Geographic Access Disparities to Clinical Trials in Diabetic Eye Disease in the United States

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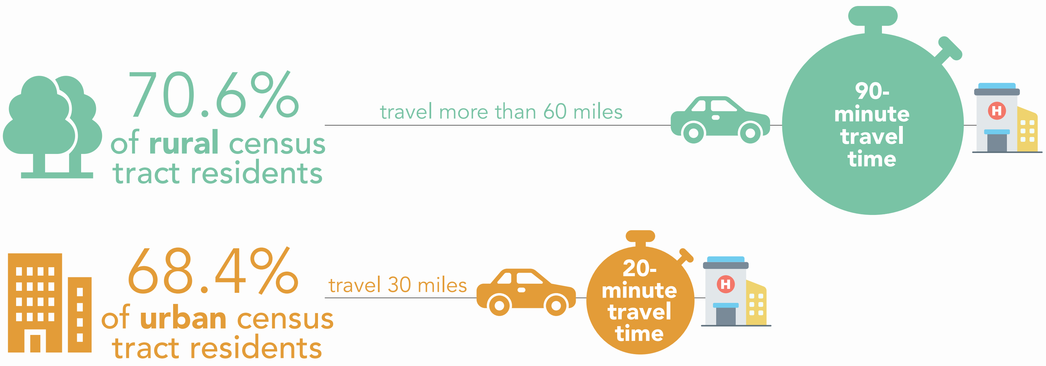
This cross-sectional, retrospective study identified geographic and socioeconomic variables predictive of residential proximity to diabetic eye disease clinical trial locations, utilizing driving distance > 60 miles and time traveled > 60 minutes to the nearest trial site for main outcome meaures.

Geographic maldistributions of clinical trial sites exist for diabetic eye disease in the United States

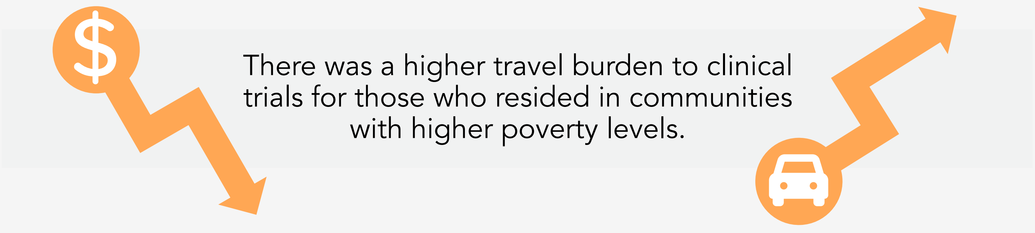
	Travel Distance (miles) to Nearest Clinical Trial Site				Total Number of Census Tracts	Population
	<30	30 to 60	>60 to 120	>120		
Travel time (min), mean ± SD	19.33 ± 9.59	52.49 ± 11.52	89.93 ± 18.48	180.59 ± 58.71		
Rural, no. (% of rural census tracts)	612 (4.7)	3,186 (24.6)	5,603 (43.3)	3,532 (27.3)	12,933	50,142,010
Urban, no. (% of urban census tracts)	40,308 (68.4)	8,842 (15.0)	6,038 (10.2)	3,777 (6.4)	58,965	270,484,922
Total, no. (% of total census tracts)	40,920 (56.9)	12,028 (16.7)	11,641 (16.2)	7,309 (10.2)	71,898	320,626,932

Census tract = a stable geographic unit of 1,200 to 8,000 people used statistically over long periods.



Census tract residents who had to travel for more than 60 minutes to reach the nearest clinical trial site were at significantly higher odds of traveling from a rural location, living among a higher percentage of the population at less than 200% of the federal poverty level, having completed only high school, and living in a census region of the Midwest, West or South as compared with the Northeast.

Census tract residents who did not have to travel more than 60 minutes to reach a clinical trial site had a significantly higher odds of being Black, Asian, or Hispanic; the association between driving distance of less than 60 miles and minority status may be the result of trending higher rates of minority urban residence.



Lower income previously was associated with increased rates of diabetic retinopathy. Findings suggest that clinical trials may not capture populations with the highest prevalence of diabetic retinopathy.

The limitations of this study are inherent to its observational design

In larger metropolitan areas, the distance between areas where high- and low-income White and minority populations reside is quite small, often differing from block to block. It is possible that in densely populated areas, by using census tract centroids, populations with varied sociodemographic backgrounds are considered equidistant to a clinical trial site, thereby masking potential socioeconomic or demographic predictors of the model. This may be another explanation as to why census tract residents of minority backgrounds showed a significantly higher odds of shorter distance and time to clinical trial sites.

Centroids = mean center of population in a given area.

Conclusions

Geographic maldistributions of clinical trial sites exist for diabetic eye disease in the United States. Those with higher travel burden are more likely to reside in a census tract that is rural, low income, and from areas outside the Northeast.

Access to clinical trials is important both for recruitment and retention of participants and for the generalizability of clinical trial data. It is imperative that clinical trial investigators expand efforts to provide access to patients from rural and other demographically disadvantaged communities.