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Predictors of Glycemic Control Among Type 2 Diabetes Mellitus Patients in Owerri, Nigeria

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Walden University

College of Health Professions

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Jideuma Egwim

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2022

Abstract

Predictors of Glycemic Control Among Type 2 Diabetes Mellitus Patients

in Owerri, Nigeria

by

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MSc, University of Liverpool, 2017

MBBS, University of Ibadan, 1999

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health—Epidemiology

Walden University

May 2022

Abstract

Diabetes mellitus (DM) is a significant public health concern globally and in Owerri, Nigeria. The deleterious effects of diabetes have been linked to poor glycemic control. According to the International Diabetes Federation, poor glycemic control is reflected in glycosylated hemoglobin (HbA1c) levels greater than 7.0%, which are associated with substantial morbidity and mortality. Studies have shown a dramatic rise in diabetic complications in Nigeria, particularly in Owerri. However, evidence is lacking on specific risk factors associated with poor glycemic control among DM patients in Owerri. With health insurance assuming a significant position in healthcare service delivery in Nigeria, addressing this gap is valuable. This was a cross-sectional study of predictors of glycemic control among 160 Type 2 diabetic patients attending the diabetes clinic at the Federal Medical Center, Owerri. The independent variables were health insurance (not insured, insured—private, and insured—public/National Health Insurance Scheme [NHIS]), education, body mass index, and blood pressure, while the dependent variable was glycemic control measured using HbA1c. Eco-social theory was the theoretical framework of this research. Bivariate and multiple logistic regression analyses showed that only health insurance (not insured and insured—public) was a predictor of glycemic control, with uninsured subjects at 32 times increased risk of poor glycemic control compared to insured—NHIS subjects. This finding has potential to promote positive social change through optimization of the NHIS in line with its enabling regulations and design of policies to explicitly cover diabetes preventive and control services in the scheme.

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Dedication

I dedicate this dissertation to my wife, Dr. Adanna; my parents; and my siblings for their sound support all through the period of my PhD program. The same goes to my children, Chigozirim, Chidiadi, Ikenna, and Adanna, for coping with my tight schedules that affected their own programs. You have all been a wonderful family.

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Chapter 1: Introduction to the Study

Introduction

Diabetes mellitus (DM) is a chronic metabolic disorder resulting in hyperglycemia from defective insulin secretion and/or action. It is a major cause of morbidity and mortality globally, accounting for 1 in 9 deaths annually with a global prevalence that has quadrupled in the last 30 years (Zheng et al., 2018). Globally, about 463 million people had DM in 2019 (International Diabetes Federation [IDF], 2019), with 25 million sufferers living in Africa (Essiet & Osadolor, 2019). Nigeria, the most affected nation in Africa, is home to about 3.9 million diabetic patients (Dahiru et al., 2016), with the prevalence reported to be escalating giving an overall pooled prevalence of DM in Nigeria at 5.8% (95% CI 4.3–7.1) in 2019 (Uloko et al., 2019). The pooled prevalence of DM in the six geopolitical zones of Nigeria ranged from 3.0% (95% CI 1.7–4.3) in the northwest to 3.8% (95% CI 2.9–4.7) in the north-central zone, to 4.6% (95% CI 3.4–5.9) in the southeast, to 5.5% (95% CI 4.0–7.1) in the southwest, to 5.9% (95% CI 2.4–9.4) in the northeast, and 9.8% (95% CI 7.2–12.4) in the south-south zone. The mean prevalence of DM in southeast Nigeria is reported to be 4.6%, but studies have noted far higher rates in some towns in the southeast compared to any other locations in Nigeria. For instance, Ogbu et al. (2012) reported a prevalence of 15.6% in Owerri in 2012, which is by far the highest prevalence rate reported in Nigeria. More recently, Onoh and Nwaogazie (2015) observed a prevalence of 7.5% in Owerri; it is expected that this level has risen higher at the present time following the general trend in DM prevalence.

Current research on diabetes has aimed at drawing attention to the associations between socioeconomic factors/behavioral patterns and DM control. In line with this, I

aimed in this research to assess the association between risk factors and the state of glycemic control among diabetic patients to serve as a guide to healthcare providers in developing more efficient strategies toward the reduction in the burden of DM. This chapter includes background information for the study and contains a brief summary of existing literature related to this research with the identified gap that this study was conducted to address; the problem statement, which defines the research problem with its relevance and significance to the field of epidemiology; the study purpose, which stipulates the study intent and study variables; the research questions and hypotheses; the theoretical framework that underpinned the research; and the nature of the study with a concise rationale for the choice of study design and methodology. Other sections include definitions of the variables and any relevant terms used in the study; assumptions; scope and delimitations, which deal with issues of internal and external validity; limitations; and significance, which addresses social change implications of study.

Background

The deleterious effects of diabetes have been linked to poor glycemic control. Studies have shown a high prevalence of poor glycemic control among diabetic patients, ranging from 40% to 85% globally (Gopinath et al., 2013; Haghightapanah et al., 2018; Mahmood et al., 2016; Noor et al., 2017). Prevalence rates of poor glycemic control in Nigeria range from 50.1% (David et al., 2019) to 83.3%, with the 83.3% reported in southeast Nigeria (Anioke et al., 2019). Despite the high prevalence of DM in Owerri, and with the disease constituting a substantial percentage of inpatient care in tertiary centers in Owerri (Ezeama & Enwereji, 2019), no studies have been conducted on the effect of health insurance on glycemic index. Of significance, Anoshirike et al. (2019)

reported that 91.7% of adult diabetic patients in Owerri had poor glyceemic control; thus, it is probable that, in Owerri, there may be a prevalence of poor glyceemic control much higher than the global and Nigerian average. Owerri is geographically located in southeast Nigeria but is a city at the borders of south-south Nigeria, the region with the highest prevalence of DM in the country. Owerri has a huge influx of patients from neighboring south-south states. This factor, in combination with the very high prevalence of poor glyceemic control in diabetic subjects in Owerri, offers evidence that diabetes is a major problem in Owerri. This was the basis of my choice of topic for the dissertation and selection of Owerri as the ideal location for conducting this study in Nigeria.

Problem Statement

The standard marker for glyceemic control is glycosylated hemoglobin (HbA1c). The IDF recommended an HbA1c of 7.0% as the threshold for glyceemic control, with levels below and above this reflecting good and poor control, respectively (American Diabetes Association, 2018). Factors associated with poor control include poor medication adherence, unhealthy diet, obesity, duration of diabetes > 10 years, hyperlipidemia, elderly age, high systolic blood pressure (BP), and male gender (Anioke et al., 2019); poor health literacy, low education, and unemployment (Asmelash et al., 2019; Dedefo et al., 2020). While generally the prevalence of DM has been on the rise in Nigeria, studies have shown a dramatic increase in diabetic complications such as leg ulcers, cardiovascular illness, and renal ailments in Owerri (Ezeama & Enwereji, 2019). Unique to Owerri, Ezeama and Enwereji (2019) reported that most of the diabetic subjects admitted for various complications were civil and public servants, and 65% of them had a sedentary lifestyle with excess body weight. Owerri is essentially a civil and

public service town with a huge population of federal government staff on public health insurance coverage.

Insurance coverage in Nigeria is broadly of two types, the public and private schemes. The public type (National Health Insurance Scheme [NHIS]) is run by the government. Though the law establishing the NHIS makes provision for all citizens, only a few are enrolled in the scheme presently. These are primarily employees and students in federal government institutions. The private scheme is run by health management organizations (HMOs) and mostly includes employees of the organized private sector and international nongovernmental organizations (NGOs). Nigeria's NHIS is analogous to Medicaid, which is the U.S. public health insurance program, but while Medicaid is the principal source of long-term care coverage for Americans, including low-income earners, NHIS covers primarily federal government staff, leaving state government staff, local government staff, small and medium enterprise (SME) employees, the retired, self-employed persons, most students, and the unemployed without any coverage. While the enabling law for the NHIS made provision for these classes of individuals, poor implementation has grossly limited its coverage despite great efforts over the years by operators of the scheme to broaden its enrollment base and enhance its services. It is known that a lack of insurance coverage results in low utilization of healthcare services, which may result in elevated HbA1c levels in diabetic subjects and lead to increased risk of complications, reduced quality of life, and worsening morbidity and mortality (Mahmood et al., 2016).

In Nigeria, progressive improvement in public health insurance scheme enrollment, service utilization, and overall enrollee satisfaction have been observed

(Michael et al., 2020). While unpublished data have shown a high utilization of healthcare service by diabetic patients on health insurance coverage in Owerri, the level of poor glycaemic control remains high (Anoshirike et. al., 2019). There are reports of frequent delay and denial of payments to healthcare providers (HCPs), such that HCPs may resort to unethical practices such as use of poor quality medications and denial of adequate care to diabetic patients on health insurance coverage, a situation that may retard or reverse the expected gains of health insurance coverage toward improved diabetes care in Owerri and Nigeria as a whole (Campbell, 2018; Chukwu & Ezenduka, 2020). Furthermore, there exists significant differential on premium rates, extent of coverage, and valuation of fee-for-service payments to HCPs by HMOs for enrollees under the public and private health insurance schemes. This may result in differential quality in service offered to diabetic patients under the different health insurance packages, with attendant differences in glycaemic control between enrollees under the public and private health insurance programs. This study yielded knowledge on factors related to glycaemic control in diabetic patients in Owerri and Nigeria in general, which may guide policies targeted at reducing the burden of diabetes-related morbidity and mortality in Nigeria.

Purpose

The purpose of the study was to determine the prevalence of poor glycaemic control among Type 2 diabetic patients in Owerri in southeast Nigeria, measured using HbA1c, and to investigate the associations between health insurance, education, BMI, and BP with glycaemic control in the subjects. The primary data collected were demographic variables of the participants, namely sex, age, occupation, and

socioeconomic factors such as health insurance status and education. Participants self-performed weight and height measurements while the following biometric data—BP, fasting blood glucose (FBG), and HbA1c readings—were retrieved from their clinical records. Data collected were analyzed for associations between the risk factors and glycemic control. This research was unique because among the few studies on predictors of glycemic control among adult diabetic subjects in Nigeria, none had assessed the effect of health insurance status (Anioke et al., 2019; David et al., 2019; Onodugo et al., 2019; Ufuoma et al., 2016). Health insurance is at the evolutionary stage in Nigeria; less than 22% of Nigerian citizens have some form of coverage (NOI Polls, 2019), and of the few who have coverage, the majority belong to the poorly run public NHIS. Health insurance coverage as a tool to advance universal health coverage will be a major determinant of health in Nigeria in the near future. It is expected that findings and recommendations from this study on the effect of health insurance on glycemic control in diabetic subjects will lead to tangible changes promoting optimal utilization of health insurance in achieving improved care for citizens of Nigeria.

Research Questions and Hypotheses

Bivariate Research Questions

RQ 1: Is there an association between health insurance status (not insured, insured—private, insured—public) and glycemic control among Type 2 diabetic patients?

H₀: There is no association between health insurance status (not insured, insured—private, insured—public) and glycemic control among Type 2 diabetic patients.

H₁: There is an association between health insurance status: (not insured, insured—private, insured—public) and glycemic control among Type 2 diabetic patients.

RQ 2: Is there an association between education and glycemic control among Type 2 diabetic patients?

H₀: There is no association between education and glycemic control among Type 2 diabetic patients.

H₁: There is an association between education and glycemic control among Type 2 diabetic patients.

RQ 3: Is there an association between body mass index (BMI) and glycemic control among Type 2 diabetic patients?

H₀: There is no association between BMI and glycemic control among Type 2 diabetic patients.

H₁: There is an association between BMI and glycemic control among Type 2 diabetic patients.

RQ 4: Is there an association between blood pressure (BP) and glycemic control among Type 2 diabetic patients?

H₀: There is no association between BP and glycemic control among Type 2 diabetic patients.

H₁: There is an association between BP and glycemic control among Type 2 diabetic patients.

Multivariable Research Question

Is there is an association between health insurance (not insured, insured—private, insured—public), education, BMI, and BP as independent variables and glycemic control among Type 2 diabetic patients measured using HbA1c as the outcome, controlling for medication adherence, age, and gender?

H₀: There is no association between health insurance (not insured, insured—private, insured—public), education, BMI, and BP as independent variables and glycemic control among Type 2 diabetic patients measured using HbA1c as the outcome, controlling for medication adherence, age, and gender.

H₁: There is an association between health insurance (not insured, insured—private, insured—public), education, BMI, and BP as independent variables and glycemic control among Type 2 diabetic patients measured using HbA1c as the outcome, controlling for medication adherence, age, and gender.

Theoretical Framework

The theoretical framework for this study was eco-social theory. Eco-social theory is a multilevel theory of disease occurrence that explains how social and biologic reasoning are integrated with an ecological perspective to address population levels of disease (Anderson, 2020). Eco-social theory was first proposed in 1994 by Nancy Krieger, as a broad and complex theory with the purpose of describing and explaining

causal relationships in disease distribution. Epidemiology is the science of public health, and in eco-social theory there is a concerted effort to articulate how diverse aspects of human living—involving work, economic conditions, and social factors—and interactions with the environment become literally incorporated biologically into people's lives and manifest in the health status of individuals and populations (Krieger, 2011). The eco-social theory offers a conceptual underpinning for how diverse factors such as health insurance, age, gender, education, medication adherence, BP, and BMI interact at biological, social, and ecological levels to impact blood glucose control in diabetic individuals. Table 1 shows the relationship between the theoretical framework and study variables. Further details on how the eco-social theory was applied to this study are discussed in Chapter 2.

Table 1*Theoretical Framework and Study Variables*

Theoretical framework— Eco-social theory	Predictors of glycemic control among Type 2 diabetic patients in Owerri, southeast Nigeria
List of constructs	Study variables
1. Social	1. Health insurance (independent) <ul style="list-style-type: none"> • Not insured • Insured—Private • Insured—Public
2. Biological	2. Age (independent)
3. Social	3. Education (independent) <ul style="list-style-type: none"> • No school • Primary school • Secondary school • Tertiary
4. Biological	4. Gender (independent) <ul style="list-style-type: none"> • Female • Male
5. Ecological	5. BMI (independent)
6. Biological	6. Blood pressure (independent) <ul style="list-style-type: none"> • Normal • Elevated
7. Social/biological/ecological	7. Glycemic control (outcome) <ul style="list-style-type: none"> • Controlled • Not controlled

Nature of the Study

This was a quantitative study using a cross-sectional design. The study population was adult Type 2 diabetic patients aged 18 years and above attending the diabetes clinic of the Federal Medical Center, Owerri, a tertiary health facility in southeast Nigeria for at least 6 months. A cross-sectional study uses an observational study design to assess exposure and the outcome in the study participants simultaneously and possibly any

association existing between them (Setia, 2016). Such a design is valuable in population-based surveys and in the measurement of disease prevalence.

My study involved the measurement of predictors of glycemic control in diabetic subjects as explanatory variables and glycemic control levels as outcome variable at the same time; thus, cross-sectional study was the most suitable design for this research. Furthermore, a cross-sectional design, being a snapshot of a population, delivers a faster and less expensive study compared to other designs (Setia, 2016). For these reasons, this design was well suited for my dissertation research. Additionally, cross-sectional studies have the benefit of yielding information useful for the design of further epidemiological studies of more robust design such as longitudinal studies, and policy frameworks for healthcare planning. These are expected benefits of the outcomes of my research.

Primary data were utilized to collect participants' sociodemographic information while the biometric measurements were retrieved from their clinical records. Primary data are original data collected firsthand by a researcher for a particular research purpose (Ajayi, 2017). They offered the benefit of my collecting information for the specific purposes of this study; thus, data collection was tailored to elicit data distinctly targeted to provide answers to the research questions. Thus, sources of data were existing clinical records of patients and direct interviews via a survey.

The diabetes clinic runs on daily basis and has a registry of diabetic patients. A set of inclusion and exclusion criteria was defined for the selection of participants. A systematic random sampling technique was used to recruit participants who satisfied the eligibility criteria. A survey was conducted for data collection using an interviewer-administered questionnaire. Information contained in the questionnaire included

participants' biodata such as age and gender; FBG; medication adherence; the independent variables—health insurance, education, BMI, and BP; and the dependent variable (HbA1c level). HbA1c is a blood test, and the results were recoded into a binary variable with < 7% indicating good control and > 7% indicating poor control, according to American Diabetes Association (2018) recommendation. Both descriptive and inferential statistics were used to discuss the data. Logistic regression was applied for inferential statistics as the dependent variable, glycemic control, was a binary variable. All the participants offered signed informed consent.

Definitions

Independent Variables

Health insurance: Defined as a participant having access to health insurance coverage (insured—private and insured—public or insured—NHIS) or not (uninsured).

Education: Defined as highest educational attainment of participant, classified as no formal education, primary education, secondary education, or tertiary education.

Body mass index (BMI): Defined as participant's height/weight² in kg/m².

Blood pressure (BP): Defined as the arterial BP measured using a sphygmomanometer and expressed as systolic/diastolic BP. Recoded as presence of elevated BP > 139/89 mmHg in a subject or not if systolic BP/diastolic BP or both exceeded this threshold.

Confounders

Age: Age of patient at time of enrollment in the study.

Gender: Defined as male or female.

Medication adherence: Defined as a ratio of the number of drug doses taken to the number of doses prescribed over a given time period (Morrison et al., 2015). Adherence was classified as poor or good.

Dependent Variable

Glycemic control: Defined as state of diabetic control in a participant measured by level of HbA1c in % and dichotomized at 7%.

