International Scholars Journals

African Journal of Agriculture and Food Security ISSN 2375-1177 Vol. 5 (4), pp. 193-201, April, 2017. Available online at www.internationalscholarsjournals.org © International Scholars Journals

Full Length Research Paper

Food insecurity and the food store environment in the Southern United States: A Case Study of Alabama counties

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Accepted April 27, 2017

Access to nutritious and healthy food, a key pillar of food security, has become a national and global challenge particularly for individuals and families living in low-income neighborhoods and communities of color. Although no real consensus exists about the definition of food access, researchers have agreed that the components include nutritionally adequate, culturally appropriate and affordable food. Access involves households possessing sufficient income to purchase healthy food and includes proximity and the ability to travel to sources that offers such food. The lack of access contributes not only to poor health outcomes but to social inequity. Studies that measure food insecurity find major disparities in the food store environment by race and income and other socio-economic measures. This research assesses food store density as an indicator of the health of the food environment and its relations to food insecurity. It concluded that food insecurity rates were highest in rural, high minority counties located primarily in Alabama Black Belt. The results question the role of supermarkets as a solution to food security and conclude that the location of supermarkets and large grocery stores may not be the most effective solution to the "grocery gap" in low-income communities.

Key words: Food security, food access, food store density, food environment, grocery gap.

BACKGROUND/INTRODUCTION

Food security is a concept used to identify households which have high physical and economic limitations to food consumption (Maxwell, 1996; Maxell et al., 1999). The Food and Agricultural Organization's Rome Declaration on World Food Security indicates that persons are food secure, when, at all times, they have physical, social and economic access to food that is sufficient, safe, nutritious and meet dietary and cultural needs for healthy, active lifestyles. According to the United States Department of Agriculture (USDA), food security includes not only ready accessibility of nutritionally adequate and safe foods, but the guaranteed capability of households to obtain foods in socially suitable ways, not having to resort to the use of emergency food supplies, scavenging, stealing, or other coping strategies.

Food security, considered one of the most challenging social justice issues with which families and communities struggle on a daily basis, is a pervasive problem in Alabama and the United States as a whole. According to USDA's September 2015 Economic Research Report (ERR-194), an estimated 17.4 million American households (14.0%) were food insecure at least

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sometime during 2014 (Coleman-Jensen et al., 2015). Ten states exhibited statistically significant higher household food insecurity rates than the U.S. national average between 2000 and 2012; Alabama was the fourth largest behind Mississippi, Arkansas and Texas, with 17.9% (Feeding America, 2012). Rates of food insecurity were higher than the national average for households headed by non-Hispanic African Americans (26.1%) and Hispanics (22.4 percent). Coleman-Jensen et al. (2015) also show that the prevalence of food insecurity was highest for households located in nonmetropolitan areas (17.1%).

The four pillars of food security are availability, access, utilization and stability; the focus of this paper is on access. Access to wholesome, nutritious and healthy food has become a major national and global challenge, particularly for individuals and families living in low-income neighborhoods and communities of color (Morland et al., 2002; Franco et al., 2008). Maxwell (1996) discusses post-modern trends in food security and describes the shifts in the dimensions. Research and discussions shifted from global to national to the household and then to the individual perspectives and using more subjective indictors shifting from a food first perspective to a livelihood perspective.

In its 2007 Policy Guide, APA contends that although there is no agreed upon formal definition of food access, researchers have often established that the components of food access are three pronged. Access includes the availability of nutritionally adequate and culturally appropriate food, households possessing adequate income to acquire such food, and the proximity and the ability to travel to sources that offers such food. The literature shows that disparities in food access are influenced by geographic, economic, and social factors, but also by a community's food production, processing, distribution, consumption, and waste recovery policies and practices. Food access is more than a health issue; it is a key component for an equitable and sustainable society (APA Policy Guide, 2007).

