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Pre-consent education about research processes improved African Americans' willingness to participate in clinical research

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Abstract

Objective—To determine whether pre-consent education about research processes and protections affects African-Americans' willingness to participate.

Design—This study examined the willingness of 192 African-American outpatients (stratified by age, gender, and education) to participate in a hypothetical clinical study under varying consent conditions: Phase I participants underwent a typical informed consent process and were asked to indicate whether they would be willing to participate in the hypothetical clinical study and the reasons for their decision; their responses were used to develop a pre-consent educational DVD. Phase II participants viewed the DVD prior to the consent process. We compared the proportion of those who stated they were willing to participate in the clinical study using Fisher's exact tests, and used qualitative methods to analyze open-ended responses.

Results—When the consent process included education about research processes and protections, significantly more patients reported willingness to participate in the hypothetical clinical study (43% vs. 27%; $p=0.002$). Patients receiving pre-consent education were significantly less likely to cite mistrust, fear of side effects, lack of perceived benefits, and privacy as reasons for not participating.

Conclusion—Pre-consent education may improve the willingness of African-Americans to participate in clinical research and may address important concerns about research participation.

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Keywords

clinical trial; consent; HIPAA; minority groups; patient participation

Introduction

African Americans are disproportionately affected by hypertension, heart disease, and cancer and experience poorer health outcomes from chronic diseases compared to whites, but they are under-represented in clinical research trials for these and other diseases [1-3]. The adequate representation of racial and ethnic minorities in clinical trials is critical to the development of appropriate strategies to promote health and treat disease among these populations. Increasing the representation of minorities in clinical research is a national priority [4].

Numerous barriers to African Americans' participation in clinical research have been identified, with mistrust of medicine and research being a consistent finding [5-7]. A systematic review and a study involving focus groups with urban African Americans conclude that the consent process and the language of the consent form are potential barriers to research participation and may foster mistrust [8,9]. Focus group research also reveals that accurate knowledge about research is limited among potential participants and lack of understanding and trust of informed consent procedures is problematic [10], and that the goal of the consent process is often misinterpreted by minorities as the 'signing away rights' [11,12].

Attempts to increase the participation of African Americans in clinical research have been hampered by a lack of evidence-based successful recruitment and retention strategies. c

Methods

Design overview

This study examined patients' willingness to participate in a hypothetical clinical research study (involving a Phase III clinical research trial of an experimental anti-hypertensive medication) and elicited open-ended responses regarding reasons for participating or not, under one of two experimental consent conditions. The study was conducted in two phases, with separate samples participating in each phase. During Phase I (standard consent), participants underwent a typical informed consent process. A qualitative content analysis [13] of textual data from Phase I participant responses was performed, and these findings were used to guide the development of an educational DVD addressing research processes and human research protections. During Phase II (pre-consent education) participants viewed the educational DVD prior to undergoing informed consent. The main outcome was the proportion of participants in each phase who stated that they were willing to participate in the clinical research study, and the reported reasons for declining enrollment (among those who were not willing). This study was approved by the Institutional Review Board of Emory University.

Setting/Participants

Study participants were recruited from two private and two public primary care clinics affiliated with an academic medical center in metropolitan Atlanta. Eligible participants were African American (self-identified) outpatients 18 years of age, who spoke English, and were able to provide informed consent. For each phase, a purposive strategy was used to systematically construct a sample of 192 African American outpatients stratified by age (< 40 yrs, 40 yrs), gender (male, female), and educational level (high school diploma, > high school), resulting in 16 cells with 12 individuals per cell in each group. The goal of sampling was to include participants with a range of demographic characteristics with sufficient power to detect inter-group differences by age, gender, and education categories. Data collection took place at the clinic sites from August 2005 through May 2006 (Phase I) and from September 2006 through February 2007 (Phase II).

