RETHINKING MINORITY PARTICIPATION IN CLINICAL TRIALS: MORE THAN MISTRUST

by

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Table of Contents

List of Tables

List of Figures

Chapter 1: Introduction

Clinical trials are research studies that involve people and test new methods of screening, prevention, diagnosis, or treatment of health conditions and diseases.[1] Clinical trials may benefit individual volunteers by providing access to new treatments before they are available to the public and serve the general population by evaluating the safety and efficacy of medical treatments; potentially leading to improved treatment options in the future.[2] With regard to cancer, clinical trials can be categorized by site (breast), type (treatment vs. prevention), phase (see Table 1), and stage (degree to which cancer has spread). The decision-making process and barriers to enrollment may differ by phase. For example, phase 1 patients are often sicker and have fewer treatment options,[3,4] whereas patients considering phase 3 trials often have standard treatment alternatives. It should be noted that before medications and therapies are tested in humans, they are first evaluated in animal models and laboratory research.

Table 1: Phases of cancer clinical trials[1,5]

Phases	**Purpose**	**# Patients**
Phase 1	Evaluate safety, dose range, side effects, and method of delivery (e.g., mouth or vein).	~ 15 to 80
Phase 2	Test effectiveness and further evaluate safety.	Usually <100, but up to 300
Phase 3	Compare effectiveness of a new intervention, or new use of an existing intervention, with the current standard of care.	Hundreds or thousands
Phase 4	Evaluate a drug or treatment *after* it has been FDA approved and marketed to the general public (e.g., side effects associated with long-term use and potential differential effects on various populations).	Hundreds or thousands

Lack of insurance coverage for routine patient care costs is one of the many barriers to enrollment for patients who might otherwise take part in a clinical trial. With regard to healthcare policy for cancer clinical trials, approximately 35 states have passed legislation or instituted special agreements requiring health plans to pay the cost of routine medical care received by a participant in a clinical trial.[6] Additionally, there are provisions in the new Patient Protection and Affordable Care Act related to clinical trials. Beginning in 2014, the act will require health insurers to pay for routine costs of care in approved clinical trials for cancer and other life-threatening diseases. The types of clinical trials that may be covered include treatment, prevention, and early detection trials.[7] As the general public learns about these insurance provisions, more patients may seek out information and participate in clinical trials. For example, a study conducted by Comis et al. found that 8 in 10 cancer patients were unaware that clinical trials could have been an option during their diagnosis and treatment period. Yet of those unaware patients, 76% reported that they would have been somewhat or very receptive to participate.[8]

Minority Participation in Clinical Trials: A Complex Issue

In addition to barriers to enrollment that affect the entire population, several studies have shown racial and ethnic disparities in barriers to enrollment. One barrier is, quite simply, that minority groups are often unaware of clinical trials.[9-12] For example, two studies using data from the National Cancer Institute's Health Information National Trends Survey (HINTS) demonstrated that a significantly smaller proportion of black respondents had heard of clinical trials compared with white respondents.[11,12] In addition, black respondents reported fewer positive feelings about sharing their medical data than white respondents.[12] In another study entitled *The Unmet Needs of African-American Women with Breast Cancer* conducted by the

University of California at Davis Comprehensive Cancer Center, 78% of African-American breast cancer survivors reported that their doctors did not talk to them about clinical trials, yet the same percentage said they would have enrolled if eligible.[13]

The literature regarding minority willingness to participate in clinical trials is mixed, with growing evidence that African Americans are as willing as other groups to participate when provided an equal opportunity.[14-18] For example, a meta-analysis of 20 health research studies with approximately 70,000 participants found that African Americans and Hispanics were just as willing as their white counterparts to participate in health research when invited.[14] The authors concluded that "efforts to increase minority participation in health research should focus on ensuring access to health research for all groups, rather than changing minority attitudes."

Several explanations have been given as to why minorities, and in particular, African Americans are not participating in clinical trials. These studies have focused primarily on individual-level cultural factors such as mistrust of healthcare professionals because of the US Public Health Service Study of Untreated Syphilis in the Negro Male and perceptions of racism.[19] My goal with this dissertation and future research is to expand the conversation beyond issues of mistrust and racism with regard to minority enrollment in clinical trials. Other factors, if addressed adequately, may reduce disparities in clinical trial participation. Claudia Baquet, MD, summarizes this issue well, "Often physicians don't discuss the availability of trials with minority patients, and there is a lack of information in the community about the potential benefits of participating in clinical trials. In addition, there aren't enough trials in community settings where people affected by disparities often live. Another problem is the design of clinical trials themselves — the eligibility criteria are very rigorous, are standardized, and may exclude patients with multiple health problems, many of whom are minorities."[20]

Theoretical Background

Minority enrollment into clinical trials encompasses a complex set of interacting behaviors, structures, and attitudes; thus, I have created a grand conceptual model using constructs from the Theory of Planned Behavior and an ecologic framework (Fig. 1). Adapting models by Ford,[21] as well as Schultz and Northridge,[22] I have included key variables that have empirically been shown to affect participation. I have also added variables that I deem to be understudied, yet critically important. The essence of ecologic models is that behavior (e.g., clinical trial participation) is affected by multiple circles of influence. These circles of influence include intrapersonal, interpersonal, organizational, community, physical environment, and policy.[23] The Theory of Planned Behavior has been applied to clinical trials and is well suited for explaining the psychological factors that may influence a patient's decision to enroll in a clinical trial.[24-26] The theory suggests that attitudes, subjective norm, and perceived behavioral control create *behavioral intention*, which may ultimately lead to the desired outcome or behavior change (e.g. clinical trial enrollment).

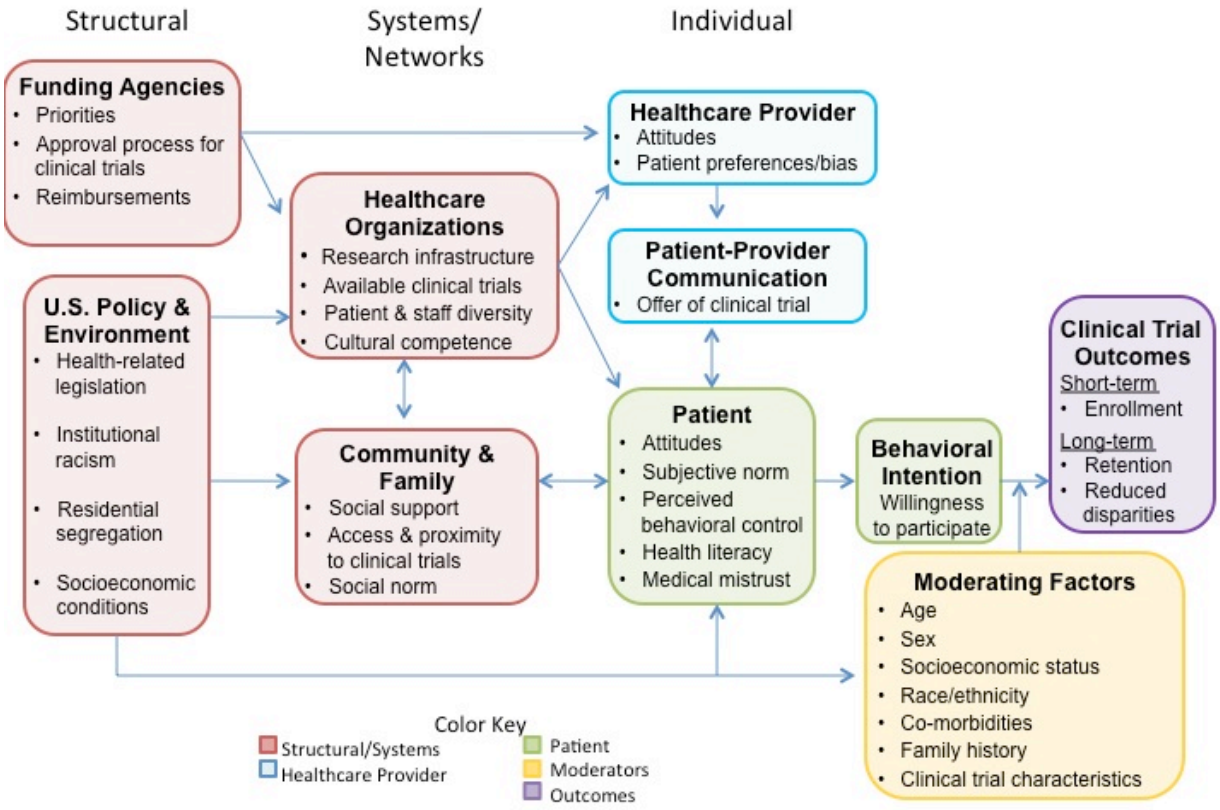

Figure 1: Grand conceptual model of minority enrollment in clinical trials

The primary hypothesis of this thesis is that medical mistrust and knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male are not the underlying drivers of low minority participation in clinical trials. Instead, I posit that African Americans are willing to participate in medical research and will enroll in clinical trials at rates equivalent to other racial and ethnic groups when explicitly invited and given the opportunity to participate. For the purposes of this dissertation, I define African American as anyone of African descent, living and socialized in the United States, who self-identifies as African American; I do not examine *within* group differences in clinical trial participation (e.g., blacks born in the Caribbean or Africa compared to American born blacks).

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Chapter 2: Willingness of African Americans to Participate in Clinical Trials

Abstract

Objective: This study examined predictors of willingness to participate in a clinical trial in a sample of 745 African American church members in Southeast Michigan.

Methods: Two linear regression models were run to evaluate predictors of willingness to participate in a clinical trial, controlling for potential confounders. The first model examined demographics and aggregate scales for global trust, patient-provider communication, personal benefit, global benefit, and global barriers as predictors of willingness to participate in clinical trials. The second model assessed a combination of aggregate scales and single items as predictors of willingness to participate in a clinical trial.

Results: The mean score for willingness to participate in a clinical trial was 7.22 on a scale of 1 – 10, with 10 indicating higher willingness. In Model 1, sex (β=0.43, p=.038), personal benefit (β=1.21, p<.001), global benefit (β=1.16, p<.001) and global barriers (β= -0.51 p=.002) were significant predictors of willingness to participate in a clinical trial. In Model 2, personal benefit (β=0.5, p=.003), global benefit (β=0.79, p<.001), global barriers (β= -0.63, p<.001), amount of payment or incentive for participating (β=0.23, p=.011), being involved in decisions about one's health care (β=0.3, p=.013), and trust in the organization conducting the clinical trial (β=1.3, p<.001) were significant predictors of willingness to participate in a clinical trial.

Conclusion: Our results demonstrate a general willingness among African Americans to participate in medical research. Future efforts to increase enrollment into clinical trials should highlight personal and global benefits, while reducing barriers. Continued strategies to increase

trustworthiness of healthcare organizations among African Americans and their communities may also help broaden the pool of African Americans willing to participate in research.

Introduction

Clinical trials are the mechanism by which new methods of screening, prevention, diagnosis, or treatment of disease are developed and tested.[1] Clinical trials may benefit individual volunteers by providing access to new treatments before they are available to the public, and serve the general population by evaluating the safety and efficacy of medical treatments, potentially leading to improved treatment options.[1] Low participation of racial/ethnic subgroups in clinical trials can impede scientific progress by masking disparities in medication effectiveness and disease progression across populations. Underrepresentation of African Americans in particular has received considerable attention since 1993 when NIH required that all sponsored research include adequate representation of women and minorities.[2] While it cannot be assumed that African Americans will always derive benefit from clinical trials, it is important to ensure that they have equitable opportunities to participate in medical research when appropriate and desired.

Barriers to clinical trial participation among African Americans are well documented and include: medical mistrust, fear of experimentation, lack of awareness of clinical trials and how to find them, disparities in patient-provider communication, proximity of clinical trials to minority communities, and lack of culturally tailored interventions.[3-10] In particular, the US Public Health Service Study of Untreated Syphilis in the Negro Male is one of the most well-known and cited cases of scientific abuse in the African American community, and is commonly referenced as a key factor in low willingness of African Americans to participate in research. Given these barriers, it is often assumed that African Americans are more likely to decline an

offer of a clinical trial than other groups, or have lower motivation to participate. These assumptions may not be valid and warrant empirical study, as there is some evidence that African Americans may be just as willing to participate in health research as their white counterparts when provided equivalent invitation.[11-13] More research is needed to elucidate the factors that influence clinical trial participation among African Americans. A better understanding of these factors may enhance future recruitment and retention strategies.

The objective of this study was to examine predictors of willingness to participate in a clinical trial in a sample of African American church members living in Southeast Michigan. Specifically, we were interested in the role of benefits, barriers, trust, and patient-provider communication on willingness.

The primary hypotheses were:

1) Perceived personal benefit of medical research is associated with more willingness to participate in a clinical trial.

2) Perceived global benefit of medical research is associated with more willingness to participate in a clinical trial.

3) Perceived quality of patient-provider communication is associated with more willingness to participate in a clinical trial.

4) Perceived barriers to participating in medical research are associated with less willingness to participate in a clinical trial.

5) Perceived trust of healthcare professionals and researchers is associated with more willingness to participate in a clinical trial.

6) Knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male is associated with less willingness to participate in a clinical trial.

Methods

This study was part of a larger intervention entitled the Body & Soul Clinical Trials Project. The goal of the parent project was to examine the effect of a culturally tailored clinical trials education module on African American church members' willingness to participate in medical research and subsequently, their enrollment into the University of Michigan Clinical Studies registry. We chose to work with African American churches because churches are trusted social institutions and efficient vehicles for reaching portions of the African American community.[14] Additionally, faith-based interventions have been effective in improving health outcomes for African Americans and for delivering health education programs.[15,16] Our project provided participants in the control group with health and nutrition information, and participants in the intervention group with information about medical research.

For the purposes of this paper, we focus on the baseline data of the entire sample, without regard to treatment condition, to assess demographic and psychosocial correlates of willingness to participate in clinical trials. The University of Michigan Institutional Review Board approved this study.

Pastors Advisory Board

A Pastors Advisory Board (PAB) was created to provide feedback about what would be feasible and appropriate in a church setting. The PAB was comprised of seven ordained clergy members serving as head pastors or support clergy from small (<200 members), medium (200-400 members), and large (>600 members) churches. The group included five men and two women; three with Masters of Divinity degrees and one with a PhD in microbiology. All clergy were from local predominantly African American Christian churches and represented the following denominations: Baptist, Apostolic, African Methodist Episcopal, and Free Methodist.

The PAB met quarterly in the first year of the project then twice a year after the project was implemented. The PAB provided feedback on several aspects of the project including content for recruitment materials, content for our clinical trials video and educational workshops, pre-test and post-test survey items, and strategies for successful recruitment and retention. At each PAB meeting, breakfast was served and a $50 Visa gift card was given in return for the pastors' time and feedback.

Church Recruitment

When recruiting churches, we focused initially on churches with which we had an existing relationship from prior health programs. Additionally, we worked with our Pastors Advisory Board, colleagues from the American Cancer Society, and other community-based organizations to identify other potential churches within a 60-mile radius of Ann Arbor. Church recruitment began with a hard copy mailing of an introductory letter and a study brochure to approximately 200 African American churches, followed by telephone calls and e-mails with interested pastors or health ministry members, and when possible, an in-person meeting. After personal contact was made with the pastor, both the pastor and designated church coordinator signed a commitment agreement that outlined roles and responsibilities for the church and the study team. A total of 16 churches were recruited between July 2011 and January 2012. Of the churches that declined participation, some of the concerns expressed included not having someone in the church to serve as the coordinator, competing church activities (i.e., the church was too busy to add another project at the time), time burden of study requirements, and generating enough interest for 40 – 60 members to participate. We used a clustered randomized design to assign churches to the control group or intervention group. Before randomization, we

pair-matched churches by size (<200, 200-400, >400) and when possible, by denomination (e.g., African Methodist Episcopal, Baptist, Church of God in Christ).

Participant Recruitment

The church coordinators were given a goal of recruiting 40 - 60 members from their church. The recruitment strategy was left to the discretion of the coordinators; however, we developed promotional flyers for display around the church and talking points for church announcements. Coordinators were encouraged to recruit individuals by making church announcements, posting information on bulletin boards, and by making appeals to groups within the church that met regularly (e.g. choir, bible study, and women's ministry).

Data Collection

All study participants completed a self-administered survey at baseline. Graduate level research assistants from the University of Michigan were present at each baseline data collection session to introduce the study, distribute and collect consent forms and surveys, and to answer questions. The baseline survey was 13 pages long, contained 66 questions, and took participants approximately 15 - 25 minutes to complete. Two copies of the consent form (one to be returned to the study team, the other to be signed and kept by the participant) were attached to each survey. A pen, survey, and a University of Michigan clinical studies brochure and enrollment form were included in all baseline survey packets to ensure that both intervention and control churches had equal opportunity to enroll into the registry. The University of Michigan Clinical Studies registry allows people to create a profile based on interests and health conditions so that they can be matched with relevant clinical trials. Once enrolled into the registry, the participants determine the method (letter, phone, or e-mail) and frequency (as available, weekly, monthly) by

which they are alerted of relevant studies. Enrollment into the registry was the primary outcome of the larger study.

Most baseline data collections were done in a group setting in the churches' fellowship hall. Most participants completed baseline surveys on Sunday afternoons, immediately following church service. In some cases, participants completed surveys in a group setting on a different day of the week at the request of the study coordinator (e.g., Saturday morning or after Tuesday night bible study). A few participants completed the survey at home if they wanted to be in the study but could not attend the group sessions due to scheduling conflicts. In these cases, the survey was returned to the church coordinator in a sealed envelope and later picked up by one of the research assistants from the University of Michigan. All participants completed the pen and paper survey independently unless they requested assistance from the study team or church coordinator. For example, a few participants (less than 10) had limited reading skills and/or mobility issues with their hands. In these cases, research assistants from the University of Michigan read the survey questions to the participant and/or filled out the form on their behalf. Refreshments were provided during each data collection event, and participants were given a $10 cash bill for completing the baseline survey.

