Original Article

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

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BACKGROUND: 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 years (OR = 1.51, 95% CI = 1.28-1.79), males (OR = 2.28, 95% CI = 1.92-2.71), and non-Hispanic black race (OR = 1.53, 95% CI = 1.2-1.96) were significantly associated with more *physical/medical conditions*. Age ≥ 65 years was significantly associated with lower CT enrollment (OR = 0.83, 95% CI = 0.7-0.98). Males (OR = 0.78, 95% CI = 0.65-0.94) and a higher grade level score for consent form readability (OR = 0.9, 95% 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, 95% CI = 0.58-0.98). **CONCLUSIONS:** 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. 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 comorbidities, sex, age, and consent form characteristics on CT participation. ***Cancer*** **2014;120:877–84.** © *2013 American Cancer Society.*

KEYWORDS: racial/ethnic, African Americans, Hispanic, minorities, clinical trials, medical research, cancer.

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,

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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, comorbidities, low literacy, language differences, practical obstacles (eg, child care, 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 nonminority 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 nonminority 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 article describes the general details and trends of the log.[13]

The objective of this article 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.

MATERIALS AND 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 article, data from 2009 to 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 (eg, 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 (eg, 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 article, race/ethnicity was collapsed into one variable with 5 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. In addition, 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 to 4509 depending on which covariates were used. Log entries comprised patients screened for at least 1 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 comorbidities 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) Comorbidities; 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, comorbidities, 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 years. 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 US 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 & 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 (eg, abnormal laboratory results or comorbidities). Logistic regression was used to assess the effect of race/ethnicity, age, sex, region, consent form length, and consent form readability on 4 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 (ie, a Pearson's $r \geq 0.7$). Considering 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, version 9.3.

RESULTS

Demographic, Log, and Consent Form Characteristics

The mean age was 62 years, with approximately 57% of patients being under the age of 65 and women comprising 68% of the sample (Table 1). 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 (eg, American Indian, Alaska Native, Native Hawaiian or Pacific Islander). The average consent form page length was 17 pages (range, 3-50 pages), with 60% of consent forms being < 20 pages. The average SMOG reading score for the consent forms was 10th grade (range, 8th to 12th 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.

TABLE 1. Demographic, Log, and Consent Form Characteristics for the Full Sample (N = 4509)

Characteristic	%	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	

Chi Square Analyses

Chi square tests indicated a significant association between the patient's race/ethnicity and enrollment into a CT (Table 2). Asians had a significantly lower proportion of CT enrollment. The chi square test also indicated a significant association between race/ethnicity, CT ineligibility, and comorbidities. Non-Hispanic blacks had a higher proportion of not meeting eligibility criteria for a CT and having comorbidities. 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 (eg, abnormal laboratory results).

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 4 logistic regression models with multiple independent variables. The odds ratios and confidence intervals are reported in Tables 3 and 4. In Model 1, variables significantly associated with *physical/medical conditions* (ie, health conditions that would make a patient ineligible) included age ≥ 65 (OR = 1.51, 95% CI = 1.28-1.79), males (OR = 2.28, 95% CI = 1.92-2.71), and non-Hispanic black race (OR = 1.53, 95% CI = 1.2-1.96). In Model 2, the only variable significantly associated with lower *enrollment into a CT* was age ≥ 65 (OR = 0.83, 95% CI = 0.7-0.98). In Model 3 (Table 5), variables significantly associated with *eligible patients less likely to decline a CT* included males (OR = 0.78, 95% CI = 0.65-0.94) and a higher SMOG score (ie, written at a higher grade level) on the consent form (OR = 0.9, 95% 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 ≥ 20 pages (OR = 0.75, 95% CI = 0.58-0.98).

DISCUSSION

The primary aim of this article 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 years, being male, and being non-Hispanic black were all significantly associated with

TABLE 2. Breakdown of Enrollment, Refusal, Physical/Medical Conditions and Reasons for MD Not Offering a Trial by Demographics (N = 4509)