In 2008, Congress, through the Food Conservation and Energy Act, directed the USDA to conduct a study to assess the extent of food access and to identify characteristics, causes and effects of limited access on local populations. Results indicate that some consumers are constrained in their ability to access affordable nutritious food because they live far from a supermarket or large grocery store and do not have easy access to transportation (Nord et al., 2005). Other findings include that economic access is constrained by the fact that convenience food stores and other nearby fringe food establishments often have higher prices than supermarkets and large grocery stores. In addition, many minority households and communities of color have low incomes and may not be able to afford the amount and type of food needed for a healthy lifestyle. Access barriers are both physical and economic. Some minority neighborhoods and communities of color are typified by unbalanced food options, with an overabundance of fast food and convenience stores rather than the healthy fresh produce often found in supermarkets and grocery stores (Franco et al., 2008).

Several studies (Pothukuchi, 2005; Powell et al., 2007; Franco et al., 2008; AlHasan and Eberth, 2016) highlight the problem that is addressed by this research; there are significantly fewer groceries and supermarkets located in poor urban areas than in suburban areas and as a result many poor urban residents often do not have access to the low prices and variety of selection of foods as their more wealthy counterparts. As a result, as concluded by these studies, economically disadvantaged communities have less access to supermarkets that offer affordable healthy food choices. These communities often become dependent on other food outlets such as fast foods and convenience stores. The presence of grocery stores and supermarkets, and the availability of healthy products, are important contributors to healthy eating patterns among neighborhood residents (Morland et al., 2002; Franco et al., 2008). Food insecure and low-income people are especially vulnerable due to the additional risk factors associated with insufficient resources and under-resourced communities. Flournoy and Treuhaft (2006) cites the Center for Food and Justice at the Urban and Environmental Policy Institute's 2002 study which found that middle and upper-income communities in Los Angeles County had twice as many supermarkets per capita as low-income communities. The same study found that white communities had three times the number of supermarkets as African American communities, and nearly twice those of Latino communities. The Policy Link and the Food Trust refer to the absence of large grocery stores and supermarkets as the "grocery gap" (Treuhaft and Karpyn, 2010).

Supermarkets and large grocery stores are deemed to have greater economic as well as nutritional advantages in comparison to other types of food stores. These stores often offer a wider selection of foods and brands and their operating capacity and economies of scale allow them lower wholesale costs in comparison to smaller stores, the latter of which theoretically pass their incrementally higher costs on to consumers (Alwitt and Donley, 1997). The lack of transportation is also echoed throughout the literature declaring that many low-income households do not have access to a car and cannot afford the costs associated with getting to a supermarket outside of their immediate neighborhood (Alwitt and Donley, 1997; Guy et al. 2004; Hendrickson et al., 2006). Eisenhauer (2001) also highlighted the tendency of persons to do their grocery shopping within two miles of their homes emphasizing the importance of transportation. As a result of this lack of transportation, low-income households are often less likely to travel to a supermarket outside of their neighborhood and instead purchase food items from nearby fast food and

convenience stores, forgoing cost and quality for convenience.

Research strongly suggests that making affordable, healthy foods more available to underserved residents would lead to their making healthier choices about what to eat and, ultimately, better health, while contributing to economic and neighborhood revitalization (Morland et al., 2002). Pothukuchi (2005) and Treuhaft and Karpyn (2010) also cite a number of studies about the lack of supermarkets. One such study conducted by USDA in 2009 found that 23.5 million people lack access to a supermarket within a mile of their home. Another multistate study found that low income census tracts had half as many supermarkets as wealthy tracts while another study found that eight percent of African Americans live in a tract with a supermarket, compared to 31 percent of whites. While individuals do make choices about their eating and exercise habits, the environment in which they live significantly impacts the choices they make.

Purpose of the Study and Conceptual Framework

There are myriad of factors that influence food choice. In addition to physiological and nutritional needs, there are biological (hunger, appetite), economic (cost, income), physical (access, distance), social (culture, family) and psychological (mood, attitude, beliefs) determinants (The Determinants of Food Choice, 2005). This study focuses on physical determinants of food access.

