## The Socio-Economic and Behavioural Factors Associated with Poor Glycaemic Control Among Adult Type 2 Diabetic Patients Attending the Outpatient Diabetes Clinic in Tertiary Hospitals in Abuja, Nigeria

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A minithesis submitted in partial fulfilment of the requirements for the degree of Magister in Public Health in the School of Public Health in the Faculty of Community and Health Sciences, University of the Western Cape.

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### **KEY WORDS**

Chronic noncommunicable diseases

Diabetes

Glycaemic control

Glycosylated Haemoglobin

Fasting Plasma Glucose

Anti-diabetic medications

Adherence

Socio-economic factors

Healthcare providers

Health System



### **ABSTRACT**

Title: The Socio-Economic and Behavioural Factors Associated with Poor Glycaemic Control Among Adult Type 2 Diabetic Patients Attending the Outpatient Diabetes Clinic in Tertiary Hospitals in Abuja, Nigeria.

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Background: The prevalence of diabetes in Africa has been on the increase. A prevalence of 1%-10% has been reported by different authors in different regions in Nigeria. The International Diabetes Federation estimates that 1.9% of Nigerians are diabetic and most of them have complications at the time of diagnosis. Laboratory measurement of Glycosylated hemoglobin (HbA1c) is the method of choice for monitoring glycaemic control but due to its cost and limited availability, most developing countries use fasting plasma glucose (FPG) measurement (which is less reliable) to assess glycaemic control. Most diabetic patients in Nigeria have poor glycaemic control and several factors have been implicated especially socio-economic, behavioral and treatment-related factors. Understanding the reasons for poor glycaemic control is essential in order to reduce the rate of diabetes complications.

**Aim:** To determine the prevalence of poor glycaemic control and analyze the socio-economic and behavioural factors influencing glycaemic control of outpatient adult type 2 diabetic patients in tertiary hospitals in Abuja, Nigeria.

**Methodology:** A cross-sectional analytical study involving 327 type 2 diabetic patients aged between 20 and 79 years on follow up outpatient visits at tertiary hospitals in Abuja (National Hospital and University of Abuja Teaching Hospital) between December 2016 to March, 2017. A semi-structured questionnaire was used to collect data from the participants on their socioeconomic attributes and behaviours. The level of glycaemic control was assessed through the patient's treatment record review. The data was entered into the Microsoft Excel 2013 package and analysis of the data was done using Epi Info 7 statistical software.

**Findings:** The mean age of the patients sampled was 54 years and 60% of them were females. Majority of the patients (47%) were middle income earners and have completed tertiary education

(56%). Most of the patients were employed (63%) and about three quarter of them resided in urban settings. Just above 50% of the patients had a positive family history. Two thirds of the diabetic patients sampled were being treated with only oral medications while 8% are on insulin-only treatment. Twenty-eight percent are on a combination regimen of oral medications and insulin injection. Seventy-five percent of the patients had other comorbidities especially hypertension and dyslipidemia. The average pill load of the patients on oral medications was 4.8 tablets per day. The mean BMI and waist circumference of the study population was 28.9 kg/m2 and 97.6cm respectively. About 35% of the patients were physically active and only 34% of the respondents had done daily self-monitoring of blood glucose in the past one week. The level of satisfaction was high with 91% of the patients being happy with the services they received from their healthcare provider. Fifty-three percent of the patients had poor glycaemic control and the mean HbA1c and FPG of the respondents were 7.6% and 142 mg/dl respectively.

The associations between glycaemic control and the different socio-demographic variables were not statistically significant but the trends were consistent with previous studies done in similar settings. Patients at extremes of ages had the highest rate of poor glycaemic control (20-29: 67% and 70-79: 70%). Poor glycaemic control was more prevalent in males (54% vs 52% in females), married (54% vs 47% in 'not married'), rural dwellers (55% vs 52% in urban dwellers), and patients without family history of diabetes (56% vs 50% in those with family history). Patients with high income, tertiary education and employment had the worst level of glycaemic control compared with those with lower income, less education and unemployed.

Behavioural and lifestyle factors also influenced glycaemic control amongst the patients sampled. Dietary habits emerged as the most significant factor that affects glycaemic control in diabetic patients. Patients with poor dietary habits had worse glycaemic control compared to those who eat healthy. This was found to be statistically significant across several dietary behaviours that were assessed. Although not statistically significant, physical inactivity, obesity and frequent self-monitoring of blood glucose were found to be risk factors of poor glycaemic control.

Patients on combination therapy of insulin and oral medications had the highest rate of poor glycaemic control (65%) compared to insulin-only (48%), oral-only (49%) and non-pharmacological (40%) group. Patients taking 5 or less number of tablets per day had higher rate of poor glycaemic control (55%) compared to those on more than 5 tablets per day (48%). Patients

who are dissatisfied with the quality of service of their healthcare provider were also found to have poorer glycaemic control (70% vs 51% in the 'satisfied' group). This difference was statistically significant.

Conclusion: Socio-demographic, behavioural and treatment related-factors affect glycaemic control of adult type 2 diabetic patients but the most significant influence on glycaemic control is behavioural/lifestyle factors. Patients with poor dietary habits had the worst glycaemic control. Physical inactivity, obesity, extremes of age, male gender, being married, high income, being employed, completing tertiary education, frequent self-monitoring of blood glucose, combination therapy with oral medications and insulin and being dissatisfied with the healthcare provider were all seen to be associated with poorer glycaemic control. Collaborative efforts should therefore be made by political leaders, healthcare providers, health promoters and most importantly the patient in ensuring that the conducive environment that will make it easier for the patients to adopt healthier lifestyles (e.g. healthy eating, physical activity) is created. Patients should also make sincere efforts in being completely involved in their management and also devise means to improve adherence not only to medications but also to lifestyle recommendations.

Date: November 4, 2017

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### **Declaration:**

I declare that *The Socio-Economic and Behavioural Factors Associated with Poor Glycaemic Control Among Adult Type 2 Diabetic Patients Attending the Outpatient Diabetes Clinic in Tertiary Hospitals in Abuja, Nigeria* is my own work, that it has not been submitted for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged by complete references.

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Chapters

Signed:

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### **ACRONYMS**

ADA: American Diabetic Association

DCCT: Diabetes Control and Complications Trial

DM: Diabetes Mellitus

FPG: Fasting Plasma Glucose

HbA1c: Haemoglobin A1c or Glycosylated Haemoglobin

IDF: International Diabetes Federation

LMICs: Low and Middle-Income Countries

NCD: Noncommunicable Diseases

NHANES: National Health and Nutrition Examination Survey

OR: Odds Risk

T2DM: Type 2 Diabetes Mellitus

UKPDS Group: United Kingdom Prospective Diabetes Study Group

WHO: World Health Organization

NHA: National Hospital Abuja

UATH: University of Abuja Teaching Hospital

### **CHAPTER 1 INTRODUCTION**

Diabetes mellitus (DM) is a chronic noncommunicable disease (NCD) characterized by persistent high blood glucose in which the body cannot produce enough insulin (a hormone that regulates blood glucose) or cannot use it effectively (Masharani, 2017: 1210). There are 3 main types of DM i.e. type 1, type 2 and gestational diabetes. For the purpose of this research the focus will be on type 2 diabetes because it constitutes about 90% of all diabetes cases (World Health Organisation (WHO), 2017).

Type 2 diabetes was previously regarded as a disease of affluence but prevalence data over the past decades have shown remarkable increase in the incidence of diabetes in traditionally poor communities and in Low and Middle-Income Countries (LMICs) (International Diabetes Federation (IDF), 2015). Globally, an estimated 415 million adults have diabetes and 75% of these live in LMICs (IDF, 2015).

Despite the higher prevalence of diabetes in sub-Saharan Africa, the region accounts for only 0.5% of the global health expenditure on diabetes (IDF, 2015). According to the IDF, African countries spent the least amount on diabetes healthcare in comparison with other regions despite bearing the greatest burden. This has further stretched the health system which has been crippled by communicable diseases, HIV/AIDS and violence (Boutayeb & Boutayeb, 2005).

Local studies report a diabetes prevalence between 2% and 10% (Chinenye et al, 2012; Enang et al, 2014; Ogbera & Ekpebegh, 2014; Ejike, Uka & Nwachukwu, 2015; Olayemi & Osazuwa, 2016) but the IDF 2015 diabetes atlas estimates that 1.9% (1.4% to 4.6%) of Nigerians aged between 20-79 years are diabetic. The major challenges faced in the provision of care of diabetics in Nigeria are centered around late detection and/or misdiagnosis and exorbitant cost of diabetes management. Poverty, ignorance, attribution of disease symptoms to myths and deities, lack of basic infrastructure and poor access to health care are some of the factors that have increased the risk of misdiagnosis of diabetes, late detection and early onset of complications amongst diabetic patients in Nigeria (Oguejiofor, Odenigbo & Onwukwe, 2014).

Many diabetic patients in Nigeria simply cannot afford to pay for adequate care of their ailment because diabetes management is quite expensive. The costs of treating diabetes are incurred from treating the disease itself, treating the possible complications and treating other diseases where diabetes is a risk factor. This burden is worsened when we consider the reduction in the economic productivity of these patients and the effects this may have in their family. The above-mentioned factors have contributed to the high prevalence of complications in Nigerian diabetic patients (Chinenye et al, 2012) due to their poor level of glycaemic control (HbA1c greater than 7% and/or FPG persistently greater than 126mg/dl) (American Diabetic Association (ADA), 2017).

Twenty-four percent of patients who had stroke in Abuja, Nigeria were found to be diabetic (Alkali et al, 2013) and diabetic foot disease is the major indication for limb amputation in National Hospital, Abuja (Umaru, Madubueze, Alada & Onu, 2015). Several factors have been implicated in the high prevalence of poor glycaemic control among Nigerian diabetic patients but socioeconomic and behavioural factors are the most incriminated (Enwere, Salako & Falade, 2006; Yusuff, Obe & Joseph, 2008; Adisa, Alutundu & Fakeye, 2009; Adibe, Aguwa, Ukwe, Okonta & Udeogaranya, 2009; Adisa et al, 2011; Pascal et al, 2015). Diabetes treatment is unattainable for most diabetic patients in Nigeria in the absence of health insurance and with 33% of the population living below the poverty line.

Most studies select certain socio-economic variables (often one or two) to establish an association between them and poor glycaemic control but this study aims to evaluate a wider range of social, economic and demographic factors. Some lifestyle factors that have been implicated in poor glycaemic control are lack of physical activity, dietary intake patterns and attitude towards self-monitoring of blood glucose. Nigerians have abandoned their traditional staple foods (mainly roots and tubers) and adopted western-style diets with high glycaemic index like refined white rice, pastries (Mattei et al, 2015), sugary beverages and red meat (Harvard School of Public Health (HSPH), 2016).

In addition to behaviour and lifestyle, several treatment-related factors also play a role in achieving good glycaemic control: correct choice of drugs, correct dosage of drugs and patients' adherence to medications and recommendations.

The only effective way to reduce complications from diabetes is to maintain good glycaemic control throughout the duration of the disease. It is therefore very important to understand the reasons why diabetic patients have poor glycaemic control. This is the essence of this study.

### **CHAPTER 2 LITERATURE REVIEW**

#### 2.1 What is Diabetes?

Diabetes mellitus (DM) is a 'syndrome of chronic hyperglycaemia (persistently elevated blood glucose) due to relative insulin deficiency, resistance or both' (Masharani, 2017; Gale & Anderson, 2017). It affects about 415 million people worldwide and it is estimated that 642 million people will be diabetic by 2040 (IDF, 2015). To diagnose someone with diabetes, the following WHO criteria must be met: fasting plasma glucose >126mg/dl or random plasma glucose >200mg/dl (one abnormal value if patient is symptomatic, otherwise two abnormal values) and a HbA1c >6.5% (Gale & Anderson, 2017).

Diabetic patients have a long latent period during which they show no symptoms and are mostly unaware that they have the disease (Gale & Anderson, 2017). When symptoms develop, the initial classic triad of symptoms include polyuria, weight loss and thirst. Other subacute symptoms include lack of energy, visual blurring or fungal infections. Many diabetics develop complications like retinopathy, nephropathy, neuropathy, erectile dysfunction and arterial disease (Gale & Anderson, 2017) if their blood glucose level is not adequately controlled.

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### 2.2 Glycaemic Control

Glycaemic control is the regulation and maintenance of blood glucose levels within normal ranges. Achieving good glycaemic control is the primary treatment target for all diabetic patients (IDF, 2015; ADA, 2017) and it entails preventing high blood glucose (hyperglycaemia) and low blood glucose (hypoglycaemia). Diabetic patients with fasting plasma glucose (FPG) consistently less than 126 mg/dl or a HbA1c less than 7% are said to have good glycaemic control (WHO, 2011; IDF, 2015). Poor glycaemic control leads to poor quality of life (Kamarul Imran et al, 2010), frequent hospital admissions, more expenses on treatment (Testa & Simonson, 1998), more complications and higher mortality rates. Good glycaemic control helps to reduce the cost of diabetes management (Roebuck et al, 2011) by reducing the rate of complications (Agboola-Abu, Ohwovoriole & Akinlade, 2000; Zimmet, 2003; Wild et al, 2004;) and mortality (Diabetes Control and Complications Trial [DCCT] Research Group, 1993; United Kingdom Prospective Diabetes Study [UKPDS] Group, 1998; Nathan et al, 2005; Adebisi et al, 2009).

### 2.2.1 Monitoring of Glycaemic Control

Glycaemic control can be monitored using intermittent fasting plasma glucose (FPG) measurement and the measurement of Glycosylated haemoglobin (HbA1c) (Saudek, Derr & Kalyani, 2006; Rodbard et al, 2009; ADA, 2017). The FPG is simple to perform, cheap and widely available (WHO, 2011; Pascal et al, 2015; Harris, 1993). However, its values represent the blood glucose level at the point of testing and are affected by day-to-day fluctuations, exercise and recent food or drug intake. It is therefore not a reliable proof of adequate glycaemic control (Dailey, 2007). The cost-friendliness and wide availability of FPG in developing countries makes it a preferred choice for monitoring glycaemic control (Adisa et al, 2011; Pascal et al, 2015). Generally, patients whose FPG are below 126mg/dl during follow up can be said to have adequate glycaemic control (WHO & IDF, 2006). However, it is important to note that several studies have used cut-off points lower than this (UKPDS Group, 1998; Adisa et al, 2011; Pascal et al, 2015).

HbA1c is regarded as the gold standard for monitoring glycaemic control because of its ability to indicate sustained hyperglycaemia-which is a major trigger for complications. HbA1c gives an overview of the average plasma glucose in the preceding three months (Adebisi, Oghagbon, Akande & Olarinoye, 2009; ADA, 2011; WHO, 2011), it does not fluctuate with time of day, exercise, food or drug ingestion and is a more reliable predictor of glycaemic control (DCCT Research Group, 1993; UKPDS Group, 1998). The normal HbA1c levels for normal individuals ranges from 4.5% to 6%. The American Diabetes association (ADA) accepts any value <7.0% as normal (ADA, 2017). For most persons who have been previously diagnosed with diabetes, an HbA1c of 7% is often the treatment target. Consequentially, the cutoff point for poor vs. good glycaemic control in most studies is 7% (Al-Rasheedi, 2014; Khattab et al, 2010). In managing a diabetic patient, achieving a 1% absolute reduction in HbA1c reduces the risk of a major cardiovascular event (by 15% to 20%) and microvascular complications (by 37%) (Sigal et al, 2007). The ADA (2017) recommends that the HbA1c test is performed at least two times in a year in patients who are meeting treatment goals and have stable glycaemic control and quarterly in patients whose treatment regimen has changed or are not meeting glycaemic targets. Patients who have the opportunity of point-of-care HBA1c test are more likely to benefit from timely treatment adjustments (ADA, 2017)

### 2.3 Causes of Poor Glycaemic Control

The causes of poor glycaemic control can be broadly classified into socio-economic, psychological, healthcare provider related causes, health system causes, lifestyle/behavioural factors, disease related causes and treatment related causes (Delamater, 2006).

#### 2.3.1 Socio-Economic Factors

Socio-economic factors play the most significant role in the level of glycaemic control amongst diabetic patients (Shilubane, 2010). Poor glycaemic control is highest among individuals with low income (Delamater, 2006), financial constraints (Adisa et al, 2011; Pascal et al, 2015), no formal education and no employment (Almutairi, Said & Zainuddin, 2013). Individuals who are socio-economically disadvantaged are not able to buy their medications, do their laboratory investigations or keep up with their follow-up appointments. They cannot afford healthy diets and often lack the means to visit recreation or sports parks for physical activities. It is therefore more difficult for this group of persons to maintain a good level of glycaemic control.

Adisa et al (2011), in their cross-sectional study of type 2 diabetic patients attending the diabetes clinic in a tertiary hospital in Nigeria, reported that 34.4% of the respondents identified financial constraints as the major reason for not adhering to their medications. In another study, 59% of the diabetic patients were non-adherent to their medications due to lack of finance (Yusuff, Obe & Joseph, 2008). High cost of diabetes medications has been implicated by a large proportion of diabetic patients (35.5% [Adisa, Alutundu & Fakeye, 2009] and 52.2% [Enwere, Salako & Falade, 2006]) as a major cause of nonadherence. Most of the diabetes medications are imported and this further worsens the plight of Nigerian diabetics (Adibe, Aguwa, Ukwe, Okonta & Udeogaranya, 2009).

Socially deprived diabetics have been shown to have a higher mortality than those who are not deprived (Robinson, Lloyd & Stevens, 1998). The mortality rate for type 2 diabetics is higher for those of lower social class vs higher social class (Odds Risk(OR) 2.0). The mortality rate was three times higher for patients who left school before the age of 16 compared to those who left school at or above 16 years of age. Unemployed diabetics had a higher mortality rate than employed

patients (OR 2.88) (Robinson, Lloyd & Stevens, 1998). These higher rates of mortality were linked with a higher rate of complication in the disadvantaged populations. In a cohort of type 2 diabetics in London, James et al (2012) reported a persistently worse glycaemic control despite more intensive treatment amongst socially disadvantaged populations. The rate of improvement of the control was even less in these populations. At the beginning of the study, 44% of the White population had a good glycaemic control (HbA1c < 7.5%) while 38% of the Black African/Caribbean population had a similar level of control. These figures improved to 56% and 53% respectively at the end of the 5-year study period.

