Density and Proximity of Fast Food Restaurants and Body Mass Index Among African Americans

Lorraine R. Reitzel, PhD, Seann D. Regan, MA, Nga Nguyen, MS, Ellen K. Cromley, PhD, Larkin L. Strong, PhD, David W. Wetter, PhD, and Lorna H. McNeill, PhD

Obesity and its associated health conditions are a growing problem in the United States, with obesity prevalence having more than doubled since the 1960s.1 The health care cost of Americans' growing waistlines is substantial and expected to top \$860 billion by 2030.² Racial/ethnic disparities in obesity are of particular concern for the nation's health, with African Americans experiencing the highest prevalence of obesity relative to other racial/ ethnic groups.1 The National Health and Nutrition Examination Survey from 2009 to 2010 indicated that 38.8% of African American men and 58.5% of African American women were obese compared with 36.2% of non-Hispanic White men and 32.2% of non-Hispanic White women.³ Racial/ethnic disparities have also been cited for body mass index (BMI), with the gap in BMI growth widening between African Americans and Whites in recent decades.4

To better understand the factors associated with these trends, researchers and policymakers are paying increased attention to the retail food environment. The growing availability of low-cost, calorie-dense consumables from fast food restaurants (FFRs) is one of the factors implicated in the nation's rising BMI. 5-7 The availability of FFRs may be particularly relevant to the growing racial/ethnic disparities in BMI because several studies support a higher density of FFRs among predominately African American neighborhoods relative to predominately White neighborhoods. 8-11 Moreover, at least 1 study reports stronger relations between fast food availability and fast food consumption among non-White versus White populations.12 Thus, African Americans may be more likely to consume fast food if it is available, and it may be more available to them because FFRs tend to be clustered in African American neighborhoods. Not surprisingly, greater fast food consumption is associated with higher $\mathrm{BMI}.^{13\text{--}15}$

Several studies examined associations between the availability of fast food and BMI.

Objectives. The purpose of this study was to address current gaps in the literature by examining the associations of fast food restaurant (FFR) density around the home and FFR proximity to the home, respectively, with body mass index (BMI) among a large sample of African American adults from Houston, Texas.

Methods. We used generalized linear models with generalized estimating equations to examine associations of FFR density at 0.5-, 1-, 2-, and 5-mile road network buffers around the home with BMI and associations of the closest FFR to the home with BMI. All models were adjusted for a range of individual-level covariates and neighborhood socioeconomic status. We additionally investigated the moderating effects of household income on these relations. Data were collected from December 2008 to July 2009.

Results. FFR density was not associated with BMI in the main analyses. However, FFR density at 0.5, 1, and 2 miles was positively associated with BMI among participants with lower incomes ($P \le .025$). Closer FFR proximity was associated with higher BMI among all participants (P < .001), with stronger associations emerging among those of lower income (P < .013) relative to higher income (P < .014).

Conclusions. Additional research with more diverse African American samples is needed, but results supported the potential for the fast food environment to affect BMI among African Americans, particularly among those of lower economic means. (*Am J Public Health.* 2014;104:110–116. doi:10.2105/AJPH.2012. 301140)

Fast food availability was most commonly conceptualized as the density of FFRs near a person's home, work, or school environment. Findings about the associations of FFR density with BMI and overweight or obesity status, however, were mixed, 5,11 with some studies supporting positive associations, 16-19 and others citing null results.14,20 Less commonly, studies conceptualized fast food availability as the proximity of the closest FFR to a person's home. Studies taking this approach yielded mixed results regarding relations between FFR proximity and fast food consumption, 21,22 as well as between FFR proximity and BMI or obesity status. 11,23 Unfortunately, most of these studies focused predominately on White populations, and many had methodological limitations (e.g., self-reported BMI) that could have contributed to mixed results.5,11 We found only

