

Geographic Proximity and Racial Disparities in Cancer Clinical Trial Participation

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Key Words

Catchment area, health services area, clinical trials, accruals to cases ratio, accruals to cases ratio relative risk, Poisson regression, disparities

Abstract

This study assessed the effects of race and place of residence on clinical trial participation by patients seen at a designated NCI comprehensive cancer center. Clinical trial accrual to cancer case ratios were evaluated using a database of residents at the continental United States seen at The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins from 2005 to 2007. Place of residence was categorized into 3 nonoverlapping geographic areas: Baltimore City, non-Baltimore City catchment area, and non-catchment area. Controlling for age, sex, county poverty level, and cancer site, significant race and place of residence differences were seen in therapeutic or nontherapeutic clinical trials participation. White non-Baltimore City catchment area residents, the designated reference group, achieved the highest participation rate. Although the test of interaction (control group compared with all others) was not significant, some race-geographic area group differences were detected. In therapeutic trials, most race-place of residence group levels were statistically lower and different from reference; in nontherapeutic trials, race-specific Baltimore City groups participated at levels similar to reference. Baltimore City residents had lower participation rates only in therapeutic trials, irrespective of race. County poverty level was not significant but was retained as a confounder. Place of residence and race were found to be signifi-

cant predictors of participation in therapeutic and nontherapeutic clinical trials, although patterns differed somewhat between therapeutic and nontherapeutic trials. Clinical trial accruals are not uniform across age, sex, race, place of residence, cancer site, or trial type, underscoring that cancer centers must better understand their source patients to enhance clinical trial participation. (*JNCCN* 2010;8:1343-1351)

A fundamental goal of cancer centers is to improve cancer care through the design and conduct of therapeutic clinical trials.¹ Progress in prevention and control of cancer depends on research that identifies treatments that prevent or delay death caused by cancer or improve quality of life for patients living with cancer. Clinical trials, to whatever extent possible, should address disease across broad categories of age, sex, race, and ethnicity,² both to ensure that targeting of interventions can be fine-tuned and generalizability of results.³ Clinical trial participation may be one way to assess diversity and equitable access to cutting-edge cancer care.^{4,5}

Cancer centers are charged with ensuring equitable access to care among patients. Equitable access is inherently multidimensional, with patient/case characteristics, such as cancer type, stage, age, race, ethnicity, sex, socioeconomic class, education level, marital status, and comorbid conditions, affecting participation. Thus, depending on how the question is framed, equitable access can be defined across multiple patient or case subgroups. From the standpoint of NCI reporting, assessment of diversity in clinical trial participation has been accomplished primarily by comparing the proportions of racial and ethnic categories across¹ the population from which a cancer center draws (an institution-defined catchment area),² the cancer cases seen within the center,³ and the participants in therapeutic clinical trials.⁶ Two limitations of this approach are that the determination

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of catchment area from which a cancer center draws may be somewhat arbitrary and designated without regard to patient willingness to travel for care,¹ and that percent participation is influenced by a host of factors outside the control of the institution, including health insurance coverage, referral patterns, cultural preferences, and competing providers.^{2,7-9}

The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins (JH SKCCC) is situated in the city of Baltimore, where two thirds of the population consists of racial minorities (non-white). Cancer treatment services are provided by many other hospitals in Baltimore City.¹⁰ The JH SKCCC catchment area was defined through a data-based cluster assessment, using SaTScan, as a contiguous cluster of 58 counties centered on Baltimore City. The defined catchment area has remained stable.¹¹