Diabetes is an expensive disease to manage. It is therefore understandable that patients who are financially and socially constrained might not be able to meet up with the financial commitment of a proper diabetes management plan. An efficient social health insurance scheme would have been an easy way out of the quagmire but such a system does not exist in the Nigerian healthcare system. Only 5% of Nigerians have any form of prepaid health care through social or voluntary private insurance (Onwujekwe, Hanson & Uzochukwu, 2012). Most Nigerian patients buy their drugs, pay for laboratory tests and consultation fees out-of-pocket. In a country with high level of poverty and a minimum wage that cannot provide enough food or shelter, it is clear that health care will definitely not be adequate. The chronic nature of type 2 diabetes further complicates this scenario because these patients spend their entire lifetime buying drugs, attending follow ups and doing laboratory investigations. Type 2 diabetic patients without insurance for self-monitoring supplies often have significantly worse glycaemic control (Bowker et al, 2004; Karter et al, 2000). In a Canadian study, the average HbA1c of the insured patients was 7.1% and uninsured patients had an average HbA1c of 7.4% (Bowker et al, 2004). Bowker et al in their cross-sectional study, sampled patients at community pharmacies in Alberta and Saskatchewan provinces in Western Canada with an initial hypothesis that insured patients were more likely to self-monitor their blood glucose and therefore have a better glycaemic control. This hypothesis was confirmed in their study. Forty-one percent of their subjects had a form of health insurance, in sharp contrast to the Nigerian setting.

Saydah et al (2007) did not find any association between socio-economic status (using only education and poverty status) and glycaemic control of patients in the United States. Saydah et al, having recognized the incompleteness of the measures of socio-economic status in the NHANES

1999-2002 questionnaire (which they used in their survey), adjusted for other probable socioeconomic factors that can influence glycaemic control. After the adjustment, obesity, healthcare access and utilization, diabetes treatment and racial/ethnic differences remained significant influences on glycaemic control in the surveyed patients.

### 2.3.2 Lifestyle/Behavioural Factors

Behavioural factors like dietary pattern, physical activity level, body weight, alcohol and smoking influence the glycaemic control in type 2 diabetic patients. Close monitoring of the diet and involvement in regular physical activities promote good glycaemic control (Almutairi, Said & Zainuddin, 2013). This is evidenced in the U.K. Prospective Diabetes Study (UKPDS) in which newly diagnosed type 2 diabetics underwent 3 months' dietary treatment which reduced their HbA1c from approximately 9% to 7%. Nutrition therapy is a key component of American Diabetes Association's guidelines on lifestyle management of diabetes patients (ADA, 2017). While the choice of diet remains the most challenging component of diabetes management, the lack of a onesize fits all eating pattern makes diet a recurrent topic in improvement of glycaemic control in patients with diabetes (ADA, 2017). Dietary patterns of diabetic patients should be tailored to personal and cultural food preferences and the calorie needs of the patient (Ley, Hamdy, Mohan & Hu, 2014). In order to achieve glycaemic control, diets rich in wholegrains, fruits, vegetables and nuts have been shown to be effective in the nutritional management of diabetes (Ley, Hamdy, Mohan & Hu, 2014). Similarly, the blood glucose and lipid levels of diabetic patients are better controlled with diets lower in refined grains, red or processed meat and sugar-sweetened beverages (Ley, Hamdy, Mohan & Hu, 2014).

An alternative approach to consider diet in diabetes is to consider food patterns rather than isolated food items. The relationship between different food patterns and glycaemic control have been widely studied. The Mediterranean, DASH (Dietary Approaches to Stop Hypertension) and 'moderately low carbohydrate' diets are some of the food patterns that have been studied and their beneficial effects on glycaemic control was evident (Ley, Hamdy, Mohan & Hu, 2014). Mediterranean diet entails the high consumption of minimally processed plant-based foods, low-to-moderate consumption of dairy products, fish and poultry, low consumption of red meat, and low-to-moderate consumption of wine with meals. The major source of fat in the Mediterranean

diet is olive oil. In addition to the role of Mediterranean diet in improving glycaemic control, studies have shown that patients on such diet have also an improved insulin sensitivity and a reduced cardiovascular risk (Shai et al, 2008; Esposito et al, 2009, Esposito et al, 2010 & Estruch et al, 2013).

The DASH diet is rich in fruits and vegetables, low-fat dairy products, wholegrains, poultry, fish and nuts but is low in saturated fat, red meat, sweets, sugar containing beverages and sodium. The DASH diet has been shown to be beneficial in the control of glycaemia in patients with diabetes and the reduction of cardiovascular risk factors (Azadbakht et al, 2011).

The 'moderately low carbohydrate' diet involves the reduction of the amount of carbohydrate in the diet and the increase in the quantity of fats and protein from animal or plant food sources. This form of diet has been shown to improve glycaemic control, reduce blood lipids, led to greater weight loss in diabetic patients in comparison to conventional control diets (Ajala, English & Pinkney, 2013).

Vegetarian and vegan diets did not show consistently positive effects on glycaemic control or the cardiovascular risk reduction in diabetic patients (Barnard et al, 2009; Ajala, English & Pinkney, 2013). Moreover, the effect of vegetarian diet is difficult to isolate due to the cofounding effect of the calorie restriction associated with vegetarian or vegan diets (Ley, Hamdy, Mohan & Hu, 2014).

Diabetic patients who are physically active have better glycaemic control. In a randomized controlled trial involving 251 adult type 2 diabetics in community-based exercise facilities in Canada, aerobic exercises or resistance training was found to improve glycaemic control (reduced the average HbA1c by an absolute percentage value of 0.51% (aerobic training) and 0.38% (resistance training)) after 22 weeks of intervention (Sigal et al, 2007). Sigal et al did not blind their participants and this could have a Hawthorne effect. Their findings cannot be generalized to diabetics who are less adherent to exercise programs. However, their findings are comparable to the results of some systematic reviews in which an absolute reduction of 0.6% was achieved through exercise (Boulé et al, 2001; Thomas, Elliott & Naughton, 2006).

Other studies have withdrawn physical activity in diabetics and found that blood sugar levels of these patients increased (Mikus et al, 2012). Most local studies in Nigeria dwell on patients'

adherence to medications ignoring the important role played by behavioural modification. The risk associated with unhealthy diet, sedentary lifestyle and alcohol abuse does not stop at causing the disease, it perpetuates it and hastens complications. While moderate consumption of alcohol has a positive effect on glycaemic control, excessive use worsens glycaemic control (Howard, Arnsten & Gourevitch, 2004; Ahmed et al, 2008). Alcohol abuse can precipitate hyperglycaemic crisis in type 2 diabetic patients (Kitabchi et al, 2001). Physical inactivity and poor dietary patterns are closely associated with overweight and obesity which are risk factors for poor glycaemic control amongst diabetic patients (Almutari, Said & Zainuddin, 2013).

#### 2.3.3 Treatment-Related factors

The prescribing pattern for diabetic patients is another key determinant of glycaemic control. Cost of medicines (Piette, Wagner, Potter & Schillinger, 2004; Enwere, Salako & Falade, 2006), route of administration, pill burden and multiple dosing regimens are some prescription-related factors that influence glycaemic control (Ary, Toobert, Wilson & Glasgow in Delamater, 2006). Patients on simpler regimens (fewer tablets, monotherapies, fewer dosing frequencies) tend to adhere better to their medications. Donnan, MacDonald & Morris (2002) reported that diabetic patients on one tablet per day had better adherence rates (and better glycaemic control) than patients on multiple tablets. They also found a linear trend between the number of tablets and the level of adherence. Diabetic patients also adhere better to their medications than behavioural recommendations (Delamater, 2006). This makes it more difficult to achieve good level of glycaemic control due to the role played by the lifestyle factors in diabetes care.

Patients' satisfaction with the quality of health care service provided by the managing hospitals is also an important determinant of the possible outcome of the treatment. One way in which this quality has been assessed is by eliciting the level of patient satisfaction with the services they receive. Alazri & Neal (2003) reported that there is an association between patients' satisfaction and outcome in diabetes-HbA1c. They submitted that steps taken to increase patients' satisfaction (by actualisation of their values and expectations) improve outcome by increasing compliance and adherence to treatment regimens. Patients' satisfaction could therefore be linked to glycaemic control amongst diabetic patients.

The above review shows that glycaemic control in diabetes is influenced by a wide range of factors and failure to adequately control it can lead to serious complications. Understanding the causes of poor glycaemic control among diabetic patients is a key step in preventing complications. In addition to identifying the reasons why diabetic patients have poor blood glucose control, it is envisaged that this study will fill in some gaps that exist in the currently available literature.



### CHAPTER 3 RESEARCH DESIGN AND METHODOLOGY

### 3.1 Aim

To describe glycaemic control and determine the socio-economic, behavioural and treatment-related factors that influence glycaemic control among adult diabetic patients attending outpatient clinics in tertiary hospitals in Abuja, Nigeria

### 3.2 Objectives

- To determine the level of glycaemic control amongst adult type 2 diabetic patients in Abuja
- To determine if there is an association between socio-economic factors and glycaemic control
- To determine if there is an association between behavior and lifestyle and glycaemic control
- To determine if the nature of treatment influences glycaemic control in adult type 2 diabetes patients

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### 3.3 Methods

### 3.3.1 Study Setting WESTERN CAPE

The study was done in 2 tertiary hospitals in Abuja, Nigeria. Abuja became the capital of Nigeria in 1991 and has a land mass of about 7,315 km². The population is growing rapidly and the rate of development is high. Currently the population stands at about 1.5 million, 60% of whom still reside in rural settlements. Abuja is made up of 6 area councils- 3 rural (Abaji, Kuje and Kwali) 2 semi-urban (Gwagwalada and Bwari) and 1 urban (Abuja Municipal Area Council). The seat of the country's political power is in the municipal council but development is slowly spreading into the other councils. The healthcare facilities and health manpower in Abuja are inadequate and are inequitably distributed and accessibility is poor especially for rural dwellers. There are 2 tertiary hospitals in Abuja viz. the National Hospital (located in the municipal council) and University of Abuja Teaching Hospital (located in Gwagwalada). Twenty percent of confirmed diabetic patients in Nigeria attend diabetes clinics in the tertiary hospitals. Majority of the patients (about 50%)

follow up their diabetes at the secondary-level general or specialist hospitals and private hospitals (Fasanmade & Dagogo-Jack, 2015). The remaining 30% of the diagnosed diabetic patients either buy antidiabetic drugs from pharmacy outlets and patent medicine dealers or simply ignore their ailment.

It is worth noting that the most comprehensive multidisciplinary diabetes care can only be provided in the tertiary hospitals because of the constant availability of the specialists in different fields and the required equipment for diabetic care. These third-tier hospitals also serve as a reference hospital for the secondary and primary care hospitals and are often overwhelmed by the volume of patients they attend to. Most of the Abuja inhabitants (like in the entire Nigeria) has no health insurance and so pay out of pocket for all medical expenses. Amongst the insured patients, majority are only enjoying a partial insurance scheme. The poverty rate per capita in Nigeria is 33.1% with a wide gap between the rural areas (44.9%) and urban areas (15.8%) (World Bank, 2014). Fiftyeight percent of the Abuja population are literate (National Bureau of Statistics, 2010).

### 3.3.2 Study Design

An analytical cross-sectional study design was utilized because it was more logistically plausible than a prospective cohort or a randomized controlled trial (Stone & Campbell, 1984). With the cross-sectional design, the prevalence of poor glycaemic control among diabetic patients was determined and at the same time, the social-economic attributes of the population were described. The nature of the treatment was also explored (oral vs. insulin, number of medications, cost of medications). The questionnaires were interviewer-administered. The socio-economic and behavioral characteristics of the people with good glycaemic control (HbA1c <7% or average FPG <126mg/dl) was then compared with the group with poor glycaemic control (HbA1c >7% or average FPG >126mg/dl). Although this design could establish association between poor glycaemic control and social factors, it cannot prove causality (Stone & Campbell, 1984).

### 3.3.3 Study Population

The study included type 2 diabetic patients aged between 20 and 79 years attending outpatient diabetes or endocrinology clinic with a confirmed diagnosis (by a physician) as evidenced in the treatment records. The included patients must have had at least one HbA1c or two FPG tests done

within the last 3 months. Only patients who have been on drug treatment or lifestyle modification for at least 6 months were included. Pregnant women were excluded because they represent a different group of diabetic patients whose problem might be due to the pregnancy and their motivation for positive adherence behaviours is different. Patients with debilitating mental illness were also excluded due to inability to give informed consent. Patients who have attended the diabetes clinic for any reason previously during the survey period and has been interviewed already were also excluded to avoid inclusion of a person multiple times. To ensure single response, a note was attached to the patient's case note after the interview.

### 3.3.4 Sample Size and Sampling Procedure

The sample size calculation was reworked when saturation (most patients who were presenting at the diabetes clinic have already been interviewed previously) was reached during data collection. This was a sign that the sample size was previously overestimated. Therefore, the parameters in the calculation below differs from the parameters used in the research proposal.

The sample size was calculated using Epiinfo Statcalc function. At first the population size was calculated using the population figures and IDF prevalence of diabetes (diagnosed and undiagnosed) in Nigeria. According to the 2006 National census figures (Nigeria Population Commission, 2017) the estimated population of Abuja is 1,406,239. With a diabetes prevalence of 1.9% (IDF, 2015), the population of diabetics in Abuja was calculated to be 26,719. Amongst this population, about 90% are type 2 diabetics (IDF, 2015) and this gives the population of type 2 diabetic patients in Abuja to be 24,047. Since only 33.3% of diabetic patients are diagnosed or confirmed in Nigeria (IDF, 2015), the number of diagnosed cases in Abuja was calculated to be 8,008. When we narrowed down to the study population (tertiary hospitals) -where only 20% of diagnosed cases of diabetes receive care-, we arrived at a population size of 1602. In other words, about 1,602 diabetic patients were being managed in the two tertiary hospitals in Abuja.

Secondly, an expected frequency of 68% was used in the sample size calculation. This represented the proportion of diabetic patients in Nigeria with poor glycaemic control (Chinenye et al, 2012). Considering the above assumptions, a 95% confidence interval, 5% acceptable margin of error, a design effect of 1, and 2 clusters, a raw sample size 278 was calculated using the Statcalc function of Epiinfo. In order to compensate for potentially missing or incomplete data, an additional 15%

of the raw sample size was added and this yielded a minimum sample size of 320. However, a total of 327 diabetic patients were sampled using a consecutive sampling technique on the outpatient clinic days at the diabetes or endocrinology clinics of the two study hospitals.

### 3.3.5 Data Collection and Processing

The data was collected between 15<sup>th</sup> December 2016 and 9<sup>th</sup> March 2017 at National hospital (NHA) and University of Abuja teaching hospital (UATH). Each of the two hospitals had one endocrinology clinic day per week (NHA-Tuesdays, UATH-Thursdays). On each of those days the clinic runs from around 9.00am to 3.00pm. They care for patients with endocrine abnormalities with about 70% of the patients being managed for diabetes.

Patients' case notes and semi-structured interviewer-administered questionnaires were the tools used in data collection. Data such as medical history (age of onset, duration of disease, family history), demography (age, sex, educational level), HbA1c test value and/or latest two FPG test results were extracted from the case notes if available. This information was also corroborated by the patients. Seven data collectors/interviewers were recruited and trained specifically for this study. The other variables being assessed in the study i.e. sociodemographic attributes, treatment related factors, healthcare provider associated variables, behaviour and lifestyle and complications, were ascertained from the patients through the questionnaire which was in English language. Most of the patients understood English language but a few of them who did not understand English were interviewed through the help of an interpreter who in all cases were the patient's relative.

The patients were interviewed in the morning of their clinic days before or after consulting their doctor. Informed consent was obtained after providing full information to the patient. A copy of the questionnaire, participant information sheet and informed consent have been included in the appendix.

### 3.3.6 Data Analysis

The data collected in the questionnaire was coded and entered into Microsoft Excel with the columns representing the variables and the rows representing the participants. Data cleaning was done in Microsoft Excel by sorting each column/variable to pick out outliers and omitted data. Misspelt entries and wrong codes were corrected after double checking against the original

questionnaire. The cleaned-up data was then exported to Epi Info software for analyses. The hard copies of the questionnaires and consent forms will be stored in a safely secured place and will be disposed after 5 years.

Descriptive analyses were done using the Epi Info based on the objectives of the study. Numerical variables were analysed by generating the mean, median, standard deviation, variance and range of the values. Frequency tables were generated for the categorical variables. Some of the categorical variables were converted to binary/dichotomous variables to allow for the calculation of a relative measure for comparison and estimation of strength of association.

The measures of central tendency and dispersion were calculated for the outcome variables-HbA1c and FPG. These variables were converted from numerical to categorical variables in order to have two outcome categories of 'good glycaemic control' and 'poor glycaemic control'. Patients who had a HbA1c value of 7% or more (or average FPG of 126mg/dl or more when HbA1c test is not available) were grouped as having poor glycaemic control. This new grouping was used to calculate the prevalence of poor (and good) glycaemic control in our study population.

In each of the exposure variables considered, the level of glycaemic control was compared across the different categories using cross-tabulations in Epi Info.

### 3.3.7 Validity, Reliability and Generalizability

The sample calculation was based on 95% confidence level and 5% margin of error in order to obtain a sample large enough to limit the probability of chance influencing the results. All diabetic patients attending the clinic within the data collection period were approached. To ensure reliability, we recruited experienced data collectors who were further retrained for this study in particular. The same set of data collectors were used in the two study hospitals and efforts were made to question the respondents in similar conditions to minimize measurement error. We also utilized standard tools of measurement especially by adopting many questions in the already validated diabetes self-care questionnaire by Toobert, Hampson & Glasgow (2000). Clear operational definitions of the variables were used and the data collectors were conversant with these definitions. The anthropometric measurements (Height, body weight and waist

circumference) where measured by the data collectors during the interview as the data in the case notes were sometimes outmoded.

The results of this study can only apply to the study population but it is anticipated that the findings and recommendations will be relevant to a wider population of diabetes patients and diabetes care providers in Nigeria.

