Original Contribution

Perceptions of Participation in a Phase I, II, or III Clinical Trial Among African American Patients With Cancer: What Do Refusers Say?

By Richard F. Brown, PhD, Debbie L. Cadet, PhD, Robert H. Houlihan, DHA, Maria D. Thomson, PhD, Emily C. Pratt, Amy Sullivan, EdD, and Laura A. Siminoff, PhD

Virginia Commonwealth University School of Medicine; Massey Cancer Center, Virginia Commonwealth University, Richmond, VA; and Beth Israel Deaconess Medical Center-Harvard Medical School, Boston, MA

Abstract

Background: Less than 5% of all adult patients with cancer enter clinical trials. These rates are lower in racial/ethnic minority populations, negatively affecting the generalizability and validity of trial results. Many studies have identified barriers to minority enrolment, yet few have gathered in-depth insights into minority patients' reasons for trial refusal. We aimed to (1) explore trial refusal reasons in a sample of African American (AA) patients with cancer who declined trial participation and (2) gather patients' perceptions of the potential benefit of an array of decision support tools.

Methods: Participants were 22 consecutively recruited AA patients with cancer who had declined participation in a therapeutic clinical trial. Within 3 months of the trial refusal decision, participants completed an audio-recorded semistructured interview that asked about demographic and disease information, psychosocial factors, and patients' experience with clinical trials. Two months later, participants completed a questionnaire that asked about their trial decision.

Results: Few patients received positive recommendations about joining a trial. Patients gave multiple refusal reasons. Only two participants refused to join a clinical trial as a result of issues of mistrust. Most participants refused as a result of fears of additional burdens and adverse effects. Many patients and family members misunderstood trial information. Family members mostly recommended against trial participation. Most patients felt that question prompt lists or decision aids would assist information seeking and decision making.

Conclusion: Low rates of physician recommendations for clinical trial participation of AA patients with cancer warrant further investigation. Interventions to reduce misunderstandings and aid decision making, both within and external to the clinical interaction, need to target both patients and family members.

Introduction

Conducting rigorous clinical trials is key to new drug development, yet it is estimated that less than 5% of all adult patients with cancer enter clinical trials.[1-3] Even lower rates of enrollment have been reported in racial/ethnic minority populations,[4] compromising the generalizability of trial results[4,5] and threatening external validity as a result of selection bias.[6] Several studies and systematic reviews have detailed barriers to minority recruitment,[7,8] such as lack of trust in the research enterprise and the medical system[9] and factors related to the patient-provider relationship.[7] One way to remediate this unequal burden is to develop strategies and interventions to increase enrollment in clinical trials by understanding and addressing patient-provider barriers to minority trial participation.[7,10]

Patient race has been shown to be associated with trial eligibility and refusal.[7,11] Despite the number of studies exploring barriers that result in underrepresentation of minorities in clinical trials, there is limited research that explicitly explores racial differences in reasons for refusal to participate in cancer clinical trials.[7,12-17] Existing studies often lack adequate representation of minorities in their study samples to permit comparisons.[3,18] Of 36 studies included in a systematic review of barriers to minority participation in trials, few actually identified statistically significant barriers to trial participation, and none reported the barriers according to racial groups.[7]

We previously addressed this gap in the literature, using a novel data capture system[19] to explore refusal reasons in a sample of 1,995 patients with cancer who were evaluated for a therapeutic clinical trial at our cancer center over a 4-year period.[20] In that study, African American (AA) patients were 1.8 times more likely to refuse trial participation than white patients. When we assessed 11 specific refusal reasons, we found that, compared with white patients, AA patients were more likely to cite no interest in trials, pressures from family members, and feeling overwhelmed by the decision-making process, or to provide no reason for refusal. These results suggest that AA patients may value interventions that promote information exchange and decision support. Although these data were collected prospectively, they are limited because refusal reasons were reported by clinical research staff and thus represent staff perspectives and understandings rather than those of the patients. In addition, staff reported only one primary refusal reason for each patient.[20]

The twofold aims of the current research study were to (1) explore trial refusal reasons in a sample of AA patients with cancer who declined trial participation and (2) gather insight

into these patients' perceptions of the potential benefit of an array of decision support tools.

Methods

Participants

We recruited a sample of patients with cancer from a National Cancer Institute–designated cancer center located within a safety net provider hospital in central Virginia. Eligible participants were AA patients with cancer who had been approached by a clinician to consider participation in a therapeutic cancer clinical trial that they declined within 3 months before commencement of this communication study. We chose 3 months to ensure that participants could recall the consultation and trial they were offered. Participants were ≥ 18 years and had adequate English skills and cognitive ability to complete the interview.

