RESEARCH

Spatial Analysis of Clinical Trial Accrual Within an NCI Comprehensive Cancer Center Catchment Area by Race and Ethnicity

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ABSTRACT

Accrual into cancer clinical trials is concerningly low, approximately 5% of all U.S. adult cancer patients enroll into a trial, and racial/ethnic disparities in clinical trial accrual between White and minority patients, (i.e., Native American, Latino, Asian, and Black) are well documented [1-5]. This paper uses Geographic Information System (GIS) spatial analysis to identify racial and ethnic disparities in clinical trial accrual within the Stanford Cancer Institute (SCI) Comprehensive Cancer Centers (CCC) catchment area between 2012-2020 and compares drive times to the SCI by ethnicity overall and within each county it serves. 215 studies in the adult gastrointestinal oncology clinic trials department were reviewed to collect patient data on race and ethnicity, zip code at registration, and the type of trial they enrolled in. ArcGIS was used to plot ethnicity and zip code, and to calculate drive times to the clinical trial site in Palo Alto within the 10-county catchment area. 848 patients were available for analysis. The ethnicities of our trial patients were 61% White (n=514), 25% Asian/Pacific Islander (n=210), 13% Latino (n=107), 2% Black (n=14), and <1% Native American (n=3). Most patients enrolled into non-interventional studies (54.83%), followed by treatment trials (33.13%) and non-therapeutic trials (12%). Latino patients had the longest drive on average (mean maximum drive time of 67 minutes) and minority patients faced longer drive times than White patients in 8/10 counties in the catchment area. This analysis showed racial disparities in clinical trial accrual at the SCI CCC as well as disparities in drive times to the clinical trial site. Counties closest to the SCI had minority patient accrual approximately equal to that of the general population and higher accrual in general compared to counties further away, suggesting the need for additional clinical trial sites within the catchment area.

KEYWORDS: cancer clinical trial accrual, health disparity, race/ethnicity, nci, comprehensive cancer center, catchment area, spatial analysis, drive time, San Francisco

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Introduction

Accrual into cancer clinical trials is concerningly low, approximately 5% of all U.S. adult cancer patients enroll into a trial and approximately 40% of National Cancer Institute (NCI) trials fail to attain their minimum accrual goals(Hamel et al., 2016). Since the 1970's, studies have documented racial and ethnic disparities in clinical trial accrual between White and minority patients, (i.e., Native American, Latino, Asian, and Black)(Duma et al., 2018; Loree et al., 2019; Nazha et al., 2019; Siegel et al., 2020) despite other studies reporting that minorities are just as interested in engaging in cancer clinical trials as Whites(Katz et al., 2007), especially when controlling for previous knowledge of trials(Durant et al., 2011). In addition to disparities in accrual, there are also significant ethnic disparities in incidence and mortality rates of various cancers(Axtell and Myers, 1978; Cancer Prevention Institute of California and Greater Bay Area Cancer Registry, 2018; Zahnd et al., 2021). Increasing clinical trial accrual overall and achieving health equity among different ethnicities as outlined by the American Society of Clinical Oncology (ASCO)(Patel et al., 2020; Winkfield et al., 2021) will undoubtedly require an increase of minority enrollment in clinical trials.