a single study that focused on an all-African American sample, which yielded null results regarding associations between FFR density and BMI.²⁴ Although this study had several strengths, including a sample of more than 4500 African Americans and investigatormeasured BMI, limitations included only 1 conceptualization of FFR availability (FFR density), and the use of Euclidean distances ("as the crow flies") in density buffer calculation, which may be less realistic than buffers based on road networks (i.e., the only places along which FFRs can be found).5 In addition, we found no previous studies that examined whether associations between FFR availability and BMI were moderated by household income. Because reasons cited for frequent fast food consumption include both accessibility and affordability,⁶ it might be that relations of FFRs and BMI are stronger among

those of lower economic means for whom fast food might be more affordable than other dining options. Therefore, additional research is needed to better understand the relations of fast food availability and BMI among African Americans.

The purpose of this study was to address current gaps in the literature by examining the associations of FFR density around the home and FFR proximity to the home, respectively, with BMI among a large sample of African American adults from Houston, Texas. We additionally investigated the moderating effects of household income on these relations.

METHODS

Participant data were from the initial year of a longitudinal cohort study designed to investigate associations of behavioral, social, and environmental factors with health behaviors among African American adults recruited from a mega-church in Houston, Texas. Recruitment strategies included printed and televised media within the church and in-person solicitation during church services and at a church health fair. Individuals were eligible to participate if they were 18 years old or older, resided in the Houston area, had a functional telephone number, and attended church (membership was not a requirement).

Participants were 1467 African American adults enrolled from December 2008 to July 2009. Surveys were completed in person at the church. Participants were compensated with a \$30 Visa Debit Card following survey completion.

Measures

Participant residential locations. Participants provided their residential mailing address and their tenure at that address. These addresses were geocoded so that FFR density and proximity could be calculated. Specifically, an address locator was built using the ArcGIS software version 10.0 (ESRI, Redlands, California) with data from the Southeast Texas Addressing and Referencing Map. Overall, 1403 participants were successfully geocoded, with failures primarily caused by insufficient address information (e.g., P.O. Boxes). All geocoded participants resided

within the Houston Metropolitan Statistical Area.

Fast food restaurant locations. We obtained the locations of FFRs in the Houston Metropolitan Statistical Area from InfoUSA (March 2010 release). InfoUSA is a commercial database containing spatial data on various business types classified by the North American Industry Classification System (NAICS) and Standard Industrial Classification (SIC) codes. We defined FFRs as limited service restaurants (i.e., restaurants in which patrons generally order and pay before eating; NAICS code 722211 and Standard Industrial Classification code 5812) and hamburger and hotdog establishments (NAICS code 72221311). FFR locations (n = 3220) were integrated into a geodatabase for density and proximity variable calculation.

Fast food restaurant density. Four FFR density variables were created for each participant using the Service Area tool in the ArcGIS Network Analyst. Density variables were based on road network distances of 0.5, 1, 2, and 5 miles around the geocoded residential address. Although there are no standard distances used for density calculation in FFR research, these distances are among the most commonly used in accessibility studies^{14,21} and are consistent with those used in a similar study focused on African Americans.²⁴ The locations of FFRs were linked to the road network areas, and a count of FFRs within each buffer was obtained using the Spatial Join tool within ArcGIS. The resulting number of FFRs was then divided by the sum of the lengths of each road segment within the buffer area to obtain each of the FFR density variables. Using the road network distance for the calculation of density is a more accurate measure than polygon-derived area measurement because it better captures the spaces in which FFRs can be located (i.e., along the road network).

Fast food restaurant proximity. In this study, proximity represented the distance in miles from each participant's residence to the closest FFR along the road network, which was measured using the Closest Facility tool in ArcGIS Network Analyst.

Body Mass Index. Body mass index (BMI; defined as weight in kilograms divided by the square of height in meters) was a continuous

variable calculated by using staff-administered height and weight measurements. Height and weight (with shoes off) were each measured twice by stadiometer or scale and an average of the 2 consecutive measurements was used for BMI calculation.

