Participation in Cancer Clinical Trials: Why Are Patients Not Participating?

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Participation in Cancer Clinical Trials: Why Are Patients Not Participating?

Margaret M. Byrne, PhD, Stacey L. Tannenbaum, PhD, Stefan Glück, MD, PhD, Judith Hurley, MD, Michael Antoni, PhD

Background. *Participation in cancer clinical trials is low, particularly in racial and ethnic minorities in some cases, which has negative consequences for the generalizability for study findings. The objective of this study was to determine what factors are associated with patients' participation or willingness to participate and whether these factors vary by race/ethnicity.* ***Design or Methods***. *White, Hispanic, and black participants were obtained through the Florida cancer registry and who were diagnosed with breast, lung, colorectal, or prostate cancer (N = 1100). Participants were surveyed via telephone to obtain demographic information, past participation, and willingness to participate in clinical trials, as well as barriers and facilitators to participation. Logistic and Poisson regressions were performed.* ***Results***. *Respondents were on average 67.4 years old, 42.7% were male, and 50.1% were married. In this population, 7.7% of respondents had participated in a clinical trial, and 36.5% stated that they would be willing to participate. In multivariate models, blacks and Hispanics were equally likely as whites to be willing to participate in cancer trials, but Hispanics were less likely to have participated, and this was especially more likely in non–English-speaking Hispanics compared with English-speaking Hispanics. Notable barriers across race/ethnicity were mistrust and lack of knowledge of clinical trials.* ***Limitations***. *Cross-sectional design limits cause-and-effect conclusions.* ***Conclusions***. *There are racial differences in participation rates but not in willingness to participate. We hypothesize that willingness to participate is not very high because people are uninformed about participating, particularly in non–English-speaking Hispanics. Barriers and facilitators to participation vary by race. Improved understanding of cultural differences that can be addressed by physicians may restore faith, comprehension, and acceptability of clinical trials by all patients.* ***Key words:*** *cohort studies; population-based studies; patient decision making.* ***(Med Decis Making XXXX;XX:XXX–XXX)***

Clinical trials are essential for the development of new and effective treatments. But for trials to produce valid and generalizable results, effective accrual of participants is necessary. Unfortunately, rates of participation in adult cancer clinical trials in the United States of America are very low. National studies of recruitment to National Cancer Institute–sponsored trials estimate the overall recruitment rate to be less than 2% of all newly diagnosed cancer patients.[1] At individual cancer centers, recruitment of newly diagnosed patients is higher but still very low, approximately 12% to 14%.[2,3] An additional concern is the underrepresentation of minorities in cancer clinical trials. With the exception of prostate cancer, national population-based studies have shown that blacks and Hispanics participate in clinical trials at much lower rates than would be expected from cancer incidence rates in these populations.[1,4,5] This underrepresentation of minorities is not improving; to the contrary, a study that compared enrollment rates of whites, blacks, and Hispanics in 1996–1998 with rates in 2000–2002 showed that participation by blacks and Hispanics had fallen over time, even though overall recruitment had risen.[1]

Recent research has also looked at reasons why cancer patients are not participating in clinical trials.

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Access to trials may be an issue and could be caused by geographic location of patients, insurance status, or other factors. In these cases, patients may be effectively barred from even being in the position to make a decision about participation. Knowledge about what trials are available may also be a factor; however, previous interventions and statewide strategies, such as the Florida Cancer Clinical Trial Matching Service,[6] which matches cancer patients to available trials within the state, have done little to improve participation rates. Thus, there may be nonaccess barriers to participation that lead cancer patients to decide not to participate. Some patient-provided reasons for deciding not to participate include reluctance to be in a ''study,'' financial and time constraints, work and child care conflicts, and lack of understanding of trials.[7–10] Therefore, we believe that it is essential to understand patients' perspectives on the barriers and facilitators of participation in cancer clinical trials, as well as their attitudes toward clinical trials, to gain an understanding of what is influencing cancer patients' decisions about participating in trials. Our approach in the larger study—of which these results are a part—was framed by the theory of planned behavior.[11] Thus, a main focus is on patient-reported intentions for action, that is, ''willingness'' to participate in a clinical trial, and the perceived barriers and facilitators to perform that action. The objective of the results presented here is to explore what factors are associated with participation or willingness to participate in cancer clinical trials, as well as to elicit and compare barriers and facilitators of participation by race/ethnicity. We also wanted to explore whether patient characteristics, including demographic characteristics (e.g., age, sex, socioeconomic status) and psychosocial variables such as anxiety and optimism, were associated with past participation or willingness to participate in a clinical trial. We anticipated that individuals who were more anxious or more pessimistic might be less willing to participate in a clinical trial.