Catchment or health service areas are characterized by a balance of market share and proximity.^{12,13} Moreover, there is a distance over which patients are willing to travel for the service provided, irrespective of disease.¹⁴ We would expect this to be true for those participating in cancer clinical trials. The authors' previous research found that size of the catchment area for the JH SKCCC differs between whites and blacks (58 vs. 15 counties, respectively), a finding that might contribute to clinical trial enrollment disparities.¹¹ The authors were also interested in how well JH SKCCC served Baltimore City as the immediate neighborhood, and therefore assessed 3 main geographic areas: Baltimore City, the remainder of the catchment area, and the non-catchment area as defined by county of residence. Using these geographic definitions, the authors hypothesized that overall, therapeutic and nontherapeutic clinical trial participation and clinical trial participation according to race also may vary by location. They assessed the clinical trial accrual to cancer case ratio (ACR) in this study to simultaneously evaluate racial and geographic disparities, including a race-geographic area interaction, at JH SKCCC. Independent effects and differences accounted for by sex, age, cancer site, and county poverty also were examined.

Methods

Patients with newly diagnosed cancer or patients undergoing all or part of their initial treatment at JH SKCCC were identified through the Johns Hop-

kins Hospital (JHH) cancer registry. All accruals to cancer clinical trials, including therapeutic and non-therapeutic studies, were recorded by the JH SKCCC Clinical Research Office. This study was designated as exempt by the institutional review board of the Johns Hopkins School of Medicine.

This study included analytic cancer cases and accruals to clinical trials enrolled from 2005 to 2007. Year of diagnosis for each case was defined based on the composite medical record, with preference going to a pathology report of cancer for date of diagnosis. Cancer center analytic cases are defined by the American College of Surgeons as initially diagnosed or receiving all or part of the first course of treatment within the center.¹⁵ Study subjects were residents of the continental United States at diagnosis. This analysis comprised 17,637 analytic patients and 5068 accruals.

Level of clinical trial participation was measured by the ACR and defined as the number of accruals divided by the number of cancer cases diagnosed in the same period and population subgroup. JH SKCCC cancer cases and clinical trial accruals were aggregated by case characteristics of age, race, sex, place of residence, and cancer site. Because the portfolio of therapeutic and nontherapeutic clinical trials differed substantively, results were presented by clinical trial type separately.

Numbers of clinical trial accruals among Hispanic individuals were small and thus not considered in this Poisson, multivariate analysis, which requires sufficient and non-zero sample size in most cells. During the 5-year period, the JH SKCCC registered 163 Hispanic patients and 79 accruals; nevertheless, these patients are included in the race (white, black, and other races) analysis. Place of residence and race were the independent variables of interest.

Place of residence was categorized as Baltimore City; non-Baltimore City catchment area, consisting of 57 surrounding counties; or non-catchment area (i.e., all other continental United States counties of residence). The JH SKCCC catchment area is a SaTScan-determined geographic cluster of any cancer case seen within the center (1998-2002).^{11,12}

County of residence was maintained as state and county/city name in the JHH cancer registry, which were converted to Census Bureau Federal Information Processing Standards (FIPS) codes. Zip codes of residence were converted to county FIPS codes using

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Market Planner Plus software (Solucient) for patients whose addresses were incomplete. Cancer cases and clinical trial accruals with county address of residence unresolved were coded as “unknown” (cancer cases, N = 741; clinical trial accruals, N = 132).

Race was abstracted by the JHH cancer registry staff from the medical record. Most JH SKCCC patients could be categorized as white or black (97%); all persons of non-white or non-black race were coded as “other races.”

Cancer case and clinical trial accrual characteristics of age (< 20, 20–64, > 64 years), sex (male, female), and cancer site (brain, breast, gastrointestinal, hematologic cancers, prostate, upper aerodigestive, and all other sites) were abstracted from the medical record. In therapeutic accrual data, 3 patients are missing race information, 94 are missing age, and 1 is missing the cancer site. Among nontherapeutic accruals, 8 are missing race, 61 are missing age, and 1 is missing cancer site. Observations with missing information were excluded in multivariate analysis.

Cancer site groupings were based on the JH SKCCC organizational structure and reflect programmatic structures within JH SKCCC. During Poisson regression analyses, cancer sites were further aggregated into 3 classes based on the level (high, medium, and low) of the unadjusted therapeutic trial accrual ratio. The first cancer site grouping consisted of hematologic malignancies; the second, prostate and gastrointestinal; and the third, all others. This strategy also had the advantage of allocating approximately one third of the therapeutic trials to each group.