Assumptions

This was a quantitative study using a deductive approach. The first assumption was that the sample was representative of the overall population of Type 2 diabetic subjects in Owerri. The sample size was calculated using a sound approach with appropriate power to give a minimum sample size of 159 participants comprising both insured and uninsured individuals. A systematic sampling strategy allowed for a good spread of the sample among the study population, and the diabetes clinic of FMC, Owerri has a catchment area covering the entire Owerri area and beyond. The second assumption was that the information extracted from the participants was true. A third assumption was that the data retrieved from the participants' clinical records were true and valid. Cause-and-effect relationships could not be measured in this study because exposure and outcome were assessed simultaneously; however, it was assumed that any association observed in this research suggests that the exposure(s) predict(s) the outcome.

Scope and Delimitations

This quantitative study addressed a research problem, the predictors of glycemic control among diabetic subjects. Specifically, health insurance, education, BMI, and BP were assessed for associations with glycemic control in diabetic subjects. The predictors

were selected based on the unique need to present a biological, social, and ecological dimension to diabetes control and to highlight the close interaction that exists among these in line with eco-social theory. Owerri was chosen as study area because of its relatively high prevalence of DM and upsurge in many social factors that may impact control in diabetic subjects as discussed above.

The study population comprising Type 2 diabetic patients 18 years and above was carefully chosen because Type 2 DM is the predominant type of diabetes globally, and the age bracket would effectively suit generalization of the results to adult diabetic subjects. Owerri is geographically centrally located in southeast Nigeria and has a predominant population of the Ibo ethnicity with natural origin in this region of Nigeria. Thus, the setting allows for generalization of the study outcomes to southeast Nigeria. Though causality cannot be established with this study being of a cross-sectional design, the scope of this research is useful in yielding preliminary data for future longitudinal research on risk factors for glycemic control in diabetic patients.

Limitations

My study involved the collection of primary biodata and access to the clinical records of diabetic patients in a health institution. Potential challenges included protection of the rights of the participants and confidentiality of data. Strategies including a meticulous informed consent process and early interphase with the hospital's ethics committee concerning ethical approval for this study were deployed to address any concerns that the participants might have had. Secondly, this was a cross-sectional study, and the data cannot be applied in asserting a cause-effect relationship, unlike a longitudinal or experimental study.

Significance

In order to minimize the burden of DM in Nigeria, there is need for improved access to healthcare services by diabetic patients as occurs in developed nations. The outcomes and recommendations of my study may be applied to impact significant positive alteration over time on implementation and utilization of NHIS services, and a policy thrust on diabetes care, both of which may have long-term social change implications. For instance, diabetes preventive and control services have been included in health insurance coverage plans since 2010 in the United States. Such an approach is possible in Nigeria with advocacy canvassed under an evidence-based framework to provide a template for healthcare delivery plan decision making and new policy formulation.

My dissertation topic was designed to yield information on the burden of diabetes as reflected in the level of glycemic control among diabetic patients and the determinants. The outcomes and recommendations of this research are expected to drive population-based secondary preventive strategies targeted at limiting the occurrence of complications among diabetic patients, with the objective of reducing morbidity and mortality in the community, thus creating social change. Social change aims “to generate, conserve, and transform knowledge by making connections among and between ideas to improve human and social conditions” (Walden University, 2005). By focusing on diabetes, which affects most communities, I intend to cause improvement in the health status of populations and thus overall human conditions. Furthermore, the effects of diabetes cut across all strata of society and significantly impact national economies and global health

expenditure. Mitigating this negative impact is another sphere of positive social change inherent in the improved control of diabetes, which is the goal of my research outcomes.

Summary

In this chapter, I have introduced my research on the predictors of glycemic control among diabetic subjects by providing the background for the topic, discussing the statement of problem, and stating the purpose of the study. The research questions and study variables were specified for this quantitative cross-sectional study with the eco-social model as the theoretical framework. Issues of internal and external validity were discussed with limitations, significance, and social change implications. Chapter 2 will focus on the literature review, search strategy, and details on DM. The chapter will also include a detailed discussion of the theoretical foundation for the study and a review of epidemiological studies on glycemic control in diabetic subjects.

Chapter 2: Literature Review

Introduction

With improvement in community diagnosis of DM and advances in treatment, it is expected that morbidity and mortality from the disease will be on a downturn. However, literature from across the globe has suggested otherwise (Anioke et al., 2019; David et al., 2019; Gopinath et al., 2013; Haghightapanah et al., 2018; Mahmood et al., 2016; Noor et al., 2017). The goal of diabetes management, which is defined clinically as good glycemic control, has remained largely unmet. Glycemic control is a factor of many variables, encompassing biological, social, and ecological determinants. This study assessed the predictors of glycemic control among Type 2 diabetic subjects and specifically determined the associations between patients' health insurance status, type of health insurance coverage, education, BP, and BMI and glycemic control.

In Owerri, Nigeria, the prevalence of DM, put at over 15%, is high, and the disease has constituted a significant proportion of admissions in tertiary health facilities in the town (Ezeama & Enwereji, 2019). Furthermore, over 90% of the diabetic patients in Owerri have been reported to have poor glycemic states (Anoshirike et al., 2019). While the literature offers information on the burden of diabetes in Owerri, existing studies have not addressed the possible factors contributory to this; thus, this poor state of affairs does exist probably because there is a gap in the knowledge of predictors of glycemic control in Owerri. In Nigeria, most patients access medications by out-of-pocket payments, and with the high level of poverty in the country, regular funding for medications is challenging; the social health insurance scheme offers a unique opportunity for patients to access drugs under health insurance coverage, which

eliminates the effect of out-of-pocket financing. This notwithstanding, it has been observed that many diabetic subjects enrolled and accessing care under the scheme still have poor glyceemic control.

Researchers in Nigeria with interest in diabetes have not assessed the interaction between health insurance and glyceemic control in diabetics (Anioke et al., 2019; David et al., 2019; Onodugo et al., 2019; Ufuoma et al., 2016). Gaps exist on the effect of diabetic patients' health insurance status and type of health insurance coverage on glyceemic control. In this study, I aimed to address these gaps using data from subjects attending the diabetes clinic of the Federal Medical Centre, Owerri. At present, healthcare planners in Nigeria have intensified efforts at advancing health insurance coverage among the citizens with incorporation of aspects of care for noncommunicable diseases. The conclusion of this study is expected to give valuable information on the best approaches to improving glyceemic control among diabetic patients in Owerri and yield guidelines on the place of social health insurance in population-based control of diabetic complications. This chapter starts with a brief outline of the literature search strategy, followed by the study's theoretical foundation. The theoretical framework, as stated in Chapter 1, hinged on the eco-social model. Lastly, a review of existing literature on glyceemic control in diabetic patients, prevalence of poor control, and possible predictors is discussed.

Literature Search Strategy

The literature referenced in this study was identified and extracted mostly from electronic database searches of PubMed, CINAHL Plus, OVID, EMBASE, and EBSCO. The literature search occurred predominantly through the Walden library and Google Scholar. Inclusion criteria were articles published since 2015, article in English, and

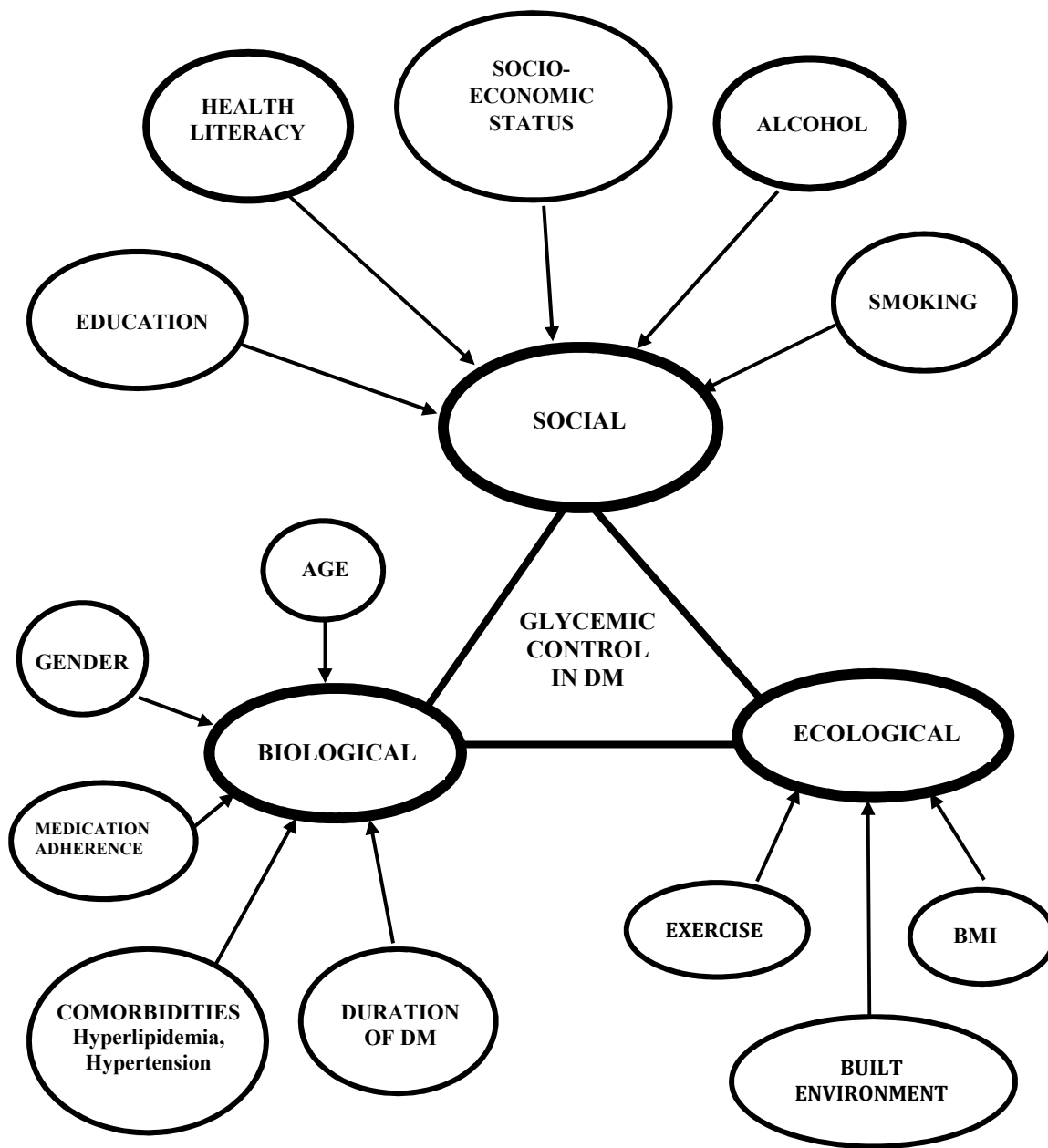
articles in peer-reviewed journals. A few seminal articles such as the work of Ogbu et al. on the prevalence of diabetes in Owerri in 2012 and references from textbooks published more than 5 years ago but relevant to the topic of study were included. The key words/terms used for search were *Type 2 diabetes*, *glycemic control*, and *predictors*. In addition to using key words to search, the reference lists from research articles obtained were reviewed, and relevant articles were called up and read for further information. Dissertations at Walden and other universities on glycemic control in diabetic subjects were also searched, though none was found worthy of referencing in this study.

Theoretical Foundation

Eco-social theory provides the framework for explanation of the many factors that influence glycemic control in diabetic subjects (see Figure 1). Factors such as age, gender, medication adherence, duration of diabetes, and comorbidities (hyperlipidemia and hypertension) represent factors at the biological level that may influence glycemic control in diabetic subjects (Anioke et al., 2019). Education, health literacy, socioeconomic status, alcohol, and tobacco smoking are social factors that may be considered to affect glycemic control in DM (Asmelash et al., 2019; Dedefo et al., 2020; Onodugo et al., 2019), while diet (BMI), exercise, and the built environment are factors at the ecological level that may predict glycemic control in diabetic subjects (Fekadu et al., 2019).

Figure 1

The Eco-Social Theory of Glycemic Control in Diabetic Subjects



Eco-social theory helps researchers to conceptualize a much broader array of social determinants with the key function to draw capacity to identify specific and strategic opportunities for intervention to improve population health. To lay a valid framework for my dissertation, it is important to gauge the association between the variables of study to drive the conception that health insurance status, education, BMI, and BP may influence glycemic control in diabetic subjects. According to Homan's theory of interaction as reported by Creswell and Creswell (2018), the interaction between variables is such that one would expect the independent variable(s) to influence the dependent variable(s). Secondly, the independent variables or potential predictors include an array of social determinants of health such as education and health insurance interacting with environmental and biological factors to determine the dependent variable, glycemic control in diabetic patients. This highlights eco-social theory in practice as a theoretical foundation for essential knowledge that is valuable for improved control of diabetes, thus minimizing the burden of the disease and advancing population health.

Diabetes Mellitus

Definition of Diabetes Mellitus

DM is a clinical syndrome characterized by hyperglycemia due to absolute or relative deficiency of insulin. Lack of insulin affects the metabolism of carbohydrate, protein, and fat and causes a significant disturbance of water and electrolyte homeostasis. Diabetes is defined as a FBG equal to or above 126mg/dl (7.0mmol/L) or random blood glucose equal to or above 200mg/dl (11.1mmol/L) with symptoms of DM, except for patients already on treatment for diabetes, who may have blood glucose levels that are

within normal range (Powers et al., 2020). A HbA1c $\geq 6.5\%$ in adults is also diagnostic of DM (Punthakee et al., 2018). The characteristic symptoms are polydipsia, polyuria, polyphagia, and unexplained weight loss. In some scenarios, the initial presentation may follow a complication such as diabetic ketoacidosis or leg ulcer, while in a few patients, especially in Type 2 diabetes, the disease may be asymptomatic and the diagnosis obtained on routine blood or urine glucose test.

Classification

Advances in the study of DM in the last decade have led to the classification of the disease on the basis of the pathogenic process that leads to hyperglycemia, as opposed to criteria such as age of onset, natural history, and therapeutic distinction as regards insulin requirement. Four broad categories exist in this classification. They are Type 1, Type 2, other specific types, and gestational DM (Powers et al., 2020).

Type 1 DM

This has two subtypes, A and B. Type 1A DM results from autoimmune beta cells destruction, which usually leads to insulin deficiency, while Type 1B DM differs from Type 1A in that these individuals lack immunologic markers indicative of an autoimmune destructive process of the beta cells. The mechanism leading to beta cell destruction in Type 1B is unknown. Most Type 1 patients belong to the Type 1A subtype. Type 1 DM was previously known as insulin dependent DM (IDDM) due to resistance to oral hypoglycemic agents and reliance on insulin by the subjects to achieve glycemic control.

Type 2 DM

This was once referred to as non-insulin-dependent diabetes mellitus (NIDDM) and comprises a heterogeneous group of disorders characterized by variable degrees of

insulin resistance, impaired insulin secretion, and increased glucose production. Distinct genetic and metabolic defects in insulin action and/or secretion give rise to hyperglycemia in Type 2 DM. Type 2 DM is much commoner than Type 1 and constituted the study population for this research.

Gestational DM

As the name suggests, this is glucose intolerance that develops and is first recognized during pregnancy. In this, there are metabolic changes, especially in late pregnancy, resulting in insulin resistance with subsequent increase in insulin requirement leading to hyperglycemia or impaired glucose tolerance. Most of the women revert to normal glucose tolerance after birth but have increased risk (30-60%) of developing DM later in life.

Other Specific Types of DM

This wide and varied category comprises a host of conditions that impair glucose tolerance and include specific genetic defects in insulin secretion or action, genetic defects of B-cell function characterized by mutations, diseases of the exocrine pancreas, endocrinopathies, drug-or chemical-induced diabetes, infections, genetic syndromes sometimes associated with diabetes, and metabolic abnormalities that impair insulin secretion. In this category is maturity onset diabetes of the young (MODY), a subtype of DM characterized by autosomal dominant inheritance, early onset of hyperglycemia, and impairment in insulin secretion.

This current classification differs from previous classifications in that the terms IDDM and NIDDM are obsolete, as many patients with Type 2 DM ultimately will require insulin for glycemic control. Secondly, the use of age as a criterion for

classification is inappropriate. In terms of person, although Type 1 DM commonly develops before the age of 30, an autoimmune beta cell destructive process can develop at any age. Similarly, although Type 2 DM commonly develops with increasing age, it also occurs in children, and particularly in obese adolescents. However, it is noted that Type 2 DM predominantly occurs in middle-aged and older individuals, with family history of DM and overweight being the key driving factors (Zheng et al., 2017). Type 2 DM is much commoner than Type 1 and constituted the study population for this research.

In terms of place, Type 2 DM has a global distribution and is a pandemic. The prevalence is higher and rising at a faster rate in low-income nations, with Africans, Hispanics/Latinos, American Indians, and Asians at greater risk of developing the disease. Time trends also indicate increasing prevalence of Type 2 DM worldwide. In 2017, 6.28% of the global population had Type 2 DM, split into 4.4% in the 15–49 years group, 15% in the 50–69 years group, and 22% aged 70 years and above at a prevalence rate of 6,059 cases per 100,000 (Khan et al., 2020). This is projected to increase to 7, 079 cases per 100,000 by 2030. Selection of Type 2 diabetic subjects, who constitute 90% of all diabetic patients (Zheng et al., 2017), as the study population offers a valuable approach to access the majority of individuals living with DM and assess the influence of BMI on glycemic control.

Diagnosis of Diabetes Mellitus

The current criteria for the diagnosis of DM issued by consensus panels of experts and the World Health Organization (WHO) reflect new epidemiologic and metabolic evidence based on variation in normal individuals on the spectrum of FBG and response

to oral glucose load, and the level of glycemia at which diabetes-specific complications are observed.