The purpose of this study is to assess the relationship between food insecurity rates in Alabama counties and their food environment mediated by key socio-economic characteristics of the counties' households. In this study we use a simple conceptual model, which hypothesizes that there is a direct correlation between the food environment - the density of healthy versus non healthy food stores - and food insecurity influenced by socio-economic characteristics of a community. The model focuses on geographic food access which has the advantage of readily and simple to obtain data and assessment methods which are relatively easy to use. Objective measures of geographic food access include density, which is the concentration of food outlets within a defined geographic area, specifically the number of stores per 1000 population and variety, which measure the degree to which different types of food outlets exist within a specific area.

METHODOLOGY

The methodology consists of a quantitative analysis of the relationship between the density of the food store environment and the rate of food insecurity. The food environment consisted of healthy food sources and unhealthy food sources. This research uses supermarkets and large grocery stores as a proxy for sources of healthy and available food. These retailers contain all the major food departments and offer a wide variety of food products, including perishable items like meat, produce and dairy, along with general merchandise items like cleaning supplies, paper products, and health/beauty care products. Convenience stores and fast food outlets are categorized as unhealthy food sources. Convenience stores are small establishments that provide commonly used foods and products that people use on a day to day basis. A convenience store's inventory is typically limited to high-convenience items and food basics that people commonly use and need quickly, such as soft drinks, and microwavable and prepared foods. Block et al. (2004) defined fast-food restaurants as chain restaurants that have two or more of the following characteristics: expedited food service, takeout business, limited or no wait staff, and payment tendered prior to receiving food.

Social and demographic factors are seen as mediating or moderating the impact of food environment variables on eating patterns and food security. The present study aims to extend the understanding of how local food environments vary across socioeconomic areas. Specifically, this study examines the relationship between four types of food store densities - fast food restaurants, convenience stores, supermarkets/wholesale club stores, and grocery stores- and food insecurity rates of Alabama's 67 counties. Food affordability and quality are not addressed in this study. The conceptualized framework, although oversimplified, is an effective starting point to look at the connections between household characteristics and the physical food environment in urban and rural counties.

Multiple secondary data sources were used. Data on about the number and density of the four types of food outlets were extracted from the USDA's Food Environmental Atlas (ERS, nd). Food security rates were extracted from the Feeding America's 2012 Overall Food Insecurity: Data by County -and Congressional District. Socio-economic variables were extracted from the US Census Bureau. All of the data used was publically available. The Alabama county map was retrieved from the US Census TIGER Line Files for 2012. County polygons were joined with county-level covariates using the spatial join tool in ArcGIS Desktop Version 10.2.2 for Windows from Environmental Systems Research Institute (ESRI).

Descriptive statistics and Pearson's correlation coefficients were computed to assess the crude relationship between each type of food outlet density and socio-economic characteristics using Statistical Package for Social Scientists [SPSS] software, Version 23 for Windows. To analyze the association between each food outlet density and socio-economic characteristics, linear regression models using ordinary least squares (OLS) method were calculated in SPSS. OLS regression was completed with food insecurity rate

as the dependent variable. The output was exported into Microsoft Excel to generate figures and graphs. The Excel database was also used to create bivariate maps in ESRI ArcGIS to represent the geographical distribution of the study variables.

RESULTS

The state of Alabama has 67 counties with a 2010 population of_ 4,779,736 ranking 29th _among the USA states with a population density of 94.4 persons per square mile. Figure 1 shows the mean scores for the variables used in the research.

Twenty counties had 10% or more of their populations that were considered as having low income and low access to a food store. These counties had 33% of their population at least one mile (or 10 miles in the rural areas) from the nearest grocery store or supermarket. They also had at least 20% of their population in poverty with median family incomes less than 80% of State-wide or metropolitan median family income. These counties range from the smallest, Greene County with 9,045 persons to Jefferson County whose 2010 population was 658,466. Wilcox and Greene are among the five counties with the highest proportions of their population with low income and low access to stores. The other three counties were Lowndes, Bullock and Macon. These five counties had some of the lowest populations, lowest median household incomes, highest poverty rates, highest proportion of households with no vehicles and low access and they exhibited persistent poverty. They also had some of the highest percentage of their households with no car and low access. Greene, Lowndes and Wilcox also had the highest African American population with 81.25%, 73.31% and 72.15%, respectively.