Sociodemographics. Sociodemographic characteristics included age, gender, partner status (single, widowed, or divorced vs married or living with partner), total annual household income (<\$40~000/year vs \ge40~000/year$), educational level (< bachelor's degree, bachelor's degree, \ge master's degree), employment status (unemployed vs employed), tenure in years at the reported home address (\le 1 year or > 1 year), and presence of children in the home (yes or no). These variables were treated as covariates in the analyses because of known associations with the variables of interest. $^{5.14}$

Physical activity. Physical activity was assessed with the International Physical Activity Questionnaire—Short Format (IPAQ), a self-report questionnaire that measures the amount of time spent engaging in physical activity during the past 7 days.²⁵ The IPAQ was scored according to recommended guidelines (see Guidelines for data processing and analysis of the IPAQ, 2005, available at https://sites.google.com/site/theipaq/scoringprotocol), and the number of minutes of walking, moderate, and vigorous physical activities per week was included as a covariate in analyses because of its potential for confounding the associations of interest in this study.5

Television viewing time. The amount of television viewing time was calculated based on the self-reported number of hours spent watching television during a typical week. Television viewing time was included as a covariate in analyses given its association with BMI. ^{5,16}

Neighborhood median household income. Median household income at the tract level was obtained from the US Census (2000). Census tracts are administratively created units that have been supported as suitable local area proxies in previous health-related research. Neighborhood median household income was included as a covariate in analyses because of known associations with FFR density. 5,24,30

Statistical Analysis

Statistical analyses were performed using SAS version 9.2 (SAS Institute, Cary, North Carolina). Participant characteristics were examined using descriptive statistics. For the main analyses, a series of adjusted generalized linear regression models with Gaussian variance and the logarithmic link function (SAS PROC GENMOD) were used to examine the associations between FFR density and proximity, respectively, and BMI. This approach was selected in response to the positive skewness and heteroscedasticity of BMI. All models accounted for participant clustering at the Census tract. The first 4 models examined associations of FFR density 0.5, 1, 2, and 5 miles (respectively) around participants' homes and BMI. The fifth model examined associations of FFR proximity (in distance) and BMI. The antilogarithms of the parameter estimates were calculated using the inverse link function to present the percentage change in the mean value of BMI corresponding to the change in the predictor. All models controlled for participants' age, gender, partner status, total annual household income, educational level, employment status, residential tenure, the presence of children in the home, physical activity, television viewing time, and neighborhood median household income. Missing data for covariates were maintained in all models, resulting in a final sample size of 1244. Because we were interested in examining whether income was a significant moderator of adjusted associations between FFRs and BMI, we repeated the main analyses with an interaction term. Resulting models with significant interaction terms were followed by stratified analyses.

RESULTS

Participants (n = 1244; 76% female) were a mean age of 46 years (SD = 12.6), and slightly less than half reported being married or living with a significant other. A quarter of participants reported an annual household income of less than \$40 000 year. The average BMI among participants was 31.66 kg/m^2 (SD = 7.24; Table 1).

Participants were spread throughout the Houston Metropolitan Statistical Area, with at least 1 participant in each of 262 represented

TABLE 1—Participant Characteristics (n = 1244): 2008-2009

Variable	No. (%)	Mean ±SD
Age, y		45.52 ±12.60
Gender		
Male	299 (24.0)	
Female	945 (76.0)	
Education		
< bachelor's degree	625 (50.2)	
Bachelor's degree	384 (30.9)	
≥ master's degree	235 (18.9)	
Partner status		
Single/widowed/divorced	690 (55.5)	
Married/living with partner	554 (44.5)	
Employment status		
Unemployed	307 (24.7)	
Employed	937 (75.3)	
Annual household income, \$		
< 40 000	304 (24.4)	
≥ 40 000	940 (75.6)	
Residential tenure		
> 1 y	1064 (85.5)	
≤ 1 y	180 (14.5)	
Children (< 18 y old) in home		
No	779 (62.6)	
Yes	465 (37.4)	
Television viewing time, h/wk		27.63 ±20.50
Physical activity (self-reported min/wk)		713.23 ±699.49
Neighborhood median household income, \$		20 901.66 ±8481.2
Body mass index	1244 (100)	31.66 ±7.24
Underweight (range in sample = 16.7-18.4)	10 (0.8)	17.61 ±0.61
Normal (range in sample = 18.5–24.9)	193 (15.5)	22.74 ±1.63
Overweight (range in sample = 25.0-29.9)	371 (29.8)	27.69 ±1.40
Obese (range in sample = 30.0–70.5)	670 (53.9)	36.65 ± 6.00