Procedure

Potential participants were identified through research assistant (RA) attendance at multidisciplinary team meetings, working with individual oncologists and their research staff and through the cancer center's online Clinical Trials Eligibility Database.[19] All identified and eligible patients were approached consecutively and invited to participate. Eligible patients were mailed a study information packet and an invitation to join the study. The invitation letter informed patients that (1) they were being asked to join a research study about why people choose not to join clinical trials and (2) they were contacted because they had declined an offer to join a clinical trial at the center. Patients could decline to be contacted further by returning a card, which indicated this opt-out preference, in a prepaid envelope provided with the invitation packet. Those who did not opt out were contacted within 2 weeks to determine whether they wished to participate. Recruited participants completed a 60-minute audio-recorded semistructured interview at a mutually agreed-on time. The interview asked about patients' demographic and disease information, psychosocial factors, and their experience with clinical trials. A follow-up telephone survey was obtained 2 months later that asked about patients' levels of satisfaction and regret about their trial decision. We chose to interview patients 2 months after they joined this communication study in order to ensure that all participants had commenced, and in some cases completed, cancer treatment and could thus assess feelings about their treatment decision. Psychosocial factors and patient's feelings about the trial decision were measured with validated instruments. The institutional review board of the participating institution granted approval for this study, and all patients provided signed informed consent.

Semistructured Patient Interview

Demographic and disease information. Participant characteristics assessed included sex, age, race/ethnicity, religion, education, employment, income level, living situation, primary tumor site, and the phase of trial offered. Health information and data related to eligibility for clinical trial participation were extracted from medical records. Participant's perceptions of their health status and barriers to seeking medical care were also assessed.

Psychosocial information. Information preferences were measured with the Cassileth Information Style Questionnaire.[21] Decision-making involvement preferences were assessed with the Control Preferences Scale.[22] Self-rated levels of distress associated with cancer were assessed with the Distress Thermometer.[23] Patients' functional social support was measured using the Measure of Social Support survey.[24] Patient self-efficacy in productive communication and positive attitude toward consultation communication was measured with the Communication and Self Efficacy Scale.[25]

Questions About Trials

Participants were asked study-specific questions about their knowledge, beliefs, and attitudes about clinical trials; who described clinical trials; how they experienced this communication; and what factors went into their decision not to participate. Patients were also questioned about the potential for different decision support tools, a decision aid, informational video, patient navigator, or a question prompt list to aid their levels of trial knowledge and make trial decisions. The RA provided descriptions and examples of each of these during the interview.

2-Month Postinterview Survey

Patients' levels of satisfaction with their treatment decision was measured with the Satisfaction with Health Care Decisions Scale.[26] Patient levels of regret concerning their treatment decision were measured using the Decisional Regret Scale.[27]

Data Analyses

Quantitative data: Aim 1. All demographic and questionnaire data were entered into IBM SPSS V 19.0. Frequencies and average scores were calculated for demographic variables and for all other quantitative scales according to published scale scoring procedures. These data were gathered for descriptive purposes, and no statistical comparisons were planned.

Qualitative data: Aim 2. Transcripts of audio-recorded interviews were analyzed by using the constant comparative method proposed by Glaser.[28] Consistent with this method, each member of the research team independently developed themes to represent the underlying meaning of the text. The research team conducted regular consensus meetings during which identified themes were presented and discussed. Any disagreements were resolved through successive rounds of iterative consensus work. Initially, as the methodology requires, only a few transcripts were analyzed. Once an exhaustive analysis of this original data set was complete, further small samples of transcripts were analyzed. The themes that emerged from these data were compared with those from the original data set and, if necessary,

new thematic categories were defined. This process continued until no new themes emerged.

Sample size calculation. Qualitative research uses saturation to achieve an appropriate sample size.[29] Recent research that has examined at what point researchers achieve thematic saturation have concluded that saturation can be achieved after 12 data collection episodes.[30] Using these results as a guide, and based on the constant comparative method, we aimed to recruit approximately 25 eligible participants.

Results

A total of 58 patients were identified. Of these, one patient opted out of contact. Forty-one were able to be contacted and were invited to participate in the study. The study enrollment rate was 68% (28 of 41). One participant withdrew from the study before completing the interview. Five participants were excluded after the interview as a result of technical difficulties with the recording (n = 2), not being offered a therapeutic trial (n = 2), and cognitive impairment (n = 1). Thus, 54% (n = 22) completed the interview and were included.

