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Barriers to therapeutic clinical trials enrollment: Differences between African-American and White cancer patients identified at the time of eligibility assessment

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Abstract

Background—Clinical trials (CTs) are the mechanism by which research is translated into standards of care. Low recruitment among underserved and minority populations may result in inequity in access to the latest technology and treatments, compromise the generalizability, and lead to failure in identification of important positive or negative treatment effects among under-represented populations.

Methods—Data were collected over a 39-month period on patient eligibility for available therapeutic cancer CTs. Reasons for ineligibility and refusal were collected. The data were captured using an automated software tool for tracking eligibility pre-enrollment. We examined characteristics associated with being evaluated for a trial, and reasons for ineligibility and refusal, overall and by patient race.

Results—African-Americans (AAs) were more likely than Whites to be ineligible (odds ratio, (OR) = 1.26, 95% confidence interval (CI) = 1.0–1.58) and if eligible, to refuse participation (OR = 1.79, 95% CI = 1.27–2.52), even after adjusting for insurance, age, gender, study phase, and cancer type. White patients were more likely to be ineligible due to study-specific or cancer characteristics. AAs were more likely to be ineligible due to mental status or perceived noncompliance. Whites were more likely to refuse due to extra burden, due to concerns with randomization and toxicity, or because they express a positive treatment preference. AAs were more likely to refuse because they were not interested in CTs, because of family pressures, or they felt overwhelmed (NS)).

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Conflict of interest

None declared.

Discussion—This study is the first to directly compare ineligibility and refusal rates and reasons captured prospectively in AA and White cancer patients. The data are consistent with earlier studies that indicated that AA patients more often are deemed ineligible and, when eligible, more often refuse participation. However, differences in reasons for ineligibility and refusal by race have implications for a cancer center to participate in CTs appropriate for the population of patients served. On a broader scale, consideration should be given to modifying eligibility criteria and other design aspects to permit broader participation of minority and other underserved groups.

Introduction

Clinical trials (CTs) are used to evaluate new therapies and are the mechanism through which research is translated into standards of care. The effectiveness of this translational process is greatly dependent on the number and representativeness of participants enrolled in trials, yet less than 5% of all adult cancer patients enter CTs. Despite a nearly 20-year effort by the National Institutes of Health (NIH) to enhance CT accrual, these rates are not improving, and even lower participation rates are reported in minority and underserved populations [1–7]. Low representation of these populations in CTs results in inequity in access to the latest technologies and cancer treatments, compromises the generalizability and external validity of the CT results [4–8], and may fail to identify important positive or negative treatment effects among under-represented populations [7–10].

Barriers to CT accrual that are related to patient and physician characteristics and the health care system have been identified [11–17]. Eligible patients may refuse to participate for many reasons, including concerns regarding experimentation and loss of control over treatment decisions [11–13,18] and failure to understand important trial procedures, such as randomization [19,20]. Physician barriers may represent a significant component of nonaccrual, due to difficulty initiating CT discussions and reconciling the dual roles of treating physician and clinical researcher [15,21–26].

Patient race has been shown to be associated with trial eligibility and refusal [27,28]. Despite the number of studies exploring barriers resulting in underrepresentation of minorities in CTs [28–34], there has been limited research that explores racial differences in reasons for ineligibility and for refusal to enroll in cancer CTs at the time of recruitment [28,33,34]. Those that did collect prospective information often lacked adequate representation of minorities in the study samples to permit comparisons of different racial groups [3,35]. Of the 36 studies identified in a systematic review of barriers to minority participation in trials, none reported the barriers according to racial groups [28].

To examine reasons for ineligibility and refusal among cancer patients in real time, we prospectively collected data on patients evaluated for CTs at an urban cancer center that treats significant numbers of both African-American (AA) and White patients. The aims of this study were to examine characteristics associated with being designated as ineligible for a trial and characteristics associated with refusing trial participation. The focus of this analysis is on comparison of reasons for ineligibility and refusal among AA and White cancer patients.