Experimental intervention

Phase I participants underwent a typical informed consent process for a hypothetical Phase III clinical research study comparing an experimental antihypertensive medication to an established medication. The consent document was prepared according to recommended templates available from the Emory University Institutional Review Board (www.emory.edu/IRB/consent_sample.php; www.emory.edu/IRB/hipaa_forms.php). The “additive” approach [14] of including all language required for authorization into the consent process was used because this is the process required by most institutional review boards [15]. After reviewing the informed consent document with the potential participant, an interviewer asked the patient whether he or she would be willing to participate in the clinical research study (yes/no) and the reasons for their decision (using an open-ended approach). Verbatim audio recorded responses were analyzed (as described below) with the goal of understanding patient concerns about participating in the hypothetical clinical research study.

Identified patient concerns were used to develop a pre-consent educational DVD (11 minutes in duration) to provide targeted patient education about research processes and human research protections (Table 1). The educational DVD did not communicate study-specific information particular to the protocol for the clinical research study into which patients were to consider enrolling. Rather the educational DVD communicated information about clinical research in general and common research procedures (e.g., basis for phases of clinical trials and standard research practices such as randomization, placebos, and blinding), policies and institutions governing research processes and human protections (e.g., U.S. Office of Research Protections, institutional review boards, community oversight committees, informed consent), rationale and infection precautions for drawing blood, and the importance of including individuals of both genders and all races and ethnicities into clinical research trials. Study-specific information was provided in the written informed consent document. The Phase II (pre-consent education) participants viewed the pre-consent educational DVD and then reviewed the consent forms with the interviewer such that they received general information about research processes and protections via the DVD followed by study-specific information via the written consent form.

Data Collection

Potential participants were approached by the study interviewer (an African American female) while in the waiting room of the outpatient clinic site. The interviewer explained that we were conducting a research study to better understand why people do and do not choose to take part in medical research, and that if s/he chose to take part in this research study s/he would review with the interviewer an informed consent form for a study that is being planned at a later time. Potential participants were asked to give verbal consent to participate in this interview study because no identifying information was collected, and we did not want to influence participant responses to the hypothetical informed consent documents. The study was considered to have minimal risks.

After giving verbal consent, participants were asked about their age, level of education, gender, and household income (above or below the federal poverty level). Phase I participants then reviewed the informed consent form for the hypothetical Phase III trial with the interviewer. The interviewer started by reading the forms to all participants, although many participants took over reading the forms for themselves. Upon having reviewed the informed consent form and having any questions answered, the participant was asked whether s/he would or would not be willing to participate in such a study, and was asked to explain why s/he would or would not be willing to participate. Participants could give multiple reasons for their decision. The interviewer asked probe questions, as necessary, to elicit a response (“What thoughts or concerns do you have?”, “Any additional thoughts or concerns?”) and to clarify participants’ reasons for their answer (“What do you mean by that?”). The same approach was followed during Phase II. However, Phase II participants were shown the pre-consent education DVD prior to review of the informed consent documents with the study interviewer.

All interviews took place in a private area of the outpatient clinic sites. Responses were audio-recorded and transcribed into text files. If participants refused audio-recording, the interviewer recorded their responses verbatim. A random sample of audio cassettes was reviewed independently to check for accuracy.

Data Analysis

Participant responses to whether they would participate were dichotomized: ‘willing to participate’ for those who responded they would participate (‘yes’) or consider participating (‘maybe’); ‘unwilling to participate’ for those who responded they would not participate (‘no’). The proportion of interviewees in each phase who were ‘willing to participate’ was compared using Fisher’s exact test using the software program SPSS for Windows (version 14.0). All statistical tests were two-sided and performed at the $\alpha=0.05$ level.

A qualitative descriptive content analysis approach was used to analyze textual data related to participants’ reasons for not participating [13]. A priori topics for the coding scheme, as guided by the literature and investigators’ experience, included mistrust of medicine and research, perceived lack of benefit, fear of adverse reactions, fear of medical procedures, and socio-structural barriers (e.g., time lost from work, lack of transportation or child care).