Poverty level was assigned based on county of residence using FIPS code and defined as percentage of individuals living at or below 100% poverty in 2003.¹⁶ The authors presented poverty level by county quartiles (≥ 16.2 ; 12.6–16.1; 9.8–12.6; $\leq 9.8\%$) and unknown in bivariate analyses. In Poisson analyses, binary categories of poverty of 16.2 or more, and poverty less than 16.2, including poverty unknown, were used to minimize the number of combinations during multivariate analysis.

This study measures the accruals among JH SKCCC patients. Poisson regression modeling of clinical trial accruals adjusted to JH SKCCC cancer cases (i.e., offset) was used to estimate the ACR for therapeutic and nontherapeutic clinical trials. Results of Poisson regression modeling did not differ from zero-inflated models was presented here.

A clinical trial ACR “relative risk” (RR) was calculated. The ACR RR compared the ACR for various subpopulations to the reference group. Subpopulations were based on age, race, sex, cancer site, place of residence, or county poverty. The ACR RR is the ratio of 2 ratios: the subpopulation ACR and the reference group ACR. The authors hypothesized an interaction of residence in Baltimore City and participation in clinical trials by African Americans; that is, this grouping of clinical trial accruals, adjusted for patients from the same grouping, differs from any other race–geography grouping. This was tested explicitly and was not significant, so the final multivariable models considered all independent variables and covariates without interaction terms. Statistical significance of subpopulation differences was based on analysis of variance (ANOVA).

Because poverty and minority race are closely associated,¹⁷ the authors calculated the variance inflation factor (VIF) statistic, which measures the magnitude of multicollinearity, for the final regression model. The VIF was less than 2.8 for all predictors, well within the judgement of little evidence for multicollinearity.¹⁸ Statistical software R was used for all analyses.

Results

From 2005 to 2007, 17,637 cancer cases diagnosed among people living in the continental United States were treated at the JH SKCCC. Persons of white race (82%), male sex (61%), age 20 to 64 years (65%), the non-Baltimore City catchment area (63%), and least-poor counties (85%) predominated. Regarding cancer site, prostate cancer comprised the largest single subset, at almost one quarter of all cancers diagnosed. These predominant characteristics were the same for non-Baltimore City catchment area and non-catchment area geographic groups. Among Baltimore City residents, however, African Americans were the majority race (55%), the number of men and women were nearly equal (49.8% and 50.2%, respectively), and upper aerodigestive cancers (21%) represented the most commonly diagnosed cancer site (Table 1).

Across therapeutic and nontherapeutic clinical trials, the proportions of accruals was greatest for persons of white race, male sex, and age 20 to 64 years; those from the non-Baltimore City catchment

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Table 1 Patient Demographics, Cancer Site of Diagnosis, and County Poverty by Place of Residence