Measures

The survey tool assessed past participation in clinical trials and future willingness to participate in a clinical trial, as well as knowledge, attitudes, and beliefs about medical research. Demographic measures included age, sex, household income, education, and work status. We were particularly interested in the roles that perceived barriers, benefits, patient-provider communication, and mistrust played on willingness to participate in clinical trials, as these

factors have been shown to be predictive of willingness and enrollment in past studies, but have not been adequately explored.

Both new and existing single items,[17-19] as well as new aggregate scales created by the study team were used as predictors of willingness to participate in a clinical trial in the linear regression models. In these cases, the aggregate scale and related single item were not included in the same model to avoid multicollinearity. Factor analysis was used to guide the structure of the aggregate scales. The final aggregate scales were created by producing a mean score for all items included in scale. Alpha coefficients for each scale are reported.

Dependent Variable

The primary outcome of interest for this paper was self-reported willingness to participate in a clinical trial. The survey question was worded as, "On a scale from 1 to 10, with 1 being not at all willing and 10 being very willing, how willing would you be to participate in a clinical trial in the future?" Word anchors were used to help give meaning to the number options along the 1 - 10 scale and included: not at all willing, somewhat unwilling, neutral, somewhat willing, and very willing.

Independent Variables

Global Trust

To assess general trust for healthcare providers and related organizations, a 6-item global trust scale (α=.76) was created by the research team. A mean score for global trust was created from new items developed for the project and adapted items from past surveys including: 1) I trust my primary care doctor; 2) I trust the place where I get most of my medical care; 3) I trust my health insurance provider; 4) I trust the University of Michigan; 5) Medical researchers are generally honest in telling participants about different treatment options available for their

conditions; and 6) All in all, medical researchers would not conduct experiments on people without their knowledge. The response options were: strongly disagree, disagree, neutral, agree, and strongly agree.

Patient-Provider Communication

Based on prior work in clinical trials and more broadly, general patient-provider communication, we proposed that the quality of patient-provider communication might impact willingness to participate in clinical trials.[20,21] As such, we created a 6-item communication scale (α=.91) by adapting items from NCI's Health Information National Trends Survey to assess if quality of patient-provider communication was predictive of willingness to participate in a clinical trial. At the beginning of the patient-provider communication section, participants were prompted to respond with the primary care physician or specialist that they saw most often for their medical care in mind. A mean score for patient-provider communication was produced by using responses to the following questions: 1) During the past 12 months, how often did doctors, nurses, or other health professionals give you the chance to ask all the health-related questions you had during a medical appointment; 2) During the past 12 months, how often did doctors or other health providers listen carefully to you during a medical appointment; 3) How often did they explain things in a way you could understand during a medical appointment; 4) How often did they show respect for what you had to say during a medical appointment; 5) How often did they spend enough time with you during a medical appointment; and 6) How often did they involve you in decisions about your health care as much as you wanted during a medical appointment? Response options were: always, usually, sometimes, never, don't know, and not applicable.

Benefits

We assessed perceived personal benefit of a clinical trial as well as perceived global benefit (i.e. potential benefit for others, the community, or society at large). The 3-item personal benefit scale was created by the study team (α=.71) and a mean score was produced by using responses to the question, "How much would each of the following reasons increase your willingness to participate in a clinical trial?": 1) The benefits of the research for my health; 2) Having access to new drugs or treatments; and 3) Getting closer monitoring of my health. Response options were: not at all, a little, somewhat, greatly and don't know. "The amount of payment or incentive for participating" item was evaluated as a separate single item because it did not load in factor analysis on either the personal or global benefit factors.

A 5-item global benefit scale was created by the study team (α= .73). The mean score for global benefit was produced by using responses to the following statements: 1) To determine what is best for African Americans health now and for future generations; it's important for us to participate in clinical trials; 2) Participating in medical research is part of my responsibility to the African American community; 3) In general, I think that medical research are trying to help society; 4) Medical research has improved the health of African Americans; and 5) More African Americans would participate in clinical trials if they understood how the research would help them or their community. Response options were: strongly disagree, disagree, neutral, agree, strongly agree, and don't know.

Barriers

An 11-item global barriers scale created by the study team (α=.84) and a mean score for barriers was produced by using responses to the following question: "How much would each of

the following reasons decrease your willingness to participate in a clinical trial": 1) The risks involved with the study; 2) The possibility I will receive only a "placebo" or no treatment; 3) Additional testing or procedures required because of the clinical trial; 4) The amount of pain or discomfort involved; 5) Whether or not my insurance will cover the costs related to the clinical trial; 6) The amount of time required to participate; 7) Extra demands on my family members because of the study; 8) Travel distance to the medical facility or transportation; 9) Need for childcare during medical appointments; 10) Difficulty taking time off from work; and 11) Inconvenience or "hassle." Response options were: not at all, a little, somewhat, greatly, and don't know.

Knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male

This survey question was worded as, "Have you ever heard of the U.S. Public Health Service Syphilis Study at Tuskegee?" Response options were yes and no. This item was of particular interest based on mixed evidence that knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male is associated with enrollment in clinical trials and overall willingness to participate in research.

Data Analysis

Frequencies and means were generated for demographic variables and two linear regression models were run to evaluate predictors of willingness to participate in a clinical trial, controlling for age, sex, household income, work status, and education. The first model examined the impact of demographics and aggregate scales for global trust, patient-provider communication, personal benefit, global benefit, and global barriers on willingness to participate in a clinical trial. The second model assessed the impact of a combination of the significant scales and demographics from Model 1, plus single items on willingness to participate in a

clinical trial. We chose to include single items in Model 2 (e.g., distrust of healthcare professionals), as their role on willingness to participate in clinical trials was of particular interest and we wanted to ensure that their potential impact was not masked by being included in an aggregate scale. We investigated clustering effects within church by running a random intercept model, however the random intercept variance was not significant, indicating that there is not substantial correlation of individuals within churches, thus a more parsimonious linear regression model without random intercept was used. Cases with missing data were removed using listwise deletion. All analyses were conducted with IBM's SPSS version 20.

Results

We recruited 745 participants from 16 churches in Southeast Michigan. The average number of surveys per church was 46, with a range of 19 – 77 surveys per church. As shown in Table 2, the average age was 48 and approximately 68% were female. With regard to educational attainment, 5% had less than 11^{th}-grade education; 60% had a high school degree, some college or vocational training; and 36% had a 4-year college degree or beyond. In terms of work status, 39% of members were employed full-time, 11% were employed part-time, and 50% were not working ("not working" included those who were unemployed, retired, students, and/or homemakers). The distribution of household income was 51% of households earning less than $40K, 31% earning between $40,001 -$80,000, and 18% earning more than $80,001. The mean score for willingness to participate in a clinical trial was 7.22 (SD=2.48) for the sample overall, with 1 being not at all willing and 10 being very willing.

Using willingness to participate in a clinical trial as the dependent variable, we ran two linear regression models with multiple independent variables. The unstandardized beta coefficients and adjusted R^2 are reported. The first model (Table 3) assessed sex, education,

work status, household income, age, and aggregate scales for patient-provider communication, personal benefit, global benefit, global trust, and global barriers on willingness to participate in a clinical trial (R_a^2=0.26), F (10,455)=17.75, p<.001). Sex (female β=0.43, p=.038), personal benefit (β=1.21, p<.001), global benefit (β=1.16, p<.001) and global barriers (β=-0.51 p=.002) were significant predictors of willingness to participate in a clinical trial in Model 1. The second model (Table 4) evaluated sex, the personal benefit scale, the global benefit scale, the global barriers scale, as well as single items including: amount of payment or incentive for participating, being involved in decisions about one's health, trust in the organization conducting the clinical trial, knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male, and distrust of healthcare professionals (R_a^2=0.38, F(10, 497)=31.79, p<.001). In Model 2, significant predictors of willingness to participate in a clinical trial included personal benefit (β=0.5, p=.003), global benefit (β=0.79, p<.001), global barriers (β= -0.63, p<.001), amount of payment or incentive for participating (β=0.23, p=.011), being involved in decisions about one's healthcare (β=0.3, p=.013), and trust in the organization conducting the clinical trial were (β=1.3, p<.001).

Discussion

The primary aim of this study was to evaluate predictors of willingness to participate in a clinical trial among members of African American churches in Southeast Michigan. Overall, the mean score of 7.22 in willingness to participate in clinical trials indicates a general openness to participate in medical research. Sex was the only demographic variable found to be predictive of willingness to participate in a clinical trial in Model 1 and was thus included in Model 2; however, sex did not remain significant once the model was expanded. In Model 1, women on average had a 0.43 higher score in willingness to participate in clinical trials, controlling for all

other covariates. While our study focused on willingness to participate in clinical trials versus actual enrollment into a clinical trial, females have generally being shown to have lower levels of participation in clinical trials than men,[22-26] although some studies show that racial/ethnic men are underrepresented in research.[27,28] Future work should evaluate differences between men and women in response to various recruitment methods, interest and enrollment in specific studies, as well as retention and attrition rates over time.

In both models, aggregate scales for perceived personal benefit, global benefits, and global barriers were significant predictors of willingness to participate in clinical trials. In particular, perception of how a clinical trial might benefit an individual appears to be an important aspect of the decision-making process. While healthcare providers cannot promise that patients will directly benefit from a study or overstate potential positive effects of an experimental therapy, special attention should be given to thoroughly explaining the hypothesized benefits of a trial during the informed consent process. Also related to personal benefit, the "amount of payment or incentive for participating in a clinical trial," was associated with willingness to participate in a clinical trial in Model 2. This finding is consistent with past research that shows that financial reward can be a motivating factor for healthy volunteers when deciding to participate in clinical trials.[29]

Potential benefits to others and the greater community also appear to be important considerations when evaluating willingness. The global benefit scale included items about the general benefits of clinical trials to society and in particular, the African American community. This finding supports the idea that some people participate in clinical trials for altruistic purposes.[30,31] That is, even if clinical trial participants do not get a direct benefit from being in a study, they may take comfort in the idea of "paying it forward" by helping researchers find better

treatments and potential cures for future patients.[32] In future work, efforts to clearly articulate how the research may specifically help individuals *and* the African American community or society at large may enhance enrollment. This concept is similar to term *conditional altruism*. While not assessed in our study, the idea of conditional altruism is that "willingness to help others that may initially incline people to participate in a trial, but that is unlikely to lead to trial participation in practice unless people also recognise that participation will benefit them personally."[33] As hypothesized, fewer perceived barriers increased one's willingness to participate in a clinical trial. This finding suggests that more attention should be paid to reducing logistical and psychosocial barriers (e.g. amount of time required or perceived risk involved) when clinical trials are being designed and implemented.

The aggregate scale for global trust in Model 1 (mean score for trust of healthcare providers and researchers in general) did not predict willingness to participate in a clinical trial, nor did the single items in Model 2 about knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male and distrust in healthcare professionals. However, the single item "trust in the organization conducting the trial" was a significant predictor of willingness in Model 2. Given that clinical trials are conducted by a variety of organizations for which participants do not necessarily have to be patients, this finding shows that organizational reputation or perceived trustworthiness matters a great deal. For example, a person can obtain their medical care in one place out of geographic convenience or insurance restrictions, but not necessarily trust the institution. Moving forward, it will be important for healthcare organizations to increase their trustworthiness among African Americans, which will include building and in some cases mending relationships with African American communities which have often felt used and abused by research institutions. Finally, while the patient-provider communication

scale was not significant in Model 1, the single item "being involved in decisions about one's health care" was significant in Model 2, further highlighting the need to help patients to be active partners in their health care plan, which may include participating in a clinical trial.

Study strengths and limitations

While other studies that have evaluated willingness of African Americans to participate in research broadly, our study is one of the first efforts to assess willingness to participate in research in a large sample of African Americans from diverse denominations and church environments. Given the growing number of researchers who are partnering with African American faith-based institutions to deliver health interventions and to recruit for studies, a better understanding of the attitudes and beliefs of this population may inform future projects. Additionally, our survey items covered a broad range of potential factors that may affect willingness to participate in research including: quality of patient-provider communication, personal and community benefit, trust, and barriers. The diversity of survey questions provides rich insight into the reasons why African Americans may or may not be participating in medical research. Building upon prior community outreach efforts and relationships with health ministries in black churches, we worked collaboratively with church coordinators and our Pastors Advisory Board to ensure that our project would be well received by local churches.

Several limitations should be noted. The sample of churches invited to participate in this study were not randomly selected, therefore there may be a degree of selection bias both at the individual and church level. All of the churches were located in Southeast Michigan and the majority of participants were female, thus results may not be generalizable to other parts of the country or to men overall. Given that our sample was predominantly African American members of Christian churches, our results may not apply to African Americans who do not

attend church and/or have different religious affiliations or spiritual views. Additionally, our results may not be applicable to non-African Americans.

The catchment area for churches included Ann Arbor, Ypsilanti, Flint, and Detroit Michigan – all areas where the University of Michigan has a strong to modest presence with regard to medical and community-based research. Ongoing community work by the University of Michigan, brand recognition, and public relations/marketing campaigns may have positively skewed results with regard to willingness to participate in clinical trials and perceived benefits of participating in medical research. Conversely, this also could reflect the negative experiences that this African American community has had with University of Michigan (i.e., willingness could have been higher) if participants interpreted the questions as being primarily relevant to clinical trials conducted at the University of Michigan. It is also possible that the participants in our study, by the very fact that they volunteered to be in our project, are more likely to volunteer for clinical trial in the future. Furthermore, we were only able to assess hypothetical willingness to participate in a clinical trial among African American church members in the community who were generally in decent health. Finally, willingness to participate in a clinical trial may differ for African American patients in a clinical setting or for those dealing with chronic or acute conditions.

Conclusion

In summary, our results demonstrate a general willingness among African Americans to participate in clinical trials. This finding is consistent with other studies showing a growing trend of expressed interest among African Americans to be involved in medical research. For example, among 5,979 individuals assessed across five sites, African Americans expressed more willingness than any other racial/ethnic group to participate in research that required blood

samples, genetic samples, access to medical records, an overnight stay in a hospital, or use of medical equipment.[34] Our study findings indicate that future efforts to increase enrollment into clinical trials should highlight personal and global benefits, while reducing barriers to full participation. Continued strategies to build trust in healthcare organizations and to engage patients in discussions about their health care may also help broaden the pool of African Americans willing to participate in research.

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Table 2: Demographics and willingness to participate in a clinical trial among African American church members in Southeast Michigan. (N=745)

Age (Mean)	48
Sex (%)	
Female	68
Male	32
Education (%)	
11th Grade or Less	5
High School, Some College, Vocational	60
4 Year College +	35
Work Status (%)	
Not working	50
Part-Time	11
Full-Time	39
Household Income (%)	
Less than $40K	51
$40,001 to $80,000	31
$80,001 +	18
Willingness to participate in a clinical trial in the future (Mean)	7.22

Table 3: Multivariate Linear Regression Model 1. Willingness to participate in a clinical trial by demographic and aggregate scale correlates (n=466)

	Unstandardized Beta	P-value
Sex*	.433	.038
Education	.29	.152
Work Status	.134	.228
Household Income	-.131	.344
Age	-.004	.515
Global Trust Scale	.179	.352
Patient-Provider Communication Scale	-.151	.379
Personal Benefit Scale*	1.21	<.001
Global Benefits Scale*	1.64	<.001
Global Barriers Scale*	-.51	.002

*Statistically significant, p< .05

Table 4: Multivariate Linear Regression Model 2. Willingness to participate in a clinical trial by demographic, aggregate scale, and single item correlates (n=508)

	Unstandardized Beta	***P*-value**
Sex	.33	.076
Personal benefit scale*	0.5	.003
Global benefit scale*	.78	<0.001
Global barriers scale*	-.63	<0.001
Amount of payment or incentive for participating in a clinical trial*	.23	.011
Healthcare providers involve you in decisions about your health care*	.3	.013
Healthcare providers explain things in a way that you can understand	-.28	.056
Knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male	.06	.73
Distrust of healthcare professionals	-.05	.558
Trust in organization conduction the trial*	1.32	<0.001

*Statistically significant, p< .05

Chapter 3: Racial/ethnic differences in clinical trial enrollment, refusal rates, ineligibility, and reasons for decline among patients at sites in the National Cancer Institute's Community Cancer Centers Program

Abstract

Objective: This study examined racial/ethnic differences among patients in clinical trial (CT) enrollment, refusal rates, ineligibility, and desire to participate in research within the National Cancer Institute's Community Cancer Centers Program (NCCCP) *Clinical Trial Screening and Accrual Log*.

Methods: Data from 4509 log entries were evaluated in this study. Four logistic regression models were run using *physical/medical conditions*, *enrollment into a CT*, *patient eligible but declined a CT*, and *no desire to participate in research* as dependent variables.

Results: Age ≥ 65 (OR=1.51, CI: 1.28 -1.79), males (OR=2.28, CI: 1.92 – 2.71), and non-Hispanic black race (OR=1.53, CI: 1.2 – 1.96) were significantly associated with more *physical/medical conditions*. Age ≥ 65 was significantly associated with lower CT enrollment (OR=0.83, CI: 0.7 - 0.98). Males (OR=0.78, CI: 0.65 -0.94) and a higher grade level score for consent form readability (OR=0.9, CI: 0.83 - 0.97) were significantly associated with lower refusal rates. Consent page length ≥ 20 was significantly associated with lower odds of "no desire to participate in research" among CT decliners (OR=0.75, CI: 0.58 – 0.98).