METHODS

Participants

Pilot study participants included 20 individuals who had been diagnosed with 1 of 4 cancer types: breast, prostate, lung, or colorectal. These participants were recruited from The Wellness Community (TWC), using posters and flyers. TWC is an international nonprofit organization dedicated to providing free support and education to people with cancer and their friends and families.

Participants for the finalized survey (N = 1100) included individuals 21 years or older with a recorded diagnosis of breast, prostate, colorectal, or lung cancer in the Florida Cancer Data System (FCDS). FCDS is a population-based, statewide cancer registry of all cancer diagnoses established by mandate of the Florida legislature to which all hospitals and outpatient facilities licensed in Florida are required to report. Participants were located from all geographic areas of Florida, including both rural and urban settings. Equal numbers of white, black, and Hispanic participants with breast, prostate, lung, and colorectal cancer were targeted.

Procedures

The study employed a cross-sectional survey design of cancer patients living in Florida. Primary data were collected using a quantitative survey, which was an expanded version of previous research.[12] The survey collected information about sociodemographic characteristics, type of cancer, clinical trial participation history, attitudes associated with participating in clinical trials, and potential barriers and facilitators of participating in a clinical trial. The survey was translated into generic Spanish by a certified medical interpreter/translator, using forward and back translation.

The survey was first pilot tested by a research associate who met each pilot study participant at his or her home or at TWC in Miami, Florida. The research associate reviewed the survey with each participant and invited him or her to ask questions, request clarification, and make suggestions on the wording and content of all items in the survey. Participants were given $20 to compensate them for their time and effort. Based on the information from the pilot, the finalized survey components were modified for clarity and completeness. The survey began with an introductory paragraph that described clinical trials and the study in the following manner:

> Cancer research studies or clinical trials test new treatments for people with cancer. Research studies are often referred to in different ways. You may have heard the term experimental studies, research protocols, or just protocols. All of these phrases refer to research studies that try to answer specific scientific questions like finding better ways to prevent or treat cancer. We are conducting a study to find out more about how people decide whether or not to be

in research studies, and to examine what information is helpful in making decisions to be in a research study.

The FCDS contacted 9482 white, black, or Hispanic individuals by mail from rural or urban settings throughout Florida who were diagnosed with breast, colorectal, lung, or prostate cancer from 2004–2007 and not known to be deceased. This mailing was performed to inform potential participants about the study, explain the details of the study, and allow individuals the choice to opt out of the study. Of these individuals, 2551 were excluded (318 opted out and 2233 were found to be deceased). The names of the remaining 6931 patients were then given to the Institute for Public Opinion Research (IPOR), a telephone survey center located at Florida International University in Miami, Florida. Between January and April 2009, IPOR made 8 attempts to contact by telephone each possible participant at different times of the day to obtain verbal consent and complete the survey. Verbal consent was obtained before the telephone survey began. The protocol was approved by the University of Miami Institutional Review Board.

The finalized survey was completed and tallied for 1100 participants. The sampling frame ensured that the resulting survey population was representative of the cancer population in Florida. There was no follow-up period for this study.

Survey Instruments

Demographic information. We collected basic demographic, information including age, sex, self-reported race and Hispanic origin, education level, household income, and general health status.

Participation and willingness to participate in cancer clinical trials. Participants were asked if they had participated in a cancer clinical trial in the past and asked on a 5-point Likert-type scale (*definitely not, probably not, maybe, probably, definitely*) if they would be willing to participate in a cancer clinical trial if one were available and offered to them. Participants were counted as ''willing to participate'' if they responded a) ''probably'' or ''most likely'' and, as a secondary measure, b) ''maybe,'' ''probably,'' or ''most likely.''