Methods

Study patient identification

Patient data for this study were captured and reported through the Clinical Trials Eligibility Database (CTED). CTED is an automated software system developed at Virginia Commonwealth University's Massey Cancer Center that facilitates the clinical research evaluation process by linking longitudinal patient data from multiple electronic sources that include clinical reports (e.g., pathology and radiology reports, inpatient and outpatient clinical notes), clinical laboratory results, as well as billing records and scheduled visits. Clinical research staff (clinical research associates and research nurses) evaluate a patient's eligibility for a specific CT through review of the linked data in CTED and/or by review of additional records in the Electronic Health Record (EHR) or from reports obtained from outside providers. For each evaluation, clinical research staff manually record a variety of parameters relevant to the patient's status with respect to a specific CT or set of trials. These details include eligibility, specific reasons for ineligibility and refusal status and reasons for refusal, and referral source for the specific combination of patient and study. A detailed description of CTED functionality has been published [36].

During the development period for CTED, potential reasons for trial ineligibility and refusal were obtained by interviewing clinical research staff, by performing a comprehensive literature review, and then revising the initial ineligibility and refusal list to include additional reasons identified during the first 6 months of usage that had not been captured through the initial processes. Reasons were subjected further to qualitative thematic analysis techniques [37,38], and the resulting discrete categories were programmed as pull-down menus to be used by research staff to select pertinent reasons for ineligibility of and refusal by the individual patients evaluated. Reasons not included in the pull-down list could be specified by research staff. Thus, the CTED application provides a repository for clinical research staff to easily enter information for every patient evaluated for a CT. This system feeds data to the Clinical Trials Data Management System (OnCore®) that is used to track the patient once enrolled.

Study sample

The initial sample for this study was derived from all the patients with a scheduled visit to a National Cancer Institute (NCI)-designated cancer center in Richmond, Virginia, from June 2006 to March 2010 and who had an eligibility evaluation record completed in the CTED system. The analytic sample included patients with scheduled visits who also had a billing diagnosis for a specific cancer. The billing diagnosis for cancer in populations with a high prevalence of cancer patients has been demonstrated to have a high sensitivity, specificity, and positive predictive value [39,40].

Exclusion criteria for the analytic sample included age less than 21 years, incarceration, and race other than AA or White. Also excluded were patients who were evaluated only for nontherapeutic, companion, or ancillary studies.

Measures

Several data domains were captured and used in these analyses. Each is described below:

1. *Demographic characteristics*: Demographic information included gender, race (race determined either from the insurance record or entered by a registration clerk), age, and insurance status (commercial/health maintenance organization (HMO), Medicaid, Medicare, uninsured) available from patient scheduling or billing records and were used to represent characteristics that have been reported to be associated with CT enrollment.
2. *Cancer diagnosis*: Patients were classified as having a primary diagnosis of either a solid tumor cancer (e.g., breast, colorectal, lung) or a hematological malignancy (e.g., lymphoma, leukemia).
3. *Trial characteristics*: The trial phase (I, II, III, or IV) was obtained from the linked Clinical Trials Data Management system (OnCore) used to track patients post CTs enrollment.
4. Outcomes variables:
 - a. Eligibility status: Trial eligibility status (eligible or ineligible) was recorded in CTED by the clinical research staff who completed the assessment according to the eligibility criteria for an individual trial protocol. Those records with an eligibility ascertainment noted as pending (including records where the full evaluation had not been completed or eligibility status had not been determined at the time of data capture for this analysis) were coded separately as ‘final eligibility status not determined’.
 - b. Refusal status: Patients who were trial eligible were followed to ascertain whether they chose to participate in the offered CT and were classified as refusing or not refusing a trial.
5. *CT ineligibility reasons*. Reasons for patient ineligibility were coded for each patient. (A list of these reasons is provided in Table 1.) Reasons for ineligibility that were determined by the research nurse based on an interview with the patient or discussion with the attending physician, which included noncompliance and inappropriate mental status. Noncompliance included (1) consistent ‘no-shows’ for clinic appointments, (2) active substance abuse, and (3) ‘perceived instability’. Ineligibility due to inappropriate mental status was recorded whenever a patient was deemed incapable of understanding and providing informed consent.
6. *CT refusal reasons*. Reasons for refusal of participation were coded for each patient (a list of these reasons is provided in Table 2). The refusal category labeled ‘perceived extra burden’ included the following reasons: additional out-of-pocket expenses, lack of insurance coverage, extra clinic visits, and travel.