According to Powers et al. (2020), glucose tolerance is classified into three categories based on FBG:

- normal glucose tolerance (NGT)—FBG \leq 6.1mmol/L (110mg/dl)
- impaired fasting glucose (IFG)—FBG $>$ 6.1mmol/L but $<$ 7.0mmol/L
- diabetes mellitus (DM)—FBG \geq 7.0mmol/L(126mg/dl)

IFG is analogous to impaired glucose tolerance (IGT), defined as blood glucose between 7.8 and 11.1mmol/L (140 and 200mg/dl) 2 hours after a 75g oral glucose load. Though individuals with IFG or IGT do not meet criteria for DM, they are at substantial risk for developing Type 2 DM and cardiovascular disease in the future and are classified as “prediabetes.”

Other criteria for the diagnosis of DM are as follows:

- random blood glucose of \geq 11.1mmol/l (200mg/dl) plus symptoms of diabetes
- two hours blood glucose \geq 11.1mmol/l during an oral glucose tolerance test

A positive result should be confirmed by repeating the test on a different day unless there is no doubt as to the presence of significantly elevated glucose levels.

Risk Factors Associated With Diabetes Mellitus

The risk factors associated with DM are many and varied. Of these, genetic and environmental factors play strong roles (Powers et al., 2020).

Genetic Factors

Type 1 DM. This develops as a result of the synergistic effects of genetic, environmental, and immunologic factors that ultimately destroy the pancreatic beta cells except the few that fall into the type IB idiopathic category, who lack immunologic markers indicative of an autoimmune destructive process of the beta cells (Powers et al., 2020). According to the authors, evidence for genetic predisposition to Type 1 is proven in many studies. This genetic contribution involves multiple genes. The concordance of Type 1A DM in identical twins ranges between 30 and 70%. The risk of developing Type 1 DM for relatives of individuals with the disease is considerably higher compared to the risk for the general population.

Type 2 DM. Genetic factors play a stronger role in Type 2 than Type 1 diabetes. (Powers et al., 2020). The concordance rate for Type 2 DM in identical twins is between 70 and 90%, and about 25% of those with the disease have a family history of diabetes. Those with first-degree relatives with Type 2 DM have a much higher risk of developing Type 2, increasing with the number of those relatives. Various genetic loci contribute to susceptibility with further modulation of the phenotypic expression of the disease by environmental factors. The disease is polygenic and multifactorial. Individuals with one parent with Type 2 DM have an increased risk of diabetes; if both parents have Type 2 DM, the risk in offspring may reach 40%.

Environmental Factors

Certain environmental factors have been linked to the pathogenesis of DM in adults, particularly in cases of Type 2 DM (Powers et al., 2020). These factors are obesity; increased consumption of a high-calorie, high-carbohydrate diet, especially with

refined sugars; and sedentary lifestyle. In the last three decades, Nigeria has undergone drastic lifestyle changes associated with urbanization and modernization resulting in change of diets to high-calorie, high-carbohydrate diets and more sedentary jobs with less physical activity. Owerri as a city has become the new hub of the hospitality industry in Nigeria with the proliferation of hotels and restaurants at every corner.

Management of Diabetes Mellitus

The objective of treatment in diabetes is to achieve a steady good glycaemic control to prevent or lower the occurrence of vascular disease and specific diabetic complications and to allow the patient to achieve as normal a life-style as possible. To reach these goals, the physician needs to

1. Identify a target level of glycaemic control for the patient to establish therapeutic goal.
2. Yield the patient educational and pharmacologic resources essential to reach this level.
3. Counsel the patient on the relevance of lifestyle adjustment such as having regular aerobic exercises, observing a healthy diet, maintaining an ideal body weight, reduction in alcohol consumption and avoidance of smoking.
4. Monitor and prevent DM-related complications using a multi-disciplinary team approach including a family physician, an endocrinologist, an ophthalmologist, a podiatrist, a nutritionist, and other sub-specialists skilled in DM-related complications when these arise.

5. Consider social, environmental, family, financial, cultural, and employment related issues that may impact on diabetes care and ensure patient's participation, input and enthusiasm.

During treatment patient's blood glucose is closely watched to ensure good glycemic control. HbA1c is primarily used as a treatment-tracking test reflecting average glucose levels over the preceding 90 days. The recommended goal for diabetic subjects is <7.0% which is defined as good glycaemic control. Diabetic subjects who have HbA1c levels within this range have a significantly lower incidence of complications from the disease.

Review of Epidemiological Studies on Glycemic Control in Diabetic Subjects

The deleterious effects of diabetes have been linked to poor glycemic control. Of all the literature reviewed, the highest prevalence for poor glycemic control was reported in Owerri by Anoshirike et al. (2019), put at 91.7%. Studies showed a high prevalence of poor glycemic control among diabetic patients ranging from 40% to 85% in other parts of the globe (Gopinath et al., 2013; Haghghatpanah et al., 2018; Mahmood et al., 2016; & Noor et al., 2017). Across Nigeria excluding Owerri, prevalence rates of poor glycemic control ranged from 50.1% (David et al., 2019) to 83.3%, with the latter reported in the south-east region where Owerri is located (Anioke et al., 2019). Poor glycemic control is worse in the developing nations with high values reported across Asia and Africa particularly. Studies reviewed included research conducted in India, Saudi Arabia and Malaysia for Asia; and Ethiopia, Sudan, Uganda, and Nigeria for Africa.

Mahmood et al., (2016) and Abdullah et al., (2020) conducted cross-sectional studies on glycemic control in diabetic patients in Malaysia. Mahmood et al. focused on

the prevalence of glycemic control and factors associated with poor glycemic control in Type 2 DM (T2D), with poor glycemic control reported as HbA1c values $\geq 6.5\%$. Seven hundred and six participants aged over 18 years and with a diagnosis of Type 2 DM for > 1 year were recruited across 13 public health clinics using the National Diabetic Registry database. Relevant information included biodata, type of treatment, HbA1c, and other parameters of glycemic control. Abdullah et al. were interested in biopsychosocial predictors of glycaemic control and recruited 300 diabetic subjects. Mahmood et al. established that 68% of the respondents had poor glycemic control with the mean HbA1c calculated as 7.8%. Of the patients with poor glycemic control, four out of every five was obese and the predictors of poor glycemic control using multiple logistic regression analysis were age (<60 years), male gender, duration of diabetes (>5 years), BMI (obese), and co-morbidity (dyslipidemia). Unique strengths of the study include a large sample size spread across 13 sites which enhanced the generalizability of the findings, however, adoption of 6.5% as threshold for poor glycemic control in contrast to 7.0% recommended by most authorities may have contributed to the high prevalence of poor control noted in this study. Despite using an HbA1c threshold of $\geq 7.0\%$, the prevalence of poor glycaemic control reported as 69% by Abdullah et al. was similar to the finding of Mahmood et al; and the predictors were longer duration of DM, a greater number of days of missed medications, and younger age. Though no psychological factors were associated with poor glycaemic control in this study, biopsychosocial factors by virtue of being social determinants of health remain an area of further studies to assess association with glycemic control.

Shrestha et al. (2019) conducted a primary research in a tertiary hospital in India among 422 respondents attending the Medical Outpatient Patient Department using structured questionnaire through interview method. The prevalence of poor glycemic control was 40%. The authors noted that longer duration of disease is associated with poor glycemic control. A factor that could have contributed to this is good compliance among majority of the respondents, who were also observed to attending diabetic counseling, and showed adequate knowledge. It is difficult; however, to generalize this finding as this was a hospital based single site research, though; it is a perfect template for implementation of regular counselling for diabetic patients at follow-up visits.

Haghighatpanah et al. (2018) conducted a retrospective study on factors that correlate with poor glycemic control in 657 Type 2 DM patients in India, who were aged 40 years and older. The study was conducted retrospectively on medical records (in-patient and out-patient) obtained from a South Indian teaching hospital. The patients included in the study had FBG, postprandial blood glucose, and HbA1c measured at least twice during follow-ups the previous year. In the study, 78.2% had poor glycemic control with gender (female), age, duration of diabetes and co-morbidities (dyslipidemia) recorded as significant factors for poor control.

In Saudi Arabia, Abdelwahid et al. (2017) assessed a cohort of 78 diabetic subjects using primary data collected via structured questionnaire to assess pattern and predictors of glycemic control among Type 2 diabetic subjects based on both HbA1c and fasting plasma glucose (FPG). The results showed that 75.6% of the respondents in the study had poor glycemic control using HbA1c > 7.0 % with long duration of diabetes and co-morbidity as predictors. However, this study had a low sample size and, therefore, difficult to generalize.

Several studies across Africa were reviewed. In Sudan, DM is a key health challenge and major cause of morbidity and mortality (Noor et al., 2017). Noor in their study recruited 387 respondents on treatment for diabetes in selected diabetes centers in different cities in Sudan for at least a year and used primary data collected using pretested questionnaire. Information gathered included individual medical records, socio-demographic features, BP, BMI, and HbA1c levels. The glycemic control indicator was $HbA1c > 7$. Chi square and logistic regression were used as statistical methods. The prevalence of poor glycemic control was 85% in the patients. Factors associated with poor glycemic control were prolonged duration of diabetes, and co-morbidities specifically dyslipidemia and low glomerular filtration rate. This was a multi-center study with a fair sample size, almost equally distributed among the sexes (50.4% males and 49.6% females). The outcome of this study offered an explanation on why DM is a leading public health issue in Sudan, and the need for a robust nationwide approach to its control.

Among African nations, Ethiopia has a huge population of diabetic patients only excelled by Nigeria; consequently, a substantial number of studies in Ethiopia were reviewed. Dedefo et al. (2020) used existing clinical record of patients and direct interview during patient hospital visit for data collection, and logistic regression to determine the association between glycemic control and the predictor variables in 252 study participants in Nekemte, Ethiopia. Still in the same Nekemte, Ethiopia, Fekadu et al. (2019) conducted a study on challenges and factors associated with poor glycemic control among 228 Type 2 DM patients. Dedefo et al. observed the prevalence of poor glycemic control as 59.5%. Associated factors were unemployment, lack of family/social

support, duration of diabetes of >10 years, and poor knowledge of diabetes while Fekadu et al. reported 64.9% as prevalence of poor glycemic control with younger age group (40-60 years), low level of education, duration of DM > 10 years, inadequate exercise, and smoking implicated as associated factors. Importantly, more than two-third of the participants in the study by Dedefo et al. had poor knowledge about DM while over 75% lacked any form of self-monitoring. Similarly, majority of the participants in the study by Fekadu et al. were either illiterate or had only informal education. Tekalegn et al. (2018) conducted a Hospital-based cross sectional study among 412 Type 2 diabetic patients attending diabetic clinics also in a tertiary health facility in Addis Ababa, Ethiopia. Primary data were collected through structured interview questionnaire, with additional information from each patient's medical records. Eighty percent of the respondents had poor glycemic control, and duration of diabetes longer than 10 years was significantly associated with poor glycemic control. Asmelash et al. (2019) conducted their study on 403 diabetic subjects attending the University of Gondar Hospital, Ethiopia using primary data collected via questionnaires, and applied logistic regression for analysis. The results showed that barely half of the participants had good knowledge, attitude, and practice towards glycemic control. Further studies in Ethiopia included hospital based cross-sectional research of 384 and 325 diabetic adults respectively on factors associated with glycemic control among diabetic outpatients in Northeast and Southwest Ethiopia by Fiseha et al. (2018), and Kassahun et al. (2016) respectively. Fiseha et al. recorded a prevalence of 70.8% for poor glycemic control and on logistic regression analysis, rural residence, low educational level and longer duration of diabetes were significantly associated with increased odds of poor glycemic control. The study by Kassahun et al.

reported similar outcomes to the latter. The prevalence of poor glycaemic control was 70.9 % and poor education and farming which tantamount to rural residence in Ethiopia had increased odds of poor glycaemic control. All the studies reviewed from Ethiopia used FBG of 130mg/dl as threshold value for glycaemic control. In Ethiopia, just like other parts of Africa, it is essential that health practitioners integrate regular diabetes counselling in the management of the disease while improving population education and health literacy as approaches to glycaemic control in diabetic patients.

In Egypt, Ismail et al. (2019) conducted a study on prevalence of depression and predictors of glycaemic control among Type 2 DM patients. The results showed that 74.3% of the respondents had poor glycaemic control, and the predictors for glycaemic control were depression, co-morbidities and presence of complications from diabetes. In Uganda, Kibirige et al. (2017) sampled a population of 423 outpatient diabetic patients to assess the frequency and predictors of suboptimal glycaemic control in an African diabetic population. They noted that 73.5% had poor glycaemic control which was associated with metformin monotherapy.

Across Nigeria, several studies were reviewed. David et al. (2019) conducted a retrospective review of 385 patient medical records to determine the glycaemic control and its determinants among patients with Type 2 DM in northern Nigeria based on FBG, similar to the study by Haghghatpanah et al. (2018) in India. Majority of respondents (62.6%) were females. Half of the subjects had poor glycaemic control associated with obesity, low education and low physical activity levels. Educational and lifestyle interventions were recommended to address factors associated with poor glucose control. Onodugo et al. (2019) conducted a cross-sectional study on glycaemic control among

medical outpatients in southern Nigeria. Majority (62.2%) were females. Over half of the patients (52.9%) had poor glycemic control with medication adherence and substance use associated. Ufuoma et al. (2016) and Anioke et al. (2019), conducted similar studies in Nigeria's Niger Delta and South-east regions respectively. According to Ufuoma et al., the prevalence of poor glycemic control was 55% and associated factors identified were longer duration of diabetes and poor knowledge of DM while Anioke et al. identified the elderly, obesity, and elevated systolic BP as significant factors associated with poor glycemic control.

Of all the studies reviewed, only the study by Anioke et al. (2019) was conducted in a town geographically close to Owerri and with similar climate and culture but different socio-demographic distribution. Instructively, the study reported the highest level of poor glycemic control globally (83.3%) but for Noor et al. (85%) at Sudan, and Anoshirike et al. (2019) 91.7% in Owerri. Results from all the studies reviewed showed that majority of diabetic subjects globally have poor glycemic control which on its own is a gap; and the figures on prevalence of DM in Owerri and state of glycemic control in the patients create further gap that justifies this study especially on the background that from the literatures no previous study exists on predictors of glycemic control in Owerri, Nigeria. Furthermore, the literature review justifies the choice of predictors for this study.

Health Insurance

The key independent variable is health insurance status and only a few studies reviewed assessed for association between this risk factor and glycemic control in diabetic subjects. This risk factor is important in Owerri because while the majority of the inhabitants are uninsured, a significant proportion of the population are staff of the

federal civil and public service who are enrolled into the NHIS, and employees of the organized private sector who are beneficiaries of the private health insurance program. In a survey of 16.9 million insured Type 2 diabetic subjects in the US by States, the prevalence of poor control ranged from 29% in Minnesota and Iowa to 53% in Texas (Dall et al., 2016). There was a correlation between poor control and increased prevalence of neurological, renal, and peripheral vascular complications. Additionally, patients with poor control averaged \$4,860 higher average annual health care expenditures - ranging from \$6,680 for commercially insured patients to \$4,360 for Medicaid and \$3,430 for Medicare patients. In another study in the United States (National Health and Nutrition Examination Survey [NHANES]) comparing quality indicators among privately and publicly insured diabetic subjects, there were no differences in diabetes quality measures between the groups (Doucette et al., 2016). HbA1c levels were also not different among insurance groups but patients with insurance were more likely to meet 3 of 5 quality indicators for diabetes care compared with those without insurance, thus, access to health insurance was associated with improved diabetes management in this study. These, however, contrast from another study in Switzerland which found no difference in quality of diabetes care between insured and uninsured patients in a public hospital (Jackson et al., 2016).

Education

Several studies reported on the occurrence of a significant association between poor level of education and poor glycemic control. These were particularly observed in studies conducted in parts of Africa that were educationally disadvantaged in Ethiopia and Nigeria. Fekadu et al. (2019) in Nekemte, Fiseha et al. (2018) in north-east, and

Kassahun et al. (2016) in south-west, reported this finding in Ethiopia while David et al. (2019) reported same in northern Nigeria. While the entire northern Nigeria is demographically classified as educationally disadvantaged by the government of Nigeria, in contrast, Owerri as most of south-east Nigeria is classified as educationally advantaged. It is yet to be seen how this relative educational advantage will interact with glycemic control in diabetic subjects.

Body Mass Index

The role of weight in glycemic control in diabetic subjects is best assessed using the individual participants BMI. Weight is important in diabetes because beyond reflecting the available body mass for insulin activity, it is a marker for dietary discretion and physical activity which are useful parameters in both primary and secondary control of diabetes. Thus, it is a key independent variable and risk factor for assessment in studies on diabetes. Mahmood et al. (2016) in Malaysia, David et al. (2019) in northern Nigeria, and Anioke et al. (2019) in south-east Nigeria all reported on obesity as a significant contributor to poor glycemic control in diabetic subjects. While these authors categorized weight and only reported on obesity, overweight is a unique category in BMI classification which also carries a risk for diabetic complications, thus, my study will also assess any association between overweight and glycemic control. Of more importance, the role of increasing and decreasing body weight in glycemic control in diabetic subjects is important and my study will be focusing on this as an addition by measuring weight as a continuous variable as against a categorical variable used in the studies reported.