Barriers and facilitators to participation. We asked each participant to indicate (yes/no) whether 11 specific factors might be barriers to participation for them and whether 10 specific factors might be facilitators to participation. We present results from these questions as percentages endorsing ''yes'' by race/ethnicity. In addition, we also summed the number of facilitators and number of barriers each individual endorsed as ''aggregate facilitators'' and ''aggregate barriers'' as a general measure of overall promoters and inhibitors to participation.

Trait anxiety scale. This measure is one part of the State-Trait Anxiety Inventory.[13] Trait anxiety reflects the existence of stable individual differences in the tendency to respond with anxiety when anticipating a threatening situation. Each item is rated on a 4-point scale ranging from *not at all* to *very much so*, with higher values of the final score indicating greater anxiety. All 20 items are scored and summed; a higher final score is associated with higher trait anxiety.

Life Orientation Test–Revised Scale.[14]. The Life Orientation Test–Revised (LOT-R) scale measures positive expectations for future outcomes. Participants answered on a scale ranging from 1 = *agree a lot* through 5 = *disagree a lot* for 6 active items for a total score where lower scores equated to a more optimistic outlook.

Statistical Analysis

Data are reported as means and standard deviations (SD) for continuous variables and percentages for all other descriptive data. Multiple logistic regression analysis was performed to produce odds ratios for factors associated with participating and being willing to participate in clinical trials. Percentages stratified by race were reported for endorsing barriers and facilitators to participation in clinical trials. Poisson regression controlling for type of cancer and demographics was performed to determine whether there were differences in the summed number of barriers and facilitators by race/ethnicity after controlling for demographics characteristics. All analyses were performed using STATA version 11 (StataCorp LP, College Station, TX).

Funding Source

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Table 1 Demographics by Race/Ethnicity ($N = 1100$)

Demographic Variable	Overall	White ($n = 386$)	Black ($n = 295$)	Hispanic ($n = 419$)
Age, mean (SD), y[a,b,c]	67.4 (11.7)	70.3 (11.2)	63.9 (11.7)	67.3 (11.3)
Male sex	42.7	38.6	43.7	45.8
Education[b]				
High school graduate or less	43.2	35.1	44.3	49.8
Some trade school/some college	24.0	26.4	26.5	20.0
College graduate	22.6	25.7	18.6	22.6
Postgraduate	10.3	12.8	10.7	7.7
Living arrangement				
Live with spouse	50.1	55.9	43.6	49.3
Live with children	8.7	5.6	13.2	8.3
Live with spouse and children	13.1	8.6	13.2	17.0
Live alone	21.8	25.9	19.5	19.7
Other	6.4	4.0	10.5	5.8
Income[a,b,c]				
Less than $10,000	19.2	8.2	20.3	27.6
$10,000–$20,000	18.0	14.6	16.5	21.9
$20,000–$35,000	18.7	21.0	18.1	17.2
$35,000–$50,000	16.9	17.6	20.9	13.6
$50,000–$75,000	13.1	18.0	11.0	10.4
Over $75,000	14.1	20.6	13.2	9.3
General health				
Excellent	13.5	13.8	10.9	15.0
Very good	26.1	25.5	27.8	25.5
Good	33.9	35.8	35.6	31.0
Fair	21.5	18.2	23.4	23.2
Poor	5.0	6.8	2.4	5.3
Cancer site				
Breast	42.8	47.7	40.0	40.3
Prostate	28.7	26.4	29.8	30.1
Colorectal	17.9	14.3	18.6	20.8
Lung	10.6	11.7	11.5	8.8
Trait anxiety, mean (SD)[b,c]	30.5 (9.7)	31.5 (9.6)	31.8 (10.1)	28.8 (9.4)
Life Orientation Test–Revised, mean (SD)[b,c]	18.6 (5.1)	17.6 (5.1)	17.1 (4.9)	20.5 (4.5)

Values are presented as percentages unless otherwise indicated.
[a]Whites significantly different from blacks ($P < 0.05$).
[b]Whites significantly different from Hispanics ($P < 0.05$).
[c]Blacks significantly different from whites ($P < 0.05$, $P < 0.001$).