### 3.4 Limitations of the Study

Being a cross-sectional study, it is not possible to make causal inferences from the study due to lack of temporality between the outcome and exposure. The measured outcome represents a snapshot of the population characteristics and this might differ if a different time-frame is chosen (seasonal bias). For example, the number of patients coming to the diabetes clinic reduced significantly during the Christmas period (23<sup>rd</sup> December 2016 to 8<sup>th</sup> January 2017) and very few patients were interviewed during this period and these were mostly Muslim patients and are mainly from the Northern part of the Nigeria. This could lead to bias. Secondly, patients who are surveyed immediately after the festive period could have gained more weight than usual because of the increased dietary intake associated with the Christmas season. If these patients have no HbA1c test result, their FBG could also be higher than usual and this could bias the level of glycaemic control in the study population.

Due to unknown confounders, interpreting the result from different categories of an exposure variable may be misleading. It is possible that the respondents may not have provided the accurate information especially for socially undesired behaviours such as smoking, alcohol, unhealthy diet and drug dose omission. The quality of the data that was extracted from patient's case notes cannot be authenticated. However, the anthropometry was measured for all patients as the values in the case notes were mostly out of date. A lot of the patients did not provide information regarding their income because of the sensitivity of the issue in the study setting and also the high number of persons with informal and irregular income. The missing income information was more prevalent in the unemployed group which led to the underrepresentation of the unemployed individuals in the income analyses.

Being teaching hospitals, our study clinics were also research institutions. The effect of this was that convincing patients to enroll into the study was more difficult as most of the patients have been involved in several researches during the course of their follow ups. Some patients declined from the study due to this reason. The study is therefore prone to a non-response bias as the patients who declined could differ in some ways with the study participants. It is possible that patients who have been on follow ups for a longer time would have partaken in more surveys and are more likely to refuse to be interviewed. These group of patients could have more complications or could have better lifestyle. This study is not able to analyse this effect.

The use of two different criteria for glycaemic control (HbA1c and FPG) is a significant limitation in the study. The lack of HbA1c test for all patients in our study setting makes a uniform criterion unachievable. However, the proportion of patients who have a HbA1c test (74%) is higher than reported in other studies in Nigeria. The FPG is not a reliable index to estimate glycaemic control because it fluctuates with exercise, food or drug intake. The 26% of the study population whose level of glycaemic control was determined using the FPG could have HbA1c level of any value. The result f the study therefore may not be an accurate representation of the glycaemic control of the study population.

### 3.5 Ethical Considerations

The proposal was approved by the Ethics Committee of the University of the Western Cape (reference number- BM/17/1/16) and permission was granted by the Ethics committee of the University of Abuja Teaching Hospital (reference number- FCT/UATH/HREC/PR/569) and National Hospital Abuja (reference number- NHA/EC/091/2016). Copies of the 3 letters of ethical approval has been attached as appendices (Appendix 4-6).

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All respondents participated voluntarily after a detailed explanation with the aid of the participants' information sheet (a copy of which was also made available to all respondents). The benefits, risks and voluntary nature of the study were clearly communicated to them and the assurance of the confidentiality of their data was given. A written and signed informed consent was obtained. As the study did not involve any invasive procedure, the adverse physical, psychological or emotional harm to the respondents was low. However, the indirect harm that may have arisen during the course of the study was addressed accordingly. There were no consequences whatsoever for

patients who refused to participate in the study. Participant names were not written on the questionnaires and the results of the study will only be made available to the public as averaged figures.



#### CHAPTER 4 RESULTS

### 4.1 Introduction

This chapter will present the findings from the study including the characteristics of the study population and their glycaemic control. The association between the level of glycaemic control of the patients and their socio-demographic characteristics and nature of treatment were determined by crosstabulations and the Pearson's  $\chi^2$  p value used to determine significance (Table 4.2, 4.3 and 4.4).

The association between patients' behaviour and glycaemic control was determined using both crosstabulations and ANOVA test. The ANOVA test was done for certain behavioural variables which were lifted from the Diabetes Self-Care Activities (SDSCA) questionnaire. The responses were scored and the mean number of days that the behaviour was performed calculated and then compared in the two outcome groups (good vs. poor blood glucose control) (Table 4.5). Although some authors have used ANOVA to analyze the SDSCA questionnaire (Toobert, Hampson & Glasgow, 2000; Lin et al 2016) due to its robustness and ability to manage some violations in normality in the absence of outliers, the non-parametric distribution of these set of variables necessitated the use of the Kruskal-Wallis test statistic which is a one-way ANOVA for non-parametric data. In order to understand the practices of patients, these behavioural/lifestyle variables were also analysed as categorical data (Table 4.3).

Prior to performing the analyses, missing information analyses was done to determine if any biases may be present. The only variable where the participants with missing information differed significantly from those who provided information, was income. The relative distribution of age, gender, residence, education, duration of treatment, nature of treatment, employment and blood glucose control in the 'missing income' and 'given income' group were compared and only employment status varied significantly amongst those that provided income information and those who did not (Table 4.1). About 13.5% and 13.6% respectively of the 'employed' and 'retired' population had missing income data whilst 30.2% of the 'unemployed' group had missing income data. Income data is therefore skewed towards those that earn some form of income.

### 4.2 Socio-demographic characteristics

Three hundred and twenty-seven type 2 diabetic outpatients attending follow-up clinics in two tertiary hospitals in Abuja, Nigeria-National hospital (n=144) and University of Abuja Teaching Hospital (n=183)- were surveyed in an effort to determine the relationship between their level of glycaemic control and their sociodemographic background, behaviour and treatment modality.

### 4.2.1 Age and Gender

The respondents, aged between 25 and 79 had an average age of  $54 \pm 11$  years and their mean age at first diagnosis was  $45 \pm 11$  years. The male to female ratio was 2:3 with about 88% of the respondents being married.

### 4.2.2 Income, Education, Employment and Residence

Regarding their monthly family income, 32%, 57% and 11% of the respondents were low (< 50,000 Naira), middle (50,000 to 200,000 Naira), and high income (>200,000 Naira) earners respectively (Table 4.2). Eight percent of the respondents had no education at all whereas 11%, 25% and 56% had completed primary, secondary and tertiary education respectively. In terms of employment, 16%, 20% and 64% of the surveyed patients were unemployed, retired and employed respectively during the period of the data collection. Seventy-four percent of the respondents were urban dwellers while 26% resided in rural settlements (Table 4.2).

### 4.2.3 Family History, Comorbidities and Medications

Fifty two percent of the participants had a positive family history of diabetes. Sixty-two percent of respondents were being treated with oral medications only, 8% on insulin-only treatment while 28% were on both insulin and oral medications (Table 4.4). The average duration of diabetes treatment for the study population was  $9.2 \pm 6.8$  years. Seventy-five percent of the patients had other comorbidities like hypertension (64%), dyslipidemia (5%), cardiac problems (4%), osteoarthritis (5%) and other diseases. The average pill load for the patients on oral medication was 4.8 tablets per day. Two thirds of the respondents were taking 5 or less tablets per day and the rest is taking >5 tablets per day. A further subanalysis revealed that most of the patients (55%)

were on more than  $4 \pm 2.4$  tablets per day, while 10% and 35% of them were on  $\leq 2$  tablets and 3-4 tablets respectively per day.

### **4.2.4** Health Insurance coverage and Finance

Seventy percent of the patients had no health insurance coverage and therefore had to pay for their treatment either out-of-pocket or sponsored by their family. Insurance coverage for the rest of the patients were mainly partial (24%) with just 6% of the respondents having full insurance coverage. Forgetfulness (33%) and financial constraints (14%) were the most implicated reason for poor adherence to diabetes medications.

### 4.2.5 Anthropometry and Physical Activity

322 of the respondents had a complete set of anthropometric data available. The other 5 respondents were physically unable to tolerate the measurement procedure. The mean BMI for the study population was  $28.9 \text{ kg/m}^2 \pm 6.4 \text{ kg/m}^2$  (male average=  $28.9 \text{ kg/m}^2$ ; female average= $29.0 \text{ kg/m}^2$ ) while the mean waist circumference was  $97.6 \text{cm} \pm 15.0 \text{cm}$  (male average=98.0 cm; female average=97.3 cm). About 34% of the study population were obese (i.e. BMI  $\geq 30 \text{ kg/m}^2$ ) and 65% were physically inactive (Table 4.3).

# 4.2.6 Self-monitoring of Blood Glucose, Patients' Satisfaction, Counselling by Healthcare Providers and Adherence to Healthy Eating Plan

Thirty-four percent of the respondents had done daily self-monitoring of blood glucose in the past one week. Majority of the patients (91%) were satisfied with the level of care provided by the managing hospitals (Table 4.4). Over 90% of the respondents reported having been properly counselled about diet, exercise and blood glucose measurement by the diabetes management teams. However, only 49% of the patients sampled adhered strictly (followed the plan for 6-7 days/week) to a healthful eating plan and 33% consumed fruits and vegetables regularly (consumed at least 5 portions of fruits and vegetables in 6-7 days/week) (Table 4.3).

### 4.2.7 Complications

In terms of complications, 37%, 28%, 9%, 7%, 7% and 2% of the respondents have suffered from or are suffering from diabetic retinopathy, neuropathy, nephropathy, foot ulcer, stroke and myocardial infarction respectively.

### 4.3 Glycaemic Control

Glycated haemoglobin (HbA1c) and fasting plasma glucose were the two parameters used to assess the level of glycaemic control of the patients. HbA1c, being the internationally recommended gold standard for monitoring glycaemic control was given a priority in assessing how well the patients' blood glucose was controlled. Although the HbA1c test is not usually accessible to most diabetic patients in LMICs, about 74% of our study sample (241) had a HbA1c test result not older than 6 months. For this group of patients, a HbA1c of less than 7% was regarded as good glycaemic control based on the American Diabetes Association diabetes protocol. The mean HbA1c of the respondents was  $7.6\% \pm 2.4\%$  and the value ranged from 3% to 15.3%. Ten of the participants (3%) had a HbA1c value of less than 4%, which is subnormal considering that healthy persons without diabetes have a HbA1c concentration of 4-6% (Chu, Wang, Sun, Lee & Lam, 2007). Possible causes of this will be discussed in Chapter 5.

For the rest of the participants (n=86) who had no recent HbA1c test result, the average of their latest 2 fasting plasma glucose (FPG) measurements was used to ascertain their level of glycaemic control. Patients with average FPG of less than 126 mg/dl were categorized as having good glycaemic control whereas those with greater than or equal to 126 mg/dl average FPG were classed as poor glycaemic control. The average FPG of our study population was  $142 \text{ mg/dl} \pm 53.8 \text{mg/dl}$  ranging from 63 mg/dl to 423 mg/dl.

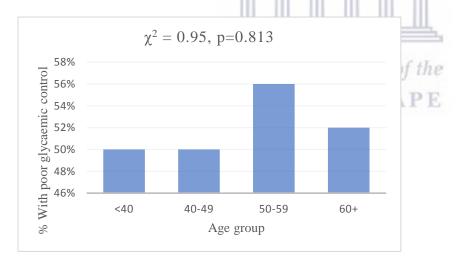
With the above criteria, a new outcome variable-Glycaemic control- was defined in which two groups of outcomes emerged- good glycaemic control (HbA1c <7% or average FPG less than 126 mg/dl if HbA1c is not available) and poor glycaemic control (HbA1c  $\geq$ 7% or average FPG  $\geq$ 126 mg/dl if HbA1c is not available). The final analysis revealed that 53% of the patients sampled (n=173) had poor glycaemic control and 47% (n=154) had good glycaemic control.

# 4.4 Socio-demographic Factors and Glycaemic Control

Some of the socio-demographic factors that has been explored in this study include: age, gender, marital status, residence, family history of diabetes, income, education, employment and available means of healthcare financing.

#### 4.4.1 Age

The values presented in Table 4.2 shows that the majority of our study population fall within the age group 50-59 (33%) and 40-49 (28%). Fifty percent of the patients in the '<40' and '40-49' age group had poor glycaemic control while 56% of the patients in the '50-59' age group had poor glycaemic control. Fifty-two percent of the patients in the '60+' category had poor glycaemic control (Figure 4.1). This observed difference is however not statistically significant ( $\chi^2$ =0.95, df=3, p=0.813). A further subcategorization of the age revealed that the worst glycaemic control was seen in extremes of ages (20-29 age group-67% of whom had poor control and 70-79 age group- 70% of whom had poor control) (df=5, p=0.178). It is important to note that the small frequencies in the 20-29 age group (n=6) might have influenced this statistic.



**Figure 4.1**: Proportionate distribution of poor glycaemic control by age group of patients attending the two tertiary hospitals (NHA and UATH) in Abuja, Nigeria

#### 4.4.2 Gender

There was no statistically significant difference between female diabetic patients and male diabetic patients in terms of glycaemic control ( $\chi^2$ =0.069, p=0.793) (52% of the females had poor control while 54% of the males had poor control) (Table 4.2).

#### 4.4.3 Marital Status

Forty-six percent of the married patients had good glycaemic control while half of the patients who were single or widowed had good blood glucose control. The 2 patients who were separated from their spouses had good glycaemic control. These differences were not statistically significant (( $\chi^2$ =3.2, df=3, p=0.357).

#### 4.4.4 Residence

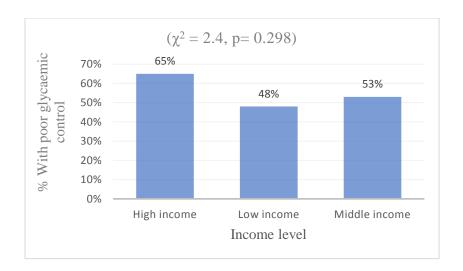
There was no statistically significant difference in the rate of poor glycaemic control between rural (55%) and urban (52%) inhabitants ( $\chi^2$ =0.2, p=0.609).

## 4.4.5 Family History of Diabetes

Patients who had a previous family history of diabetes had better glycaemic control (50% had good control) than those without a family history (44% had good control). This difference was not statistically significant (( $\chi^2$ =1.5, p=0.226) (Table 4.2).

#### **4.4.6** Income

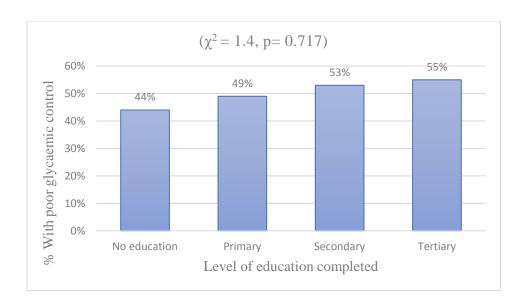
The differences observed across the different income groups were not statistically significant ( $\chi^2$ =2.4, p=0.298). However, the high-income group had a higher rate of poor glycaemic control (65%) compared to middle-income (53%) and low-income (48%) earners (Figure 4.2). It should, however be noted that 17% of the study population did not report income information and that missing income information was more prevalent in the unemployed group which leads to the underrepresentation of unemployed individuals in the analyses.



**Figure 4.2**: Proportionate distribution of poor glycaemic control by income of patients attending the two tertiary hospitals (NHA and UATH) in Abuja, Nigeria.

#### 4.4.7 Education

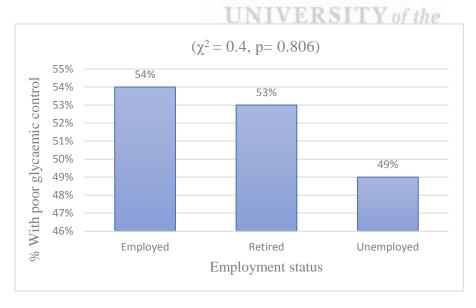
No statistically significant association was seen between glycaemic control rate and level of education but the trend shows worsening glycaemic control with increasing level of education ( $\chi^2$ =1.4, df=3, p=0.717) (Table 4.2, Figure 4.3). Patients who had no education had the lowest rate of poor glycaemic control (44%) while the patients who had tertiary education had the highest rate of poor glycaemic control (55%). Diabetic patients who had completed primary education and secondary education had a poor glycaemic control rate of 49% and 53% respectively (Figure 4.3).



**Figure 4.3**: Proportionate distribution of poor glycaemic control by level of education of diabetic patients attending the two tertiary hospitals (NHA and UATH) in Abuja, Nigeria.

# 4.4.8 Employment

In terms of employment, the differences in the rate of poor glycaemic control in the different categories (employed-54%, retired-53% and unemployed-49%) was not statistically significant ( $\chi^2$ =0.4, df=2, p=0.806) (Table 4.2, Figure 4.4).



**Figure 4.4**: Proportionate distribution of poor glycaemic control by employment status of diabetic patients attending the two tertiary hospitals (NHA and UATH) in Abuja, Nigeria.

# 4.5 Behavioural and Lifestyle-related Factors and Glycaemic Control

In order to determine a link between the level of glycaemic control and diabetic patients' behaviour and lifestyle, certain behaviours of diabetic patients were analyzed as categorical data and statistical significance determined using Pearson's  $\chi^2$  statistic. Categorically analyzing these variables gives a better insight into the distribution of practices of patients. The variables considered include adherence to medication, level of physical activity, self-monitoring of blood glucose, adherence to healthful eating plan, patients' consumption of fruits and vegetables and body mass index (as an outcome of lifestyle) (Table 4.3).

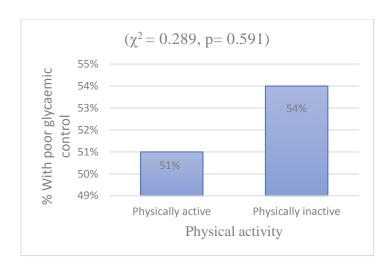
Since a negligible number of the patients were current smokers or heavy drinkers, these behaviours were not included in the analysis. Only one patient admitted to being a current smoker. Nine of the respondents (2.8%) have taken alcohol within the last week while 11 of them (3.4%) have had an alcoholic drink within the last month. Out of the 9 persons who have taken alcohol within the last week, five of them admitted to have taken alcohol only once within the last 7 days while 3 of them have taken alcohol on 2 different days in the last week. One patient had taken alcohol on 3 different days within the last week. Eighty-nine percent of the study population took some alcoholic beverage more than two years prior to the survey or have never taken an alcoholic beverage.