Statistical approach

Descriptive statistics were computed for gender, age, insurance status, and cancer type for the total sample, by race, by phase of trial, and by eligibility status. Frequencies for the

reasons for trial ineligibility and for refusing the index CT (index CT = CT for which the patient was judged eligible) were also computed for the total sample and by race. Either a t-test or chi-square test was used to compare distributions among AAs and Whites. Probabilities of 0.05 or less were defined as statistically significant, without accounting for multiple comparisons of AAs and Whites.

A logistic regression model with eligibility status as the dependent variable was used to identify characteristics associated with ineligibility for a therapeutic cancer CT. A second logistic regression model with refusal status as the dependent variable was used for the subset of patients eligible for a CT to identify factors associated with refusal to participate in a therapeutic CT.

Covariates were entered simultaneously into each logistic regression model; these included race, age (grouped into quartiles), gender, insurance status (using commercial insurance as the reference category), type of cancer (using hematologic cancers as the reference group for diagnosis), and phase of trial (using either phase I or III, alternately, as the reference for other phases). The data from the patients for whom evaluation records had no study phase indicated (N = 207) were excluded from the regression analyses (Typically, no study phase was specified whenever a patient had been considered for a group of CTs but was determined to be ineligible for any of them before eligibility for a specific trial was considered.) Statistical significance of regression parameters was based on the probability that the odds ratio (OR) was not unity ($p < 0.05$) and the 95% confidence interval (CI) on the OR did not include unity.

Results

Patient sample

Table 3 presents by race and for the total sample the characteristics for 1955 patients who had at least one evaluation for a therapeutic CT during the study interval. The majority of these patients were White (64%) and female (68%); the mean age was 56 years. Approximately half (49.8%) had private insurance, while 28.6% had Medicare and 11.2% had Medicaid; the remaining patients were uninsured. More than half of the patients in the sample (56.5%) were assessed for a phase III trial. Rates of ineligibility by trial phase were as follows: phase I = 55.2%, phase II = 49.0%, phase III = 43.8%, and phase IV = 35.7%. A total of 38% were eligible for a therapeutic study; of these 742 patients, 46.6% refused to participate in a CT for which they were eligible.

Compared to AA patients, White patients were slightly older (57.6 vs. 55.9 years, $p < 0.004$) and more often had private, commercial insurance (59.9% vs. 32.3%, $p < 0.0001$). AA patients more often had been deemed ineligible compared to White patients (47.8% vs. 40.8%, $p < 0.004$). A higher proportion of eligible AA patients refused trial enrollment than did eligible White patients (54.6% vs. 42.8%, $p < 0.003$).

Reasons for ineligibility and refusal

We identified 18 reasons for ineligibility for a therapeutic CT among the analytic sample (Table 1). The most common reason was comorbidity (18.8% of the total number of

ineligible patients); the second most common reason was that the patient had received prior treatment that excluded them from the index trial (17.3%). Other important reasons for ineligibility included extent of the disease and histo-pathologic findings that did not satisfy requirements for the study.

Among the differences in reasons for ineligibility among AAs and Whites, AA patients more often than White patients had been designated as ineligible due to ‘mental status’, that is, perceived or documented inability to provide informed consent, and expected noncompliance based on a history of missed appointments, drug abuse, and so on. White patients were more frequently ineligible than AA cancer patients due to a history of prior treatment. The proportions of AA and White patients were similar with respect to comorbidity and cancer-related characteristics (Table 1). Few patients in this sample were excluded due to age.