RESULTS

Demographics

Demographic information is presented in Table 1. The mean (SD) age of participants was 67.4 (11.7) years. There were more female than male participants (57.3% and 42.7%, respectively). Overall, there were significantly more white than black participants (35.1% and 26.8%, respectively; $P < 0.01$) and more Hispanic than black participants (38.1% and 26.8%, respectively; $P < 0.01$). The percentage of all participants broken down by cancer site was not different between race/ethnicity: 42.8%, breast; 28.7%, prostate; 17.9%, colorectal; and 10.6%, lung.

Overall, 43% of the respondents had a high school education or less, and whites had significantly higher educational attainment than Hispanics and blacks. Overall, about half of the participants lived with spouses only. Self-reported general health was surprisingly good for these cancer survivors, with approximately 40% reporting very good to excellent health and another third reporting good health.

The trait anxiety scores for our participants had an overall average of 30.5 out of a possible score of 80, with higher scores indicating higher anxiety. Hispanics had significantly lower scores than whites or blacks. For all 3 groups, the scores were lower than the norms for working adults, with a mean (SD) of

Table 2 Past Participation and Willingness to Participate in Cancer Clinical Trials

Characteristic	Overall (*n* = 1096/963)	White (*n* = 384/328)	Black (*n* = 295/262)	Hispanic (*n* = 417/373)
Past participation	84 (7.66)	44 (11.46)	21 (7.12)	19 (4.56)
Willingness				
Most likely/probably	351 (36.45)	125 (38.11)	102 (38.93)	124 (38.73)
Most likely/probably/maybe	659 (68.43)	231 (70.43)	202 (77.10)	226 (60.59)

Values are presented as *n* (% within that race/ethnic group or overall). Not all participants answered willingness questions. *n* is given as those answering past participation/willingness to participate questions.

Table 3 Past Participation and Willingness to Participate in Cancer Clinical Trials for Participants with Stage 3 or 4 Disease at Diagnosis

Characteristic	Overall (*n* = 158/137)	White (*n* = 57/50)	Black (*n* = 33/28)	Hispanic (*n* = 68/59)
Past participation	14 (8.86)	6 (10.53)	4 (12.12)	4 (5.88)
Willingness				
Most likely/probably	59 (43.07)	16 (32.00)	15 (53.57)	28 (47.46)[a]
Most likely/probably/maybe	97 (70.80)	31 (62.00)	25 (89.29)	41 (69.49)

Values are presented as *n* (% within that race/ethnic group or overall). Not all participants answered willingness questions. *n* is given as those answering past participation/willingness to participate questions.
[a]Significantly different from willingness to participate in those with nondistant disease (stages 1 and 2).

34.9 (9.2) for men and 34.8 (9.2) for women published by the scale's developer in 1983,[13] and lower than a recent Australian study of adults, which found a mean (SD) score of 36.4 (11.4).[15] The LOT-R score was a mean (SD) of 18.6 (5.1) out of a possible 60; this was somewhat lower than recently published norms for persons in an age category of 61 to 70 years (mean [SD], 14.8 [3.4]).[16]

Participation and Willingness to Participate in Clinical Trials

In our cancer survivor population, fewer than 8% overall reported participating in a cancer clinical trial (Table 2). There was a statistically significant difference ($P < 0.001$) among our racial/ethnic groups, with whites having the highest level of past participation (11.5%) and Hispanics having less than half that level (4.6%). However, on the more stringent measure of willingness to participate, there were no significant differences among the groups in willingness to participate ($P = 0.254$), with overall 36.5% of respondents reporting at least being ''probably'' willing to join a trial. A large percentage of individuals overall and in each group did select the response of ''maybe'' being willing to participate if a trial were available.

Table 3 shows participation rates and willingness to participate for those cancer survivors who had stage 3 or 4 cancer at diagnosis. In almost all instances, percentages were higher than for responses overall; the exception was for willingness to participate in white cancer survivors.

