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Associations Between Healthcare Utilization Factors and Diabetic Retinopathy Among Adult African Americans

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

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The Office of the Provost

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2019

Abstract

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by

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MPH, Walden University, 2015

MBBS, University of Lagos, 1983

Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Public Health

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Abstract

African Americans are disproportionately affected by diabetes mellitus (DM) and complications that include diabetic retinopathy and its disease and socioeconomic burdens. This study examined the relationships between diabetic retinopathy and health care utilization factors, such as gender, DM comorbidities of hypertension and hyperlipidemia, and health care access, among sampled African Americans with DM in the United States. The Andersen health care utilization model was the framework for the study. In this correlational cross-sectional study, data from the 2011-2016 National Health and Nutrition Examination Survey datasets were analyzed. Results of complex samples logistic regression showed that there were no significant associations between diabetic retinopathy and DM comorbidities of hypertension and hyperlipidemia, gender, and health care access, after controlling for hemoglobin A1C level, urine albumin-to-creatinine ratio (UACR), marital status, education level, and annual household income. UACR, annual household income, and adult education level were significantly associated with diabetic retinopathy ($p < .005$). Researchers might use findings from this study for further studies to establish cause-and-effect relationships between diabetic retinopathy and the related health utilization factors in this population. Positive social change might be effected by using results from the study in planning and developing effective public health interventions targeting specific African American populations, which might result in a reduction of the associated physical and socioeconomic burdens on these populations.

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Dedication

This study is dedicated to God all mighty for all his guidance and protection. This study is also dedicated to my parents, Pa. Ebenezer Olusanya Adesanya (deceased) and Ma. Dorcas Atoke Adesanya for instilling in my siblings and me the importance of pursuing quality higher education. I dedicate this study to my brother, Dr. Ayo-Oluwa Adesanya, for believing that I possess the ability, capability, capacity, and competence required for achieving this very important milestone in my life. I also thank you for your unprecedented support. My loving daughter, Folasade Olutayo Adesanya. This study is dedicated to you. I thank you for not giving up on me throughout this course, especially during the research period.

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Section 1: Foundation of the Study and Literature Review

Introduction

Diabetes mellitus (DM) is a disorder of metabolism characterized by chronic hyperglycemia due to defective insulin action, secretion, or both (American Diabetes Association [ADA], 2018; Chawla, Chawla, & Jaggi, 2016; World Health Organization [WHO], 2018). DM is commonly classified as Type 1 (T1DM) and Type 2 (T2DM) based on age and insulin requirements, with T1DM patients requiring insulin for sugar control and T2DM patients usually managed with lifestyle modification and oral medications, though parenteral insulin administration may be required for some cases (ADA, 2018; Punthakee, Goldenberg, & Katz, 2018; Shields et al., 2015; Skyler et al., 2017; Yan, Li, Qin, Mayberry, & Daniels, 2018). T1DM results from defective insulin secretion, whereas T2DM, the most prevalent type of DM globally, is usually seen in adults and occurs due to insulin resistance or decreased insulin secretion (ADA, 2018; WHO, 2018). A common clinical feature of DM, irrespective of its type, is chronic hyperglycemia that results from defective insulin secretion, insulin resistance, or both, which leads to continuous hyperglycemia and increasing insufficiency of insulin with time (ADA, 2018; Chawla et al., 2016; Okur, Karantas, & Siafaka, 2017; Punthakee et al., 2018; Shields et al., 2015; Skyler et al., 2017; Zaccardi, Webb, Yates, & Davies, 2016). Etiologic factors for DM pathophysiology (defective insulin secretion, insulin resistance or both, with resultant hyperglycemia) include genetics, age, race and ethnicity, gender, hyperlipidemia, hypertension, unhealthy diet, sedentary lifestyle, overweight and obesity, smoking, alcohol use, and socioeconomic status (ADA, 2018;

Baynes, 2015; Centers for Disease Control and Prevention [CDC], 2017; Skyler et al., 2017).

Uncontrolled DM, irrespective of its type, can lead to macrovascular (large vessel) disease affecting the heart and arteries, and microvascular (small vessel) disease affecting the eyes, kidneys and nerves (Beckman & Creager, 2016; Chawla et al., 2016; Ozawa, Bearse, & Adams, 2015; Solomon et al., 2017; WHO, 2018). DM is associated with concordant comorbidities, such as hypertension and hyperlipidemia, that are major intermediate factors in the development of macro- and microvascular diseases (Abdulghani, et al., 2018; Atchison & Barkmeier, 2016; Beckman & Creager, 2016; Cheng et al., 2014; Klimek, Kautzky-Willer, Chmiel, Schiller-Frühwirth, & Thurner, 2015; Lin, Kent, Winn, Cohen, & Neumann, 2015; Magnan et al., 2015; Mozaffarian et al., 2016; Pantalone et al., 2015; Romero-Aroca et al., 2016; Rosiek et al., 2016; Solomon et al., 2017; Wat, Wong, & Wong, 2016; Zhuo et al., 2014).

DM is currently diagnosed in about 23.1 million adults in the United States; 90% to 95% of adults living with diabetes have Type 2 DM (CDC, 2017b). Adult African Americans are disproportionately affected by DM, with a total percentage of 13.4% compared to 7.4% among Whites (ADA, 2018; CDC, 2017b). There was an increase in the prevalence of coexisting diabetes, hypertension, and hypercholesterolemia among U.S. adults from 3% in 1999–2000 to 6.3% in 2011–2012; higher among African Americans (10.2%), compared to Mexican Americans (6.1 %), other Hispanics (6.6%), Whites (5.6%), and 7.3% among other racial and ethnic groups (Song et al., 2016). DM concordant comorbidities, such as hypertension and hyperlipidemia, are major intermediate factors underlying cardiovascular disease such as diabetic retinopathy disparities of African-American populations (Beckman & Creager, 2016; Lin et al., 2015; Magnan et al., 2015; Mozaffarian et al., 2016; Pantalone et al., 2015; Rosiek et al., 2016; WHO, 2018; Zhuo et al., 2014). Chronic complications of diabetes, hyperlipidemia, and hypertension are associated with increased physical, mental, and socioeconomic burdens on populations, especially African Americans, who are disproportionately affected (Lang, & Marković, 2016; Lin et al., 2015).

Diabetic retinopathy occurs when chronic high levels of blood glucose cause damage to blood vessels in the retina, which can lead to (a) swelling and leaking, or (b) closure of the retinal blood vessels that can prevent passage of blood through the blocked vessels, and (c) new blood vessel formation in the retina (American Academy of Ophthalmology, 2018b). It is separated into two main stages that include non-proliferative diabetic retinopathy in the early stage, which may be symptomless, and proliferative diabetic retinopathy in the late and more advanced stage that may be vision-threatening (American Academy of Ophthalmology, 2018b). Diabetic retinopathy is a significant cause of preventable eye damage that includes blindness; each year, between 12,000 and 24,000 new cases of blindness are caused by diabetes retinopathy (Skaggs et al., 2017).

Between 2005 and 2008, the prevalence of non-vision-threatening diabetic retinopathy and that of vision-threatening diabetic retinopathy among adults 40 years and older in the United States was 28.5 % and 4.4%, respectively (Zhang et al., 2010). African American populations are disproportionately affected by diabetic retinopathy with a higher crude prevalence of 38.8% compared to 26.4% among Whites, and a higher vision-threatening retinopathy crude prevalence of 9.3% compared to 3.2% among Whites (CDC, 2017a; Zhang et al., 2010). Duration of diabetes, uncontrolled hyperglycemia, and hypertension are common important risk factors for the progression of diabetic retinopathy to vision-threatening diabetic retinopathy or loss of vision; glycemic and blood pressure control are effective in preventing diabetic retinopathy-related loss of vision (Chen et al., 2014; Chew et al., 2010; Do et al., 2015; Lee, Wong, & Sabanayagam, 2015; Lima, Cavalieri, Lima, Nazario, & Lima, 2016; Mendanha, Abrahão, Vilar, & Nassaralla, 2016; Romero-Aroca et al., 2016; Ting, Cheung, & Wong, 2016; Wat et al., 2016). Longer duration of diabetes, uncontrolled hyperglycemia, hypertension, and dyslipidemia are associated with diabetic retinopathy in African Americans (Papavasileiou et al., 2017; Penman et al., 2016).

Diabetic retinopathy, including its vision-threatening type, is preventable by strict blood sugar control, control of concordant comorbid conditions (hypertension and hyperlipidemia), early detection through regular eye-screening of patients with DM, and prompt management of diabetic retinopathy (ADA, 2018; Chew et al., 2014; Do et al., 2015; Rosiek et al., 2016; Yu et al., 2015). However, achieving tight control of blood sugar, hypertension, and hyperlipidemia; early detection through regular eye-screening of patients with DM; and prompt management of diabetic retinopathy depend on health care access (ADA, 2018; Chew et al., 2014; Do et al., 2015; Rosiek et al., 2016; Yu et al., 2015). Strict glycemic control and control of concordant comorbidities depend on self-management skills and activities such as medication adherence, self-monitoring of blood glucose, healthy eating, and regular physical activity that are gained through diabetes self-management education (ADA, 2018; Brunisholz et al., 2014; Chew et al., 2014; Dirani, Crowston, & vanWijngaarden, 2014; Do et al., 2015; Rosiek et al., 2016; Yu et al., 2015). Although adult African Americans are disproportionately affected by DM and diabetic retinopathy, adequate management of the disease—including early detection of diabetic retinopathy—may be elusive to this population due to racial and ethnic disparities in health care access in the United States (Hu, Shi, Liang, Haile, & Lee, 2016; Laiteerapong et al., 2015). There is a need to understand the association between some of the factors affecting health care utilization and diabetic retinopathy in adult African Americans with DM.

This research examined the association between health utilization factors of gender (predisposing), concordant comorbidities of hypertension and hyperlipidemia (need), health access (enabling), and diabetic retinopathy among sampled adult African Americans with DM in the United States. I analyzed data from a nationally representative dataset, the 2011-2016 National Health and Nutrition Examination Survey (NHANES) dataset (National Center for Health Statistics (NCHS), 2017a). Participants were adult African Americans with self-reported diabetes. I utilized the Andersen model of health services use, which purports that predisposing, enabling, and need factors influence individuals' health care utilization (Andersen, 1968; Andersen & Newman, 1973). I used the model in examining the relationships between diabetic retinopathy in African Americans and the demographic predisposing factor of gender; need factors of DM, hypertension, and hyperlipidemia, and enabling factors that facilitate health care access such as health insurance, availability of preventive, diagnostic services including eye screening services, and treatment services for DM and its comorbidities; availability of doctors and diabetes specialists; and geographic accessibility (Andersen, 1968; Andersen & Newman, 1973). There is a paucity of research on the associations between (a) a predisposing demographic factor of gender, (b) need factors such as DM comorbidities of hypertension and hyperlipidemia, and (c) enabling factors of health care access, which are all determinants of health care utilization and diabetic retinopathy in adult African Americans with DM in the United States. I conducted this research to identify health utilization factors associated with diabetic retinopathy that disproportionately affects adult African Americans with its sight-related functional and socioeconomic burdens. Through this research, a gap will be filled in literature with the understanding of the factors mentioned above responsible for diabetic retinopathy disparities in African-American populations.

This section includes (in the following order) the problem statement, purpose of the study, research questions and answers, theoretical foundation of the study, nature of the study, literature search strategies, literature review related to key variables and research questions, definitions, assumptions, scope and delimitations, significance, summary, and conclusions.

Problem Statement

In the United States, African American populations are disproportionately affected by diabetic retinopathy, which is related to the duration of diabetes, uncontrolled hyperglycemia, and hypertension (Beckman & Creager, 2016; Lin et al., 2015; Magnan et al., 2015; Mozaffarian et al., 2016; Pantalone et al., 2015; Rosiek et al., 2016; Zhuo et al., 2014). Diabetic retinopathy can be prevented through strict control of blood sugar, hypertension, and hyperlipidemia, early detection of diabetic retinopathy through regular eye-screening of patients with DM, and prompt management of diabetic retinopathy, which depends on health care utilization that may be elusive to adult African Americans with DM (Atchison & Barkmeier, 2016; Chen et al., 2014; Chew et al., 2014; Do et al., 2015; Hu et al., 206; Laiteerapong et al., 2015; Lee et al., 2015; Lima et al., 2016; Mendanha et al., 2016; Romero-Aroca et al., 2016; Ting et al., 2016; Wat et al., 2016). There is a dearth of research on the association between (a) predisposing demographic factor of gender; (b) need factors such as DM comorbidities of hypertension and hyperlipidemia; and (c) enabling factors of health care access that are determinants of health care utilization and diabetic retinopathy in adult African Americans in the United States. This research was informed by the Andersen model of health services use. This study helps fill the gap in the literature regarding the factors responsible for diabetic retinopathy disparities in African American populations.

Purpose of the Study

This was a quantitative research study, aimed at investigating the relationships between health utilization factors such as DM comorbidities, gender, health care access, and diabetic retinopathy among African Americans. I examined the relationship between the independent variables of (a) gender, (b) comorbidities of DM (e.g., hypertension hyperlipidemia), and (c) facilitators of health care access (e.g., current health insurance, primary care provider, diabetes specialists, and eye screening service) and the dependent variable of diabetic retinopathy. Covariates included education level, gender, and marital status (predisposing factors), annual household income (health care access), and urinary albumin-creatinine ratio (UACR) and HBA1C (need factors). For this study, I analyzed data from a nationally representative dataset, the 2011-2016 NHANES dataset.

Research Questions and Hypotheses

Research Question 1: Is there an association between gender and diabetes retinopathy among adult African Americans in the United States?

H_o1: There is no association between gender and diabetes retinopathy among adult African Americans in the United States

H_11: There is an association between gender and diabetes retinopathy among adult African Americans in the United States.

Research Question 2: Is there an association between DM-related comorbidities of hypertension, hyperlipidemia, and diabetic retinopathy among adult African American populations in the United States?

H_o2: There is no association between DM-related comorbidities of hypertension, hyperlipidemia, and diabetic retinopathy among adult African American populations in the United States.

H_12: There is an association between DM-related comorbidities of hypertension, hyperlipidemia, and diabetic retinopathy among adult African American populations in the United States.

Research Question 3: Is there an association between health care access and diabetic retinopathy among adult African Americans in the United States?

*H*o3: There is no association between health care access and diabetic retinopathy among adult African Americans with DM in the United States.

$H_1$3: There is an association between health care access and diabetic retinopathy among adult African Americans with DM in the United States.

Framework for the Study

As a framework for this study, I used the Andersen model of health services use, which purports that predisposing, enabling, and need factors influence individuals' health care utilization (Andersen, 1968; Andersen & Newman, 1973). Predisposing factors are sociodemographic characteristics, such as age, gender, race/ethnicity, education, employment, and marital status; need factors are motivators of health care use, including perceived need by individuals and assessed health status, which includes chronic health; enabling factors are those factors that facilitate the use of health care services by individuals, such as household income, availability of health care insurance, having a regular doctor, availability of needed services, and distance to the health care facility (Andersen, 1968; Andersen & Newman, 1973). The model is adaptable, and researchers have widely used it to examine factors that lead to health services utilization in various settings (Andrej et al., 2016; Brzoska et al., 2017; Hirshfield et al., 2018; Li et al., 2016; Luo et al., 2018; McClure et al., 2016; Petrovic & Blank, 2015; Tesfaye et al., 2018) The model is suitable in examining the relationship between the (a) demographic predisposing factor of gender; (b) enabling factors that facilitate health care access, including health insurance, availability of preventive and diagnostic services (e.g., eye screening services), treatment services for DM and comorbidity of hypertension and hyperlipidemia, availability of doctors and diabetes specialists, and geographic accessibility; and (c) need factors that include hypertension, hyperlipidemia, and diabetic retinopathy, which is an indirect measure of health care utilization in adult African Americans (Andersen, 1968; Andersen & Newman, 1973).

