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Cartographic Mapping and Travel Burden to Assess and Develop Strategies to Improve Minority Access to National Cancer Clinical Trials

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Abstract

Purpose—To assess how accrual to clinical trials is related to U.S. minority population density relative to clinical trial site location and distance traveled to Radiation Therapy Oncology Group (RTOG) clinical trials sites.

Methods—Data included member site address and zip codes, patient accrual, and patient race/ethnicity and zip code. Geographic Information System (GIS) maps were developed for overall, Latino and African American accrual to trials by population density. The Kruskal-Wallis test was used to assess differences in distance traveled by site, type of trial and race/ethnicity.

Results—From 2006–2009, 6168 patients enrolled on RTOG trials. RTOG U.S. site distribution is generally concordant with overall population density. Sites with highest accrual are located throughout the U.S. and parts of Canada and do not cluster, nor does highest minority accrual cluster in areas of highest U.S. minority population density. Of the 4913 U.S. patients with complete data, patients traveled a median of 11.6 miles to participate in clinical trials. Whites traveled statistically longer distances (12.9 miles; $p < 0.0001$) to participate followed by Latinos (8.22 miles), and African Americans (5.85 miles). Patients were willing to drive longer distances to academic sites than community sites and there was a trend toward significantly longer median travel for therapeutic vs cancer control or metastatic trials.

Conclusions—Location matters, but only to a degree, for minority compared to non-minority participation in clinical trials. GIS tools help identify gaps in geographic access and travel burden for clinical trials participation. Strategies that emerged using these tools are discussed.

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Keywords

cancer clinical trials; recruitment; geographic information systems; travel distance

Introduction

Approximately 1.7 million new cancer cases were diagnosed in 2014.¹ Randomized cancer clinical trials (CCTs) conducted by the National Cancer Institute (NCI) National Clinical Trials Network (NCTN) provide much of the evidence for clinical guidelines and standards of care.² Enrollment on clinical trials, independent of the experimental treatment, has a positive effect on patient-centered outcomes due to high-quality care, quality assurance of treatment modalities, fidelity to treatment protocols, and increased patient surveillance.³ In one study, patients who traveled more than 15 miles to participate in a CCT had a third of the risk of death compared to patients who traveled less distance. Further, with every 10 miles that a patient traveled the risk of death decreased by 3.2%, even after adjusting for potential “fitness to travel indices” (e.g., age, income, tumor stage and site, performance status, etc).⁴

Thus, for reasons including representation, generalizability, and quality of care, all patients should have access to clinical trials. Yet, despite national initiatives to increase the enrollment of racial and ethnic minorities into CCTs, such as the Minority Based Community Clinical Oncology Program (MB-CCOPs) and the NCI AccrualNet, participation by Latino and African American (AA) populations remains low relative to their representation in the United States (U.S.) population and to the burden of cancer they bear.

Latinos comprise approximately 16.9% of the population.⁵ Latinos have lower incidence and mortality rates than White Americans for the most common cancers; however, Latinos are more likely to be diagnosed at a more advanced stage. Additionally, cancer mortality rates are 22% higher among U.S.-born Latinos than their foreign-born counterparts who have immigrated to the U.S.⁶ AAs comprise 13.1% of the total U.S. population⁷, and have the highest death rate and shortest survival of any racial and ethnic group in the U.S. for most cancers.⁸ The causes of these inequalities in cancer outcomes among different races/ethnicities are complex and most likely due to social and economic disparities more than biologic differences.⁸

CCT accrual for all adult cancer patients is only about 3 to 8% and White patients make up the majority of trial participants (85.6%).⁹ Latinos and AAs constitute a much lower percentage (5.6% and 8%, respectively).⁹ Research has shown that with equal access Latinos and AAs appear to have similar CCT participation rates as Whites.⁹ Access is multifactorial, however, logistical barriers that may have significant influence such as geographic location and travel distance to participating site have received only modest attention. Thus, the purpose of this project was to examine how accrual to CCTs is related to U.S. minority population density relative to clinical trial site location and distance traveled to institutions who were members of the NCI sponsored Radiation Therapy Oncology Group (RTOG) clinical trials network. In addition, distance traveled was also assessed as it is of particular

importance in radiation therapy (RT) CCTs since daily travel for four to eight weeks is often required.