Multivariate Regressions of Participating or Being Willing to Participate

The odds ratios (ORs) and confidence intervals (CIs) from the logistic models of factors associated with participating or being willing to participate in clinical trials—as measured by our more stringent measure—are presented in Table 4. Controlling for demographic characteristics, self-reported health, and cancer site, Hispanics were about one-third as likely (OR, 0.36; 95% CI, 0.17–0.79) to have participated in clinical trials as whites but were just as willing as whites to participate (OR, 0.84; 95% CI, 0.53–1.32). Blacks were equally as likely as whites to have participated (OR, 0.68; 95% CI, 0.32–1.43) and were also as willing to participate (OR, 1.06; 95% CI, 0.65–1.73) in clinical trials. Individuals with higher trait anxiety were significantly more likely to report being willing to participate, although the effect size was small.

Barriers and Facilitators of Participation by Race/Ethnicity

Overall, the largest barrier for not participating in a clinical trial was the concern that insurance would

Table 4 Regressions on Factors Associated with Participating in Cancer Clinical Trials and Being Willing to Participate

	Participated	Willing to Participate
Race/ethnicity		
Black	0.68 (0.32–1.43)	1.06 (0.65–1.73)
Hispanic	0.36 (0.17–0.79)[a]	0.84 (0.53–1.32)
Age	0.97 (0.94–0.99)[a]	0.99 (0.98–1.02)
Male sex	0.62 (0.21–1.86)	1.67 (0.91–3.07)
Education		
Some trade school/some college	3.63 (1.29–10.2)[a]	0.89 (0.55–1.43)
College graduate	5.80 (2.02–16.7)[a]	1.60 (0.97–2.64)
Postgraduate	3.91 (1.18–12.9)[a]	1.53 (0.81–2.89)
Living arrangement		0.81 (0.60–1.11)
Live with children	1.02 (0.33–3.16)	2.20 (1.11–4.35)[a]
Live with spouse and children	0.82 (0.32–2.08)	1.13 (0.64–1.99)
Lives alone	1.49 (0.68–3.25)	1.60 (0.99–2.58)
Other	1.73 (0.54–5.56)	2.04 (0.87–4.80)
Income		
$10,000–$20,000	0.61 (0.17–2.21)	1.01 (0.55–1.83)
$20,000–$35,000	0.52 (0.15–1.86)	1.41 (0.77–2.58)
$35,000–$50,000	0.98 (0.30–3.23)	1.38 (0.71–2.67)
$50,000–$75,000	1.35 (0.40–4.58)	1.93 (0.94–3.98)
Over $75,000	0.97 (0.26–3.57)	1.85 (0.88–3.92)
Health		
Very good	0.81 (0.32–2.04)	0.76 (0.43–1.34)
Good	0.94 (0.37–2.41)	0.79 (0.45–1.37)
Fair	1.25 (0.44–3.54)	0.64 (0.34–1.19)
Poor	1.33 (0.23–7.58)	1.17 (0.46–2.95)
Cancer site		
Prostate	1.11 (0.30–4.09)	0.83 (0.40–1.72)
Lung	0.82 (0.31–2.17)	1.15 (0.63–2.08)
Colorectal	1.12 (0.41–3.09)	1.60 (0.83–3.09)
Trait Anxiety	0.97 (0.93–1.01)	1.03 (1.01–1.05)[a]
Life Orientation Test	0.98 (0.91–1.05)	1.04 (0.99–1.08)

Values are presented as odds ratios (95% confidence interval). Willingness measured as responding ''probably'' or ''most likely'' willing to participate. Reference categories: white race, female, high school or less education, lives with spouse, less than $10,000 income, excellent health, and breast cancer.
[a]Significant at $P < 0.05$.

not cover the cost associated with additional tests or treatments that might arise from participation (85%), and the smallest barriers were related to child care (6.7%) and elder care (6.8%) (Figure 1). Because of our large sample size and multiple comparisons, we only report as significant those differences across race/ethnic groups with $P < 0.001$. Even with this strict threshold, there were several differences across groups in the percentage of patients endorsing barriers of participating in a clinical trial. More Hispanics than whites or blacks endorsed not knowing about studies as a barrier to participation. For blacks, not wanting to be a ''guinea pig'' was significantly reported more often as a barrier than for whites or Hispanics. Finally, a higher percentage of Hispanics than whites reported that fear of adverse effects was a barrier to participation.