Nature of the Study

This research was a quantitative, nonexperimental, correlational cross-sectional study aimed at exploring the relationships between independent variables (i.e., gender, comorbidities of DM and hypertension, and health care access) and the dependent variable of diabetic retinopathy among a large sample of adult African Americans in the United States from 2015 to 2016. Covariates included education level, age group, marital status, albuminuria, HBA1C level, and income level. Data analyzed in this study were from a nationally representative dataset, the 2015-2016 NHANES dataset (CDC, 2017a).

Literature Search Strategies

In conducting the literature review, I used academic search engines and databases, including the Walden University Library search catalog, PubMed, Medline, ProQuest, Google Scholar, SAGE Journals, ScienceDirect, Thoreau Multi-Database Search, CINAHL & MEDLINE combined Search, and Cochrane. Criteria for inclusion in the literature review were primary peer-reviewed research articles on diabetic retinopathy, risk factors for developing diabetic retinopathy generally and among African Americans, diabetes comorbidities and diabetic retinopathy, eye care service utilization among adult African Americans with diabetes, and access to health care in African Americans. Keyword search emphasized locating articles on *Andersen model of health services use,* *and studies informed by the Andersen model of health services use*. To find literature on adult African Americans with diabetes and retinopathy search terms included *comorbidities and retinopathy, perceptions of adult African Americans on diseases, sociodemographic influence on diabetic retinopathy, access to health care in African-Americans, access to health care in African Americans with DM, access to health care in African Americans with DM and retinopathy, eye screening service use among adult diabetics,* and *screening service utilization among adult African Americans with diabetes*. The selected articles were written in English, peer reviewed, and not older than 2014 except seminal articles on the Andersen model of health services use, which is the theoretical framework for this research, and articles that filled gaps in the literature. In addition to the academic search engines, grey literature sources such as non-peer-reviewed government and nonprofit publications including the CDC and the Agency for Healthcare Research and Quality websites were searched for data; the U.S. Department of Agriculture and U.S. Department of Health and Human Services websites were searched for dietary practice guidelines; the U.S. Department of Health & Human Services/Office for Human Research Protections website was also searched for information on basic health and human services policy on protection of human research participants; and the ADA and American Academy of Ophthalmologists websites were searched for practice guidelines and definitions.

Literature Review Related to Key Variables and Concepts

From the literature search, I selected 56 articles that met the inclusion criteria. Among these articles were critical reviews of the literature related to DM comorbidities and diabetic retinopathy, sociodemographic risk factors for diabetic retinopathy, and factors that determine health care access among African Americans. The study design for many of the selected articles was cross-sectional; other study designs used included longitudinal, prospective, retrospective, randomized clinical trial, case study, quasi-experimental, mixed methods, pre-post, surveys, and systematic reviews. The literature review is presented according to the framework for this study and key variables of diabetic retinopathy, gender, DM comorbidities associated with diabetic retinopathy, health care access, and research questions.

Constructs of the Andersen model of health services use suggest that predisposing, enabling, and need factors influence individuals' health care utilization (Andersen, 1968; Andersen & Newman, 1973). Predisposing factors are sociodemographic such as age, gender, race/ethnicity, education, employment, household income, and marital status; need factors are motivators of health care use that include perceived need by individuals, assessed health status that includes chronic health such as DM, hypertension, hyperlipidemia, albuminuria, and HBAIC; and enabling factors that facilitate the use of health care services by individuals such as availability of health care insurance or ability for out-of-pocket-payment, having a regular doctor, availability of needed services, and distance to the health care facility (Andersen, 1968; Andersen & Newman, 1973). The model was developed by Andersen in 1968 but has evolved (Andersen, 1968; Andersen & Newman, 1973). It has been widely utilized in examining the factors that lead to health services utilization in various settings (Andrej, Rok, & Prevolnik, 2016; Brzoska, Erdsiek, & Waury, 2017; Hirshfield et al., 2018; Li et al., 2016; Luo et al., 2018; McClure et al., 2016; Petrovic & Blank, 2015; Tesfaye et al., 2018). For example, Hirshfield et al. (2018) used this model as a framework for a cross-sectional study to examine risk factors for developing hypertension among a sample of 7,454 men with male sexual partners in the United States. According to Hirshfield et al., even though about a third of U.S. men are living with hypertension, the diagnosis and management of which depend on health care utilization, there is a dearth of studies on hypertension among men who have sex with men. The following factors were identified: predisposing factors of race, age, education, relationship status; need factors such as perception of being overweight, living with DM, heart disease, stroke, anxiety or depression; and enabling factors of having a regular doctor, current income, current health insurance, residence in South Atlantic or South Central; self-report of hypertension was used as a proxy measure of health care utilization (Hirshfield et al., 2018).

In this research, the Andersen model of health services use is suitable for examining the associations between the main independent variables and covariates of sociodemographic predisposing factors, need factors, enabling factors, and the dependent variable of diabetic retinopathy that is an indirect measure of health care utilization (Andersen, 1968; Andersen & Newman, 1973).

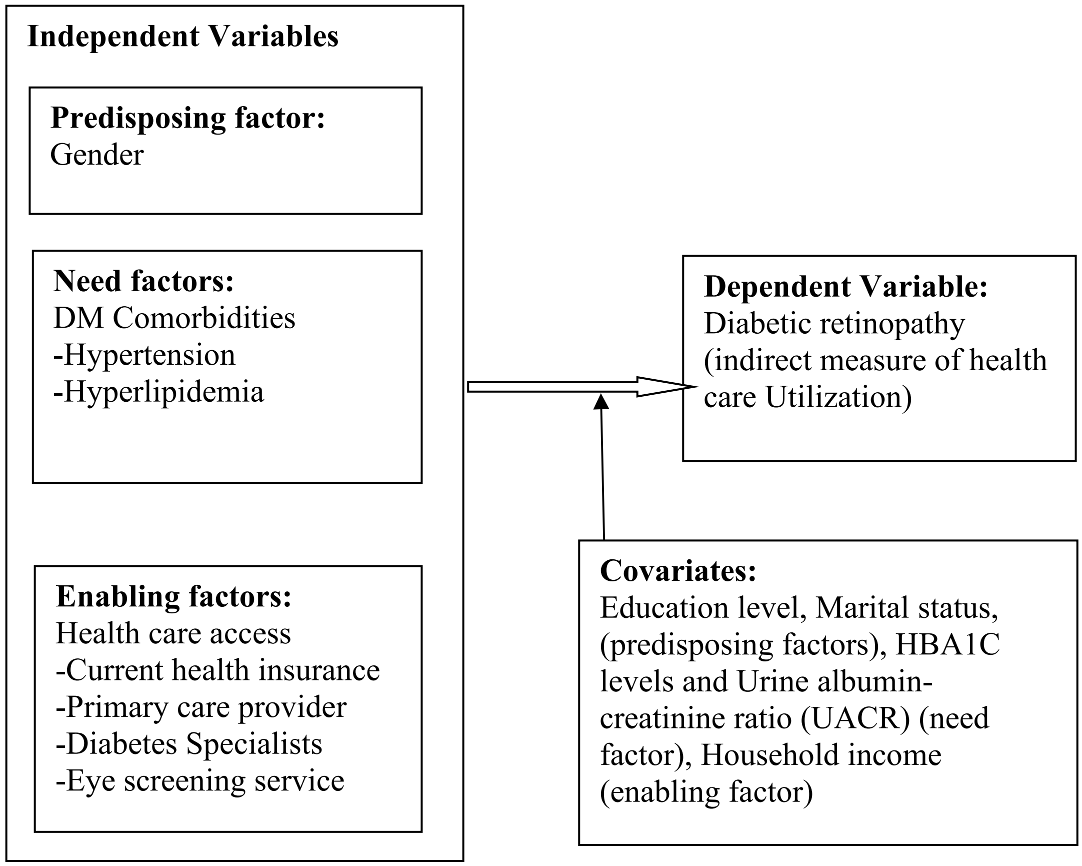

Figure 1. Conceptual framework for associations between DM comorbidities, gender, and diabetic retinopathy among adult African Americans with DM.

Diabetic Retinopathy

Diabetic retinopathy is a common DM complication (Lin et al., 2015; Magnan et al., 2015; Pantalone et al., 2015; Rosiek et al., 2016). Diabetic retinopathy occurs when chronic high levels of blood glucose cause damage to blood vessels in the retina, which can lead to (a) swelling and leaking, or (b) closure of the retinal blood vessels that can prevent passage of blood through the blocked vessels, and (c) new blood vessel formation in the retina (American Academy of Ophthalmology, 2018b). Diabetic retinopathy is separated into two main stages that include the early stage, nonproliferative diabetic retinopathy, which affects many individuals with diabetes and may be symptomless, and proliferative diabetic retinopathy in the late and more advanced stage, which may be vision-threatening (American Academy of Ophthalmology, 2018b).

In the United States, diabetic retinopathy is the most common microvascular complication of diabetes and is the primary cause of new cases of blindness among adults living with diabetes between ages of 20 and 74 years (Jani et al., 2017). Results of a cross-sectional study (analysis of data from NHANES 2011 - 2014 cycles) conducted by Shah (2016) suggested that the prevalence of diabetic retinopathy among U.S. adults, 40 years old and over, was 14.7% (95% confidence interval [*CI*], 11.7–17.8%); prevalence among males was 16.1% (95% *CI*, 13.0–19.1%), and among females was 13.4% (95% *CI*, 9.2–17.5%). In a cross-sectional study from the analysis of NHANES 2005-2008 data, Zhang et al. (2010) demonstrated diabetic retinopathy prevalence of 28.5% (95% *CI*, 24.9–32.5%) and vision-threatening diabetic retinopathy prevalence of 4.4% (95% *CI*, 3.5–5.7%), which was higher among adult African Americans compared to Whites (38.8% versus 26.4%, $p = .01$), and slightly higher among males than females (31.6% versus 25.7%, $p = .04$); independent risk factors were male gender, longer duration of diabetes, insulin use, higher HBA1C level, and higher systolic blood pressure. Duration of diabetes, uncontrolled hyperglycemia, and hypertension are common important risk factors for the progression of diabetic retinopathy to the vision-threatening type or loss of vision (Atchison & Barkmeier, 2016; Chen et al., 2014; Chew et al., 2014; Do et al., 2015; Lee et al., 2015; Lima et al., 2016; Mendanha et al., 2016; Romero-Aroca et al., 2016; Ting et al., 2016; Wat et al., 2016). Longer duration of diabetes, uncontrolled hyperglycemia, hypertension, and dyslipidemia are associated with diabetic retinopathy in adult African Americans (Papavasileiou et al., 2017; Penman et al., 2016).

Diabetic retinopathy is a leading cause of preventable eye damage, which includes blindness; each year 12,000–24,000 new cases of blindness are caused by diabetic retinopathy (Skaggs et al., 2017). Diabetic macular edema is a significant cause of sight loss in 1038 individuals living with DM (Varma et al., 2014). Results of a cross-sectional study (data from NHANES 2005-2006 and 2007-2008 cycles were analyzed) by Varma et al. (2014) suggested that African Americans with diabetes have a higher likelihood of developing diabetic macular edema. Longer duration of diabetes and elevated levels of HBAIC were associated with its prevalence. As a significant cause of socioeconomic burden in the United States, results of a cross-sectional study by Willis et al. (2017) on 1004 adults living with diabetes in the United States showed a significant relationship between sight-related functional burden and types of diabetic retinopathy with high severity.

There is a need for preventive measures against diabetic retinopathy of high severity to minimize sight-related functional burden among adults living with diabetes in the United States because there is a higher likeliness of not being involved in any gainful employment due to decreased vision (Sherrod et al., 2014; Willis et al., 2017). Understanding the factors that determine the utilization of treatment and preventive DM services by adult African Americans with diabetes will be useful for developing appropriate services. As such, research on the relationships between health care utilization factors and diabetic retinopathy in this population was necessary.

Gender

In the United States, there is no significant gender-related difference in the prevalence of diagnosed DM among adults (CDC, 2017). Systematic reviews by Ozawa et al. (2015) and Wat et al. (2016) did not demonstrate a strong association between gender and retinopathy. However, the results of Zhang et al.'s (2010) cross-sectional study in the United States showed that male gender is an independent risk factor for diabetic retinopathy. Similar results were obtained from a cross-sectional study among adult Saudi diabetic patients by Abdulghani et al. (2018), which showed an association between male gender and diabetic retinopathy. Although there was no statistically significant difference in diabetic retinopathy incidence in the Los Angeles Latino eye study, males had a 50% higher risk of having any diabetic retinopathy (OR = 1.50; p = .006) compared with women as demonstrated by their stepwise multivariate model (Varma et al., 2007). Similar results were demonstrated by the United Kingdom prospective diabetes 50 study; there was no difference in diabetic retinopathy rates between male and female sexes (p = 0.67), but there was a lower risk ratio of diabetic retinopathy progression in women as shown by a multivariate model (Strutton et al., 2001).

Review of literature on the relationship between gender and diabetic retinopathy showed that the association between gender and development of diabetic retinopathy has not been established. Even though the results of Zhang et al.'s (2010) study on a representative sample of the United States population suggested that male gender is an independent risk factor for diabetic retinopathy, the prevalence was higher among Whites

59.7 %; 95% *Cl*, 49.5%–69.1%) compared to African Americans (24.0%; 95% *Cl*, 18.2%–30.8%; $p = .008$). The cross-sectional design of this study will affect the generalizability of the result beyond the study population. The study by Penman et al. (2015) was on adult African Americans with diabetes, but only the results for female participants was reported and was statistically insignificant (60.3%; $p = .27$); moreover, small sample size and purposive sampling design utilized will affect the generalizability of the results beyond the study population. There was a need to carry out a study on the association between gender and diabetes retinopathy among adult African American population on a large sample that is representative of this population.

Comorbidities

DM is associated with concordant comorbidities such as hypertension and hyperlipidemia that are major risk factors in the development of macro and microvascular diseases (Abdulghani, et al., 2018; Atchison & Barkmeier, 2016; Beckman & Creager, 2016; Cheng et al., 2014; Klimek et al., 2015; Lin et al., 2015; Magnan et al., 2015; Mozaffarian et al., 2016; Pantalone et al., 2015; Raum et al., 2015; Romero-Aroca et al., 2016; Rosiek et al., 2016; Solomon et al., 2017; Song et al., 2016; Wat et al., 2016; Walraven et al., 2015; Zhuo et al., 2014). Cardio-metabolite risk factors for diabetic retinopathy include hypertension, hypertriglyceridemia, hypocholesterolemia (HDL), and abdominal obesity (Cheng et al., 2014). According to the results of a study by Cheng et al. (2014) in China, diabetic retinopathy prevalence when associated with one, two, three, and four of the cardio-metabolites was 16.0%, 17.6%, 21.3%, and 25.1%, ($p = .001$) respectively. However, results of a prospective cohort study on 759 adult diabetic patients

(25-75 years) without diabetic retinopathy in Korea (followed up for 11 to 12 years), suggested that glycemic control, age, and albuminuria were significant risk factors for the development of diabetic retinopathy (Yun et al., 2016).