Materials and Methods

Following IRB approval, address and zip codes of RTOG academic full and affiliate members and their satellite sites along with Community Clinical Oncology Program (CCOP) members and their component sites were obtained. Higher levels of patient accrual to CCTs are required for full members, and they may count their health-system owned satellite site accrual as a part of their total accrual. Academic sites may also have affiliates from separate health systems, which accrue at a lower rate than full members. Affiliate accrual is counted separate from their full member partner. CCOPs are community sites and their component sites may or may not be owned by the CCOP. Many CCOP sites come together for CCTs participation as a consortium and accrual was counted as a total by CCOP. Canadian site members contributed to RTOG accrual and were included in the site maps but excluded from the distance travelled analysis since a separate geocoder would have been required for Canadian postal codes and was beyond the scope of this work. Patient accrual to all RTOG clinical trials per site from 2006–2009 was collected. Patient data included only race/ethnicity and zip code. RTOG did not collect patient street addresses. Racial/ethnic categories included Latino, AA, and other. The other category included 96% Whites and was subsequently labeled Whites.

Next, a series of thematic maps was created. These maps display the spatial locations and accrual rate (by minority and general population) of each of the RTOG sites. Specifically, ArcMap Geographic Information System (GIS) 9.3 software maps were color-coded for Latino and AA population density by census block group (a sub-county geographical unit used by the U.S. Census Bureau) with a darker color representing greater density in population. Population density by race/ethnicity is visually displayed based on the natural breaks/Jenks classification system. This classification system is widely used in GIS applications and is a form of variance-minimization. Population density breaks are typically uneven for different populations and are selected to separate values where large changes in value occur. The natural breaks in population density may be significantly affected by the number of classes selected and tends to have unusual class boundaries.¹⁰ RTOG member sites were placed on the maps by street address and designated with color-coding by quartile of overall, Latino, and AA accrual to RTOG trials over the 4 year period of analysis (2006 to 2009). Sites that had no (0) accrual over the time period were not placed on the maps.

In order to compare overall population density to RTOG site location, an additional map was included from the U.S. Census Bureau which displays population density (average population per square mile) from 2009 census data, corresponding with the last date of the study data collection. In addition, the distance (direct straight line distance in miles) was calculated between the centroid of the U.S. postal zip codes of all individual patients and the RTOG site address where the patient was accrued to a CCT. The Kruskal-Wallis test was used to assess differences in distance traveled by full member or CCOP site and by type of CCT (curative, metastatic or cancer control) and race/ethnicity. The Wilcoxon-Mann-

Whitney Test was used to assess pairwise comparisons of distance traveled by race/ethnicity.

Results

RTOG Sites and Overall Patient Accrual

From 2006–2009, 6168 individuals were enrolled on a RTOG trial (1234 on phase II studies and 4735 on phase III) from 400 sites. Patients enrolled by Canadian sites accounted for 17.8% accrual over this time period.

For the distance traveled analysis, 4913 U.S. participants had complete information (zip code and race/ethnicity) with 4072 treated on a CCT at full/affiliate/satellite sites and 841 at CCOP/component sites. Of these, 4369, 450 and 94 patients, respectively, were enrolled on a curative, cancer control or a metastatic treatment CCT. Figure 1 illustrates the number of member sites and patient participants included in each analysis.

RTOG site distribution across the U.S. (Figure 2) shows geographic access to RTOG sites is highest in high density areas, across all sites (full member, CCOP, etc). RTOG accrual to community sites (CCOP) versus accrual to full and affiliate member sites varies across the country. The sites with best accrual numbers (dark green in Figure 2) are located throughout the country and do not cluster. Canadian RTOG sites are generally in the top quartile for overall accrual.