Conclusion: There were no racial/ethnic differences in CT enrollment, refusal rates, or "no desire to participate in research" as the reason given for CT refusal. However, higher odds of physical/medical conditions were associated with older age, males, and non-Hispanic blacks. Better management of physical/medical conditions before and during treatment may increase the

pool of eligible patients for CTs. Future work should examine the role of co-morbidities, sex, age, and consent form characteristics on CT participation.

Introduction

Cancer is the second leading cause of death in the United States, with approximately $201 billion spent each year in direct medical and indirect mortality costs.[1] In 2012, it was estimated that 1,638,910 people would be diagnosed with cancer and that 577,190 people would die from the disease (all types combined).[2] As of January 1, 2009, there were approximately 12,553,337 people in the United States who had a history of cancer (all types combined),[2] yet only 3-5% of adults with cancer participate in cancer clinical trials.[3] Of those who do participate, enrollment rates are lower for minority groups compared to non-Hispanic whites.[4] This is a growing area of concern because racial/ethnic minorities bear the greatest cancer burden in the United States.[5] Clinical trials (CTs) are the mechanism by which new methods of screening, prevention, diagnosis, and treatment of disease are developed. A better understanding of what makes minority recruitment and involvement in CTs successful is critical, as it will help maximize research investments, investigator time, patient commitment, trial generalizability, and allow research questions that are germane to minority populations to be more relevantly addressed.

Commonly cited reasons for lower CT participation among minorities include: lack of awareness, mistrust, cultural barriers, co-morbidities, low literacy, language differences, practical obstacles (e.g. childcare, transportation), lack of invitation, CT design, and lack of health insurance.[6] Given these barriers, it is often assumed that minorities have less interest in medical research or are more likely to refuse an offer to participate in a CT than non-minority

groups. These assumptions may not be valid, and warrant empirical study, as there is growing evidence that minorities may be just as willing to participate in health research as their non-minority counterparts when provided an invitation and opportunity.[7-9] Other, potentially more important, factors may play a role in the CT participation disparity such as: 1) Access/proximity of CTs to minority communities; 2) Readability and length of consent forms; 3) Provider bias in offering CTs; 4) Eligibility criteria, and 5) Regional impact on CT attitudes.

To explore these issues, the NCCCP implemented a *Clinical Trials Screening and Accrual Log* designed to track cancer patients at NCCCP sites who were screened and enrolled into selected NCI Cooperative Group treatment and cancer control CTs. The NCCCP sites selected trials for the log based on the majority of sites having access to the trial and the cancer type being studied. A primary goal of the log was to identify challenges to trial accrual and to provide information about successful practices to address them, including those for recruiting under-represented populations into CTs.[10,11] Additionally, implementation of the log has allowed NCCCP sites to: 1) Monitor enrollment rates over time; 2) Identify gaps in available CTs; 3) Enhance awareness of patient and physician reasons for declining trial participation in order to address them; and 4) Raise the visibility and importance of CTs within community cancer centers.[12] Another paper describes the general details and trends of the log.[13]

The objective of this paper was to specifically examine racial/ethnic differences among patients in the following areas: CT enrollment, refusal rates, ineligibility, and desire to participate in research. A better understanding of these issues may inform future CT recruitment, retention, and communication strategies.

Methods

NCCCP Clinical Trial Screening and Accrual Log Data Set

In 2008, the *Clinical Trial Screening and Accrual Log* was developed and piloted at 15 of the original 16 NCCCP sites. It officially launched in 2009 and later opened to the additional 14 sites that joined the program in 2010, for a total of 29 sites entering data. For the purposes of this paper, data from 2009 – 2012 were used in the analyses. Full details about the development and implementation of the log are reported elsewhere.[12] Items in the log include demographic information such as age, race, ethnicity, and sex; methods for identifying patients for CTs (e.g., chart review or cancer registry); whether the patient enrolled into the CT; reasons for ineligibility; patient-related reasons for declining a CT; and physician-related reasons for not offering a CT to an eligible patient.

Procedures

Log entries were completed by members of the research team (e.g., a study coordinator or research nurse). Data from the log was reported to the NCI via an online reporting system on an ongoing basis. To determine how race/ethnicity would be categorized on the logs, guidelines from the Office of Management and Budget were followed.[14] For this paper, race/ethnicity was collapsed into one variable with five categories: non-Hispanic white, non-Hispanic black, Hispanic, Asian, and other. The other category included American Indian or Alaska Native, and Native Hawaiian or Other Pacific Islander. To avoid potential overlap of categories, logs that had "more than one race" selected were excluded from the analyses. Additionally, if a patient was Hispanic *and* a racial category, we treated them as Hispanic. Only logs with complete race/ethnicity data were included in our analyses, thus logs with unknown ethnicity or race, or logs with race not reported were excluded from the analyses.

Logs

A total of 4509 log entries were collected on cancer patients screened from March 2009 through May 2012. Sample sizes for analyses ranged from 4184 – 4509 depending on which covariates were used. Log entries comprised patients screened for at least one of 27 trials open at various times during the data collection period, with most being treatment trials (81.5%). By cancer type, the most common trials were of breast (25.9%), colorectal (22.2%), and genitourinary (18.5%) cancers. The most common methods for identifying patients for screening were chart reviews (59.8% of log records), provider referral (30.8%), and clinic schedule review (29.2%).

Measures

Dependent variables

Four dependent variables were evaluated and included *physical/medical conditions*, *enrollment into a protocol*, *patient was eligible but declined participation*, and *no desire to participate in research*. *A priori*, we were interested in examining reasons why patients were ineligible for a CT, with an assumption that co-morbidities would be the driving force behind ineligibility. The full question was worded as, "If the patient did not meet trial eligibility criteria, indicate the reason why (select all that apply): 1) Abnormal labs; 2) Abnormal organ function; 3) Co-morbidities; 4) Does not meet biomarker testing criteria; 5) Insufficient or unavailable pathologic samples for study; 6) Patient had progressive disease; 7) Performance Status; 8) Prior Therapy; 9) Second Cancer; and 10) Time requirement. A binary variable for physical/medical conditions was computed by summing responses to the items: abnormal labs, abnormal organ function, co-morbidities, progressive disease, and performance status. A patient with one or more of these conditions would constitute a "yes" for physical/medical conditions

and were therefore not considered eligible for a CT. Patients with no conditions would receive a "no" for physical/medical conditions. The enrollment question was worded as, "Did the patient enroll in the protocol (yes/no)?" The *patient was eligible but declined participation* item was a part of a larger question written as, "If the patient did not enroll in the protocol, indicate the reason why (select only one): 1) Patient did not meet trial eligibility criteria, 2) *Patient was eligible but declined participation*, 3) Patient was eligible but the MD declined to offered participation, and 4) Patient was eligible but started treatment prior to completion of screening. Lastly, the item *no desire to participate in research* was one of 22 social, attitudinal, and/or logistical response options to the question, "If the patient was eligible, but the patient declined participation, indicate the patient-related reason why (select all that apply)." Given our specific interest in racial and ethnic differences in *no desire to participate in research* as the reason given for CT refusal, this was the only response of the 22 choices selected to be a dependent variable and included in analyses.

Independent variables

Demographic

Age, sex, race, and ethnicity were treated as potential confounders. Age was recoded into a binary variable of < 65 and ≥ 65, with the reference group being those under 65. Sex was coded as male and female, with females serving as the reference group. Finally, race and ethnicity were coded as non-Hispanic white, non-Hispanic black, Hispanic, Asian, and other, with non-Hispanic whites as the reference group. The "other" category included American Indian, Alaska Native, Native Hawaiian, and Pacific Islander. For all demographic and other independent variables, the category with the highest frequency was selected as the reference group.[15]

Region of Country

A regional variable was computed to specify the area of the country for which the NCCCP sites were located. Following U.S. Census guidelines, regions were categorized as West, Midwest, South, and Northeast, with the West serving as the reference group.

Informed Consent Characteristics

We were interested in the role of page length and grade level readability on CT participation. It should be noted that page length and readability were not asked on the log, but rather, calculated independently by evaluating the NCI Cooperative Group version of the consent form. Continuous and categorical variables for page length were created by counting the number of pages of the consent forms for each of the 27 CTs included in the log. We selected a cutoff point of 20 pages to create a binary variable for page length coded as < 20 pages and ≥ 20 pages. To assess readability of the consent forms, a Simple Measure of Gobbledygook (SMOG) score was generated using Readability Software by MicroPower and Light Co.[16]

Data Analysis

Frequencies and means were generated to assess how demographic, consent form, and regional variables were distributed. Chi square tests were used to compare patient racial/ethnic group differences by CT enrollment, refusal rates, ineligibility, and the medical reasons for ineligibility (e.g. abnormal labs or co-morbidities). Logistic regression was used to assess the effect of race/ethnicity, age, sex, region, consent form length, and consent form readability on four dichotomized dependent variables including *physical/medical conditions, enrollment into a CT*, *patient eligible but declined participation*, and *no desire to participate in research* as the reason given for CT refusal. All analyses were done with the full sample of log data. Correlation analyses were conducted for all covariates in the logistic regression models and none were highly

correlated (i.e., a Pearson's $r \geq 0.7$). Considering the fact that patients are nested within hospitals, and hospitals are nested within regions, we treated the hospital as a random effect and region as fixed effect to adjust for potential similarity of patients within hospital, as well as potential similarities of hospitals within a region. All logistic regression models with random effects were run using the GLIMMIX Procedure within SAS 9.3.

Results

Demographic, log, and consent form characteristics

As shown in Table 5, the mean age was 62, with approximately 57% of patients being under the age of 65 and women comprising 68% of the sample. With regard to race/ethnicity, 78% were non-Hispanic white, 13% were non-Hispanic black, 4% were Hispanic, 4% were Asian, and 1% was classified as other (e.g. American Indian, Alaska Native, Native Hawaiian or Pacific Islander). The average consent form page length was 17 pages (range of 3-50 pages), with 60% of consent forms being less than 20 pages. The average SMOG reading score for the consent forms was 10^{th} grade (range of 8 – 12 grade). With regard to geographic region of the country, 31% of patients were located in the West, 30% in the South, 21% in the Northeast, and 19% in the Midwest.

Chi Square Analyses

As shown in Table 6, chi square tests indicate a significant association between the patient's race/ethnicity and enrollment into a CT. Asians had a significantly lower proportion of CT enrollment. The chi square test also indicates a significant association between race/ethnicity, CT ineligibility, and co-morbidities. Non-Hispanic blacks had a higher proportion of not meeting eligibility criteria for a CT and having co-morbidities. There were no significant associations between patient racial/ethnicity and CT refusal rates, "no desire to participate in

research" as the reason for given for declining a CT, or other medical reasons for ineligibility (e.g. abnormal labs).

Logistic Regression Models

Using *physical/medical conditions*, *enrollment into a CT*, *patient was eligible but declined CT*, and *"no desire to participate in research"* as dependent variables, we ran four logistic regression models with multiple independent variables. The odds ratios and confidence intervals are reported in Tables 7 and 8. In Model 1, variables significantly associated with *physical/medical conditions* (i.e., health conditions that would make a patient ineligible) included age $\geq$ 65 (OR=1.51, CI: 1.28 -1.79), males (OR=2.28, CI: 1.92 – 2.71), and non-Hispanic black race (OR=1.53, CI: 1.2 – 1.96). In Model 2, the only variable significantly associated with lower *enrollment into a CT* was age $\geq$ 65 (OR=0.83, CI: 0.7 - 0.98). In Model 3 (Table 9), variables significantly associated with *eligible patients less likely to decline a CT* included males (OR=0.78, CI: 0.65 -0.94) and a higher SMOG score (i.e., written at a higher grade level) on the consent form (OR=0.9, CI: 0.83 - 0.97). Finally, in Model 4 (table not shown), the only variable significantly associated with fewer instances of *"no desire to participate in research"* as the reason for decline was consent page length $\geq$ 20 pages (OR=0.75, CI: 0.58 – 0.98).

Discussion

The primary aim of this paper was to examine, via the NCCCP *Clinical Trial Screening and Accrual Log* data, racial/ethnic differences in patient enrollment into a CT, rates of CT refusal, CT ineligibility, and desire to participate in research. Model 1 evaluated the association of age, sex, and race/ethnicity with physical/medical conditions. Being over the age of 65, being male, and being non-Hispanic black were all significantly associated with higher odds of physical/medical conditions, with co-morbidities comprising the majority of responses within the

physical/medical conditions item. Future work should examine how to design CTs that are more tolerable for patients with co-morbidities, which may include loosening the eligibility criteria to widen and diversify the pool of candidates. Another point of consideration is *how* patients are cared for prior to getting a cancer diagnosis and how their co-morbidities are managed in general. Better management and earlier identification of co-morbid conditions prior to and during cancer treatment may improve CT participation for men, those over 65, and blacks in particular, while also improving cancer survival rates over time.[17,18]

With regard to patient CT enrollment, there were no racial/ethnic differences in the second logistic regression model. While the chi square analysis initially showed a significantly lower proportion of Asians enrolling into a CT, this effect was no longer significant once race was evaluated in a logistic regression model that controlled for region and site. In particular, there was no black/white difference in CT enrollment after controlling for region, site, age, sex, consent form length, and SMOG readability. Our finding is consistent with other studies that have demonstrated that disparities in willingness to participate in research and actual participation are often reduced or eliminated when participants have equal access to participate and when they are explicitly offered a CT.[7,19] Also notable is that consent page length was not associated with enrollment into a CT, which is consistent with other studies.[20]

Older age (≥65) was associated with lower enrollment into a CT. This finding is not surprising, as several studies have shown that older cancer patients are under-represented in CTs, despite the fact that many cancers are diagnosed in patients over the age of 65 and that age alone is not a valid reason to exclude patients from CTs.[21,22] It is notable that in the NCCCP *Clinical Trial Screening and Accrual Log* data set, approximately 43% of CT enrollees were over age 65. Future research should explore potential age bias among providers when offering CTs, use of

geriatric assessment tools that may help determine if a patient can tolerate a CT, and ways to educate older patients about the option of CTs.[23]

Among patients that were *eligible, but declined a CT*, there were no racial/ethnic differences in refusal rates, although males were less likely than females to decline participation. While it not clear why this may be the case, some potential explanations include differences in the characteristics of the specific CTs offered to men vs. women, male comfort with research in general, or how, if at all, providers communicate differently to men about their treatment options, which may include a CT. Surprisingly, as SMOG readability score for consent form increased (i.e., as the grade level at which the form was written increased), CT refusal among eligible patients decreased. Since there is limited information on the role of consent form readability and CT participation, more research is needed to better understand this relationship.[24,25] It should be noted that the most common reasons that MDs declined offering a CT to an eligible patient were preference for standard of care (49%) and concerns about the patient's ability to tolerate a CT due co-morbidities/frailty (27%).

Finally, there were no racial/ethnic differences in "no desire to participate in research" as the reason given for declining a CT. However, consent page length ≥ 20 was associated with lower odds of "no desire to participate in research" among CT decliners. This finding is somewhat counter intuitive. More research is needed to better understand the relationship between consent form page length and CT participation. It should be noted that NCI has launched a transformed informed consent document template in an effort to address patient burden and to enhance participant understanding. This template includes decreases in page length and is required for use in NCI trials as of May 2013.[26]

Strengths and Limitations

This study evaluated a large data set of *Clinical Trial Screening and Accrual Log* entries from geographically, racially, and ethnically diverse patients from 29 cancer centers in the NCCCP, with race and ethnicity percentages of the logs mimicking the 2010 Census data.[27] Continual assessment and monitoring of sites' CT accrual via the logs provided a rich data set to evaluate the impact of race/ethnicity on different aspects of CT participation. It is possible that this consistent tracking of CT trends was an important factor in equivalent participation among whites and blacks in particular. More work is needed to intervene early with patients having co-morbid conditions and other under-represented groups in cancer CTs to maximize participation.

Limitations of this study include differences in how the log was implemented at each site. For example, some sites were more consistent than others with regard to filling out the log and entering data to the NCI online reporting tool. Additionally, the log was revised over time to improve usability and to reduce the time burden for staff, thus earlier versions may have had more incomplete, inconsistent, or written in log entries that were later reclassified for analysis by log administrators. Despite the fact that each trial had specific screening criteria to help guide providers in identifying eligible patients, it is possible that some patients were never identified and captured on the log; thus, the true number of potentially eligible patients is not known and may have biased the results. Moreover, there was some missing data for race/ethnicity (~13% of all logs) and a limited number of Hispanic patients, which may have biased the results and limited our ability to generalize the findings.

While we did not fully explore physician characteristics and patient CT participation, the primary reasons that MDs declined offering a CT to an eligible patient were preference for standard of care and concerns about the patient's ability to tolerate a CT due co-

morbidities/frailty. It should be noted that we did not have objective measures to confirm if such concerns were valid (e.g., if a patient was actually too ill to participate in a trial), as all log data were self-report and completed by a member of the study team. Future work should explore how, if at all, physician preference impacts a patient's decision to enroll into a CT, the physician's reasons for not offering CTs to eligible patients (e.g. preference for standard treatment), and whether a patient's race/ethnicity influences patient-provider communications about CTs and other treatment options.