Note. Participants were grouped into body mass index (BMI) categories for the purpose of sample description based on the following: underweight = BMI $16-<18.5\ \text{kg/m}^2$, normal = BMI $18.5-<25\ \text{kg/m}^2$, overweight = BMI $25-29.9\ \text{kg/m}^2$, and obese = BMI $25-29.9\ \text{kg/m}^2$. There were no severely underweight participants in this sample. BMI was treated as a continuous variable in analyses.

Census tracts (range = 1-85 participants per tract). Although all participants in the sample attended a single church, they resided from 0.2 to 71.5 miles from it, with a mean distance of 11.7 miles (SD = 8.9). Among the represented tracts of residence and irrespective of participant clustering, the neighborhood median household income ranged from \$6856 to \$79 400, with a mean of \$26 072 per year (SD = \$12 061). The proportion of African Americans in the represented tracts ranged from 0.3% to 98.3% with a mean of 29.9% (SD = 29.7%).

On average, there were 2.5 FFRs (SD = 1.9; range = 0–8) within 0.5 miles, 4.5 FFRs (SD = 4.2; range = 0–25) within 1 mile, 11.4 FFRs (SD = 9.8; range = 0–57) within 2 miles, and 71.3 FFRs (SD = 50.4; range = 0–261) within 5-miles of the geocoded residential addresses. Proximity from the residence to the closest FFR was a mean of 1.01 miles (SD = 0.768; range = 0.002–5.745). There were no significant differences in the average densities of FFRs around the home by participant income. However, participants of lower income were more likely to live closer to the closest FFR

TABLE 2—Relations of Fast Food Restaurant Density and Proximity with Body Mass Index Among All Participants and as Stratified by Income: 2008–2009

Predictors	All Participants		Income < \$40 000		Income ≥ \$40 000	
	Exp(B) (Exp[95%CI]) ^a	Р	Exp(B) (Exp[95%CI]) ^a	Р	Exp(B) (Exp(95%CI]) ^a	Р
Density 0.5-mile buffer	1.011 (0.968, 1.057)	.619	1.154 (1.036, 1.285)	.009	0.979 (0.939, 1.021)	.332
Density 1-mile buffer	1.010 (0.941, 1.085)	.777	1.276 (1.067, 1.526)	.008	0.959 (0.888, 1.035)	.281
Density 2-mile buffer	1.035 (0.906, 1.183)	.609	1.687 (1.069, 2.664)	.025	0.922 (0.808, 1.052)	.226
Density 5-mile buffer	0.922 (0.723, 1.176)	.513	0.884 (0.455, 1.717)	.716	0.889 (0.689, 1.148)	.367
Proximity, in distance	0.976 (0.965, 0.987)	< .001	0.924 (0.868, 0.983)	.013	0.985 (0.974, 0.997)	.014

Note. CI = confidence interval. Density was calculated by taking the number of fast food restaurants within the respective buffers and dividing it by the length of the associated road network. Proximity was calculated as the distance in miles along the road network from the participant's residence to the closest fast food restaurant. Generalized linear models with generalized estimating equations accounted for participant clustering within Census tracts. All models were adjusted for age, gender, partner status, total annual household income, educational level, employment status, residential tenure, the presence of children in the home, physical activity, television viewing time, and neighborhood median household income.

*aDenotes antilogarithm of parameter estimates and 95% CI.