The mean poverty rate for the state was 22%. A total of 19 (28%) of the 67 counties are persistently in poverty; of these counties, 3 are classified as metropolitan (Hale, Lowndes and Pickens). USDA-ERS has defined counties as being persistently poor if 20.0% or more of their populations were living in poverty over the last 30 years (measured by the 1980, 1990 and 2000 decennial censuses and 2007-11 American Community Survey 5-year estimates). Using this definition, there are currently 353 persistently poor counties in the United States (comprising 11.2 percent of all U.S. counties). The large majority (301 or 85.3%) of the persistent-poverty counties are non-metro, accounting for 15.2% of all non-metro counties. Persistent poverty also demonstrates a strong regional pattern, with nearly 84% of persistent-poverty counties in the South

The mean number of households with no car and low access was 874 or 4.5%. This indicator shows the percentage of housing units that do not have a car and are more than one mile from a supermarket or large grocery store if in an urban area, or more than 10 miles from a supermarket or large grocery store if in a rural area. Lowndes, Wilcox, Perry, Macon, Hale, Green and Sumter had the top percentages of households with no car and low access (12.7%, 12.6%, 11.5%, 9.9%, 8.1% and 8.0%, respectively). Only two were metro counties (Lowndes and Hale). They were all majority African American. Macon County had the largest proportion of African Americans of all 67 counties with 82% followed by Green, Sumter, Lowndes and Wilcox with 81%, 75%, 73% and 72%, respectively. Thirty five counties had 15% and higher of their populations aged 65 years and older. Wilcox, Sumter, Greene, Hale and Perry counties were in this category.

The mean number of grocery stores fell from 12.8 to 11.4 representing a 10.9% decrease, while supermarkets showed a small increase from an average of 1.15 per county in 2007 to 1.73 in 2010 representing an 18.1% change. Supermarkets per 1000 persons increased also by 1.0% from .01 to .02 between 2007 and 2012 while grocery stores per 1000 decreased from 0.23 to 0.19, a 17.4% decrease. The number of convenience stores was much larger with an average of 44 stores in 2007 and 47 in 2012, an increase of 6.8%. Between 2007 and 2012, the mean number of convenience stores per 1000 person increased from 0.58 to 0.70 or 20.7%.

The mean number of convenience stores and fast food restaurants in Alabama Counties in 2012 was 46.79 and 51.97, respectively compared to grocery stores with 11.42 and supermarkets, 1.73. However, the density of grocery stores was 0.19, supermarkets 0.02, convenience stores 0.7 and fast food restaurants 0.58. In terms of accessibility measures (absolute numbers and density) convenience stores and fast food restaurants scores were much higher, implying a food imbalance with more unhealthy options. The healthy food stores had a density of 0.21 stores per 1000 persons, while the unhealthy food stores had a density of 1.28 stores per 1000 persons. The access to these fringe food outlets in Alabama counties was six times greater than healthy food sources. Sumter, Choctaw and Connech had no supermarkets and had the highest density of convenience food stores with 1.42, 1.17 and 1.16 respectively.

High food-insecurity rate counties were analyzed according to the geographic classifications of metropolitan, micropolitan and nonmetropolitan (rural). Based on the December 2005 listing of metropolitan and micropolitan statistical areas by the Office of Management and Budget, 28 counties in Alabama are part of metropolitan statistical areas, and 15 counties are part of micropolitan areas. Micropolitan areas, a nonmetropolitan classification, include an urban area with a population of 10,000 to 49,999 and surrounding counties that are linked through commuting ties. The remaining 24 counties in Alabama are considered noncore, rural counties. Consistent with Feeding America findings in 2012, the high food-insecurity rate counties were less likely to be metropolitan and more