Participants were mostly female (n = 15; 68%), with an average age of 57 years; slightly less than half (n = 10; 46%) had been diagnosed with breast cancer. The minority (n = 5; 23%) were married or cohabitating; however, most (n = 18; 83%) indicated that they lived with others. Most (n = 14; 63%) were employed, and slightly less than half (n = 10; 46%) earned less than $20,000 annually. Slightly more than half of participants (n = 12; 55%) rated their health status as poor or fair, and almost a third (n = 7; 32%) reported that the cost of care prohibited them from seeking health services. The overwhelming majority (n = 20; 91%) affirmed that religious or spiritual beliefs lay behind their approach to life. Most (n = 14; 64%) were asked to consider a phase III therapeutic clinical trial. Table 1 reports participant characteristics.

Responses to Psychosocial Questionnaires

The majority of participants (n = 20; 91%) had high needs for information and wanted to share decisions (n = 14; 68%) Participants were not distressed ($\bar{x} = 4$). Participants indicated high levels of social support ($\bar{x} = 84.7$), as well as self-efficacy to understand and participate in care ($\bar{x} = 3.9$; standard deviation [SD] = 0.31), maintain a positive attitude ($\bar{x} = 3.9$; SD = 0.41), and seek/obtain information ($\bar{x} = 3.9$; SD = 0.22). At the 2-month postinterview survey, participants were satisfied with their treatment decision ($\bar{x} = 26.1$; SD = 3.9) and not regretful ($\bar{x} = 8.26$; SD = 4.6).

Patient Knowledge and Beliefs About Clinical Trials

Of the 22 participants, nine (41%) stated that they had no prior knowledge or opinions about clinical trials. Patients who did have previous knowledge viewed trials as necessary to advance cancer treatment. Yet some were less confident that they would personally benefit from joining a trial (Table 2).

Table 1. Patient Demographic and Disease Information

Variable	No.	%
Sex (n = 22)		
Female	15	68.2
Male	7	31.8
Age, years (n = 22)		
Mean	57	
Range	39-77	
Education (n = 22)		
High school graduate or less	8	36.3
College or post–high school training	9	40.9
Some postgraduate work or postgraduate degree	5	22.7
Marital status (n = 22)		
Single	8	36.4
Married or cohabitating	5	22.7
Divorced or separated	8	36.4
Widowed	1	4.5
Employment (n = 22)		
Employed	14	63.6
Unemployed (as a result of illness)	6	27.3
Unemployed (not as a result of illness)	2	9.1
Attendance of church and/or religious meetings (n = 22)		
A few times a year or less	9	40.9
A few times a month or more	13	59.1
Religious/spiritual beliefs are what really lie behind my whole approach to life (n = 22)		
Tends to be true or definitely true	20	90.9
Definitely not true or unsure	2	9.1
Income, $ (n = 21)		
19,999 or less	10	45.5
20,000-39,999	3	13.6
40,000-59,999	5	22.7
60,000 or more	3	14.3
No response	1	4.5
Self-rated health status (n = 22)		
Poor/fair	12	54.5
Good/excellent	10	45.5
Primary tumor site (n = 22)		
Breast	10	45.5
Colon/rectum/stomach	5	22.7
Mouth/throat	3	13.6
Other (ovary, lung, or bone marrow)	4	18.1
Phase of trial (n = 22)		
II	8	36.4
III	14	63.6

Discussing Clinical Trial Participation

All participants discussed a clinical trial with either a physician alone or a physician and nurse in combination. Most participants (n = 17; 77%) were able to identify that a physician or a nurse spoke to them; however, five (23%) were not able to