Minority Accrual and Distance Traveled

Of the almost 5000 U.S. patients accrued to RTOG trials with racial/ethnicity and zip code data, 204 were Latinos: this represents 4.1% of the patients participating at full and affiliate sites and 4.5% of patients at CCOP sites. The sites that accrued Latinos overlaid on U.S. population density of Latinos are shown in Figure 3. The darkest shaded areas show where the population equals 18% or greater and are located mainly in the southwest in the states of: Texas, New Mexico, Arizona, California, Colorado, and Nevada. Additional high density pockets of Latinos are seen in southern Florida and the New York City area. Overall, RTOG sites that accrue Latinos well are not specifically in the highest areas of U.S. Latino population density.

There were 543 AA participants in RTOG CCTs during this period, representing 11% of participants at full and affiliate sites and 11.4% of patients at the CCOP sites. Figure 4 uses the darkest shaded areas to indicate where the population equals greater than 29%, but, as with the Latino maps, the RTOG sites that accrue the highest number of AAs to CCTs are not specifically located in the geographic areas of highest AA population density.

Patients travel significantly further to participate in a CCT at a full/affiliate site compared to a CCOP site (Table 1). White patients traveled significantly longer distances to either full/affiliate or CCOP sites compared to Latino or AA patients ($p<0.0001$). Overall, all patients combined traveled on average 11.6 miles (range 0.003 – 2733.00 miles) to participate in CCTs.

By type of RTOG site (full/affiliate or CCOP) Whites traveled the longest distance to full/affiliate sites and AAs the least distance (Table 1). Whites and Latinos traveled a significantly greater distance to participate in a CCT at a full/affiliate site compared to a CCOP site ($p<0.0001$), whereas AA travel distance to a full/affiliate compared to a community site was not significantly different ($p=0.60$). Post-hoc analysis confirms racial/ethnic significant differences ($p<0.0001$) among participants to either full/affiliate sites or CCOP sites, with the exception of no difference in travel between Latinos and AAs to CCOP sites only ($p=0.95$).

Of participants enrolled on a CCT of curative intent, 84.7% were White, 11.2% were AA and 4.1% were Latino, compared to 89.4% White, 9.6% AA and 1.1% Latino on trials for metastatic disease. The racial/ethnic representation on cancer control trials was 84.9% White, 10.0% were AA and 5.1% Latino. There were no statistical differences within groups of the number enrolled on each type of trial (data not shown). By trial type, Table 2 shows a trend for Whites and all patients combined toward a longer median distance traveled to participate in therapeutic vs cancer control or trials for metastatic disease. We document a further raw mean distance traveled by minorities for trials of curative intent vs other types of trials but small numbers do not give us the power to comment further.

Discussion

Cartographic Mapping of Clinical Trials Accrual

RTOG site distribution and levels of participant accrual generally appear concordant with U.S. population density. The visual maps help identify several gaps in patient accrual not as readily recognized through traditional tables and graphs. Location gaps are easily identified where there are fewer RTOG sites in higher density Latino regions. For example, mapping indicates that the highest Latino accruing sites to RTOG trials are predominantly not in the higher density geographic Latino population areas. Viewing the maps of total accrual and minority accrual depicts a similar pattern of the highest CCT accrual occurring in urban settings. In general, sites that accrue well overall also appear to accrue minorities well. This is not to suggest that minority population density does not matter. The NCI MB-CCOP, which specifically funds sites with high minority population density ($> 40\%$), has found it successful in boosting minority CCT accrual. In 2003 the MB-CCOPs accounted for less than 20% of the CCOP grantees and contributed 33% of the CCOP network's minority accruals and 7% of the minority patients enrolled by all cooperative group sites.¹¹ While the MB-CCOPs may contribute to NCTN minority accrual there is obvious room for improvement. In this study, CCT minority accrual vs US population representation by minority¹² was 4.3% vs 15.1% for Latinos and 11.2% vs 12.4% for AAs, respectively. The map also helps us identify member sites in high density Latino and AA locations where strategies to increase efforts to improve recruitment may be employed. Additionally, maps helped identify geographic gaps in RT site members where the group could strategically reach out to encourage membership, an increasingly viable option since RTOG has joined with two other cooperative groups in the NCTN to form NRG Oncology. The merger provides opportunities to offer RT clinical trials to sites where primarily medical oncology trials dominated.