Text files containing qualitative data were reviewed independently by members of the study team, and the initial coding scheme was refined based on content of responses. The study team then collaborated to develop a final data coding scheme, which was applied to all textual data by two coders independently. Key coding categories were: mistrust or fear of research, researchers, or research institutions; perceived lack of benefit to self; fear of side effects or unknown reactions; fear of pain or medical procedures; socio-structural barriers; poor understanding of forms or procedures; concerns about privacy; concerns about health insurance. Participants whose responses could not be coded (e.g., “just not interested”, “can’t say why”, “just wouldn’t”) despite interviewer probes were coded as ‘no reason given’.

The qualitative analyses were performed using MaxQDA for Windows (version 2.0). Discrepancies in coding between the two coders were resolved by a majority decision rule with a third researcher serving as a tie-breaker. Inter-coder agreement was assessed for each code applied to participant responses using Cohen’s kappa [16]. Cohen’s kappa coefficient was > 0.80 (range 0.839 – 0.962) for each reason code, indicating satisfactory inter-coder agreement for each.

For this paper, the codes assigned to each participant’s reason for non-participation were analyzed as a binary variable according to whether the participant mentioned a given topic or not [17]. Fisher’s exact test was used to compare the proportion of participants in each group (who had stated they would not participate in the hypothetical clinical trial) who gave specific reasons for declining enrollment.

Results

To achieve the target sample size of 192 participants for this study, a total of 206 individuals were invited to participate (93.2% participation rate). Of the 192 participants, 16 (8.3%) refused to be audio-recorded and the interviewer recorded their responses verbatim in writing.

Considering all demographic groupings together, a significantly higher proportion of African American patients reported willingness to participate in the hypothetical clinical research study during Phase II (pre-consent education) compared to Phase I (standard consent), (43% vs. 27%; $p=0.002$), as shown in Table 2. Examining the differences by demographic groupings, preconsent education was significantly more effective among those who were less than 40 years of age (50% vs. 31%; $p=0.012$), with high school level of education or less (29% vs. 16%; $p=0.037$), with greater than a high school level of education (56% vs. 39%; $p=0.021$), and for both males (35% vs. 20%; $p=0.023$) and females (50% vs. 34%; $p=0.040$).

Phase II participants were significantly less likely to cite concerns related to mistrust of medicine and/or research, fear of side effects and/or unknown effects, lack of perceived benefit to self or others from participation in the research, and breeches of privacy as reasons for being unwilling to participate in the hypothetical clinical research study than were Phase I participants (Table 3). Concerns about fear of pain and medical procedures and

poor understanding of the forms were reported less often by those in Phase II compared to Phase I, although differences did not achieve statistical significance.

Discussion

This study comparing African American patients' willingness to participate in a hypothetical clinical trial under two different consent procedures (standard consent vs. pre-consent education) demonstrates that a greater proportion were willing to participate in the research when they received education about general clinical research processes and human research protections via DVD prior to the consent process. For each demographic grouping of African American patients, a significantly higher proportion were willing to participate when they received the preconsent education except for those 40 or more years of age, for whom a non-significant increase was observed. Patients shown the educational DVD prior to the consent procedure were also significantly less likely to cite key reasons related to mistrust and fear of side effects or unknown effects as reasons for not participating.

Based upon our findings, we conclude that pre-consent education addressing general clinical research processes (including phases of clinical trials; standard research practices such as randomization, placebos, and blinding) and human research protections (including the U.S. Office of Research Protections, institutional review boards, and community oversight committees) may improve the willingness of African Americans to participate in clinical research and may address concerns related to mistrust and fear of side effects/unknown effects, particularly for those younger than 40 years of age. Notably, the non-significant increase in willingness to participate among those 40 or more years of age suggests that different strategies may be important for increasing the participation of middle aged and older African Americans in clinical research.

Importantly, however, there remain several other well-documented and important barriers to the participation of African Americans' in clinical research, such as structural barriers (time and financial constraints; home, childcare, and job duties), exclusions based on disease severity and co-morbid conditions, and failure to be invited to participate in research [5,18] that would not be influenced by pre-consent education. Thus, researchers should actively consider and address each of these barriers as a means of enhancing the recruitment and enrollment of minority subjects as well as considering how they might improve their consent processes.