In addition to the analysis above, an ANOVA test was done for the behavioural variables. A continuous scale ranging from 0-7 was used to numerically score the items based on the number of days of the week that the behaviour was performed. The mean of each item score was calculated and compared across the two groups of outcomes (good vs poor glycaemic control) (Table 4.5). These items were lifted from the Diabetes Self-Care Activities (SDSCA) questionnaire. The ANOVA test is a preferred method of analysis for many authors (Toobert, Hampson & Glasgow, 2000; Lin et al, 2016). Toobert et al further analysed the behaviours in groups- physical activity, self-monitoring of blood glucose, foot care, adherence to recommended medication and diet. With the exception of diet (due to low inter item correlation), all the other behaviours in this study were analysed in groups after the mean number of days were calculated for all the items in a particular 'behaviour' group. The average score of items 24 and 25 in the questionnaire (Appendix 3) was used for physical activity. The individual average scores of each of the items 32, 33, 34, 35 (after

reversing the item) and 37 were used to analyse the 'diet' activity and the means compared across the two glycaemic control outcomes. In terms of adherence to recommended medication, item 38 mean score was used. The average scores of items 39 and 40 were used to analyse the 'self-monitoring of blood glucose' behaviour. The mean scores of items 41-45 (with reversal of 42) were used to analyse the footcare activities of the patients across the glycaemic control groups. Table 4.5 summarizes the statistic. Because of the non-parametric nature of these score variables, the Kruskal-Wallis test was used to determine the significance of the differences in means.

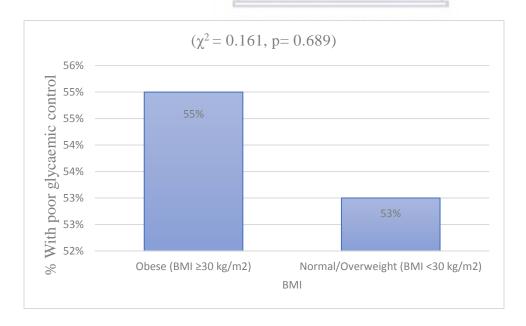
The proportion of patients who never missed their medications with good glycaemic control was 52% while that of those in the 'seldom', 'sometimes' and 'often' group were 38%, 39% and 52% respectively. This was not statistically significant ( $\chi^2$  p= 0.199) (Table 4.3). There was also no statistically significant difference in the mean number of days that patients ingested their recommended medications within the last one week in the two glycaemic control groups (good BG mean=6.32 days, poor BG mean= 6.35 days, Kruskal-Wallis test p= 0.955) (Table 4.5). Generally, the respondents were adherent to their medications on most days. In terms of footcare behaviours, no statistically significant difference was seen in the two outcome groups (3.31days (good glycaemic control) vs 3.12 days (poor glycaemic control) (Kruskal-Wallis test p=0.247) (Table 4.5).

There was no statistically significant difference observed in the poor glycaemic control rate between physically active (51%) and physically inactive (54%) diabetic patients ( $\chi^2$ =0.289, p=0.591, OR=1.133 (95% CI 0.717-1.789)) (Table 4.3, Figure 4.5). The ANOVA analysis of the physical activity level of the patients (Table 4.5) shows that patients who had good glycaemic control had higher mean number of days in which they were physically active compared to those with poor glycaemic control (2.99 days vs. 2.52 days). This finding was also not statistically significant (Kruskal Wallis test p= 0.117).



**Figure 4.5**: Proportionate distribution of poor glycaemic control by physical activity level of diabetic patients attending the two tertiary hospitals (NHA and UATH) in Abuja, Nigeria.

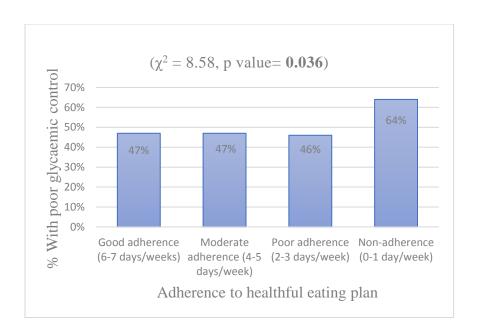
In terms of BMI, there was no statistically significant difference in the rate of poor glycaemic control between patients who were normal or overweight and those who were obese (53% and 55% respectively;  $\chi^2$  =0.161, p=0.688, OR=0.910 (95% CI 0.572-1.445) (Figure 4.6). Obese diabetic patients are 0.91 times less likely to have good control of their blood glucose in comparison with normal/overweight patients.



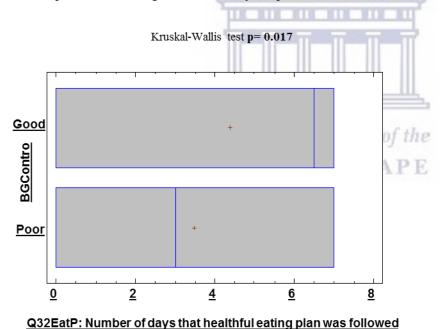
**Figure 4.6**: Proportionate distribution of poor glycaemic control by BMI of diabetic patients attending the two tertiary hospitals (NHA and UATH) in Abuja, Nigeria.

Table 4.3 also shows that patients who self-monitored their blood glucose infrequently had a higher rate of good glycaemic control (51%) compared to the patients that monitored more frequently (41%). This association was not statistically significant (( $\chi^2$  p=0.076, OR=1.490 (95% CI 0.958-2.325)). Similar trend was also found when the average number of days was compared across the two outcome groups. Patients with poorly controlled blood glucose had a higher mean score of 3.68 days while patients with good blood glucose control had a lower mean score of 3.21 days. This finding was also not statistically significant (Kruskal-Wallis test p=0.169) (Table 4.5).

Adherence to a healthful eating plan was found to be a significant factor in blood glucose control as patients in the 'non-adherence' group (patients who follow a healthful eating plan for 0-1 day/week) were found to have the worst level of glycaemic control. Sixty-four percent (64%) of the patients in this group had a poor glycaemic control. Not much difference existed between the other three categories- 'good adherence' (47% had poor glycaemic control), 'moderate adherence' (47% with poor control) and 'poor adherence' (46% with poor control) group. (Table 4.3, Figure 4.7a). This finding was statistically significant. ( $\chi^2 = 8.58$ , **p=0.036**). When this variable was considered as a numeric variable (by calculating the mean number of days in the last week that patient followed a healthful eating plan), the difference in the mean of the 'good' and 'poor' glycaemic control groups was also found to be statistically significant. On the average, patients with good glycaemic control followed a healthful eating plan for 4.38 days within the last week. On the other hand, patients with poor control followed a healthful eating plan only for 3.47 days in the last week (Kruskal-Wallis test p=0.017) (Figure 4.7b). Other dietary behaviours (fruits and vegetables consumption, avoidance of high fat foods like red meat and full cream dairy products) were also found to be significant in determining glycaemic control. The patients with good glycaemic control generally adopted healthier diet-related behaviours (Table 4.5). The only dietrelated behaviour that was not significantly different in the two outcome groups was frequency of evenly spacing carbohydrates (Kruskal-Wallis test p=0.357). It should be noted however, that patients with good glycaemic control, on the average, spaced their carbohydrate meals more frequently that those with poor glycaemic control (4.64 days vs. 4.31 days).



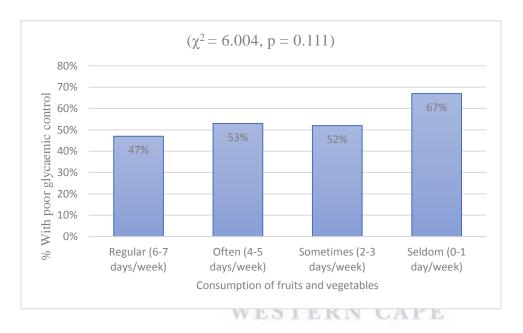
**Figure 4.7a**: Proportionate distribution of poor glycaemic control by adherence to healthful eating plan by diabetic patients attending the two tertiary hospitals (NHA and UATH) in Abuja, Nigeria.



**Figure 4.7b**: Box plot comparing the mean number of days diabetic patients attending the two tertiary hospitals Abuja followed a healthful eating plan stratified by Glycaemic control. (Y-axis: BGContro-blood glucose control; X-axis: number of days patients followed a healthful eating plan)

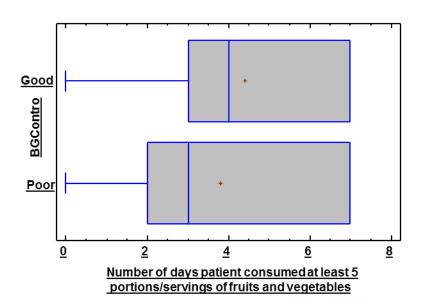
Patients who consumed fruits and vegetables regularly (consumed daily at least 5 portions of fruits and vegetables on 6-7days/week) had the best glycaemic control (53% had good control) while

those who seldom (No consumption or only 1 day per week) ate adequate amounts of fruits and vegetables had the worst glycaemic control (36% had good control and 64% had poor control) (Table 4.3, Figure 4.8a). This result was however not statistically significant ( $\chi^2$ =6.004, df=3 p=0.111). When the 'fruits and vegetables' variable was analyzed using the ANOVA test, the difference in the two outcome groups was found to be significant (Kruskal-Wallis test p=0.040). The 'good blood glucose control' group consumed adequate amount of fruits and vegetables on average 4.4 days in the last week while the 'poor blood glucose control' group consumed adequate fruits and vegetables, on average for 3.80 days in the last week (Table 4.5, Figure 4.8b)



**Figure 4.8a**: Proportionate distribution of poor glycaemic control by consumption of fruits and vegetables by diabetic patients attending the two tertiary hospitals (NHA and UATH) in Abuja, Nigeria

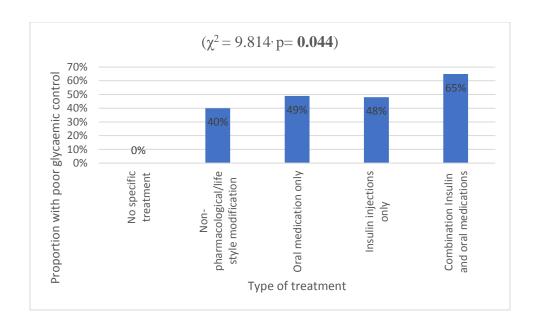
#### Kruskal-Wallis test p=0.040



**Figure 4.8b**: Box and whisker plot comparing the mean number of days diabetic patients attending the two tertiary hospitals Abuja consumed at least 5 portions/servings of fruits and vegetables stratified by Glycaemic control. (BGContro-blood glucose control)

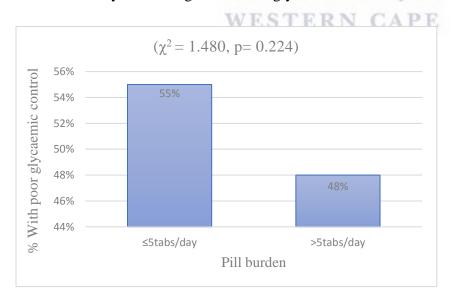
## 4.6 Nature of Diabetes Treatment and Glycaemic Control

The type of medication, pill burden and healthcare providers' influence are some treatment related variables that were considered in this study. As seen in table 4.4, glycaemic control rate varied according to the nature of diabetes treatment. Fifty-one percent of patients on only oral medications had good glycaemic control while 52% of patients on insulin-only treatment had good glycaemic control. Patients on combined insulin and oral treatment had a much lower rate of glycaemic control (35% had good control). Out of the 5 patients who were on non-pharmacological treatment/lifestyle modification, 3 had a well-controlled blood glucose level. Two patients were not on any specific treatment and both had a good glycaemic control. These differences were found to be statistically significant ( $\chi^2$ =9.814, df=4, p=0.044) (Figure 4.9).



**Figure 4.9**: Proportionate distribution of poor glycaemic control by 'type of treatment' prescribed for diabetic patients attending the two tertiary hospitals (NHA and UATH) in Abuja, Nigeria

The study shows that pill burden and glycaemic control had no statistically significant association but the tendency shows that patients with higher pill burden (>5 tablets/day) had a better level of glycaemic control (52%) compared to those with lower pill burden (45%) (Table 4.4, Figure 4.10) ( $\chi^2$ =1.480, p=0.224, OR=0.752 (95% CI 0.474-1.193)). The low pill burden group were 0.752 times less likely to have a good level of glycaemic control.



**Figure 4.10**: Proportionate distribution of poor glycaemic control by pill burden of diabetic patients attending the two tertiary hospitals (NHA and UATH) in Abuja, Nigeria

Ninety-one percent (91%) of the study population were generally satisfied with the quality of care provided by their management team and 49% of them had good glycaemic control. In the case of the 'dissatisfied' group, 30% of them had good glycaemic control. This difference was found to be statistically significant (( $\chi^2$ =3.862, p=**0.049**, OR=0.450 (95% CI 0.190-1.003) (Figure 4.11, Table 4.4).

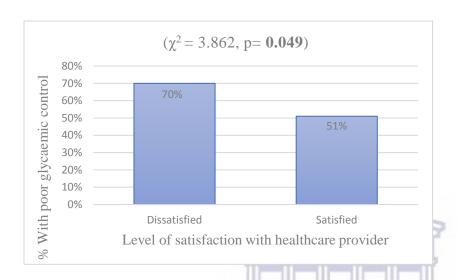


Figure 4.11: Proportionate distribution of poor glycaemic control by level of satisfaction of diabetic patients attending the two tertiary hospitals (NHA and UATH) in Abuja, Nigeria

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Table 4.1 Missing income analysis by Employment

$\chi^2 p = $ <b>0.011</b> , df=2							
	income						
EMPLOYMENT	0 (missing)	1 (given)	Total				
0 (Unemployed)	16 (30.19%)	37 (69.81%)	53 (16.26%)				
1 (Employed)	28 (13.53%)	179 (86.47)	207 (63.50%)				
2 (Retired)	9 (13.64%)	57 (86.36%)	66 (20.24%)				
TOTAL	53 (16.26%)	273 (83.74%)	326 (100%)				



Table 4.2 Socio-demographic characteristics of diabetic patients by glycaemic control

Indicator	Number (n) Total (%)	Blood Glucose Control		Chi- square p-	Odds risk	95% CI of OR	
	` ,	Good	Poor	value	(OR)	Lower	Upper
Age							
< 40	24 (7%)	12(50%)	4 (50%)	0.813			
40-49	90 (28%)	45 (50%)	45(50%)				
50-59	108 (33%)	47 (44%)	61 (56%)				
60+	105 (32%)	50 (48%)	55 (52%)				
Gender							
Male	132 (40%)	61 (46%)	71 (54%)	0.793	0.943	0.604	1.469
Female	195 (60%)	94 (48%)	101(52%)				
Marital Status (	4 categories)						
Single	6 (2%)	2 (33%)	4 (67%)	0.357			
Married	289 (88%)	134(46%)	155(54%)				
Widowed	30 (9%)	16 (53%)	14 (47%)				
Separated	2 (1%)	2 (100%)	0				
Marital status (2	2 categories)			E-C=	•	•	
Married	289 (88%)	134(46%)	155(54%)	0.467	0.779	0.391	1.543
Not married	38 (12%)	20 (53%)	18 (47%)				
Residence	, ,	LH-HU			<u> </u>	<b>!</b>	
Rural	85 (26%)	38 (45%)	47 (55%)	0.609	0.879	0.532	1.445
Urban	242 (74%)	116(48%)	126(52%)				
Family History	, ,				<u> </u>		
No Family	156 (48%)	68 (44%)	88 (56%)	0.226	0.764	0.493	1.183
History			, ,	-			
Positive Family	171 (52%)	86 (50%)	85 (50%)	DW7 0.7			
History		UNIV	EK51	Y of the			
Income		TATE OF	THE REAL	CADE	•	•	
High income	31 (11%)	11 (35%)	20 (65%)	0.298			
Low income	87 (32%)	45 (52%)	42 (48%)				
Middle income	155 (57%)	73 (47%)	82 (53%)				
Education					•	•	
No education	27 (8%)	15 (56%)	12 (44%)	0.717			
Primary	37 (11%)	19 (51%)	18 (49%)				
Secondary	81 (25%)	38 (47%)	43 (53%)				
Tertiary	182 (56%)	82 (45%)	100(55%)				
Employment	, ,	. , ,			•		
Employed	207 (64%)	95 (46%)	112(54%)	0.806			
Retired	66 (20%)	31 (47%)	35 (53%)				
Unemployed	53 (16%)	27 (51%)	26 (49%)				
Means of finance			/		L		
Full insurance	21 (6%)	9 (43%)	12 (57%)	0.359			
Partial	77 (24%)	37 (48%)	40 (52%)				
insurance							
Self-payment	150 (46%)	77 (51%)	73 (49%)				
Family	79 (24%)	31 (39%)	48 (61%)				
sponsored							

Table 4.3 Behaviour and lifestyle of diabetic patients by glycaemic control

Indicator	Number	Blood glucose		Chi-	Odds		of OR	
	(n)	control		square p-	Risk	_	<b>T</b> 7	
4 33	(TT 0)	Good	Poor	value	(OR)	Lower	Upper	
Adherence to medication (How often the patient forgets to take their medication)								
Never	186(57%)	97(52%)	89(48%)	0.199				
Seldom (once/month)	56 (17%)	21(38%)	35(62%)					
Sometimes	59 (18%)	23(39%)	36(61%)					
(once/week)								
Often (>once/week)	23 (7%)	12(52%)	11(48%)					
Exercise/Physical activi	ty					_		
Physically active	114 (35%)	56(49%)	58(51%)	0.591	1.133	0.717	1.789	
Physically inactive	213 (65%)	98(46%)	115(54%)					
Body Mass Index								
Obese (BMI ≥30	111 (34%)	50(45%)	61 (55%)	0.689	0.910	0.572	1.445	
kg/m <sup>2</sup> )								
Normal/Overweight	211 (66%)	100(47%)	111(53%)					
$(BMI < 30 \text{ kg/m}^2)$			ĺ					
Self-monitoring of Bloo	d glucose				•	•	•	
Infrequent (0-3	187 (57%)	96 (51%)	91 (49%)	0.0762	1.490	0.958	2.325	
days/week)		N RIN RI	CHOCKET	811				
Frequent (4-7	140 (43%)	58 (41%)	82 (59%)					
days/week)	` '							
Adherence to a healthfu	ıl eating plaı	1			•	•	•	
Good adherence (6-7	159 (49%)	84 (53%)	75 (47%)	0.036				
days/weeks)	للب	1. 11. 11						
Moderate adherence (4-	17 (5%)	9 (53%)	8 (47%)					
5 days/week)	TI	NIVEL	SITV	of the				
Poor adherence (2-3	35 (11%)	19 (54%)	16 (46%)	oj ine				
days/week)	W	ESTE	RNC	PE				
Non-adherence (0-1	116 (35%)	42 (36%)	74 (64%)					
day/week)		, ,						
Frequency of daily cons	sumption of a	at least 5 po	rtions/servi	ngs of fruits	and veget	tables	I	
Regular (6-7	109 (33%)	58 (53%)	51 (47%)	0.111				
days/week)	, ,							
Often (4-5 days/week)	64 (20%)	30 (47%)	34 (53%)					
Sometimes (2-3	102 (31%)	49 (48%)	53 (52%)					
days/week)	- ( )		- (,)					
Seldom (0-1 day/week)	52 (16%)	17 (33%)	35 (67%)					