(mean = 0.79 miles [SD = 0.48]) than were those of higher income (mean = 1.09 miles [SD = 0.83]; P < .001).

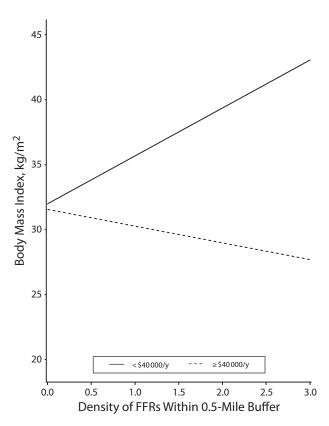
The density of FFRs around participants' residences was not significantly associated with BMI, regardless of buffer size. However, closer proximity to the closest FFR was associated with higher BMI (Table 2).

We found significant interactions between participant income and FFR density at the 0.5-, 1-, and 2-mile buffers (P=.013, .013, and .009, respectively), but not the 5-mile buffer (P= .596). Follow-up analyses stratified by participant income indicated significant and positive associations between FFR densities (within the 0.5-, 1-, and 2-mile buffers) and BMI among those of lower income, but not among those with higher income (Table 2). Figure 1 illustrates the adjusted relations of FFR density and BMI by income at the 0.5mile buffer. As shown, increased density of FFRs around the home was associated with higher BMIs among those earning less than \$40 000 a year in annual household income, but not among those earning \$40 000 a year or more. Figures for the 1- and 2-mile buffers were similar (data available as a supplement to the online version of this article at http:// www.ajph.org).

In addition, results indicated a significant interaction between participant income and FFR proximity (P=.029). Follow-up analyses indicated that the relation between closer FFR proximity and higher BMI was stronger among participants of lower income relative to those

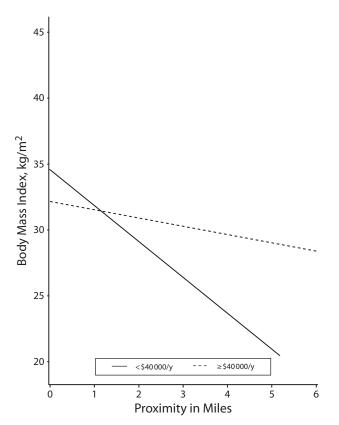
of higher income, but was significant for both groups (Table 2). Figure 2 displays the adjusted relations of FFR proximity and BMI by income.

As illustrated, increased distance between the home and the closest FFR was associated with lower BMI among both the lower and higher



Note. Density is the number of FFRs divided by the road network distance within the buffer; higher values indicate a greater density of FFRs.

FIGURE 1—Adjusted relations of the density of fast food restaurants (FFRs) within a 0.5-mile buffer and predicted body mass index by participants' annual household income: 2008–2009.



Note. Proximity is the distance in miles from the participants' home to the closest fast food restaurant; higher values indicate a greater distance between the home and the fast food restaurant.

FIGURE 2—Adjusted relations of fast food restaurant proximity and predicted body mass index by participants' annual household income: 2008–2009.

income groups, but at a steeper negative slope within the former.

DISCUSSION

We examined the associations of FFR density and proximity with BMI among an African American sample of adults in Houston, Texas. Consistent with a recent study conducted among African American adults in Jackson, Mississippi, ²⁴ our main analyses failed to support associations of FFR density with BMI. Similar null results were found in other studies conducted among more racially/ethnically diverse participants, but the literature was mixed overall. ^{5,11} The density by income interactions demonstrated in this study, however, pointed to a possible explanation for the inconsistency of previous research. Specifically, our study suggested that FFR density within 2 miles of

the home might factor into BMI, but only among people of lower economic means. This interaction did not receive targeted attention in previous research. However, because fast food is particularly affordable, it might have greater appeal among individuals with limited funds devoted to satisfying dietary needs. For these individuals, a greater number of FFRs around the home might make the consumption of fast food convenient in the context of their daily travels, or might represent ready destinations for socialization with friends who live nearby. Perhaps the greater number of FFRs functioned as a cue for the craving of caloriedense foods among those who tend to patronize FFRs.31 The potential for a biologically and psychologically based addiction to fast foods as fueling the obesity epidemic was explored in previous literature, with suggestions that obese individuals would be at increased vulnerability

for overeating in response to environmental cues like FFRs. 31 Additional research is needed to understand how FFR density affects dietary consumption among African Americans of varying economic means to identify potential mechanisms and elucidate the implications of these findings. Future studies in this area are especially important, given that results from this convenience sample of relatively well-educated, mostly female, church-going African Americans might not generalize to other samples.