DM concordant comorbidities of hypertension and hyperlipidemia are major intermediate factors underlying cardiovascular disease such as diabetic retinopathy disparities of African American populations (Beckman & Creager, 2016; Lin et al., 2015; Magnan et al., 2015; Mozaffarian et al., 2016; Pantalone et al., 2015; Rosiek et al., 2016; Zhuo et al., 2014). Results of a cross-sectional study (analysis of NHANES data from 1999 to 2012) by Song et al. (2016), showed an increase in the prevalence of coexisting diabetes, hypertension and hypercholesterolemia among United States adults from 3% in 1999–2000 to 6.3% in 2011–2012 ($p < .001$). According to Song et al. concordant comorbidities of DM, hypertension, and hyperlipidemia in 2012 was higher among African Americans (10.2%, $p < .001$), compared to Mexican Americans (6.1 %, $p = .020$), other Hispanics (6.6%, $p = .220$), Whites (5.6%, $p < .001$), and other racial and ethnic groups (7.3%, $p = .450$). A study was carried out by Penman et al. (2015) to examine individual and demographic risk factors for proliferative diabetic retinopathy in adult African Americans with T2DM. African Americans with Type 2 diabetes ($n = 358$) were recruited from four sites in Mississippi and Massachusetts (Penman et al.). The results demonstrated that longer duration of diabetes (OR, 1.62, $p < .001$), systolic hypertension (OR 1.65, $p < .001$), and insulin treatment (OR 6.65, $p < .001$) were strong risk factors for the development of proliferative diabetic retinopathy (Penman et al.). Although HBA1C was statistically significant in the univariate analysis (OR 1.3, $p =$

.002), it was not significant in multivariate analysis (OR 1.04, *p* = 0.68) (Penman et al). Total cholesterol (p = 0.42), triglyceride (*p* = 0.49); LDL cholesterol (p = 0.39); and HDL cholesterol (p = 0.52), were not statistically significant (Penman et al.).

Hypertension and hyperlipidemia are modifiable diabetes concordant comorbidities. Several studies have demonstrated that hypertension and hyperlipidemia have positive associations with the development of diabetic retinopathy (Abdulghani, et al., 2018; Beckman & Creager, 2016; Cheng et al., 2014; Do et al., 2015; Klimek, Kautzky-Willer, Chmiel, Schiller-Frühwirth, & Thurner, 2015; Lin et al., 2015; Magnan et al., 2015; Mozaffarian et al., 2016; Pantalone et al., 2015; Romero-Aroca et al., 2016; Rosiek et al., 2016; Solomon et al., 2017; Song et al., 2016; Wat et al., 2016; Zhuo et al., 2014). A meta-analysis by Wang et al. (2015) found a decreased risk of retinopathy of about 7 %, decreased risk of progression of diabetic retinopathy of about 5%, and an increased probability of diabetic retinopathy regression in diabetics on renin-angiotensin system inhibitor. There was a statistically significant decreased risk of diabetic retinopathy progression (0.84, *p* =.002), and an increased probability of diabetic retinopathy regression (1.50, p=.003) in diabetics on treatment with angiotensin-converting enzyme inhibitors; however, there was only an association between the use of angiotensin receptor blockers and decreased diabetic retinopathy progression (1.32, p=.008) (Wang et al.). However, the result of a Cochrane review by Do et al. (2015) showed hypertension treatment can prevent diabetic retinopathy but does not slow its progression. Results of a Danish study showed that use of statins before diagnosis of DM was associated with diabetic retinopathy development; its use was also linked to improvement in visual acuity in those with diagnosed diabetic retinopathy (Nielsen & Nordestgaard, 2014).

Researchers have identified comorbidities associated with diabetic retinopathy and the advanced types of proliferative retinopathy and macular edema. Most of the studies were on mixed populations with minimal representation of African Americans, purposive sampling and cross-sectional study designs were mostly used, which will affect the generalizability of the study results beyond the study populations. There was a need to identify comorbidities associated with diabetic retinopathy on a large representative sample of adult African Americans.

Health Care Access

Health care access is the ability to gain entry into or utilize personal health care service for achieving optimum outcomes in health (HealthyPeople.gov., 2018). Three steps involved in achieving health care access include (a) getting into the health care system that is commonly through medical insurance coverage, (b) geographic accessibility of required health care services, and (c) identifying a trustworthy health care provider that can be easily communicated with (HealthyPeople.gov., 2018). Prevention of diabetic retinopathy and its progression to its vision-threatening type depend on health care access (Atchison & Barkmeier, 2016; Chen et al., 2014; Chew et al., 2014; 2016; Do et al., 2015; Lee et al., 2015; Lima et al., 2016; Mendanha et al., Romero-Aroca et al., 2016; Ting et al; Wat et al., 2016).

Obtaining recommended diabetes preventive services is dependent on the status of medical insurance (Bailey et al., 2016). Bailey et al. (2016) carried out a retrospective cohort research to determine any relationship between disparities in diabetes prevention services obtained and status of medical insurance during health care facility visit. Medicaid and electronic health record data of study participants from 38 community health centers in Oregon from 200-2007 were analyzed (Bailey et al.). Study participants were categorized as patients that were insured throughout the study period (continuously insured), uninsured throughout the study period (continuously uninsured), and those without insurance for part of the study period (discontinuously insured). There were 1,466 patients that were insured continuously; 1,117 uninsured continuously; and 336 insured discontinuously (Bailey et al.). Results suggested that patients without continuous insurance had lower odds of obtaining diabetes prevention services during scheduled visits compared to patients with continuous insurance (odds ratio = 0 .73, 95% CI = 0.66); and among the patients without insurance for part of the study period, probability of not obtaining diabetes preventive services due for the scheduled visit was associated with not being insured at that particular clinic visit (odds ratio =0.77, 95% CI = 0.64) compared to when insured at the particular clinic visit (Bailey et al.).

Early detection of diabetic retinopathy is of extreme importance in preventing loss of vision, and timely medical and surgical treatments have dramatically reduced diabetic retinopathy progression (Jani et al., 2017). The effectiveness of diabetic retinopathy screening programs depends on how patients adhere to the schedule of follow-up eye management as recommended by the diabetic retinopathy screening program (Keenum et al., 2016). Although African Americans are among those at highest risk for diabetic retinopathy, they had one of the lowest rates of diabetic retinopathy screening and scheduled follow-up eye care utilization (Keenum et al., 2016; Maclennan et al., 2014; Yu et al., 2015). Factors that influence screening include lack of health care access that is influenced by health insurance coverage, transportation, and accessibility to an eye specialist, late or non-referrals from primary care physicians, inadequate communication between primary care physicians and eye specialists, misinformation about diabetic retinopathy screening, miscommunication about patients' addresses, patients' detachment from diabetes care, and lack of diabetes-management education in those living with diabetes (Al-Alawi et al., 2016; Chou et al., 2014; Hipwell et al., 2014; Jani et al., 2017; Kashim et al., 2018; Lindenmeyer et al., 2015; MacLennan et al., 2014; Piyasena et al., 2019; Spears et al., 2018; Strutton et al., 2016).

In a prospective follow-up study, Keenum et al. (2016) examined the rate of adherence to recommended follow-up eye care in a diabetic retinopathy screening program administered in a health care facility that provides access to care irrespective of the patients' affordability. Study participants were individuals with Type 1 diabetes or T2DM receiving care in an internal medicine clinic of a health system with retinopathy screening program in Alabama that is publicly funded, which serves a predominantly uninsured African American population (Keenum et al.). Results suggested that after the diabetic retinopathy screening, only a third of study participants adhered to scheduled intervals for follow-up eye care despite minimizing accessibility and costs as barriers to eye care (Keenum et al.). Keenum et al. suggested incorporating eye education strategies to promote adherence to recommended eye care that can prevent loss of vision from diabetic retinopathy.

Telemedicine is an emerging strategy for improving evaluation for diabetic retinopathy through retinal imaging in the primary care setting with remote interpretation by an expert (Jani et al., 2017; Mansberger et al., 2015). In the United States, diabetic retinopathy was identified in 1 out of 5 individuals living with diabetes through a diabetic retinopathy telemedicine screening offered in urban clinical or pharmacy environments largely that were mostly utilized by racial and ethnic minorities (Owsley et al., 2015). A pre- and post-implementation evaluation by Jani et al. (2017) at five primary care clinics providing health care services to underserved populations in North Carolina showed that rate of diabetic retinopathy evaluation is increased by retinal telemedicine screening for diabetic retinopathy in patients in underserved populations; access to care for minorities and patients with diabetic retinopathy requiring treatment in the primary care setting might also be increased. With early identification of patients at risk of loss of vision, retinal telemedicine programs can lead to decreased health care costs and reduce the socioeconomic burden of vision-threatening visual loss on the society (Jani et al.).

Although health care access plays a vital role in diabetic retinopathy screening, the quality of services offered may not be equal in all health care institutions due to disparities in preventive care that are usually provided in primary care encounters. Even though primary care encounters usually provide opportunities for preventive health care such as diabetes self-management education (DSME), there are considerable race and ethnic disparities in preventive care that are usually provided in primary care encounters; access to quality health care as offered in primary care centers is limited to many African Americans with diabetes, they rely on government-subsidized and less-resourced community health centers located in their residential areas for medical care (Agency for Healthcare Research and Quality, 2017; Fiscella, K. & Sanders, 2016). Racial and ethnic disparities exist in quality of care provided for control of chronic noncommunicable diseases such as hypertension, hyperlipidemia, and diabetes that are risk factors for diabetic retinopathy, with African Americans and other minority patients having suboptimal control for blood sugar, blood cholesterol, and blood pressure with resultant complications that include diabetic retinopathy (Agency for Healthcare Research and Quality, 2017; Laiteerapong et al., 2015; Yoon et al., 2015). Abramson, Hashemi, and Sánchez-Jankowski (2015) carried out a cross-sectional study that employed a multi-level approach to examine perceptions of United States racial health care discrimination and micro and macro-level factors that influence behaviors, health experiences, and outcomes among and between racial groups. Data on 43,020 adults between 18 and 85 years from California's major racial and ethnic groups obtained from the California Health Interview Survey 2005 were analyzed (Abramson et al.). Results showed that racial minorities, especially African-Americans reported more racial health care discrimination; increased perceptions of discrimination were associated with poor communication with health care provider across all racial and ethnic groups; and perceptions of discrimination were associated with an increased level of education in all racial and ethnic groups except Whites (Abramson et al.).

Laiteerapong et al. (2015) carried out a cross-sectional study to determine disparities in diabetes care. The study sample was a nationally representative sample of Hispanics, African Americans, and Whites, aged 20 years or over, with self-reported diabetes in the NHANES, 2007–2010. There were individualized glycemic goals that were assigned based on duration, age, duration, comorbidity, and complications; and, low-density lipoprotein cholesterol goals assigned based on the history of cardiovascular disease (Laiteerapong et al.). The results showed that more Whites achieved $HBA1_C <$ 8% goal than African Americans (81% versus 74%, $p < .001$); fewer African Americans were recommended individualized LDL goals compared to Whites (10% versus 33%, $p <$ .003 ; more Whites (51%) achieved individualized LDL control; and adequate blood pressure control goal of less than 140/90 mmHg was reached by fewer African Americans compared to Whites (53% versus 69%, $p < .001$).

A cross-sectional study was carried out by Assari et al. (2017) on 163 African Americans with T2DM in outpatient clinic of a large Midwestern urban health care system to examine dissimilarities in levels of racial health care discrimination perceptions and the relationship between the perceived discrimination and blood sugar control. Results demonstrated that racial health care discrimination is reported more by African American men with T2DM than women with T2DM; perceived discrimination is associated higher levels of HBA1C in African American men (Assari et al.). Assari et al. suggested that consideration should be given to gender by clinicians and academics when the effects of racial health care discrimination on health outcomes are being examined.

Several factors may influence racial disparities in diabetes management services. Hu et al. (2016) carried out a cross-sectional study to determine the factors that may influence racial disparities in primary care access and quality in those with diabetes by a secondary data analysis on 2,617 adults with self-reported T2D derived from the household part of the Medical Expenditure Panel Survey of 2012. The results showed that although there were initial racial and ethnic disparities in the access to primary care and quality, socioeconomic status is a stronger determinant of access to primary care and quality and outcomes in those with T2DM than race and ethnicity (Hu et al.). According to the authors, the policy implication of the result is that policymakers should ensure equitable health care access and quality to all by focusing on the health care needs of the underprivileged and underserved populations such as those with lower socioeconomic status (Hu et al.). In Canada, Bird, Lemstra, Rogers, and Moraros (2015) from a cross-sectional study found that household income has a strong and independent association with the prevalence of T2DM and some concordant comorbidities and physical inactivity. Relationship between disparities in diabetes prevention services obtained and status of medical insurance during health care facility visit was suggested by results of a retrospective cohort research by Bailey et al. (2016); however, the internal and external validity of the results are compromised by the purposive sampling method used and a predominantly Hispanic population.

According to results of the study by Ascari et al, (2017), discrimination is reported more by African American men with T2DM than women with T2DM and perceived discrimination is associated higher levels of HBA1C in African American men; however internal and external validity of the results are affected by the cross-sectional study design and purposive sampling method. Results of studies by Bird et al. (2015) and Hu et al. (2016) highlighted the intrapersonal and community-level factors that influence health care access and quality in T2DM patients. Results of the study by Hu et al. (2016)

showed that socioeconomic status is a stronger determinant of access to primary care and quality and outcomes in those with T2DM than race and ethnicity; however, self-report of DM and primary care experience without measuring health outcomes, use of secondary data source, nonprobability sampling, and cross-sectional study design, and a predominantly White study population will affect both internal and external validity of study findings. Also results of a cross-sectional study by Bird et al. showed that household income has a strong and independent association with the prevalence of T2DM and some concordant comorbidities and physical inactivity; absence of African Americans in the study population affects the generalizability of the results beyond the study population. Research findings from studies carried out by Chow et al. (2016) and Young et al. (2017) highlighted the importance and quality of health care access; although the study by Young et al. was supposed to be a randomized control trial, not all patients stuck to their assigned groups; also, the purposive sampling method utilized by Chow et al. and lack of information about the racial or ethnic composition of the study population will affect the generalization of the study results.

There are low eye care service utilization rates among adult African Americans with DM, which result in lower screening rates among this population (Maclennan et al., 2014; Yu et al., 2015). Research is scarce specifically on the associations between DM comorbidities of hypertension and hyperlipidemia, gender, health care access diabetic retinopathy among adult African Americans with diabetes in the United States. There was a need to conduct research specifically on these factors that affect health care utilization among adult African Americans with DM and diabetic retinopathy in the United States.

Studies Related to the Research Questions

In this study, I analyzed the associations between gender, DM related comorbidity of hypertension and hyperglycemia, and diabetic retinopathy among adult African Americans in the United States. Studies reviewed on the association between gender and diabetic retinopathy in adult African Americans are indeterminate, which warranted a study to examine this relationship in this population (Research Question 1). Although the literature review showed that concordant comorbidities of DM, hypertension, and hyperlipidemia are risk factors for the development of diabetic retinopathy and its progression to proliferative diabetic retinopathy, the study populations were predominantly not African Americans (Atchison & Barkmeier, 2016; Chen et al., 2014; Chew et al., 2014; Do et al., 2015; Lee et al., 2015; Lima et al 2016; Mendanha et al., 2016; Romero-Aroca et al., 2016; Ting et al., 2016; Wat et al., 2016). The cross-sectional design used for the studies on African Americans and purposive sampling can affect the generalizability of the research findings (Papavasileiou et al., 2017; Penman et al., 2016). There is a need for research on the association between DM comorbidities and diabetic retinopathy among adult African Americans in the United States (research question 2). Literatures reviewed showed that the achievement of metabolic control of hyperglycemia, hypertension, and hyperlipidemia, early detection through regular eye-screening of patients with DM, and prompt management of diabetic retinopathy could prevent the development of early diabetic retinopathy and the progression to the late stages; these diabetes preventive services are dependent on health care utilization that depend on health care access (Atchison & Barkmeier, 2016; Chen et al., 2014; Chew et al., 2014; Do et al., 2015; Lee et al., 2015; Lima et al., 2016; Mendanha et al., 2016; Romero-Aroca et al., 2016; Ting et al., 2016; Wat et al., 2016). Three studies showed that although African Americans are among those are disproportionately affected by diabetic retinopathy, they had one of the lowest rates of diabetic retinopathy screening and scheduled follow-up eye care utilization (Keenum et al., 2016; Maclennan et al., 2014; Yu et al., 2015). There was a need to research the factors that affect health care access among adult African Americans with DM (research question 3).