Table 4.4 Nature of diabetes treatment by glycaemic control

Indicator	Number (n)	Blood control	glucose	Chi- square	Odds Risk	95% CI of OR	
		Good	Poor	p-value	(OR)	Lower	Upper
Type of treatment							
No specific treatment	2 (0.6%)	2(100%)	0	0.044			
Non-	5 (1.5%)	3 (60%)	2 (40%)				
pharmacological/lifestyle modification							
Oral medication only	203(62.1%)	104(51%)	99(49%)				
Insulin injections only	25 (7.7%)	13 (52%)	12(48%)				
Combination Insulin and oral medications	92 (28.1%)	32 (35%)	60(65%)				
Pill burden (Number of ta	blets per day)	)			I		
≤5tabs/day	217 (66%)	97 (45%)	120(55%)	0.224	0.752	0.474	1.193
>5tabs/day	110 (34%)	57 (52%)	53 (48%)				
Level of Satisfaction with Healthcare provider							
Dissatisfied	30 (9%)	9 (30%)	21 (70%)	0.049	0.450	0.190	1.003
Satisfied	297 (91%)	145(49%)	152(51%)				

**Table 4.5** Summary of Diabetes Self-Care Activities (SDSCA) by Glycaemic control in type 2 diabetes patients attending outpatient diabetes clinic in tertiary hospitals in Abuja, Nigeria

Activities (Mean number of days patient engaged in the behaviour)	Good blood glucose control	Poor blood glucose control	ANOVA p- value	Kruskal-Wallis test P-value
Physical activity	2.99	2.52	0.996	0.117
Adherence to recommended	6.32	6.35	0.873	0.955
medications				
Self-monitoring of blood glucose	3.21	3.68	0.128	0.169
Footcare	3.31	3.12	0.306	0.247
Diet				
Following a healthful eating plan	4.38	3.47	0.010	0.017
in the past week				
Following a healthful eating plan	4.32	3.49	0.017	0.017
in the past month (average per				
week)				
Adequate fruits and vegetables	4.40	3.80	0.025	0.040
consumption				
Avoidance of High fatty foods	5.39	4.97	0.079	0.042
such as red meat and full cream				
dairy foods				
Even carbohydrate spacing	4.64	4.31	0.263	0.357

#### **CHAPTER 5: DISCUSSIONS**

#### 5.1 Socio-demographic Characteristics

About 60% of the respondents were females. This is similar to the figures (60.6%) reported by Chinenye et al (2012) in a multicenter study across 7 tertiary hospitals in Nigeria. This, however differs from the 1:1 female to male ratio reported in other studies outside tertiary centers in Nigeria. The female preponderance could be related to sex-related lifestyle differences amongst the two genders. For example, women in many sub-Saharan African countries are likely to be more obese or overweight than their male counterparts because of the cultural acceptability of overweight/obesity amongst women in these societies (BeLue et al, 2009). This could also be due to the higher life expectancy of the females in Nigeria compared to the males (National Bureau of Statistics (NBS), 2015). Additionally, the healthcare finance model in Nigeria makes it more likely that female patients are supported by their relations and loved ones than their male counterparts (Chinenye et al, 2012). Furthermore, in the study setting, men are often the bread winners of the house and are more likely to ignore or omit clinic visits as this would usually have some economic implications to the family.

The mean age of the study population was  $54 \pm 11.3$  years. Chinenye et al (2012) reported a mean age of  $57.1 \pm 12.3$  years. In another study, Adisa et al (2011) reported that the average age of diabetic patients in a tertiary hospital in Ibadan, southwestern Nigeria was 61 years. The mean age of diabetic patients is generally lower in developing countries compared to developed countries where most diabetics are above 64 years (Wild, Roglic, Green, Sicree & King, 2004). The older age of diabetics in developed countries could be as a result of longer survival or later onset due to better and well financed health system. The lower life expectancy of Nigerian diabetics also means that most do not advance to older ages as they develop complications earlier and are at higher risk of early mortality (Chinenye et al, 2012).

In terms of age distribution, majority (60%) of the patients sampled in this study were between 40 and 59 years. This is the age group with the highest prevalence of type 2 diabetes as corroborated by other studies: Adebisi et al (2009) reported that 68% of their diabetes patients attending the outpatient diabetes clinic in a teaching hospital in Ilorin, Nigeria were within this age group while Adisa et al (2011) had 42% of their respondents within this age group. The International Diabetes Federation reported that 50% of all adults with diabetes are between the ages of 40 and 59 (IDF,

2013). In a rural South African population, Motala et al (2008) reported a peak prevalence between the ages 55-64 years. These findings all support the fact that older age is a key risk factor in onset of type 2 diabetes (IDF, 2015). Although, many cases of diabetes are beginning to set in at earlier ages, majority are still diagnosed after 40 years. In our study, the mean age at diagnosis was 45 years. Chinenye et al (2012) reported a mean age at onset of diabetes of 48 years. In the United States of America, between 1988 and 1994, the mean age of onset of type 2 diabetes was reported to be 52 years but this value has decreased to 46 years in the period 1999 to 2000 (Koopman et al, 2005). The gap in the age of onset between developing and developed countries is closing down as the global age of onset of diabetes is in constant downward trend.

In terms of monthly family income, 17% of the respondents did not provide any information regarding their income. This is viewed as sensitive information by lots of people in the study setting and as such, many prefer not to reveal the details of their income. Secondly, for many patients who earn money through informal means like subsistence farming, aids from relatives and friends, it is difficult to quantify the amount of income they receive and moreover, these means of income are not regular. For the remainder of the study population that provided information about their income, 11% were in the 'high income' category (> 200,000 Naira), 32% were in the 'low income' group (< 50,000 Naira) and 57% were in the 'middle income' category (50,000 to 200,000 Naira). This goes to support the fact that diabetes is not (in contrast to the early and mid-20<sup>th</sup> century) a disease only for the wealthy communities (IDF, 2015) as most of the patients are either low or middle-income earners. This is reflected generally in the recent high prevalence of diabetes in LMICs.

The educational profile of the study population shows that 8% had no formal education, 11% completed only primary education, 25% completed secondary and 56% had a post-secondary education. This is comparable to the educational level of a diabetic population studied by Adisa et al (2011) in which 9.6% of the patients had no formal education, 19.3% completed only primary education, 28.1% completed secondary while 43% had tertiary education. The high level of education amongst the respondents reflects the nature of Abuja as a metropolitan state where people from all regions of the country migrate to and naturally higher proportions of educated people live in the environs of our study hospitals.

Sixteen percent (16%) of the sampled population were unemployed, 20% were retired while 64% were employed. This is comparable to what was reported by Adisa et al (2009) in a study in south western Nigeria where 17% of the sampled diabetic patients were unemployed. On the other hand, Ababio et al (2017) in a study in two tertiary hospitals in Nigeria and Ghana reported a high unemployment rate (41%) amongst the diabetic population. Similarly, Al-Akour et al (2011) while studying the determinants of glycaemic control in type 2 diabetic patients in a tertiary hospital in Jordan, reported that 59.5% of the diabetic patients were unemployed. The relatively lower rate of unemployment in our study population may be as a result of the setting in which the hospital is located. A lot of the patients are educated and so may be the reason why a good number of them are employed. In comparison to the unemployment rate in the Nigerian population, the unemployment rate of 16% is slightly higher than in the general population (14%) (National Bureau of Statistics (NBS), 2017). This could be a reflection of the limitations imposed on these patients by diabetes.

About 62% of the respondents were taking only oral antidiabetic medications. This is lower than figures reported in other studies (Yusuff, Obe, & Joseph, 2008; Chinenye et al, 2012) where over 85% of the diabetic patients were on oral medications only. Twenty-eight percent of the diabetic patients sampled in the study were on combination therapy of insulin and oral medications. This is twice as much as the value reported in Yusuff et al (2008) and thrice that reported by Chinenye et al (2012). Only 8% of the respondents were on insulin-only therapy and this is comparable to the 9.9% reported by Chinenye et al (2012). The differences in the pattern of prescription seen in our study and that of other previous studies reflect an increased usage of insulin by medical practitioners in Nigeria and the increased acceptability of insulin usage by Nigerian diabetic patients (Ezeani et al, 2017)

The average duration of diabetes treatment in the study was 9.2 years and this is consistent with the findings of Chinenye et al (2012) who reported a mean duration of diabetes treatment of 8.8 years. This short duration of treatment may be because Nigerian diabetics do not live long enough to have a prolonged duration of treatment. They develop complications early which could be fatal. Comorbidities were found in 75% of the patients with hypertension being the most prevalent (64%). Struijs et al (2006) reported that 44% of diabetic outpatients visiting general practitioners (GP) in the Netherlands had at least one comorbidity. While this value may seem significantly

lower than of our study, it should be noted that GP clinics are not specialist clinics and as such complicated cases with possibly other comorbidities would have been referred to specialist clinics. Specialist clinics (like our study hospitals) are expected to have more complicated diabetic cases with more comorbidities.

In comparison to other diabetic populations, our study population seem to be taking a lot more tablets. About 55% of our respondents are taking > 4 tablets per day. This is in sharp contrast to what was reported by Blüher et al (2015) in a large multicenter study of German diabetic patients where just 5.9% of the patients were on > 4 tablets per day. This discrepancy may be a result of more complications and comorbidities in the Nigerian diabetic patients necessitating the use of more medications. The greater availability of more fixed dose combinations of anti-diabetic medications in developed countries such as Germany may explain why the patients in these countries consume less number of tablets in the treatment of chronic diseases (Blüher et al, 2015).

Insurance coverage for the sampled patients was poor. Only 6% of the respondents had a full insurance coverage. About a quarter of the patients had a partial insurance coverage while 70% had no form of health insurance. Other authors have reported insurance coverage of about 10% amongst diabetic patients in Nigeria (Fasanmade & Dagogo-Jack, 2015). In Africa, health insurance coverage is minimal or non-existent (Leive & Xu, 2008; Oguejiofor, Odenigbo & Onwukwe, 2014) compared to developed countries where coverage rates approach 100% (Bowker et al, 2004; Ellis, Chen & Luscombe, 2014). The weak insurance system in African countries may be a result of their lower income, poor health system or inefficient leadership.

Thirty-four percent (34%) of the patients were obese (BMI  $\geq$  30 kg/m²) and this is twice the value reported in most hospital-based diabetes studies in Nigeria (Fasanmade & Dagogo-Jack, 2015). The mean BMI of the study population was 28.9 kg/m² and this was slightly more than that reported by Chinenye et al (2012) (27.2kg/m²) in studying Nigerian diabetics in 6 different tertiary hospitals. In their study, Chinenye et al reported that only 35.9% of the diabetic patients adhered regularly to exercise as prescribed and 26.7% not exercising at all. This is in agreement with the findings in our study population in which 35% were found to be physically active. This is better than that reported in other diabetic populations (Chuang et al, 2002; Solberg et al, 2008).

About one-third of the study population (34%) monitored their blood glucose at home on regular basis. Other Nigerian studies (Chinenye et al, 2012; Fasanmade & Dagogo-Jack, 2015) have

reported a lower rate of self-monitoring of blood glucose (27.2% and 25.4% respectively). This figure is still low as all diabetic patients are expected to monitor their blood glucose by themselves on a regular basis as this improves their level of glycaemic control. The possible reasons why most Nigerian diabetics are unable to monitor their blood glucose regularly includes the lack of health insurance coverage, inadequate patient counselling by healthcare provider and poverty.

The high level of satisfaction expressed by the study population is in keeping with previous studies (Wredling et al, 1995; Redekop et al, 2002; Alazri & Neal, 2003). Generally, patients are often positive in evaluating their healthcare providers and reluctant to express dissatisfaction (Fitzpatrick, 1991; Baker & Streatfield, 1995; Grol et al, 2000).

About a third of our study population did not follow a healthful eating plan within the last seven days. Chinenye et al (2012) reported that only 6.9% of their study population did not follow any eating plan but the timeline was not limited to seven days. Many diabetic patients in Nigeria assume that diabetic meals are expensive and do not bother to strictly adhere to these dietary requirements. They cannot afford to have a separate meal from that consumed by the rest of the family. It is possible that the patients are not aware of cheaper healthy meals for diabetic patients.

The most prevalent diabetic complication in the study was retinopathy (37%). This retinopathy prevalence rate is in keeping with other Nigerian studies (Chinenye et al 2012, Oguejiofor et al, 2014). The prevalence of peripheral neuropathy in the study by Chinenye et al (59.2%) was more than twice that of our study population (27%). In general, the high prevalence of complications in Nigerian diabetics is due to late diagnosis, poor adherence to treatment and lifestyle recommendations, limited access to care and therefore poor glycaemic control. The higher prevalence of coexisting comorbidities (like hypertension) in African diabetics also increases the chances of having more complications (especially microvascular) (Oguejiofor et al, 2014).

#### 5.2 Glycaemic Control

The Glycaemic control of the participants was determined using HbA1c and FPG. HbA1c was given a priority because it is the gold standard for glycaemic control monitoring (Adebisi, Oghagbon, Akande & Olarinoye, 2009; WHO, 2011; ADA, 2017). A good glycaemic control was defined as patients who had HbA1c of < 7% according to the ADA guidelines (ADA, 2017). For

patients who had no HbA1c test result, an average FPG of < 126 mg/dl (from the latest 2 FPG measurements) was used as a criterion for good glycaemic control.

About 74% of the participants had a recent HbA1c measurement and this represents a significant proportion when compared with other Nigerian studies where lower proportions of diabetics have a HbA1c measurement. Chinenye et al (2012) found only 49.5% of Nigerian diabetics to have a recent HbA1c measurement. Generally, only 5% of African diabetics have access to HbA1c measurement (Whiting, Hayes & Unwin, 2003). HbA1c is a relatively expensive investigation and the resource limitation often associated with African patients and healthcare system makes it difficult to provide this service at regular basis for diabetic patients. Several local glycaemic control studies are based on fasting plasma glucose assessment (Adisa et al, 2011). The higher level of HbA1c availability in this study could be attributed to the fact that our study hospitals are highly specialized tertiary healthcare institutions and naturally have more funding and expertise. Secondly, our participants are mainly of middle and high social class and can afford to perform the test as and when due. However, majority of diabetic patients are not cared for in such institutions but rather in primary and secondary health centres who often lack the facility to perform more expensive and or complex laboratory procedures like HbA1c. The glycaemic control of the remaining 24% of the respondents who had no HbA1c measurement was assessed using the average FPG. Both measurements were combined to yield a new variable-Glycaemic control- for all patients. WESTERN CAPE

The final analysis revealed that 53% of the participants had poor glycaemic control. Other Nigerian studies reported a poor glycaemic control rate between 60% and 70% (Adebisi et al, 2009; Adisa et al, 2011; Chinenye et al, 2012). The variance in the level of glycaemic control in Nigerian diabetics could be linked to the type of hospital where the patients were sampled, the laboratory parameter used in assessing the glycaemic control or the cut-off criteria used by the researchers. For example, Adebisi et al utilized a HbA1c cut-off of 7.2% and 64% of their participants had a HbA1c greater than 7.2% (poor glycaemic control). The higher cut-off (compared to our study) could increase the proportion of patients with good glycaemic control. Adisa et al (2011) assessed glycaemic control in diabetic patients attending a tertiary hospital in Ibadan, southwestern Nigeria using FPG  $\leq$  110 mg/dl as the cut-off criteria for good glycaemic control based on the United Kingdom Prospective Diabetes Study Group definition of intensive control for diabetes patients

(as FPG of less than 108 mg/dl) (UKPDs, 1998). This lower criterion of 110 mg/dl could explain why their rate of poor glycaemic control (60%) was higher than that of our study population. Chinenye et al (2012) utilized the same criterion as in our study (HbA1c >7%) to describe poor glycaemic control rate. In their multicenter study across Nigeria, 68% of the patients had poor glycaemic control. In the same study, they analysed glycaemic control using IDF target of 6.5% and the proportion of patients with poor glycaemic control rose to 80%. Their study spread across 6 different geopolitical regions in Nigeria and may represent a better picture for the Nigeria diabetic patients and may explain the higher proportion of patients with poor glycaemic control even with similar criteria.

In other African countries, high rate of poor glycaemic control (60% to 90%) has been consistently reported (Erasmus et al, 1999; Longo-Mbenza et al, 2008). The 53% rate of poor glycaemic in our study is comparable (and with similar criteria of HbA1c >7%) to that obtained in Jordan (Al-Alkour, Khader & Alaoui, 2011), USA (Shaya et al, 2016) and Saudi Arabia (Al-Nuaim et al, 1998).

Modebe & Masoomi (1999) reported that 78.2% of Barhrani diabetic patients had poor glycaemic control but their paper did not clarify the exact criteria they used. A series of retrospective studies done in the United Kingdom revealed that 79% and 76% in 1998 and 2002 respectively of UK diabetic patients had poor glycaemic control (HbA1c cutoff > 7%) (Fox, Bolinder, Chen & Kumar, 2006).