Our study also examined the associations of

FFR proximity to the home and BMI. Results supported a strong cross-sectional relationship between these variables, even after controlling for a wide range of individual-level variables and neighborhood median household income. Specifically, we found that every additional mile participants lived from the closest FFR was associated with a 2.4% lower BMI. Thus, results for the sample as a whole suggested that the presence of even a single FFR in close proximity to the home might be enough to influence BMI, although longitudinal studies are needed with attention to dietary intake and FFR patronization to draw definitive conclusions. Relations between FFR proximity and BMI might reflect that only a single FFR is needed to purchase fast food, and the closer a FFR is to the home, the less the cost in effort (time and distance traveled) needed to patronize it. Having to travel farther to obtain fast food might be less appealing because it is simply less convenient. Perhaps the farther a FFR is from the home, the lower the likelihood of traveling past it in daily travels into and out of the neighborhood, thereby reducing the potential "cueing" for fast food consumption.31 Again, these hypotheses require additional research. It was also notable that associations of FFR proximity and BMI were stronger among those of lower economic means. These relations might again reflect the salience of FFRs among those who have difficulty affording a diverse range of dietary options. In addition, because FFRs were closer to the homes of those of lower income in this sample, this pattern of results might also reflect the increased convenience of FFRs for this group.

The stronger relations between FFR availability and BMI found among those of lower

income in this study, however, might also suggest the relevance of transportation availability. That is, those of lower income might have more difficulty obtaining transportation to shop for healthy foods or to eat at healthier restaurants outside of the immediate neighborhood, making fast food patronization a likely or frequent choice if FFRs are prevalent or close. Previous research suggested a stronger association of FFRs and BMI among those who did not have access to cars relative to those who did own a car.32 Transportation availability might also explain why relations between FFR density within 2 miles of the home (a reasonable walking distance) but not 5 miles of the home (a distance more amenable to automotive transport) was associated with higher BMI among those of lower income. Transportation availability was not measured in the present study, but should be included in future research assessing relations of FFR availability and BMI to further elucidate its influence among those of lower economic means.

Strengths and Limitations

Strengths of this study included attention to 2 dimensions of the FFR landscape: density and proximity. One of the largest previous studies in the area that included an all-African American sample examined only FFR density, 24 and so the examination of FFR proximity represented a novel contribution to the literature. An additional strength was the use of the road networks to measure FFR density. Many previous studies in this area used Euclidian distances, 5,24 which represented less realistic measures of FFR availability because they did not take into account the fact that FFRs could only be found along road networks. Also, our study was the first that we are aware of to investigate the moderating influence of household income on the relationships of interest. Other strengths of this study included the use of investigator-measured height and weight and attention to the control of potential confounders (e.g., physical activity) in the analyses.⁵ Of course, it was possible that we omitted additional variables of importance from our models, such as area-level racial/ethnic characteristics. Results from post hoc analyses additionally controlling for the percentage of African Americans at the tract level, however,

did not change the pattern of results. Finally, an additional strength was that we considered alternate conceptualizations of FFRs, including those most prevalent at a regional and national level, and examined proximity to FFRs in both distance and travel time, with consistent results (data available as a supplement to the online version of this article at http://www.ajph.org.).