Racial segregation is one mechanism of systemic racism theory(Feagin, 2006) that has propagated various health disparities in the U.S., yet no studies have addressed its' role on cancer clinical trial accrual(Kanarek et al., 2010). Segregation creates health disparities by excluding minority patients from communal resources limited to wealthy (mostly White) neighborhoods – including housing, schools, and hospitals(Coleman, 1992; Cornely, 1956; Firebaugh and Acciai, 2016; Jha et al., 2011; National Academies of Sciences, Engineering, and Medicine et al., 2017; Rothstein, 2017) – and forcing them to live in areas with increased environmental and social risk factors linked to worse health outcomes, such as pollution, food desserts, lack of mental health resources, and crime, in order to maintain access to jobs in those areas(Alexander, 2012; Cheng et al., 2020; Chhatre and Jayadevappa, 2018; Hilmers et al., 2012; Krieger et al., 2020; McGuire and Miranda, 2008; McGuire et al., 2006; Nardone et al., 2020; New York Law School Racial Justice Project., 2012; Williams and Mohammed, 2013). Racial segregation reflects the root cause of other factors associated with barriers to cancer clinical trials for minority patients(Hamel et al., 2016) by means of the disinvestment in their communities and the devaluation of their lives. Though most NCI comprehensive cancer centers (CCC) are in metropolitan areas where much of the patient population is White,(Onega et al., 2017) the association between ethnically segregated areas and proximity to treatment centers is confounded by covariates such as inadequate community engagement and attitudes towards clinical trials, as well as the availability of trials in hospitals that serve patients with similar socioeconomic factors such as low-income and public health insurance(McCaskill-Stevens et al., 2005; Sutton et al., 2019; Wenzel et al., 2015). For example, the Sidney Kimmel CCC in Baltimore performed a spatial analysis of their catchment area and found that even though minorities constituted a majority of the ethnic demographic in that area, White patients that lived outside of Baltimore City in wealthy suburbs made up a majority of their clinical trial patients(Kanarek et al., 2010). On a national level, research suggests that the effects of segregation on clinical trial accrual may be more significant in other CCC catchment areas. Two decade after the National Institute of Health's (NIH) Revitalization Act of 1993(Institute of Medicine, 1994), which mandated the enrollment of women and minority race patients in NIH-funded research, approximately 2% of trials

have enrolled enough minority patients to meet the goals outlined by the Act(Chen et al., 2014).

Racial segregation in the Stanford Cancer Institute (SCI) catchment area (i.e., the San Francisco Bay Area) began with the state-sanctioned genocide of Native American tribes from the 17th to 19th centuries – the Native American population in the Bay Area today is <1%(Madley, 2016). In the 20th century, discriminatory real estate practices only approved home loans for racial and ethnic minorities in less desirable neighborhoods within big cities like the Mission District in San Francisco, or adjacent to wealthy suburbs, like Palo Alto and *East* Palo Alto(Rothstein, 2017). The only clinical trial sites for Bay Area patients are in wealthy neighborhoods in the peninsula, at UCSF and Stanford (i.e., *West* Bay). This paper analyzes gastrointestinal cancer clinical trial patient accrual at the Stanford Cancer Institute (SCI) between 2012-2020 by ethnicity and trial type and compares drive times to the SCI between patients of different ethnicities. It hypothesizes that the location of the SCI contributes to racial disparities in clinical trial accrual within its' catchment area (as designated by the NCI) by requiring minority patients in historically segregated communities to travel to the clinical trial site to receive treatment on trial.

Methods

This cohort is derived of adult gastrointestinal (GI) oncology patients (i.e., colorectal, pancreatic, hepatic, bile duct, gastric, and esophageal) that enrolled in a clinical trial at the SCI between 2012 to 2020. Data was made available through internal review and verified through OnCore (Forte Research Systems, Madison, WI). 215 studies were reviewed for demographic data – i.e., self-reported race, ethnicity, and zip code at time of enrollment (U.S. patients only) – and study type – therapeutic, non-therapeutic, and non-interventional (i.e., observational). Only patients with self-reported race and ethnicity were included in the final analysis. Under California state law, health insurers are required to cover routine or standard of care costs for all clinical trial patients, so the type of insurance a patient had (private, public, or uninsured) was not considered a relevant factor in deciding to enroll.

Geographic analysis was limited to the SCI catchment area as designated by the NCI. The 10 counties served by the SCI are Alameda, Contra Costa, Merced, Monterrey, San Benito, San Joaquin, San Mateo, Santa Clara, Santa Cruz, and Stanislaus Counties. San Francisco and the counties north of the Golden Gate Bridge are served by the UCSF Cancer Center and are not addressed in this analysis. Though patients from all over the world come to the SCI for cancer clinical trials, these patients were not appropriate for this analysis.