	Place of Residence			All JH SKCCC Patients N = 17,637 (%)
	Catchment Area			
	Baltimore City N = 1952 (%)	Non-Baltimore City* N = 11,145 (%)	Non-Catchment Area† N = 4540 (%)	
<i>Race</i>				
White	839 (43.0)	9468 (85.0)	4159 (91.6)	14466 (82.0)
Black	1082 (55.4)	1229 (11.0)	245 (5.4)	2556 (14.5)
Other	31 (1.6)	448 (4.0)	136 (3.0)	615 (3.5)
<i>Sex</i>				
Male	973 (49.8)	6519 (58.5)	3311 (72.9)	10803 (61.3)
Female	979 (50.2)	4626 (41.5)	1229 (27.1)	6834 (38.7)
<i>Age (y)</i>				
< 20	60 (3.1)	313 (2.8)	100 (2.2)	473 (2.7)
20–64	1148 (58.8)	7179 (64.4)	3122 (68.8)	11449 (64.9)
65+	744 (38.1)	3653 (32.8)	1318 (29.0)	5715 (32.4)
<i>Cancer site</i>				
Brain	42 (2.2)	432 (3.9)	167 (3.7)	641 (3.6)
Breast	301 (15.4)	1153 (10.3)	281 (6.2)	1735 (9.8)
Gastrointestinal	302 (15.5)	1767 (15.9)	819 (18.0)	2888 (16.4)
Hematopoietic	174 (8.9)	1149 (10.3)	229 (5.0)	1552 (8.8)
Prostate	241 (12.3)	2180 (19.6)	1967 (43.3)	4388 (24.9)
Upper aerodigestive	410 (21.0)	1397 (12.5)	337 (7.4)	2134 (12.1)
Other	482 (24.7)	3067 (27.5)	750 (16.5)	4299 (24.4)
<i>County poverty (quartile)</i>				
Unknown	–	0 (0.0)	741 (16.3)	741 (4.2)
1 (least)	–	9760 (87.6)	1372 (30.2)	11132 (63.1)
2	–	996 (8.9)	1072 (23.6)	2068 (11.7)
3	–	52 (0.5)	917 (20.2)	969 (5.5)
4 (most)	1952 (100.0)	337 (3.0)	438 (9.6)	2727 (15.5)

Abbreviation: JH SKCCC, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins.

*57 Counties clustering around Baltimore City.

†All other counties in the continental United States.

area; and living in counties with the lowest poverty levels (Table 2). A total of 5068 clinical trial accruals were included in this study, 64.5% of which were therapeutic. Hematologic cancers (36%) predominated in therapeutic clinical trial accruals, whereas gastrointestinal cancer cases (19.0%) represented the largest portion of nontherapeutic trial accruals.

Unadjusted ACRs by category are presented in Table 2. These were highest for both therapeutic and nontherapeutic studies in persons of white race, female sex, aged 20 years and younger, residing in the non-Baltimore City catchment area, and of the

wealthiest quintile counties. Patients with hematologic cancers had the highest unadjusted therapeutic ACR, and those with brain cancers had the highest unadjusted nontherapeutic ACR. Unadjusted therapeutic trial ACRs were greater than nontherapeutic trial ACRs in all patient subgroups, except those with brain cancer, prostate cancer, and upper aerodigestive malignancies (Table 2).

Multivariate Poisson regression was performed to obtain therapeutic and nontherapeutic ACR RRs according to patient/case category (Table 3). Reference groups included those aged 20 to 64 years, of

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Table 2 Therapeutic and Nontherapeutic Clinical Trial Accruals and Unadjusted Clinical Trial Accrual to Cancer Case Ratio

	Clinical Trial Accruals		Clinical Trial Accruals to Patient Ratio (Unadjusted)	
	Therapeutic N = 3269 (%)	Nontherapeutic N = 1799 (%)	Therapeutic	Nontherapeutic
<i>Race</i>				
White	2791 (85.4)	1494 (83.1)	19.3	10.3
Black	357 (10.9)	248 (13.8)	14.0	9.7
Other	118 (3.6)	49 (2.7)	19.2	8.0
Missing	3 (0.1)	8 (0.4)	–	–
<i>Sex</i>				
Male	1881 (57.5)	815 (45.7)	17.4	9.1
Female	1388 (42.5)	984 (54.3)	20.3	11.9
<i>Age (y)</i>				
< 20	323 (9.9)	175 (9.7)	68.3	37.0
20–64	2018 (61.7)	1203 (66.9)	17.6	10.5
65+	834 (25.5)	360 (20.1)	14.6	6.3
Missing	94 (2.9)	61 (3.4)	–	–
<i>Place of residence</i>				
Baltimore City	251 (7.8)	193 (10.7)	12.8	9.9
Non-Baltimore City catchment area [‡]	2352 (73.1)	1258 (69.9)	21.1	11.3
Non-catchment area [†]	666 (19.1)	348 (19.3)	15.7	7.7
<i>Cancer site</i>				
Brain	117 (3.6)	184 (10.2)	18.3	28.7
Breast	318 (9.7)	306 (17.0)	18.3	17.6
Gastrointestinal	817 (25.0)	341 (19.0)	28.3	11.8
Hematopoietic	1179 (36.1)	263 (14.6)	76.0	17.0
Prostate	357(10.9)	292 (16.2)	5.9	6.7
Upper aerodigestive	227 (6.9)	273 (15.2)	8.1	12.8
Viral/other	353 (7.7)	140 (7.8)	10.6	3.3
<i>County poverty (quartile)</i>				
Unknown	80 (2.5)	52 (2.9)	10.7	7.0
1 (least)	2269 (69.4)	1239 (68.9)	20.4	11.1
2	357 (10.9)	163 (9.1)	17.3	7.9
3	152 (4.7)	84 (4.7)	15.7	8.7
4 (most)	411 (12.6)	261 (14.5)	15.1	9.6