Among the 11 categories of reasons for refusal to participate in the index trial, the most common category overall was the extra financial or logistical burden associated with CT participation (patient costs of participation, extra visits, travel time, etc.), accounting for 17.6% of the 346 refusals (Table 2). Other reasons for refusal were lack of interest in the trial, not wanting a specific treatment (primarily chemotherapy) provided as part of the trial, and preference for a specific treatment. No reason for refusal was recorded for 12.1% of the evaluations for which the patient refused participation.

As with reasons for ineligibility, some reasons given for refusing trial participation differed by patient race (Table 2). Whites refused about twice as often as AAs due to additional financial or logistical burden associated with CT participation (22.2% vs. 10.0%), because they had a preference for a specific treatment (13.0% vs. 7.7%), and due to discomfort with randomization (9.3% vs. 4.6%). Eligible AA patients about twice as often as Whites refused due to a lack of interest in the index CT (25.4% vs. 12.0%). AA patients also declined to provide a reason for refusal more often than White patients (16.1% vs. 9.7%). Eligible AA patients cited family pressures or cultural factors as reasons for refusal more frequently than White patients.

Logistic regression model for eligibility status

The first logistic regression model used ineligibility for a therapeutic cancer CT as the dependent (outcome) variable and sociodemographics, disease, and trial characteristics as the independent variables. Adjusted ORs for ineligibility among AAs compared to Whites and their 95% CIs are shown in Table 4. AAs were more likely to be ineligible for a trial but the lower bound of the CI was 1 (OR = 1.26, 95% CI = 1.0–1.58). Women were more likely to be ineligible than men (OR = 1.77, 95% CI = 1.41–2.25). Medicaid, Medicare, and uninsured patients were each more likely to be ineligible than commercially insured patients with ORs of 1.64 (95% CI = 1.14–2.35) for Medicaid, 2.35 (95% CI = 1.64–3.36) for Medicare, and 2.02 (95% CI = 1.38–2.94) for the uninsured patients. Patients were more likely to be ineligible when evaluated for a phase II or III trials (OR = 1.66, 95% CI = 1.14–2.43) compared with patients evaluated for a phase I study. Conversely, in a second model, in which phase I was replaced by phase III as the reference category, patients were less likely to be ineligible for phase III trials (OR = 0.76, 95% CI = 0.60–0.95), and there were

no substantive changes to the other model parameters (data not presented). Neither age nor cancer type was associated with ineligibility after accounting for other covariates. In a third regression model, we removed age and cancer type from the independent variables; race, gender, and type of insurance remained associated with ineligibility (data not shown).

Logistic regression model for trial refusal

In a separate analysis of factors associated with trial refusal among patients eligible for a therapeutic CT, the logistic regression model used refusal status as the dependent variable and sociodemographics, disease, and trial characteristics as independent variables (Table 4). AA patients were 1.8 times as likely as White patients to refuse participation in a therapeutic CT (OR = 1.79, 95% CI = 1.27–2.52). Cancer type was the only other covariate in this model that was significantly associated with refusal; patients with solid tumors were nearly twice as likely to refuse trial participation as patients with hematologic malignancies (OR = 1.92, 95% CI = 1.16–3.18). When the phase III replaced phase I as the reference phase in this regression model for comparison to all other phases, patients were nearly twice as likely to refuse phase III trials (OR = 1.91, 95% CI = 1.33–2.75) compared to trials of all other phases. In this model, cancer type was no longer significantly associated with refusal, but there were no other substantive changes to parameter estimates (data not shown). We repeated the analysis using a model without age and cancer type; the association of refusal with race remained.

Discussion

This study is the first to compare directly ineligibility and refusal reasons captured prospectively in AA and White cancer patients. The data are consistent with earlier studies that indicated that AA patients more often are deemed ineligible [15,33,41] and when eligible, more often refuse participation [27,28]. This prospective analysis adds to our current understanding of why there are racial differences in CT enrollment and provides data to suggest interventions to address barriers pertaining to the patient, the physician, and the health-care system [42].