Definitions

Comorbidity: Is when there is concurrent existence of a disease and one or more other diseases in an individual (Pantalone et al., 2015).

DM comorbidity: Can be concordant (similar) or discordant (not similar) according to the management of DM (Magnan et al., 2015).

DM concordant comorbidities: DM, hypertension, hyperlipidemia, large and small arterial diseases (Lin et al., 2015; Magnan et al., 2015; Mozaffarian et al., 2016; Pantalone et al., 2015; Rosiek et al., 2016).

Diabetic Retinopathy: An extreme small blood vessel (arteriole) complication of the eyes in both Type 1 and Type 2 diabetes; it is strongly related to both the duration of poor blood sugar control in diabetes, and how controlled the blood sugar level is (ADA, 2018).

Health care access: The ability to gain entry into or utilize the health care service (HealthyPeople.gov. (2018).

Albuminuria: Presence of albumin (type of protein) in the urine (ADA, 2018).

African American: Individuals with any ancestry of African tribes, especially those of Black African ancestors (Merriam-Webster, Incorporated, 2018).

Eye screening: Useful for those with DM in identification eye conditions such as diabetic retinopathy that may result in vision loss (American Academy of Ophthalmology, 2018a). An appropriate referral can then be made to an eye specialist for further management (American Academy of Ophthalmology, 2018a).

Blood glucose: Principal sugar found in the body and the body's primary source of energy (ADA, 2018).

Diabetes mellitus (DM): A metabolic disorder characterized by chronic hyperglycemia (continuing elevated levels of blood sugar) resulting from defects in insulin action, insulin secretion, or both (WHO, 2018).

Type 1 Diabetes mellitus (T1DM) Medical problem with the body when blood glucose level rises higher than normal because insulin is not being produced enough (ADA, 2018).

Type 2 Diabetes mellitus (T2DM): Medical problem with the body when blood glucose level rises higher than normal because insulin is not being appropriately used, insulin not being produced enough (ADA, 2018).

Hemoglobin A1c (HBA1C): A biochemical measure of average blood sugar within three months (WHO, 2018).

Macroangiopathy: Diseases of large arteries (WHO, 2018).

Microangiopathy: Diseases of small arteries called arterioles (WHO, 2018).

Neuropathy: Diseases of nerves (WHO, 2018).

Nephropathy: Kidney disease (WHO, 2018).

Assumptions

NHANES 2011-2016 datasets were utilized in answering the proposed research questions in this study. However, for the datasets' appropriateness of secondary analysis, it is assumed that they are adequate to answer the research questions (Mohajan, 2017; Salimi & Ferguson-Pell, 2017). It is therefore assumed that the datasets have an appropriate sample, the random sampling method was utilized, and the quality of the measurement instruments has been assured by the reliability and validity of measurements that have been established in other settings (Anand et al., 2017; Salimi & Ferguson-Pell, 2017). The study sample of adult African Americans with DM represented the population of interest in the study. Andersen model of health services use allowed for the exploration of factors that affect health care access that is very significant in the prevention of diabetic retinopathy among African Americans. As such it was suitable for examining the association between independent variables of predisposing factor of gender, the need factor of DM comorbidities, enabling factor of health care access, and health care utilization measured as the dependent variable of diabetic retinopathy.

Scope and Delimitations

This was a cross-sectional study that explored the association between diabetes comorbidities of hypertension and hyperlipidemia, gender, health care access, and diabetic retinopathy in adult African Americans by secondary data analysis of 2011-2016 NHANES datasets. Adult African Americans with DM are disproportionately affected by diabetic retinopathy, as such this population was suitable for this study. However, there are delimitations of the study such as the exclusion of institutionalized individuals, Americans resident outside the 50 states and the district of Colombia, and all active-duty servicemen and women with their families residing overseas; as such the results of this research may not be generalizable to those that did not qualify for inclusion in the survey (CDC, 2017a). Also, a cross-sectional study examines relationships between multiple variables in a specified population at a particular time-frame, so the results are fixed without any indication of the order of events; cause and effect from simple association cannot be established (Caruana, Roman, Hernández-Sánchez, & Solli, 2015; Mariani & Pego-Fernandes, 2014; Omair, 2015; Setia, 2016).

Significance

Implications for positive social change from this study is that knowledge gained from the study will be useful in planning and developing effective public health interventions targeting specific African American populations, resulting in decreased physical, mental, and socioeconomic burdens on this population. In this study, determining the factors that influence health care utilization disparities among adult African American populations with DM concordant comorbidities will help in identifying barriers to the successful implementation of public health interventions in this population.

According to Walden University (2014), positive social change denotes participation in activities that lead to an improvement in the lives of community members, nationally or globally (Walden University, 2014). Understanding factors responsible for DM comorbidity disparities and diabetic retinopathy in adult African American populations can be utilized for their prevention and effective care through development and implementation of culturally appropriate interventions (Sachdeva et al., 2015). Social change implication of the research is that the results can be useful for the successful planning and implementation of public health prevention programs for African American populations. The consequence of which should be a decrease in the prevalence DR and associated physical, mental, and socioeconomic burdens on populations, especially the African American populations that are disproportionately affected (Lang, & Marković, 2016; Lin et al., 2015). This should lead to less morbidity, disability, and mortality from these diseases, which should lead to increased productivity that will lead to an improvement of the socioeconomic status of individuals and the economic status of the affected community.

Andersen model of health services use allowed for the exploration of factors that affect health care access that is very significant in the prevention of diabetic retinopathy among African Americans. The model's constructs applied to this study should help in understanding the predisposing, need, and enabling factors of health care utilization that determine diabetic retinopathy among adult African Americans. In this study, a literature review was conducted to identify studies on the influences of gender, DM comorbidities, and health care access on diabetic retinopathy. The search yielded several articles, and some of the articles related to this present study were selected. Major themes in the selected articles are outlined below.

Summary

Andersen model of health services utilization allowed for the exploration of factors that affect health care access that is very significant in the prevention of diabetic retinopathy among African Americans; it was suitable for examining the association between independent variables of predisposing factor of gender, the need factor of DM comorbidities, and enabling factor of health care access and health utilization that is indirectly measured as the dependent variable of diabetic retinopathy (Andersen, 1968; Andersen & Newman, 1973). Hypertension and hyperlipidemia have positive associations with the development of diabetic retinopathy (Abdulghani, et al., 2018; Beckman & Creager, 2016; Cheng et al., 2014; Do et al., 2015; Klimek et al., 2015; Lin, Kent et al., 2015; Magnan et al., 2015; Mozaffarian et al., 2016; Pantalone et al., 2015; Romero-Aroca et al., 2016; Rosiek et al., 2016; Solomon et al., 2017; Song et al., 2016; Wat et al., 2016; Zhuo et al., 2014). Duration of diabetes, uncontrolled hyperglycemia and hypertension are common important risk factors for the progression of diabetic retinopathy to vision-threatening diabetic retinopathy or loss of vision (Chen et al., 2014; Chew et al., 2014; Mendanha et al., 2016; Do et al., 2015; Lee et al., 2015; Lima et al., 2016; Romero-Aroca et al., 2016; Ting et al., 2016; Wat et al., 2016). Longer duration of diabetes, uncontrolled hyperglycemia, hypertension, and dyslipidemia are associated with diabetic retinopathy in adult African Americans (Papavasileiou et al., 2017; Penman et al., 2016). There are racial, ethnic, and socioeconomic disparities in health care access in the United States (Bailey et al., 2016; Hu et al., 2016; Laiteerapong et al., 2015).

However, there is a dearth of public health research on the associations between a predisposing factor of gender, need factors of DM comorbidities (hypertension and hyperlipidemia), and enabling factor of health care access and utilization and diabetic retinopathy among adult African Americans. This research examined the association between these predisposing, need, enabling factors of health care utilization, and diabetic retinopathy among adult African Americans. The results should fill a gap in public health knowledge that should contribute to an improvement in population health planning and implementation.

Conclusions

This research aimed at examining the association between predisposing, need and enabling health care factors that influence health care utilization among African Americans, which is responsible for diabetic retinopathy disparities in adult African American populations. This should help in identifying barriers to the successful implementation of public health interventions. A gap will be filled in literature with the understanding of the factors responsible for diabetic retinopathy disparities in African American populations.

In the next section, there is discussion about the research study design and data collection that include research study design and the rationale for choosing the design; methodology with its sub-sections of study population including its size, sampling and sampling procedures used in data collection, study instrumentation, and study variables operationalization; threats to validity; ethical considerations; and summary.

Section 2: Research Design and Data Collection

Introduction

In this quantitative research, I examined associations between gender, DM comorbidities, health care access (independent variables), and diabetes retinopathy (dependent variable), among sampled adult African Americans in the United States. Covariates were age groups, UACR, HBA1C level, marital status, adult education level, and household income. I analyzed data from nationally representative datasets from the NHANES 2011-2012, 2013-2014, and 2015-2016 cycles (see NCHS, n.d.) on DEMO (demographics), DIQ (diabetes questionnaire), BPQ (blood pressure and cholesterol questionnaire), ALB_CR (urine levels), HIQ (health insurance questionnaire), BPX (blood pressure measurements), HDL, TCHOL, TRIGLY (blood levels), and GHB (HBAIC level). Individual datasets for each cycle were merged to produce a final cycle's dataset, datasets from the three NHANES cycles were appended to produce the final dataset, and new a data set specific to the study sample was created. Participants were adult African Americans, aged 20 years and above, with a self-reported diagnosis of diabetes (NCHS, n.d; Li et al., 2010; Yan et al., 2018). In this section, I discuss the research study design and data collection. The discussions are in order of research study design and the rationale for choosing the design; methodology with its subsections of study population including its size, sampling and sampling procedures utilized used in data collection, study instrumentation, and study variables operationalization; threats to validity; ethical considerations; and summary.

Research Design and Rationale

The design for this research was a quantitative cross-sectional study. The research was approached through a retrospective analysis of nationally representative secondary datasets, with both the independent and dependent variables extracted from NHANES 2011 – 2016 datasets. The independent variables and covariates represent constructs of the Andersen model of health services utilization such as predisposing factors (age, gender, marital status, education level, and household income); need factors of comorbidities (DM, hypertension, hyperlipidemia, HBA1C and UACR); and enabling factors of health care access (household income, level, current health insurance, availability of regular diabetes doctor, diabetes specialists, and eye-screening service); and the dependent variable of diabetic retinopathy that is a proxy measure of health services utilization.

Quantitative research is used in quantifying relationships between the independent or predictor variable(s) and the dependent or outcome variable(s) by way of experiments or data analysis (Creswell, 2014). Researchers conduct cross-sectional studies to examine relationships between multiple variables in a specified population (a representative sample from the population) at a particular timeframe (Caruana et al., 2015; Mariani & Pego-Fernandes, 2014; Omair, 2015; Setia, 2016). A correlational research design is used to examine the existence of a significant linear relationship between the independent (predictor) and dependent (outcome) variables; the direction and strength of that relationship are also determined (Curtis et al., 2016; Omair, 2015). Correlational research designs can be explanatory or predictive (Curtis et al., 2016; Omair, 2015). An explanatory correlational research design involves a cross-sectional data collection approach, whereas for a predictive correlational research design, longitudinal data are collected (Curtis et al., 2016; Omair, 2015). For this study, I used a correlational cross-sectional design in examining whether there were significant associations between some specific health care utilization factors and diabetic retinopathy among African Americans. I chose the correlational cross-sectional study design considering the time available for this dissertation, which would not have permitted a longitudinal study design because of repeated observations that might be required over a long period (Caruana et al., 2015; Curtis et al., 2016; Omair, 2016). Moreover, secondary data used for this study were collected within specific time-periods (see NCHS, n.d.).

Cross-sectional studies are comparatively cheap and quick to carry out; multiple measurements can be taken at the same time and is exclusive of variable(s) manipulation. Although the results from cross-sectional studies are fixed without any indication of the order of events and cause and effect from the simple association cannot be established, the associations identified can then be studied rigorously by utilizing randomized control trial (RCT) or cohort study (Mariani & Pego-Fernandes, 2014; Setia, 2016). For example, identified associations and significant relationships between gender, DM comorbidities of hypertension and hyperlipidemia, health care access, and diabetic retinopathy are indicators of what can be studied further to ascertain cause and effect through RCT or cohort study.

Methodology

Population

The target population for the NHANES 2011-2012, 2013-2014, and 2015-2016 cycles was the noninstitutionalized civilian resident population of the United States (Asiamah, Mensah, & Oteng-Abayie, 2017; NCHS, 2017a). The researchers used oversampling to ascertain accurate representation of underrepresented groups that included African Americans, adults Whites 60 years and over, Hispanics, and Asians (NCHS, 2017). The target sample for this study were African Americans 20 years or over with DM that were study participants in the 2011-2012, 2013-2014, and 2015-2016 NHANES cycles; a total of 634 (n = 634) study participants. The minimum sample size of 308 for this research was calculated from an a priori power analysis utilizing G*POWER 3.1.9.2 (Faul, Erdfelder, Buchner, & Lang, 2009).

Sampling in NHANES

Sampling is the procedure for selecting sampling units (individuals) from the sample frame (Martinez-Mesa et al., 2016). It is important that the sampling plan is specified early in the research process since the sample size estimation may be affected by the method of sampling (Martinez-Mesa et al., 2016).

Sampling frame. The sample frame for research is a list of all individuals within a target population that can be sampled based on the sampling procedure employed in the study (Martinez-Mesa, Gonzalez-Chica, Duquia, Bonamigo, & Bastos, 2016). The sampling frame for NHANES is all the U.S. counties (CDC, 2017a).

Sampling techniques. Quantitative researchers can use either probability sampling methods that employ random participants selection or nonprobability sampling methods that utilize convenient and opportunistic sampling techniques for participant selection (Martinez-Mesa et al., 2016; Omair, 2014). Probability sampling includes simple random sampling, systematic random sampling, cluster sampling, multistage sampling, and stratified random sampling (Martinez-Mesa et al., 2016; Omair, 2014). Probability sampling techniques are preferred to nonprobability sampling techniques because study results can be generalized beyond the study sample to the target population (Martinez-Mesa et al., 2016; Omair, 2014). Complex multistage probability sampling technique was utilized for 2011-2012, 2013-2014, and 2015-2016 NHANES cycles (NCHS, n.d.). Multistage probability technique utilized involves (a) counties sampling (primary sampling units); (b) segments sampling; (c) household sampling; and (d) person sampling with the use of a computer algorithm that randomly selects some, all, or none of the household members (CDC, 2018; Martinez-Mesa et al., 2016; Omair, 2014).

The combined datasets for 2011-2012, 2013-2014, and 2015-2016 NHANES cycles was the sampling frame for this research. NHANES combined interviews (household interview, questionnaires, and mobile examination center [MEC] questionnaires), physical examination, and laboratory tests (CDC, 2017). After obtaining written consent, trained personnel, including medical doctors, administer the questionnaires and perform the medical examinations and laboratory tests (CDC, 2017 n.d.). In this research, I analyzed data on the target sample from the 2011-2012, 2013-2014, and 2015-2016 NHANES cycles.