[‡]57 Counties clustering around Baltimore City.

[†]All other counties in the continental United States.

male sex, of white race, living in a county with less poverty, residing in non-Baltimore City catchment area at diagnosis, and with cancer diagnosed at a site other than hematologic, gastrointestinal, or prostate (Table 3). Adjusted (for age, sex, race, place of residence, and county poverty level) therapeutic ACRs were statistically higher than expected for those aged

65 and older, female, or diagnosed with a hematologic, gastrointestinal, or prostate malignancy. Lower-than-expected adjusted therapeutic ACRs were found among African Americans (0.73; 95% CI, 0.65–0.82; $P < .001$) or living nearer or further away (Baltimore City, 0.64; 95% CI, 0.52–0.79; $P < .001$, and non-catchment area, 0.76; 95% CI, 0.70–0.84;

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Table 3 Poisson Multivariate Models of Therapeutic and Nontherapeutic Clinical Trial Accrual to Cancer Case Ratio

	Therapeutic			Nontherapeutic		
	β Coefficient (SD)	ACR*	P Value	β Coefficient (SD)	ACR*	P Value
<i>Age (y)</i>						
< 20	-0.04 (0.09)	0.96	.64	0.31 (0.12)	1.37	.009
20–64	Reference	1.00	–	Reference	1.00	–
> 64	0.12 (0.04)	1.12	.002	-0.14 (0.05)	0.87	.007
<i>Sex</i>						
Male	Reference	1.00	–	Reference	1.00	–
Female	0.29 (0.04)	1.33	< .001	0.26 (0.05)	1.29	< .001
<i>Race</i>						
White	Reference	1.00	–	Reference	1.00	–
Black	-0.31 (0.06)	0.73	< .001	-0.15 (0.08)	0.86	.05
Other	-0.01 (0.10)	0.99	.90	-0.36 (0.15)	0.70	.02
<i>County poverty (%)</i>						
< 16.2	Reference	1.00	–	Reference	1.00	–
16.2	0.13 (0.08)	1.14	.10	-0.13 (0.13)	0.88	.31
<i>Place of residence</i>						
Non-Baltimore City catchment area [†]	Reference	1.00	–	Reference	1.00	–
Baltimore City	-0.44 (0.10)	0.64	< .001	0.02 (0.15)	1.02	.89
Non-catchment area [‡]	-0.27 (0.05)	0.76	< .001	-0.33 (0.06)	0.72	< .001
<i>Cancer site</i>						
Other	Reference	1.00	–	Reference	1.00	–
GI/Prostate	0.58 (0.05)	1.79	< .001	0.03 (0.06)	1.03	.61
Hematologic	2.03 (0.04)	7.60	< .001	0.52 (0.07)	1.68	< .001

Abbreviation: ACR, accrual to cancer case ratio.

*Clinical trial accrual to cancer case ratio is adjusted for all other variables in the model.

[†]57 Counties clustering around Baltimore City.[‡]All other counties in the continental United States.