Table 2. Patient Quotes

Patient knowledge and beliefs about clinical trials	Participant and date
"I had no idea about clinical trials. It was foreign to me. It's like a foreign word. I had never heard of it before."	Participant 17, 6/6/11
"I believe in them, and I do believe that they help in doing things and improving medicine, and improving the different kinds of things that happen to people. I always believed in MCV, VCU."	Participant 27, 8/18/11
"They are necessary, and they are needed to help with bringing about changes in the medical field; as far as what I do with my research, stuff is going to help somebody down the road with their illness. So it is necessary, but this particular one, the one I denied, I could not see, just looking at all the statistics, the bad outweighed the good. You understand? I know sometimes we do things to try to help others, but I could not see putting my body through all that, and it may not even have helped."	Participant 12, 7/19/11
"I believe that clinical trials are great, and they give great help to people who are really needing help in whatever it is. I do believe in them, and I would participate if I were at a level in my illness where, you know, I was getting close to last resort or something. Maybe not even then, but just to make sure that I got the best of care and the best of medicine."	Participant 20, 6/27/11
Discussing clinical trial participation	
"Well, why don't we call it a protocol person or something like that."	Participant 6, 12/7/10
"No, just was another lady that I talked to before I had seen my doctor. So, she was some administrator. I don't know who she was exactly. But she had asked me some time ago."	Participant 5, 12/3/10
"He talked to me about my options and the different things I could do if I wanted to do anything at all. And I'm like, OK, and he's talking, and then . . . he told me right there that there is a drug trial and it's very promising, and that we have to do the trial before it can be used, and would I be interested in doing that? And he was like, I would recommend it, when I put him to the test, that you try this and everything, OK, and as we went on and I'm thinking, OK, so I'm going to get this drug. But as I found out later, you may and you may not get it. And then that was the no answer."	Participant 8, 12/9/10
"Yeah, we talked about it. I talked about it with him, and he told me that was my prerogative not to do it, but don't deny myself other research, clinical trials. And so I am actually participating in one as we speak."	Participant 12, 7/19/11
Factors influencing the decision not to participate	
Randomization by computer	
"And then the random picking, you know . . . it sounds like you're picking numbers or lottery numbers or stuff. I didn't really like that part, that you don't pick what you want, a machine or computer picks what you're going to get; I didn't really like that."	Participant 14, 4/29/11
"My understanding was that they put your information in the computer . . . and it decides which one would be best for you . . . initially I thought I wanted to do that, but then I was like no I didn't want to be experimented on. So I went with the standard one, since that's the one they think is helping most people, so I went with that one. Because I couldn't choose the one I wanted, I would have picked the three medicines, but because I couldn't choose myself that's why I went with the standard one."	Participant 10, 3/9/11
Extra adverse effects	
Patient: "I think that my health is in a situation where I needed to have something as predictable as possible, or as effective and predictable as possible."	Participant 25, 7/29/11
Interviewer: "OK, and then you had also mentioned a concern about side effects. Was it your understanding that the side effects would be greater with the trial?"	
Patient: "Yes, I would have more, I would already have side effects and then I would have additional side effects."	
Extra burden and family influence	
"My mom is very supportive of me. Even though I'm 50, my mom still thinks I'm five . . . She didn't want me to do no kinds of clinical trial at all, because like she said, this is the way she put it . . . I don't want . . . you [to be] no guinea pig . . . She say you know you're too fragile, I don't want nothing to happen to you . . . so her answer was no. But like I said, my reason was the timing. But my mom is my support, so . . . I take to heart what she has to say."	Participant 5, 12/3/10
"I think my son was with me. We talked about it, and he was like, it wasn't worth the risk. I explained, and we talked about it, and he was like, Mom, you're going to have to wear a diaper, you don't know what's . . . and you know, he's 23, 24 years old, so that has a profound effect on him. He was like, I really don't want you to do this. He was scared; it was a frightening time . . . So, not just him, but my entire family, we had an entire discussion on it. I have a nurse practitioner in my family, I have two nurse practitioners, I have a doctor, and I have a nurse, so I ultimately went to them and said, help me. And they were like, you could end up with kidney cancer."	Participant 12, 7/19/10
"With, OK, you have cancer, you have to do chemo, you have to have surgery, you have to do all this stuff, and they want to put you on this drug that's not been approved by [the] FDA, and it's a clinical trial, and you could possibly have kidney cancer by the time it's all over. And like I said, I understand the process, but maybe it needs to be dealt with more delicately. Because like I said, initially coming in, everything is new, all this information; I had information overload, my brain was about to combust, and it was just too much."	Participant 12, 7/19/11

identify the staff member. Nearly one third of the participants (n = 7; 32%) reported receiving written information that they could take home to review. Some participants (n = 3; 14%) remembered receiving a positive recommendation from their physician to participate in the trial. For eight participants (36%), the trial principal investigator was also the treating physician. In one case, after refusing participation, the patient reported being asked to consider other suitable trials (Table 2).