Blood Pressure

BP and blood glucose have a close association. Persistently elevated BP or hypertension and diabetes constitute a greater percentage of non-communicable diseases globally and are components of the metabolic syndrome. Research has reported a higher prevalence of elevated BP among diabetic subjects compared to the general population in Owerri (Onuoha & Egwim, 2017) but few studies have assessed the association between BP and glycemic control in diabetic patients. There are factors that predispose diabetic patients to hypertension such as atherosclerosis and diabetic nephropathy resulting from poor glycemic control, and these are well researched. However, the same cannot be said of the effect of BP as a risk factor for poor glycemic control in diabetic subjects. In the literature reviewed, Anioke et al. (2019) reported an association between elevated systolic BP and glycemic control in diabetic subjects in a city proximal to Owerri. Mention was not made of diastolic BP. It may be premature to conclude on the merit of this study that isolated systolic hypertension among other risks it carries, is also an independent risk factor for poor glycemic control in diabetic individuals. My research will test the result of Anioke et al., and more importantly yield information on whether elevated BP is a risk factor for poor glycemic control in diabetic individuals when it is known that the latter is a risk factor for hypertension, thus, creating a vicious circle which knowledge will be of immense public health importance.

Link Between Literature Review and Methodology

The literature review revealed a huge burden of diabetes and associated poor glycemic control among the subjects in Owerri with attendant lack of knowledge on risk factors responsible for this state of affairs. This is the gap that justifies my research. The

set out for this study, therefore, was to define the present burden of diabetes control in terms of prevalence of poor glycaemic control among the subjects in Owerri and assess factors contributory to this prevalence. This presents an observational research scenario with a descriptive component and an inferential statistics which is well suited for a cross-sectional design. The study design involved a concurrent assessment of the explanatory variables or exposure and the outcome in a cross-section of adult Type 2 diabetic subjects selected by systematic random sampling using primary data survey and biometric data retrieved from patients' clinical records.

With paucity of studies on social predictors of glycaemic control in diabetic subjects from the literature, emphasis in my research was on social factors and two namely - health insurance status and education were selected as independent variables. BMI which has both a social and biological component was also selected with BP which is a biological factor completing the list of risk factors. The need to assess the effect of numerous or multiple characteristics on diabetic subjects at a single point in time lends this research to a cross-sectional design which has the unique strength of affording the researcher the opportunity to assess several prevalent attributes on a given population in a snapshot. Findings from cross-sectional studies are particularly valuable in healthcare planning which aligns with the purpose of this research to drive decision-making and related policies to control glycaemic levels among diabetic patients.

Summary and Conclusion

Except for two studies which used retrospective method, all the studies in this review used cross-sectional approach with primary data to determine prevalence of poor glycaemic control and predictors. The studies were hospital based and sample size ranged

from 78 and 706. The studies were conducted predominantly in the last five years mostly in Type 2 diabetic patients on treatment for at least one year. The work by Mahmood et al., (2016) and Noor et al., (2017) involved multiple sites in Malaysia and Sudan respectively which enhanced their generalizability. A major aspect of variation among the authors was criteria for determination of glycemic control. Some authors used glycosylated hemoglobin; others used FBG while some used both criteria. Among those that used glycosylated hemoglobin, the threshold was 7.0% though Mahmood et al. applied 6.5% as cut-off. From the literature, among authors that applied both criteria, there seemed to be no significant difference in glycemic control among the respondents. In this study, however, HbA1c of 7.0% was used as the threshold following recommendation of the American Diabetes Association (2018). Of significance, in majority of the studies reviewed, over half of the diabetic subjects had poor glycemic control.

Several predictors were assessed across the studies. In most of the studies, long duration of DM (more than 10 years), younger age, low adherence to medications, and presence of co-morbidity particularly dyslipidemia were associated with poor glycemic control. Most of the studies focused on biological factors with little consideration of social factors. The role of social factors such as health insurance, and education as predictors of glycemic control in diabetic subjects is not well known to the field of epidemiology in south-east Nigeria. In keeping with the eco-social theoretical framework, this research took cognizance of the emerging influence of social determinants on health. This study's purpose was to determine the prevalence of poor glycemic control in

diabetic subjects and the association between health insurance, education, BMI, and BP as independent variables, and glycemic control as the dependent variable.

Chapter 3: Research Method

Introduction

In this chapter, I describe the research design used in this quantitative study. As stated in Chapter one, the purpose of the study was to determine the prevalence of glycemic control among Type 2 diabetic patients in Owerri, Nigeria, measured using HbA1c as part of the descriptive analyses; and to investigate the associations between health insurance, education, BMI, and BP as independent variables, and glycemic control as the dependent variable, in the subjects, while controlling medication adherence, age, and gender. Published studies on predictors of glycemic control among diabetic patients in Nigeria have focused on biological factors. Little attention has been given to social factors, and none have considered health insurance. The results of this study may yield important information on optimal utilization of health insurance services in achieving improved diabetes care for citizens of Nigeria. This research may contribute to positive social change by identifying contributing factors to poor diabetes control so as to stimulate the development of innovative and socially inclined approaches to secondary prevention of diabetes-related illnesses with the aim of reducing morbidity and mortality in populations.

This chapter begins with a description of the study site, the research study design, rationale, and the methodology, using primary data including the procedure for sampling and subject recruitment. The chapter also contains a discussion of the operationalization for each variable, the data analysis plan, threats to validity, and finally, any potential confidentiality and ethical issues.

Study Site

The study site was the Medical Out-Patient (MOP) Clinics. The MOP Clinics include a diabetes clinic, which runs on a daily basis from 8:00 a.m. to 4:00 p.m. and has a registry of diabetic patients attending the Federal Medical Center, Owerri, a tertiary health facility. The clinic has four consulting rooms, a waiting room, a counseling room, and a test room. It is run by consultant endocrinologists and resident doctors. The counseling room served as study site; it was spacious, well ventilated, and conducive to administering the informed consent process as well as ensuring patient privacy, data collection, and confidentiality of data collected.

Federal Medical Center is the leading health institution in Imo state, South-East Nigeria, and is situated in the capital city, Owerri. The hospital has been in existence as a health center and then general hospital for over 100 years but was upgraded to a tertiary center in 1996. It serves as the tertiary receiving hospital for primary and secondary health institutions as well as private hospitals in the state and parts of neighboring states in both southeast and south-south Nigeria. Owerri has a dense population mostly comprising government-employed staff, students, entrepreneurs, core professionals, and semiskilled, mostly self-employed workers predominantly from the Ibo tribe. The staple foods of the residents comprise mainly heavy starch bolus swallowed with soup, rice, beans, plantain, and cereals. In the new millennium, the city has become the haven of fast food restaurants and hotels in Nigeria, with a resultant dramatic rise in the intake of dense, saturated food; products containing huge volumes of refined sugars; and alcohol by the residents.

Research Design and Rationale

This was a quantitative cross-sectional study. The study population was adult Type 2 diabetic patients aged 18 years and above attending the diabetes clinics of the Federal Medical Center, Owerri, a tertiary health facility in South-East Nigeria. The study was cross-sectional because I took a snapshot observation of a group of Type 2 diabetic patients. A cross-sectional observational design allows a simultaneous assessment of exposure(s) and outcome(s) in the study participants for possible associations and thus saves money and time when compared to other observational designs such as longitudinal studies (Setia, 2016). It is therefore well suited for dissertation research, where a limited timeframe is applicable, and prevalence studies. Primary sociodemographic data and biometric data retrieved from patients' clinical records were utilized. The independent variables were health insurance, education, BMI, and BP in the respondents, while the confounders were medication adherence, age, and gender. The dependent variable was glycemic control as determined by HbA1c. The results of the blood test were recoded to < 7% (good control) and > 7% (poor control) according to American Diabetes Association (2018) recommendation.

Study Population and Sample Size

The study population was adult diabetics aged 18 years and above attending the diabetes clinic of the Federal Medical Center, Owerri. The study population comprised already-diagnosed diabetic patients attending the clinic on follow-up for at least 6 months. On the average, the clinic sees about 15 already diagnosed diabetic patients each clinic day on follow-up, which is about 75 patients a week and 300 a month. An appropriate sample was calculated and recruited from the study population based on

subjects who satisfied the inclusion criteria. Two approaches were employed for sample size calculation for this study: manually and G*Power software. The latter took precedence because G*Power allowed for analyses to be adjusted and for accommodation of the multivariable relationship among the covariates in the sample size calculation.

Using the formula for sample size calculation for cross-sectional studies (Charan, & Biswas, 2013),

$$n = \frac{Z^2 pq}{d^2}$$

n = minimum sample size

Z = standard normal variate at 5% type 1 error = 1.96

p = prevalence of poor glycemetic control among diabetic patients from previous studies.

83.3%, reported by Anioke, et al (2019) in a city proximal to Owerri in South-East Nigeria is used,

$$q = 1 - p$$

d = absolute error or precision allowed which for this study is fixed at 5%

$$n = 1.96^2 \times 0.833 \times 0.167 / 0.05^2; n = 0.5344 / 0.0025$$

$n = 213.8$ which is approximately 214 subjects.

However, the study population was less than 10,000. Hence, the desired sample size was adjusted using the following formula (Onsongo & Peter, 2016):

$$n_f = n / 1 + \left(\frac{n}{N}\right)$$

Where n_f = desired sample when population is less than 10,000.

n = desired sample size when the population is more than 10,000.

N = estimate size of target population (average number of Type 2 DM patients seen at the diabetic clinic in two months = $300 \times 2 = 600$)

$$\text{Therefore, } n_f = 214 / 1 + \left(\frac{214}{600} \right) = 157.8 \approx 158$$

Thus, calculated sample size by the manual approach was 158.

Using G*Power under multiple logistic regression, input parameters were two-tailed test; level of significance = 5%; power of 80%; and probability of poor glycemic control in uninsured = 83.3%, as reported by Anioke et al. (2019) in a city proximal to Owerri in South-East Nigeria. R^2 is the amount of variability in the main predictor (health insurance status) accounted for by the covariates. The presumption is the occurrence of a significant level of multivariable relationship among the covariates; therefore, moderate association is assumed among them = 0.25; distribution is binomial. It is expected that the number of insured and uninsured subjects will be equal, thus, X parm # = 0.5. The adjusted OR calculated was 3.3, and the calculated sample size was 159, as shown in Appendix C. This was similar to the manually calculated sample size as shown above. Therefore, a sample size of 160, split into 80 participants for insured and uninsured subjects, was used for this study.

Inclusion Criteria

Inclusion criteria applied to already diagnosed Type 2 diabetic adults aged 18 years and above attending the diabetes clinic of FMC, Owerri for at least 6 months who gave consent.

Exclusion Criteria

The following patient populations were excluded from this study:

- patients with acute illness or critical illness that would impair their ability to participate in the study
- patients with major psychiatric illness or impaired cognitive function

Sampling Strategy

A systematic random sampling technique was used to recruit participants who met the selection criteria. Systematic random sampling offered the benefit of a reduction in the potential for bias in the selection of cases included in the sample (Laerd Dissertation, 2012). It provided a sample that was highly representative of the population being studied, thus allowing for generalizability of results. Adoption of systematic sampling offered a superior strategy to simple random sampling because across the study population there was an enhanced chance of spreading the units more evenly.

The projected duration of this research was 8 weeks. Based on 5 clinic days a week giving 40 clinic days in 8 weeks, a minimum of $160/40 =$ four subjects was recruited on each clinic day for each of insured and uninsured subjects. This was feasible considering that on the average, the diabetes clinic saw about 15 patients each clinic day. The first patient was selected using a simple random sampling by balloting among the first four patients who presented to the diabetes clinic each day; thereafter, every fourth patient was recruited until four patients were enrolled per clinic day for insured and uninsured subjects. Following enrollment of the participants and satisfaction of ethical requirements, accrual of data was via interviewer administered questionnaires. An interviewer-administered questionnaire approach minimized the potential for missing data. The only contact with the subjects was at obtaining consent and data on sociodemographic factors. The participants measured their height and barefoot weight

with support from diabetes clinic staff where necessary while biometric data, specifically BP, FBG, and HbA1c, were retrieved from patients' clinical records. Although FBG and HbA1c are part of routine care for patients with diabetes, routine care for diabetic subjects in Nigeria does not always involve HbA1c testing due to cost constraints. The approach was enrollment of only participants with complete data until the calculated sample size was achieved.

Operationalization of the Variables

This study assessed the association between four independent variables and one dependent variable. The operational definitions of the variables were stated in Chapter 1, while the levels of measurement and coding scheme were as shown in Table 2: Health insurance, education, BMI, and BP were the independent variables, while glycemic control was the dependent variable. Adjustment was made for medication adherence, age, and gender as confounders.

Table 2*Study Variables With Levels of Measurement and Coding Scheme*

Theoretical framework— Ecosocial theory	Predictors of glycemic control among Type 2 diabetic patients in Owerri, South-East Nigeria	Variable nature/coding scheme
List of constructs	Study variables	
1. Social	1. Health insurance (independent) <ul style="list-style-type: none"> • Not insured • Insured—private • Insured—public 	Polychotomous/not insured coded as reference variable
2. Biological	2. Age (independent)	Continuous
3. Social	3. Education (independent) <ul style="list-style-type: none"> • No school • Primary school • Secondary school • Tertiary school 	Ordinal/No school coded as reference variable
4. Biological	4. Gender (independent) <ul style="list-style-type: none"> • Female • Male 	Dichotomous/Male or female, male coded as reference variable
5. Ecological	5. BMI (independent)	Continuous
6. Biological	6. Blood pressure (independent) <ul style="list-style-type: none"> • Normal • Elevated 	Dichotomous/Normal or elevated
7. Social/biological/ ecological	7. Glycemic control (outcome) <ul style="list-style-type: none"> • Controlled • Not controlled 	Dichotomous/Controlled or uncontrolled

Data Collection Tools

Following ethical approval, a formal introduction of the research, its purpose, and its benefits were fully presented to potential subjects via the Participants' Information Sheet (Appendix B), and informed consent was obtained. Data collection occurred via an interviewer-administered questionnaire to eligible participants. I designed the questionnaire (Appendix A). Prior to use, it was put to peer review by two different researchers as a way to establish face and content validity (Tsang et al., 2017). The study instrument contained the following sections.

Section A: Sociodemographic Information of Participants

This included age measured as a continuous variable and gender measured as a dichotomous variable. Others were health insurance status, type of health insurance coverage, and level of education.

Section B: Medical History and Clinical Characteristics

These included duration of diabetes, adherence to medications, and presence of hypertension with duration. Medication adherence was assessed using the eight-item Morisky Medication Adherence Scale (8-MMA) (Tan et al., 2016). Adherence was categorized as either poor or good based on the score.

Section C: Physical Measurements

Blood Pressure

BP was retrieved from the participants' clinical records. Hypertension was defined as systolic and/or diastolic BP $\geq 139/89$ mmHg or history of use of antihypertensive drug/s (Whelton et al., 2018). Participants' BPs were recorded as a

dichotomous variable $\geq 139/89$ mmHg as hypertension, and lower values as normotension.

Weight Measurement

A weighing scale (Seca® model number 786 2021994, designed in Germany, made in China) was used in measuring the weight of the participants. Participants did a self-barefoot weight measurement while standing straight on the scale with head raised and looking forward after removing extra clothing, removing shoes, and emptying their pockets. The weighing scale was calibrated before each use, and the weight was measured to the nearest 0.1 kg. Weight was measured and reported as a continuous variable.

Height Measurement

Stadiometer, a standard height-measuring instrument (Seca® model number 786 2021994, designed in Germany, made in China) was used to measure height. Participants stood erect without shoes, cap, or head gear and backing the stadiometer to conduct a self height measurement. The horizontal sliding head piece of the stadiometer was adjusted to rest on the top of the participant's head, depressing the covering hair while the participant was facing forward. The height was measured to the nearest 0.1m and reported as a continuous variable.

Body Mass Index

This was calculated using the following formula: $\text{weight (kg)} / \text{height}^2 (\text{m}^2)$. Participants' BMI was categorized according to the WHO International classification of adult weight as 18.50 to ≤ 24.99 as normal weight, 25.00 to ≤ 29.99 as overweight, and ≥ 30.00 as obesity (Aminde et al., 2017). BMI was recoded as a categorical variable in

terms of descriptive statistics but retained as a continuous variable in relation to inferential analysis.

Section D: Biochemical Measurement

Fasting Blood Glucose Measurement

The FBG was retrieved from the patients' clinical records as measured using a standardized Fine test Auto-coding Premium glucometer (OSANG Healthcare Co. Ltd, Korea). A drop of blood from the ethylenediaminetetraacetic acid (EDTA) tube containing 1 milliliter (ml) of fasting venous blood was applied to the mounted glucometer test strip via capillarity. The blood was automatically drawn into the test strip and as soon as enough blood has filled the confirmation window of the test strip, the blood glucose result appeared on the LCD panel and was stored in the meter memory automatically. Blood glucose was recorded in millimols/liter (mmol/L) with normal FBG defined as ≤ 6.1 mmol/L.

Glycosylated Hemoglobin

Glycemic control over the past 2 - 3 months was assessed via HbA1c. HbA1c results of participants as measured using the Infopia CLOVER A1c machine were retrieved from their clinical records. The test kit comprised two components, a test cartridge and cartridge holder. The machine has a test chamber with a cover slip. First, the cover of the test chamber is opened and the cartridge holder is slotted into the corresponding compartment in the machine. The tip of the test cartridge is inserted into the collected sample of blood to get a whole blood smear. The test cartridge is then inserted into the test cartridge holder in the machine and the cover slip is closed. Once the slip is closed the test starts automatically. The results were displayed on the LCD screens

which were then recorded. The machine uses boronate affinity chromatography to yield HbA1c levels in five minutes. Test solution from the manufacturers containing known HbA1c value were applied to the instrument prior to use and after every 20 tests to establish validity of the instrument. HbA1c was measured as a continuous variable but recoded to a binary variable with values $<7\%$ reported as good glycemic control, and values above this reported as poor glycemic control (American Diabetes Association, 2018).