An alternative way to picture the glycaemic control level of a diabetic population is to calculate the mean value for the HbA1c and/or the FPG. This way, one could avoid the extra hurdle of determining the exact criteria used by the researchers to classify patients into good or poor control and comparison between groups is easier. The average HbA1c of the diabetic patients that were sampled was  $7.6\% \pm 2.4\%$  and the mean FPG was  $142 \text{ mg/dl} \pm 53.8 \text{ mg/dl}$ . This is lower than the values reported by Chinenye et al (2012) while studying Nigerian diabetic patients-a mean HbA1c of  $8.3\% \pm 2.2\%$  and a mean FPG of  $146 \text{ mg/dl} \pm 70 \text{ mg/dl}$ . The diabetic patients studied by Adisa et al (2011) in Ibadan, Nigeria had a mean FPG of  $139 \text{ mg/dl} \pm 71 \text{ mg/dl}$ . Although the patients in our study had a better overall picture in terms of HbA1c, the level of glycaemic control is still far from the target value of 7%. The mean FPG values in the three Nigerian populations are comparable. The reasons for poor glycaemic control amongst Nigerian diabetic patients include

financial limitation (Yusuff, Obe & Joseph, 2008; Adsia et al, 2011), high cost of diabetes medications (Adibe et al, 2009; Adisa, Alutundu & Fakeye, 2009) poor knowledge about the disease condition (Chinenye et al, 2012), inadequate diabetes care providers, absence of health insurance coverage (Fasanmade & Dagogo-Jack, 2015) and lack of effective diabetes policy implementation (Chinenye, Oputa & Oko-Jaja, 2014).

The mean HbA1c in the study does not vary significantly with what was reported in diabetic patients in Kinshasa, Congo-7.4%  $\pm$  1.4% (Longo-Mbenza et al, 2008) but differed from what was seen in black South African diabetics attending diabetes clinic at a peri-urban hospital - 9.6%  $\pm$  0.1% (Erasmus et al, 1999). In addition to the factors listed above that are responsible for the poor glycaemic control amongst Nigerian diabetics, sub-Saharan African countries generally have limited resources which are often shared between communicable and noncommunicable diseases (Longo-Mbenza et al, 2008).

Ten of the interviewed patients (about 3% of the study population) had a HbA1c value of less than 4%, which is subnormal considering that healthy persons without diabetes have a HbA1c concentration of 4-6% (Wiener 2001; Chu, Wang, Sun, Lee & Lam, 2007). Other studies considered a HbA1c value less than 4.7% as subnormal (Camargo & Gross, 2004). Six percent of our respondents (21 patients) had a HbA1c level of less than 4.7%. This rate is considerable higher than previously reported. Camargo & Gross (2004) while studying the causes of very low HbA1c among diabetic patients in a university hospital in Brazil reported that 0.4% (130 out of 29,657 HbA1c measurements) of the entire study participants had a HbA1c of less than 4.7%. It is important to note that a very low or falling HbA1c level in a diabetic patient is not always a pointer to improving glycaemic control (Wiener, 2001). Measurement errors in the laboratory and clerical errors either by laboratory personnel or members of the management team who transfer laboratory values into patients' case note must be conclusively excluded in cases of very low HbA1c.

In the absence of measurement or clerical errors, abnormal variants of haemoglobin and alterations in the lifespan of red blood cells are significantly implicated in diabetic patients with very low HbA1c (Wiener, 2001; Camargo & Gross, 2004; Chu, Wang, Sun, Lee & Lam, 2007). Some abnormal variants of haemoglobin that can give a low HbA1c include HbAS, HbAD, HbAC and HbSC. Therefore, the haematological history of diabetic patients with very low HbA1c must be properly reviewed to rule out these haemoglobin variants. Some modern HbA1c measurement

techniques is not affected by these variants. The exact method of HbA1c measurement in our setting was not ascertained. HbA1c levels may also be reduced by alcoholism, lipaemia and chronic ingestion of salicylates and haemolysis causing drugs (Camargo & Gross, 2004).

#### 5.3 Socio-demographic Factors and Glycaemic Control

#### **5.3.1** Age and Glycaemic Control

There was no statistically significant difference in glycaemic control between different age groups but the trend shows worsening glycaemic control with increasing age. Amongst the '50-59' age group, 56% of them had poor glycaemic control while 52% of patients aged 60 years or more had poor glycaemic control. Half of the patients in the younger age group categories had a poor level of glycaemic control. Generally, previous studies reported no significant association between age groups of diabetic patients and the achievement of glycaemic control (Arai et al, 2009; Al-Akour, Khader & Alaoui, 2011) and the reported trends are not consistent across different literatures. While some studies reported better glycaemic control in younger age groups (Almutari, Said & Zainuddin, 2013), others reported better control in older age groups (Ahmad, Islahudin & Paraidathathu, 2014)

# **5.3.2** Gender and Glycaemic Control

There was no statistically significant difference in glycaemic control between the male (46% had good control) and female (48% had good control) diabetic patients. Other previous studies have also found no statistically significant difference in glycaemic control between the two gender groups (Al-Akour, Khader & Alaoui, 2011; Ahmad, Islahudin & Paraidathathu, 2014). The common trend in previous studies, although not statistically significant, is a better glycaemic control in female patients and this could be due to the higher rate of adherence to medications of female patients (Adisa et al, 2009).

## **5.3.3** Marital Status and Glycaemic Control

There was no statistically significant difference in glycaemic control between married patients (54% had poor control) and 'not married' patients (47%). Al-Akour et al (2011) also found no statistically significant difference in glycaemic control between the two groups although the trend is similar to that of our study (married patients having poorer control (53%) than 'not married' patients (48%)). Adisa et al (2011) found a significant correlation between adherence to

medications in diabetic patients and their marital status. In their report, widowed patients adhered better to their medications than married and single patients. With the exception of the two patients who were separated from their spouses, the rate of glycaemic control in our study seem to follow the trend reported by Adisa et al- widowed patients having a better glycaemic control (53% with good control) than married (46% with good control) and single (33% with good control). More recent studies found no association between marital status and glycaemic control (Yokobayashi et al, 2017).

#### 5.3.4 Residence and Glycaemic control

No statistically significance difference in glycaemic control was observed between patients who reside in rural areas and those in urban areas. The trend shows however that the proportion of patients in rural settlements with poor glycaemic control is higher than those in urban settlements (55% vs 52% respectively). This finding is in keeping with the findings of other studies (Andrus et al, 2004). Rural patients are less likely to be diagnosed early due to lower probability of screening and diabetes prevention education. They often are less educated than their urban counterparts and so have a poorer understanding of the disease. Their access to healthcare service is often limited. Income level of rural patients are often lower (World Bank, 2014) and hence might not be able to afford their medications or to self-monitor their blood glucose or perform all the required laboratory tests.

#### 5.3.5 Family history of diabetes and Glycaemic control

Patients with positive family history had a higher rate of good glycaemic control (50% vs. 44%; p=0.226). Similarly, Al-Akour et al (2011) reported a better glycaemic control amongst diabetic patients with positive family history (49% vs. 46%; p=0.754). A possible explanation of this trend is the Health Belief Model which links up an individual's behaviour to his/her perception about the seriousness of the disease, his/her susceptibility to the disease, perceived benefits and barriers (Munro et al, 2007). Patients with positive family history are more likely to perceive diabetes as being serious and perceive a higher level of susceptibility to diabetes and its complications (Munro et al, 2017). This would motivate them to adopt behaviours which would improve their level of glycaemic control.

#### **5.3.6** Income and Glycaemic Control

The worst glycaemic control was found in patients with high income (65% of them had poor glycaemic control) followed by those with middle income (53% of them had poor glycaemic control). This is in contrast to what has been reported in most studies (Delamater, 2006). The belief is that patients with high income is able to afford their medications and laboratory investigations. The possible explanation of the scenario in our study is that diabetes management goes beyond medication financeability. Diabetic patients must invest their time and energy in other behaviours like exercising regularly, weight loss and being dietary conscious. The high-income patients in our study might be found wanting in these behaviours much more than their counterparts with middle and low income. Secondly, 16.5% of the study population did not report income information and this missing income information was more prevalent in the unemployed group which led to an underrepresentation of unemployed individuals in the analyses. In addition, people in our study setting have some reservations regarding revealing their income and as such could provide a fictitious income information in the questionnaire. A good number of the patients also have an informal employment or self-employed and sometimes are not able to give an exact income information.

# 5.3.7 Education and Glycaemic Control

An inverse relationship (although not statistically significant) exists between level of education and glycaemic control. Patients with highest level of education had the worst glycaemic control and vice versa. Al-Akour et al (2011) also documented a similar trend of statistically insignificant inverse proportionality between level of education and glycaemic control. Adisa et al (2011) reported that there is no significant association between educational status and glycaemic control.

## **5.3.8** Employment and Glycaemic Control

No significant association was found between employment status and glycaemic control. The rate of poor glycaemic control was highest amongst the 'employed' patients (54%) followed by retired (53%) and then 'unemployed' patients (49%). Comparably, Al-Akour et al (2011) reported that 53% of the employed patients in their study had a poor glycaemic control while 51% of those who are not employed had a poor glycaemic control. This was also not statistically significant. In

contrast (and more understandably), Almutairi, Said & Zainuddin, (2013) stated that diabetic patients in Saudi Arabia without a job had worse glycaemic control and this was statistically significant.

#### 5.3.9 Means of Financing Diabetes Treatment and Glycaemic Control

The worst glycaemic control was found in patients whose treatment was financed through family support (61% with poor control). This was followed by patients with full health insurance (57%), partial insurance (52%) and the best glycaemic control was in patients who self-financed their treatment (49% of whom had poor control). This however was not statistically significant. This finding differs from the findings of other studies- insured patients have better glycaemic control (Karter et al, 2000; Bowker et al, 2004; Benoit et al, 2015). The possible reason for this discrepancy could be a poor structured health insurance system in Nigeria. Insured patients often have cost limitations on the type and quality of treatment they receive. Some drugs are not covered by the scheme and hence, the healthcare providers are forced to use certain drugs which often are the less preferred options. The patients who pay by themselves for their medications have the luxury of receiving the best possible treatment as far as they can afford them. Secondly, the number of patients with full health insurance was too small (6 patients) and this can influence the outcome of the analysis.

#### 5.4 Behavioural and Lifestyle-related Factors and Glycaemic Control

## 5.4.1 Adherence to Medication and Glycaemic control

The association between medication adherence rate and glycaemic control was not significant. The best glycaemic control rate was found in the 'Never' and 'Often' group (52% respectively had good control). Patients who seldom or sometimes forget to take their medications had about 40% good glycaemic control rate. Similarly, there was no significant difference in the mean number of days that the patients consumed their medications in both outcome groups (Table 4.5). Although medication adherence is an important component of achieving glycaemic targets (Delamater, 2006), some studies have found that even high levels of medication adherence does not equate to good glycaemic control (Adisa et al, 2011). Adherence to lifestyle/behavioural recommendation is more beneficial in glycaemic control.

#### 5.4.2 Physical Activity and Glycaemic Control

The difference in glycaemic control between 'physically active' (49% had good control) and 'physically inactive' (46% had good control) diabetic patients was not statistically significant. Comparison of the mean number of days patients engaged in physical activity revealed that patients with good glycaemic control engaged in sport more frequently (2.99 days per week) than those with poor glycaemic control (2.52 days per week). Although these findings were not statistically significant, it reflects the stance of most studies (Boulé et al, 2001; Thomas, Elliott & Naughton, 2006; Sigal et al, 2007; Mikus et al, 2012;). Physically inactive patients are often overweight or obese and these are also independent risk factors for poor glycaemic control. Involvement of diabetic patients in regular physical activities promote good glycaemic control (Almutairi, Said & Zainuddin, 2013).

#### 5.4.3 Body Mass Index and Glycaemic Control

There was no statistically significant difference in glycaemic control between obese diabetic patients and normal/overweight patients. Fifty-five percent (55%) of obese diabetic patients (BMI  $\geq$ 30 kg/m<sup>2</sup>) had poor glycaemic control while 53% of those who are either overweight or have a normal weight (BMI <30 kg/m<sup>2</sup>). The increased risk of poor glycaemic control in obese diabetic patients found in the study was not statistically significant but the observed trend is in agreement with the findings of Khattab et al (2010)-obese patients having the highest rate of poor glycaemic control of 69.5%- and Al-Akour et al (2011)- obese patients having also the highest rate of poor glycaemic control of 53.8%. The outcome of these two studies were also not statistically significant. Obesity has been reported to account for 80% of the risk of developing type 2 diabetes and obese people are 80 times more likely to develop type 2 diabetes than those with a BMI of less than 22 kg/m<sup>2</sup> (European Association for the Study of Obesity, (EASO), 2016). This risk of diabetes onset associated with obese persons also accounts for the increased likelihood of obese diabetic patients having a poor glycaemic control. The exact mechanism through which obesity causes diabetes (or poor glycaemic control) is unclear but three key mechanisms have been proposed and they include- increased production of adipokines/cytokines, including tumor necrosis factor-α, resistin, and retinol-binding protein 4, that contribute to insulin resistance as well as reduced levels of adiponectin; ectopic fat deposition, particularly in the liver and perhaps also

in skeletal muscle, and the dysmetabolic sequelae; and mitochondrial dysfunction which decreases insulin sensitivity and compromises pancreatic βcell function (Eckel et al, 2011).

## 5.4.4 Self-monitoring of Blood Glucose and Glycaemic Control

Patients who self-monitored their blood glucose more frequently (4-7 days per week) had a higher rate of poor glycaemic control (59%) compared to those who self-monitored their blood glucose less frequently (0-3 days per week) (49%). Similarly, when the mean number of days that the patients self-monitored their blood glucose were compared across the two groups of outcomes, patients with poor glycaemic control had a mean of 3.68 days while those with good glycaemic control had a mean of 3.21 days. The difference was not statistically significant in both analyses. However, Harris (2001) reported a similar trend between self-monitoring of blood glucose among diabetic patients and their level of glycaemic control. In his study, the HbA1c value was found to be directly proportional to the frequency of self-monitoring of blood glucose. This finding suggests that patients with poorer glycaemic control have a greater tendency to self-monitor. The patients with poorer level of glycaemic control are more likely to use insulin injections and as such, must self-monitor their blood glucose to avoid dose-related insulin complications.

## 5.4.5 Adherence to Healthful Eating Plan and Glycaemic Control

This variable was found to be statistically significant in both types of analyses done (categorical and mean comparison (Table 4.3; Table 4.5). The 'non-adherence' category (those who adhered to a healthful eating plan 0-1 day per week) had the highest level of poor glycaemic control-64% (p=0.036). The other three categories- good adherence (6-7 days/week), moderate adherence (4-5 days/week) and poor adherence (2-3 days/week)- had a poor glycaemic control rate of 47%, 47% and 46% respectively (Table 4.5).

In comparing the mean number of days patients adhered to a healthful eating plan across the two outcome groups (good glycaemic vs poor glycaemic control), a statistically significant difference was found as the patients with good glycaemic control were seen to have followed a healthful eating plan on more number of days (4.38 days) compared to those who had poor glycaemic control (3.47 days) (p=0.017) (Table 4.5). The importance of diet in the management of diabetes cannot be overemphasized as demonstrated by several publications (Almutari, Said & Zainuddin, 2013; ADA, 2017). A healthful eating plan includes diets which are low in fat and carbohydrate and high

in fibre content and such plan when included in the management plan of diabetic patients, often leads to improved glycaemic control (UKPDS, 1998). The Mediterranean diet (Esposito et al, 2009), the DASH diet (Cespedes et al, 2016) and plant-based diets (Rinaldi et al, 2016) are good examples of healthful eating patterns that has been shown to improve glycaemic control among diabetic patients. These dietary patterns could serve as a model for dietary planning in diabetes management.

A collaborative development of an individualized eating plan-medical nutrition therapy (MNT)-is a key recommendation by the American Diabetes Association for the management of patients with diabetes (Inzucchi et al, 2015; ADA, 2017). The medical nutrition therapy is aimed at promoting and supporting healthful eating patterns, addressing the dietary needs of patients based on personal and cultural preferences, maintaining the pleasure of eating by providing nonjudgmental messages about food choices and providing the patients with practical tools for developing healthy eating patterns (Evert et al, 2014, ADA, 2017). A medical nutrition therapy administered by a registered dietician who is knowledgeable and skilled in dietary treatment of diabetes is more efficient and has been shown to lower HbA1c values in both type 1(Rossi et al, 2010 & Scavone et al, 2010) and type 2 diabetes (UKPDS, 1998; Ziemer et al, 2003; Wolf et al, 2004 & Coppell et al 2009). Making dietary decisions can be quite challenging for diabetic patients and they need the support of the health care team at every stage of the illness especially at the onset. Each member of the health care team should be well informed on the basic principles of medical nutrition therapy (ADA, 2017).

Designing a healthful eating plan for diabetic patients is one thing and adhering to this plan is another. In our setting only 48.6% of the respondents adhered strictly to a healthful eating plan (good adherence group- followed a healthful eating plan for 6-7 days in the last week) although 95% of the participants admitted that they have been counselled by their healthcare provider regarding choice of diet in their management. The quality of this dietary counselling could not be established. However, counselling done by medical doctors or nurses who are not trained to be dieticians are likely not going to be as efficient as that done by professional dieticians who are knowledgeable in the nutritional management of diabetes (ADA, 2017). The patients' poor adherence to a healthful eating plan could also be due to patients' poor interpretation of what a healthful diet should be (Bisogni, Jastran, Seligson & Thompson, 2012). Some diabetic patients

believe that a healthful diet is an expensive diet and so make no effort in trying to adhere to such nutritional recommendation. A proper patient education is required to address this problem and the ADA dietary guidelines (ADA, 2017) provides the basic framework that should be adopted in educating the patients on what their dietary plan should be.

#### 5.4.6 Consumption of Fruits and Vegetables and Glycaemic Control

The mean number of days that patients consumed adequate amounts of fruits and vegetables was compared across the two outcome groups (good vs poor glycaemic control) (Table 4.5) and a statistically significant difference was found to exist between the two groups. Patients with good glycaemic control consumed on the average adequate amount of fruits and/or vegetables on more days than those with poor control. Fruits and vegetables in general, are sources of fibre, minerals, vitamins, antioxidants and phenolics. Although the definitive roles of these substances are unclear, they help in the reduction of serum lipids and prevent oxidative damages to the body cells (Jenkins et al, 2011). Over time, they reduce cardiovascular complications of diabetes by improving glycaemic control in diabetic patients (Jenkins et al, 2011). The fibre in fruits and vegetables makes it more difficult for digestive enzymes to break down the starches into glucose. This leads to lower, slower increases in blood sugar and insulin, and a lower glycemic index. This reduces the stress on the body's insulin-producing machinery, and so may help prevent type 2 diabetes or improve control in those already suffering from the disease (Villegas et al, 2007). Fruits and vegetables consumption is the most reliable index in accessing the general quality of diet consumed by individuals (Hendrie & Noakes, 2017).