NHANES data describe the prevalence or trends of disease, nutrition, risk behaviors, and environmental exposures in the US population (CDC, 2017). Probability sampling allows the survey results to be generalizable to the larger population from which the study sample was drawn (CDC, 2017a; NCHS, n.d.). NHANES, which was conducted on a periodic basis from 1970 but turned to a continuous survey in 1999, is a cross-sectional population-based survey that collects data on demographics, diet and nutritional status, risk factors, adolescent health, environmental exposure, reproductive health, and chronic diseases on a nationally representative sample of the U.S. population (NCHS, 2017). Although 43,090 individuals were selected for NHANES 2011-2012, 2013-2014, and 2015-2016 cycles from 30 different counties in each cycle, the interview was completed by 29,902 individuals, and 28,695 persons went through physical examination; response rate for the interviewed sample was 69%; and 66.6% for the examined sample (NCHS, n.d.).

Data Collection and Utilization Procedures for the Current Study

I analyzed data from the combined 2011-2012, 2013-2014, and 2015-2016 NHANES datasets, such as DEMO.XPT (demographics), DIQ.XPT (diabetes questionnaire), BPQ.XPT (blood pressure and cholesterol questionnaire), ALB_CR.XPT (urine levels), HIQ.XPT (health insurance questionnaire), BPX.XPT (blood pressure measurements), HDL.XPT, TCHOL.XPT, TRIGLY.XPT and GHB.XPT (blood levels) were analyzed (NCHS 2013; NCHS, 2015; NCHS, 2017b). NHANES data have been utilized as secondary data sources for some descriptive and analytical research that include behavioral and chronic disease-related studies such as diabetes retinopathy

(Ahluwalia et al., 2017; Shah, 2016; Song et al., 2016; Zhang et al., 2010). The 2015-2016 NHANES cycle dataset that was previously downloaded for the study did not yield sufficient study sample to meet the minimum study sample requirement of 308 obtained from a priori power analysis, this necessitated the acquisition of additional datasets from 2011-2012 and 2013-2014 NHANES cycles. NHANES datasets are in the public domain like other data and materials created by federal agencies, which may be reproduced; there was no requirement for special permission for gaining access to them (CDC, 2017a).

Study Sample Size: Power Analysis

Performing sample size determination by power analysis requires effect size, desired Type I error rate (α) that is often set at $p < .05$, and the power, that is based on the desired Type II error rate, which is also conventionally set at 80% (Columb & Atkinson, 2016; Faul et al., 2009). In using power analysis to determine the sample size for multiple regression analysis of the dataset for this research, the G*Power application was used (Faul et al., 2009). I selected *z* test as test family and logistic regression as the statistical test were selected. Power was set to .80, the desired Type I error rate (α) was set to .05; odds ratio at 1.5, and 2-tail hypothesis direction were selected based on the non-directional hypothesis for this research. The minimum sample size of 308 for this research was calculated from an a priori power analysis utilizing G*POWER (Faul et al., 2009).

Instrument and Operationalization of Variables

Data for 2011-2012, 2013-2014, and 2015-2016 NHANES cycles were from initial home interviews and health examination section of the study conducted in the mobile examination center (NCHS, n.d.). Specific items and scales utilized from the combined 2011-2012, 2013-2014, and 2015-2016 NHANES datasets included DEMO.XPT (demographics), DIQ.XPT (diabetes questionnaire), BPQ.XPT (blood pressure and cholesterol questionnaire), ALB_CR.XPT (urine levels), HIQ.XPT (health insurance questionnaire), BPX.XPT (blood pressure measurements), HDL.XPT, TCHOL.XPT, TRIGLY.XPT and GHB.XPT (blood levels) were analyzed (NCHS 2013; NCHS, 2015; NCHS, 2017b). I did not need any permission to use these datasets. The different datasets from particular NHANES cycle were merged, the final datasets from the three NHANES cycles were appended, and new data set peculiar to the study sample was created.

To answer the research questions, there was a need to recode some of the variables that have been used by NHCS in the original data collection to new variables and merging of variables to form composite variables such as DM comorbidity and health care access. The new dataset contains some demographic variables such as age groups, marital status, gender, annual household income, and adult education level; health insurance coverage; diabetes affected eyes/had retinopathy; high blood pressure and high cholesterol; UACR and HBAIC level. The variables were arranged into diabetic retinopathy (dependent variable); DM comorbidities, gender, health care access (independent variables); and age groups, HBA1C level, UACR, marital status, household income, and education level (covariates). A complex sample plan for complex sample analysis was created. The complex sampling plan was developed to assure correct data weighting, considering the effect of oversampling of African Americans and some other groups that would have resulted in samples that were no longer representative of the populations, with consequential inaccurate findings. The final dataset was stored.

Diabetic retinopathy, the dependent variable utilized for this study was assessed by participants' self-report of having been informed by a doctor that the eyes were affected by diabetes; the level of measurement is binomial categorical. Assessment of DM comorbidities of hypertension and hyperlipidemia were through participants self-report of being informed of by a health professional about having high blood pressure more than twice, an average systolic blood pressure at the medical examination center (MEC) of ≥130mmhg, and self-report of current use of medications for high cholesterol and low blood HDL level at the MEC; level of measurement is binomial categorical (American Heart Association (2019; U.S. National Library of Medicine [NIH], 2018). Gender is assessed through a self-report of being female or male; binomial categorical. Health care access was assessed by combining covered by health insurance, seeing a regular doctor for diabetes, last time had pupils dilated for exams variables into one variable with a binomial categorical level of measurement.

Covariate of age groups was assessed by self-report of age in years at screening, the age groups are as advised by NCHS; it is an ordinal categorical variable (NCHS, 2018). HBA1C level was assessed by the participants HBA1C level, a continuous level of measurement (ADA, 2018; Garber et al., 2018). Assessment of participants' UACR was by the participants' UACR levels, a continuous level of measurement (ADA, 2018). Marital status is a binomial categorical variable. Annual household income and education level variables are ordinal categorical. For complex sample analysis, variables that identified the sample strata, sample clusters, and sample weight are included. The following table shows the operationalization of study dependent and main independent variables, covariates, and complex sample parameters

Table 1

Operationalization of Study Independent, Dependent, and Covariate Variables

Variables	Survey questions	Data code	Variable type
Diabetes retinopathy	Diabetes affected eyes/had retinopathy?	0 = No. 1 = Yes	Binomial dependent
DM comorbidities	1. Ever told you had high blood pressure 2+ times 2. Systolic hypertension 3. Now taking meds for high cholesterol 4. Low HDL	0 = No DM comorbidity 1 = DM comorbidity	Binomial independent
Age groups	Age in 20-39; 40-59; and 60 years and over	1 = 20-39 years 2 = 40-59 years 3 = 60 years and over	Ordinal covariate
Gender	Gender	0 = male 1 = female	Binomial independent
Health care access	1. Covered by health insurance 2. Has a regular doctor for diabetes 3. Last time had pupils dilated for exam?	0 Did not have health care access 1 Had health care access	Binomial independent
UACR	Urine Albumin/creatinine ratio (mg/g)	0.21 to 9000	Continuous covariate
HBAIC	Blood HBAIC level %	3.5 to 17.5	Continuous covariate
Adult education level	Adult Education level	1 = Less than high school 2 = High school Grad/ GED or Equivalent	Ordinal covariate

(table continues)

Variables	Survey questions	Data code	Variable type
		3 = Some College or AA degree	
		4 = College graduate or above	
Marital status	Marital status	1 Married 2 Divorced, widowed, and separated 3 Never married and living with a partner	Categorical covariate
Annual household Income	Annual household income	0 = Refused, Don't know, Missing 1 = less than $20,000 2 = $20,000-$44,999 3 = $45,000-$74,999 4 = $75,000-$99,999 5 = $100,000 & over	Ordinal covariate
Masked variance pseudo-stratum	SDMVSTRA	n/a	Complex sampling weighting variable
Masked variance pseudo-PSU	SDMVPSU	n/a	Complex sampling weighting variable
Full sample 2-year MEC exam weight	WTMEC2YR	n/a	Complex sampling weighting variable

Data Analysis

Data analysis was conducted with SPSS (Version 25). I downloaded datasets from 2011-2012, 2013-2014, and 2015-2016 NHANES cycles, such as DEMO.XPT (demographics), DIQ.XPT (diabetes questionnaire), BPQ.XPT (blood pressure and cholesterol questionnaire), ALB_CR.XPT (urine levels), HIQ.XPT (health insurance questionnaire), BPX.XPT (blood pressure measurements), HDL.XPT, TCHOL.XPT, TRIGLY.XPT and GHB.XPT (blood levels) (NCHS 2013; NCHS, 2015; NCHS, 2017b).

To answer the research questions, some variables previously used by NCHS in the original data collection were transformed into new variables, including composite variables. Final variables for this study are mostly categorical with two continuous variables (HBAIC and UACR). Individual files from each NHANES cycle were merged into datasets for the respective cycles that were then appended to form a final dataset for 2011-2012, 2013-2014, and 2015-2016 NHANES cycles. A new dataset peculiar to the study sample of African Americans, 20 years and over, with a self-reported diagnosis of DM was subsequently created. The final dataset was then prepared for analysis.

A complex sampling plan was developed to assure correct data weighting that should lead to accurate findings, considering the effect of oversampling of African Americans and some other groups that would have resulted in samples that were no longer representative of the populations with consequential inaccurate findings (NCHS, 2018). Missing values were managed by listwise default deletion function of SPSS that automatically drops a missing case from analysis instead of its deletion from the dataset; it is automatically applied with logistic regression analysis in SPSS irrespective of any previous data cleaning method (IBM, 2016). In preventing the introduction of bias to estimates such as mean values with resultant misestimated values, handling outliers is important prior to data set analysis (Kwak & Kim, 2017). Identified outliers by an outlier detection function in binary logistics for glycohemoglobin and urine albumin-creatinine ratios were less than 5% of values of the two variables (Kwak & Kim, 2017; Sindhumol, Gallo, & Scrinivasan, 2017). High collinearity presence in a multiple linear or logistic regression model may result from predictors' high variances leading to inaccurate estimations, which can evoke doubts about the results of the analysis (Salmerón, García, & García, 2018). As such, collinearity detection by a variance inflation factor (VIF) and tolerance is a necessary initial step compulsory first step in every multiple regression analysis (Salmerón et al., 2018). A variance inflation factor value of less than 10 or tolerance value greater than 0.1 is accepted as the absence of collinearity in a multiple regression model (Salmerón et al., 2018). Absence of extreme collinearity within the independent variables for this study was asserted with variance inflation factor values of less than 10 (see Table 7).

I conducted preliminary descriptive statistics. Frequencies and percentages were calculated for the categorical variables, and minimum and maximum scores, means, and standard deviations were computed for the two continuous variables (see Table 2)

Table 2

Descriptive Analysis Plan for Dependent and Independent Variables, and Covariates

Variables	Variable type	Descriptive analysis
Diabetes retinopathy	Binomial Dependent	Percentages or Proportions
Age groups	Ordinal Covariate	Means and standard deviations
DM Comorbidities	Binomial Independent	Percentages or Proportions
Gender	Binomial Independent	Percentages or Proportions
Health Care Access	Binomial Independent	Percentages or Proportions
Adult Education Level	Ordinal Covariate	Percentages or Proportions
Marital Status	Categorical variable	Percentages or Proportions
Annual Household Income	Ordinal Covariate	Percentages or Proportions
UACR level	Continuous Covariate	Minimum, Maximum, Means and Standard deviations
HBAIC level	Continuous Covariate	Minimum, Maximum, Means, and Standard deviations

Research Questions and Hypothesis

The following research questions and hypothesis were addressed in this study:

RQ1: Is there an association between gender and diabetes retinopathy among adult African Americans in the United States?

H_o1: There is no association between gender and diabetes retinopathy among adult African Americans in the United States

H_11: There is an association between gender and diabetes retinopathy among adult African Americans in the United States.

RQ2: Is there an association between DM-related comorbidities of hypertension, hyperlipidemia, and diabetic retinopathy among adult African American populations in the United States?

H_o2: There is no association between DM-related comorbidities of hypertension, hyperlipidemia, and diabetic retinopathy among adult African American populations in the United States.

H_12: There is an association between DM-related comorbidities of hypertension, hyperlipidemia, and diabetic retinopathy among adult African American populations in the United States.

RQ3: Is there an association between health care access and diabetic retinopathy among adult African Americans in the United States?

H_o3: There is no association between health care access and diabetic retinopathy among adult African Americans with DM in the United States.

$H_1 3$: There is an association between health care access and diabetic retinopathy among adult African Americans with DM in the United States.

Level of significance (α) = 0.05.

Statistical Tests and Interpretation of Results

Sample characteristics were described with descriptive statistics. Percentages or proportions are for the categorical independent and dependent variables, and minimum and maximum scores, means, and standard deviations were computed for the continuous variables. The dependent variable (diabetic retinopathy) in this study is dichotomous, as such the relationships between diabetic retinopathy and the independent variables for this study can be examined by logistic regression (Ranganathan, Pramesh, &Aggarwal, 2017). Three logistic regressions were conducted to examine (a) the association between gender and diabetic retinopathy among adult African Americans in the United States; covariates include age groups, HBA1C level, UACR, marital status, adult education level, and annual household income; (b) the association between DM comorbidities of hypertension and hyperlipidemia and diabetic retinopathy among adult African American populations in the United States; covariates are age groups, HBA1C level, UACR, marital status, adult education level, and annual household income; and (c) association between health care access and diabetic retinopathy among adult African-Americans in the United States; covariates are age groups, $HBA1_C$ level, UACR, marital status, adult education level, and annual household income. These chosen covariates have been reported as risk factors for diabetic retinopathy in various studies on risk factors for diabetic retinopathy in various ethnic/racial populations, including adult African-American populations.

For statistical analysis, the independent variables and the covariates were included in all models; the results might have shown any significant relationship between gender and diabetic retinopathy in model 1, between DM comorbidities of hypertension and hyperlipidemia and diabetic retinopathy in model 2, and between health care access and diabetic retinopathy in model 3, after controlling for HBAIC level, age group, UACR, marital status, adult education level, and annual household income. Results of logistic regression analysis were interpreted as odds ratios, the associated confidence intervals, and p-values (Sperandei, 2014). Interpretation formats for both dependent and independent variables are shown in Table 3.

Table 3

Plan for statistical analysis

Variables	Statistical analysis method	Interpretation of results
Model 1	Multiple logistic regression analysis	Odds ratios, the associated confidence intervals, and p values
Model 2	Multiple logistic regression analysis	Odds ratios, the associated confidence intervals, and p values
Model 3	Multiple logistic regression analysis	Odds ratio, the associated confidence intervals, and p values

There are assumptions to be met to ensure the accuracy of statistical findings of logistic regression analysis; these assumptions are different from those of multiple linear regression analysis in some areas (McDonald, 2014; Sperandei, 2014). For example, linear relationship between the dependent and independent variables is not required, residuals are not required to be normally distributed, and there is no requirement for homoscedasticity (McDonald, 2014; Sperandei, 2014). However, assumptions associated with logistic regression include correct specification of the logistic regression model, specified absence of multicollinearity absence, inclusion of all relevant predictors, and large sample size (McDonald, 2014; Pituch & Stevens, 2016; Sperandei, 2014).

From the omnibus test of model coefficients table and the Nagelkerke R^2 from the model summary table, the overall model was significant (Pituch & Stevens, 2016) The individual predictors are relevant based on p values of .000 (< 0.05), the Wald test, and the EXP(B) (odds ratio) (Pituch & Stevens, 2016). Absence of collinearity within the independent variables for this study was determined with VIF values of less than 10 (see Table 7). According to Long (1997), for logistic regression, sample size larger than 500 is sufficient (Long, 1997). The sample size for this study (634) is adequate (see Long, 1997).