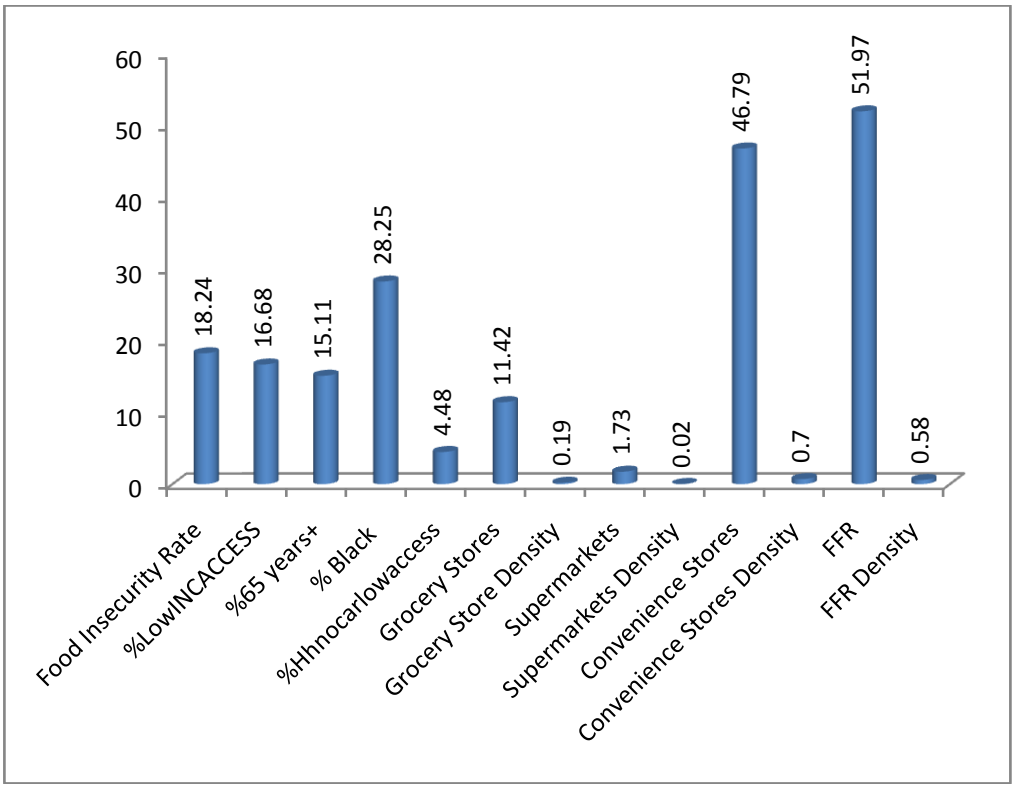

Figure 1. Mean Scores for Alabama Counties.

likely to be rural nonmetropolitan areas. Overall, the food insecurity rates were highest in rural counties (20.04%) and lowest in metropolitan counties (16.55%).

More than half (50.75% or 34) of Alabama's counties had food insecurity rates ranging from 15% and 20.99%. Six counties (10.45%) had rates above 25%. These six counties included Lowndes (25.6%), Perry (26.3%), Greene (26.6%), Sumter (27.7%), Dallas (28.6%) and Wilcox (29.8%). One of the six counties is considered urban (Lowndes) while the other five were rural counties. All of the six counties were located in Alabama's Black Belt, a region which is home to persistent poverty, high unemployment, limited education, poor health, single parenthood and heavy dependence on public assistance programs (Zekeri 2003). Of these six counties, Wilcox, Lowndes, Dallas, and Greene had no supermarket and Sumter County had the highest density of convenience food stores in 2012. Figure 2 displays the bivariate maps which depict the four food outlet densities and the rate of food insecurity prevalence, each based on three ranks (i.e., low, medium, high).

All 67 counties were considered low density for supermarkets while 61 counties were considered low density for grocery stores. On the other hand, one county and 10 counties were considered low density for convenience stores and fast food retailers, respectively. Twenty four and 21 counties were considered high density for convenience stores and fast food restaurant, respectively. Approximately 50% of the high concentration of convenience stores was located in rural counties. The five counties with the highest densities included Sumter, Choctaw, Connecuh, Tallapoosa and Marengo counties

Correlations

Pearson correlation coefficients between each food outlet density and food insecurity rate are presented in Table 1. Three food outlet densities reached statistical significance at the 0.05 level and were moderately correlated with food insecurity: grocery store (r = .404), convenience stores (r=.277) and fast food restaurants (r = -.300). Supermarkets (r = -0.168) had weak correlations with food insecurity rate and did not reach statistical significance. Food security is also correlated with population density (r=-.301), to the percentage of African Americans (r=.931) and with households with no car and low access (r=.786).