Conclusions

In summary, there were no racial/ethnic differences among eligible patients in CT enrollment, refusal rates, or "no desire to participate in research" as the reason given for CT refusal within NCCCP's *Clinical Trial Screening and Accrual Log* data set. However, higher odds of physical/medical conditions were associated with older age, males, and non-Hispanic blacks. Future work should examine the role of demographics and consent form characteristics on CT participation. In particular, the role of co-morbidities warrants more attention, especially with regard to minorities. Future work should explore how better management of a patient's health *before* a cancer diagnosis (through primary care), as well as improved management of these conditions *during* cancer treatment will impact the future pool of eligible patients. Additionally, it is possible that more Phase 4 trials are needed to evaluate how FDA approved cancer therapies are tolerated in cancer patients with co-morbidities over time. A better understanding of these issues may inform future CT recruitment, retention, and communication strategies.

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Table 5: Demographic, log, and consent form characteristics for the full sample (N=4509).

	%	n
Age	62 (mean)	4467
< 65	57	2546
≥ 65	43	1921
Sex		4509
Female	68	3060
Male	32	1449
Race and Ethnicity		4225
Non-Hispanic White	78	3303
Non-Hispanic Black	13	532
Hispanic	4	163
Asian	4	175
Other	1	52
Logs by Region of the Country		
West	31	1378
Midwest	19	854
South	30	1345
Northeast	21	932
SMOG Readability of Consent Forms	10 (mean grade)	4509
Page Length of Consent Forms	17 (mean)	4509
< 20 pages	60	2716
≥ 20 pages	40	1793
Clinical Trial by Type		
Treatment	82	
Symptom management	11	
Prevention	4	
Other	3	
Trials by Most Common Cancer Type		
Breast	26	
Colorectal	22	
Genitourinary	19	

Table 6: Breakdown of enrollment, refusal, physical/medical conditions and reasons for MD not offering a trial by demographics (N=4509).

	%	n	P-value
Patient enrolled into a CT*			0.007
Overall enrollment rate for full sample	18	816	
Non-Hispanic White	20	663	
Non-Hispanic Black	18	94	
Hispanic	22	35	
Asian*	10	17	
Other	14	7	
Patient eligible but declined CT			0.114
Non-Hispanic White	22	713	
Non-Hispanic Black	21	112	
Hispanic	21	32	
Asian	13	23	
Other	17	12	
Patient did not meet eligibility criteria*			0.004
Non-Hispanic White	50	1328	
Non-Hispanic Black*	56	248	
Hispanic	49	70	
Asian	58	91	
Other	54	21	
"No desire to participate in research" as reason for decline			0.785
Non-Hispanic White	7	250	
Non-Hispanic Black	9	46	
Hispanic	9	13	
Asian	6	10	
Other	6	4	
Co-morbidities ineligibility*			<.001
Non-Hispanic White	11	337	
Non-Hispanic Black *	16	85	
Hispanic	6	12	
Asian	6	11	
Other	10	2	
Abnormal labs ineligibility			0.215
Non-Hispanic White	2	76	
Non-Hispanic Black	4	19	
Hispanic	3	4	
Asian	3	3	
Other	4	3	

*Statistically significant, $p < .05$

Table 6 (continued): Breakdown of enrollment, refusal, physical/medical conditions and reasons for MD not offering a trial by demographics (N=4509).

	%	n	P-value
Abnormal organ function ineligibility			0.241
Non-Hispanic White	1	35	
Non-Hispanic Black	2	9	
Hispanic	2	3	
Asian	2	3	
Other	3	2	
Performance status ineligibility			0.272
Non-Hispanic White	2	69	
Non-Hispanic Black	3	15	
Hispanic	1	1	
Asian	1	1	
Other	2	1	
Disease progression ineligibility			0.498
Non-Hispanic White	3	89	
Non-Hispanic Black	4	19	
Hispanic	2	3	
Asian	3	5	
Other	0	0	
Patient was eligible but MD declined to offer participation			0.024
Non-Hispanic White	16	409	
Non-Hispanic Black	13	57	
Hispanic	12	15	
Asian	21	33	
Other*	27	12	
Age			0.374
≥65	16	253	
< 65	16	317	
Sex			< .001
Males	12	135	
Females*	17	439	

*Statistically significant, $p < .05$

Table 7: Multivariate Logistic Regression Model 1: Physical/medical conditions as the reason for ineligibility by demographic characteristics (N=4184)

	Odds Ratio	CI	P-value
Age ≥ 65 (ref, <65)*	1.51	1.28 – 1.79	<0.001
Males (ref, females)*	2.28	1.92 – 2.71	<0.001
Race and Ethnicity*			0.005
Non-Hispanic White (ref)	1.0		
Non-Hispanic Black*	1.53	1.20 - 1.96	
Hispanic	0.66	0.4 - 1.11	
Asian	0.85	0.51 - 1.53	
Other	1.1	0.45 - 2.71	

*Statistically significant, $p < .05$

Table 8: Multivariate Logistic Regression Model 2: Enrollment into a CT by demographic, region, and consent form characteristics (N=4184)

	Odds Ratio	CI	P-value
Age ≥ 65 (ref, < 65)*	0.83	0.7 – 0.98	0.03
Males (ref, females)	1.12	0.93 – 1.35	0.24
Race and Ethnicity			0.18
Non-Hispanic White (ref)			
Non-Hispanic Black	0.83	0.64 - 1.08	
Hispanic	1.33	0.86 – 2.04	
Asian	0.62	0.34 – 1.14	
Other	0.92	0.38 – 2.23	
Consent Form Length			0.78
≥ 20 pages (ref, < 20 pages)	0.98	0.81 – 1.16	
Consent Readability			0.4
SMOG score	0.97	0.89 - 1.05	
Region of Country			0.45
West (ref)			
Midwest	1.06	0.38 - 2.99	
South	0.45	0.13 – 1.54	
Northeast	1.04	0.34 – 3.23	

*Statistically significant, $p < .05$

Table 9. Multivariate logistic Regression Model 3: Patient eligible but declined a CT by demographic, region, and consent form correlates (N=4184)

	Odds Ratio	**95% CI**	***P*-value**
Age ≥ 65 (ref, < 65)	0.86	0.73 – 1.01	.07
Males (ref, females)*****	0.78	0.65 – 0.94	.001
Race and Ethnicity			.78
Non-Hispanic White (ref)			
Non-Hispanic Black	1.05	0.82 - 1.35	
Hispanic	0.97	0.63 - 1.49	
Asian	0.85	0.51 – 1.44	
Other	1.44	0.68 – 3.04	
Consent Form Page Length			.28
≥ 20 pages (ref, < 20 pages)	0.91	0.77 - 1.08	
Consent Readability*			.005
SMOG score	0.9	0.83 – 0.97	
Region of Country			.45
West (ref)			
Midwest	0.83	0.36 – 1.91	
South	0.7	0.27 – 1.81	
Northeast	1.42	0.59 – 3.42	

*Statistically significant, $p < .05$

Chapter 4: Predictors of African American Enrollment in a University-Based Clinical Studies Registry

Abstract

Objective: This study examined predictors of enrollment in the University of Michigan Clinical Studies Registry in a sample of 745 African Americans from 16 churches in Southeast Michigan.

Methods: Our study is part of a larger intervention called the Body and Soul Clinical Trials Project. The parent project enrolled churches to either receive a clinical trial education program (intervention) or education about healthy eating (control). Study participants recruited from the churches filled out a baseline survey and were given educational programs. We examined the baseline data of the entire sample to determine predictors of enrollment in the University of Michigan Clinical Studies registry. We ran three logistic regression models to evaluate predictors of enrollment in the registry, each controlling for treatment condition (i.e., intervention or control churches).

Results: In total, 60 people enrolled in the registry over the 1-year period. In all three models, treatment condition was a significant predictor of enrollment. Demographic variables were not significant predictors of enrollment, nor were baseline aggregate scales for patient-provider communication, personal and global benefits, global barriers, or global trust. However, baseline willingness to participate in a clinical trial (OR = 1.17, CI: 1.01–1.36; P = 0.04) and inconvenience/hassle associated with a clinical trial (OR = 0.73, CI: 0.55-0.98; P = 0.03) were significant predictors of enrollment.

Conclusion: Certain baseline characteristics, including willingness to participate in a clinical trial and perceptions of inconvenience/hassle associated with a clinical trial significantly predicted enrollment in a university-based registry. More work is needed to test the effectiveness of delivering clinical trial education programs in faith-based settings and how, if at all, African Americans may view registries differently than other racial and ethnic groups.

Introduction

Clinical trials are the gold standard for testing new methods of screening, preventing, diagnosing, and treating various medical conditions. Each year, thousands of clinical trials are opened at medical centers across the United States,[1] yet estimates of clinical trial participation among all adults in the U.S. (across diseases) range from as low as 1% to as high as 11%, despite ongoing campaigns to inform the public about research.[2,3] Low participation in clinical trials is a public health concern because many studies close early due to low accrual,[4-6] resulting in the inefficient use of patient and investigator time, limited generalizability of findings, and ineffective spending of research dollars.[7] Women, rural populations, older adults, and racial/ethnic minorities have historically been underrepresented in clinical trials.[8-10] In particular, African Americans, who suffer disproportionately from cancer, diabetes, hypertension, and heart disease compared with whites, remain underrepresented in clinical trials for these conditions.[8,11-13]

Common barriers to clinical trial enrollment among African Americans include medical mistrust, fear of experimentation, co-morbid conditions, limited awareness about medical research, and logistical burdens associated with participating in clinical trials (e.g., extra time, testing, and transportation).[14,15] Facilitators to clinical trial participation include good patient-

provider communication, a positive relationship with one's healthcare provider, perceived personal benefit, and feelings of altruism.[16] Despite the need to include more African Americans and other racial and ethnic groups in medical research, there is paucity of research on the most effective recruitment strategies for increasing enrollment in clinical trials.[17] Traditional methods of recruiting participants include: mailed, telephone, and/or in-person invitations based on medical record or disease registry audits; flyers on hospital and community bulletin boards; paid advertisements in print, online, or television media; word of mouth; hiring study coordinators and recruiters of the same demographic as the population being studied; and on-site recruitment at public events or in clinical settings.[18-20] Participants can also find clinical trials on websites like ClinicalTrials.gov, through disease-specific organizations like the National Cancer Institute, or by contacting local medical centers.

Over the last 10 years, the use of registries as a method to recruit study participants has grown, although the efficacy of such registries is under-researched. For example, RegistryMatch.org was the first national registry to promote clinical trials across NIH-funded Clinical and Translational Science Award (CTSA) programs.[21] Created in 2008, the goal of ResearchMatch.org is "to bring together people who are trying to find research studies and researchers who are looking for people to participate in their studies."[22] Investigators are able to post approved studies to the website and subsequently recruit volunteers from across the U.S. for their studies. As of July 22, 2013, ResearchMatch.org had approximately 40,000 volunteers in the registry, with 300 studies listed and 80 institutions represented.

In the same spirit, a small number of research institutions (< 10), including the University of Michigan, have created local registries to match potential volunteers with clinical trials at their institutions.[23] In contrast to passive approaches to informing patients about clinical trials (e.g.,

ClinicalTrials.gov) or postings to hospital websites, these newer "opt-in" registries allow healthy volunteers and patients with health conditions to proactively enroll in the registry. A study team member may contact volunteers if a clinical trial opens and they meet the eligibility criteria. For example, the University of Michigan registry (UMClinicalStudies.org) allows people to create a profile based on their interests and health conditions. As of July 22, 2013, the UMClinicalStudies.org website had approximately 14,000 volunteers in the registry, with approximately 9% being African American. To enroll in the registry, volunteers complete a consent form and a questionnaire about their medical conditions, demographics, site preferences for studies (e.g., Ann Arbor campus), and other interests (e.g., stress or weight management). Volunteers determine the method (letter, phone, or e-mail) and frequency (as available, weekly, monthly) by which they are contacted. After the profile is created, they begin receiving "personalized study recommendations,"[24] thus eliminating the need for a health care provider to serve as the gatekeeper of this information. A 2005 study conducted by Beskow et al. found that more than 60% of cancer patients preferred that researchers contact them directly about research participation rather than checking with their physician first.[25]

Additional research is needed to test the efficacy of registries for recruiting more African Americans into clinical trials and how, if at all, African Americans view enrolling into a registry differently than receiving a direct invitation from their physician to join a clinical trial. Ideally, registries help connect community members to health studies at medical centers in their area, while also raising awareness about the importance of medical research. The Education Network to Advance Cancer Clinical Trials, the National Medical Association, and the National Cancer Institute advocate for community-based approaches to increase minority involvement in clinical trials, yet there is surprisingly little controlled research of such interventions, and in particular,

few studies that control for the opportunity to enroll into a registry. Moreover, the role of faith-based interventions as a means to enhance minority participation in clinical trials has not been adequately explored.

The objective of this study was to evaluate baseline predictors of enrollment in a university-based registry. The primary hypotheses were:

1) Enrollment in the registry will be moderated by baseline characteristics including age, sex, education, work status, and household income.

2) Willingness to participate in a clinical trial in the future will predict higher enrollment in the registry.

3) Quality of patient-provider communication will predict higher enrollment in the registry.

4) Knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male will predict lower enrollment in the registry.

Methods

This study is part of a larger intervention entitled the Body & Soul Clinical Trials Project. The goal of the parent project was to examine the effect of a culturally tailored clinical trials education program on African American church members' willingness to participate in clinical trials and subsequently, their enrollment in the University of Michigan Clinical Studies registry. The parent project was built upon two existing programs: Body & Soul: A Celebration of Healthy Eating & Living, and the National Medical Association's Project IMPACT (Increase Minority Participation and Awareness of Clinical Trials). Participants in the control group received information about healthy eating and participants in the intervention group received information about participating in medical research. A manuscript reporting intervention effects and the efficacy of the Body & Soul Clinical Trials Project is forthcoming. For the purposes of

this paper, we focus on the baseline data of the entire sample and how these variables predict subsequent enrollment in the registry over the 1-year intervention period.

Control Group Protocol

The control churches received an adapted version of the national Body & Soul program, which promotes fruit and vegetable intake among African American church members. The original Body and Soul program used four program pillars: pastoral support, church activities, church environment, and peer counseling. We added information on heart disease, cancer, Type 2 diabetes, stress management, how to read nutrition labels, and healthy eating recommendations from the Academy of Nutrition and Dietetics (formerly the American Dietetic Association). This additional information was added at the suggestion of our Pastors' Advisory Board since many of their members suffer from chronic diseases and obesity. A website was created for the control group with general information about clinical trials and medical research taken directly from the University of Michigan Clinical Studies website.

Intervention Group Protocol

The intervention churches received a clinical trials education module that was developed from materials from the National Medical Association's Project IMPACT campaign, feedback from our Pastors Advisory Board, and feedback from colleagues at the University of Michigan Clinical Studies Registry (UMClinicalStudies.org). The goals of the tailored clinical trials module were to: 1) Raise awareness about clinical trials, 2) Discuss the research process, and 3) Discuss the role of race and culture in medical research. Given the sensitive nature of medical research for some African Americans, we addressed issues related to race and medical exploitation but also presented potential positive reasons that African Americans may want to participate in research and how diversity in clinical trials may improve the health of African

Americans over time. Other topics in the module included discussions on epigenetics (the concept that the human genome dynamically responds to social and environmental factors such as toxins and stress), common terminology (e.g., informed consent, randomization), process for developing new therapies (e.g., phase 1–4), and participant rights and protections.

Participants in the intervention group watched a short, locally-produced video about clinical trials at the University of Michigan that highlighted the need for more African Americans to be represented in medical research. This video was shown at the first data collection session *after* the baseline surveys were completed. The video featured three local African-American clergy members in Southeast Michigan, three African-American physicians, and one African-American clinical trial participant from the University of Michigan Health System. A website was created for the intervention group churches with clinical trial and medical research information adapted from the National Medical Association's Project IMPACT. Lastly, intervention church members received two e-mail invitations to the join the registry. Those without e-mail addresses received a hard copy letter with the same information.

Educational Workshops for Control and Intervention Churches

All workshops (healthy eating for control churches and clinical trials for intervention churches) were conducted at the churches and lasted approximately one hour. A one-hour time frame was selected based on feedback from the coordinators and the Pastors Advisory Board. Brevity of the workshops was particularly important because many church members attend church for 2–4 hours on Sundays. Members of the research team (one doctoral candidate and two master's-level graduate students) facilitated the workshops. We initially planned to use a "train the trainer" model in which the church coordinators would deliver the educational workshops; however concerns about this strategy were expressed early on by both church coordinators and

the Pastors Advisory Board. Many of the coordinators did not have a medical background and were not comfortable presenting information about clinical trials or healthy eating, and thus requested that the study team conduct the workshops.

Church Recruitment

Church recruitment began with a hard-copy mailing of an introductory letter and a study brochure to approximately 200 African-American churches, followed by telephone calls and e-mails with interested pastors or health ministry members, and when possible, an in-person meeting. After personal contact was made with the pastor, both the pastor and designated church coordinator signed a commitment agreement that outlined roles and responsibilities for the church and the study team. A total of 16 churches (the number determined though sample size calculations) were recruited between July 2011 and January 2012. We randomly assigned churches to the control group or intervention group. Before randomization, we pair-matched churches by size (< 200, 200-400, > 400) and when possible, by denomination (e.g., African Methodist Episcopal, Baptist, Church of God in Christ).

Participant Recruitment

The church coordinators were given a goal of recruiting 40 to 60 members from their church. The recruitment strategy was left to the discretion of the coordinators; however, we developed promotional flyers for display around the church and talking points for church announcements. Coordinators were encouraged to recruit individuals by making church announcements, posting information on bulletin boards, and by making appeals to groups within the church that met regularly (e.g., choir, bible study, and women's ministry).