Limitations of this study included a crosssectional design, which precluded establishing temporal relationships between FFR measures and BMI. Future studies might incorporate a longitudinal design, perhaps taking advantage of naturally occurring conditions, such as the opening and closing of FFRs in a community over time. 11 Because FFRs are increasingly offering healthier menu items,³³ studies assessing consumption choices are increasingly important to understand the impact of FFR availability on BMI. It was possible that our classification of FFRs missed important venues for fast food (e.g., convenience stores), as suggested by previous research.34,35 Future studies might also account for the broader food environment, including availability and accessibility of supermarkets and fresh produce, which might offset the effects of FFR proximity on BMI. 16

Additionally, although attention was paid to using FFR location information from the same year that the individual-level data were collected, the present study was unable to verify the accuracy of FFR locations. Previous research suggested inconsistencies between commercial databases and field observations of FFRs,³⁶ although the nature of this divergence was likely to vary spatially and might be more attenuated in urban than rural settings.³⁷ The use of a single data source for FFR locations, however, was common among studies in this area.⁵ An additional limitation included the use of neighborhood median household income data that were collected before the collection of individual-level data. Unfortunately, the most recent Census from 2010 did not include median household income at the tract level. and American Community Survey data were not ideal for this purpose because of concerns about population representativeness and geographically varying error.³⁸ Also, although this study controlled for self-reported physical activity, attention to the availability and accessibility of environmental resources for physical

activity would have further controlled for this pathway to BMI.

Our results might not be generalizable to other metropolitan areas or to rural areas, or to other samples of African Americans, including those with a greater representation of males or those who did not attend church. Likewise, our designation of what constituted lower versus higher income in this study was sample dependent, and information relevant to the calculation of poverty status or disposable income was not collected. Finally, we focused on FFR density and proximity around the home, and information about FFR locations around other areas of importance (e.g., participants' work locations) were unknown.

Conclusions

More research is needed to establish causal relations between FFR proximity, FFR density, and BMI among African Americans. Results, however, support the potential for the fast food environment to affect BMI among African Americans, at least among this sample of predominately female, well-educated African American church attendees. Results might suggest the utility of zoning laws or conditional use permits to regulate the locations and numbers of FFRs around residential areas.³⁹ Because racial/ethnic disparities in BMI and obesity have deleterious consequences for the health of African Americans, the importance of additional research in this area is clear.

About the Authors

At the time of the study, Lorraine R. Reitzel was with and Seann D. Regan, Larkin L. Strong, David W. Wetter, and Lorna H. McNeill are with the Department of Health Disparities Research, The University of Texas MD Anderson Cancer Center, Houston. Nga Nguyen is with the Department of Biostatistics, The University of Texas MD Anderson Cancer Center. Ellen K. Cromley is with the Department of Community Medicine and Health Care, The University of Connecticut School of Medicine, Farmington.

Correspondence should be sent to Lorraine R. Reitzel, PhD, Department of Educational Psychology, College of Education, University of Houston, 491 Farish Hall, Houston, TX 77204-5029 (e-mail: Lrreitze@mdanderson. org). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

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Contributors

L. R. Reitzel, S. D. Regan, E. K. Cromley, and D. W. Wetter conceptualized the research questions and methodologies. N. Nguyen scored the data, cleaned the data, performed all data analyses, interpreted results, and reviewed the data analysis and results sections.

S.D. Regan conducted the geocoding and all ArcGIS analyses, and contributed substantially to the Methods and Results sections. E. K. Cromley provided senior guidance over the ArcGIS analyses and contributed to their interpretation and the presentation of results. L. H. McNeill is the principal investigator of the research project on which the article is based, and L. R. Reitzel, L. L. Strong, and D. W. Wetter are co-investigators on the project and were vital in the conceptualization of the underlying research project and data collection. L. R. Reitzel wrote the article, and S. D. Regan, E. K. Cromley, L. L. Strong, D. W. Wetter, and L. H. McNeill reviewed and edited the article drafts.

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Human Participant Protection

Study procedures were approved by the institutional review board at The University of Texas MD Anderson Cancer Center, and informed consent was obtained from all participants.

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