Table2 shows the multiple linear regression model summary and overall fit statistics. We find that the adjusted R^2 of our model is 0.223 with the R^2 = .270 which means that the linear regression explains 27.0% of the variance in the data. The Durbin-Watson d = 2.084, which is between the two critical values of 1.5 < d < 2.5 and therefore we can assume that there is no first order linear auto-correlation in our multiple linear regression data.

The F-test is highly significant and shows that our model is significant.

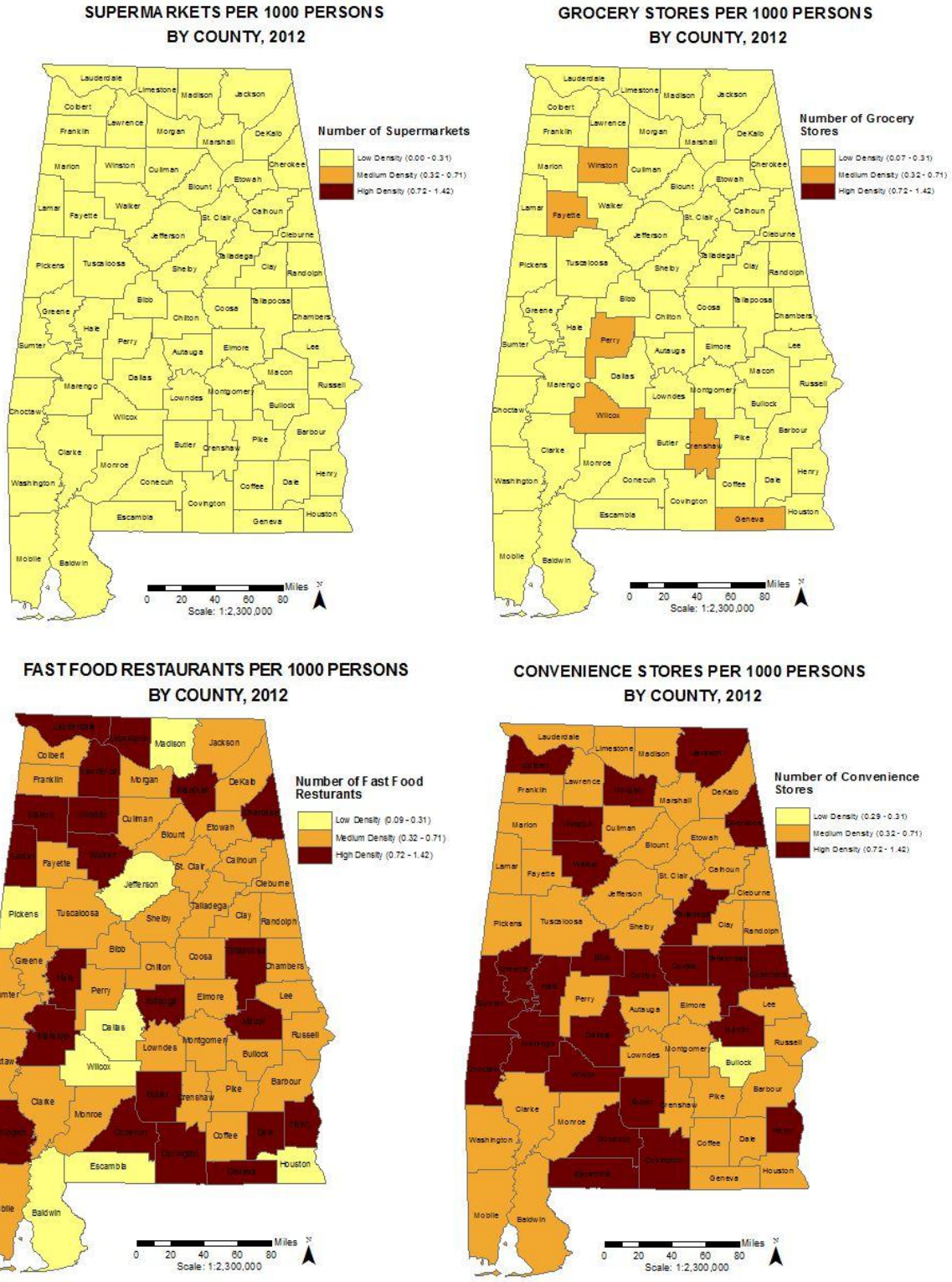

Figure 2. Food Outlet Density by Alabama Counties, 2012

DISCUSSION

Controlling for all covariates, the results showed that, compared to the availability in urban areas, all food store types and in particular, supermarkets and large grocery stores are significantly less available among rural areas. These results are consistent with the literature (Pothukuchi, 2005; Powell et al., 2007; Franco

Table 1. Pearson's Correlation Coefficients between density of food outlets and county level food insecurity rates in Alabama, 2012.

		Grocery Store Density	Supermarkets Density	Convenience Stores Density,	Fast Food Restaurants Density	Food Insecurity Rate
Grocery Store Density	Pearson Correlation	1	-.255*	.058	-.254*	.404**
	Sig. (2-tailed)		.037	.641	.038	.001
Supermarkets Density	Pearson Correlation	-.255*	1	-.066	.594**	-.168
	Sig. (2-tailed)	.037		.594	.000	.175
Convenience Stores Density	Pearson Correlation	.058	-.066	1	-.050	.277*
	Sig. (2-tailed)	.641	.594		.687	.023
Fast Food Restaurants Density	Pearson Correlation	-.254*	.594**	-.050	1	-.300*
	Sig. (2-tailed)	.038	.000	.687		.014
Food Insecurity Rate	Pearson Correlation	.404**	-.168	.277*	-.300*	1
	Sig. (2-tailed)	.001	.175	.023	.014	

**Correlation is significant at the 0.01 level (2-tailed).
* Correlation is significant at the 0.05 level (2-tailed).
N = 67

OLS regression

et al., 2008; AlHasan and Eberth, 2016) highlighting that convenience stores and fast food options tend to be more prevalent in more-deprived neighborhoods. Supermarket availability was found to be 6 times greater in urban versus rural areas. These findings are similar to other studies. Morland et al. (2002) underscored the importance of including