Threats to Validity

The main aim of NHANES is the production of a wide range of health and nutrition statistics based on age, gender, and race composition of the United States population (NCHS, 2017). All secondary data that include NHANES data requires a thorough assessment of not only the results but also rigors of the studies by assessment of data collection methods through measurement of validity and reliability measurement of instruments (Mohajan, 2017). Validity is the extent to which a concept is accurately measured in a quantitative study (Mohajan, 2017; Salimi & Ferguson-Pell, 2017). Types of validity include internal validity that refers to whether the observed effects on the dependent variable are related to the independent variables and not due to confounding variables; external validity, which is the extent the results can be generated beyond the study population; and construct validity that refers to how well the research instrument measures the constructs being studied (Mohajan, 2017; Salimi & Ferguson-Pell, 2017).

Threats to external validity affect the generalization of the study results beyond the study population, which in the NHANES, may be significant because of the oversampling of specific subgroups such as the African-Americans that could have resulted in response rate bias, the study result may not be representative of the general population (Meterko et al., 2017). The large sample used for the NHANES could have reduced the generalizability threat of the study results. Threats to internal validity include research factors, which have not been accounted for the effect on the outcome variables such as confound bias and reverse causation in correlational studies; self-reporting that can lead to recall bias due to inaccurate or incomplete recollections of past events or experiences, and reporting bias, which could arise from study participants prior knowledge of participation and the process involved, leading to suppression of information that may be deemed not to be socially acceptable (Salimi & Ferguson-Pell, 2017). Internal validity was minimized in 2011-2012, 2013-2014, and 2015-2016 NHANES cycles with the multistage probability sampling technique that was used. Confounding occurs when the observed effect on the dependent variable is related to the independent variable(s) and another factor that is independently associated with both dependent and independent variables, this can be corrected by covariate analysis (Salimi & Ferguson-Pell, 2017). The threat to construct validity may be due to the poor operationalization of study constructs, which for NHANES may be minimal because of previous repeated use of the measurement instruments (Pierannunzi, Hu, & Balluz, 2013; Salimi & Ferguson-Pell, 2017). In a cross-sectional study, reverse causation is due to the inability to define the temporal precedence of variables (Salimi & Ferguson-Pell, 2017).

Ethical Procedures

This study utilized secondary data using de-identified data from 2011-2012, 2013-2014, and 2015-2016 cycles datasets such as DEMO.XPT, DIQ.XPT, BPQ.XPT, HIQ.XPT, BPX.XPT, HDL.XPT, TCHOL.XPT, TRIGLY.XPT and GHB.XPT (NCHS 2013; NCHS, 2015; NCHS, 2017b).

I did not need any permission to use these datasets, and I did not need to obtain permission from NCHS before acquiring the dataset. The datasets were acquired upon obtaining the required Walden University Institutional Board (IRB) approvals before accessing the datasets for analysis. The IRB approval number is 03-26-19-0397499

Ethical guidelines for the protection of human subjects that must have been followed by NCHS included: the approval of the original request for new protocol #2011-17 by the NCHS review board; review process was utilized by NHANES; data collection was protected by public law (45 CFR 46); and participant consent was approved and documented by the NCHS review board before the commencement of the study (NCHS, 2017f; Office for Human Research Protections. 2016). Verbal consent was provided by the primary study participants for 2011-2012, 2013-2014, and 2015-2016 NHANES during the process of recruitment, and data were subsequently anonymized (NCHS, n.d). 2011-2012, 2013-2014, and 2015-2016 NHANES datasets do not contain any identification of study participants. Upon obtaining IRB approval from Walden

University, the four datasets will be downloaded from the NCHS site and saved in a separate jump drive secured in my workbag and will only be accessed as needed for my doctoral study alone. The datasets and all related files will be kept in my home safe and destroyed later.

Summary

In this chapter, I provided a detailed discussion of the research design and data collection for my study on the association between gender, DM comorbidity, health care access, and diabetic retinopathy among adult African Americans. The chapter commenced with a discussion of the study research design and the rationale for its use, followed by an exhaustive discussion on methodology including study population and its size determined by a priori power analysis utilizing G*Power; sampling and sampling procedures utilized used in data collection for the 2011-2012, 2013-2014, and 2015-2016 NHANES cycles, and the current research; study instrumentation and study variables operationalization; data analysis plan; threats to validity with particular reference to internal, external, and construct validity; and ethical considerations. In the next section, I will discuss the presentation of results and findings.

Section 3: Presentation of the Results and Findings

Introduction

This research is aimed at examining associations between health utilization factors of gender, DM comorbidities of hypertension and cholesterol, and health care access, and diabetic retinopathy among adult African Americans. In this section, after describing the data collection method for the 2011-2012, 2013-2014, and 2015-2016 NHANES cycles data, I present the results and findings from data analysis using SPSS (Version 25). Discourse on results encompasses descriptive statistics on study participants, evaluation of statistical assumptions as appropriate to the study, report on statistical analysis findings organized by research questions and hypotheses, and report on results of posthoc analyses of statistical tests, as applicable.

Data Collection Method of 2011-2016 NHANES Data

For this study, I used data from a nationally representative combined dataset of 2011-2012, 2013-2014, and 2015-2016 NHANES cycles. NHANES uses complex, multistage probability design with a large sample to assure reliability and precision of the health status of the target population and selected sample (CDC/NCHS, 2017a). Upon obtaining IRB approvals, I downloaded individual datasets for each of the three cycles (see NCHS 2013; NCHS, 2015; NCHS, 2017b) such as DEMO.XPT (demographics), DIQ.XPT (diabetes questionnaire), BPQ.XPT (blood pressure and cholesterol questionnaire), ALB_CR.XPT (urine levels), HIQ.XPT (health insurance questionnaire), BPX.XPT (blood pressure measurements), HDL.XPT, TCHOL.XPT, TRIGLY.XPT and GHB.XPT (blood levels). Acquiring the three combined datasets was necessary to obtain a large sample of 500 or more participants for logistics regression analysis for this study (see Long, 1997).

I merged the individual datasets for each respective year by participant sequence number and subset to include only observations pertinent to this research to form a dataset for the year. The resulting three datasets were appended to create a combined dataset that I sorted based on variables of the African American race, age 20 years and over, and DM. The number of sampled individuals for the 2011-2012, 2013-2014, and 2015-2016 NHANES cycles was 43,090; of these participants, 29,902 (69%) had been interviewed, and 28,695 (66.6%) had been examined (NCHS, 2013, 2015, 2017). There were 7121 (18.2%) African Americans interviewed, 3809 (52.8%) of whom were 20 years of age or older, and 634 (8.9%) of whom were 20 years of age or older with self-report of diabetes diagnosis (NCHS, 2013, 2015, 2017).

To answer the research questions, I transformed some of the variables that have been used by NHCS in the original data collection into new variables, including composite variables (diabetes comorbidity and health care access). Final variables for this study were predominantly categorical, except for two continuous variables (HBA1C levels and UACR). A complex sampling plan was developed to assure correct data weighting that should lead to accurate findings, considering the effect of oversampling of African-Americans and some other groups that would have resulted in samples that were no longer representative of the populations, with consequential inaccurate findings and poor generalizability (see NCHS, 2018).

Using SPSS (Version 25), I performed descriptive and inferential data analysis of the final dataset utilizing the created complex sample plan developed to assure correct data weighting and national representativeness of the findings.

Independent categorical variables are automatically dummy coded by SPSS in logistic regression, with 0 as a reference factor. I obtained weighted and unweighted frequencies and percentages for the categorical independent variables and the dependent variables, as well as mean, standard deviation, minimum, and maximum scores for the continuous variables of HBAIC and UACR.

Results

Descriptive Statistics of Demographic and Baseline Study Variables

The final dataset consisted of 634 African Americans age 20 years or older with self-report of diabetes (n = 634); average age was 58.96 years (SD = 12.875). Males were 52.7% of the study sample, and married participants were 40%. The proportion of study sample in the age group 60 years and over was 62.1%. Over half of the study sample (63.2%) reported annual household income of less than $50,000, and the proportion of study participants with at least some college education or higher was 66.4%. Table 4 illustrates dependent and independent variables for this study, with unweighted and weighted frequencies and percentages for the variables.

Table 4

Unweighted and Weighted Frequencies and Percentages for the Dependent and Categorical Independent Variables for the Study

Characteristic	Unweighted frequencies	Unweighted percentage	Weighted frequencies	Weighted percentage
Diabetic retinopathy				
No	498	78.5	8502144.436	80.1
Yes	136	21.4	2110093.204	19.9
Diabetes comorbidity				
No	391	61.7	6454005	60.8
Yes	243	38.3	4158233	39.2
Gender				
Male	334	52.7	4805837	45.3
Female	300	47.3	5806400	54.7
Health care access				
No	603	61	6454005	60.8
Yes	31	38	4158233	39.2
Age groups				
20-39 years	23	3.6	564420	5.3
40-49 years	217	34.2	4864844	45.8
60 years and over	394	62.1	5182974	48.8
Annual household income				
Less than $20,000	177	30.1	2895258	29.2
$20,000 to $44999	162	27.5	2716332	27.4
$45,000 to $74,999	118	20.0	1964410	19.8
$75,000 to $99,999	38	6.5	632913	6.4
$100,000 and over	57	9.7	1121392	11.3
Marital status				
Married	260	41.0	4122288	38.8
Widow, divorced	240	37.9	4079050	38.4
Separated				
Never married				
Living with a partner	33	21.0	2398910	22.6

Descriptive statistics for continuous pertinent baseline and independent variables are shown in Table 5. The average HBAIC level was 7.5% (*SD* = 2.11) and UACR was 232.00 mg/g (*SD* = 687.14). Average systolic blood pressure was 134 mmhg (*SD* = 20.67) and diastolic blood pressure was 69 mmhg (*SD*= 16.44). Average total cholesterol was 181.46 mg/dl (*SD* = 48.72), HDL cholesterol was 51.3 mg/dl (*SD* =15.49), and LDL was 102.64 mg/dl (*SD* = 39.04).

Table 5

Descriptive Statistics for Continuous Pertinent Baseline and Independent Study Variables

	Minimum	Maximum	*M*	*SD*
HBA1C (%)	4.60	17.80	7.52	2.11
UACR (mg/g)	1.91	5928.00	232.00	687.14
Systolic blood pressure (mmHg)	86	190	134	20.667
Diastolic blood pressure (mmHg)	0	110	69.80	16.493
Total cholesterol (mg/dl)	75	389	181.46	48.723
Direct HDL-Cholesterol (mg/dl)	22	156	51.43	15.489
LDL-Cholesterol (mg/dl)	15	240	102.64	39.040

Table 6 depicts the unweighted and weighted frequencies and percentages for the composite independent categorical variables' factors. For example, for health care access, 89.6% of study participants reported having health insurance coverage, 80.0% reported having a regular diabetes doctor, and 76.8% reported having had recommended dilated eye examination. For diabetic comorbidities, about 68.5% reported being informed that they had high blood pressure twice and 35.7% had systolic high blood pressure recorded; current use of cholesterol medications was reported in about 55.25%, and 18.5% had low HDL blood measurement.

Table 6

Descriptive Statistics for Composite Independent Categorical Variables' Factors

Factor	Unweighted frequencies	Unweighted percentage	Weighted frequencies	Weighted percentage
Covered by health insurance				
No	65	10.3	1304773	12.3
Yes	568	89.6	9294088	87.6
Regular diabetes doctor				
No	127	20.0	2176647	20.5
Yes	507	80.0	8435590	79.5
Last dilated eye exam				
Not as recommended	139	21.9	2463269	23.2
As recommended	495	78.1	8148969	76.8
Told had high blood pressure twice				
No	59	9.2	976194	9.2
Yes	438	68.5	7271466	68.5
Systolic high blood pressure				
No	425	64.3	6824038	64.3
Yes	209	35.7	3788200	35.7
Now taking cholesterol meds	44	6.9	788858	7.4
No	350	55.2	5790169	54.6
Yes				
Low HDL				
No	325	81.5	5297295	82.0
Yes	74	18.5	1161142	18.0

Inferential Statistics

Three research questions and hypothesis were addressed in this study. The dependent variable of diabetic retinopathy was a binary response variable. Complex samples logistic regression was conducted due to the absence of complex samples binary logistic regression option in SPSS. Assumptions associated with logistic regression such as the correct specification of the logistic regression model, the inclusion of all relevant predictors, large sample size, and absence of multicollinearity were met (McDonald, 2014; Pituch & Stevens, 2016; Sperandei, 2014). Absence of multicollinearity was assured with the variance inflation factor (VIF) values of the independent variables that were less than 10, as shown in Table 7.

Table 7

Variance Inflation Factor Values for Independent Variables and Covariates

Variables	VIF*
Urine albumin-creatinine ratio	1.067
Marital status	1.246
Age groups	1.248
Annual household income	1.439
Diabetes comorbidity	1.046
Health care access	1.551
Adult education level	1.164
Gender	1.128
HBAIC	1.128

**Note*: Multicollinearity is absent with VIF value of < 10 (Pituch & Stevens, 2016; Salmerón et al., 2018).

I conducted a two-step complex samples logistic regression analysis to answer each research question (see Sperandei, 2014). The first step was a model to investigate the relationship between the main predictor variable and the dependent variable of diabetic retinopathy; it served as a comparison model (Sperandei, 2014). The second step was a full model to determine the strength of the effect of multiple independent variables (main independent variables and covariates) on the dependent variable (see Sperandei, 2014).

Research Question 1

Is there an association between gender and diabetes retinopathy among adult African Americans in the United States?

H_o1: There is no association between gender and diabetes retinopathy among adult African Americans in the United States.

H_11: There is an association between gender and diabetes retinopathy among adult African Americans in the United States.

$\alpha = .05$

To address this question, a two-step complex samples logistic regression analysis was conducted (see Sperandei, 2014). The first step of the regression analysis was a reduced model with the predictor variable of gender and the dependent variable of diabetic retinopathy. From the default predicted versus observed classification table in SPSS, this regression model correctly classified participants 80.1% of the time. The overall model for this step was not significant, x^2 (1) = 3.795, p = .063, Nagelkerke R^2 = .006. The null hypothesis that there was no association between gender and diabetes retinopathy among adult African American populations in the United States was not rejected. This model functioned as the model for comparison.

The second step of logistic regression analysis was full a full model with the predictor variable of gender, the dependent variable of diabetic retinopathy, and all covariates of age groups, $HBA1_C$ level, UACR, marital status, education level, and annual household income. This model correctly classified participants 81.2% of the time; a statistically significant improvement over the comparison model was provided, x^2 (7) = 134.113, $p < .001$, Nagelkerke $R^2 = .141$. UACR, annual household income, and adult education level were statistically significant. The null hypothesis that there was no association between the combined predictor variables of gender and the covariates and diabetic retinopathy among adult African American populations in the United States was rejected.

However, gender, the main variable of interest was not significant in the two models (p = .063 and .271); the null hypothesis for Research Question 2 was not rejected. Table 8 displays the results of the comparison and full models for the logistic regression for the association between gender and diabetic retinopathy in African Americans.

Table 8

Complex Samples Logistic Regression for Association Between Gender and Diabetic Retinopathy

Step	Variable	Wald x^2	*p*	*OR*	95% *CI* for OR	
					Lower	Upper
1	Gender	3.80	.063	0.73	0.53	1.02
2	Gender (ref: Male)	1.28	.271	0.76	0.45	1.27
	HBAIC	0.01	.919	1.00	0.93	1.07
	Urine Albumin-Creatinine Ratio	107.34	.000	1.03	1.01	1.04
	Marital Status (ref: Married)	0.25	.623	0.90	0.65	1.30
	Annual Household Income (ref: Less than $20,000)	17.31	.000	1.15	1.07	1.24
	Age Groups (ref: 60-80 years old)	3.51	.075	0.73	0.51	1.04
	Adult Education Level (ref: Less than High school Education)	4.42	.048	0.86	0.74	1.00

Research Question 2

Is there an association between DM-related comorbidities of hypertension, hyperlipidemia, and diabetic retinopathy among adult African American populations in the United States?