Factors Influencing the Decision Not to Participate

Participants declined participation for many reasons, for example, that the trial would increase treatment-related burden (n = 12; 55%). Other participants (n = 8; 36%) expressed concerns about the process of computerized randomization to a treatment arm and wanted to know, before participation, the treatment group in which they would be placed (Table 2).

Potential adverse effects of the treatments received as part of a clinical trial were a primary concern for many (n = 11; 50%). For some, the standard care was preferred over the trial treatment because there was greater knowledge about treatment effectiveness and long-term adverse effects. There was additional concern about being able to tolerate adverse effects. Some participants were concerned that they would experience increased adverse effects if they were to receive the clinical trial treatment in addition to standard care (Table 2).

Finally, participants described pressures from family members and feeling overwhelmed as reasons for declining clinical trial participation. Of 14 participants who discussed the trial decision with a family member, either during or after the visit, eight stated that family members directly encouraged them to decline participation; three stated that such advice was indirect. Reasons for this included feeling that the trial was too risky and they didn't want their family member to be a research "guinea pig." In addition, many participants reported feeling too overwhelmed to be able to make a trial decision so shortly after receiving a cancer diagnosis and receiving too much information at once (Table 2).

Potential Decision Support Tools

Participants were asked to consider the potential utility of four decision support tools. Most participants (n = 14; 64%) felt that being provided with a question prompt list before their discussion about the clinical trial may have been helpful. Having the opportunity to use a decision aid to discuss the advantages and disadvantages of participation with a physician was supported by the majority of participants (n = 16; 73%). Receiving a DVD that would provide information about clinical trials in addition to communication skills training to prepare patients for the consultation appealed to more than half of participants (n = 12; 55%). Having access to a patient navigator was thought to be potentially useful by almost half of participants (n = 10; 45%). Ten participants (45%) viewed all four options as potentially beneficial.

Discussion

Clinical trial accrual rates are not improving despite a nearly 20-year effort by the National Institutes of Health to understand and address this need. Some evidence suggests participation rates among AA patients with cancer are decreasing.[2,3,31] Low AA representation in clinical trials has negative individual consequences, such as inequity in access to the latest technologies and cancer treatments[6,32,33] and a failure to identify important positive or negative treatment effects specific to AA patients.[34,35] We aimed to comprehensively explore AA trial refusal reasons and to use this knowledge to develop targeted interventions to aid AA patients' trial knowledge and treatment decision making.

Because institutional factors have been identified as a significant impediment to AA trial accrual,[7] we were interested in exploring participants' perceptions of the recruitment process. Only about a third of participants reported that they received written trial information to take home, which may reflect the fact that approximately half of the participants made immediate refusal decisions during the consultation. Very few participants recalled that they received a positive recommendation from their physician about participating in a trial. This finding is at odds with other literature suggesting that oncologists routinely make recommendations to their patients about trial participation.[36-39] Physician trial recommendations are a powerful predictor of patients' decisions to enroll onto a clinical trial.[36,38,40] Further research is warranted to determine whether there are differences in the frequency of trial recommendations based on patient race.

Lack of trust in medical research has been identified as a primary reason for AA refusal to participate in clinical trials[7,41] However, in our sample, only one participant refused because they did not believe they would receive the best treatment; one other participant refused as a result of lack of trust in medical researchers. This may be partly due to strategies to improve minority participation in clinical trials implemented by the participating institution during the course of the study period, which included targeted education and information provision. In addition, this institution is a trusted safety net hospital that is the provider of choice for the uninsured and underinsured of the region.

Participants reported positive attitudes to trials in general. Most participants were motivated to join a trial by a sense of altruism. These participants wanted to assist future patients make treatment decisions by contributing to the evidence base for new medications. However, many were concerned that joining a trial was not their best treatment option. Participants cited well-known refusal reasons as their primary reason for refusal,[7] such as: significant fears about additional adverse effects and discomfort with randomization. We compared the accuracy of each participant's specific expressed concerns with the study information they were given. We found that patients misunderstood critical information such as the existence of a placebo control or identified extremely rare adverse effects as their primary concern. These findings are consistent with research that has identified significant patient misunderstanding of trial information.[40,42-47]

This interaction was further complicated by the misunderstandings of family members either during or after the consultation. Only two of the nine family members influenced the patients toward joining a trial. Five of the 13 unaccompanied participants talked about their decision with a family member after the consultation and most (3/5) family members recommended against trial participation. Family members can exert significant influence on decision making and possess divergent values and priorities from the patient.[4849] These discordant views can confuse patient decision making and cause excessive stress directly resulting in diminished quality of life.[50] Our results suggest that clinician researchers consider several actionable items: (1) that clinicians provide a clear recommendation about joining a clinical trial, (2) that the role of the person discussing the trial be clearly identified, (3) that lay language handouts be provided to accompany trial information and consent forms, and (4) that patients' family member or other support person be encouraged to attend the consultation.