Earlier studies that captured data prospectively either did not focus on cancer [14] or had insufficient numbers of AA patients to provide meaningful results for racial comparisons [3,35]. Studies that retrospectively capture reasons for refusal may suffer from recall bias [43]. Capture of reasons at the time of a patient's evaluation and decision regarding participation in a CT reduces such biases [9,16,44–46].

In comparing differences in reasons for ineligibility among AA and White cancer patients, some reasons for ineligibility were based on subjective judgment on the part of the nurse or physician. These reasons were recorded more often for AA than White patients. While a relatively small proportion of all reasons, impaired mental status and expected noncompliance have been identified in other studies as reasons for ineligibility [15,33,41,47]. These reasons assigned by the health-care provider may reflect social or economic barriers for the patient, such as time or cost of travel, alternate child-care arrangements, or other factors that impact the ability or willingness to attend scheduled visits [47]. At our urban cancer center, AA patients are more often uninsured and have less

social support than our White patients. These logistical issues may be viewed by research staff as impediments to successful trial participation [47]. Nevertheless, identification of these reasons for ineligibility offers an opportunity to expand access by designing trials that reimburse expenses related to participation, that require fewer clinic visits, or that provide for assessments at locations more convenient to participants.

Reasons for refusal to participate in a trial for which a patient had been judged to be eligible differed between AA and White patients. AA cancer patients more often expressed family or cultural barriers as reasons for nonparticipation. These barriers emphasize the need to elicit family participation in the decision-making process. A higher proportion of eligible AAs than Whites refused participation because they were overwhelmed with the decision-making process, suggesting the need for additional support infrastructure designed to serve minority and under-served populations (or any patients in need). Identifying and addressing these cultural differences have been shown to have a positive impact on enrollment of AA patients in at least one study [48].

Methods to address exclusionary criteria, such as limited insurance coverage of CT-related costs, may reduce disparities in enrollment and simultaneously increase generalizability of CT results as studies have shown that providing financial coverage of the CT-related costs eliminated insurance as a predictor of trial participation [49,50]. Nevertheless, disparate enrollment and limited generalizability among AA and patients with lower socioeconomic status likely will continue until other barriers, such as the additional direct costs that are unlikely to be covered by insurance (out-of-pocket expenses, extra visit co-payments), indirect costs (travel, child care), and lack of social support for CT participation, are eliminated [25,48,50].

The proportion of AA patients who cited fear of randomization or extra burden as reasons for refusal of trial participation was only half that for Whites similar to findings by Gadegbeku *et al.* [12]. He identified health-related factors and other burden-related factors rather than psychosocial factors as influencing CT participation by AAs [12]. In an analysis of refusers who cited 'extra burden' as the reason for refusal, we found that AA patients more often reported the higher costs and additional visits associated with CT participation as the primary reason for refusal, while White patients in this refusal category more often stated that they preferred another more convenient location for treatment.

Treatment preferences also were reported as a reason for refusal more often among White patients than AA patients. However, overall, nearly 23% of all the patients cited either a positive or negative preference for the treatment under consideration as a reason for refusal to participate in a CT. Patient refusal due to treatment preference may hinder recruitment to phase III trials in particular where standard-of-care alternatives are available outside the trial.

Limitations

While the data reported herein were collected prospectively from patients, they were captured by clinical research staff who entered the data into the system. Thus, reasons for

refusal and ineligibility were filtered through the nurses' perspectives and understanding of the patients. However, the findings are consistent with other prospective studies [3,14,15,23,25,35,47]. The data were drawn from the patient population of a single urban cancer center, which may limit the generalizability of results. Conversely, an important benefit of our concurrent data capture within a single system is that the information directly reflects the cancer patient population seen at that institution so that the findings are locally applicable.

We were not able to assess whether differences in comorbidity that may confound the differences in eligibility were associated with insurance status (i.e., Medicare population) because comorbidity was a reason for ineligibility and therefore could not be assessed as an independent variable.