*H*o2: There is no association between DM-related comorbidities of hypertension, hyperlipidemia, and diabetic retinopathy among adult African American populations in the United States.

$H_1$2: There is an association between DM-related comorbidities of hypertension, hyperlipidemia, and diabetic retinopathy among adult African American populations in the United States.

$\alpha = .05$

To address this question, a two-step complex samples logistic regression analysis was conducted (Sperandei, 2014). The first step of the regression model was a reduced model with the predictor variable of DM comorbidities and the dependent variable of diabetic retinopathy. From the default predicted versus observed classification table in SPSS, this regression model correctly classified participants 80.1% of the time. The overall model for this step was not significant, x^2 (1) = 1.505, $p < .232$, Nagelkerke R^2 = .001. The null hypothesis that there was no association between DM comorbidities of hypertension, hyperlipidemia, and diabetic retinopathy among adult African American populations in the United States was not rejected. This model functioned as the model for comparison.

The second step of the logistic regression model was full a full model with the predictor variable of DM comorbidities, the dependent variable of diabetic retinopathy, and all covariates of age groups, $HBA1_C$ level, UACR, marital status, education level, and annual household income. UACR and annual household income were statistically significant. This model correctly classified participants 81.2% of the time; a statistically significant improvement over the comparison model was provided, x^2 (7) = 131.769, $p < .001$, Nagelkerke $R^2 = .141$. The null hypothesis that there was no association between the combined predictor variables of DM comorbidity and covariates and diabetic retinopathy among adult African American populations in the United States was rejected.

However, DM comorbidity, the main variable of interest was not significant (p = .232 and .098); the null hypothesis for Research Question 1 was not rejected. Table 9 displays the results of the comparison and full models for the logistic regression for the association between DM comorbidity and diabetic retinopathy in African Americans.

Table 9

Complex Samples Logistic Regression for Association Between DM Comorbidity and Diabetic Retinopathy

Step	Variable	Wald x²	*p*	*OR*	95% *CI* for OR Lower	Upper
1	Diabetic comorbidity	31.55	.232	1.30	0.95	1.78
2	Diabetic comorbidity (ref: No comorbidity)	3.00	.098	1.30	0.95	1.78
	HBAIC	0.02	.905	1.00	0.93	1.06
	Urine Albumin-Creatinine Ratio	108.54	.000	1.02	1.00	1.04
	Marital Status (ref: Married)	0.12	.734	0.99	0.67	1.32
	Annual Household Income (ref: Less than $20,000)	12.38	.002	1.13	1.05	1.23
	Age Groups (ref: 60-80 years old)	3.47	.077	0.73	0.51	1.04
	Adult Education Level (ref: Less than High school Education)	4.25	0.052	0.88	0.70	1.01

Research Question 3

Is there an association between health care access and diabetic retinopathy among adult African Americans in the United States?

H_o3: There is no association between health care access and diabetic retinopathy among adult African Americans with DM in the United States.

H_13: There is an association between health care access and diabetic retinopathy among adult African Americans with DM in the United States.

α = .05

To address this question, a two-step complex samples logistic regression analysis was conducted (Sperandei, 2014). The first step of the regression analysis was a reduced model with the predictor variable of health care access and the dependent variable of diabetic retinopathy. From the default predicted versus observed classification table in SPSS, this regression model correctly classified participants 80.1% of the time. The overall model for this step was not significant, x^2 (1) = 1.929, p = .178, Nagelkerke R^2 = .010. The null hypothesis that there was no association between health care access and diabetic retinopathy among adult African American populations in the United States was not rejected. This model functioned as the model for comparison.

The second step of logistic regression analysis was full a full model with the predictor variable of health care access, the dependent variable of diabetic retinopathy, and all covariates of age groups, $HBA1_C$ level, UACR, marital status, education level, and annual household income. This model correctly classified participants 81.0% of the time; a statistically significant improvement over the comparison model was provided, x^2

(7) = 134.69, p <.001, Nagelkerke R^2 = .148. UACR and annual household income were statistically significant. The null hypothesis that there was no association between the combined predictor variables of health care access and the covariates and diabetic retinopathy among adult African American populations in the United States was rejected.

However, health care access, the main variable of interest was not significant (p = .178 and .177); the null hypothesis for Research Question 3 was not rejected. Table 10 displays the results of the comparison and full models for the logistic regression for the association between health care access and diabetic retinopathy in African Americans.

Table 10

Complex Samples Regression for the Association Between Health Care Access and Diabetic Retinopathy

Step	Variable	Wald x^2	*p*	*OR*	95% *CI* for OR	
					Lower	Upper
1	Health care Access	1.93	.178	0.35	0.73	1.67
2	Health Care Access (ref: No health care access)	1.96	.177	0.23	0.03	2.06
	HBAIC	0.00	.992	1.00	0.93	1.07
	Urine Albumin-Creatinine Ratio	111.05	.000	1.03	1.01	1.04
	Marital Status (ref: Married)	0.05	.828	0.97	0.70	1.34
	Annual Household Income (ref: Less than $20,000)	15.00	.001	1.15	1.07	1.23
	Age Groups (ref: 60-80 years old)	2.75	.112	0.75	0.52	1.08
	Adult Education Level (ref: Less than High school Education)	3.94	.060	0.87	0.76	1.01

Summary

There were three two-step complex samples logistic regression (reduced and saturated models) conducted to address the three research questions. Null hypotheses for Research Questions 1, 2, and 3 were not rejected because of the main predictor variables of DM comorbidity of hypertension and hyperlipidemia, gender, and health care access, respectively, were not significant. Covariates of UACR, annual household income, and adult education level were statistically significant in Model 1; UACR and annual household income were statistically significant in Models 2 and 3.

In the next section, I will discuss the implications of the results relative to similar studies or publications. There will also be discussions on recommendations for the professional practice among public health professionals, advocates, policymakers, and clinicians, which should result in a positive social change with the reduction of physical, mental, and socioeconomic burdens of diabetic retinopathy in African Americans.

Section 4: Application to Professional Practice and Implications for Social Change

Introduction

The purpose of this research was to examine associations between health utilization factors of gender, DM comorbidities of hypertension and cholesterol, health care access, and diabetic retinopathy among adult African Americans. In this section, the research findings will be interpreted; I will also discuss the study limitations; recommendations for the professional practice among clinicians and public health professionals, advocates, and policymakers; implications for professional practice and social change. The section ends with a conclusion. Data analyzed for this research were from a nationally representative combined dataset of 2011-2012, 2013-2014, and 2015-2016 NHANES cycles. Descriptive and inferential data analysis of the final dataset was performed with SPSS (Version 25), using the complex sample plan I developed to assure correct data weighting that should lead to accurate findings representative of adult African American population in the United States.

This study revealed a diabetic retinopathy prevalence of 21.5 % among the study participants. Albuminuria, annual household income, and education level were significantly associated with diabetic retinopathy.

Interpretation of the Findings

Prevalence of Diabetic Retinopathy

Diabetic retinopathy is the dependent variable for this study. More than one fifth (21.5%) of the study participants and almost one fifth (19.5%) of study participants who were 40 years and older were affected by diabetic retinopathy. Males (22.6%) were affected a little more than females (17.6%) (*OR* = 0.73 *CL*, 0.53 – 1.019). The overall prevalence was lower than the result of previous research involving African Americans For example, results of Zhang et al.'s (2010) cross-sectional study using data on a similar population from the 2005-2008 NHANES cycles, showed almost two-fifths (38.8%, $p = .01$) of African Americans had diabetic retinopathy. However, diabetic retinopathy was diagnosed from ophthalmic digital images (fundus photographs) of participants taken for the NHANES 2005–2008 cycles (Zhang et al., 2010).

Results of the current research suggested a decline in the prevalence of self-reported diabetic retinopathy, which is consistent with results of previous studies that have shown a declining trend in the prevalence of self-reported diabetic retinopathy. For example, Shah (2016), from a cross-sectional analysis of data from the NHANES 2011–2012 and 2013–2014 cycles reported a decline in the prevalence of self-reported diabetic retinopathy among U.S. adults, 40 years old and over, with a rate of 14.7% (95% *CI*, 11.7–17.8%). This represents a decline of 24.1% from the prevalence of 38.8% reported by Zhang et al. Luo et al. (2018) reported a significant decrease of 33% (trend $p = .003$) in the prevalence of self-reported diabetic retinopathy in North Carolina from 27.2% in 2000 to 18.3% in 2015; a decrease from 21.7% to 17.6% in Whites (trend $p = .04$), and a decrease of 39.4% to 20.2% in African Americans (trend $p = .002$). Luo et al. used data from the behavioral risk factor surveillance system (BRFSS). According to Luo et al., even though a declining trend in the prevalence of self-reported diabetic retinopathy was observed, African Americans were still disproportionately affected.

Research Question 1

Is there an association between gender and diabetes retinopathy among adult African Americans in the United States?

The logistic regression models showed that the main independent variable, gender, was not significantly associated with diabetic retinopathy in African Americans. The result of this study is inconsistent with previous findings. However, after adjusting for covariates, urine albumin-creatinine ratio ($p < .001$), annual household income ($p = .002$), and adult education level ($p < .048$) were independently associated with diabetic retinopathy in adult African Americans.

Results of the present study revealed that males (22.6%) were affected a little more than females (17.6%; *OR* = 0.73 *CL* .53 – 1.019). Previous studies have not established a consistent association between gender and development of diabetic retinopathy; and in the United States, there is no significant gender-related difference in the prevalence of diagnosed DM among adults (CDC, 2017; Ozawa et al., 2015; Wat et al., 2016). For example, Varma et al. (2007) reported that males had a 50% higher risk of having any diabetic retinopathy compared with women in the Los Angeles Latino eye study (*OR* = 1.50; $p = .006$). Although the results of Zhang et al.' (2010) study on a representative sample of the U.S. population suggested that male gender is an independent risk factor for diabetic retinopathy, the prevalence was higher among Whites (59.7 %; 95% *CI*, 49.5%–69.1%) compared to African-Americans (24.0%; 95% *Cl*, 18.2%–30.8%; $p = .008$). Abdulghani et al. (2018) reported an association between male gender and diabetic retinopathy in adult Saudi diabetic patients. However, results of a prospective diabetes study 50 in the United Kingdom showed no difference in diabetic retinopathy rates between male and female sexes ($p = 0.67$), but it was a nonsignificant association (Stratton et al., 2001).

Association between albuminuria and diabetic retinopathy in this study is consistent with previous studies, as discussed under Research Question 1. Also, the association between annual household income and education level, both components of SES, and diabetic retinopathy is consistent with previous findings (Bird et al., 2015; Emoto, Okajima, Sugihara, & Goto, 2016; Funakoshi et al., 2017; Hu et al.,2016; Kim et al., 2018; Lee, 2018; Tao et al., 2016). The results of the current research will be discussed in the last paragraph of this subsection because of their consistent relationship with diabetic retinopathy concerning the three research questions.

Research Question 2

Is there an association between DM comorbidities of hypertension, hyperlipidemia, and diabetic retinopathy among adult African American populations in the United States?

The logistic regression showed no significant association between DM comorbidity of hypertension and hyperlipidemia, the main variable of interest, and diabetic retinopathy. However, after adjusting for covariates, UACR ($p < .001$) and annual household income ($p = .002$) were independently associated with diabetic retinopathy in African Americans. Research on the association between DM comorbidity of hypertension and hyperlipidemia in African American populations is scarce. However, the result of this present research is inconsistent with the findings of a previous study in

China by Cheng et al. (2014) that depicted a significant association between diabetic retinopathy prevalence and one, two, three, and four of the cardio-metabolites (hypertension, hypertriglyceridemia, HDL, and abdominal obesity) of 16.0%, 17.6%, 21.3%, and 25.1%, (p = .001) respectively.

The presence of modifiable DM comorbidities of hypertension and hyperlipidemia in individuals may not lead to complications. Hypertension exists when systolic blood pressure is greater than or equal to 140 mmHg or diastolic blood pressure is greater than or equal to 90 mmHg, or an individual is currently taking prescribed medicine to lower high blood pressure or told by a healthcare professional on two or more different visits that she/he had high blood pressure (American Heart Association, 2019). Normal systolic pressure is 120mmhg or below, and normal diastolic blood pressure is 80mmhg or lower. Average total cholesterol level is less than 200mg/dL, LDL is less than 100mg/dL, and HDL is 40mg/dL or higher (U.S. National Library of Medicine [NIH], 2018). Hypertension and hyperlipidemia are fairly controlled among the study participants.

Average measured systolic blood pressure of 134mmhg and HDL-cholesterol of 51.43 mg/dL suggest fairly controlled hypertension and hyperlipidemia among the study participants. The nonsignificant association between diabetic retinopathy and diabetic comorbidity of hypertension and hyperlipidemia in this study could have been caused by the fairly controlled hypertension and hyperlipidemia among the study participants, which is consistent with previous research findings. For example, a Cochrane review by Do et al. (2015) showed that hypertension treatment could prevent diabetic retinopathy but does not slow its progression, and results of a Danish study by Nielsen and Nordestgaard (2014) showed that use of statins before diagnosis of DM was associated with decreased rate of retinopathy development; its use was also linked to improvement in visual acuity in those with diagnosed diabetic retinopathy.

Complications such as diabetic retinopathy arise when hypertension and hyperlipidemia are uncontrolled. Studies have shown that uncontrolled hypertension and hyperlipidemia although modifiable, are major intermediate factors underlying macro and microvascular disease such as diabetic retinopathy disparities of African American populations (Beckman & Creager, 2016; Lin et al., 2015; Magnan et al., 2015; Mozaffarian et al., 2016; Pantalone et al., 2015; Rosiek et al., 2016; Zhuo et al., 2014). Papavasileiou et al. (2017) and Penman et al. (2016) reported that diabetic retinopathy in African Americans is associated with longer duration of diabetes, uncontrolled hyperglycemia, and hypertension. Nonsignificant association between DM comorbidity of hypertension and hyperlipidemia may be related to their reasonably controlled levels.

For example, this present study revealed that for the composite variable of DM comorbidity, 68.5% of study participants were informed they had high blood pressure twice, and systolic high blood pressure was recorded on 35.7% of them. However, average recorded systolic blood pressure was 134mmhg, and average diastolic pressure 69.80 mmHg (see Tables 5 and 6). Likewise, for the composite variable of hyperlipidemia, 55.2% of participants reported taking cholesterol medications, and 18.5% of them had low HDL; yet average total cholesterol was 181.46 mg/dl, direct HDL cholesterol was 51.43 mg/dl, and LDL was 102.64 mg/dl (see Tables 5 and 6).

Albuminuria (proteinuria) is a recognized marker of nephropathy (kidney disease), and in patients with DM, it is a marker of diabetic nephropathy, which reflects microvascular complications of diabetes that include diabetic retinopathy (ADA, 2018). According to ADA, albuminuria can be detected by UACR screening in a spot urinalysis, and UACR of less than 30 mg/g Cr is accepted as normal. Average UACR in this study was 232.00 (*SD* = 687.14). Albuminuria and estimated glomerular filtration rate should be monitored regularly in diabetic patients for (a) timely diagnosis of diabetic nephropathy that may occur late in the course of DM, especially in individuals with Type 1 diabetics, or might be present at the time of diagnosis of Type 2 DM; (b) monitoring diabetic nephropathy progression; and (c) detection of other kidney diseases such as acute kidney injury that might be imposed on diabetic nephropathy (ADA). There is a paucity of literature on the relationship between albuminuria and diabetic retinopathy among African Americans.