Five facilitators affected more than 90% of all participants; these facilitators were that the study 1) might help improve cancer treatment (95.5%), 2) was advised by the doctor (94.8%), 3) offered the best treatment (94.3%), 4) provided more information (94%), and 5) was the only treatment option available (92.8%) (Figure 2). There were few differences between race/ethnicity in the percentage endorsing facilitators of participating in a clinical trial. Blacks were less likely than whites or Hispanics to endorse that a facilitator was that a doctor thought it was advisable for them to participate. However, there was a significant difference in the percentage of

Figure 1 Barriers to participation endorsed by participants across the racial ethnic groups. †*Whites significantly different from blacks.* §*Whites significantly different from Hispanics.* ¶*Blacks significantly different from Hispanics.* P < *0.001.*

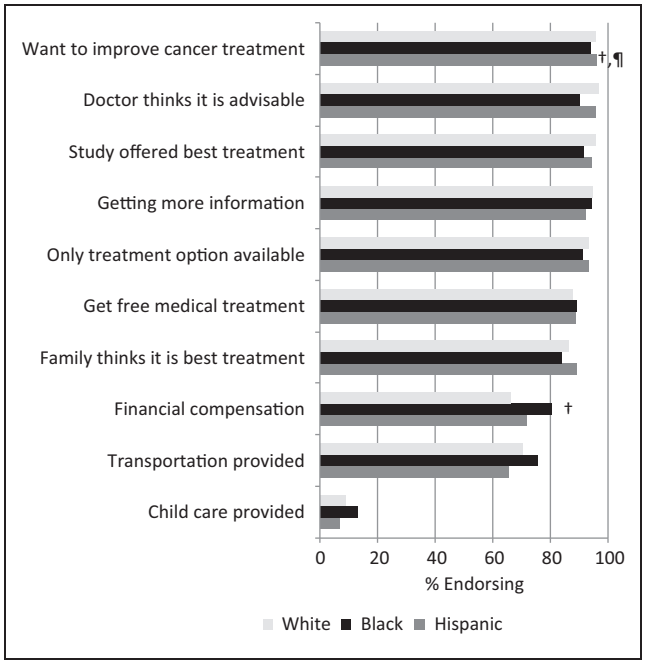

Figure 2 Facilitators to participation endorsed by participants across racial/ethnic groups. †*Whites significantly different from blacks.* ¶*Blacks significantly different from Hispanics.* P < *0.001.*

whites and blacks reporting that financial compensation would be important in a decision about participation, with compensation being a facilitator for a larger percentage of blacks.

Poisson Regression of Aggregate Barrier and Facilitator Scores

Poisson regression controlling for type of cancer and demographics showed that individuals' aggregate barrier and facilitator scores were not different across the racial/ethnic groups. The mean (SD) aggregate barrier score was 12.3 (1.7), while the mean (SD) aggregate facilitator was 9.54 (1.3).

Logistic regression was performed on participation ($n = 363$) and on willingness to participate ($n = 322$) in Hispanics by the primary language spoken with the physician. Using English as the reference category (only English, English more than Spanish, or both English and Spanish equally), those speaking Spanish only or mostly Spanish to their physician were about one-fourth as likely to have participated in clinical trials as their English-speaking counterparts (OR, 0.22; 95% CI, 0.07–0.67) and were nearly half as likely to be willing to participate (OR, 0.45; 95% CI, 0.28–0.74) (results not shown).

DISCUSSION

Patients with cancer may face a decision about participation in a cancer clinical trial, and in this situation, there will be attendant barriers and facilitators.