Data Analysis Plan

At completion of data collection, the data was cleaned, sorted, and fed into SPSS version 25. Data analysis involved three steps. The first step was a univariate analysis of each independent and the dependent variable to assess and describe the data. Second step was a bivariate analysis between each independent variable and the dependent variable. Finally step 3 analysis involved multiple logistic regression run to assess association between independent variables and the dependent variable after controlling for confounding effect and to answer research questions. Additionally, study participants socio-demographic characteristic were described.

Multiple logistic regression was the appropriate test for the step 3 analysis based on levels of measurement of the explanatory and outcome variables. The research had multiple predictors classified as independent variables at regression analysis which were health insurance, education, BMI, and BP with a single binary dependent variable (HbA1c). Multiple logistic regression is an appropriate statistical methodology to answer questions relating to predicting the occurrence of an event on a single categorical dependent (criterion) variable, in this scenario glycemic control; from more than one

predictor variable (Walden University, n. d). The hypotheses tests were conducted at 5% level of significance. I tested the assumption that the model fits the data using the Hosmer-Lemeshow Goodness of Fit test.

Threats to Validity

Possible threats to validity include confounding variables that may be associated with glycemic control in diabetic subjects not assessed in this research due to scope of the study such as presence of co-morbidities examples dyslipidemia and renal impairment, lifestyle, and dietary pattern.

Ethical Procedures

Prior to commencement of the study ethical approval was sought for and received from the Institutional Review Boards of the Federal Medical Center, Owerri (Study site) and the Walden University. The study design and conduct were in accordance with relevant ethical requirements following national and international guidelines relating to conduct of non-interventional biomedical studies in human subjects especially as concerns patients' privacy, controlled access to data and prohibition of data sharing (IRB, 2019; Tucker, et al, 2016). As regards to my study the general approach to research ethics was ensuring absolute respect for participants' autonomy (IRB, 2019). Furthermore, I ensured that risks were minimized, that the risks were reasonable in the face of overwhelming benefits, and that subject selection was equitable, that informed consent process was adequate, and that coercion no matter how subtle was avoided (Walden Institutional Review, n. d).

The study was introduced to the participants at the diabetes clinic while they were seated during health talk which was traditionally done before clinic started on every

clinic day by the clinic staff. The Participants' Information Sheet (Appendix B) which introduced the researcher, the study title and the reason for the study was distributed to each participant. There was a section explaining the inclusion criteria, study procedure, ways to ensure confidentiality of participant's data, discomfort, risks and benefits of the study to the participants. Participants were informed that participation was entirely voluntary and they could decide not to participate or withdraw from the study at any time. Selected patients proceeded to the counseling room to complete the informed consent process by signing of individual consent forms. At the end of data collection, participants were debriefed and informed to keep contact with the diabetes clinic to be informed on the results at publication.

The contact details of the researcher was included should there be any questions or need for clarifications/further counseling. Information obtained from each participant was handled with utmost confidentiality, and electronic data files were password-protected. Hard copies of completed questionnaires will be in custody of the researcher for five years before archival. The Participants' Information Sheet is attached as Appendix B.

For the purpose of ethical requirement, step by step data collection process was as stipulated below-

Step 1- The researcher and purpose of visit was introduced to the patients at the diabetes clinic while they were seated during health talk which was traditionally done before clinic started on every clinic day by the clinic staff.

Step 2- I introduced the study; and distributed the invitation document (Participants' Information Sheet) to the patients.

Step 3- I explained every statement in the invitation document as the patients read through and gave opportunity for questions, answers and feedback. At the completion of this process I had a pool of potential participants who were informed to meet me at the counseling room (room 15) between 11am and 2pm on clinic days, if they wished to participate in the study.

Step 4- In the counseling room, I attended to any individual concerns, questions, feedback, and further clarifications the volunteers had on their participation in the study as part of the informed consent process with signing of individual consent forms. After this, the volunteer's clinical record was sorted out by diabetes clinic staff and made available to the researcher (me) for data collection.

It is noted that I obtained consent from all the participants and collected all data myself, no assistance or support was needed in these regard from the diabetes clinic staff. No biometric data was obtained from any participant directly. The only contact with participants was at obtaining consent and information on socio-demographic factors.

Summary

This research was a quantitative cross- sectional study using primary socio-demographic data and biometric data retrieved from patients' clinical records from 160 consenting known Type 2 diabetic subjects attending the diabetes clinic at the Federal Medical Centre, Owerri, Nigeria. Bivariate analysis and logistic regression were used to assess the statistical significance of the predictor variables.

Chapter 4: Results

Purpose of the Study

The purpose of this quantitative cross-sectional study was to determine the prevalence of poor glycemic control among Type 2 diabetic patients in Owerri, South-East Nigeria measured using HbA1c, and to investigate the associations between health insurance status, education, BMI, and BP with glycemic control in the subjects. The primary data collected were demographic variables of the participants, which were sex, age, occupation, and socioeconomic factors including health insurance status and education. Weight and height were accessed via self-measurement, while BP, FBG, and HbA1c levels were retrieved from the participants' clinical records. Data were input into SPSS; descriptive analyses were done and reported prior to test of associations between the explanatory variables and glycemic control.

Research Questions and Hypotheses

Bivariate Research Questions

RQ 1: Is there an association between health insurance status (not insured, insured—private, insured—public) and glycemic control among Type 2 diabetic patients?

H₀: There is no association between health insurance status (not insured, insured—private, insured—public) and glycemic control among Type 2 diabetic patients.

H1: There is an association between health insurance status: (not insured, insured—private, insured—public) and glycemic control among Type 2 diabetic patients.

RQ 2: Is there an association between education and glycemic control among Type 2 diabetic patients?

H0: There is no association between education and glycemic control among Type 2 diabetic patients.

H1: There is an association between education and glycemic control among Type 2 diabetic patients.

RQ 3: Is there an association between body mass index (BMI) and glycemic control among Type 2 diabetic patients?

H0: There is no association between BMI and glycemic control among Type 2 diabetic patients.

H1: There is an association between BMI and glycemic control among Type 2 diabetic patients.

RQ 4: Is there an association between blood pressure (BP) and glycemic control among Type 2 diabetic patients?

H0: There is no association between BP and glycemic control among Type 2 diabetic patients.

H1: There is an association between BP and glycemic control among Type 2 diabetic patients.

Multivariable Research Question

Is there is an association between health insurance (not insured, insured—private, insured—public), education, BMI, and BP as independent variables and glycemic control among Type 2 diabetic patients measured using HbA1c as the outcome, controlling for medication adherence, age, and gender?

H₀: There is no association between health insurance (not insured, insured—private, insured—public), education, BMI, and BP as independent variables and glycemic control among Type 2 diabetic patients measured using HbA1c as the outcome, controlling for medication adherence, age, and gender.

H₁: There is an association between health insurance (not insured, insured—private, insured—public), education, BMI, and BP as independent variables and glycemic control among Type 2 diabetic patients measured using HbA1c as the outcome, controlling for medication adherence, age, and gender.

Organization of Chapter 4

This chapter reports the statistical analyses and findings from the study in consideration of the research questions and the study hypotheses. It also contains a detailed description of the study cohort.

Data Collection

Data collection involved obtaining information from the participants at completion of informed consent process on age, gender, health insurance status, type of health insurance coverage, and level of education using a questionnaire. Other data

collected were adherence to medications and presence of hypertension with duration. Participants took self-measurements of their heights and weights, which were shared with me. I obtained clinical parameters, namely BP, FBG, and HbA1c of participants, from their clinical records made available to me at the diabetes clinic. The sample size was 160, split into 80 each of insured and uninsured diabetic subjects. Data collection spanned November 2021 in its entirety at the rate of a maximum of four insured and four uninsured subjects recruited on each clinic day based on the sampling strategy adopted for the study as described in Chapter 3.

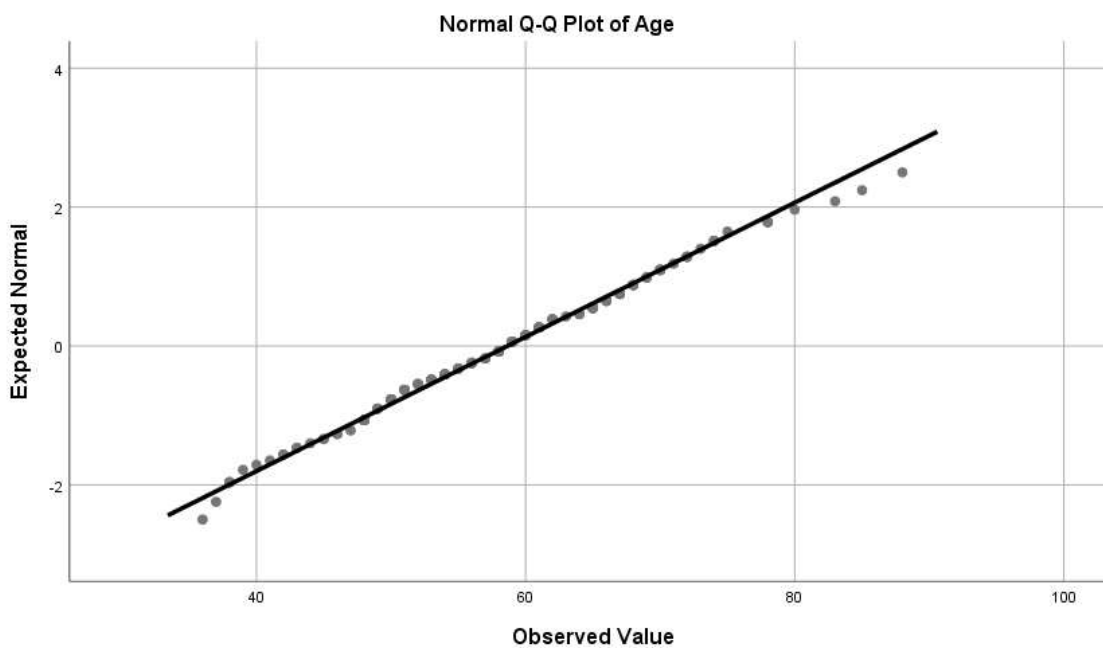
HbA1c was collected as a continuous variable but recoded with values less than 7% coded as 1.00 = good control and 7% and above coded as 2.00 = poor control. All the independent variables and confounders were categorical variables except BMI and age.

Tests for Normality

The data were tested for normality using Shapiro-Wilk test and Q-Q plots for age and BMI. These were continuous variables.

Age

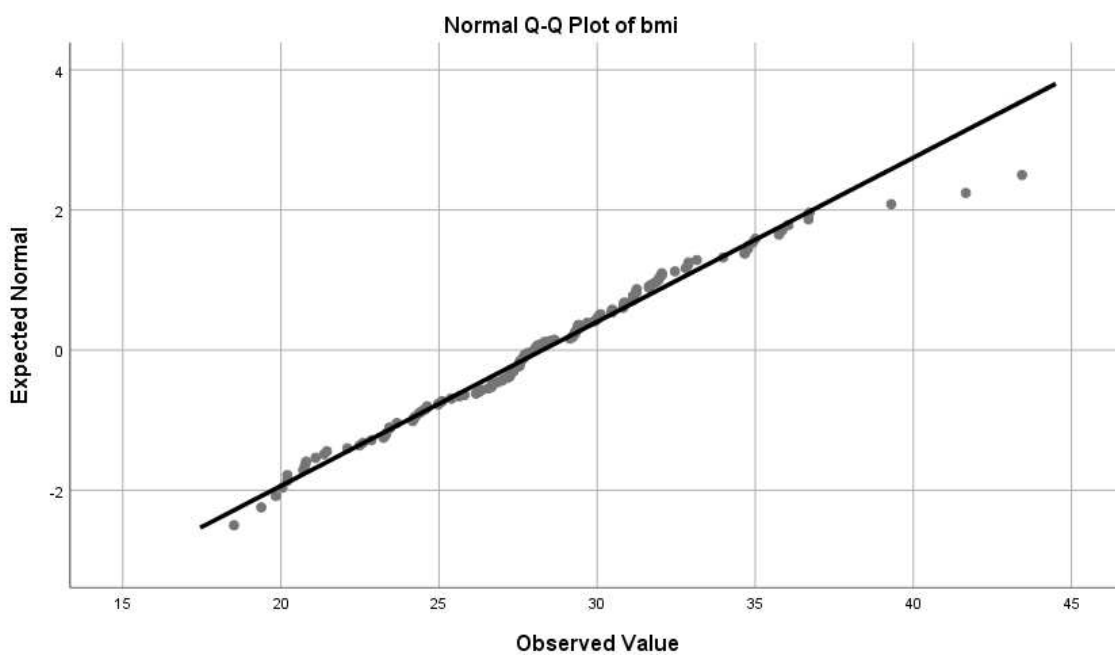
Shapiro-Wilk test statistic was 0.992. When the value of the Shapiro-Wilk Test is greater than 0.05, the data can be considered to be normal, so age has a normal distribution. The Q-Q plot is shown in Figure 2.

Figure 2*Q-Q Plot for Age*

It is expected that sampled data from a normal distribution would fall along the dotted line as reflected in Figure 2 with age.

Body Mass Index

The Shapiro-Wilk test statistic was 0.982. When the value of the Shapiro-Wilk test is greater than 0.05, the data are normal, so BMI has a normal distribution. The Q-Q plot is shown in Figure 3.

Figure 3*Q-Q Plot for Body Mass Index*

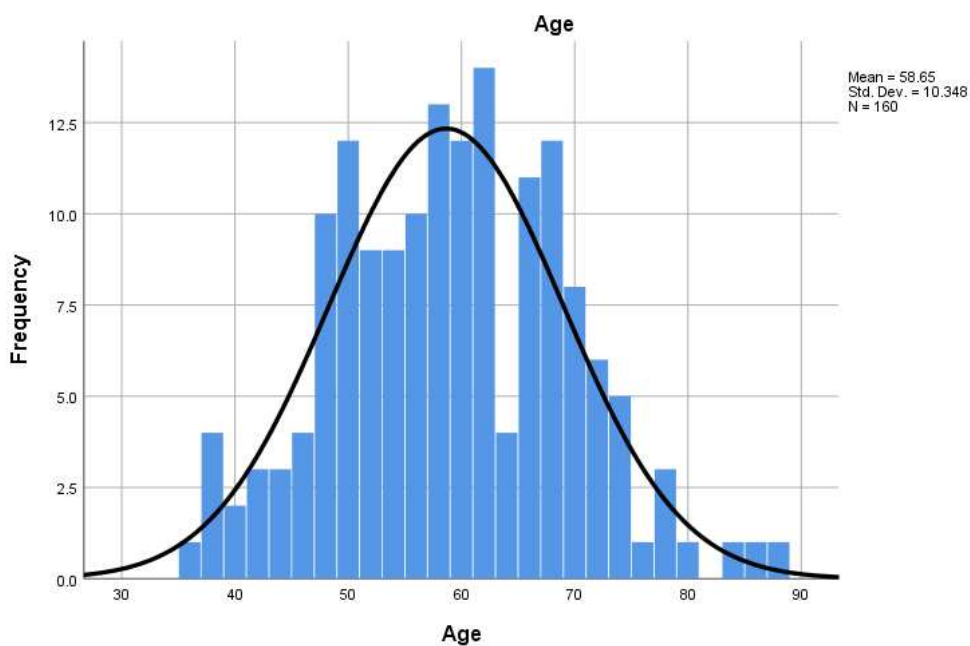
It is expected that sampled data from a normal distribution would fall along the dotted line; just like with age, the data in Figure 3 fall along the dotted line, so BMI has a normal distribution.

Results: Descriptive Statistics

Distribution of the Study Variables Among the Participants

Gender and Age Distribution

Of the 160 participants, 45 were males and 115 were females, with the ratio of males : females essentially 2:5 in the study sample. Their ages ranged from 36 to 88 years with a mean of 58.7 +/- 10.4 years. Age has a normal distribution, as shown in Figure 4.

Figure 4*Age Distribution of Participants*

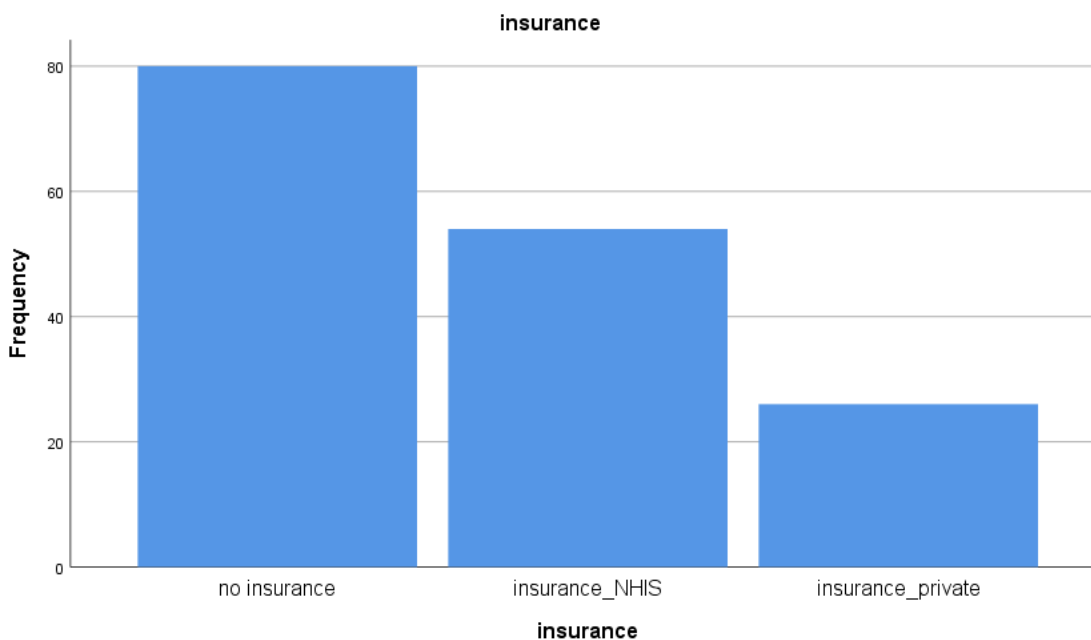
For the purpose of descriptive statistics, age was transformed as 1.00 for participants less than 60 years old and 2.00 for elderly subjects.