The association between albuminuria and diabetic retinopathy in this study is consistent with previous studies globally (Ahmed, Elwali, Awadalla, & Almobarak, 2017; Hammes et al., 2015; Jeng et al., 2016; Korlarsky et al., 2015; Lee et al., 2017; Park et al., 2015). The results will be discussed fully at the end of this subsection because of the consistency of the relationship between albuminuria and diabetic retinopathy across the three research questions. The association between annual household income, a component of SES, and nephropathy is also consistent with previous findings. Annual household income is a component of SES. Results from the United States and other parts of the world have also depicted the relationship between diabetic retinopathy and SES.

The results from the present study will be discussed in the last paragraph in this subsection because of their consistent relationship with diabetic retinopathy concerning the three research questions.

Research Question 3

Is there an association between health care access and diabetic retinopathy among adult African Americans in the United States?

The logistic regression models showed that the main independent variable, health care access, was not significantly associated with diabetic retinopathy in African Americans. However, after adjusting for covariates, UACR ($p < .001$) and annual household income ($p = .001$), were independently associated with diabetic retinopathy among adult African Americans. The result that health care access is not associated with diabetic retinopathy is inconsistent with previous studies. For example, the results of several studies showed that health care access is crucial to achieving control of hyperglycemia, hypertension, and hyperlipidemia; early detection of diabetic retinopathy through regular eye-screening of DM patients; and prompt management of diabetic retinopathy that can prevent the development of early diabetic retinopathy and the progression to the late stages (Atchison & Barkmeier, 2016; Chen et al., 2014; Chew et al., 2014; Do et al., 2015; Lee et al., 2015; Lima et al., 2016; Mendanha et al., 2016; Romero-Aroca et al., 2016; Ting et al., 2016; Wat et al., 2016).

Health care access involves getting into the health care system, which is commonly through medical insurance coverage, geographic accessibility of required health care services that include diabetes eye screening, and identifying a trustworthy health care provider that can be easily communicated with (Chou et al., 2014; Do et al., 2015; Lee et al., 2015; Mendanha et al., 2016; Romero-Aroca et al., 2016; Wat et al., 2016). The present study revealed that only 39.2% of the study population had access to health care, lack of which could have affected their adequate management, including regular eye screening for diabetic retinopathy. Relationship between disparities in diabetes prevention services obtained and status of medical insurance during health care facility visit was depicted by results of a retrospective cohort research by Bailey et al. (2016); with lower odds (AOR=0.73, 95% *CI* = 0.66, 0.80) of receiving services at scheduled visits in those that were continuously insured, compared to the continuously uninsured patients. However, the internal and external validity of the results is compromised by the purposive sampling method used and a predominantly Hispanic population.

Results of a prospective follow-up study by Hu et al. (2016) depicted that socioeconomic status is a stronger determinant of access to primary care and quality and outcomes in those with T2DM than race and ethnicity. Bird et al. (2015) reported that household income has a strong and independent association with the prevalence of T2DM and some concordant comorbidities; however, African Americans were not included in the study. Even though socioeconomic barriers were eliminated, there might be difficulties in identifying a trustworthy health care provider that can be easily communicated with, due to perceived racial discrimination.

Quality of health care service and the ability to identify a trusted health care provider are related to racial health care discrimination. Racial and ethnic disparities exist in quality of care provided for control of chronic noncommunicable diseases such as hypertension, hyperlipidemia, and diabetes that are risk factors for diabetic retinopathy, with African-Americans and other minority patients having suboptimal control for blood sugar, blood cholesterol, and blood pressure with resultant complications that include diabetic retinopathy (Agency for Healthcare Research and Quality, 2017; Laiteerapong et al., 2015; Yoon et al., 2015). According to Abramson et al. (2015), racial minorities, especially African-Americans reported more racial health care discrimination; and increased perceptions of discrimination were associated with poor communication with health care provider across all racial and ethnic groups, and perceptions of discrimination were associated with an increased level of education in all racial and ethnic groups except Whites. Laiteerapong et al. (2015) carried out a cross-sectional study on a nationally representative sample to determine disparities in diabetes care. The results showed that more Whites achieved A1C < 8% goal than African Americans (81% versus 74%, $p < .001$); fewer African Americans were recommended individualized LDL goals compared to Whites (10% versus 33%, $p < .003$; more Whites (51%) achieved individualized LDL control; and adequate blood pressure control goal of less than 140/90 mmHg was reached by fewer African-Americans compared to Whites (53% versus 69% $P < .001$). Results of a cross-sectional study by Assari et al. (2017) demonstrated that racial health care discrimination is reported more by African American men with T2DM than women; and perceived discrimination is associated higher levels of HBA1C in African American men.

Previous studies showed that even though African Americans are among those that are disproportionately affected by diabetic retinopathy, they had one of the lowest rates of diabetic retinopathy screening and scheduled follow-up eye care utilization (Keenum et al., 2016; Maclennan et al., 2014; Yu et al., 2015). Results of a prospective follow-up study by Keenum et al. (2016) showed that despite minimizing accessibility and costs as barriers to eye care, only a third of study participants adhered to scheduled intervals for follow-up eye care after the diabetic retinopathy screening.

Association between albuminuria and diabetic retinopathy in this study is consistent with previous studies, as discussed under research question 1. Also, the association between annual household (a component of SES) and nephropathy is consistent with previous findings. They are also consistent with findings in Research Questions 1 and 2. The relationship between annual household income alone and as a component of SES will be discussed in the last paragraph of this subsection.

Associations Between Albuminuria, Annual Household Income, Education Level, and Diabetic Retinopathy in African Americans

The association between albuminuria and diabetic retinopathy in this study is consistent across the three research questions in the current study and also with previous studies globally (Ahmed et al., 2017; Hammes et al., 2015; Jeng et al., 2016; Korlarsky et al., 2015; Lee et al., 2017; Park et al., 2015). For example, Lee et al. (2017) in South Korea from a cross-sectional study reported an independent association between UACR level and diabetic retinopathy and its severity in those with Type 2 DM. Results of a cross-sectional study in South Korea by Park et al. (2015), showed that there was a significant association between albuminuria and diabetic retinopathy and vision-threatening diabetic retinopathy in Type 2 diabetics with chronic kidney disease ($p < .001$

and .043) respectively. Ahmed et al. (2017) in Sudan reported a significant association between diabetic nephropathy and diabetic retinopathy ($p = .009$).

In Germany, microalbuminuria was independently associated with diabetic retinopathy, and the strongest predictors of severe retinopathy were micro- and macroalbuminuria and HbA1c (Hammes et al., 2015). Korlasky et al. (2014) in a retrospective study carried out in southern Israel reported a unidirectional association between diabetic nephropathy and diabetic retinopathy, with diabetic nephropathy preceding diabetic retinopathy ($p < .001$) and level of kidney damage was proportionate to the level of retinopathy. In Taiwan, Jeng et al. (2016) found that diabetic nephropathy was an independent risk factor for diabetic retinopathy development and progression ($p < .001$).

Associations between annual household income and education level, both components of SES and nephropathy are consistent with previous findings. They are also consistent with findings across the three research questions for the current study. According to APA, SES refers to the social class of an individual or group that is generally assessed by combining income, education, and occupation level (American Psychological Association, 2019). SES creates health inequity and inequality, including diabetic retinopathy that disproportionately affects disadvantaged groups such as the African American population. Studies showed that even though African Americans are among those are disproportionately affected by diabetic retinopathy, rates of diabetic retinopathy screening and scheduled follow-up eye care utilization were lowest in this population, which are related to limited health care access influenced by factors that include socioeconomic status (Hu et al., 2016; Keenum et al., 2016; Maclennan et al., 2014; Piyasena et al., 2019; Yu et al., 2015).

In South Korea, the odds of developing diabetic retinopathy is significantly decreased in men with highest household income (OR, 0.59; 95% *CI*, 0.37 - 0.95), while men in lower SES group had higher odds of developing diabetic retinopathy and poor metabolic control (Kim et al., 2018). In a cross-sectional study on Type 2 DM patients in China, Tao et al. (2016) reported that those with the least education were at higher risk for developing cardiovascular diseases such as diabetic retinopathy ($p < .001$) and cerebrovascular diseases ($p < .001$); the highest prevalence of diabetic retinopathy ($p < .001$), and diabetic neuropathy ($p < .001$) was among patients with the lowest income. Among adults 20 - 40 years old with T2DM in Japan, when compared to those with a higher SES, there were higher odds of developing retinopathy among junior high school graduates (OR1.91, 95% *CI* 1.09 - 3.34); patients on public assistance (OR 2.19, 95% *CI* 1.20 - 3.95); patients without employment (OR 2.23, 95% *CI* 1.36 - 3.68); and patients with temporary employment (OR 1.72, 95% *CI* 1.03 - 2.86) after adjusting for covariates of gender, age, and BMI (Funakoshi et al., 2017). In South Korea, lower education level was associated with lower diabetic retinopathy screening (Lee, 2018). Emoto et al. (2016) reported that among individuals with poorly controlled Type 2 DM in Japan, there was a strong association between lower educational attainment and diabetic retinopathy, which is independent of the economic status.

Limitations of the Study

This was a cross-sectional study that utilized data on a nationally representative sample of adult African Americans with diabetes to examine the association between diabetic retinopathy and diabetes comorbidities of hypertension and hyperlipidemia, gender, health care access, and covariates (UACR, annual household income, age, marital status, $HBA1_C$, and education level). However, there are some limitations to the study. Study participants for NHANES were only noninstitutionalized legal residents in the 50 states and the District of Colombia; as such the results of this research may not be generalizable to those that did not qualify for inclusion in the survey (CDC, 2017a). The prevalence of diabetic retinopathy in this study could have been inaccurate because it was based on data from self-reported diagnosis, which could have resulted in recall bias due to inaccurate or incomplete recollections of past events or experiences, thus affecting the prevalence. Also, self-reported diagnosis without fundus photography of participants in 2011-2012, 2013-2014, and 2015-2016 NHANES cycles compared to 2005-2008 NHANES cycle could have underestimated the prevalence of diabetic retinopathy in this study.

As a cross-sectional study, the relationships between the dependent variable of diabetic retinopathy and the independent variables were examined in a specified population within a specific timeframe; the association between diabetic retinopathy and the identified risk factors of albuminuria, annual house income, and education level were demonstrated. There was no indication of the order of events, limiting inference of cause and effect (Caruana et al., 2015; Mariani & Pego-Fernandes, 2014; Omair, 2015; Setia, 2016).

Recommendations

This cross-sectional study examined the relationships between the dependent variable of diabetic retinopathy and the independent variables that were in a specified population with a specific timeframe. Risk factors for diabetic retinopathy such as albuminuria, annual house income, and education level were identified, but cause and effect from simple association could not be established from the type of study design that was utilized. There is a paucity of literature on studies that established the identified risk factors as causes of diabetic retinopathy in adult African Americans. I recommend that the associations identified in the present study should be studied rigorously by utilizing longitudinal study designs to establish cause and effect (Mariani & Pego-Fernandes, 2014; Setia, 2016).

Prevalence of diabetic retinopathy in this study was based on data from self-reported diagnosis that could resulted in recall bias due to inaccurate or incomplete recollections of past events or experiences, which could have affected the prevalence. Self-reported diagnosis without fundus photography of participants in 2011-2012, 2013-2014, and 2015-2016 NHANES cycles compared to 2005-2008 NHANES cycle could have underestimated the prevalence of diabetic retinopathy in this study. Prevalence of diabetic retinopathy in all adults in this study was 21.5% and 19.5% in those 40 years and older, similar to 14.7% reported by Luo et al. (2018), suggesting a decline in the prevalence of self-reported diabetic retinopathy. The prevalence is lower than the result of similar research by Zhang et al. (2010) that utilized digital retinal imaging system to assess the retina, with a prevalence rate of 38.8% among adults 40 years. I recommend the use of fundus digital imaging system photographs in assessing the retina of future NHANES participants, thus eliminating the recall bias associated with a self-reported diagnosis of diabetic retinopathy (Katulanda, Ranasinghe, & Jayawardena, 2014).

Implications for Professional Practice and Social Change

In this cross-sectional study, albuminuria, annual household income, and education level were identified as risk factors for diabetic retinopathy. Albuminuria (need factor), education level (predisposing factor), and annual household income (health care access factor) were identified as risk factors for diabetic retinopathy that affects about one-fifth of adult African Americans. The Andersen model of health care utilization was the framework for the research. Diabetic retinopathy is a significant cause of preventable eye damage that includes blindness; each year, between 12,000 and 24,000 new cases of blindness are caused by diabetes retinopathy (Skaggs et al., 2017).

The vision-threatening diabetic retinopathy, although a preventable complication of DM, is associated with disease, economic, health care system, and social burdens. Quality of life of persons with any degree of moderate or total visual loss is affected in many ways such as their psychological and physical well-being, their work and possible loss of earning power, social integration, independence, and greater need for quality health and social support that could be overwhelmed in disadvantaged communities that include some African American communities where such services barely exist (International Diabetes Federation, n.d.; Skaggs et al., 2017; Willis et al., 2017). Early detection of diabetic retinopathy is crucial in preventing visual impairment; and progression of diabetic retinopathy has been dramatically reduced by timely medical and surgical treatments (Jani et al., 2017).

Even though African Americans are among those disproportionately affected by diabetic retinopathy, rates of diabetic retinopathy screening and scheduled follow-up eye care utilization were lowest in this population, which are related to limited health care access influenced by factors that include socioeconomic status (Hu et al., 2016; Keenum et al., 2016; Maclennan et al., 2014; Piyasena et al., 2019; Yu et al., 2015). SES creates health inequity and inequality which can only be addressed by interventions that target the societal determinants of health, developed and implemented by considering the broader, proximal, population-focused determinants that influence health inequalities and inequities among African Americans (Gehlert et al, 2008; Thornton et al., 2016; U.S. Department of Health and Human Services, 2010; WHO, 2016).

Positive social change can be affected in African American populations and other disadvantaged communities by public health officials, policymakers, and advocates by utilizing knowledge on the strong relationships between the health care utilization factors (need, predisposing, and enabling factors) and diabetic retinopathy in planning and developing effective public health interventions targeting these communities. This should result in a decreased burden of diabetic retinopathy on individuals, families and friends, health care systems, and social support systems among specific African American populations and other disadvantaged communities. Suggested policy interventions include quality housing and health services, elimination of health discrimination, improvement in education, and reduction in income disparity in some African American populations and other disadvantaged communities (Thornton et al., 2016).

Conclusion

This study investigated the associations between DM comorbidities of hypertension and hyperlipidemia (need factor), gender (predisposing factor), health access (enabling factor), and diabetic retinopathy in adult African Americans. The results demonstrated that DM comorbidities, gender, and health care access were not significantly associated with diabetic retinopathy. However, albuminuria (need factor), education level (predisposing factor), and household income (enabling factor) were significantly associated with diabetic retinopathy. These variables may be central to future studies to determine cause and effect relationships between diabetic retinopathy and the determinants of health care utilization among adult African Americans with DM.

The result of this study is consistent with those of previous studies, which depicted that albuminuria, annual household income, and education level are risk factors for diabetic retinopathy among different racial groups. As such, it is crucial to consider the need, predisposing, and enabling factors that determine health care utilization and detection of diabetic retinopathy when planning public health intervention policies targeting disadvantaged populations.

Chronic diseases such as DM, hypertension, and hyperlipidemia are modifiable risk factors for developing macro- and microvascular diseases such as diabetic retinopathy and nephropathy with their often-burdensome end stages that disproportionately affect African Americans and other disadvantaged racial and ethnic groups. The socioeconomic and health disparities can be reduced by public health advocates and policymakers developing policy interventions that address the socioeconomic drivers of health inequalities and inequities among African Americans and other disadvantaged racial and ethnic groups, and communities.

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