Participation and Willingness to Participate

A finding of our study was that although Hispanics were less likely than whites to take part in cancer clinical trials, they reported equal willingness to consider participation in future clinical trials as did whites. One reason for this discrepancy may be a communication barrier between physician and patient. We found that Spanish-speaking or mostly Spanish-speaking individuals were less likely than English-speaking Hispanics to have participated (or be willing to participate) in cancer clinical trials.

Few studies have compared Hispanics with whites on participation and willingness to participate. In 1 study using a national database, similar results were found in Hispanics compared with whites for trial participation, but willingness to participate was not examined in this study.[1] In contrast to our findings, a comprehensive literature review of 10 clinical

interventions revealed that Hispanics had a higher consent rate than whites; however, these studies offered enrollment to fewer Hispanics than to whites, which may be a sign that enrollment was offered only to those patients whom the researcher/physician judged were more likely to accept participation.[17] In addition, all were English speakers. A 2012 review by Schmotzer[18] found a strong presence of physician bias in selecting the perceived ''best'' participants for trials, and assumed noncompliance, increased difficulty, or nonpreference for participation by minorities may have affected whether minorities were offered participation. Therefore, our findings coincide with a previous finding that the inability to meet the linguistic needs of Hispanics decreases participation in clinical trials.[19] However, decisions to enroll in cancer clinical trials are greatly enhanced when there is clear and understandable shared communication between the physician and patient.[20] Our and previous findings suggest that if offers of enrollment and linguistic competency were increased, Hispanic cancer patients' consent would improve.

We found that blacks had no difference from whites in terms of previous enrollment and future willingness to participate in cancer clinical trials. Although some investigators have found similar results,[5,17] many other studies have reported that blacks are less likely to enroll in clinical studies than are whites.[21–24] Simon and others[25] reported that although white women were more likely than black women to be offered participation into breast cancer clinical trials, race was not a significant predictor of enrollment, which suggests that more blacks would enroll if given the option. Unfortunately, physicians may consider blacks more likely to be ineligible than their white counterparts,[25] again suggesting implicit physician bias.

Finally, we found that overall, and for Hispanics and blacks, individuals with stage 3 and 4 cancer at diagnosis were more likely to report having participated in a clinical trial and being more willing to participate. This might be expected because patients with metastatic or more advanced cancer may have fewer proven treatment options and thus may be more inclined to participate. However, these differences were mostly not statistically significant and did not hold for whites.

Barriers and Facilitators

A concern about insurance not covering costs associated with participation in a trial was the most cited barrier for all groups. This is a real concern. However, currently 36 states have legislation or special agreements requiring health plans to pay the cost of routine medical care received by patients in clinical trials, although the extent of coverage varies (e.g., Baquet and others[26]). In addition, starting in 2014, the Patient Protection and Affordable Care Act requires health insurers to pay for routine costs of care delivered in all clinical trials,[27] and thus this barrier may be less problematic in the future.

Other barriers cited were more prominent for specific racial/ethnic groups. For example, Hispanics were significantly more likely to state that not knowing enough about research studies was a barrier to participation than were blacks or whites. Because of the wording of the question, this answer could have arisen either because there were not trials available at the site of care or because a health care provider had not discussed trials with the patient. Lara and others[28] also reported less awareness of clinical trials but equal willingness to participate in Hispanics as compared with whites. Hispanics also reported that the fear of adverse effects would prevent them from participation in a clinical trial to a greater degree than whites, which coincides with findings from previous studies.[29] Since Hispanics reported being just as willing as whites to participate in future clinical trials, these findings suggest that if Hispanics were more informed about trials and side effects, as well as reassured about communications with doctors, they may be more accepting of participation.

A leading factor that would affect participation decisions for white patients appears to be the attitude of their primary care doctor. Important barriers to whites were if their doctor did not want them to participate and not wanting to leave their doctor (not significant), and a facilitator was if their doctor thought it advisable to participate. Go and others[30] also found that a leading barrier to accrual into a cancer clinical trial for whites was if their physician did not want them to participate.