This study is in keeping with a growing body of work that indicates that investigators should pay careful attention to the consent process and to educating patients about research processes in order to enhance minority recruitment into research studies [8-12]. The importance of the informed consent process in participant enrollment is further underscored by a recent study demonstrating increased rates of study participation, especially for African Americans, after a waiver of written informed consent and HIPAA authorization were granted for a minimal-risk survey [19] and by another study demonstrating a reported increase in willingness to participate in a hypothetical clinical study among those who viewed consent documents that did not include HIPAA authorization compared with one that did [20].

“Due to the hypothetical nature of the clinical study into which interviewees were asked to consider enrolling, we were not able to conclude whether modifying the HIPAA authorization process would enhance African Americans participation in research

Further support for the education of potential participants about research processes includes evidence that participant-investigator communication about study-related research processes facilitates the recruitment process [21]. Also, a study of a physical activity intervention found that pre-intervention meetings for potential participants to learn more about study-related research processes enhanced minority recruitment by approximately two-fold [22]. Our study is different from these studies, however, in that the pre-consent educational DVD provided general information about research processes and human research protections rather than study-specific information, which was communicated via the written consent form. Given the time and expense that might be required for developing study-specific materials, it may be more feasible for some researchers or research institutions to invest in general educational materials that could be utilized for a host of studies rather than study-specific materials.

Aside from improving minority recruitment into research studies, an important ethical consideration for improving the informed consent process is the enhancement of potential participants’ understanding of research. A systematic review of interventions to improve research participants’ understanding of the informed consent process found that having a study team member or an educator spend time talking one-on-one to study participants was the most effective available way of improving research participants’ understanding, while multimedia approaches and enhanced consent forms had only limited success [23]. However, a large randomized trial of the effectiveness of a multi-media aided consent procedure involving participants with serious mental illness found that comprehension of the disclosed consent information was significantly better among participants randomized to the DVD-aided consent process compared to those randomized to the routine consent process [24]. Using the same multimedia materials, researchers also conducted a qualitative study of general reactions to the multimedia consent from a diverse sample of laypersons and found that the vast majority of laypersons preferred the use of multimedia tools that enabled them to gain more information about key topics during the consent procedure [25].

Our study did not measure participant understanding of the research processes under the varying consent conditions, thus we are unable to draw firm conclusions about whether the pre-consent educational DVD enhanced participants’ understanding. A further limitation of this study is the hypothetical nature of the clinical research study into which participants were asked to consider enrolling. Finally, this study is unable to estimate whether the observed results could be generalized to people of other race/ethnicities as this study exclusively focused upon African American individuals because they are under-represented in clinical research, addressing barriers to research participation among minority groups is a national goal, and the informed consent process has previously been identified as a potential barrier to research participation among African-Americans [8-12].

Important next steps are to continue to seek effective approaches to increase the participation of middle aged and older African Americans in clinical research and to

examine the effects of preconsent education of potential participants in a clinical trial that is actively enrolling patients. Ideally, this would be done with participants of diverse racial/ethnic and sociodemographic backgrounds. Future studies should also explore the potential impact of various strategies toward enhancing the retention of minority research subjects since participant withdrawal and loss to follow-up also occurs disproportionately for minority subjects [26,27].