ArcGIS Pro by Esri® was used to plot patients within our catchment area and generate descriptive statistics. Patients were plotted using their zip code at the time of enrollment. The ethnicity field of the patient was layer was joined to the SCI catchment area polygon using the Spatial Join tool. The Summarize Within tool was then used to generate the proportion of patient ethnicities by county. The location of the SCI in Palo Alto was geocoded to derive drive times to the clinical trial site. Drive times to the SCI were calculated by ethnicity overall and by county using the Network Analysis Service Area tool. Polygons with a radius of x minimum and maximum drive time to the SCI were used to compare drive times among patients by ethnicity. The minimum and maximum cutoff times chosen for this calculation are 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 60, 70, 80, 90, 100, 110, 120, 140, 160, and 180 minutes, based on expected drive times to the SCI without traffic.

Results

848 patients were available for analysis. Overall, 61% of patients were White, 25% Asian and Pacific Islander (AAPI), 13% Latino, 2% Black, and <1% Native American (Table 1). Most patients enrolled into non-interventional studies (54.83%), followed by treatment trials (33.13%) and non-therapeutic trials (12%). White patients were the most represented in each trial type.

Table 1. GI Clinical Trial Patients by Ethnicity and Trial Type.

Ethnicities	Total	Therapeutic Trials	Non-Therapeutic	Non-interventional
White	514	176	64	274
Black	14	3	1	10
AAPI	210	66	26	118
Latino	107	36	10	61
Native American	3	0	1	2
Total	848	281	102	465

The approximate location of trial patients within the SCI's catchment area are plotted in Figure 1. The breakdown of trial patient ethnicity by county within the catchment area was 44% White, 41% Asian, 11% Latino, and 4% Black in Alameda. 62% White, 19% Latino, 16% Asian, and 3% Black in Contra Costa. 63% White, 31% Latinos, and 6% Asian in Merced. 49% Latino and White, and 3% Asian in Monterrey. 67% White and 33% Latino in San Benito. 73% White, 14% Black, 9% Asian, and 5% Latino in San Joaquin. 65% White, 23% Asian, 11% Latino, and 1% Native in San Mateo. 49% White, 40% Asian, 9% Latino, 2% Black, and <1% Native in Santa Clara. 89% White, 8% Latino, and 3% Asian in Santa Cruz. And 77% White, 23% Latino in Stanislaus (Table 2).

Figure 1.