Blacks have been shown to have more mistrust than whites regarding clinical trials, even if they could not accurately explain historically discriminatory events, such as Tuskegee.[31,32] We found that blacks, more so than Hispanics or whites, found that the idea of being treated like a ''guinea pig'' was a barrier to participation. Other studies reported similar findings for blacks.[31,33] On the other hand, Advani and others[21] did not find a racial difference in blacks v. whites regarding feeling like being treated as a guinea pig. When Dunlop and others[34] gave African Americans an educational DVD prior to asking

them if they would consent to be in a hypothetical clinical trial, more reported being willing to consent and less reported being afraid of side effects compared with those African Americans not given this intervention. These findings further support education and awareness as fundamental factors for improved minority accrual.

Limitations

There were some limitations to the study. This was a cross-sectional design, which limits causal inference. We were only able to assess participation in clinical trials by self-report. Therefore, our 8% accrual rate is likely an underestimate of participation, as it only takes into account surviving patients, and—as we found—patients with terminal or late-stage disease are more likely to participate in trials. Therefore, we may be missing cancer patients who participated in trials but died before being able to participate in our study. The only race/ethnicities included were whites, blacks, and Hispanics, which is both a limited sample and heterogeneous within each category. This sample of cancer patients all came from the state of Florida and may not be generalizable to the population of the United States at large. However, this sample is representative of all cancer patients in Florida and, to our knowledge, is the largest survey of Hispanics compared with whites and blacks ever reported, providing a wealth of information not available before.

CONCLUSION

Participation rates in cancer clinical trials are affected by many things, including patients' access to and the availability of trials, providers' knowledge about trials and their ability to communicate with patients about trials, patients' eligibility for a trial, and the patients' own decisions about joining a trial. Patients' decisions are influenced by their attitudes toward trials and the perceived barriers and facilitators toward participation in a trial. Deciding to join a trial is an individualized choice, and participation may not be the best decision for each individual cancer patient. Nevertheless, it is important to understand, from a patient's perspective, the barriers and facilitators that patients perceive, so that barriers can be reduced barriers and facilitators enhanced, respectively, so that decisions can be made based on patient preferences and not on systemic barriers, misconceptions, or lack of knowledge. In this way, decisions are improved, and participation rates may be improved.

In this study, we found that although Hispanics were less likely to have participated in clinical trials, willingness to participate was equivalent to whites and blacks. Interventional strategies aimed directly at improving Hispanic involvement by using the known facilitators and limiting the barriers to participation are imperative. In addition, bridging the language barrier of Spanish-only speaking prospective participants is paramount to improving inclusion of more Hispanics in clinical trials. It is possible that the National Cancer Institute's Cancer Information Service (CIS) Spanish Call Line could be extended to provide interpreter services to smaller hospitals and medical practices that are conducting cancer clinical trials. The CIS currently discusses clinical trials with a wide range of callers, including in Spanish,[35] and thus this would be a natural extension of its services.

The findings from this study can be used to enhance ongoing and future efforts to develop strategies that will be effective in reducing barriers, enhancing facilitators, and improving decision making about participation in a wider pool of cancer patients. A variety of strategies are currently being studied to determine whether they can improve patients' knowledge about cancer clinical trials and address communications concerns, with some success. For example, a 20-minute educational video developed by Hoffner and others[36] was not found to improve objective understanding of trials, but participants did report favorable experiences with the video. Wells and others[37] have developed a 9-minute DVD, with a multimedia psychoeducational intervention, to prepare patients for a discussion about cancer clinical trials. And Byrne and others (unpublished data, MM Byrne, JL Studts, ST Hawley, A Fagerlin, S Stableford 2012) have developed a web-based decision aid for improving minority cancer patient decisions about participation in clinical trials that has been shown to improve objective and subjective knowledge about trials and to be highly acceptable to patients. The content of this decision aid was informed in part by the study reported here. In addition to efforts to educate patients, however, it will be necessary to develop interventions that target health care providers to activate them to become knowledgeable about available trials, proactively offer the trials to their patients, and improve communication skills concerning trials with their patients. Taken together, a triangulation of approaches will potentially allow for improved decision making regarding participation in cancer clinical trials,

which may lead to greater participation rates. This could then facilitate needed advancements in treatments of cancer for cancer patients, particularly for minority cancer patients.

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