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References

1. Giuliano AR, Mokuau N, Hughes C, et al. Participation of minorities in cancer research: The influence of structural, cultural, and linguistic factors. *Ann Epidemiol.* 2000; 10:S22–S34. [PubMed: 11189089]
2. Murthy VH, Krumholz HM, Gross CP. Participation in cancer clinical trials: race-, sex-, and age-based disparities. *JAMA.* 2004; 291:2720–6. [PubMed: 15187053]
3. Jackson R, Yang LE, Byrne T, Watson R, Folson A, et al. Differences between respondents and nonrespondents in a multicenter community-based study vary by gender ethnicity. *J Clin Epidemiol.* 1996; 49:1441–1446. [PubMed: 8970495]
4. U.S. Department of Health and Human Services, National Institutes of Health. Guidelines on the inclusion of women and minorities as subjects in clinical research (59 FR 14508-14513). Bethesda, MD:
5. Shavers VL, Lynch CF, Burmeister LF. Racial differences in factors that influence the willingness to participate in medical research studies. *Ann Epidemiol.* 2002; 12:248–56. [PubMed: 11988413]
6. Braunstein J, Sherber N, Schulman S, et al. Race, medical researcher distrust, perceived harm, and willingness to participate in cardiovascular prevention trials. *Medicine.* 2008; 87:1–9. [PubMed: 18204365]
7. Corbie-Smith G, Thomas S, St George D. Distrust, race, and research. *Arch Intern Med.* 2002; 162:2458–2463. [PubMed: 12437405]
8. Ross S, Grant A, Counsell C, Gillespie W, Russell I, Prescott R. Barriers to participation in randomized controlled trials: a systematic review. *J Clin Epidemiol.* 1999; 52:1143–56. [PubMed: 10580777]
9. Farmer DF, Jackson SA, Camacho F, Hall MA. Attitudes of African American and low socioeconomic status white women toward medical research. *J Health Care Poor Underserved.* 2007; 18:85–99. [PubMed: 17337800]
10. Freimuth V, Quinn S, Thomas S, Cole G, Zook E, Duncan T. African Americans' views on research and the Tuskegee Syphilis study. *Soc Sci Med.* 2001; 52:797–808. [PubMed: 11218181]
11. Corbie-Smith G, Thomas SB, Williams MV, Moody-Ayers S. Attitudes and beliefs of African Americans toward participation in medical research. *J Gen Intern Med.* 1999; 14:537–46. [PubMed: 10491242]
12. Herring P, Montgomery S, Yancey A, et al. Understanding the challenges in recruiting blacks to a longitudinal cohort study: the Adventist health study. *Ethn Dis.* 2004; 14:423–430. [PubMed: 15328945]
13. Miles, MB.; Huberman, MA. *Qualitative data analysis: An expanded sourcebook.* Thousand Oaks: Sage Publications; 1995.
14. Shalowitz D, Wendler D. Informed consent for research and authorization under the Health Insurance Portability and Accountability Act Privacy Rule: an integrated approach. *Ann Intern Med.* 2006; 144:685–8. [PubMed: 16670138]

15. Breese P, Burman W, Rietmeijer C, Lezotte D. The health insurance portability and accountability act and the informed consent process. *Ann Intern Med.* 2004; 141:897–9. [PubMed: 15583246]
16. Lombard M, Snyder-Duch J, Bracken CC. Content analysis in mass communication: assessment and reporting of intercoder reliability. *Hum Commn Res.* 2002; 28:587–604.
17. Damschroder LJ, Roberts TR, Goldstein CC, Miklosovic ME, Ubel PA. Trading people versus trading time: What is the difference? *Popul Health Metr.* 2005; 3:10. [PubMed: 16281982]
18. Wendler D, Kington R, Madans J, et al. Are racial and ethnic minorities less willing to participate in health research? *PLoS Med.* 2006; 3(2):e19. [PubMed: 16318411]
19. Krousel-Wood M, Muntner P, Jannu A, Hyre A, Breault J. Does waiver of written informed consent from the institutional review board affect response rate in a low-risk research study? *J Investig Med.* 2006; 54:174–9.
20. Dunlop AL, Graham T, Leroy Z, Glanz K, Dunlop BW. The impact of HIPAA authorization on African Americans' willingness to participate in research. *Ann Epidemiol.* 2007; 17:899–905. [PubMed: 17689261]
21. Corbie-Smith G, Williams I, Blumenthal C, et al. Relationships and communication in minority participation in research: multidimensional and multidirectional. *J Natl Med Assoc.* 2007; 99:489–498. [PubMed: 17534006]
22. Banks-Wallace J, Enyart J, Johnson C. Recruitment and entrance of participants into a physical activity intervention for hypertensive African American women. *ANS Adv Nurs Sci.* 2004; 27(2): 102–16. [PubMed: 15206682]
23. Flory J, Emanuel E. Interventions to improve research participants' understanding in informed consent for research: A systematic review. *JAMA.* 2004; 292(13):1593–1601. [PubMed: 15467062]
24. Jeste DV, Palmer BW, Golshan S, et al. Multimedia consent for research in people with schizophrenia and normal subjects: A randomized controlled trial. *Schizophr Bull.* 2009; 35(4): 719–729. [PubMed: 18245061]
25. Henry J, Palmer BW, Palinkas L, Glorioso DK, Cligiuri MP, Jeste DV. Reformed consent: Adapting to new media and research participant preferences. *IRB: Ethics & Human Research.* 2009; 31(2):1–8. [PubMed: 19402337]
26. Warden D, Trivedi MH, Wisniewski SR, et al. Predictors of attrition during initial (citalopram) treatment for depression: A STAR*D report. *Am J Psychiatry.* 2007; 164:1189–97. [PubMed: 17671281]
27. Dunbar-Jacob J, Holmes JL, Sereika S, et al. Factors associated with attrition of African Americans during the recruitment phase of a clinical trial examining adherence among individuals with rheumatoid arthritis. *Arthritis Care Res.* 2004; 51:422–8.