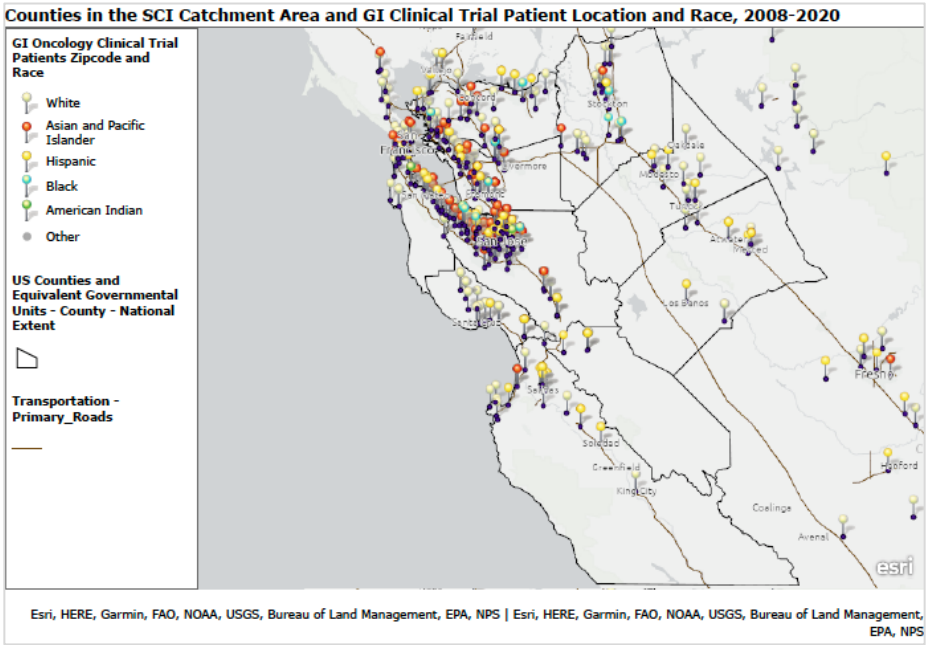

Table 2. Comparison of trial patients' ethnicity, and drive time to the cancer center by county.

Ethnicities	Alameda	Contra Costa	Merced	Monterrey	San Benito	San Joaquin	San Mateo	Santa Clara	Santa Cruz	Stanislaus
White	33	23	10	17	6	16	51	121	34	10
Black	3	1	0	0	0	3	0	4	0	0
AAPI	31	6	1	1	0	2	18	99	1	0
Latino	8	7	5	17	3	1	9	21	3	3
Native American	0	0	0	0	0	0	1	1	0	0
Total	75	37	16	35	9	22	79	246	38	13
Average Minimum/Maximum Drive Times to the SCI (minutes)										
White	41/47	68/78	125/144	89/100	70/80	96/107	16/21	26/31	55/65	117/134
Black	43/52	90/100	0/0	0/0	0/0	93/103	0/0	20/25	0/0	0/0
AAPI	35/40	60/70	140/160	80/90	0/0	90/100	17/22	26/31	70/80	0/0
Latino	31/36	76/67	134/152	85/95	70/80	100/110	26/31	26/31	63/73	110/123
Native American	0/0	0/0	0/0	0/0	0/0	0/0	25/30	30/35	0/0	0/0

Overall, Latino patients had the longest drive on average (mean max drive time of 67 minutes), while the means for Black, White, Asian, and Native patients were 60, 53, 36, and 33 minutes, respectively. In Alameda and Contra Costa Counties, Black patients faced the longest commutes to the SCI of all ethnicities, 52 and 100 minutes, respectively (Table 2). AAPI patients had the longest commutes in Merced and Santa Cruz Counties (160min. and 80min). Latino patients had the longest commutes in San Joaquin and San Mateo Counties. White patients had the longest commutes in Monterrey and Stanislaus Counties. One patient identifying as Native American in Santa Clara County had the longest commute of all ethnicities.

Discussion

This report demonstrated racial disparities in clinical trial accrual at the SCI CCC using a cohort of adult gastrointestinal cancer patients. Spatial analysis showed that the counties closest to the SCI had the highest accrual (Santa Clara and San Mateo) and there was an inverse relationship between distance the SCI and patient accrual overall. In Santa Clara and San Mateo Counties, the racial and ethnic demographics of trial patients was approximately equal to the racial and ethnic makeup of the general population. For example, approximately 2% of trial patients from Santa Clara County were Black compared to 3% in the general population, but the proportion of Black patients from Alameda County was much less than expected, approximately 4% compared to 11% in general(U.S Census Bureau Quickfacts, 2020). Drive time analysis suggested that accrual could be increased if trials were offered at satellite sites in counties further away, and minority accrual would reflect the demographics of the counties in general, as is the case for Santa Clara County.