A study by Sateren and colleagues that assessed socioeconomic factors and their impact on accrual to NCTN-sponsored CCTs showed geography matters, with higher socioeconomic level areas having higher levels of clinical trial accruals. Conversely, poorer states including Alabama, Arkansas, Florida, Georgia, Kentucky and West Virginia had the lowest CCTS accrual per number of incident cancer cases.¹³ Further, areas with NCI approved cancer programs were significantly associated with increased accrual to CCTs.¹³

The current study map of overall accrual was not based on incident cancer cases but rather percentage of accrual to RTOG trials, however some similar patterns to the Sateren et al (2002)¹³ study can be seen, with no accrual in Arkansas and West Virginia as well as Mississippi and low accrual in some of the other states in the U.S. poverty belt¹⁴ including Louisiana. Further, as in the Sateren study, some of the issues with state socioeconomic status and accrual appear to be mitigated by NCTN participation. For example, the RTOG member sites in the poverty belt, including Alabama, Texas and New Mexico accrued in the top 25% of RTOG members. However, in the current study there remain many sites with poor accrual regardless of state socioeconomic status suggesting that cancer site willingness to participate in NCTN and state higher socioeconomic status are both important but do not fully explain differences in patient accrual by site and state. Thus, identification of best practices among highest accruing sites may prove useful.

Travel Burden and Accrual

Several studies have cited travel burden, including distance to clinic and transportation issues as a specific reason for nonparticipation in clinical trials.^{11,15} Since travel distance is an important factor in general health care access it is not surprising it would be an important, albeit neglected, consideration in CCT participation. Using national data, Probst and colleagues¹⁶ reported that an average trip to seek healthcare in 2001 was 10.2 road miles and 22 minutes of travel. While the current study did not collect data on time traveled, it showed that in comparison, patients travelled a slightly longer average (as the crow flies) distance (11.6 miles) to participate in RTOG clinical trials compared to travel distance for general health care. This means the road distance traveled would be even longer than calculated for CCT participation.

In contrast, some patients with metastatic disease may be willing to drive long distances to access CCTs. A recent study calculated driving distance from each zip code in the U.S. to the nearest clinical trial site with an open therapeutic trial for first-line metastatic cancer. Patients drove a median of 54.6 (17.2–71.8); 49.6 (14.8–64.3); 40.5 (12.8–53.3); and 60.6 (19.8–80.4) miles, for prostate, breast, lung and colorectal cancers, respectively.¹⁷ These findings are dissimilar to the current study, which indicated that patients only traveled a median of 11.7 miles to participate in RTOG trials for metastatic disease. Differences in willingness to travel among studies may relate to protocol specific access to experimental options, time and/or treatment burden. The current study shows similar travel distance for metastatic and curative trials (median 11.8 miles), whereas patients only traveled a median of 9.9 miles to participate in a cancer control trial. Future studies that assess a combination of sociodemographics and patient reported decision making to participate, or not, in trials are needed to better inform reasons for the disparate findings as well as guide interventions.

In the Probst¹⁶ study, rural residents traveled farther than urban residents. Rural residents were significantly more likely to perceive the price of gasoline a problem compared to urban residents whereas urban residents were more likely to perceive highway congestion as a problem. While distance traveled did not vary by race/ethnicity, AAs did spend more time in travel than Whites even when controlling for mode of transportation: other minorities did not differ.¹⁸ This is in contrast to the current study which indicated that AAs traveled the least and Whites the greatest distance to participate in RTOG trials. The findings may be confounded by socioeconomic status; however, the data was not available for this analysis and should be considered in future research.

Study Limitations

For distance traveled, calculations would clearly be improved in precision if street or census track data were available. Further, distance traveled is different than time spent in travel; however, that data was unavailable for this analysis. Studies would also be better informed by assessing associations among public and private transportation options including access to private car, having to rely on family or friends to drive, bus, rail routes and transfers, and cost of transportation.