characteristics of individuals' local food environments into future studies to gain a better understanding of barriers to healthy eating. They also contend that the retail sector has been affected by economic policies that support corporate retail chains, public- and private-sector loan policies that favor home ownership for whites, and land use policies that facilitate development of predominately wealthy and white suburban neighborhoods. Maxwell (1996) in his examination of the changes in the dimensions of food security demonstrates the value of relating food security to other topics related to the social and economic development of households and communities and connects it to a wider philosophical and cultural current. These findings have implications regarding the relative food prices faced by rural versus urban residents as a whole and, in particular, among the rural poor populations whose shopping patterns can be expected to be further constrained by mobility issues compared to their rural non-poor counterpart residents (Burkhardt et al., 1998).

Improving access to healthy food is a critical component in building equitable and sustainable communities. Assessment of the data shows that the high food-insecurity rate counties are concentrated among rural households which are more economically disadvantaged than the metropolitan counties. Counties of concern include Wilcox, Lowndes, Dallas, Greene, Macon and Sumter County. These food insecure counties possess persistently high levels of poverty, low median incomes and high proportions of minority communities. Feeding America (2012) points out the irony of this in that many of these food-insecure households are in the very rural and farm communities whose productivity feeds the world and provides low-cost wholesome food for American consumers.

Pothukuchi (2005) examines initiatives to encourage grocery store investment in communities, and factors for successful developments; she concludes that "systematic, citywide grocery initiatives are rare", with these efforts restricted to specific sites or developments due to heavy reliance on private sector enterprise, lack of action by the community, and lower priority given to grocery stores in commercial revitalization development.