Insurance

Insurance status was placed in three categories: no insurance, with 80 subjects; insured—public (NHIS), with 54 subjects; and insured—private, with 26 subjects. Thus, the numbers of insured and uninsured subjects in the sample were equal. The distribution is illustrated in Figure 5.

Figure 5

Distribution of Insurance Status Among the Participants

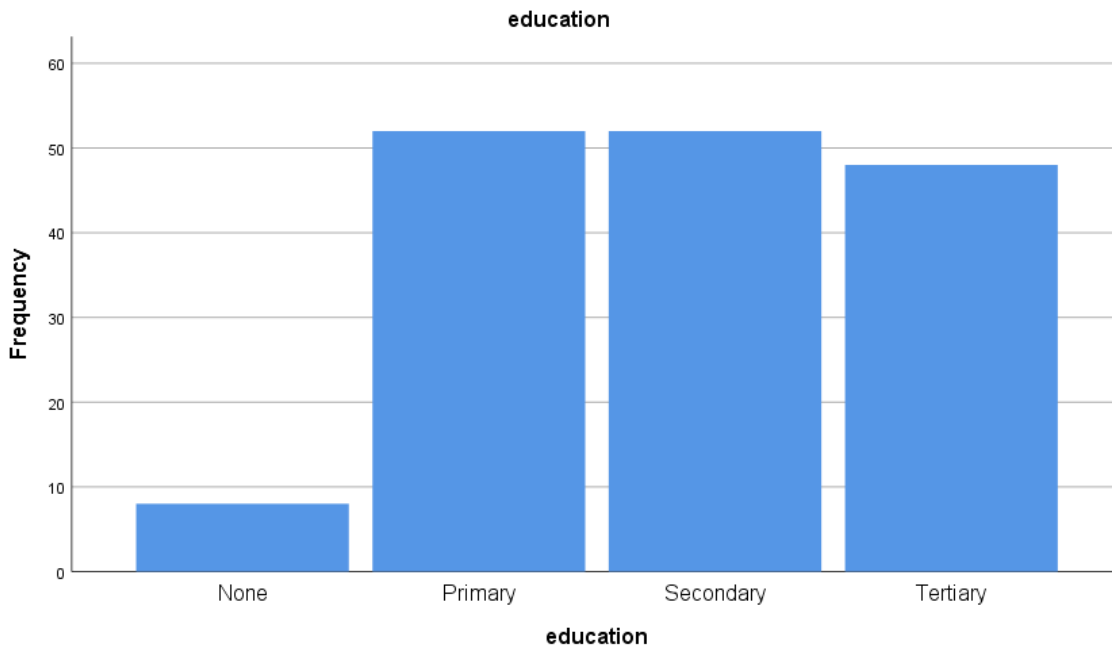


Education

This was categorized as no formal education, primary education, secondary education, or tertiary education, with eight, 52, 52, and 48 subjects, respectively. Each category represents the maximum level of education obtained by subjects. The graphical distribution is shown in Figure 6.

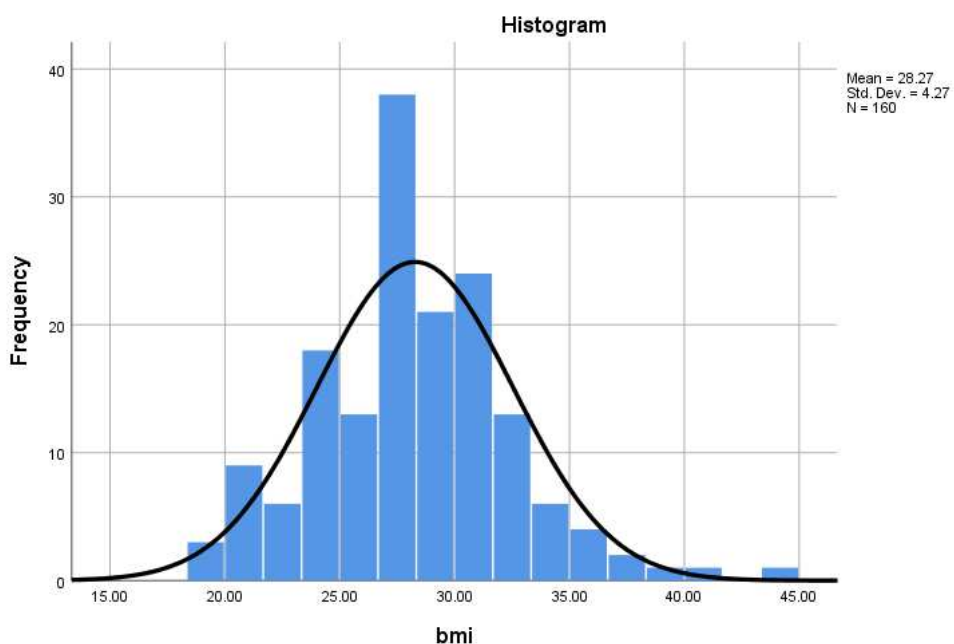
Figure 6

Distribution of Subjects According to Maximum Level of Education



Body Mass Index Distribution

The least BMI of the participants was 18.5kg/m^2 , while the maximum was 43.4kg/m^2 , with a mean of $28.3 \pm 4.3\text{kg/m}^2$. BMI of the participants also had a normal distribution, as shown in Figure 7.

Figure 7*Body Mass Index Distribution of Participants*

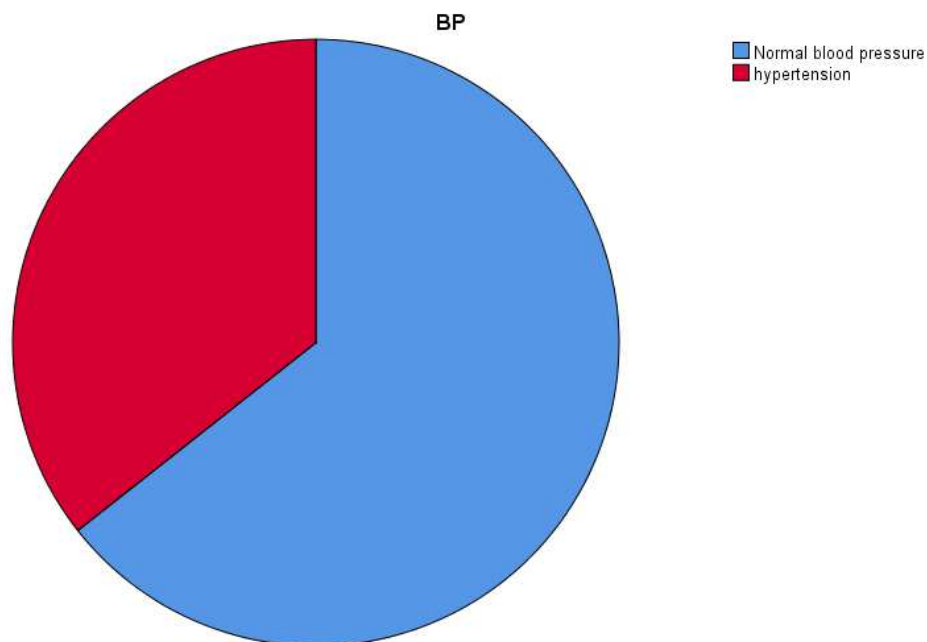
BMI was recoded for the purposes of descriptive statistics as 1.00 = normal BMI (18.50 – 24.99kg/m²), 2.00 = overweight (25.00 – 29.99kg/m²), and 3.00 = obesity (>= 30.00kg/m²) as shown in Table 3 below

Blood Pressure

This was categorized into two groups, normotensive and hypertensive subjects. One hundred and three participants had normal BP, while 57 had hypertension. This is shown in Figure 8.

Figure 8

Blood Pressure Distribution of Participants



Analyses of Descriptive Statistics

Only 37 subjects had good glycemic control yielding a prevalence of 76.9% for poor glycemic control in the participants. Descriptive statistics were used to report the key variables of the study. The distribution of glycemic control among the participants according to the co-variates is shown in Table 3.

Table 3*Pattern of Glycemic Control Among the Participants*

Variables		HbA1c_category		Total
		1.00 (good control)	2.00 (poor control)	
BMI_Category	1.00 (Normal)	13	23	36
	2.00 (Overweight)	16	56	72
	3.00 (Obesity)	8	44	52
Insurance	No insurance	5	75	80
	Insurance_NHIS	15	39	54
	Insurance_Private	17	9	26
Education	None	3	5	8
	Primary	13	39	52
	Secondary	14	38	52
	Tertiary	7	41	48
BP	Normal BP	23	80	103
	Hypertension	14	43	57
Gender	Male	6	39	45
	Female	31	84	115
Adherence	Adherent	33	3	36
	Nonadherent	4	120	124
Age	< 60years	10	78	88
	60years +	27	45	72
Total		37	123	160

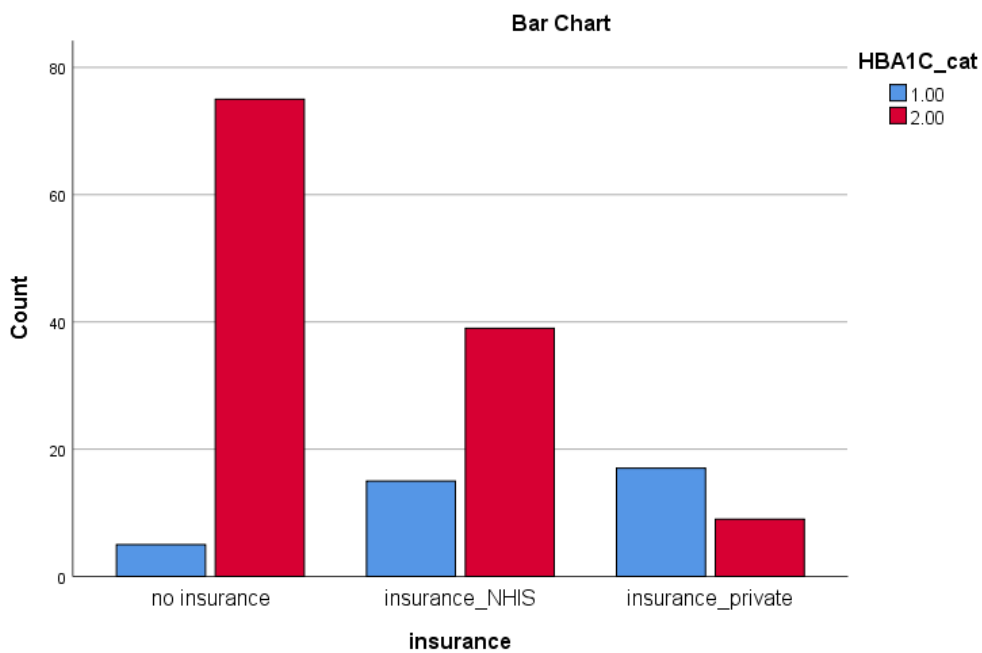
Insurance and Glycemic Control

Among the patients without health insurance the prevalence of poor glycemic control was 93.8% while in those with health insurance the prevalence was 60.0%.

Individuals on private health insurance scheme had better glycemic control as the prevalence of poor control was 34.6% compared to 72.2% for those accessing care under the public NHIS.

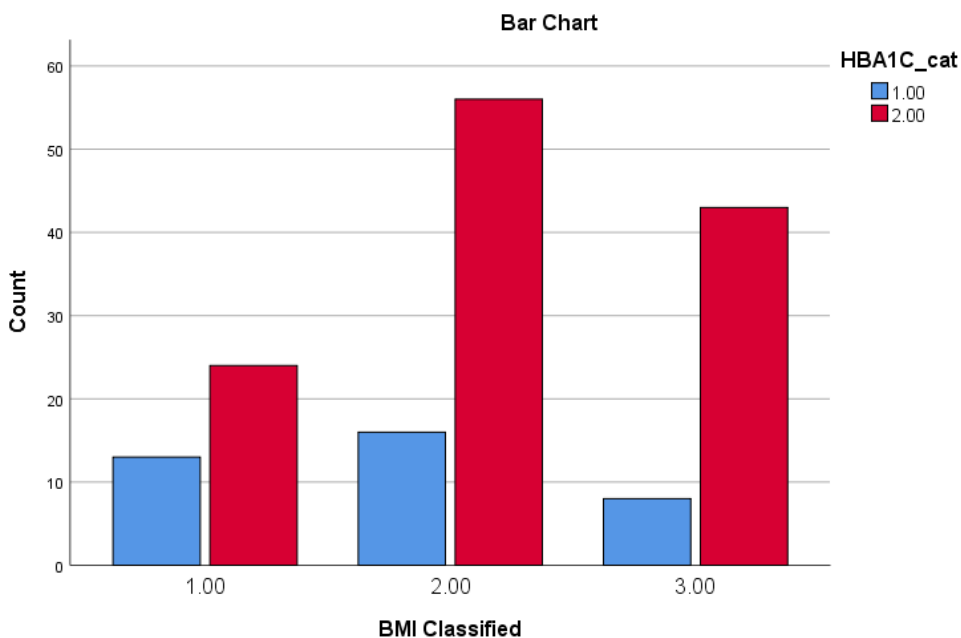
Figure 9

Illustration of Insurance and Glycemic Control

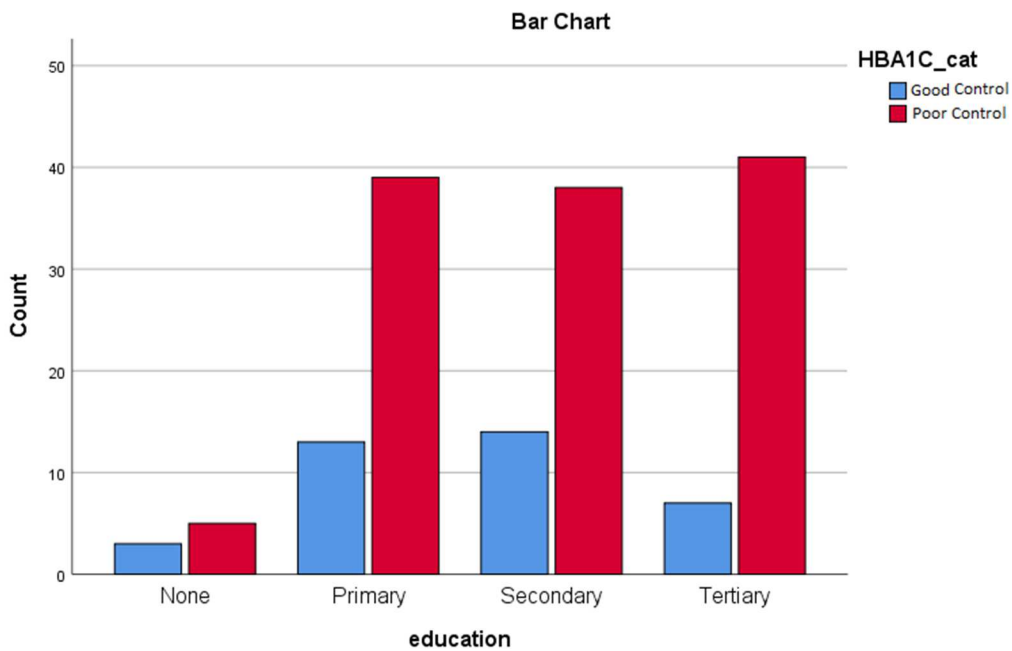


Body Mass Index and Glycemic Control

Majority of the participants (77.5%) were either overweight or obese. The prevalence of poor glycemic control in diabetic subjects with normal BMI was 63.9% compared to 77.8% and 84.6% in overweight and obese subjects respectively.

Figure 10*Illustration of Body Mass Index and Glycemic Control****Education and Glycemic Control***

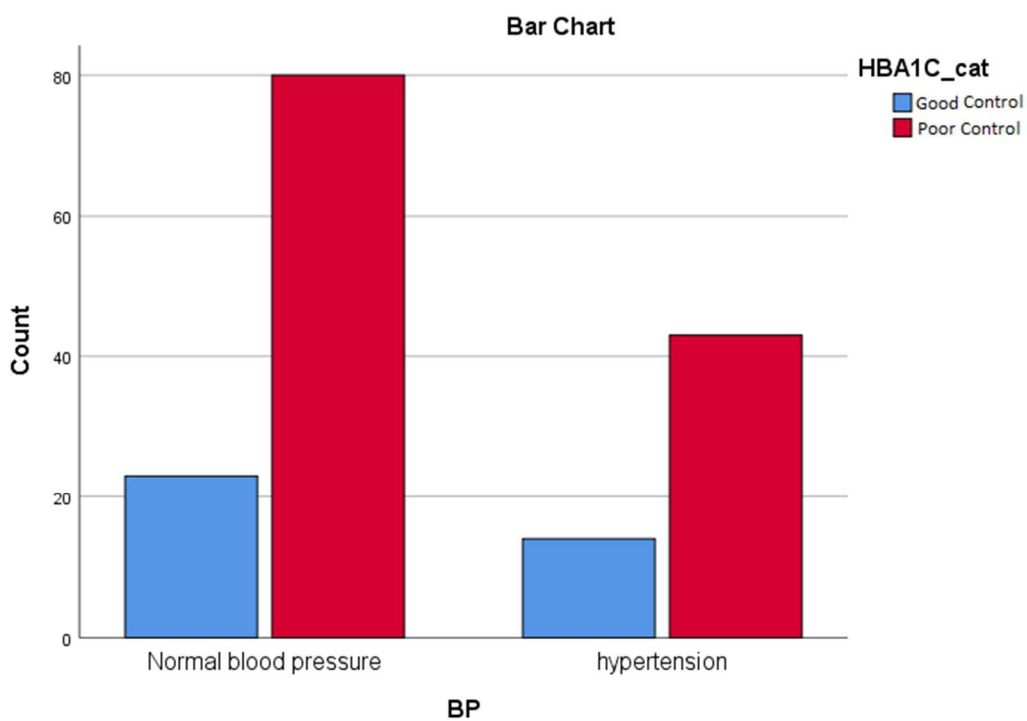
All the participants but eight (95%) had some form of education. The prevalence of poor glycemic control in participants with no formal education was 62.5% compared to 77.6% in those with some level of education. Prevalence in primary school and secondary school leavers was 75.0% and 73.1% respectively while prevalence in participants with tertiary education was 85.4%.