In addition, an important limitation of this research is the lack of information on non-accruals. Eligible patients who did not enroll on a clinical trial may have greater travel burden than accrued patients. However, this (and few if any studies in the literature) have yet to capture this data and should be a recommendation for future research.

Strategies to Improve Minority Access to National Cancer Clinical Trials

Geographic and travel burden are rarely considered in interventions to improve participation in CCTs. Consider a patient who is deciding whether he will participate in a clinical trial of radiation treatment that may require daily visits to the facility. If a more convenient site for RT without clinical trial access is available and transportation is a challenge, travel burden may be the deciding factor whether a person would join the clinical trial. The study findings have guided a partial list of suggested strategies and resources for improvement (Appendix) and other sources list additional strategies.¹⁹

Conclusion

GIS mapping has helped identify geographic patterns of overall and minority CCT accrual as well as high density minority population areas without RTOG member sites. This will help us strategically identify radiotherapy sites for outreach efforts as new partners in minority enriched locations to facilitate equal access to state-of-the-art CCTs. Mapping also identified high minority RTOG clinical trial accrual in lower minority dense sites which would not have been easily identified without mapping. Future research plans include contacting high accruing sites in areas with lower minority density to determine best practices for recruitment and accrual.

NCTN clinical trials provide quality care for cancer patients as well as contribute to national/international guidelines on care delivery. Social justice would dictate equitable access across all populations. While access to CCTs is complex and multi-dimensional,

geographic location of treatment sites relative to minority population density and travel distance to sites represent important components to equal access. GIS applications are little used tools in research, which can assist in identifying gaps in geographic access and travel burden for those who would benefit from clinical trials participation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Appendix

Strategies to Improve Minority Access to National Cancer Clinical Trials Emerging from Analysis of GIS Mapping and Travel Burden Analysis	
Strategy	Examples of Resources
Assess best practices for recruitment from sites reporting highest minority accrual	<p>Best practice assessments may include questions such as:</p> <p>System processes:</p> <p>Do you routinely assess all patients for clinical trial eligibility?</p> <p>Do you routinely discuss all new activated protocols at department meetings or tumor boards?</p> <p>Do you have a clinical trials electronic matching system?</p> <p>Are all research staff and investigators trained (shadowing experience recruiter, video training, role playing, etc.) in how to recruit patients to clinical trials?</p> <p>Do you have a script, check list or bullet points of issues to cover when discussing clinical trials (eg randomization, treatment, side-effects, calendar of activities for participation, travel issues, etc) to ensure all patients receive the same minimum information (in addition to study specific information).</p> <p>Patient processes:</p> <p>Do you have translators readily available to help discuss clinical trials?</p> <p>Do you routinely ask the patient to include the family in the discussion of clinical trials?</p> <p>Do you have a list of resources available to help the patient with transportation as needed?</p>
Conduct evidence-based, culturally and linguistically appropriate education programs for investigators and research associates	http://www.rtog.org/ResearchAssociates/EducationTraining/CulturalCompetencyandRecruitmentTraining.aspx
Identify minority rich geographic areas without cooperative group site membership and actively encourage affiliation with member sites; provide mentorship for new sites	<p>GIS maps of U.S. in this manuscript and from US census bureau of population density by state compared to NCI information on location of NCI designate cancer centers</p> <p>http://www.cancer.gov/researchandfunding/extramural/cancercenters</p>
Document transportation issues (transportation type [own car, public transportation, reliance on	<p>There are national organizations that may provide resources such as those below, however it is best to develop a list of local organizations. Internet searches by zip code or state of “free daily patient transportation” usually yields multiple resources</p> <p>www.patientadvocate.org</p> <p>www.cancer.net</p> <p>www.cancer.org</p>

Strategies to Improve Minority Access to National Cancer Clinical Trials Emerging from Analysis of GIS Mapping and Travel Burden Analysis	
Strategy	Examples of Resources
family or friends to provide transportation; elder vans or other assistance transport], transportation costs [gas, parking fees, public transportation fares], and public transportation schedules and availability) and develop strategies to address for clinical trials participation including budget item in grants or public transportation tokens or parking pass or development of philanthropic fund for such assistance.	