Baseline and Post-Test Data Collections

All study participants completed a self-administered baseline survey and a post-test survey at approximately 1-year of follow up. The baseline survey was 13 pages long, contained 66 questions, and took participants approximately 15–25 minutes to complete. The post-test survey was 17 pages long, contained 88 questions, and took participants approximately 20–30 minutes to complete. Baseline and post-test data collections were done in a group setting in the churches' fellowship hall. Graduate level research assistants from the University of Michigan were present at all data collection sessions to distribute and collect surveys and to answer questions. Most participants completed the surveys on Sunday afternoons, immediately following the church service. However in some cases, participants completed surveys in a group setting on a different day of the week at the request of the study coordinator, or completed the survey at home if they could not attend the pre-scheduled group session. In these cases, the survey was returned to the church coordinator in a sealed envelope and later picked up by one of the research assistants from the University of Michigan.

All participants completed the pen and paper survey independently unless they requested assistance from the study team or church coordinator. For example, a few participants (less than 10) had limited reading skills and/or mobility issues with their hands. In these cases, research assistants from the University of Michigan read the survey questions to the participant and/or filled out the form on their behalf. Refreshments were provided during each data collection event, and participants were given $10 in cash for completing the baseline and the post-test survey (for a total of $20).

Measures

The baseline survey tool assessed past participation in clinical trials, future willingness to participate in a clinical trial, and attitudes about medical research. Both new and existing single items[26-28] as well as new aggregate scales created by the study team were used as predictors of enrollment in the logistic regression models. Factor analysis was used to guide the structure of the aggregate scales. The final aggregate scales were created by producing a mean score for all items included in scale. Alpha coefficients for each scale are reported.

Dependent Variable

The primary outcome for this paper was *verified enrollment* in the University of Michigan Clinical Studies Registry. The registry keeper verified enrollment by tracking phone, mailed, or the website registrations from January 1, 2012 – June 30, 2013. Mailed enrollment forms were identified by the project logo placement in upper right corner of the form. If a participant called the 800 number, the registry keeper asked how the caller heard about the registry. If "church" was mentioned as the method of hearing about University of Michigan Clinical Studies, the registry keeper would then check the caller's church name against the list of churches in the Body & Soul Clinical Trials Project. Website enrollment was tracked through special URLs created for the intervention and control churches. The registry keeper and web master provided the study team with a list of church members who enrolled by mail, phone, or website. These names were coded manually as enrolled by the study team.

Independent Variables

Demographics

Age was assessed on a continuous scale, and sex was coded as male and female. Work status was categorized into three levels: not working (students, retirees, homemakers), part-time, and full-time. Household income was categorized into three levels: less than $40,000; $40,001 – $80,000; and $80, 000 plus, and education was categorized by 11th grade or less; high school, some college, and vocational training; and 4 year college plus. A dichotomous variable for education (< 4 year college and ≥ 4 year college) was used due to the small number of participants with an 11th-grade education or less.

Global Trust

To assess general trust for healthcare providers and related organizations, a 6-item scale ($\alpha = 0.76$) was created by the research team based on the following items: 1) I trust my primary care doctor; 2) I trust the place where I get most of my medical care; 3) I trust my health insurance provider; 4) I trust the University of Michigan; 5) Medical researchers are generally honest in telling participants about different treatment options available for their conditions; and 6) All in all, medical researchers would not conduct experiments on people without their knowledge. The response options were: strongly disagree, disagree, neutral, agree, and strongly agree. The aggregated mean score was used for analyses.

Patient-Provider Communication

Based on prior patient-provider communication measures, we created a 6-item scale ($\alpha = 0.91$) by adapting items from NCI's Health Information National Trends Survey. At the beginning of these items, participants were prompted to respond with the primary care physician or specialist that they saw most often for their medical care in mind. The six items, aggregated

into an overall mean, were: 1) During the past 12 months, how often did doctors, nurses, or other health professionals give you the chance to ask all the health-related questions you had during a medical appointment; 2) During the past 12 months, how often did doctors or other health providers listen carefully to you during a medical appointment; 3) How often did they explain things in a way you could understand during a medical appointment; 4) How often did they show respect for what you had to say during a medical appointment; 5) How often did they spend enough time with you during a medical appointment; and 6) How often did they involve you in decisions about your health care as much as you wanted during a medical appointment? Response options were: always, usually, sometimes, never, don't know, and not applicable. The aggregated mean score was used for analyses.

Benefits

We assessed perceived personal benefit of a clinical trial as well as perceived global benefit (i.e. potential benefit for others, the community, or society at large). The 3-item personal benefit scale was created by the study team (α=.71) and a mean score was produced by using responses to the question, "How much would each of the following reasons increase your willingness to participate in a clinical trial?": 1) The benefits of the research for my health; 2) Having access to new drugs or treatments; and 3) Getting closer monitoring of my health. Response options were: not at all, a little, somewhat, greatly and don't know.

A 5-item global benefit scale was created by the study team (α = 0.73) using the following items: 1) To determine what is best for African Americans' health now and for future generations, it's important for us to participate in clinical trials; 2) Participating in medical research is part of my responsibility to the African-American community; 3) In general, I think that medical researchers are trying to help society; 4) Medical research has improved the health

of African Americans; and 5) More African Americans would participate in clinical trials if they understood how the research would help them or their community. Response options were: strongly disagree, disagree, neutral, agree, strongly agree, and don't know. We used the aggregated mean score of responses for analyses.

Barriers

An 11-item global barriers scale created by the study team ($\alpha = 0.84$) based on answers to following question: "How much would each of the following reasons decrease your willingness to participate in a clinical trial?" 1) The risks involved with the study; 2) The possibility I will receive only a "placebo" or no treatment; 3) Additional testing or procedures required because of the clinical trial; 4) The amount of pain or discomfort involved; 5) Whether or not my insurance will cover the costs related to the clinical trial; 6) The amount of time required to participate; 7) Extra demands on my family members because of the study; 8) Travel distance to the medical facility or transportation; 9) Need for childcare during medical appointments; 10) Difficulty taking time off from work; and 11) Inconvenience or "hassle." Response options were: not at all, a little, somewhat, greatly, and don't know. We used the aggregated mean score of responses for analyses.

Willingness to Participate in a Clinical Trial

We queried willingness by asking, "On a scale from 1 to 10, with 1 being not at all willing and 10 being very willing, how willing would you be to participate in a clinical trial in the future?" Word anchors were used to help give meaning to the number options along the 1–10 scale and included: not at all willing, somewhat unwilling, neutral, somewhat willing, and very willing.

Knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male

This survey question was worded as, "Have you ever heard of the U.S. Public Health Service Syphilis Study at Tuskegee?" Response options were yes and no. This item was of particular interest based on mixed evidence that knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male is associated with enrollment in clinical trials and overall willingness to participate in research.[29,30]

Treatment Condition

A binary variable (control or intervention) was created to differentiate church members in the clinical trials education group (intervention) and healthy eating education group (control). The control churches served as the reference group.

Data Analysis

Three logistic regression models were run to evaluate predictors of enrollment in the University of Michigan Clinical Studies Registry, each controlling for treatment condition. The first model examined the impact of demographics on enrollment in the registry. The second model examined the impact of aggregate scales for global trust, patient-provider communication, personal benefit, global benefit, and global barriers on enrollment in the registry. The third model assessed the impact of single items on enrollment in the registry including willingness to participate in a clinical trial, inconvenience or hassle associated with a clinical trial, responses to the item "participating in research is my responsibility to the black community," responses to the item "I have experienced discrimination in a health care setting," and knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male. We chose to include single items in model 3 because we were particularly interested in their role with regard to enrollment into the registry. Given the volume of single items on the baseline survey, univariate analyses

were first done to identify potential predictors of enrollment into the registry (data not reported). Only seven items were significant, five of which were evaluated in model 3. Due to small sample sizes and multicollinearity, the two items that were dropped were: "Have you been asked to participate in a clinical trial, but declined" (only 200 responded yes) and difficulty taking time off work (correlated with inconvenience/hassle). Initially, we investigated clustering effects within church by running a random intercept model, however the random intercept variance was not significant, indicating that there is not substantial correlation of individuals within churches, thus a more parsimonious logistic regression model without random intercept was used. Cases with missing data were removed using listwise deletion. Finally, interaction effects of age, sex, education, work status, and household income on each scale and item were evaluated, but none were significant and are not reported. All analyses were conducted with IBM's SPSS statistics software version 20.

Results

By the end of the project, 60 participants had enrolled in the registry. All others were coded as not enrolled. Of all of the methods of enrollment (e.g., mail, phone, web), standard U.S. mail was the most common way that people signed up for the registry, with more than 90% of participants using this method. We initially recruited 745 participants from 16 churches in Southeast Michigan to participate in our study. The average number of baseline surveys per church was 46, with a range of 19–77 surveys per church. At one year follow up, 580 participants completed the post-test survey for a retention rate of 78%. Reasons for attrition included participants who passed away, moved out of the area, left the church, and/or did not want to complete the final survey for unspecified reasons.

As shown in Table 10, the average age was 48, with approximately 68% of the sample being female. With regard to education, 5% had less than an 11th grade education; 60% had a high school degree, some college, or vocational training; and 36% had a 4-year college degree or higher. In terms of work status, 50% were not working (this included unemployed, retired, students, or homemakers), 39% were employed full-time, and 11% were employed part-time. This distribution of household income was 51% of households earning less than $40K, 31% earning between $40,001 - $80,000, and 18% earning more than $80,001. The mean score for willingness to participate in a clinical trial was 7.22, and 8% of the sample enrolled into the registry.

Using enrollment in the University of Michigan Clinical Studies Registry as the dependent variable, we ran three logistic regression models with multiple independent variables. The odds ratios and confidence intervals are reported in Tables 11–13. The first logistic regression model (Table 11) assessed age, sex, education, work status, household income, and education on enrollment into the registry, controlling for treatment condition. None of these demographic variables were significant predictors of enrollment in the registry, however treatment condition was a significant predictor of enrollment (OR=2.68, CI: 1.44 – 5.0). The second logistic regression model (Table 12) assessed the role of the baseline aggregate scales for patient-provider communication, personal benefit, global benefit, global barriers, and global trust on enrollment in the registry. None of the aggregate scales were significant predictors of enrollment into the registry, although treatment condition remained significant (OR=2.94, CI:1.57 – 5.5).

The final logistic regression model (Table 13) assessed willingness to participate in a clinical trial, inconvenience or "hassle" associated with a clinical trial, "participating in research

is my responsibility to the black community," "I have experienced discrimination in a health care setting," and knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male on enrollment in the registry. Treatment condition (OR=2.86, CI: 1.47 - 5.54), willingness to participate in a clinical trial (OR=1.17; CI, 1.01 – 1.36) and inconvenience or hassle associated with a clinical trial (OR=0.73, CI: 0.55 – 0.98) were significant predictors of enrollment into the registry.

Discussion

The primary aim of this study was to evaluate baseline predictors of enrollment in a university-based registry in a cohort of African American church members living in Southeast Michigan. In total, 60 church members enrolled into the registry over a 1-year period. None of the demographic characteristics (age, sex, household income, work status, and education) nor aggregate scales for patient-provider communication, personal benefit, global benefit, global barriers or global trust predicted enrollment in the registry. Baseline willingness to participate in a clinical trial in the future and inconvenience or hassle associated with a clinical trial were significant predictors of enrollment in the registry. That is, higher willingness to participate in a clinical trial was associated with higher enrollment into the registry, and stronger perceptions of inconvenience or hassle were associated with lower enrollment.

Initially, we anticipated that there would be greater challenges with recruiting church members into this study, especially given that clinical trials may not be as popular as other health behaviors such as nutrition, physical activity, stress management, and weight loss. While we did not have challenges recruiting participants into the study, more work is needed to better understand how to engage the faith community in discussions about medical research and how to keep interest in the topic over time to reduce attrition. Additionally, more research about how

African Americans (and other racial and ethnic groups) view recruitment registries is needed. During workshops and data collection sessions, church members had questions about the purpose of the registry and whether or not they would start getting solicitations from the University of Michigan. It is possible that church members viewed the registry as a marketing tool for the university and were therefore apprehensive about signing up. The goal of the registry is to match interested volunteers with relevant clinical trials and to provide personalized study recommendations. Participants who sign up for the registry are indeed more likely to receive research-related correspondence from the University of Michigan than the general public. It should be noted that formally joining the registry is not necessary to learn about health studies at the University of Michigan and other places. Some church members may have chosen to explore clinical trials on their own as a result of being in our project, which would not have been captured in our survey data.

Study strengths and limitations

Our study is one of the first efforts to assess enrollment in a university-based registry in sample of African-American church members from diverse denominations and church environments. Given the growing number of researchers who are partnering with African-American faith-based institutions to recruit for clinical trials, a better understanding of the attitudes and beliefs of this population may inform future projects. Additionally, over the course of conducting workshops in the churches, several questions from church members about the relevance of clinical trials for African Americans and the purpose of the registry were raised, which may improve future educational campaigns about medical research, as well as the effectiveness of registries in recruiting African Americans into clinical trials.

Several limitations should be noted. The sample of churches and church members invited to participate in this study were not randomly selected (this was a convenience sample); therefore there may be a degree of selection bias both at the individual and church level. All of the churches were located in Southeast Michigan, and the majority of participants were female; thus results may not be generalizable to other parts of the country or to men overall. Additionally, given the limited number of items that predicted enrollment in the registry, it is possible that we did not measure the items or underlying constructs well. It is also possible that we missed people that did enroll in the registry due to our tracking system. That is, we were only able to query enrollment of participants who mailed back the project-branded forms provided by study team, those who called and identified that they heard about the registry from church, or those that enrolled via the websites specifically created for the project. It is possible that church members joined the registry via the general University of Michigan website or by returning the standard enrollment form disseminated to the general public at community events.

Finally, it should be noted that enrollment in the University of Michigan Clinical Studies Registry is *not* equivalent to enrolling into a clinical trial, but rather a general proxy of one's interest in learning more about research opportunities. Once a person is enrolled in the registry, there needs to be open clinical trials for which the volunteer qualifies (which is not always the case) and then, the volunteer needs complete the informed consent process to formally enroll in a clinical trial.

Conclusion

This study showed that it is possible to recruit African American church members into a university-based registry. However given the modest number of church members who enrolled, more work is needed to test the effectiveness of delivering clinical trial education programs in

faith-based settings, and how, if at all, African Americans may view registries differently from other racial and ethnic groups. Additionally, future work should examine what happens to volunteers *after* they are enrolled in a registry and whether the existence of a university-based registry actually improves enrollment in specific clinical trials across health conditions.

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Table 10: Baseline demographics of African American church members (N = 745).

Age (mean)	48
Sex (%)	
Male	32
Female	68
Work Status (%)	
Not working (retired, students, etc.)	50
Part-time	11
Full-time	39
Household Income (%)	
Less than $40,000	51
$40,001 - $80,000	31
$80,001 plus	18
Education (%)	
11th Grade or less	5
High school, some college, and/or vocational training	60
College degree and beyond	35

Table 11: Enrollment in the registry by baseline demographics, multivariate logistic regression. (n=631)

	Odds Ratio	95% CI	*P*-value
Treatment Condition (control, ref)*	2.68	1.44 – 5.0	.002
Age	1.02	.99 – 1.03	.192
Sex (males, ref)	1.8	.87 – 3.64	.104
Education (Less than 4 year degree, ref)	.84	.44 – 1.6	.592
Work Status			.234
Not working (ref)	1.0		
Part-time	1.08	.41 – 2.83	
Full-time	.56	.27 – 1.14	
Household Income			.146
Less than $40,000 (ref)	1.0		
$40,001 – $80,000	1.81	.91 – 3.6	
$80,001 plus	.92	.37 – 2.31	

*Significantly significant, $P < 0.05$

Table 12: Enrollment in the registry by baseline aggregate scales, multivariate logistic regression (n=600)

	Odds Ratio	95% CI	*P*-value
Treatment condition (control, ref)*	2.94	1.57 – 5.5	.001
Patient-Provider Communication	1.03	.61 – 1.73	.922
Personal Benefit	.96	.58 – 1.62	.889
Global Benefit	1.57	.83 – 2.96	.162
Global Barriers	.73	.46 – 1.13	.154
Global Trust	1.2	.67 – 2.13	.54

*Significantly significant, $p < .05$

Table 13: Enrollment in the registry by individual baseline survey items, multivariate logistic regression (n=595)

	Odds Ratio	95% CI	*P*-value
Treatment condition (control, ref)*	2.86	1.47 – 5.54	.002
Willingness to participate in a clinical trial in the future*	1.17	1.01 – 1.36	.04
Inconvenience or "hassle" associated with a clinical trial*	.73	0.55 – 0.98	.03
Participating in research is my responsibility to the black community	.99	0.73 – 1.34	.93
I have experienced discrimination in a healthcare setting	.81	0.64 – 1.03	.08
Knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male	1.9	0.93 – 3.95	.08

*Significantly significant, $P < .05$

Chapter 5: Closing Thoughts and Implications

The main hypothesis of my dissertation research was that logistical factors such as whether patients are offered clinical trials and have access to quality medical care are the underlying drivers of racial and ethnic disparities in clinical trial participation; more so than factors such as mistrust and perceived racism. In paper 1, I found that African Americans are willing to participate in clinical trials and that willingness to participate in a clinical trial was associated with scales for personal benefit, global benefit, and global barriers, as well as the amount of payment, trust in the organization offering the trial, and being involved in decisions about one's healthcare; however, knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male and distrust of healthcare professionals were not associated with willingness to participate in a clinical trial. In paper 2, I found no racial/ethnic differences in clinical trial enrollment, refusal rates, or desire to participate in medical research among cancer patients; however, ineligibility due to physical/medical conditions was associated with older age, being male, and non-Hispanic blacks. In paper 3, I found that enrollment in the University of Michigan Clinical Studies registry was associated with treatment condition, willingness to participate in a clinical trial, and perceptions of inconvenience. Knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male and distrust of healthcare professionals were not associated with enrollment in the registry.