Other research, including our own, suggests that patient and family member misunderstanding is due to suboptimal communication during the trial interaction.[37,51-56] Thus, we sought patient views about the potential of four evidence-based interventions to help gain salient trial information and aid decision making. The participants mostly indicated that the provision of a question prompt list or a decision aid focused on clinical trials would be most beneficial. The first author (R.B.) has developed

and pilot tested a clinical trial specific question prompt list that has shown promise in aiding clinical trial discussions.[57-59] Other researchers[60] have successfully piloted a decision aid to help clinical trial decision making in patients with breast cancer.

Future research could usefully develop, test, and evaluate decision aids that target (1) postconsultation clinical trial decision making and (2) involve both patients and family members in weighing the advantages and disadvantages of the clinical trial. Further, the decision aid could be developed as a collaborative effort between researchers, AA community groups, and stakeholders involved in increasing AA participation in therapeutic cancer clinical trials.

This study has two main limitations. First, we acknowledge the convenience sample of mostly female patients, and second, that we are not able to explore differences in refusal reasons by demographic factors such as age and educational status.

Acknowledgment

Supported by pilot funding from Massey Cancer Center.

Authors' Disclosures of Potential Conflicts of Interest

The author(s) indicated no potential conflicts of interest.

Author Contributions

Conception and design: Richard Brown, Debbie L. Cadet, Robert H. Houlihan, Emily C. Pratt, Amy Sullivan, Laura A. Siminoff

Collection and assembly of data: Richard Brown, Debbie L. Cadet, Robert H. Houlihan, Emily C. Pratt

Data analysis and interpretation: All authors

Manuscrip writing: All authors

Final approval of manuscript: All authors

Corresponding author: Richard Brown, PhD, Department of Social and Behavioral Health, Virginia Commonwealth University, School of Medicine, MCV Campus, One Capitol Square, 9th Floor, 830 East Main St, PO Box 980149, Richmond, VA 23298; e-mail: rbrown39@vcu.edu.

DOI: 10.1200/JOP.2013.001039; published online ahead of print at jop.ascopubs.org on October 15, 2013.

References

1. Ellis P, Butow PN, Tattersall MHN, et al (eds): Accrual to clinical trials in breast cancer. Annual Scientific Meeting of the Clinical Oncological Society of Australia, Brisbane, Australia, 1996

2. Avis NE, Smith KW, Link CI, et al: Factors associated with participation in breast cancer clinical trials J Clin Oncol 24:1860-1867, 2006

3. Lara PN Jr, Higdon N, Lim N, et al: Prospective evaluation of clinical trial accrual patterns: Identifying potential barriers to enrolment. J Clin Oncol 19:1728-1733, 2001

4. Robinson JM, Trochim WM: An examination of community members', researchers' and heath professionals' perceptions of barriers to minority participation in medical research: An application of concept mapping. EthnHealth 12:521-39, 2007

5. Bartlett EE, Grayson M, Barker R, et al: The effects of physician communications skills on patient satisfaction, recall, and adherence. J Chron Dis 37:755-764, 1984

6. Britton A, McKee M, Black N, et al: Threats to the applicability of randomised trials, exclusions and selective participation. J Health Serv Res Pol 4:112-121, 1999

7. Ford JG, Howerton MW, Lai GY, et al: Barriers to recruiting underrepresented populations in cancer clinical trials:a systemtic review. Cancer 112:228-242, 2007

8. Goss W, Lopez AM, Brown CL, et al: American Society of Clinical Oncology policy statement: Disparities in cancer care. J Clin Oncol 27:2882-2884, 2009

9. Corbie Smith G, Thomas SB, St George DM: Distrust, race and research. Arch Int Med 162:2458-2463, 2002

10. Fouad MN: Enrolment of minorities in clinical trials: Did we overcome the barriers? Contemp Clin Trials 30:103-104, 2009

11. Barofsky I, Sugarbaker PH: Determinants of patient non participation in randomised clinical trials for treatment of sarcomas. Cancer Clin Trials 2:237-246, 1979

12. Adams-Campbell LL, Ahaghotu C, Gaskins M, et al: Enrolment of African Americans onto clinical treatment trials: Study design barriers. J Clin Oncol 22: 730-734, 2004