Summary

This study identified how accrual to clinical trials is related to U.S. minority population density relative to location and distance traveled to Radiation Therapy Oncology Group (RTOG) sites. Findings indicate that highest minority accrual did not cluster in areas of highest minority population density. Whites traveled statistically farther compared to Latinos, and African Americans, 12.9; 8.22 and 5.85 miles, respectively. Cartographic tools help identify gaps in geographic access and travel burden for study participation.

Figure 1.
Consort Chart of Patients and Sites Included in Mapping and Distance Traveled Analyses.

Figure 2.
U. S. Population Density Concentrations* and RTOG Member Site Locations and Clinical Trials Accrual 2006–2009
*Adapted from US. Census Bureau <http://www.census.gov/popest/data/maps/2011/County-Density-11.html>

Figure 3.
U. S. Latino Population Density Concentrations and RTOG Clinical Trials Accrual 2006–2009

Figure 4.
 U. S. African American Population Density Concentrations and RTOG Clinical Trials
 Accrual 2006–2009

Table 1

Distance Traveled by Race/Ethnicity and Type of RTOG Site

	Full/Affiliate (n=4072)	CCOP (n=841)	P-value*	All sites combined	P-value#
Latinos	(n=166)	(n=38)		(n=204)	
Median	8.72	5.26	0.0115	8.22	
Min-Max	0.541–982.50	0.81 – 50.07		0.54 – 982.50	
African Americans	(n=447)	(n=96)		(n=543)	<0.0001
Median	5.75	6.257	0.6000	5.85	
Min-Max	0.08 – 658.10	0.49 – 30.68		0.08 – 658.10	
Whites	(n=3459)	(n=707)		(n=4166)	
Median	13.43	11.21	<0.0001	12.92	
Min-Max	0.00 – 2733.00	0.50 – 1568.00		0.003 – 2733.00	
All Patients	(n=4072)	(n=841)			
Median	12.04	10.06	<0.0001		
Min-Max	0.00 – 2733.00	0.489 – 1568.00			

* P-value from two-sided Wilcoxon-Mann-Whitney Test using the normal approximation

P-value from Kruskal-Wallis test for comparison among the three racial/ethnic groups

Table 2

Distance Traveled by Trial Type and Race/Ethnicity

	Cancer Control (n=450)	Curative	Metastatic (n=94)	P-value *
Distance Traveled - Latinos	(n=23)	(n=180)	(n=1)	
Mean	11.1	33.8	5.7	
Std. Dev.	12.8	108.7		
Median	7.93	8.36	5.66	N/A **
Min - Max	0.68 – 62.47	0.54 – 982.5	5.66 – 5.66	
Distance Traveled - African Americans	(n=45)	(n=489)	(n=9)	
Mean	12.5	17.0	12.8	
Std. Dev.	19.3	49.4	8.7	
Median	5.03	5.79	13.30	0.2947
Min - Max	0.08 – 78.59	0.13 – 658.1	2.17 – 29.78	
Distance Traveled - Whites	(n=382)	(n=3700)	(n=84)	
Mean	45.7	43.2	31.0	
Std. Dev.	205.2	150.4	102.6	
Median	11.39	13.20	11.67	0.0621
Min - Max	0.12 – 2733.38	0.00 – 2559.00	1.28 – 907.5	
Distance Traveled - All patients	(n=450)	(n=4369)	(n=94)	
Mean	40.6	39.9	29.0	
Std. Dev.	189.5	141.4	97.2	
Median	9.85	11.76	11.67	0.0754
Min - Max	0.08 – 2733.00	0.00 – 2559.00	1.28 – 907.50	

* P-value from Kruskal-Wallis test

** No p-value provided since Metastatic only has 1 patient