase I drug clinical trials [1], evidence still confirms low participation in research [2–4]. Numerous studies seek to explain the reasons for the low participation in research [5–9], identifying both barriers and motivators/facilitators to participation [5,6,10–13], and examining minority willingness to participate as a proxy for actual participation [12,14–17].

While these studies are varied, general consensus is that racial and ethnic minorities have generally positive attitudes toward research and are as willing as Whites to participate in research across different study types [9,12,14–17]. Not surprisingly, willingness to participate tends to depend upon the risks and level of invasiveness [15,18,19].

At the same time, however, researchers are documenting that there *are* significant differences in the numbers of minorities being asked to

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participate, far lower than would be expected based on minority representation in the country [9]. Additional studies suggest that minorities are less aware of research and research opportunities than Whites, and may rely more on their physicians or other health care professionals to provide information about research trials [12,20–22]. Yet, despite this need for communication about research studies, physician bias, both in treatment of minority patients and in the belief that minorities will not comply, may lead physicians to refrain from asking, thereby perpetuating the lower participation [1,23].

One approach for increasing minority participation in research has been to include "race matching" as a recruitment strategy. This approach has been adopted from research indicating greater patient satisfaction, longer visit times, and improved care in race matched physician-patient relationships [24,25]. While a few studies suggest that racially-matched minority researchers may increase willingness to participate, others highlight researcher characteristics other than race, such as honesty, openness and shared values, as more important contributors to recruitment success [20,26]. These studies are largely qualitative, and little empirical evidence exists to either support or refute the importance of race matching.

In an effort to further our understanding of minority willingness to participate in research and to elucidate some of the factors that influence the decision on joining a research trial, we conducted a unique study that included an all-minority sample of African Americans and Latinos who live in predominantly minority neighbourhoods. Via a random telephone survey, African Americans and Latinos responded to queries about their willingness to participate in different types of research, with different levels of invasiveness, motivations and barriers to participation, prior participation, perceived benefits of research, and attitudes toward their physician, researchers and research, in general. Analysis of the data allowed us to identify some key areas where researchers can tailor their recruitment strategies to help improve their inclusion of minorities in their research.

2. Methods

2.1. Study sample

ICF-MACRO, an international research firm, conducted the survey from June to December 2010 with 2455 African Americans (N = 1191) and Latinos (N = 1264).

2.2. Eligibility criteria

Prospective participants completed a telephone screener to assess their eligibility, which consisted of the following five questions: 1. Are you 18 years of age or older? 2. Are you of Hispanic or Latino background?; 2A. Which one of these groups best describes your own ethnic identification? (e.g., Mexican/Chicano, Puerto Rican, Cuban); 3. What is your race? (e.g., African American/Black, Asian, Caucasian/White, Native Hawaiian/Pacific Islander); 4. Would you consider your racial background to include Black or African American ancestry?

Prospective participants were randomly selected based on telephone exchanges associated with geographic areas of high concentrations of African Americans and Latinos. To identify the exchanges, directory-listed telephone numbers were mapped and assigned to a specific geographic location (census block group, census tract, or zip code); those exchanges with an estimated concentration of African Americans and Latinos of at least 40% were used. Four geographical regions were identified with a substantial sample size (> 250) for each region -Northeast, Midwest, South, and West (See Table 1 for the distribution of study respondents by region). The overall response rate was 20.3%, which is consistent with response rates from other current random-digit-dial surveys [27,28]. Sampling weights were calculated and stratified sampling was conducted to select telephone numbers for five strata defined by the estimated concentration of African Americans and Latinos within exchanges. The resulting sample represents African American and Latino populations who live in predominantly African American/Latino neighbourhoods. The survey took an average of 30 min to complete and it was offered in both English and Spanish. University of Pittsburgh Institutional Review Board approved the study and the free and informed consent of all participants was obtained.

Table 1
Distribution of respondents by region.

	Frequency N	Percent %	Cumulative %.
Northeast	319	13.7	13.7
Midwest	294	12.62	26.32
South	1011	43.41	69.73
West	705	30.27	100

2.3. Measures

Socio-Demographics: Eight socio-demographic variables were measured: race, ethnicity, gender, age, education, marital status, health insurance, and income. We collapsed education into below college and college or above, and marital status into married or living with a partner and other. Income was collapsed into below $36,000, $36,000 to $76,000 and above $76,000. Participants' health status was measured on a 5-point Likert scale (1 = poor to 5 = excellent).

Additional survey questions covered the topics of: willingness to participate, previous participation in research, value of human subjects research, motivations for participation, patient-provider interactions, beneficiaries of research, attitudes about research, researcher honesty, experimentation, race matching, and knowledge about the Tuskegee Study [29]. Questions and potential responses are shown in Table 2, including how some of the variables were constructed.

2.4. Analyses

A two-way chi-square was first performed to examine racial/ethnic differences on categorical variables. All effect sizes were small, i.e., Cramer's V ≤ 0.135. An independent samples *t*-test was performed on all other variables by race/ethnicity. Cohen's d, an effect size, is reported for each analysis.

Three factors were extracted from the items on willingness to participate in a future study by risk level, using maximum likelihood extraction method with direct oblimin rotation. There were five items loading on the first factor (Cronbach's alpha of 0.78), labeled "Risk Level: Do". These items were: 1) survey, 2) education program, 3) group interview, 4) limited/restricted diet, and 5) exercise. The second factor, labeled "Risk Level: Take", consisted of three items with a Cronbach's alpha of 0.81: 1) medicine by mouth, 2) new drug, and 3) medication by needle. Lastly, the third factor, labeled "Risk Level: Give", consisted of three items with a Cronbach's alpha of 0.75: 1) give blood, 2) DNA test, and 3) give urine. There were moderate to large correlations among the three factors. The factor scores were computed by averaging the items on each factor (Table 3).

A logistic regression was performed on each outcome variable: 1) willingness to participate in future medical research, and 2) ever participated in a research study. For the "ever participated" outcome, analysis was limited to participants who responded yes to "ever asked" (N = 518). The predictors used for each outcome variable were: socio-demographic variables, value of human subjects research, previous participation, motivations for participation, patient-provider interactions, beneficiaries of research, researcher honesty, experimentation, race matching and the Tuskegee Syphilis Study [29]. Two-way interactions between race and each covariate were tested for the moderating effect of race on covariate-outcome association. Stepwise forward