Finally, our study sample does not contain races other than AAs and Whites, limiting our ability to make statements about other under-represented groups. Because race may not be self-reported, there may be misclassification of patients according to racial group. Furthermore, given the modest sample sizes for AA patients, care should be taken to assess in future research the possible role of variables not found to be significant in the present sample.

Conclusion

In conclusion, there are marked differences in barriers to eligibility and participation in CTs among AA and White patients. Systematic use of the type of information reported here may allow cancer centers to address barriers specific to their patient population, select CTs that most appropriately target their population, and avoid commitments to participate in trials for which accrual may be difficult or impossible [47]. Such data could impact trial development on a broader scale to direct changes in eligibility criteria that restrict the participation of minority patients and help improve the CTs infrastructure [4,5,51]. Ongoing use and additional testing of the CTED system or similar systems in other cancer centers have the potential to provide data that could directly impact CT recruitment.

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Table 1

Number and percent of patients ineligible for clinical trials, overall and by race

	African-American, n = 341	White, n = 507	Total, N = 848
	n (%)	n (%)	N (%)
Comorbidity	68 (19.8)	91 (18.0)	159 (18.8)
<i>Prior treatment*</i>	48 (14.0)	99 (19.6)	147 (17.3)
Extent of disease	53 (15.4)	76 (15.0)	129 (15.2)
Histopathology nonmatch	33 (9.6)	45 (8.9)	78 (9.2)
Second/multiple primary	16 (4.7)	27 (5.3)	43 (5.1)
No available protocol	10 (2.9)	25 (4.9)	35 (4.1)
Performance status	15 (4.4)	15 (3.0)	30 (3.5)
Interval since diagnosis or treatment ^a	8 (2.3)	20 (4.0)	28 (3.3)
Stage of disease	10 (2.9)	18 (3.6)	28 (3.3)
Does not meet trial-specific eligibility requirements	9 (2.6)	19 (3.8)	28 (3.3)
Physician decision ^b	12 (3.5)	15 (3.0)	27 (3.2)
<i>Anticipated noncompliance*</i>	21 (6.1)	5 (0.99)	26 (3.1)
Cancer characteristics	7 (2.0)	16 (3.2)	23 (2.7)
<i>Mental status/cognitive impairment^c**</i>	13 (3.8)	3 (0.59)	16 (1.9)
Age exclusion	2 (0.58)	5 (0.99)	7 (0.8)
Enrolled in competing study	1 (0.29)	4 (0.79)	5 (0.6)
Language barrier	0 (0.00)	1 (0.20)	1 (0.1)
Missing reason for ineligibility	17 (5.0)	21 (4.2)	38 (4.5)

^aIncludes evaluations for patients who had insufficient time or too much time elapsed to meet a particular eligibility criterion.^bPhysician determined that a patient was not a good candidate for a trial or physician preferred standard therapy for the patient.^cJudged by research staff or attending physician as patient having an inability to comprehend informed consent.

*Chi-squared test, 0.001 < p > 0.0001.

**Chi-squared test, p < 0.0001.

Table 2

Number and percent of patients who refused clinical trial participation by reasons for refusal, overall and by race

	African-American, n = 130	White, n = 216	Total, N = 346
	n (%)	n (%)	N (%)
<i>Extra financial or logistical burden</i> *	13 (10.0)	48 (22.2)	61 (17.6)
<i>Lack of interest in trial</i> *	33 (25.4)	26 (12.0)	59 (17.0)
Avoidance of specific treatment	15 (11.5)	24 (11.1)	39 (11.3)
<i>Preference for specific treatment</i> **	10 (7.7)	28 (13.0)	38 (11.0)
Fear of toxicity/side effects	9 (6.9)	21 (9.7)	30 (8.7)
<i>Discomfort with randomization</i> ***	6 (4.6)	20 (9.3)	26 (7.5)
Physician barrier	6 (4.6)	16 (7.4)	22 (6.4)
Overwhelmed physically or emotionally	8 (6.1)	6 (2.8)	14 (4.0)
<i>Pressure from family/cultural factors</i> ***	9 (6.9)	5 (2.3)	14 (4.0)
Seen only for a second opinion	0 (0.0)	1 (0.46)	1 (0.29)
<i>No reason provided</i> **	21 (16.1)	21 (9.7)	42 (12.1)

*Chi-squared test, $p < 0.0001$.