While I acknowledge that medical mistrust and knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male are important factors in the narrative of minorities and clinical trials; these factors only tell part of the story. My research demonstrates

that other factors (e.g., co-morbidities and perceptions of benefit for self and community) may be equally or more important. Moving forward, a better understanding of the following areas may help reduce disparities in minority participation and warrant more attention.

Institutional Racism

In papers 1 and 3, I found that knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male, distrust of healthcare professionals, and past experiences of discrimination in a healthcare setting were not associated with willingness to participate in a clinical trial or enrollment in the University of Michigan Clinical Studies registry; however, this does not mean that racism is no longer a salient issue for minorities. To the contrary, any discussion about African Americans and research is incomplete without acknowledging the role that institutional racism has played and continues to play in shaping attitudes about medical research. For example, slaves were forced to participate in medical research and demonstration projects.[1] The poor and enslaved were used to fill hospital beds to help doctors practice and perfect their craft.[2] Segregated hospitals may have impacted African Americans' attitudes about clinical trials over time.[3] In many cases, they received poor care at segregated hospitals which may have affected the trust that African American patients had in the scientific establishment and to some degree, non-African American physicians. In 2013, extreme acts of racism may be less obvious and frequent, yet nuanced expressions of racism may still impact minority attitudes about clinical trials. Future work will benefit from more specific measures of racism and discrimination than were used on my Body & Soul Clinical Trials Project surveys (e.g., the Everyday Discrimination Scale).[4]

Institutional racism also impacted medical school admissions and in turn, the number of African American doctors that could be trained.[5] In 2008, the American Medical Association

(AMA), the largest physician group in the United States, apologized to African American doctors for a history of racial discrimination. "The effects of this history have been far reaching for the medical profession and, in particular, the legacy of segregation, bias, and exclusion continues to adversely affect African American physicians and the patients they serve."[5] Currently, African Americans comprise 4% of all U.S. physicians and surgeons despite being 13% of the population.[6] The lack of diversity within the medical field may affect the desire of African American patients and communities of color to participate in research. Further work is needed to examine of the impact of minority physicians on minority patient interest and participation in clinical trials.

Residential Segregation

Residential segregation refers to the "physical separation of the races in residential context"[7] and is often measured by the U.S. Census index of dissimilarity scale.[8] With regard to African Americans' ability to access quality medical and healthcare organizations for which clinical trials are offered, residential segregation impacts where hospitals are located and the number of hospitals in a given area. Healthcare facilities are more likely to close in poor and minority communities than in other areas;[9-10] thus, it is possible that hospitals in underserved areas operate on smaller budgets than large health systems and have less of a research infrastructure. Limited resources to conduct medical research may affect a community hospital's ability to open clinical trials and subsequently impacts the number of clinical trials available in minority areas. A future study could utilize geographic information system (GIS) software to examine the proximity of available clinical trials to minority-dense communities.

Healthcare Organizations

To increase the full participation of minorities in medical research, it is important that the clinical trials offered at a healthcare organization match the patient population. For example, if an organization sees 75% African American patients, then having several clinical trials for skin cancer may be problematic because skin cancer is predominantly diagnosed in white patients. Alternatively, opening clinical trials for triple negative breast cancer or prostate cancer is more appropriate, as these cancers are common among African Americans.[11] It should be noted that healthcare organizations have autonomy in deciding which clinical trials will be conducted at their site. The decision about which clinical trials are opened is influenced by investigator interest, buy-in from the research staff, administrative burden, and the cost of carrying out the trial (e.g., reimbursement rates by funders). These decisions significantly impact the number of clinical trials for which a patient is eligible, as well as a patient's proximity to relevant clinical trials for his or her disease; which has implications for travel burden.

Several factors affect an organization's ability to conduct research. Most notably, an adequate research infrastructure and efficient institutional review board are critical. The issues of infrastructure are especially challenging for hospitals in underserved areas, thus the NIH National Center for Research Resources has created a Research Infrastructure division aimed to enhance the competitiveness of investigators in underserved states and institutions.[12] Ultimately, minorities may be systematically excluded from clinical trials because the organizations in which they get their care do not have adequate resources to conduct clinical and health research. More structural interventions are needed to improve how clinical trials are conducted at health organizations. Potentials areas of focus include center-wide policies for research, infrastructure

supports (e.g., data analysts and research nurses), use of informatics to identify eligible patients, and monitoring of high and low accrual studies to determine best practices.[13]

Healthcare Provider Attitudes

In paper 2, the two leading reasons that physicians did not offer a clinical trial to a cancer patient were; 1) preference for standard treatment; and 2) concerns about the patient's co-morbidities/frailty. It is possible that physician preference/bias is a driver in the minority disparity in clinical trials. It should be noted that both primary care physicians and medical oncologists have concerns about enrolling patients onto trials if they feel that the patient does not understand what is involved.[14] Rigid protocol designs, limited time to discuss clinical trials, and limited confidence in their ability to explain clinical trials in lay terms are additional limitations.[15] For referring primary care physicians, fear of losing a patient and revenue is a commonly cited reason for not referring patients to clinical trials conducted at other medical centers.[16] Conflict of duality (the internal conflict that arises from caring for patients, but also conducting research) is another challenge for providers. Clinical trials are ideally designed to benefit the individual *and* society; however, in many cases the benefit is balanced more favorably for society and future patients. Although physicians generally agree about the value of what can be learned in clinical trials, barriers include paperwork requirements, time constraints, and concerns for patient welfare.[17] Further work is needed to understand what resources/supports providers may need to fully participate in clinical trial research.

Patient-Provider Communication

A better understanding is needed of patient-provider communication in the context of clinical trials; currently it is not clear whether all eligible patients are being offered clinical trials. For example, Albrecht et al video-recorded 235 outpatient interactions among oncologists,

patients, and family/companions video recorded at two cancer centers and found that clinical trials were explicitly offered in 20% of the interactions; however, when offers were made and patients perceived they were offered a trial, 75% of patients consented.[18] The overall conclusion was that a large percentage of patients are not offered trials; however, when they are offered trials, most patients will enroll. Factors still to be explored include *how* clinical trials are offered and explained to patients.

Given the literature on provider bias, it is possible that minority patients are underrepresented in clinical trials in part because healthcare providers are not offering this option routinely.[19-21] A recent study by Eggly et al. entitled, "A disparity of words: racial differences in oncologist-patient communication about clinical trials," found that compared to visits with white patients, clinical visits with African American patients were shorter and included fewer mentions and less discussion of clinical trials.[22] Clinical trial discussions with African American patients focused more on voluntary participation and less on the purpose and risks of the clinical trial being offered. More studies are needed to assess whether providers are offering clinical trials at the same rate across racial and ethnic groups, and which members of the study team (doctors, nurses, and study coordinators) are most effective at discussing clinical trials with patients.

Decision-Making for Clinical Trials

Future work should examine whom, if anyone helps minority patients decide to join a clinical trial. It will be informative for researchers to know what role social networks may play in this process and which entity has the biggest influence on the decision: physicians, family, friends, pastors, social workers, and/or other patients. In particular, the impact of the physician is of interest, as doctors differ in their comfort level and experience with clinical research. In some cases, a doctor may recommend *against* a clinical trial. There is some evidence that

African American cancer patients report more physical and financial challenges, as well as lower social support than white patients.[23-25] Church involvement and relationships within the faith community have been shown to be important to African Americans;[26] however, less is known about how, if at all, these social relationships might affect their decision to participant in clinical trials and whether faith-based interventions are effective channels for delivering clinical trial education programs.

Participation of African American Men in Clinical Trials

It has been historically true that men, and especially white men, were better represented in clinical trials than women.[27] However, in paper 1, I found that women were more willing to participate in a clinical trial than men. In paper 2, sex was not associated with enrollment in a cancer clinical trial nor was sex associated with enrollment in the University of Michigan Clinical Studies registry in paper 3. It is possible that these conflicting findings are due to the characteristics of each sample (i.e., church members compared to cancer patients). To further explore this issue, I examined sex-specific differences by race in the NCCCP data set (see appendix) and found that African American men did not differ from white men in cancer clinical trial enrollment, refusal, desire to participate in research, or physical/medical conditions that would make them ineligible for a clinical trial; however, Asian men had lower odds of enrollment. While it is unclear why Asian men are less represented in clinical trials, it is possible that language barriers, less awareness about clinical trials, or cultural differences are contributing factors.[28] Additionally, there were no racial/ethnic differences among men in a MD declining to offer a clinical trial to an eligible patient.

Given the inconsistencies in reporting of results from clinical trials by race and ethnicity, sub-group analyses comparing African American males to males of other racial/ethnic groups is

difficult to find;[29-30] however, a few studies exist that focus primarily on African American men.[31] For example, African American men were well represented in the Selenium and Vitamin E Cancer Prevention Trial (SELECT) for prostate cancer; comprising 15% of the sample.[32] In a study by Byrd et al entitled, "Recruiting Intergenerational African American Males for Biomedical Research Studies: A major research challenge," researchers found that African American males across all ages are willing to participate in various types of research studies; their participation is influenced by education level; and their decision to participate in research studies is often motivated by civic duty, monetary compensation, and whether they or a relative has had the disease of interest.[33]

Other studies have shown differences in clinical trial participation by male sex, but without regard to race/ethnicity. Cooke et al found that men were less likely to be enrolled in a lung injury clinical trial due to co-morbidity[34] while another study of patients with lung and colorectal cancers found that females had higher odds of enrollment than males (OR=1.36; CI: 1.1-1.68).[35] Future studies should examine gender willingness to participate in clinical trials, actual enrollment, and long-term retention by race/ethnicity. Future work should also assess whether there are racial/ethnic differences in men's response to various recruitment methods[36] and whether men's experiences once enrolled in a clinical trial may differ from women's (e.g., adverse events and satisfaction with the research team).

Health Literacy and Public Awareness

It is estimated that only 12% of American adults have proficient health literacy skills.[37] Health literacy is defined as the ability to understand health information and to use that information to make good decisions about health and medical care.[38] Health literacy also encompasses numeracy or comfort with numbers.[39] This is an important area because clinical

trials are sometimes explained in terms of risk or statistics (e.g., the chance of experiencing nausea is about 10%). It is possible that a patient's health literacy level influences his or her willingness to enroll in a study. Similarly, low literacy has been associated with poor health outcomes (e.g., more hospitalizations) and less frequent use of preventive services.[40] Future work should evaluate the use of *plain language* (sometimes referred to as plain English) and grade level readability on informed consent documents and patient education materials for clinical trials. Per Robert Eagleson's definition,

> "Plain English is clear, straightforward expression, using only as many words as are necessary. It is language that avoids obscurity, inflated vocabulary and convoluted sentence construction. … Writers of plain English let their audience concentrate on the message instead of being distracted by complicated language. They make sure that their audience understands the message easily."[41]

Finally, the impact of the media in shaping public attitudes about clinical trial warrants exploration. National campaigns promoting clinical trials have been limited[42-43] and in the last 10 years, two important books have been written about African Americans and medical research; further exposing past racism and scientific missteps. These books include Medical Apartheid: the Dark History of Medical Experimentation on Black Americans From Colonial Times to the Present and The Immortal Life of Henrietta Lacks.[1, 44] Movies about medical research have also been made such as Miss Evers' Boys about the US Public Health Service Study of Untreated Syphilis in the Negro Male and Hole in the Head: A Life Revealed, a documentary about Vertus Hardiman, who at the age of five became the victim of a medical experiment that left him with a physical deformity.[45] It is not known how, if at all, such books, movies, or national news stories have impacted minority participation in clinical trials. Cross-sectional surveys or qualitative interviews with healthy volunteers and patients with health conditions may elucidate the relationship between media and public attitudes about clinical trials.

Application of Theory

More theory-based approaches may help researchers better identify psychological and behavioral predictors of enrollment in a clinical trial. While my grand conceptual model in the introduction focused on the Theory of Planned Behavior combined with constructs from an ecological framework, using an Integrated Behavioral Model may enhance future research. Like the Theory of Reasoned Action and Theory of Planned Behavior, the Integrated Behavioral Model suggests that the most important determinant of behavior is *intention* to perform the behavior; thus, if a person is not motivated to change or implement a behavior, it is unlikely to occur. That is, even with strong behavioral intention, a person still needs to possess the knowledge and skills to do the behavior (e.g., knowledge of clinical trials and how to enroll), minimal environmental constraints that make the task difficult (e.g., transportation), and salience toward the topic (e.g., belief that a clinical trial is important to the person, their community, or someone they care about).[46]

Conclusion

In closing, I entitled this dissertation "Rethinking Minority Participation in Clinical Trials: More than Mistrust" to challenge how researchers think about this issue. It is quite possible that the problems to be fixed with regard to minority participation in clinical trials are not the attitudes or beliefs of patients, but rather the current practices of investigators. Improvements in how the research community engages minority patients, designs protocols, and communicates about clinical trials may resolve the racial and ethnic disparity in clinical trial enrollment.

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APPENDIX

R21 Baseline Survey

NCCCP Clinical Trials Screening and Accrual Log

Body & Soul Clinical Trials Project: Pre-Test Survey

This is the first survey that you will take as part of the Body & Soul Clinical Trials Project. Your answers to this survey will help us evaluate our program and better understand what people think about medical research. There are no right or wrong answers. Please answer honestly.

Your participation is voluntary and your answers will remain confidential. Your answers will not be shared with your pastor or anyone else at your church.

Today's Date: _____
Month, Day, Year (e.g. 5/16/11)

NAME: _____

Street Address: _____

City: _____ State: _____ Zip Code: _____

Home Phone: _____

Work Phone: _____

Cell Phone: _____

Email Address: _____

Church Name: _____

Q1. Clinical trials are research studies that involve people. They are designed to test the safety and effectiveness of new treatments and to compare new treatments with the standard care that people currently get. Have you ever heard of a clinical trial?

- □1 Yes
- □2 No (*if no, skip to question #6)
- □3 Don't Know

Q2. Have you ever participated in a clinical trial?

- □1 Yes
- □2 No
- □3 Don't Know

Q3. Have you ever tried to participate in a clinical trial, but were told that you could not enroll because you were not eligible?

- □1 Yes
- □2 No
- □3 Don't Know

Q4. Have you ever been *asked* by a health care professional to participate in a clinical trial?

- □1 Yes
- □2 No (*If no, skip to question 6)
- □3 Don't Know

Q5. Have you been asked to participate in a clinical trial, but *declined*?

- □1 Yes
- □2 No
- □3 Don't Know

Q6. Have you ever signed up for University of Michigan Clinical Studies Registry (aka ENGAGE or UMClinicalStudies.org)?

- □1 Yes (skip to 6a)
- □2 No (skip to question 7)
- □3 Don't Know (skip to question 7)

Q6a. *If yes, how did you enroll?

- □1 Web
- □2 Mail
- □3 Phone

Q7. On a scale from 1 to 10, with 1 being *not at all willing* and 10 being *very willing,* how willing would you be to participate in a clinical trial in the future?

Not at all willing		Somewhat unwilling		Neutral			Somewhat willing		Very willing
1	2	3	4	5	6	7	8	9	10

Many of the next questions ask about your feelings and opinions about the African American experience with health care and medical research. We are asking these questions because there is a wide variety of attitudes and opinions in our community. There are no right or wrong answers. Please answer for <u>yourself</u>, not on behalf of the African American community.

Q8. How much would each of the following reasons <u>increase</u> your willingness to participate in a clinical trial?

	Not at all	**A Little**	**Somewhat**	**Greatly**	**Don't know**
Q8a. Trust in the organization conducting the trial.	1	2	3	4	DK
Q8b. Trust in the person offering me the trial.	1	2	3	4	DK
Q8c. The benefits of the research for the health of <u>*others.*</u>	1	2	3	4	DK
Q8d. The benefits of the research for <u>*my*</u> health.	1	2	3	4	DK
Q8e. Having access to new drugs or treatments.	1	2	3	4	DK
Q8f. Getting closer monitoring of my health.	1	2	3	4	DK

How much would each of the following reasons increase your willingness to participate in a clinical trial?	Not at all	A Little	Somewhat	Greatly	Don't know
Q8g. Amount of payment or incentive for participating.	1	2	3	4	DK

Q9. How much would each of the following reasons decrease your willingness to participate in a clinical trial?

	Not at all	A Little	Somewhat	Greatly	Don't know
Q9a. The risks involved with the study.	1	2	3	4	DK
Q9b. The possibility I will receive only a “placebo” or no treatment.	1	2	3	4	DK
Q9c. Additional testing or procedures required because of the clinical trial.	1	2	3	4	DK
Q9d. The amount of pain or discomfort involved.	1	2	3	4	DK
Q9e. Whether or not my insurance will cover the costs related to the clinical trial.	1	2	3	4	DK
Q9f. The amount of time required to participate.	1	2	3	4	DK
Q9g. Extra demands on my family members because of the study.	1	2	3	4	DK
Q9h. Travel distance to the medical facility or transportation.	1	2	3	4	DK

Q10. How much would each of the following reasons <u>decrease</u> your willingness to participate in a clinical trial?