Limitations to this study include a lack of demographic information on the cohort, studies have shown that variables such as sex (male/female, non-binary), cancer type, stage at diagnosis, socioeconomic status, type of insurance, and the patients' referring hospital, are also associated with low minority patient accrual in clinical trials(Awidi and Al Hadidi, 2021; Krieger et al., 2020). These missing variables are partially due to deficiencies in the data collection processes at the SCI as well as the migration of data between the electronic medical record system and research databases. Demographic and sociological variables tend to be overlooked in cancer clinical trials research, one study found that 7.8% of trials leading to FDA oncology drug approvals between 2008-2018 reported the main race and ethnicity categories used in the United States(Loree et al., 2019). Limitations of the spatial analysis are the use of patient zip codes rather than exact addresses', and the exclusion of patients outside the SCI catchment area. Excluding non-catchment area patients from the analysis was justified to determine where a future clinical trial site would make the most impact on minority patient accrual. The calculated drive times assumed no traffic though this is rarely the case, and it also does not take into consideration the fact that East Bay patients face tolls that patients from most other counties in the catchment area do not. Though this report lacked the quantitative analysis to conclude that historical segregation played a role in minority patient trial enrollment patterns within the SCI catchment area, it did show ethnic disparities in accrual and drive times to trials within different counties.

In the past decade the NCI mandated all CCC's applying for P30 support grants to address racial disparities in their catchment area and increase community outreach and engagement (COE), leading to two approaches to increase minority patient enrollment. One approach is to invest resources into transportation programs that reduce out-of-pocket costs for low-income patients in underserved areas. For example, Massachusetts General Hospital (MGH) and the Lazarex Cancer Foundation started a patient navigation and sliding-scale reimbursement program in 2013 which funds all transportation and lodging costs for clinical trial patients, but saw no increase in minority patient enrollment in the first two years(Nipp et al., 2016). Similarly, the SCI implemented a shuttle program to Palo Alto for clinical trial patients in East Bay, though this paper suggests these efforts were also met with limited results. The other approach, used by the NCI's Community Oncology Research Program (NCORP) and several CCCs, has been to invest in new clinical trial sites within underserved minority and rural communities through partnerships with local healthcare providers. In 2014, NCORP tested whether community-based hospitals with little to no clinical research experience could develop and sustain clinical trial programs with guidance from a local, larger CCC(Wong et al., 2014). 3 of 6 hospitals received 10 years of funding through NIH U56 and U54 grants, increased their yearly patient accrual by ~60% to NCI cooperative group trials, required approximately a year into their implementation phase to fully open their programs, and all were able to recruit principal investigators to help sustain their new programs. Though the trials offered to patients were limited in comparison to their mentor site, the study showed that investing resources in underserved communities is feasible and translates to a significant increase in clinical trial accrual.

Regardless of the approach used, studies show that COE and staff cultural sensitivity training is pivotal to making underserved communities aware of clinical trial resources in their area and overcoming explicit and "implicit" racial biases that perpetuate feelings of mistrust by minority patients and create barriers to enrollment. For example, the Georgetown CCC increased enrollment of Black

patients to non-therapeutic clinical trials by 62% at two community sites in underserved areas by implementing staff cultural competence training at those sites(Wallington et al., 2016). In "Systemic Racism and U.S. Healthcare,"(Feagin and Bennefield, 2014) Feagin and Bennefield demonstrate that the degree to which a healthcare provider identifies with these biases positively correlates with preferential treatment of White patients and poor treatment of minority patients. One study among a group of healthcare professionals showed that people of color are seen as "less promising" candidates for trials, and in some cases, not considered for studies they may be eligible for(Niranjan et al., 2020). Though some studies report that Black and other minority race patients are just as willing to enroll in clinical trials as Whites when access and awareness are equivalent,(Durant et al., 2011, 2014) other patients are still skeptical due to past crimes against uninformed patients (e.g., the Tuskegee Syphilis Study(Katz et al., 2007)). To overcome this barrier, the Abramson Cancer Center formed partnerships with faith-based organizations and community health centers and achieved Black patient accrual representative of the percentage of Black cancer patients among all cancer cases in the catchment area over 5 years(Guerra et al., 2021). CCCs looking to increase minority patient accrual to clinical trials should begin by taking an honest look at accrual statistics within their catchment area and invest resources in the underserved areas that often lack clinical trials nearby, or are simply unaware of them.

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Conflicts of interest

The authors declare no conflict of interest.

Authors' contributions

The data review, literature search, manuscript development, and data analysis were done entirely by the author.

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