**Chi-squared test, $0.001 > p < 0.0001$.

***Chi-squared test $0.05 > p < 0.001$.

Table 3

Characteristics of patients evaluated for clinical trials by racial classification

		<u>African-American, n = 713</u>	<u>White, n = 1242</u>	<u>Total, N = 1955</u>
		<u>n (%)</u>	<u>n (%)</u>	<u>N (%)</u>
Gender	Women	485 (68.0)	844 (68.0)	1329 (68.0)
	Men	228 (32.0)	398 (32.0)	626 (32.0)
Age quartile	21–48 years	194 (27.2)	280 (22.5)	474 (24.2)
	49–57 years	195 (27.3)	319 (25.7)	514 (26.3)
	58–64 years	166 (23.3)	340 (27.4)	506 (25.9)
	65 years	158 (22.2)	303 (24.4)	461 (23.6)
Insurance	Private commercial	230 (32.3)	744 (59.9)	974 (49.8)
	Medicaid	140 (19.6)	79 (6.4)	219 (11.2)
	Medicare	229 (32.1)	330 (26.6)	559 (28.6)
	Uninsured	114 (16.0)	89 (7.2)	203 (10.38)
Cancer type	Solid tumor	615 (86.2)	983 (79.1)	1598 (81.7)
	Hematological	82 (11.5)	217 (17.5)	299 (15.3)
	Missing	16 (2.3)	42 (3.4)	58 (3.0)
Trial phase	I	58 (8.1)	154 (12.4)	212 (10.8)
	II	156 (21.9)	262 (21.1)	418 (21.4)
	III	426 (59.7)	678 (54.6)	1104 (56.5)
	IV	4 (0.6)	10 (0.8)	14 (0.7)
	None specified ^a	69 (9.7)	138 (11.1)	207 (10.6)
Eligibility status	Eligible	238 (33.4)	504 (40.6)	742 (37.9)
	Ineligible	341 (47.8)	507 (40.8)	848 (43.4)
	Not yet determined	134 (18.8)	231 (18.6)	365 (18.7)
Refusals ^b		130 (54.6)	216 (42.8)	346 (46.6)

^aPatients considered for a generic set of studies (e.g., breast cancer) who were determined to be ineligible for any clinical trial.^bAll refusals are considered to be among eligible patients. Final eligibility determination may not have been completed for all refused patients as the workup stopped. Denominators for percentages are number eligible for that column.

Table 4

Multivariable logistic regression models predicting ineligibility and refusal

Variable	Ineligibility		Refusal	
	OR	95% CI	OR	95% CI
Race				
White	1.00	–	1.00	–
AA	1.26	1.00–1.58*	1.79	1.27–2.52***
Gender				
Men	1.00	–	1.00	–
Women	1.77	1.41–2.25	0.939	0.641–1.375
Age				
21–48	1.00	–	1.00	–
49–57	1.21	0.90–1.63	1.08	0.71–1.65
58–65	1.38	1.02–1.87	1.19	0.78–1.83
65	1.09	0.70–1.70	1.83	0.91–3.66
Insurance				
Commercial	1.00	–	1.00	–
Medicaid	1.64	1.14–2.35***	0.89	0.52–1.55
Medicare	2.35	1.64–3.36	0.61	0.34–1.09
Uninsured	2.02	1.38–2.94	0.81	0.44–1.47
Cancer type				
Hematologic	1.00		1.00	
Solid tumor	1.19	0.85–1.69	1.92	1.16–3.18**
Study phase				
Phase I	1.00		1.00	
Phases II and III	1.66	1.14–2.43**	1.18	0.65–2.13

OR: odds ratio; CI: confidence interval; AA: African-American.

*p < 0.05,

**p < 0.01,

***p < 0.001.