	Not at all	A Little	Somewhat	Greatly	Don't know
Q10a. Need for child care during medical appointments	1	2	3	4	DK
Q10b. Difficulty taking time off from work.	1	2	3	4	DK
Q10c. Inconvenience or "hassle".	1	2	3	4	DK
Q10d. Distrust of health care professionals.	1	2	3	4	DK
Q10e. The U.S. Public Health Service Syphilis Study at Tuskegee.	1	2	3	4	DK

Q11. Now, we want to better understand your feelings about clinical trials and medical research. With "1" being *strongly disagree* and "5" being *strongly agree.* Please circle the number that best represents how much you agree or disagree with each of the statements below.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Don't Know
Q11a. Clinical trials are important to finding new cures for disease.	1	2	3	4	5	DK
Q11b. To determine what is best for African American health now and for future generations, it's important for us to participate in clinical trials.	1	2	3	4	5	DK

With "1" being *strongly disagree* and "5" being *strongly agree.* Please circle the number that best represents how much you agree or disagree with each of the statements below.	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**	**Don't Know**
Q11c. More African Americans would participate in clinical trials if they saw more African American researchers conducting the studies.	1	2	3	4	5	DK
Q11d. In general, doctors give preference to white people over black people when deciding whom to offer clinical trials.	1	2	3	4	5	DK
Q11e. Participating in medical research is part of my responsibility to the African American community.	1	2	3	4	5	DK
Q11f. There are adequate laws in place to protect people from being taken advantage of in medical research.	1	2	3	4	5	DK
Q11g. Researchers treat human beings like guinea pigs.	1	2	3	4	5	DK
Q11h. African Americans are just as willing to participate in medical research as other groups.	1	2	3	4	5	DK

With "1" being *strongly disagree* and "5" being *strongly agree.* Please circle the number that best represents how much you agree or disagree with each of the statements below.	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**	**Don't Know**
Q11i. All things being equal, I prefer to have an African American doctor.	1	2	3	4	5	DK
Q11j. Medical researchers think an African American life is worth less than a White life.	1	2	3	4	5	DK
Q11k. Medical researchers are generally honest in telling participants about different treatment options available for their conditions.	1	2	3	4	5	DK
Q11l. All in all, medical researchers would not conduct experiments on people without their knowledge.	1	2	3	4	5	DK
Q11m. I trust my primary care doctor.	1	2	3	4	5	DK
Q11n. I trust the place where I get most of my medical care. (e.g. clinic, healthcare system, hospital).	1	2	3	4	5	DK
Q11o. I trust my health insurance provider (e.g. Medicare, Blue Cross Blue Shield, HAP).	1	2	3	4	5	DK

With "1" being *strongly disagree* and "5" being *strongly agree.* Please circle the number that best represents how much you agree or disagree with each of the statements below.	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**	**Don't Know**
Q11p. I trust the University of Michigan.	1	2	3	4	5	DK
Q11q. In general, I think that medical researchers are trying to help society.	1	2	3	4	5	DK
Q11r. I have personally benefitted from past medical research.	1	2	3	4	5	DK
Q11s. Medical research has improved the health of African Americans.	1	2	3	4	5	DK
Q11t. All racial and ethnic groups benefit equally from medical research.	1	2	3	4	5	DK
Q11u. More African Americans would participate in clinical trials if they understood how the research would help them or their community?	1	2	3	4	5	DK
Q11v. More African Americans would participate in medical research if their doctor offered them a clinical trial?	1	2	3	4	5	DK

With "1" being *strongly disagree* and "5" being *strongly agree.* Please circle the number that best represents how much you agree or disagree with each of the statements below.	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**	**Don't Know**
Q11w. I have experienced discrimination in a healthcare setting (e.g. hospital, clinic)?	1	2	3	4	5	DK
Q11x. As an African American, I would feel comfortable going to the University of Michigan for my medical care.	1	2	3	4	5	DK

The following questions refer to your primary care physician or the specialist that you see <u>most often</u> for your medical care.

Q12a. During the past 12 months, how often did doctors, nurses, or other health professionals give you the chance to ask all the health-related questions you had during a medical appointment?

Always	Usually	Sometimes	Never	Don't Know	Not applicable

Q12b. During the past 12 months, how often did doctors or other health providers listen carefully to you during a medical appointment?

Always	Usually	Sometimes	Never	Don't Know	Not applicable

The following questions refer to your primary care physician or the specialist that you see <u>most often</u> for your medical care.

Q12c. How often did they explain things in a way you could understand during a medical appointment?

Always	Usually	Sometimes	Never	Don't Know	Not applicable

Q12d. How often did they show respect for what you had to say during a medical appointment?

Always	Usually	Sometimes	Never	Don't Know	Not applicable

Q13a. How often did they spend enough time with you during a medical appointment?

Always	Usually	Sometimes	Never	Don't Know	Not applicable

Q13b. How often did they involve you in decisions about your health care as much as you wanted during a medical appointment?

Always	Usually	Sometimes	Never	Don't Know	Not applicable

Q14. If you or a loved one (including children), developed a disease that needed an experimental treatment (e.g. a clinical trial), which of the institutions would you most likely go to for that treatment? Please circle only one.

1. St. Joseph Mercy, Ann Arbor
2. Detroit Medical Center
3. Henry Ford Health System
4. Beaumont Hospitals
5. University of Michigan Health System
6. Wayne State University, Detroit
7. Hurley Medical Center, Flint
8. McLaren Regional Medical Center, Flint
9. Genesys Health System, Grand Blanc
10. Can't say

Q15. Which of these institutions do you think is the best at doing medical research? Please circle only one.

1. St. Joseph Mercy, Ann Arbor
2. Detroit Medical Center
3. Henry Ford Health System
4. Beaumont Hospitals
5. University of Michigan Health System
6. Wayne State University, Detroit
7. Hurley Medical Center, Flint
8. McLaren Regional Medical Center, Flint
9. Genesys Health System, Grand Blanc
10. Can't say

Q16. Have you ever heard of the U.S. Public Health Service Syphilis Study at Tuskegee?

☐ Yes ☐ No ☐ Don't Know

DEMOGRAPHICS

Q17. Are you male or female?

☐ MALE ☐ FEMALE

Q18. What is your age? _____

Q19. What is the highest grade or degree you have completed?

☐ LESS THAN 8TH GRADE

☐ 8TH THROUGH 11TH GRADE

☐ 12TH GRADE OR COMPLETED HIGH SCHOOL OR GED

☐ POST *HIGH SCHOOL TRAINING OTHER THAN COLLEGE (FOR EXAMPLE, VOCATIONAL* OR TECHNICAL TRAINING)

☐ SOME COLLEGE

☐ 2-YEAR COLLEGE GRADUATE (ASSOCIATE'S DEGREE)

☐ COLLEGE GRADUATE (4 YEAR DEGREE)

☐ GRADUATE DEGREE (MASTERS, DOCTORATE, ETC)

Q20. What is your present work status?

☐ WORKING FULL-TIME

☐ WORKING PART-TIME

☐ HOMEMAKER

☐ STUDENT

☐ RETIRED

☐ UNABLE TO WORK OR DISABLED

☐ OUT OF WORK

Q21. Approximately what was the total income of your household last year before taxes?

- ☐ $20,000 OR LESS
- ☐ $20,001 TO $40,000
- ☐ $40,001 TO $60,000
- ☐ $60,001 TO $80,000
- ☐ $80,001 TO $100,000
- ☐ $100,001 TO $150,000
- ☐ $150,000 TO $ 200,000
- ☐ $ 200,000 OR MORE

Q22. How do you describe yourself?

- ☐ WHITE
- ☐ BLACK/AFRICAN AMERICAN
- ☐ ASIAN/PACIFIC ISLANDER
- ☐ AMERICAN INDIAN/ALASKAN NATIVE
- ☐ BI-RACIAL
- ☐ OTHER _____

Clinical Trial Screening and Accrual Log

This CRF corresponds to the electronic log located at
https://cabig.nci.nih.gov/community/screenaccruallog

NCI COMMUNITY CANCER CENTERS PROGRAM

Patient Identification Number: XXXXXXXX
Record the Patient ID for your records

1. **Date of patient screening:**
(ex. MM/DD/YYYY)

PATIENT DEMOGRAPHICS

2. **Ethnicity** (select only one): ☐ **Hispanic or Latino** ☐ **Non-Hispanic/Latino** ☐ **Unknown**
3. **Race:** ☐ **American Indian or Alaska Native** ☐ **Native Hawaiian or Other Pacific Islander**
☐ **Asian** ☐ **Black or African American** ☐ **White** ☐ **More Than One Race**
☐ **Not Reported, Patient Refused** ☐ **Not Reported, Data Not Available**
☐ Unknown, Patient Unsure of Race
4. **Gender** (select only one): ☐ **Male** ☐ **Female**
5. **Age (ex 43):**

PROTOCOL SCREENING METHODS

6. **Protocol for which the patient was screened** (select only one): Definitions on page 4.

☐ **CALGB 40603 (NeoAdjuvant Breast)**
☐ **CALGB 70604 – Zoledronic Acid (Cancer Control)**
☐ **CALGB C80405 (Colorectal)**
☐ **CALGB 80702 (Adjuvant Stage III Colon)**
☐ **CALGB 90601 (Advanced TCC)**
☐ **ECOG 1305 (1st line Rec/Met H&N CA)**
☐ **ECOG E1505 (Lung)**
☐ **ECOG E5508 (Maint. NSCLC)**
☐ **NSABP B-43 (Breast DCIS)**
☐ **NSABP B-47 (Adjuvant Breast)**
☐ **NSABP P-5 (Prevention - Colon)**
☐ **RTOG 0617 (Stage IIIA/B NSCLC)**
☐ **RTOG 0831 (Prostate, Cancer Control**
☐ **SWOG S0702 Obs ONJ-Zoledronic Acid (Cancer Control)**
☐ **SWOG S0777 Multiple Myeloma**
☐ **SWOG 1007 (Adjuvant Breast)**

7. **What method(s) were used to identify this patient for protocol screening (**select all that apply**):**

- ☐ **Cancer/Tumor Registry**
- ☐ **Chart review**
- ☐ **Multidisciplinary/disease site conferences**
- ☐ **Pathology Report**
- ☐ **Patient Care Rounds**
- ☐ **Patient self referral**
- ☐ **Patient Navigator**
- ☐ **Pharmacy/chemotherapy list**
- ☐ **Physician referral: NCCCP investigator**
- ☐ **Physician referral: outside institution**
- ☐ **Physician referral: within institution**
- ☐ **Response to advertisement**
- ☐ **Review of clinic schedule**
- ☐ **Review of surgical schedule**
- ☐ **Tumor Board**

8. **Was the patient navigator used in identifying the patient for screening:** ☐ **Yes** ☐ **No**

9. **If the patient navigator was involved, indicate how they were involved (**select all that apply**):**

- ☐ **Navigator obtained consent for treatment**
- ☐ **Navigator screened the patient**
- ☐ **Navigator referred patient to the research team**

PROTOCOL SCREENING

10. **Did the patient enroll in the protocol:** ☐ **Yes** ☐ **No**

11. **If the patient did not enroll in the protocol, indicate the reason why (**select only one**):**

- ☐ **Patient did not meet trial eligibility criteria (**skip to question 13**)**
- ☐ **Patient was eligible but declined participation (**skip to question 14**)**
- ☐ **Patient was eligible but MD declined to offer participation (**skip to question 15**)**
- ☐ **Patient was eligible but started treatment prior to completion of screening (**skip to question 12**)**

12. If the patient was not captured prior to starting treatment, indicate reason why (select only one**):**

- ☐ **Urgency to initiate treatment**
- ☐ **Patient not referred to the research team**
- ☐ **Recurring patient/ not new patient**
- ☐ **Insufficient medical records at time of screening**
- ☐ **Other : Do Not Use**

13. If the patient did not meet trial eligibility criteria, indicate the reason why (select all that apply**):**

- ☐ **Abnormal labs**
- ☐ **Abnormal organ function**
- ☐ **Co-morbidities**
- ☐ **Does not meet biomarker testing criteria**
- ☐ **Insufficient or unavailable pathologic samples for study**
- ☐ **Patient had progressive disease**
- ☐ **Performance Status**
- ☐ **Prior Therapy**
- ☐ **Second Cancer**
- ☐ **Time requirement from surgery or therapy**
- ☐ **Other : Do Not Use**

14. If the patient was eligible but the patient declined participation, indicate the patient-related reason why (select all that apply**):**

- ☐ **Cultural/religious issues**
- ☐ **Did not keep appointment**
- ☐ **Family member influenced against trial participation**
- ☐ **Financial concerns/indirect costs (work, etc)**
- ☐ **Insurance company denied coverage**
- ☐ **Insurance company refused to pay for additional testing**
- ☐ **Lack of awareness/education about trials**
- ☐ **Language barrier/ lack of access to interpreter**
- ☐ **Mistrust of research**
- ☐ **No desire to participate in research**
- ☐ **No insurance coverage**
- ☐ **Palliative care/hospice**
- ☐ **Patient declined to be retested per protocol**
- ☐ **Patient preferred another trial**
- ☐ **Perceived side effects/toxicities too great**
- ☐ **Preference for standard treatment**
- ☐ **Preferred no treatment**
- ☐ **Refused to have rebiopsy or further tissue collection**
- ☐ **Second opinion/transfer of care**
- ☐ **Social Issues(Housing, childcare)**
- ☐ **Travel &transportation issues**
- ☐ **Other: Do Not Use**

15. If the patient was eligible but the MD declined to offer participation, indicate the physician-related reason why (select all that apply**):**

- ☐ **Cultural/religious issues**
- ☐ **Did not keep appointment**
- ☐ **Family member influenced against trial participation**
- ☐ **Financial concerns/indirect costs (work, etc)**
- ☐ **Insurance company denied coverage**
- ☐ **Insurance company refused to pay for additional testing**
- ☐ **Lack of awareness/education about trials**
- ☐ **Language barrier/ lack of access to interpreter**
- ☐ **Mistrust of research**
- ☐ **No desire to participate in research**
- ☐ **No insurance coverage**
- ☐ **Palliative care/hospice**
- ☐ **Patient declined to be retested per protocol**
- ☐ **Patient preferred another trial**
- ☐ **Perceived side effects/toxicities too great**
- ☐ **Preference for standard treatment**
- ☐ **Preferred no treatment**
- ☐ **Refused to have rebiopsy or further tissue collection**
- ☐ **Second opinion/transfer of care**
- ☐ **Social Issues(Housing, childcare)**
- ☐ **Travel &transportation issues**
- ☐ **Other: Do Not Use**

16) If there was a language barrier, indicate the language spoken (Select One Only):

- ☐ **Chinese**
- ☐ **French**
- ☐ **Korean**
- ☐ **Spanish**
- ☐ **Vietnamese**
- ☐ **Other:**

17) Is the patient rural per NCCCP/site criteria?

- ☐ **Yes**
- ☐ **No**

Protocol Screening Definitions

1) **CALGB 40603** Untreated, resectable breast cancer, HER-2 Negative, Hormone Receptor (ER/PR) poor (=<10% by IHC

2) **CALGB 70604 - Zoledronic Acid (Cancer Control):**

a. Bone involvement by Breast Adenocarcinoma, Prostate Adenocarcinoma, or Multiple Myeloma.

b. No Prior IV Bisphosphonate Therapy.

3) **CALGB 80405 (Colorectal)**: Unresectable locally advanced or metastatic colorectal adenocarcinoma with no prior chemotherapy.

4) **CALGB 80702**: Completely resected Stage III colon adenocarcinoma and no prior chemotherapy.

5) **CALGB 90601 (Advanced Uroepithelial Neoplasm)**: Locally advanced or metastatic urinary tract transitional cell CA with no prior chemotherapy for metastatic disease.

6) **ECOG 1305 (1st line Rec/Met H&N CA):** Loco regional recurrent or metastatic Squamous Cell Carcinoma of the Head and Neck without prior chemotherapy for recurrent or metastatic disease.

7) **ECOG E-1505 (Lung)**: Resected non-small cell lung carcinoma Stage IB – IIIA less than 12 weeks post resection

8) **ECOG E5508 (Maint. NSCLC)**: Stage IV nonsmall cell, nonsquamous cell lung CA and no prior advanced stage disease chemotherapy.

9) **NSABP B-43 (Breast DCIS)**: Female breast DCIS following lumpectomy.

10) **NSABP B-47 (Adjuvant Breast)**: Resected invasive breast CA Stage II and III with T1 to T3, low Her-2, and no neoadjuvant chemotherapy.

11) **NSABP P-5**: Stage I or II colon adenocarcinoma completely resected within the last 12 months.

12) **RTOG 0617 (Stage IIIA/B NSCLC)**: Inoperable Stage III A or B nonsmall cell lung CA.

13) **RTOG 0831**: Men with T1b-T2b adenocarcinoma of the prostate with no distant metastases and their spouses/partners.

14) **SWOG S0702 ONJ – Zoledronic Acid (Cancer Control):**

c. Bone involvement by Multiple Myeloma, Solid Tumor Neoplasms, or other malignancy with an indication for IV bisphosphonate therapy.

d. No prior IV bisphosphonate therapy or IV bisphosphonate therapy of < 90 days prior to registration.

15) **SWOG S0777 Multiple Myeloma** Newly diagnosed multiple myeloma and no prior systemic therapy except< 2 weeks steriods

16) **SWOG 1007 Adjuvant Breast** Node positive 1-3, Hormone Receptor positive, HER2 Neg

Select Post-Test Items on Enrollment in the U-M Clinical Studies Registry.