$P < .001$). County poverty level was not significant but was retained as a confounder. An interaction term for race and geography was formally tested and was not significant ($P > .05$).

Adjusted nontherapeutic ACRs were significantly higher than expected for those younger than 20 years (1.37; 95% CI, 1.08–1.72), female (1.29; 95% CI, 1.18–1.43; $P < .001$), and with a hematologic malignancy (1.68; 95% CI, 1.29–1.93; $P < .001$). Adjusted nontherapeutic ACRs were significantly lower than 1 for those older than 64 years (0.87; 95% CI, 0.79–0.96; $P = .007$), of any minority race (African American, 0.86; 95% CI, 0.74–1.00; $P = .05$; other

racess, 0.70; 95% CI, 0.52–0.94; $P = .02$), and residents living outside the JH SKCCC catchment area (0.72; 95% CI, 0.64–0.82; $P < .001$). Again, county poverty was not significant but was retained as a confounder and important covariate.

Table 4 shows the ACR RR according to place of residence and race in each clinical trial type relative to the single reference group of white residents of the non-Baltimore City catchment area, adjusted for age, sex, county poverty level, and cancer site. Therapeutic clinical trials participation was statistically significantly lower for all but one race-geographic location group. Only those of other races

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Table 4 Poisson Model Estimates of Therapeutic and Nontherapeutic Clinical Trials ACR Relative Risk* by Race and Place of Residence

	Therapeutic [†]			Nontherapeutic [†]		
	Baltimore City	Non-Baltimore City Catchment [‡] Area	Non-Catchment Area [§]	Baltimore City	Non-Baltimore City Catchment [‡] Area	Non-Catchment Area [§]
White	0.64 (0.52, 0.79)	Reference	0.76 (0.70, 0.84)	1.02 (0.76, 1.38)	Reference	0.72 (0.63, 0.81)
Black	0.47 (0.38, 0.58)	0.73 (0.65, 0.82)	0.56 (0.48, 0.65)	0.88 (0.65, 1.20)	0.86 (0.74, 1.00)	0.62 (0.51, 0.76)
Other races	0.64 (0.48, 0.84)	0.99 (0.82, 1.19)	0.75 (0.61, 0.93)	0.71 (0.47, 1.08)	0.70 (0.52, 0.93)	0.50 (0.36, 0.69)

* Accrual to cancer case ratio (ACR) relative risk is the ratio of the clinical trial ACR for the subgroup of interest compared with the reference group ACR.

[†]Model includes age, sex, county poverty quartile, and cancer site.

[‡]57 Counties clustering around Baltimore City.

[§]All other counties in the continental United States.

residing in the non-Baltimore City catchment area were not different from that of white persons in the same geographic area. Within Baltimore City, race groups did not diverge on adjusted ACRs; all were lower than the most highly accrued group (white persons in the non-Baltimore City catchment area) and their ACRs did not differ. Although all race groups in the non-catchment area were lower than the reference group, the black ACR was statistically lower than the white ACR.

In the case of nontherapeutic trial accruals, persons of other races from the non-Baltimore City catchment area were accrued less often than the reference group, as were cases living in the non-catchment area of any race. Persons of any race living in Baltimore had an accrual experience similar to that of the reference group. Within the geographic area, Baltimore City, or non-catchment area, race groups did not diverge on adjusted ACRs; all were lower than the most highly accrued group (white persons in the non-Baltimore City catchment area) and their ACRs did not differ.

Conclusions

Monitoring equity in clinical trial participation is an important aspect of cancer center self-assessment, with the goal of ensuring representative recruitment of individuals from all subpopulations. This study focused primarily on the joint effects of race and place of residence on clinical trial participation, adjust-

ing for other factors pertinent to recruitment. Race and place of residence were important determinants of accrual to both therapeutic and nontherapeutic trials, with place of residence being a slightly more powerful predictor of clinical trial participation than race. Places of residence both near and far from JH SKCCC were associated with lower therapeutic clinical trial participation. Distant place of residence (outside the catchment area) was also associated with lower nontherapeutic clinical trial participation. Among Baltimore City residents, therapeutic clinical trial participation was lower than expected and nontherapeutic clinical trial participation was the same as the reference group, but race groups within Baltimore City did not differ significantly.