Interest in the role of food access in promoting healthy, livable communities has been growing rapidly over the past decade. Even though it is an individual and/or family decision about the type, amount and quality of food to consume, their behavior to make healthy choices is improved when there is a supportive environment with affordable, accessible and healthy choices. Change in the food environment is important because the environmental context and conditions impact what and how much people eat and what food choices are available. In addition, actions are needed to address the disparity gaps that currently exist in availability and access to healthy foods in low-income and minority communities. Access to healthy food is associated with lower risk for a variety of cardiovascular diseases and conditions, however, decisions about food store location must be driven by good policy which must be based on solid data about the issue and its consequences. The lack of healthy food retailers also hinders community economic development particularly in neighborhoods that need private sector investment, activity hubs, and places of employment for the residents.

The research shows that only grocery store and convenience store density had moderate but significant

Table 2. Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.520[a]	.270	.223	.03788	.270	5.742	4	62	.001	2.084

a. Predictors: (Constant), Fast Food Restaurants per 1000 Population, 2012, Convenience Stores per 1000 Population, 2012, Grocery Store per 1000 Population, 2012, Supermarkets per 1000 Population, 2012

b. Dependent Variable: Food Insecurity Rate

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	.033	4	.008	5.742	.001b
	Residual	.089	62	.001		
	Total	.122	66			

a. Dependent Variable: Food Insecurity Rate

b. Predictors: (Constant), Fast Food Restaurants per 1000 Population, 2012, Convenience Stores per 1000 Population, 2012, Grocery Store per 1000 Population, 2012, Supermarkets per 1000 Population, 2012

Beta expresses the relative importance of each independent variable in standardized terms. Grocery store density and convenience store density are significant predictors; however, grocery store density has a higher impact than convenience store density (beta = .348 and beta = .250, respectively).This is surprising and unexpected. This table also checks for multicollinearity in our multiple linear regression model. Tolerance should be > 0.1 (or VIF < 10) for all variables, which they are.

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	Collinearity Statistics	
		B	Std. Error	Beta			Tolerance	VIF
1	(Constant)	.138	.025		5.526	.000		
	Grocery Store per 1000 Population, 2012	.165	.054	.348	3.070	.003	.917	1.091
	Supermarkets per 1000 Population, 2012	.204	.324	.086	.630	.531	.635	1.575
	Convenience Stores per 1000 Population, 2012	.054	.023	.250	2.299	.025	.994	1.006
	Fast Food Restaurants per 1000 Population, 2012	-.049	.027	-.250	-1.836	.071	.636	1.572

a. Dependent Variable: Food Insecurity Rate.

impact on food security rates. Therefore, the results of this simple analysis question the role of supermarkets as a solution to food security. The location of supermarkets and large grocery stores may not be the most effective solution to the "grocery gap" in low-income communities. A more concerted effort is needed including engaging local partners, and developers to develop strategies and policy recommendations to address the long term issue of access to healthy food.

LIMITATIONS

The study focused on an objective measure of the food store environment – geographic food access, however, people's perceptions of their food environments have also been recognized as a valid measure of helping to better understand the complex nature of the settings in which people make food choices. Studies have indicated that often times, objective measures do not necessarily reflect persons' opinions about their community food environments. Some studies have shown that persons' perceptions of their food environment is highly correlated to food-related behaviors such as food purchasing and diet quality rather than to objective food environment measures. Questions about how people interact with their environments to buy food and eat food have not been adequately addressed in the current literature.

Another limitation is in the use of counties and other types of administrative boundaries to define the study area. These boundaries do not necessarily represent neighborhoods as experienced by residents.

ACKNOWLEDGEMENT

The authors are very appreciative of the partial sponsorship and support of the Center for Urban and Rural Research at Alabama A&M University for this study. The financial support from the United States Department of Agriculture's Capacity Building Grant program (Award # 2012-38821-20067) is also hereby acknowledged. The constructive comments of peer reviewers were appreciated.

Conflict of Interest statement

The authors whose names are listed on the cover page certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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