Table 1

Content of Pre-Consent Educational Video

To Address Concerns About ...	Topic Covered in the Video
Being a 'guinea pig' (risks); Mistrust	Lack of regulation and oversight of research in the past; Existence of regulations and oversight for today's research
Being a 'guinea pig' (risks); Mistrust	Clinical research process (phases of clinical trials, prior animal studies)
Concerns about 'signing away rights'	Purpose of informed consent
Concerns about privacy and impact on health insurance eligibility and coverage	Purpose of HIPAA authorization
Concerns about targeting minorities	The importance of including individuals of <i>ALL</i> races/ethnicities, genders, and ages in clinical research; Justification for national priority to increase minority's representation in clinical research
Lack of benefits from research	The importance of medical research in the prevention and treatment of diseases
Fear of infection from blood draws; Lack of monitoring for potential effects of medication	Purpose of drawing blood, safety procedures for drawing blood

Table 2

Patients willing to participate in a hypothetical clinical trial in standard consent and pre-consent education conditions

Demographic Group	Standard Consent	Pre-Consent Education	p-value*
< 40 years (n = 96)	30 (31%)	48 (50%)	0.012
40 years (n = 96)	22 (23%)	34 (35%)	0.080
High school education (n = 96)	15 (16%)	28 (29%)	0.037
> High school education (n = 96)	37 (39%)	54 (56%)	0.045
Male (n = 96)	19 (20%)	34 (35%)	0.023
Female (n = 96)	33 (34%)	48 (50%)	0.040
TOTAL (n = 192)	52 (27%)	82 (43%)	0.002

* p-value for Fisher's exact test

Table 3

Reported reasons for not participating in a hypothetical clinical trial in standard consent and pre-consent education conditions

Reason for not participating	Standard Consent (n=140) ^I	Pre-Consent Education (n=110) ^I	p-value*
Mistrust or fear of research, researcher, research institution	76 (54%)	42 (38%)	0.015
Fear of side effects or unknown effects	63 (45%)	33 (30%)	0.018
Privacy concerns	56 (40%)	30 (27%)	0.044
No perceived benefit to self or others from participation	53 (38%)	28 (26%)	0.042
Structural barriers (work, children)	31 (22%)	27 (25%)	0.654
No reason given	20 (14%)	12 (11%)	0.452
Fear of pain or medical procedures	19 (13%)	10 (9%)	0.323
Poor understanding of forms	18 (13%)	8 (7%)	0.210
Health insurance concerns	10 (7%)	5 (5%)	0.435

^I n = those stating that they would *not* want to participate in the hypothetical clinical trial

* p-value for Fisher's exact test