	%	n	*P*
Patient enrolled into a CT[a]			.007
Overall enrollment rate for full sample	18	816	
Non-Hispanic white	20	663	
Non-Hispanic black	18	94	
Hispanic	22	35	
Asian[a]	10	17	
Other	14	7	
Patient eligible but declined CT			.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[a]			.004
Non-Hispanic white	50	1328	
Non-Hispanic black[a]	56	248	
Hispanic	49	70	
Asian	58	91	
Other	54	21	
"No desire to participate in research" as reason for decline			.785
Non-Hispanic white	7	250	
Non-Hispanic black	9	46	
Hispanic	9	13	
Asian	6	10	
Other	6	4	
Comorbidities ineligibility[a]			<.001
Non-Hispanic white	11	337	
Non-Hispanic black[a]	16	85	
Hispanic	6	12	
Asian	6	11	
Other	10	2	
Abnormal labs ineligibility			.215
Non-Hispanic white	2	76	
Non-Hispanic black	4	19	
Hispanic	3	4	
Asian	3	3	
Other	4	3	
Abnormal organ function ineligibility			.241
Non-Hispanic white	1	35	
Non-Hispanic black	2	9	
Hispanic	2	3	
Asian	2	3	
Other	3	2	
Performance status ineligibility			.272
Non-Hispanic white	2	69	
Non-Hispanic black	3	15	
Hispanic	1	1	
Asian	1	1	
Other	2	1	
Disease progression ineligibility			.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			.024
Non-Hispanic white	16	409	
Non-Hispanic black	13	57	
Hispanic	12	15	
Asian	21	33	
Other[a]	27	12	
Age			.374
≥65	16	253	
<65	16	317	
Sex			<.001
Males	12	135	
Females[a]	17	439	

Abbreviations: CT, clinical trial; MD, physician.
[a] Statistically significant, $P < .05$.

higher odds of physical/medical conditions, with comorbidities 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 comorbidities, 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 comorbidities are managed in general. Better management and earlier identification of comorbid conditions prior to and during cancer treatment may improve CT participation for men, those individuals older than 65 years, 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. Although 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

TABLE 3. Multivariate Logistic Regression Model 1: Physical/Medical Conditions as the "Reason for Ineligibility" by Demographic Characteristics (N = 4184)

	Odds Ratio	95% CI	*P*
Age ≥ 65 (ref, <65)[a]	1.51	1.28-1.79	<.001
Males (ref, females)[a]	2.28	1.92-2.71	<.001
Race and ethnicity[a]			.005
Non-Hispanic white (ref)	1.0		
Non-Hispanic black[a]	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	

Abbreviations: CI, confidence interval; ref, reference value.
[a] Statistically significant, $P < .05$.

TABLE 4. Multivariate Logistic Regression Model 2: Enrollment Into a Clinical Trial by Demographic, Region, and Consent Form Characteristics (N = 4184)

	Odds Ratio	95% CI	*P*
Age ≥ 65 (ref, < 65)[a]	0.83	0.7-0.98	.03
Males (ref, females)	1.12	0.93-1.35	.24
Race and ethnicity			.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			.78
≥20 pages (ref, < 20 pages)	0.98	0.81-1.16	
Consent readability			.4
SMOG score	0.97	0.89-1.05	
Region of country			.45
West (ref)			
Midwest	1.06	0.38-2.99	
South	0.45	0.13-1.54	
Northeast	1.04	0.34-3.23	

Abbreviations: CI, confidence interval; SMOG, Simple Measure of Gobbledygook; ref, reference value.
[a] Statistically significant, $P < .05$.

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 years) 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, even though 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 older than 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 who 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. Although it not clear why this may be the case, some potential explanations include differences in the characteristics of the specific CTs offered to men versus 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 (ie, as the grade level at which the form was written increased), CT refusal among eligible patients decreased. Because 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 comorbidities/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]

TABLE 5. Multivariate Logistic Regression Model 3: "Patient Eligible but Declined a Clinical Trial" by Demographic, Region, and Consent Form Correlates (N = 4184)

	Odds Ratio	95% CI	*P*
Age ≥ 65 (ref, < 65)	0.86	0.73-1.01	.07
Males (ref, females)[a]	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[a]			.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	

Abbreviations: CI, confidence interval; SMOG, Simple Measure of Gobbledygook; ref, reference value.
[a] Statistically significant, $P < .05$.

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 comorbid 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. In addition, 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. Even though each trial had specific screening criteria to help guide providers in identifying eligible patients, it is possible that some eligible 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.

Although 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 comorbidities/frailty. It should be noted that we did not have objective measures to confirm if such concerns were valid (eg, 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 (eg, 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 comorbidities 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. Also, it is possible that more phase 4 trials are needed to evaluate how FDA-approved cancer therapies are tolerated over time in patients with cancer and comorbidities. A better understanding of these issues may inform future CT recruitment, retention, and communication strategies.

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The authors made no disclosures.

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