13. Gross CP, Filardo G, Mayne ST, et al: The impact of sociodemographic status and race on trial participation for older women with breast cancer. Cancer 103: 483-491, 2005

14. McCaskill-Stevens W, McKinney MM, Whitman CG, et al: Increasing minority participation in cancer clinical trials: The Minority-Based Community Clinical Oncology Program experience. J Clin Oncol 23:5247-5254, 2005

15. Mills EJ, Seely D, Rachlis B, et al: Barriers to participation in clinical trials of cancer: A meta analysis and systematic review of patient-reported factors. Lancet Oncol 7:141-148, 2006

16. Paskett ED, Katz ML, DeGraffinreid CR, et al: Participation in cancer trials; recruiting underserved populations. Clin Adv Hematol Oncol 1:607-613, 2003

17. Stewart JH, Bertoni AG, Staten JL, Levine EA, Gross CP: Participation in surgical oncology trials: Gender-, race/ethnicity-, and age-based disparities. Ann Surg Oncol 14:3328-3334, 2007

18. Go RS, Frisby KA, Lee JA, et al: Clinical trial accrual among new cancer patients at a community based cancer center. Cancer 106:426-433, 2006

19. Penberthy L, Brown R, Puma F, et al: Automated matching software for clinical trials eligibility; measuring efficiency and flexibility. Contemp Clin Trials 31:207-217, 2010

20. Penberthy L, Brown RF, Wilson-Genderson M, et al: Barriers to therapeutic clinical trials enrollment: Differences between African-American and White cancer patients identified at the time of eligibility assessment. Clin Trials (in press) doi: 10.1177/1740774512458992

21. Cassileth BR, Zupkis RV, Sutton-Smith K, et al: Information and participation preferences among cancer patients. Ann Intern Med 92:832-836, 1980

22. Degner LF, Sloan JA, Venkatech P: The Control Preferences Scale. Can J Nurs Res 29:21-43, 1997

23. Roth AJ, Kornblith AB, Batel-Copel L, et al: Rapid screening for psychologic distress in men with prostate carcinoma: A pilot study. Cancer 82:1904-1908, 1998

24. Sherbourne CD, Stewart AL: The MOS social support survey. Soc Sci Med 32:705-714, 1991

25. Wolf MS, Chang CH, Davis T, et al: Development and validation of the Communication and Attitudinal Self-Efficacy scale for cancer (CASE-cancer). Patient Educ Couns 57:333-341, 2005.

26. Holmes-Rovner M, Kroll J, Schmitt N, et al: Patient satisfaction with health care decisions: The Satisfaction with Decision Scale. Med Dec Making 16:58-64, 1994

27. Brehaut JC, O'Connor AM, Wood TJ, et al: Validation of a Decision Regret Scale. Med Dec Making 23:281-292, 2003

28. Glaser BJ, Strauss AL: The Discovery of Grounded Theory: Strategies for Qualitative Research. New York, NY, Adline Publishing Company, 1967

29. Miles MV, Huberman MA: Qualitative Data Analysis: A Sourcebook of New Methods. London, United Kingdom, Sage, 1984

30. Guest G, Bunce A, Johnson L: How many interviews are enough? An experiment with data saturation and variability. Field Meth 18:59-82, 2006

31. Ellis PM, Butow PN, Tattersall MHN, et al: Randomised clinical trials in oncology: Understanding and attitudes predict patients willingness to participate. J Clin Oncol 19:3554-3561, 2001

32. Back AL, Arnold RM, Baile WF, et al: Efficacy of communication skills training for giving bad news and discussing transitions to palliative care. Arch Int Med 167:453-460, 2007

33. Bartlett C, Doyal L, Ebrahim S, et al: The causes and effects of socio-demographic exclusions from clinical trials. Health Technol Assess 9:1-152, 2005

34. Branson RD, Davis KJ, Butler KL: African Americans participation in clinical research: Importance, barriers, and solutions. Am J Surg 193(1):32-9, 2007

35. Swanson GM, Bailer JC 3rd: Selection and description of cancer clinical trials participants: Science or happenstance. Cancer 95:950-959, 2002

36. Albrecht TL, Eggly SS, Gleeson ME, et al: Influence of clinical communication on patients' decision making on participation in clinical trials. J Clin Oncol 26: 2666-2673, 2008