Figure 11*Illustration of Education and Glycemic Control****Blood Pressure and Glycemic Control***

Only 57 participants among the study sample had elevated BP giving a prevalence of 35.6% for hypertension in the study. For normotensive individuals the prevalence of poor glycemic control was 77.7% compared to 75.4% for hypertensive diabetic subjects.

Figure 12

Illustration of Blood Pressure and Glycemic Control

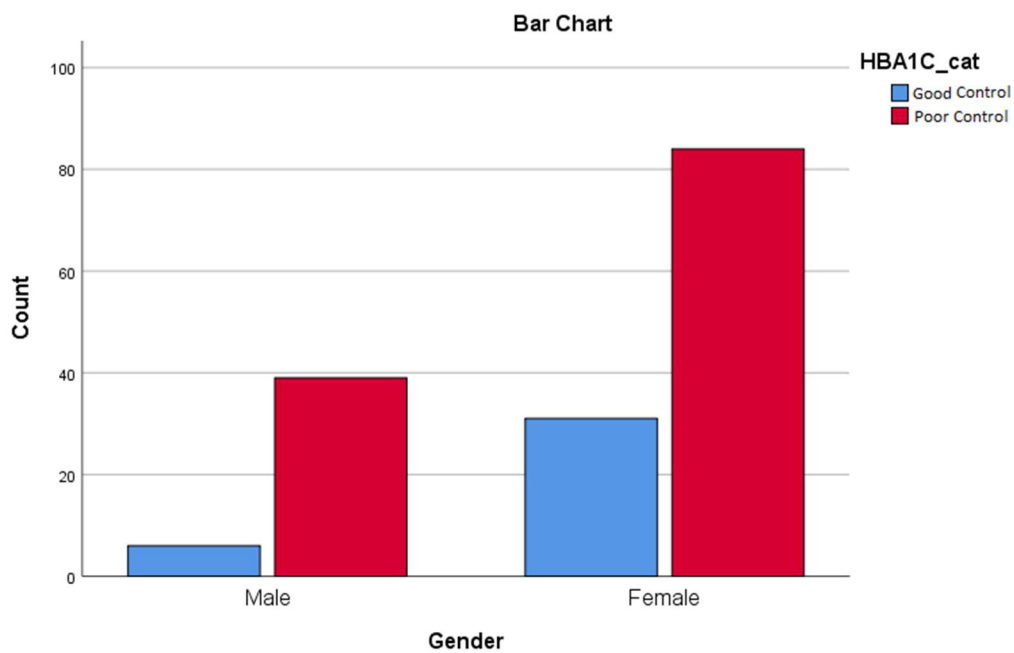


Gender and Glycemic Control

The prevalence of poor glycemic control was 86.7% in males compared to 73.0% in females.

Figure 13

Illustration of Gender and Glycemic Control

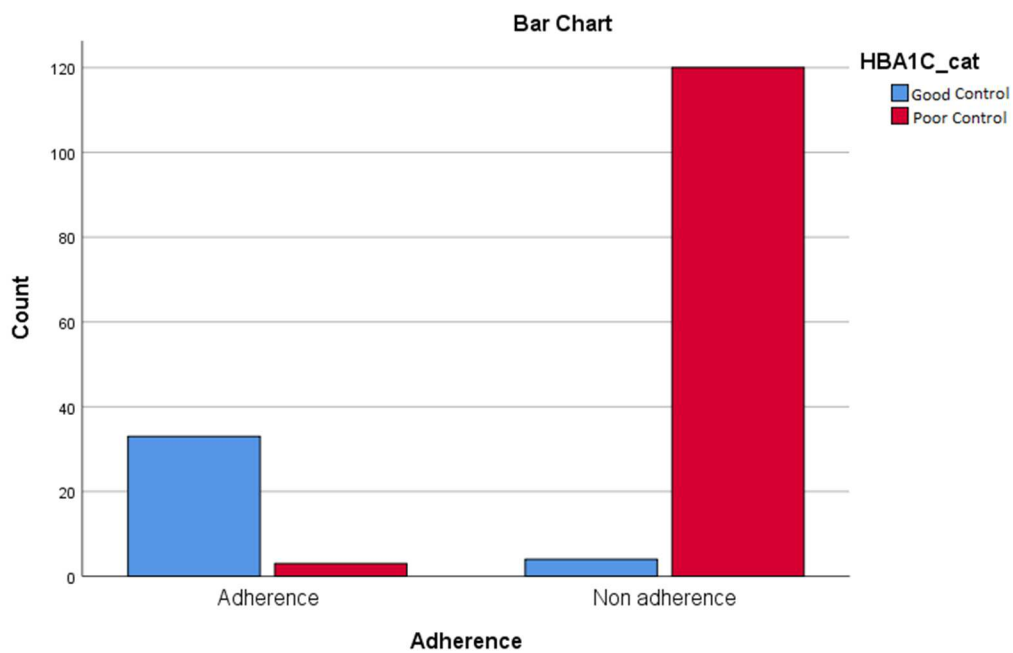


Adherence and Glycemic Control

Most of the participants (77.5%) were non-adherent to their treatment regimen. The prevalence of poor glycemic control in this group was 96.8% compared to 8.3% in the group that showed adherence to treatment medications.

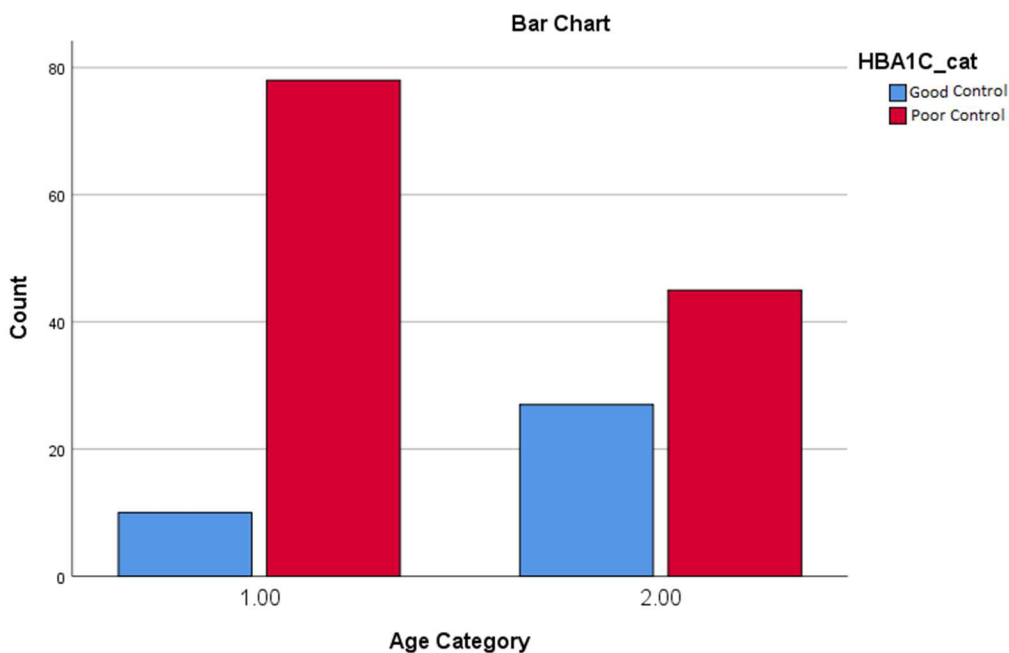
Figure 14

Illustration of Adherence and Glycemic Control



Age and Glycemic Control

More of the patients were less than 60 years (55%) with the prevalence of poor glycemic control being 88.6% compared to 62.5% in the elderly population.

Figure 15*Illustration of Age and Glycemic Control***Results: Inferential Statistical Analyses****Bivariate Analyses**

Bivariate analyses using Chi square and simple logistic regression were done to assess association between the independent variables and covariates with HbA1c in the participants and to answer research questions one to four. The results are displayed below in table 4 for the Chi square tests, tables 5 – 8 for simple regression involving the independent variables and tables 9 – 11 for simple regression involving the covariates.

Table 4*Chi-Square Tests for Association Between the Nominal Variables and Glycemic Control*

Variables	HbA1c_Category		χ^2	P value
	Good control	Poor control		
Insurance			39.59	< .001
No insurance	5	75 (93.75%)		
Insurance_NHIS	15	39 (72.22%)		
Insurance_Private	17	9 (34.62%)		
Education			3.42	.331
None	3	5 (62.50%)		
Primary	13	39 (75.00%)		
Secondary	14	38 (73.08%)		
Tertiary	7	41 (85.42%)		
Blood Pressure			.103	.749
Normotension	23	80 (77.67%)		
Hypertension	14	43 (75.44%)		
Gender			3.38	.066
Male	6	39 (86.67%)		
Female	31	84 (73.04%)		
Adherence			122.76	< .001
Adherent	33	3 (8.33%)		
Nonadherent	4	120 (96.77%)		

Of the three nominal variables, insurance, education, and BP; only insurance had an association with HbA1c ($\chi^2 = 39.6$; **p-value < .001**). Among the covariates, adherence has an association with HbA1c ($\chi^2 = 122.7$; **p-value < .001**).

Table 5*Simple Logistic Regression for Association Between Insurance and Glycemic Control*

Variables	B	S.E.	Wald	df	p-value	OR	95% CI	
							Lower	Upper
No insurance			29.24	2	< .001			
Insurance_NHIS	-1.75	.55	10.05	1	.002	.173	.059	.512
Insurance_Private	-3.34	.62	29.18	1	< .001	.035	.010	.119
Constant	-2.71	.46	34.38	1	.000	15.000		

Note. Reference category = No insurance; the results were significant, $\chi^2(2) = 38.291$, $p < .001$.

Table 6*Simple Logistic Regression for Association Between Education and Glycemic Control*

Variables	B	S.E.	Wald	df	p-value	OR	95% CI	
							Lower	Upper
Education (none)			3.301	3	.348			
Education (primary)	.588	.797	.543	1	.461	1.800	.377	8.591
Education (secondary)	.488	.794	.377	1	.539	1.629	.343	7.727
Education (tertiary)	1.257	.837	2.255	1	.133	3.514	.681	18.125
Constant	.511	.730	.489	1	.484	1.667		

Note. Reference category = education (none); the results were not significant, $\chi^2(3) = 3.524$, $p = .318$.

Table 7

Simple Logistic Regression for Association Between Blood Pressure and Glycemic

Control

Variables	B	S.E.	Wald	df	p-value	OR	95% CI	
							Lower	Upper
Blood pressure	-.124	.388	.103	1	.749	.883	.413	1.890
Constant	1.371	.564	5.899	1	.015	3.939		

Note. The results were not significant, $X^2(1) = .102, p = .749$.

Table 8

Simple Logistic Regression for Association Between Body Mass Index and Glycemic

Control

Variables	B	S.E.	Wald	df	p-value	OR	95% CI	
							Lower	Upper
BMI	.091	.047	3.739	1	.053	1.096	.999	1.202
Constant	- 1.340	1.309	1.049	1	.306	.262		

Note. The results were not significant, $X^2(1) = 3.186, p = .051$.

Similar to results obtained with Chi square tests, of the four independent variables – insurance, education, BP, and BMI only insurance had an association with glycemic control in the participants. As compared to insured subjects, a lack of health insurance coverage results in worsening glycemic control with increased odds or likelihood of 5.8 and 28.6 respectively in comparison to participants accessing care under the NHIS and Private health insurance scheme.

Table 9*Simple Logistic Regression for Association Between Gender and Glycemic Control*

Variables	B	S.E.	Wald	df	p-value	OR	95% CI	
							Lower	Upper
Gender	-0.875	.486	3.238	1	.072	.417	.161	1.081
Constant	2.747	.902	9.276	1	.002	15.592		

Note. The results were not significant, $\chi^2(1) = 3.66, p = .072$. Male was the reference category.

Table 10*Simple Logistic Regression for Association Between Adherence and Glycemic Control*

Variables	B	S.E.	Wald	df	p-value	OR	95% CI	
							Lower	Upper
Adherence	5.80	.79	54.07	1	<.001	330.00	70.34	1548.12
Constant	-8.20	1.31	39.23	1	<.001	.000		

Note. The results were significant, $\chi^2(1) = 117.06, p < .001$.

Table 11*Simple Logistic Regression for Association Between Age and Glycemic Control*

Variables	B	S.E.	Wald	df	p-value	OR	95% CI	
							Lower	Upper
Age	-.086	.022	15.881	1	<.001	.918	.880	.957
Constant	6.430	1.365	22.182	1	<.001	620.132		

Note. The results were significant, $\chi^2(1) = 19.044, p < .001$.

Similar to results obtained with Chi square tests, among the two nominal covariates, adherence had an association with glycemic control [OR = 330.00 (70.34 – 1548.12); p-value = <.001] while gender had no association with glycemic control. Age measured as a continuous variable also had an association [(OR = 0.918 (0.880 – 0.957); p-value = <.001].

Multivariable Analysis

From simple logistic regression analyses, only one independent variable, insurance, had an association with HbA1c among the participants. A multivariable analysis was run on logistic regression while controlling for adherence and age to determine if an association still holds.

Block 1: Insurance, age, and adherence in the model

Model summary

With insurance, age, and adherence in the model, the Nagelkerke R Square was .856, and the classification table showed 96.3 percentage correct, thus, the model explained 85.6% of the variance in glycemic control among the subjects and correctly classified 96.3% of cases. Hosmer and Lemeshow (H-L) Test was conducted to assess fitness of the multivariable regression model. Results yielded chi-square value of 15.43, df = 8, and significance of .051. The H-L test compares the observed cases to the number predicted by the logistic regression model (expected). If the H-L goodness of fit test statistic is greater than 0.05, we fail to reject the null hypothesis implying the model's estimates showed no evidence of lack of model fit. An outcome of non-significance indicates the

model prediction does not differ significantly from the observed cases. The test statistic in this model is 15.43; therefore, the model's estimates fit the data at an acceptable level.

Table 12 explains the predictive effect of health insurance status on glycemic control among the participants.

Table 12

Predictive Effect of Insurance on Glycemic Control in Diabetic Subjects

Variables	B	S.E.	Wald	df	p-value	OR	95% CI	
							Lower	Upper
No insurance			6.09	2	.048			
Insurance_NHIS	-3.47	1.44	5.78	1	.016	.031	.002	.527
Insurance_Private	-2.54	1.37	3.44	1	.064	.079	.005	1.155
Age	-.11	.05	5.48	1	.019	.893	.812	.982
Adherence	6.94	1.43	23.46	1	<.001	1037.196	62.449	17226.58
Constant	-1.06	2.66	.16	1	.69	.347		

Note. The results were not significant, $X^2(8) = 15.43, p = .051$.

From the table above, after controlling for age and medication adherence, there is a statistically significant association between health insurance status and glycemic control in the subjects but the association is present only among the uninsured and insured – NHIS patients. As compared to NHIS enrollees, a lack of health insurance coverage results in worsening glycemic control with increased odds or likelihood of 32.26.

Summary

In summary, bivariate analyses were performed to ascertain the effects of insurance, BMI, education, and BP on glycemic control among the participants. To

answer research questions 1 to 4, only insurance had an association with glycemic control. A multiple logistic regression was performed to ascertain the predictive effect of insurance on glycemic control adjusting for age and medication adherence. The result showed a statistically significant association between health insurance status and glycemic control (no insurance and insurance-NHIS) among the subjects. The study concludes that health insurance status is a predictor of glycemic control among diabetic patients in Owerri, Nigeria.

In Chapter 5, I will discuss the key findings of the study and compare the results with existing literature as described in Chapter 2. I will also explain the findings in the context of the eco-social theory and explain the limitations of the study, implications for social change, and recommendations for future research.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

This was a quantitative cross-sectional study conducted to assess the predictors of glycemic control among Type 2 diabetic subjects in Owerri, South-East Nigeria. The study involved determination of the prevalence of poor glycemic control measured using HbA1c and investigation of the associations between health insurance status, education, BMI, and BP with glycemic control in the subjects. The study utilized primary data on participants' demographic variables such as sex, age, and occupation; socioeconomic factors including health insurance status and education; and self-measurements of weight and height with BP, FBG, and HbA1c levels retrieved from the participants' clinical records. SPSS was used to run the analysis, with the results applied to answer the research questions.