This analysis confirmed that although clinical trial participation varied according to geographic area of residence, it was not positively associated with proximity. Race, age, and sex were important covariates in the prediction of clinical trial participation, whereas county wealth was not. Older age predicted greater participation in therapeutic trials, whereas younger age predicted more in nontherapeutic trials at JH SKCCC. Before and after adjusting for other factors, women participated more often than men in both clinical trial types. African American cases outside Baltimore City participated less often in therapeutic trials (Table 3). This distinction was not found for nontherapeutic trials.

Frequently, when examining race differences in clinical trial participation, an overall percentage of

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nonwhite participants, or of participants from each minority race, is calculated.^{1,6} These measures are inadequate representations of accrual diversity, because the interpretation of these data differs substantially depending on whether these are referenced to the city in which the cancer center resides, a larger and variably defined catchment area, or other statewide/regional demographics.¹⁹ The ACR may be calculated for any geographic area or subpopulation, representing a strength of this analysis, which used a data-based catchment area definition. Despite this advantage, ACR remains a calculation based on patients seen within the center, irrespective of their interest or capacity to participate in clinical trials. The ACR can be viewed as a global measure of clinical trial participation to be used as a tool to identify and address specific barriers to clinical trial participation among patient subgroups defined by race and location, and thus may help to define strategies for encouraging broad and representative participation by the total patient population. Some of the non-catchment area disparity in clinical trial participation may stem from the smaller race-specific JH SKCCC catchment area for African American participants. This is an adjustment that cancer centers may wish to consider as catchment areas continue to be refined.

The population of the Baltimore metropolitan area has many hospitals offering oncology care. In which hospital one should seek care may not be an individual decision, but can be dictated by an insurance company's preferred provider policies.² This study did not specifically address insurance status or specific payors, which are putative determinants of both locus of care and clinical trials participation.²⁰ Cancer site- and geographic area-specific trial accrual may be subject to local referral patterns and should be examined. Hematologic malignancies are one cancer site for which a preponderance of pediatric patients who typically participate in trials at higher levels and seek care locally may be found in Baltimore City. Another factor influencing accrual to trials is the availability of trials themselves and a cancer center's business practices according to cancer site. This could be seen in prostate cancers at JH SKCCC, which predominate in patients served but contribute a relatively small portion of accruals because of the distance traveled.¹¹

The finding of lower participation among Baltimore City residents of any race relative to those

of white race in the catchment area outside the city is somewhat surprising because proximity frequently dictates level of use of primary care services.²¹ In the case of therapeutic trials, racial disparities were observed in the catchment area, with African Americans in the catchment area outside Baltimore City participating less than white persons. This finding may indicate other contributing factors in determining participation levels. For instance, Probst et al.²² found that black patients at the same distances reported requiring more time to get to the place of treatment and Basu and Friedman²³ reported a higher disease severity in black patients relative to white patients for the same distance traveled.

The nature of clinical trial disparities is complex and inherently multifactorial.²⁴ Defining the primary factors contributing to observed disparities requires access to detailed and comprehensive databases, including cross-referenced clinical trial databases, patient case registries, and annotated population demographics both within and beyond the center's catchment area.²⁵ Thoughtful analysis of these integrated data can help identify particularly important sources of disparity, both in terms of access to care and clinical trial enrollment. Clinical trial accruals are likely not uniform across age, sex, race, Hispanic ethnicity, place of residence, or cancer site, underscoring that cancer centers must better understand their source patients to enhance clinical trial participation. Ultimately, these analyses serve the cancer research community by helping to ensure that the research has the broadest possible applicability to the patient populations served.²⁶

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