When analysed as a categorical data, no significant association was found between fruit and vegetable consumption and glycaemic control. However, the highest rate of poor glycaemic control (67%) was seen in patients who seldom consumed fruits and vegetables (0-1 day per week) while the lowest rate of poor glycaemic control (47%) was seen in patients who consumed fruits and vegetables regularly (6-7 days per week) (Table 4.3). This is consistent with several studies which have demonstrated that diabetic patients who consume fruits and vegetables on a regular basis have better glycaemic control than those who don't (Franz et al, 2003).

Despite the proven efficacy of the consumption of fruits and vegetables, its consumption is generally not optimal in Sub-Saharan Africa (Chubike, Okaka & Okoli, 2013; Silva, Ayankogbe, & Odugbemi, 2017). The WHO recommended quantity of fruits and vegetables to be consumed

daily of 400g/day (equivalent to 5 portions) is a tall order for most African countries (Nishida, Uauy, Kumanyika & Shetty, 2004). Only about 33% of the study population consumed adequate fruits and vegetables regularly (at least 5 portions of fruits and vegetables daily for the last 7 days) and this can be traced to several factors including cost, seasonal variations in availability, lack of knowledge about the potential benefits of consuming adequate amounts of fruits and vegetables and lack of satisfaction from consumption of fruits and vegetables (Silva, Ayankogbe, & Odugbemi, 2017).

# 5.4.7 Avoidance of High fatty foods and Glycaemic control

The mean number of days that diabetic patients abstained from high fatty foods such as red meat and full cream dairy foods were compared across the two outcome groups and a significant difference was observed between the two groups. Patients with good glycaemic control avoided high fatty diets on the average, more frequently (mean number of days= 5.39) than patients with poor glycaemic control (mean number of days= 4.97) (Table 4.5).

Excessive consumption of foods rich in saturated fats are major risk factors for dyslipidemia amongst diabetic patients (Lichtenstein et al, 2006). Dyslipidemia makes glycaemic control more difficult in diabetic patients and increases the risk of diabetic complications (especially cardiovascular complications). Stern et al (1992) observed that the prevalence of dyslipidemia in diabetic patients increased with worsening glycaemic control rate. Similarly, a significant association has been reported between HbA1c and serum lipids (Khan, Sobki & Khan, 2007)

The consumption of red meat (pork, beef, lamb) and processed red meat (bacon, hot dogs, deli meats) increases the risk of diabetes (Harvard School of Public Health (HSPH), 2016). Daily consumption of 3-ounce of red meat increases the risk of type 2 diabetes by 20%. A daily consumption of 2 slices of bacon or one hot dog increases diabetes risk by 51% (HSPH, 2016). The mechanism through which red meat causes diabetes is uncertain but the high iron content of red meat has been highly implicated (HSPH, 2016). The iron diminishes the effectiveness of insulin and damages the islet cells that produce insulin. In processing meats, high levels of sodium and nitrites are used as preservatives and these elements may increase the risk of diabetes (HSPH, 2016). This risk persists in patients who develop the disease and makes the control of their level of glycaemia more challenging.

Alternative and healthier sources of fat should be offered to the patients in the clinic. For example, the use of olive oil, which is the main source of fat in the Mediterranean diet (Esposito et al, 2009) could be a healthier option for the patient rather than other fatty foods and oils. The concept of DASH diet (Cespedes et al, 2016) and plant-based diets (Rinaldi et al, 2016) can also be discussed with the patient. Most importantly, the dietary specifications must be tailored to the patient and she/he must find the plan acceptable.

#### 5.4.8 Even Spacing of Carbohydrate and Glycaemic Control

On the average, patients with good glycaemic control more frequently spaced their carbohydrate meals (mean number of days=4.64) than their counterparts with poor glycaemic control (mean number of days=4.31). This difference was not statistically significant (Table 4.5). Consistency in carbohydrate intake and spacing help in blood sugar control and weight management (Canadian Diabetes Association, 2013) in diabetic patients.

# 5.5 Nature of Diabetes Treatment and Glycaemic Control

## 5.5.1 Type of treatment and Glycaemic Control

Patients who are being treated with a combination of insulin injections and oral medication had the highest rate of poor glycaemic control (65%). This is followed by patients on either insulin (48%) or oral medications (49%) only. Seven patients were not on any medications but rather being managed by non-pharmacologically or lifestyle modification. Two of these patients had a poor glycaemic control. This finding was statistically significant but the small number of patients in the 'no specific treatment' group and the 'non-pharmacological' group could have influenced this statistic (Table 4.4). In comparison, patients on insulin-only treatment was reported by Harris (2011) to have the worst rate of poor glycaemic control (51.4%) compared to those on oral-only treatment (42.2%) and dietary management (14.9%).

The reason why patients on insulin generally have worse glycaemic control could be traced to reduced probability of adherence (due to needle phobia), cost of insulin and means of insulin storage. Due to the epileptic nature of electricity supply in Nigeria, patients might not be able to store their insulin in the appropriate temperature and the potency of the insulin is often questionable after some days of purchase. Sometimes the storage shortfalls can be traced to the pharmacy outlet dispensing the insulin. Secondly the fact that patients are on insulin could signal

that patients are already in advanced stages of the disease with complications and as such more difficult to control blood glucose. This is more likely in our setting because insulin use by diabetic patients are often started very late due to both prescriber-related and patient-related factors (Sorli & Heile, 2014). Chinenye et al (2012) reported that only 20% of Nigerian diabetics had a prescription of insulin injection.

#### 5.5.2 Pill Burden and Glycaemic Control

Forty-eight percent (48%) of patients on more than 5 tablets per day had poor glycaemic control whereas 55% of the patients on less than or equal to 5 tablets per day had poor glycaemic control (Table 4.4; Figure 4.10). The higher rate of poor glycaemic control found in the patients who take fewer number of tablets was not statistically significant. In contrast to our finding, Donnan, MacDonald & Morris (2002) reported that diabetic patients on one tablet per day had better adherence rates (and better glycaemic control) than patients on multiple tablets. They also found a linear trend between the number of tablets and the level of adherence. Dezii et al (2002) also evaluated the rate of adherence of type 2 diabetic patients to glipizide prescription and found that patients on once-daily dosing adhered better than those with twice daily dosing although the adherence rate for both groups were suboptimal. The rate of adherence of patients to treatment regimens is directly proportional to the level of glycaemic control.

A possible argument to explain the better glycaemic control in patients taking more than 5 tablets per day is that these patients are more likely to be on different drugs with different mechanisms of action that act synergistically to control blood glucose. Polypharmacy in diabetic patients could be a signal for possible comorbidities and such patients might be more inclined to adopt healthier lifestyles because of their different perception of the disease and their susceptibility to its complications.

#### 5.5.3 Patients' Satisfaction and Glycaemic Control

A significant association was found between glycaemic control and the level of patients' satisfaction with the healthcare provider. A greater percentage of dissatisfied patients (70%) had poor glycaemic control compared to the satisfied patients (51%). This is consistent with findings of Alazri & Neal (2003), who reported an association between patients' satisfaction and outcome in diabetes-HbA1c. They submitted that steps taken to increase patients' satisfaction (by

actualisation of their values and expectations) improve outcome by increasing compliance and adherence to treatment regimens. Satisfied patients therefore have better glycaemic control. There is also the chicken or the egg dilemma in this argument. Could it be the good glycaemic control achieved in certain patients that make them satisfied?



#### **CHAPTER 6: CONCLUSION AND RECOMMENDATIONS**

#### 6.1 Conclusion

In this study, the sociodemographic, behavioural and treatment-related factors responsible for poor glycaemic control among adult type 2 diabetic patients attending follow-up clinics in two tertiary hospitals in Abuja, Nigeria were explored. The mean age of the patients sampled was 54 years and 60% of them were females. Majority of the patients (47%) were middle income earners and have completed tertiary education (56%). Most of the patients were employed (63%) and about three quarter of them resided in urban settings. Just above 50% of the patients had a positive family history. Two thirds of the diabetic patients sampled were being treated with only oral medications while 8% are on insulin-only treatment. Twenty-eight percent (28%) are on a combination regimen of oral medications and insulin injection. Seventy-five percent of the patients had other comorbidities especially hypertension and dyslipidemia. The average pill load of the patients on oral medications was 4.8 tablets per day. About 70% of the patients had no health insurance coverage. Amongst those who were insured, only a quarter of them had a full comprehensive coverage. The mean BMI and waist circumference of the study population was 28.9 kg/m<sup>2</sup> and 97.6cm respectively. About 35% of the patients were physically active and only 34% of the respondents had done daily self-monitoring of blood glucose in the past one week. The level of satisfaction was high with 91% of the patients being happy with the services they received from their healthcare provider.

HbA1c and FPG were used to assess the level of glycaemic control in the patients. About 74% of the study population had a HbA1c test result not older than 6 months. For this group of patients, a HbA1c of less than 7% was regarded as poor glycaemic control based on the American Diabetes Association diabetes protocol. The mean HbA1c of the participants was 7.6% and the value ranged from 3% to 15.3%. For the rest of the participants who had no recent HbA1c test result, the average of their latest two fasting plasma glucose measurements was used to ascertain their level of glycaemic control. Average FPG of greater than or equal to 126mg/dl was regarded as poorly controlled glycaemia. The average FPG of the sampled patients was 142mg/dl ranging from 63mg/dl to 423mg/dl. When collected together (HbA1c- and FPG- based glycaemic control), 53% of the patients were found to have poor level of glycaemic control.

Although none of the socio-demographic characteristics examined (age, gender, marital status, residence, family history, income, education, employment and means of financing diabetes treatment) were found to have a statistically significant association with the level of glycaemic control, the trend seen in most of the variables were consistent with the findings of other similar studies. Poor glycaemic control was found to be more prevalent in extremes of ages (20-29 and 70-79 age groups), males, married patients and patients living in rural areas. Patients without family history of diabetes had worse glycaemic control than those with a positive family history. Poor glycaemic control was also most prevalent in high income patients, those who have completed tertiary education and those who are employed. Paradoxically, patients with full health insurance coverage had the worst glycaemic control followed by those who pay out-of-pocket (either family or self).

Some of the lifestyle/behavioural factors considered in this study were adherence to medication, physical activity, healthy diet and self-monitoring of blood glucose. The body mass index was also assessed in terms of how it affects glycaemic control. Amongst all these variables, only dietary behaviours were found to have a statistically significant correlation with glycaemic control. The remaining lifestyle variables showed expected relationship patterns with glycaemic control but the differences observed in both outcome groups were not statistically significant.

The study showed that appropriate dietary habits is a very significant factor in the control of glycaemia in diabetic patients. Patients with the worst adherence rate to a healthful eating plan had the worst level of glycaemic control. Patients with poor glycaemic control averagely adhered to a healthful eating plan less frequently than patients with good control. Inadequate consumption of fruits and vegetables was seen to be a significant risk factor for poor glycaemic control. Consumption of foods high in fat content also conferred a significant risk of poor glycaemic control on diabetic patients.

A statistically non-significant but important association was found between physical activity and glycaemic control. Patients with poor glycaemic control were observed to have engaged in physical activity less frequently than those who had good control. Patients with poor glycaemic control adhered more frequently to their medications and self-monitored their blood glucose more frequently. This observed difference, however was not statistically significant.

The nature of diabetes treatment (type/route of administration, pill burden) and level of satisfaction was also assessed for their role in glycaemic control of diabetic patients. Patients on a combination of oral medications and insulin had worse glycaemic control compared to 'insulin-only' or 'oral-only' group and this finding was significant. Patients on  $\leq 5$  tablets/day had worse glycaemic control compared to those on > 5 tablets per day but this was not statistically significant. A significant association was found between level of satisfaction and glycaemic control as patients who were dissatisfied with the services of the hospital had a higher rate of poor glycaemic control.

Some of the limitations of the study include, the use of different criteria for estimation of glycaemic control, the collection of data around a festive season, high probability of a non-response bias due to frequent data collection in the study clinics and the inability to make causal inferences from the study due to lack of temporality between the outcome and exposure.

#### **6.2** Recommendations

Having established that socio-economic, behavioural and treatment related factors all influence glycaemic control, concerted efforts should be geared towards a comprehensive approach in solving the problem of poor glycaemic control amongst diabetic patients. The patient and the health care provider have a role to play.

The first problem is the need to monitor and control the glycaemic control of diabetic patients on regular bases. Diabetic patients should never be managed without regular follow ups. It is understandable that many patients travel long distances in order to attend follow up diabetes clinics and hence present to their doctors seldomly. A solution to this problem would be to adapt the chronic care model for the management of diabetes in primary settings (ADA, 2017). This model integrates several components of the health system in an effort to improve the quality of care received by chronic disease patients and it comprises 6 core elements- delivery system design, self-management support, decision support, clinical information systems, community resources and policies and health systems. At the very center of this model is the role of the healthcare delivery team and empowering patient self-management. The measurement of the HbA1c level must be taken seriously by both the managing team and the patient. It is recommended that patients whose blood glucose level is stable should have at least HbA1c test done every 6 months (ADA, 2017). This should be increased to 4 times a year if therapy is adjusted or glycaemic control is not optimal (ADA, 2017). This regular monitoring makes it possible for timely treatment modification.

In instances where it is not possible to measure the HbA1c, the fasting plasma glucose, post-prandial glucose measurement and glucose tolerance test could be used as a means to monitor the glycaemic control. However, the managing team must be aware of the limitations of using only plasma glucose measurement as a tool for glucose monitoring. Health care institutions managing diabetic patients should make efforts to acquire the equipment necessary to measure the HbA1c in addition to the other devices needed in the monitoring of treatment and complications. Patients who cannot afford the tests could join Diabetes clubs which in some instances, are able to sponsor some of these laboratory investigations and medications. Hospitals should also make efforts to subsidize the general costs of managing diabetes. The political hierarchy should review laws relating to healthcare financing in order to improve the supply of medicines at prices which are comparable to international prices. Medicines used in the treatment of chronic diseases like diabetes should be imported with little or no duties or taxes. This would help to reduce the burden of cost on the patients. A decent health insurance policy that includes all members of the society should be developed and implemented to ensure that patients are not well monitored due to financial reasons.

The eating plan of every diabetic patient must be individualized and discussed immediately after diagnosis of diabetes (ADA, 2017). A registered dietician who is knowledgeable about the medical nutrition therapy in diabetes management is in the best position to provide the dietary counselling (ADA, 2017). A written dietary plan should be made available for the patient and the patients must be asked about this written plan at subsequent visits. It should be adjusted based on patients' preferences (within accepted limits), seasonal availability of food, affordability, social and cultural background.

Healthcare providers should develop mechanisms for monitoring patients' adherence to treatment regimens- medications and lifestyle. An electronic monitoring system could be used to send reminders to patients about their follow-up appointments and also to educate them constantly on healthy lifestyles. Dietary guidelines and physical activity recommendations could be made available to patients in handbook or pamphlet formats or even phone applications.

Health care providers should conduct researches on possible ways of improving the glycaemic control of their patients. They should also develop a guideline which is tailored to the peculiar needs of their institution and these guidelines must be updated at regular intervals to ensure that

its contents are in line with current best practices. All members of the healthcare team must also be conversant with the guideline to ensure uniformity of care for all patients.

The healthcare team must operate based on the principle of collaboration amongst different diabetes experts. The diabetes management team must comprise health promoters and educators, endocrinologists, psychologists, and other specialists that may be needed at different times to manage complications arising from diabetes. Regular joint meetings should be organised by the managing team to discuss cases and review approaches to management. These meetings should sometimes involve the patients. The healthcare providers should collaborate with public health promoters in organising programmes aimed at improving the diet of the population. Such programmes should build partnerships across different government departments and parastatals and across different levels of healthcare. They should aim to inform the population on the benefits of whole grains and non-starchy vegetables as against refined carbohydrates and starches. Through these programmes, the population (and also diabetic patients) would understand how and why they need to cut down on salt and fat consumption or why the consumption of fruits and vegetables is essential. The people should also be made to know that the quality of food they eat is more important than the quantity.

Healthcare providers should understand that the time allocated for each diabetic patient on their follow-up clinic days is insufficient for counselling the patients on lifestyle modifications and behaviours that can improve glycaemic control. Through these collaborations with health promoters, the healthcare provider could create another avenue for these patients to be counselled more adequately. These campaigns for healthy lifestyles should be popularized not only in traditional media (prints, television, radio) but also in social media which is fast becoming the choice media for information dissemination. Extensive health education is also a possible means to help improve glycaemic control. This will help in transforming some of the cultural beliefs of the people regarding diabetes. Certain portion of the Nigerian population still hold the view that obesity is a sign of good living and such is accepted. Through efficient education, such beliefs could be reduced or eliminated. A registered dietician should be part of every diabetes management team and a regular consultation with a dietician is as necessary as that with an endocrinologist.

The most important member of the diabetes management team is the patient. No matter how diligent the efforts of other members of the team are, their success depends solely on the

willingness of the patient to accept their recommendations and follow their treatment plan. I therefore recommend that patients should be involved in their management at every step. They should not hesitate to ask questions regarding their illness and must strive to find ways to adhere to the treatment regimen. They should always see themselves as the protagonist in their management.

In all these, what is clear is that everybody has a role to play in the improvement of glycaemic control amongst diabetic patients.



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#### **PARTICIPANT INFORMATION SHEET**

Hello,

#### 1. Information about the Interviewer

I am Ekene Casmir Igboerika, a student of the School of Public health, University of the Western Cape, South Africa. As part of my Masters in Public Health, I am required to conduct research aimed at evaluating the socio-economic and behavioural factors associated with poor glycemic control among adult type 2 diabetic patients attending outpatient diabetic clinics in tertiary hospitals in Abuja, Nigeria. In this study, I will also explore other factors associated with poor glycemic control. I can be contacted on this email- ekeneigboerika@gmail.com and this phone number- +2348038911940.