Summary of Key Findings

A majority of the participants had poor glycemic control, with a prevalence of 76.88%. The prevalence of poor control was higher in uninsured participants (93.75% compared to 60% in insured subjects), overweight and obese subjects (77.78% and 84.62% compared to 63.89% in individuals with normal BMI), and diabetic patients with formal education (77.63% compared to 62.5% in those with no formal education). Furthermore, higher levels of poor glycemic control were recorded in males (86.67% compared to 73.04% in females), in diabetic subjects younger than 60 years (88.64% compared to 62.5% in the elderly population), and in participants with nonadherence to diabetic medications (96.77% compared to 8.33% in the group that showed adherence to treatment medications). On the contrary, normotensive and hypertensive diabetic

individuals had similar levels of poor glyceic control, at 77.67% and 75.44%, respectively. Inferential statistics analysis showed that of all the independent variables tested for association with glyceic control, only health insurance status is a predictor of glyceic control in diabetic subjects. As compared to NHIS enrollees, uninsured diabetic subjects have 32.26 times increased odds or likelihood of poor glyceic control.

Interpretation of the Findings

Prevalence of Poor Glyceic Control in the Participants

The findings from this study showed that the prevalence of poor glyceic control across the study participants was 76.88%. Further analysis showed that for the uninsured subjects, the prevalence was 93.75% compared to 60% for the insured subjects. These figures are notably high, taking into cognizance rates reported elsewhere globally. Of all the literature reviewed, the highest prevalence for poor glyceic control was reported in Owerri by Anoshirike et al. (2019), put at 91.7%, yet this value is less than the 93.8% noted in the uninsured subjects in this study, suggesting that glyceic control among diabetic subjects in Owerri is probably witnessing worsening dimensions. This is of great concern, considering that the deleterious effects of diabetes are linked to poor glyceic control.

This study shares many similarities with the literature reviewed in terms of cross-sectional design (Abdullah et al., 2020 & Mahmood et al., 2016); use of HbA1c as a benchmark for glyceic control (Mahmood et al., 2016); HbA1c threshold of $\geq 7.0\%$ (Abdelwahid et al., 2017; Abdullah et al., 2020; Haghigatpanah et al., 2018; Noor et al., 2017); conduct of study in a tertiary center (Shrestha et al., 2019); use of primary data or combination of primary data and biometric measurements retrieved from patients'

medical records (Asmelash et al., 2019; Dedefo et al., 2020; Tekalegn et al., 2018); and geographic proximity/sociocultural affinity (Anioke et al., 2019; Onodugo et al., 2019; Ufuoma et al., 2016). Most of the studies reviewed did not stratify the participants into insured and uninsured subjects but it is fair to assume that the studies reported are representative of the general population and based on location and scope many of them may have a significant proportion of both insured and uninsured subjects. My study's overall prevalence rate of poor glycemic control in the subjects which stood at 76.9% was closer to the upper limit of 40% - 85% range reported in all the studies referenced above; absolutely and relatively, this level is high. In other words, at least three out of every four diabetic subjects in Owerri had poor control and at risk of developing complications.

The sociodemographic distribution of the participants showed that females were predominant in the study sample, with 5 females for every 2 males recruited for the study. Although type-2 diabetes is more common in males than females, males generally have low health-seeking behavior compared to females in sub-Saharan Africa (Amoo et al., 2018). This may explain this variation. However, there was not much gender difference in glycemic control, as about 8 in 10 males compared to 7 in 10 females had poor control. The average age of the participants was 58.7 +/- 10.4 years, which is expected for a chronic disease that affects mostly individuals of middle age. The number of insured and uninsured participants in the study was equal at 80 each; as expected, the majority of the insured subjects were enrolled under the public NHIS, with the number just slightly more than double the number enrolled under the private insurance scheme. However, individuals in the private scheme had better glycemic control, with the

prevalence of poor control put at 34.6% compared to 72.2% for those accessing care under the public NHIS. Unpublished reports from many health maintenance organization (HMOs) and healthcare providers (HCPs) suggest that the private insurance scheme in Nigeria is more efficiently run relative to NHIS and it is possible that subjects enrolled in the private scheme had better adherence to treatment medication.

A majority of the participants were either overweight or obese, with the prevalence of combined overweight and obesity in the study participants put at 77.5%. The prevalence of poor glycemic control in diabetic subjects with normal BMI was 63.9% compared to 77.8% and 84.6% in overweight and obese subjects, respectively; therefore, there was worsening glycemic control with increasing BMI, such that at least 8 in every 10 overweight/obese diabetic subjects had poor glycemic control. This is similar to a finding by Mahmood et al. (2016), who established that 68% of the respondents in their study had poor glycemic control, with 4 out of every 5 patients with poor glycemic control having obesity.

The prevalence of poor glycemic control in participants with no formal education was 62.5% compared to 77.6% in those with some level of education. When the educated group is split along primary, secondary, and tertiary education, there is little difference in the prevalence of poor glycemic control in these groups, put at 75.0%, 73.1%, and 85.4%, respectively. Of note, almost all of the participants (95%) had some form of education, reflecting the high literacy level of residents of Owerri and environs.

The descriptive statistics of the association between BP and glycemic control showed that for normotensive individuals, the prevalence of poor glycemic control was 77.7% compared to 75.4% for hypertensive diabetic subjects. The closeness of the results

suggested that BP differences may not be a factor in the determination of glycemic control in the subjects. Furthermore, the prevalence of 35.6% for hypertension in the study subjects was similar to 44.0% reported by Onuoha and Egwim in 2017, emphasizing significant coexistence of both ailments with heightened risk for occurrence of complications in individuals affected by both diseases.

Predictors of Glycemic Control Among the Participants

The objective of the research questions was to determine predictors of glycemic control in the study subjects through an assessment of a number of independent variables, namely health insurance status, education, BMI, and BP, while adjusting for confounders such as age, gender, and medication adherence. An initial bivariate analysis to assess for association between each possible predictor and the outcome variable was conducted while the variables with significant association were input into a logistic regression model to determine the predictors. Bivariate analysis showed that only health insurance status ($\chi^2 = 39.6$; p -value $< .001$) had significant association with glycemic control among the participants. As captured in Table 5, in comparison to insured subjects, a lack of health insurance coverage results in worsening glycemic control with increased odds or likelihood of 5.8 and 28.6, respectively, when compared to participants accessing care under the NHIS and private health insurance scheme. After controlling for age and adherence, however, only “No Insurance” and “Insurance_NHIS,” p -values 0.048 and 0.016, respectively, had significant association with glycemic control in the subjects, as shown in Table 6, suggesting an existence of confounding effect from age and adherence on the association between Insurance_Private and glycemic control in the participants. Thus, access to health insurance (NHIS) was found to be the only determinant of

glycemic control among the study participants. Thus, it can be inferred from this study that health insurance enhanced glycemic control more than 32 fold as compared to out-of-pocket funding.

This findings in my study was consistent with several reports in the literature reviewed. A cross-sectional secondary analysis of diabetic patients in NHANES by Doucette et al. (2016) also concluded that access to health insurance was associated with improved diabetes management. An analysis of surveyed data by Dall et al. (2016) in the United States concluded that among uninsured populations there are more likelihood of undiagnosed of diabetes compared to insured populations, and even after diagnosis, they are at risk of poor control of diabetes. Furthermore, Soumerai et al. reported as far back as in 2004 that patients under an HMO had better glycemic control due to free glucose monitors, which led to an improved rate of self-monitoring. Perhaps the only contrasting report was noted by Jackson et al. (2016) in Switzerland, who found no difference in the control and quality of diabetes care among insured and uninsured patients. A reason for this finding could be the higher socioeconomic status of the participants in Switzerland, which may have enabled them to afford the cost of management of Type 2 DM irrespective of access to health insurance.

Study Findings and Eco-Social Theory

Eco-social theory is a multilevel theory of disease occurrence that explains how social and biological reasoning are integrated with an ecological perspective to address population levels of disease (Anderson, 2020). The findings from this study confirm the appropriateness of eco-social theory as the theoretical framework for this study. Health insurance is a social factor, with the results from this study suggesting that it is a

predictor of glycemic control in diabetic subjects. From the study results, the conceptual understanding is that health insurance, a social factor, interacts with and is integrated with biological mechanisms to affect glucose control in diabetic subjects, which is a biological phenomenon. This leads to either good or poor glycemic control in the diabetic subjects, thus impacting the development of complications, attendant morbidity or mortality, and the health of populations. The outcome of this study is a further proof that social determinants of health are significant predictors of disease occurrence and progression. It yields evidence of the need for increased focus on theoretical conceptions that incorporate social factors to cause a clearer understanding of the causal relationships in disease distribution in epidemiology.

Limitations

An interviewer-administered questionnaire was used to collect data from the participants upon completion of an informed consent process. This questionnaire addressed age, gender, health insurance status, type of health insurance coverage, and level of education. Other primary data collected were adherence to medications and presence of hypertension with duration. It is not impossible that there was some form of recall bias; for instance, some subjects may have decided to assert that they were enrolled in a health insurance scheme when they were not in one, believing that the information would not be verified and they might derive some benefit; also, some may have chosen responses that tended to suggest good adherence to medications when the reverse was true as a way to circumvent the guilt of nonadherence to medications. Secondly, participants took self-measurements of heights and weights, which were shared with me while clinical parameters, namely BP, FBG, and HbA1c of participants, were retrieved

from their clinical records and made available to me at the diabetes clinic. It is possible that there was measurement error in any of these parameters resulting in differential misclassification, which can create bias either toward or away from the null and jeopardize internal validity (Aschengrau & Seage, 2014).

This study was limited to Type 2 diabetic subjects seen at the diabetes clinic of the Federal Medical Centre, Owerri (FMCO). Other clinics such as the General Outpatient Clinics at FMCO also attend to diabetic subjects, and most other health facilities in Owerri also attend to a reasonable volume of diabetic subjects in the town. This may affect the generalizability of the results to Owerri metropolis and beyond as the diabetic clinic at FMCO is seen by some as an elitist facility and may not be fully representative of the diabetic population in Owerri. Lastly, this study used a cross-sectional design and the outcome that health insurance status is a predictor of glycemic control in diabetic subjects, which seems to suggest that causality is fraught with error due to lack of temporality. Temporal relationship offered by longitudinal studies is essential at determination of true predictor factors for glycemic control in diabetic subjects.

Recommendations

Available literature suggests that the burden of diabetes has been on the rise globally, with worsening morbidity and mortality despite concerted effort at improvement of community diagnosis and advances in treatment (Anioke et al., 2019; Haghghatpanah et al., 2018; Mahmood et al., 2016; Noor et al., 2017). The target of diabetes management, which essentially is good glycemic control, has remained largely unmet across diverse populations in different regions of the globe. The outcome of my

study lends further evidence to this, as a majority of the respondents had poor glycemic control. The study showed that access to health insurance is a predictor of glycemic control, with participants enrolled in the NHIS having a higher likelihood of good glycemic control compared to the uninsured subjects. It is thus appropriate to recommend that effort be increased to advance the enrollment of populations into the NHIS.

The law establishing the NHIS has broad provisions that are yet to be implemented due to poor execution of the policy, such as programs for the informal sector; States Health Insurance Scheme (SHIS) that will capture individuals in the formal sector under employment of the various state and local governments; and the Group, Individual, and Family Social Health Insurance Programme (GIFSHIP), which is a health insurance platform undertaken and paid for by groups, individuals, and families not covered by other NHIS coverage platforms. Additionally, diabetes preventive and control services should be included in the health insurance coverage plans to capture two key schedules—free glucometer with regular supply of test strips to patients and monthly refill of diabetic medications/insulin. Adoption of this as a policy thrust will serve as a veritable endpoint derivable from my study outcome. In view of limitations associated with cross-sectional design, I wish to also recommend a longitudinal study with a larger study population to further explore the predictors of glycemic control in diabetic subjects. Larger sample size and adoption of primary data with regard to biometric measurements of the participants will reasonably reduce measurement bias and other sources of bias that may have been encountered in this study and yield outcomes with more robust validity.

Social Change Implications

Diabetes affects a significant proportion of the global population and most communities. It is a major cause of poor quality of life among individuals and adversely affects the health status of populations and overall human conditions. Furthermore, the effects of diabetes cut across all strata of society and significantly impact national economies and global health expenditures. My study set out to determine the predictors of glycemic control among diabetic subjects with the aim of manipulating the predictors to improve diabetes control and create positive social change. The socio-ecological model of health offers a good framework for appropriately describing the positive social change inherent in optimal diabetes control.

At the individual level, patients may enjoy better quality of life and less disability-adjusted life years as conditions associated with complications such as renal, cardiovascular, and cerebrovascular injuries, erectile dysfunction, limb amputation, and frequent hospitalizations are avoided. Additionally, resources may be saved. The family is the focus of support—financial, caregiving, physical, emotional, psychological, mental, and spiritual—in the face of acute and life-threatening conditions often associated with diabetes. Good diabetes control saves these burdens on the families, and importantly, permits availability of funds that would have been channeled to diabetes care to other spheres of family needs. Organizations and communities are saved lost manpower from premature deaths and lost hours occasioned by poorly controlled diabetes-related illness with enhanced personnel output.

Diabetes negatively impacts national economies and global health expenditure. There has been an exponential increase in the cost of diabetes care over the years, and the

sheer magnitude of the total direct costs of diabetes in the United States, put at \$237 billion in 2017, is alarming (Riddle & Herman, 2018). The cost of care for people with diabetes accounts for approximately 25% of health care dollars spent in the United States, with the care for a single individual with diabetes estimated at an average cost of \$16,752 per year. The society is saved this scarce resource, which can be directed to develop other programs in need of funding in epidemiology such as COVID-19, cancer, and malaria. Any advances made in the control of these diseases, for instance, offer a positive social change, considering millions of individuals globally whose lives will be advanced.

A systematic review of over 600 papers across Asia, Latin America, and Africa showed that diabetes is a costly disease to manage in low- and middle-income countries (Moucheraud et al., 2019). The authors asserted that the rising burden of diabetes in low- and middle-income countries places a financial strain on individuals and health systems. Therefore, it should be a priority at the upstream level for the formulation of policies that will ensure massive enrollment of Nigerians in the NHIS as an approach for improved glycemic control in diabetic subjects and universal health coverage in general, thus creating a healthy population and positive social change.

Conclusion

The literature is replete with studies on DM, yet the prevalence of the disease continues to rise on an exponential projection with a worsening rate of complications. This suggests that DM demands more attention, more time, more resources, and more studies. This research has contributed greatly in providing knowledge on another aspect of diabetes control hitherto overlooked. With the manner in which the NHIS is so poorly run and the herculean challenges to its implementation, no one would believe that

something good could come out of the scheme. This study has shown that NHIS enrollees have increased odds for good glycemic control relative to uninsured subjects and that turning the scheme into an efficient and effective agency and service provider is a sure way to promote positive social change.

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Appendix A: Research Questionnaire

*Confidential***Study: Predictors of glycemic control among type-2 diabetic patients in Owerri,****Nigeria.**

1. Serial No
2. Date Seen
3. Sex: Male/Female
4. Occupation
5. Address
6. Ageyears
7. Are you a known diabetic? Yes/No
8. If yes, for how long have attended the diabetes clinic
9. Highest level of Education

 - a. No formal education
 - b. Primary School
 - c. Secondary School
 - d. Tertiary training

10. Are you enrolled into a health insurance scheme? Yes/No
11. If yes, which type of health insurance coverage? Public (NHIS)/Private (HMO)
12. Do you have hypertension? Yes/No
13. If yes for how long, specifyyears
14. Weight (barefooted) Kg
15. Height (without shoes) m
16. Body Mass Index (weight /height²) Kg/m²
17. Blood pressure mmHg
18. Fasting Blood Glucose mmol/L
19. Glycosylated hemoglobin%

Appendix B: Participants' Information Sheet

INTRODUCTION:

You are invited to participate in this study which is part of the requirements for the award of the P.hD in Public Health at Walden University to the investigator, Jideuma Egwim. This study is not part of your clinical care and is entirely voluntary. You are free to choose to participate or decline or withdraw from the study at any point without impacting the care you are receiving at the diabetes clinic. I cannot include patients who are acutely or critically ill, have major psychiatric illness or impaired cognitive function.

STUDY TITLE:

Predictors of glycemic control among type-2 diabetic patients in Owerri, Nigeria

RESEARCH QUESTION:

Is there an association between any of these predictor factors and glycemic control among type 2 diabetic patients measured using HbA1c? Health insurance status, type of health insurance coverage (public or private), age, education, gender, BMI, or hypertension?

AIM:

To assess the predictors of glycemic control among type-2 diabetic subjects in Owerri, Nigeria. as a strategy to define valuable approaches to improving glycemic control in diabetic patients.

MEANING OF PREDICTORS AND GLYCEMIC CONTROL:

Predictors are factors that explain the glycemic control in a diabetic individual. Glycemic control is a marker of how the disease is affecting the body and thus, the risk of occurrence of complications.

WHY AM I REQUESTED TO PARTICIPATE?

Because you have diabetes and have been receiving care at the diabetes clinic of the Federal Medical Center, Owerri for at least six months.

WHAT DOES MY PARTICIPATION ENTAIL?

You will be asked a few questions about your biodata and health insurance status, which should take no longer than 20 minutes. You will be asked to share your height and weight. Your blood pressure, fasting blood glucose, and HbA1c readings will be retrieved from your clinical records. If you wish to participate you will meet the researcher in room 15 between 11am and 3pm on clinic days to complete the informed consent process.

WHAT ARE THE BENEFITS OF MY PARTICIPATION?

There is no direct benefit to you but you would be contributing to the growth of the field of medicine by yielding information necessary for new knowledge on diabetes control. The study results will be documented and made available to your healthcare provider. You shall be informed of results of the study at publication.

WHAT ARE THE RISKS OF MY PARTICIPATION?

There are no risks associated with your participation in the study. Names are removed from the files to keep your privacy.

FURTHER QUESTIONS AND ANY CLARIFICATIONS:

Feel free to contact the investigator via

Address - Public Health Programs, Faculty of Public Health, College of Health Sciences Walden University

jideuma.egwim@waldenu.edu

Appendix C: G*Power Calculation of Sample Size for Study