37. Brown R, Bylund CL, Siminoff LA, et al: Seeking informed consent to phase I cancer clinical trial: Identifying oncologists' communication strategies. Psychooncology 20:361-368, 2010

38. Eggly S, Albrecht TL, Harper FWK, et al: Oncologists recommendations of clinical trial participation to patients. Patient Educ Couns 70:143-8, 2008

39. Jenkins V, Fallowfield L, Solis-Trapala I, et al: Discussing randomised clinical trials of cancer therapy: Evaluation of a Cancer Research UK training programme. BMJ 330:400-406, 2005

40. Brown RF, Butow PN, Butt DG, et al: Developing ethical strategies to assist oncologist in seeking informed consent to cancer clinical trials. Soc Sci Med 58:379-390, 2004

41. Scharff DP, Mathews KJ, Jackson P, et al: More than Tuskegee: Understanding mistrust about research participation. J Health Care Poor Underserved 21: 879-897, 2010

42. Grossman SA, Piantadosi S, Cohavey C: Are informed consent forms that describe clinical oncology research protocols readable by most patients and their families? J Clin Oncol 12:2211-2215, 1994

43. Meropol NJ, Weinfurt KP, Burnett CB, et al: Perceptions of patients and physicians regarding phase I cancer clinical trials: Implications for physician-patient communication. J Clin Oncol 21:2589-2596, 2003

44. Cox K: Informed consent and decision making: Patients' experiences of the process of recruitment to phases 1 and 2 anti-cancer drug trials. Patient Educ Couns 46:31-38, 2002

45. Cheng JD, Hitt J, Koczwara B, et al: Impact of quality of life on patient expectations regarding phase I clinical trials. J Clin Oncol 18:421-428, 2000

46. Daugherty C, Kass NE, Roter D, et al: A study of physician investigator (PI) disclosure of alternatives of care and prognostic information to advanced cancer patients (ACP) enrolling in phase I trials. J Clin Oncol 27, 2009 (suppl; abstr 6508)

47. Brown RF, Butow PN, Boyle F, et al: Seeking informed consent to cancer clinical trials: Evaluating the efficacy of communication skills training. Psychooncology 16:507-516, 2007

48. Clayman ML, Roter D, Wissow LS, et al: Autonomy related behaviors of patient companions and their effect on decision making at activity in geriatric primary care. Soc Sci Med 60:1583-1591, 2005

49. Ho A: Relational autonomy or undue pressure? Family's role in medical decision making. Scand J Caring Sci 22:128-135, 2008

50. Siminoff LA, Zyzanski SJ, Rose JH, et al: The cancer communication assessment tool for patients and families (CCAT-PF- a new measure). Psychooncology 17:1216-1224, 2008

51. Agrawal M, Grady C, Fairclough DL, et al: Patient decision making process regarding participation in phase I oncology research. J Clin Oncol 24:4479-4484, 2006

52. Albrecht TL, Penner LA, Cline RJW, et al: Studying the process of clinical communication: Issues of context, concepts and research directions. J Health Commun 14:47-56, 2009

53. Albrecht TL, Ruckdeschel JC, Riddle DL, et al: Communication and decision making about cancer clinical trials. Patient Educ Couns 50:39-42, 2003

54. Brown RF, Butow PN, Ellis P, et al: Seeking informed consent to cancer clinical trials: Describing current practice. Soc Sci Med 58:2445-2457, 2004

55. Fallowfield L, Jenkins V, Farewell V, et al: Efficacy of a Cancer Research UK communication skills training model for oncologists: A randomised controlled trial. Lancet 359:650-6, 2002

56. Fallowfield L: Can we improve the professional personal fulfilment of doctors in cancer medicine? Br J Cancer 71:1132-3, 1995

57. Brown RF, L BC, Li Y, Edgerson S, Butow PN: Testing the utility of a cancer clinical trial specific Question Prompt List (QPL-CT) during oncology consultations Patient Educ Couns 88:311-317, 2011

58. Brown RF, Shuk E, Butow PN, et al: Identifying patient information needs about cancer clinical trials using a question prompt list. Patient Educ Couns 84:69-77, 2011

59. Brown RF, Shuk E, Leighl N, et al: Enhancing decision making about participation in cancer clinical trials: Development of a question prompt list. Support Care Cancer 19:1227-1238, 2011

60. Juraskova I, Butow P, Lopez A, et al: Improving informed consent: Pilot of a decision aid for women invited to participate in a breast cancer prevention trial (IBIS -II DCIS). Health Expect 11:252-262, 2008