#### 2. Purpose and Contents of the Interview

The purpose of this study is to describe the level of glycaemic control among adult type 2 diabetic patients in Abuja and identify factors (socio-economic, behavioural and treatment-related factors) associated with poor glycemic control in these patients

#### 3. Selection and Benefits

Please understand that your participation is voluntary and you are not being forced to take part in this study. We are seeking your participation because we are using the outpatient diabetes clinic in your hospital. We are doing this in the two tertiary hospitals in Abuja National Hospital and University of Abuja Teaching Hospital. After compiling the responses from all participants, we hope to learn more about the factors that influence glycemic control among adult type 2 diabetic patients in Abuja, which will help us, make useful recommendations to the relevant authorities and organizations

#### 4. Risks and Withdrawal

I do not anticipate any adverse effects emanating from the interview. Some of the questions might be sensitive so please feel free to skip questions you would prefer not to answer. You may however withdraw from the study at any time if you no longer wish to participate. There will be no penalties and you will not be prejudiced in any way.

#### 5. Confidentiality

You will be asked questions about your socio-economic characteristics, behavioural lifestyle and other questions that are related to your diabetes treatment. I will not be recording your name anywhere on the questionnaire, and no one will be able to link you to the answers you give. Only researchers will have access to the unlinked information. All individual information will remain confidential.

#### 6. What if I have questions?

This research is being conducted by Ekene Casmir Igboerika, a student of the School of Public Health, University of the Western Cape. If you have any questions about the research study itself, please contact *Ekene Casmir Igboerika*, at <a href="mailto:ekeneigboerika@gmail.com">ekeneigboerika@gmail.com</a> and/or +2348085388430.

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

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This research has been approved by the University of the Western Cape's Senate Research Committee. (**REFERENCE NUMBER**: **BM/17/1/16**)

#### 7. CONSENT

I hereby agree to participate in research regarding the *factors that are associated with poor glycemic control among adult type 2 diabetic patients attending outpatient diabetes clinics in tertiary hospitals in Abuja*. I understand that I am participating freely and without being forced in any way to do so. I also understand that I can stop this interview at any point should I lose interest and that this decision will not in any way affect me negatively.

The purpose of the study has been explained to me and I understand what is expected of my participation. I understand that this is a research project whose purpose is not necessarily to benefit me personally. I have received the telephone number of the researcher in case I need to speak about any issues that may arise in this interview. I understand that this consent form will not be linked to the questionnaire, and that my answers will remain confidential

Signature of Participant Date NIVERSITY of the

(I acknowledge the University of the Witwatersrand, Johannesburg, and anonymous members of the HSRC Research Ethics Committee for providing a framework for this Participant information form)



## University of the Western Cape

School of Public Health
Private Bag X 17, Bellville 7535, South Africa
Tel: +27 21-959 2809, Fax: 27 21-959 2872

E-mail: soph-comm@uwc.ac.za

#### **INFORMED CONSENT:**

**Title of Research Project:** The Socio-Economic and Behavioural Factors Associated with Poor Glycaemic Control Among Adult Type 2 Diabetic Patients Attending the Outpatient Diabetes Clinic in Tertiary Hospitals in Abuja, Nigeria

The study has been described to me in language that I understand. My questions about the study have been answered. I understand what my participation will involve and I agree to participate of my own choice and free will. I understand that my identity will not be disclosed to anyone. I understand that I may withdraw from the study at any time without giving a reason and without fear of negative consequences or loss of benefits.

Participant's name
Participant's signature
Date

## Questionnaire for the study on the Socio-economic and Behavioural Factors Associated with Poor Glycemic Control Among Adult Type 2 Diabetic Patients Attending the Outpatient Diabetes Clinic in Tertiary Hospitals in Abuja, Nigeria

Questionnaire Reference Number		
A. Demography (Please check the appropriate box and fill in appropriate an	swei	rs)
1. Age (years)		
2. Hospital where you attend follow-up visits		
a. National Hospital		
☐ b. University of Abuja Teaching Hospital		
3. Gender		
☐ a. Male		
☐ b. Female		
4. Marital Status		
a. Single		
□ b. MarriedUNIVERSITY of the		
☐ c. Divorced		
d. Widowed		
e. Separated		
5. Ethnic Group		
a. Hausa		
☐ b. Fulani		
☐ c. Yoruba		
☐ d. Igbo		
e. Other (specify):		

	6.	Residence
		a. Urban
		☐ b. Rural
		☐ c. Semi urban
		d. Informal Settlements
В.		labetes Related Variables (Please check the appropriate box and fill in propriate answers)
	7.	Age at first diagnosis of Diabetes
	8.	Do you have any family history of diabetes? (Please check all that apply)
		a. Parent(s)
		☐ b. Any Sibling
		☐ c. Other Relatives
		d. None
		e. Unknown
	9.	Latest Glycated Haemoglobin (HbA1c) value
	10	. Value of last two fasting plasma glucose results (in mg/dl)
		a
		b
	11.	c. Average  . Nature of Diabetes Treatment
		a. Non-Pharmacological (Lifestyle modifications)
		☐ b. Oral Medication alone
		☐ c. Insulin injections alone
		☐ d. Combination of Insulin and Oral Medications
		☐ e. No specific treatment
	12	How long have you been on treatment for diabetes generally?

# C. Socio-economic Variables (Please check the appropriate box and fill in appropriate answers)

13. What is the average total combined monthly income of all members of your family?
a. Less than 20,000 Naira
☐ b. 20,000 to 50,000 Naira
☐ c. 51,000 to 100,000 Naira
☐ d. 101,000 to 200,000 Naira
☐ e. 201,000 to 500,000 Naira
f. Greater than 500,000 Naira
14. What is the highest level of education you have completed?
a. No education at all
☐ b. Primary school
☐ c. Secondary school
☐ d. University or post-school qualification
15. Concerning employment, which of these is applicable to you?
a. Unemployed
☐ b. Government Employee
☐ c. Non-Government Employee
☐ d. Self-Employed
a. Employer
☐ f. Retired
16. What is the nature of your job?
a. Legislator, senior official or manager
b. Professional, Technician, or associate Professional
c. Clerical
d. Personal Services, Marketing, or Sales
e. Agricultural or Fisheries Worker
☐ f. Craft, Construction, or Trades
☐ g. Plant and Machine Operators or Assemblers
☐ h. Armed Forces
i. Others (specify)

## **D.** Treatment Related Variables (Please check the appropriate box and fill in appropriate answers)

17. List all the drugs (for treatment of any disease) you take daily. If you inject insulin,
include that in the list as well
a g
b h
c i
d j
e k
f 1 1 18. Are you on treatment for any of these diseases in addition to diabetes?
· <u> </u>
☐ a. Hypertension
☐ b. Dyslipidemia
C. Cardiac Failure
d. Osteoarthritis
e. Other (specify):
☐ f. None
19. What is the average total number of tablets of medicines you take daily?
20. What is the average monthly cost of your medications?
21. How do you finance the payment for your treatment?
a. Fully paid by insurance
b. Partially paid by insurance
☐ c. Self-payment (out-of-pocket)
d. Family sponsored
22. How often do you not take your medication?
a. Never
☐ b. Seldom (once per month)
☐ c. Sometimes (once per week)
☐ d. Often (more than once per week)

23. What is your main reason for not taking your medication?					
a. Forgetfulness					
☐ b. Financial constraints					
C. Prescribed drugs not available at the pharmacy stores					
☐ d. The drugs are not effective in controlling my blood sugar					
☐ e. Lack of explanation by the healthcare provider					
☐ f. Side effects of the drugs					
E. Diabetes Self-care Factors (circle the corresponding number)					
Exercise					
24. On how many of the LAST SEVEN DAYS did you participate for at least 30 minutes					
of physical activity (total minutes of continuous activity including walking)					
0 1 2 3 4 5 6 7					
25. On how many of the LAST SEVEN DAYS did you participate in any specific					
exercise session (such as swimming, biking, walking) other than what you do around					
the house or as part of your work?					
0 1 2 3 4 5 6 7					
Smoking					
26. When last did you smoke a cigarette?					
a. More than two years ago or NEVER					
b. One to two years ago					
WESTERN CAPE					
☐ c. Four to twelve months ago					
d. One to three months ago					
e. Within the last month					
☐ f. Today					
27. If you have smoked (even one puff) within the LAST SEVEN DAYS how many					
cigarettes did you smoke on an average day? (number of cigarettes)					

Alcohol
28. When last did you have a drink containing alcohol?
a. More than two years ago or NEVER
☐ b. One to two years ago
☐ c. Four to twelve months ago
d. One to three months ago
e. Within the last month
f. Within the last week
i. If within the last week, on how many days within the LAST
SEVEN DAYS did you have a drink containing alcohol?
0 1 2 3 4 5 6 7
29. If you consume alcohol, what type of alcohol do you usually consume? (check all
relevant options)
a. Beer
☐ b. Wine
□ c. Spirit
d. Other (specify)
e. I don't drink any alcohol
Weight status
30. Body Mass Index
a. What is your body weight (in kilograms)?
b. What is your height (in meters)?
c. BMI calculation  31. What is your waist circumference (in cm)?
51. What is your waist circumference (iii ciii)?
Diet
32. How many of the LAST SEVEN DAYS did you follow a healthful eating plan?
0 1 2 3 4 5 6 7
33. On average in the past month, how many days per week did you follow your eating
plan?
0 1 2 3 4 5 6 7
34. On how many of the LAST SEVEN DAYS did you eat at least five portions /
servings of fruit and vegetables?
0 1 2 3 4 5 6 7
25. On how many of the LAST SEVEN DAVS did you get high fot feeds such as and
35. On how many of the LAST SEVEN DAYS did you eat high fat foods such as red meats and full cream dairy foods?

36. On how many of the LAST SEVEN DAYS did you consume sugar, sugar containing								
				_	sweete	ened bev	verages (	(such as carbonated drinks /
SW	eetened	tea or	,					
	0	1	2	_		5	_	7
		-	the LA	ST SEV	EN DA	AYS did	l you spa	ace carbohydrates evenly
thre	ough th	•						
	0	1	2	3	4	5	6	7
Medic	ation							
38. On	how m	any of	the LA	ST SEV	EN DA	AYS did	l you tak	te your recommended diabetes
me	dication	n?					-	
	0	1	2	3	4	5	6	7
Blood	sugar 1	testing						
39. On	how m	any of	the LA	ST SEV	EN DA	AYS did	l you tes	t your blood sugar?
	0	1	2	3	4	5	6	7
40. On	how m	any of	the LA	ST SEV	EN DA	AYS did	l you tes	t your blood sugar the number
of t	times sı	uggeste	d by yo	our healt	th care	provide	r?	
	0	1	2	3	4	5	6	7
Foot c	are					шш		
41. On	how m	any of	the LA	ST SEV	EN DA	AYS did	l you che	eck your feet?
	0	1	2	3	4	5	6	7
42. On	how m	any of	the LA	ST SEV	EN DA	AYS hav	ve you w	ashed your feet with warm
wa	ter and	mild so	oap?	FST	ED	NO	APE	
	0	1	2	3	4	5	6	7
43. On	how m	any of	the LA	ST SEV	EN DA	AYS hav	ve you d	ried in-between your toes after
wa	shing o	r bathir	ng?					
	0	1	2	3	4	5	6	7
44. On	how m	any of	the LA			AYS did	l you che	eck the insides of your shoes?
	0	1	2	3	4	5	6	7

## F. Healthcare Provider Related variables

Concerning your index/current visit to this health facility:
45. How many minutes did you spend with the doctor in the consulting room?
46. How many minutes did you spend at the pharmacy while waiting for your drugs to be
dispensed?
47. Were you reminded through any means (email, phone calls, letters etc.) by your
healthcare provider about your follow up?
□ 0. No
1. Yes
48. What is your level of satisfaction regarding the services rendered by your diabetes
management team?
a. Very satisfied
☐ b. Satisfied
☐ c. Dissatisfied
d. Very Dissatisfied
49. Concerning dietary counselling, which of the following has your healthcare team
(doctor, nurse, dietician or diabetes educator) advised you to do? (please check all
that apply)
a. Follow a low fat eating plan
☐ b. Follow a complex carbohydrate eating plan
c. Reduce number of calories to lose weight
d. Eat lots of fibre rich foods
e. Other (specify)
f. I have not been given any advice about diet by my healthcare team
50. Concerning physical activity, which of the following has your healthcare team
(doctor, nurse, dietician or diabetes educator) advised you to do? (please check all
that apply)
a. Get low level exercise (such as walking) on a daily basis
☐ b. Exercise continuously for a least 20 minutes at least 3 times a week
a c. Fit exercise into your daily routine (for example, take stairs instead of
elevators, park a block away and walk, etc.)
d. Engage in a specific amount, type, duration and level of exercise.
e. Other (specify)
f. I have not been given any advice about exercise by my healthcare team

51. Concerning blood sugar testing, which of the following has your healthcare team (doctor, nurse, dietician or diabetes educator) advised you to do? (please check all	
that apply)	
a. Test your blood sugar using a drop of blood from your finger and a color chart	
☐ b. Test your blood sugar using a machine to read the results	
☐ c. Test your urine for sugar	
d. Other (specify)	
e. I have not been given any advice about testing my blood or urine suglevel by my healthcare team	a
52. Which of the following medications for your diabetes has your doctor prescribed?	
(Please check all that apply)	
a. An insulin shot 1 or 2 times a day	
☐ b. An insulin shot 3 or more times a day	
☐ c. Diabetes pills to control my blood sugar level.	
d. Other (specify):	
☐ e. I have not been prescribed either insulin or pills for my diabetes	
53. Has any member of your healthcare team asked you about your smoking status?	
□ 0. No	
□ 1. Yes	
54. If you smoke, at your last doctor's visit (or in the index/current visit), has anyone	
counselled you about stopping smoking or offered to refer you to a stop-smoking	
program? WESTERN CAPE	
□ 0. No	
☐ 1. Yes	
☐ 2. Do not smoke	

## **G.** Complications

55. Have you suffered from or are you suffering from any of these complications of	
diabetes? (Please check all that apply)	
a. Eye Problem (Retinopathy)	
☐ b. Kidney Problem (Nephropathy)	
☐ c. Foot Ulcer/Amputation	
d. Stroke	
e. Myocardial Infarction	
f. Abnormal sensations (Neuropathy)	
☐ g. Other (specify):	
	_

Thank you for your time and participation





## OFFICE OF THE DIRECTOR: RESEARCH RESEARCH AND INNOVATION DIVISION

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19 January 2017

Dr EC Igboerika School of Public Health Faculty of Community and Health Sciences

Ethics Reference Number: BM/17/1/16

Project Title: The socio-economic and behavioural factor associated with poor

glycaemic control among adult type 2 diabetic patients attending the outpatient diabetes clinic in tertiary hospitals in Abuja,

Nigeria.

Approval Period: 15 December 2016 – 15 December 2017

I hereby certify that the Biomedical Science Research Ethics Committee of the University of the Western Cape approved the scientific methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval. Please remember to submit a progress report in good time for annual renewal.

The Committee must be informed of any serious adverse event and/or termination of the study.

pres

Ms Patricia Josias Research Ethics Committee Officer University of the Western Cape

PROVISIONAL REC NUMBER -130416-050



## UNIVERSITY OF ABUJA TEACHING HOSPITAL

P.M.B. 228, ABUJA - F.C.T. NIGERIA 907040045614, 09-2905535, www. uath.gov.ng

Our PEFUATH/HREC/PR/ 569		
Your Ref:	Date:	21/11/16

Dr Ekene Casmir
School of Public Health
University of the Western Cape

#### Letter of Approval

Proposed Title: The socio-economic and behavioural factors associated with poor glycaemic control among adult type 2 diabetic patients attending the outpatient diabetes clinic tertiary hospitals in Abuja, Nigeria.

Proposed Site: UATH

Sponsor:

Principal Investigator

Your submission to the committee on UATH Health Research Ethics Committee on the above named protocol refers.

The Committee reviewed the following documents:

- A completed UATH HREC Application form
- · Informed Consent Form
- Research Proposal
- Questionnaire/Proforma

The committee has considered the ethical merit of your submission and approved the protocol. The approval is for one year and will lapse on 21/11/17. It can be renewed on request. Modification of any part of the research methodology will require an approval.

Accept assurances of our highest regards.

Prof. B Ekele

Chairman UATH HREC



(Established by Act No 36 of 1999)

**Director of Administration** Dr. Peter O. Egwakhide NHA/ADMIN/236/V.VII Chief Medical Director/CEO

Dr. J. A. F. Momoh, MBBC, MSC, FWACP(LM)

Director of Clinical Services/CMAC

Dr. Oluseyi Oniyangi, MBBS, FWWACP (Paed), FIPNA

7<sup>th</sup> December, 2016

RE: THE SOCIO-ECONOMIC AND BEHAVIOURAL FACTORS ASSOCIATED WITH POOR GLYCAEMIC CONTROL AMONG ADULT TYPE 2 DIABETIC PATIENTS ATTENDING THE OUTPATIENT DIABETES CLINIC IN TERTIARY HOSPITALS IN ABUJA, NIGERIA NHA/EC/091/2016

Health Research Ethics Committee (HREC) Assigned number:

NHA/EC/091/2016

Name of Principal Investigator:

Dr. EKENE Casmir Igboerika

Address of Principal Investigator

Julius Berger Medical Service 6 J. T. Useni Way Lifecamp 900108 Gwarimpa Abuja

Date of Receipt of Valid Application:

9th November, 2016

#### **Notice of Approval**

This is to inform you that the research described in the submitted protocol, the consent forms, and other changes stated in the submitted research protocol addendum have been reviewed and given full approval by the Institutional Review Board (IRB) Committee, National Hospital Abuja.

This approval dates from 7<sup>th</sup> December, 2016 to 6<sup>th</sup> December, 2018. If there is delay in starting the research, please inform the HREC National Hospital Abuja so that the dates of approval can be adjusted accordingly. Note that no participant accrual or activity related to this research may be conducted outside of these dates. All informed consent forms used in this study must carry the HREC assigned number and duration of HREC approval of the study.

The National Code for Health Research Ethics requires you to comply with all institutional guidelines, rules and regulations and with the tenets of the Code including ensuring that all adverse events are reported promptly to the HREC. No changes are permitted in the research without prior approval by the HREC except in circumstances outlined in the Code. The HREC reserves the right to conduct compliance visit to your research site without previous notification.

> Dr. Oluseyi Oniyangi (DCS/CMAC)

For: Chairman, HREC, National Hospital

Plot 132 Central District (Phase II) P.M.B. 425, Garki - Abuja Nigeria

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