FIQ17. In your opinion, what percentage of your friends and family members would participate in a clinical trial? Check one.

☐ None ☐ Some ☐ Most ☐ All ☐ Can't say

FIQ18. If you decided to participate in a clinical trial, how much would your family and friends support that decision? Check one.

☐ Not at all ☐ A little ☐ Some ☐ A lot ☐ Can't say

FIQ19. Scientists are interested in the role of genetics in human diseases. Learning how people's genes interact with their behaviors and environment to cause illness is the goal of many research studies. This kind of research is seen as helpful to better understanding and treatment of certain diseases.

On a scale of 1 to 5, with 1 being "not at all willing" and 5 being "very willing," how willing would you be to participate in a clinical trial that asked you to give a blood or saliva sample to better understand the impact of genetics on a health condition?" Circle one.

Not at all willing	Somewhat unwilling	Neutral	Somewhat willing	Very willing
1	2	3	4	5

FIQ20. Do you have health insurance?

☐ Yes ☐ No (skip to #20) ☐ Don't Know

FIQ20a. If you have insurance, what kind do you have? Check all that apply.

☐ Private (e.g. Blue Cross Blue Shield, United, HAP)
☐ Medicaid
☐ Medicare
☐ Medicare supplement
☐ County health plan (e.g. Washtenaw County Health Plan)
☐ Other (specify)_____

FIQ21. In general, would you say your health is:

☐ Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent

FIQ22. Where do you regularly receive your healthcare? Check all that apply.

- ☐ Private doctor
- ☐ Hospital or health system
- ☐ Neighborhood clinic
- ☐ Health department
- ☐ Clinical trials
- ☐ Other (Specify)_____
- ☐ I do not have a regular source of healthcare.

Research suggests that having a health condition(s) may influence a person's decision to participate in a clinical trial. The following question will help us understand the relationship, if any, between health status and clinical trial participation.

FIQ23. Do you have any of the following health conditions? Check all that apply.

☐ Myocardial infarction (history of heart attack)
☐ Congestive heart failure (heart can't pump enough blood throughout the body)
☐ Peripheral disease (narrowing of the blood vessels outside of your heart)
☐ Cerebrovascular disease (stroke)
☐ Chronic pulmonary disease aka COPD (e.g. chronic bronchitis or emphysema)
☐ Connective tissue disease (cartilage and fat are examples of connective tissue)
☐ Peptic ulcer disease (sores in lining of your stomach or duodenum, the first part of small intestine)
☐ Mild liver disease (without hypertension, includes chronic hepatitis)
☐ Moderate or severe liver disease
☐ Diabetes without end-organ damage (excludes diet-controlled alone)
☐ Diabetes with end-organ damage (retinopathy, neuropathy, nephropathy, or brittle diabetes)
☐ Hemiplegia, aka paralysis (the loss of muscle function in part of your body)
☐ Moderate or severe renal disease (kidney disease)
☐ [Cancer] tumor without metastasis (spread of cancer). Exclude if more than 5 years from diagnosis
☐ Metastatic solid tumor (cancer that has spread to other places)
☐ Leukemia (acute or chronic) - cancer of the white blood cells
☐ Lymphoma (cancer of a part of the immune system called the lymphatic system)
☐ Autoimmune disease (e.g. arthritis, lupus, multiple sclerosis)
☐ Overweight/Obesity
☐ Chronic pain
☐ Refuse to answer

Table 14: Univariate post-test predictors of enrollment in the U-M Clinical Studies Registry. Logistic regression.

	Odds Ratio	95% CI	*P*-value
In your opinion, what percentage of your friends and family members would participate in a clinical trial	.95	.56 - 162	.86
If you decided to participate in a clinical trial, how much would your family and friends support that decision	1.09	.75 – 1.6	.65
Willingness to participate in a clinical trial that asked you to give blood or a saliva sample to better understand the impact of genetics on a health condition* (mean score 3.9)	1.57	1.15 – 2.14	.004
Do you have health insurance	1.27	.44 – 3.66	.67
Self-rated health	.75	.54 – 1.05	.1
# Medical/physical conditions (index)	1.26	1.0 - 1.59	.05

*Statistically significant, $p < .05$

Table 15: Post-test willingness to participate in genetics research on enrollment in the U-M Clinical Studies Registry, controlling for baseline demographics. Multivariate logistic regression.

	Odds Ratio	**95% CI**	***P*-value**
Willingness to participate in a clinical trial that asked you to give blood or a saliva sample to better understand the impact of genetics on a health condition*	1.57	1.13 – 2.19	.01
Sex	1.55	0.75 – 3.2	.24
Age	1.02	1.0 – 1.04	.24
Education	0.77	0.41 – 1.45	.42
Work Status	0.75	0.52 – 1.1	.14
Household income	1.29	0.83 – 2.01	.26

*Statistically significant, $p < .05$

Post-Dissertation Defense Analyses

Paper 1: Post-hoc analyses

Table 16: Multivariate Linear Regression. Willingness to participate in a clinical trial by demographic and aggregate scale correlates, with barriers broken into personal and structural.

(R_a^2=0.28), F (11,479)=18.19, p<.001)

	Unstandardized Beta	**P-value**
Sex	.30	.144
Education	.29	.132
Work Status	.165	.133
Household Income	-.15	.265
Age	-.006	.341
Global Trust Scale	.149	.422
Patient-Provider Communication Scale	-.102	.535
Personal Benefit Scale*	1.19	<.001
Global Benefits Scale*	1.12	<.001
Structural Barriers Scale	.038	.821
Personal Barriers*	-.484	.001

*Statistically significant, p< .05

Table 17: Multivariate Linear Regression. Willingness to participate in a clinical trial by demographic and aggregate scale correlates; with barriers broken into personal and structural, and I have heard of a clinical trial.

(R_a^2=0.4), F (13,469)=25.982, p<.001)

	Unstandardized Beta	***P*-value**
Sex	.28	.145
Personal benefit scale*	.55	.002
Global benefit scale*	.64	<.001
Structural barriers scale	-.26	.119
Personal barriers*	-.312	.02
Heard of a clinical trial	.79	<.001
I have experienced discrimination in a healthcare setting	-.029	.685
Amount of payment or incentive for participating in a clinical trial*	.19	.04
Healthcare providers involve you in decisions about your health care*	.336	.008
Healthcare providers explain things in a way that you can understand	-.227	.14
Knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male	-.093	.619
Distrust of healthcare professionals	-.077	.354
Trust in organization conduction the trial*	1.34	<.001

*Statistically significant, p< .05

Analysis of normality for willingness to participate in a clinical trial

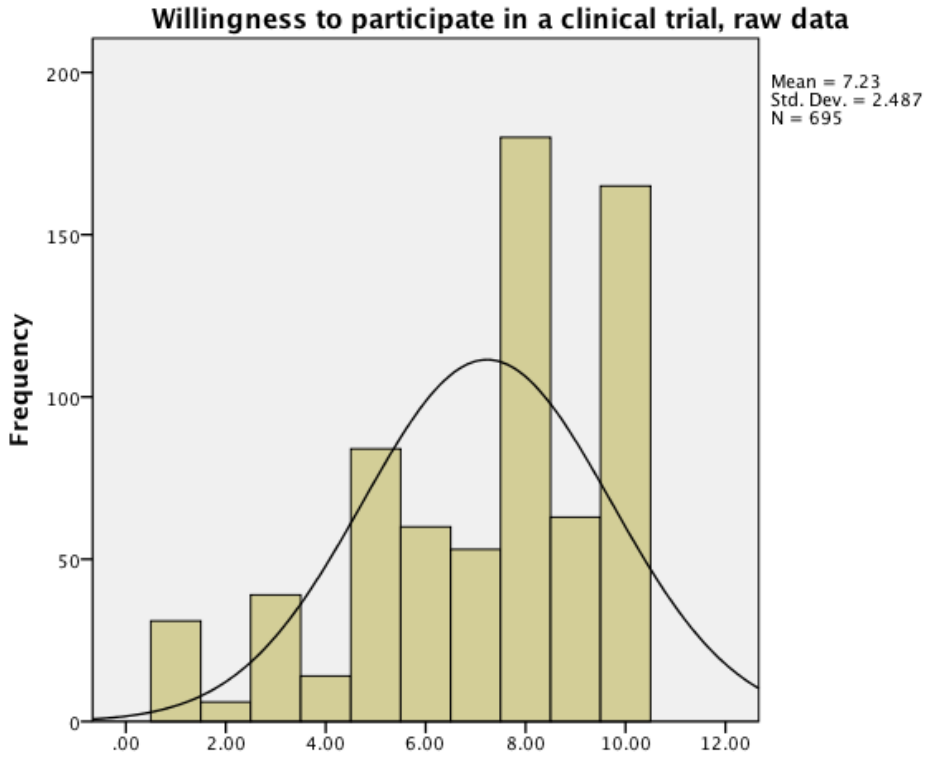

Figure 2: Histogram of willingness to participate in a clinical trial (raw data)

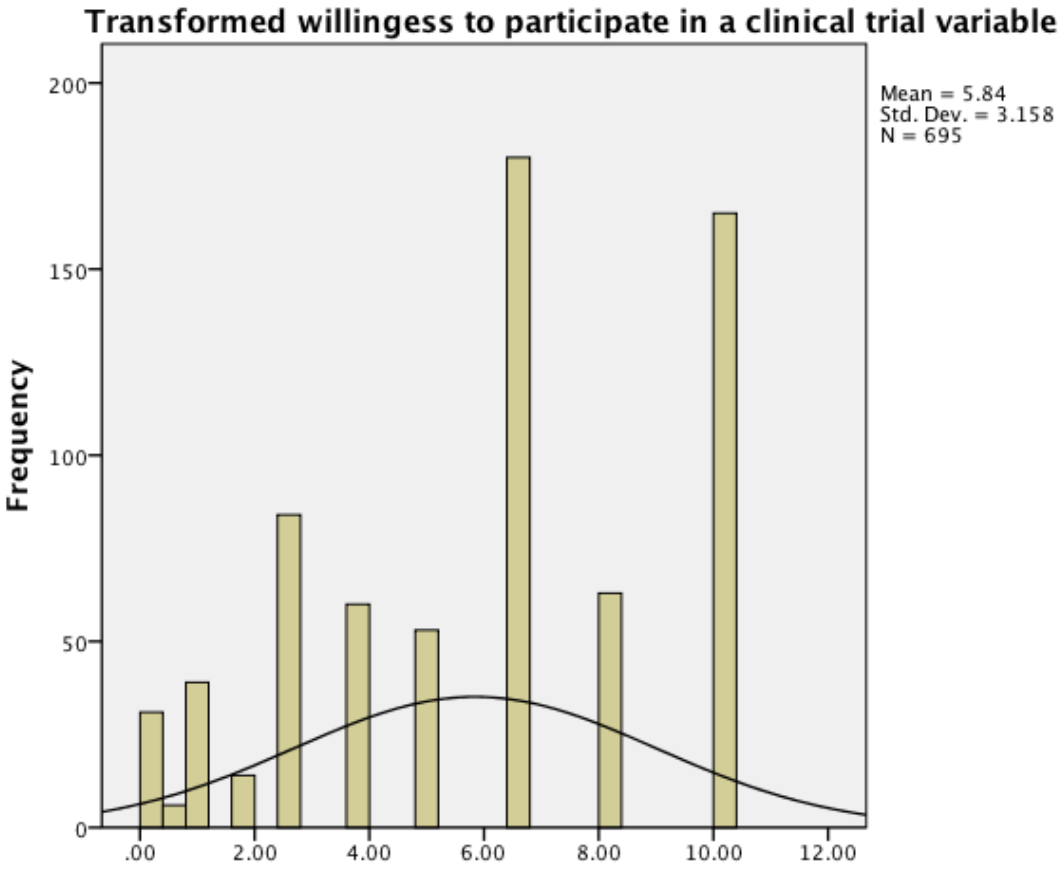

Figure 3: Histogram of transformed willingness to participate in a clinical trial.

Models run with transformed data for willingness to participate in a clinical trial.

Table 18: Multivariate Linear Regression. Transformed willingness to participate in a clinical trial item by demographic and aggregate scale correlates, with barriers broken into personal and structural.

(R_a^2=0.25), F (11,479)=15.56, p<.001)

	Unstandardized Beta	***P*-value**
Sex	.34	.198
Education	.47	.06
Work Status	.17	.225
Household Income	-.17	.344
Age	-.01	.571
Global Trust Scale	.25	.311
Patient-Provider Communication Scale	-.06	.79
Personal Benefit Scale*	1.21	<.001
Global Benefits Scale*	1.42	<.001
Structural Barriers Scale	-.101	.649
Personal Barriers	-.66	<.001

*Statistically significant, p< .05

Table 19. Multivariate Linear Regression. Transformed willingness to participate in a clinical trial by demographic, aggregate scale correlates, and individual items.

	Unstandardized Beta	***P*-value**
Sex	.38	.14
Personal benefit scale*	.55	.02
Global benefit scale*	.9	<.001
Structural barriers scale	-.44	.05
Personal barriers*	-.43	.01
Heard of a clinical trial*	1.26	<.001
I have experienced discrimination in a healthcare setting	-.05	.59
Amount of payment or incentive for participating in a clinical trial*	.18	.14
Healthcare providers involve you in decisions about your health care*	.45	.008
Healthcare providers explain things in a way that you can understand	-.2	.328
Knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male	-.1	.694
Distrust of healthcare professionals	-.06	.574
Trust in organization conduction the trial*	1.43	<.001

*Statistically significant, p< .05

Paper 2: Post-hoc analyses

Table 20: Reasons given for patients was eligible but declined clinical trial (Q. 14)

Item	n
Cultural/religious issues	0
Did not keep appointment	11
Family member influenced against trial participation	26
Financial concerns/indirect costs	28
Insurance company refused to pay for additional testing	2
Insurance company denied coverage	18
Lack of awareness/education about clinical trials	8
Language barrier/lack of access to interpreter	2
Mistrust of research	12
No desire to participate in research	364
No insurance coverage	5
Palliative care/hospice	7
Patient declined to be retested per protocol	9
Patient referred to another trial	0
Perceived side effects/toxicities too great	84
Preference for standard treatment	371
Preferred no treatment	30
Refused to have re-biopsy or further tissue collection	7
Second opinion/transfer of care	30
Social issues (housing/childcare)	12
Travel & transportation issues	30

Table 21: Men only by race/ethnicity. Enrollment in a cancer clinical trial. (n=1367)

	Odds Ratio	**95% CI**	***P*-value**
White men	1.0		
Black men	.74	.49 – 1.11	.14
Hispanic men	.48	.22 - 1.07	.07
Asian men*	.13	.03 - 56	.006
Other men	z	z	z

*Statistically significant, p< .05

Table 22: Men only by race/ethnicity. Patient eligible but declined clinical trial. (n=1367)

	Odds Ratio	95% CI	*P*-value
White men	1.0		
Black men	1.04	.7 – 1.58	.83
Hispanic men	1.25	.65 – 2.42	.5
Asian men	.6	.25 – 1.42	.25
Other men	z	z	z

Table 23: Men only by race/ethnicity. No desire to participate in research as reason given for declining a clinical trial. (n=1367)

	Odds Ratio	95% CI	*P*-value
White men	1.0		
Black men	.79	.41 – 1.51	.48
Hispanic men	1.44	.6 – 3.46	.41
Asian men	.48	.15 – 2.01	.25
Other men	z	z	z

Table 24: Men only by race/ethnicity. Physical/medical conditions. (n=1367)

	Odds Ratio	95% CI	*P*-value
White men	1.0		
Black men	.9	.63 – 1.3	.58
Hispanic men	.76	.4 – 1.44	.4
Asian men	.75	.39 – 1.347	.41
Other men	2.11	.7 – 6.3	.18

Table 25: Men only by race/ethnicity. MD declined to offer clinical trial participation to an eligible patient. (n=1367)

	Odds Ratio	95% CI	*P*-value
White men	1.0		
Black men	1.05	.6 – 1.8	.87
Hispanic men	1.32	.58 – 3.04	.51
Asian men	1.29	.56 – 2.9	.54
Other men	.65	.08 – 5.03	.68

Paper 3: Post-hoc analyses

Table 26: Enrollment in the registry by baseline aggregate scales. *Structural and personal barriers separated. Multivariate logistic regression (n = 600).

	Odds Ratio	**95% CI**	***P*-value**
Treatment condition (control, ref)*	2.72	1.48 – 5.02	.001
Patient-Provider Communication	.99	.6 – 1.63	.96
Personal Benefit	.98	.59 – 1.66	.95
Global Benefit	1.48	.78 – 2.78	.228
Personal Barriers	.75	.48 – 1.15	.181
Structural Barriers	1.02	.62 – 1.68	.94
Global Trust	1.16	.66 – 2.04	.611

*Significantly significant, $p < .05$

Table 27: Enrollment in the registry by individual baseline survey items, plus heard of a clinical trial (n=575). Multivariate logistic regression.

	Odds Ratio	95% CI	*P*-value
Treatment condition (control, ref)*	2.92	1.47 – 5.71	.002
Heard of a clinical trial	2.34	.88 – 5.65	.09
Willingness to participate in a clinical trial in the future	1.15	.98 – 1.35	.08
Inconvenience or "hassle" associated with a clinical trial*	.71	.53 – 0.94	.02
Participating in research is my responsibility to the black community	1.01	.74 – 1.37	.96
I have experienced discrimination in a healthcare setting	.78	.64– 1.0	.05
Knowledge of the US Public Health Service Study of Untreated Syphilis in the Negro Male	1.52	.72 – 3.23	.27

*Significantly significant, $P < .05$