DETERMINANTS OF GLYCEMIC CONTROL IN TYPE 2 DIABETES PATIENTS AT KENYATTA NATIONAL HOSPITAL DIABETES OUTPATIENT CLINIC

MASTER IN PUBLIC HEALTH, UNIVERSITY OF NAIROBI

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DEDICATION

This dissertation is dedicated to my husband Dr. Gituma, my sons', Gerwyn and Gray, and to my family, mum Elizabeth and dad George, and my friends for their support and encouragement. Your motivation is a true inspiration.

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ABBREVIATIONS AND ACRONYMS.

ADA……	American Diabetes Association
BMI ……	Body Mass Index
DLF ……	Diabetes Leadership Forum
FBS …….	Fasting blood sugar
IDF…….	International Diabetes Federation
IIF…….	International Insulin Foundation
KEMRI……	Kenya Medical Research Institute
KNH ……	Kenyatta National Hospital
KSPA ……	Kenya Service Provision Assessment
MIPAA…….	Madrid International Plan of Action on Ageing
NHSSP……	National Health Sector Strategic Plan
NCDs…….	Non-Communicable Diseases
NGOs …….	Non-Governmental Organizations
OGTT …….	Oral Glucose Tolerance Test
OHA.....	Oral Hypoglycemic Agents
SDT....	Self Determination Theory
T2DM…….	Type 2 Diabetes Mellitus
UN……. …….	United Nations
WHO……	World Health Organization

DEFINITION OF OPERATIONAL TERMS.

Glycemic control: -Appropriate control of blood sugar. With a fasting blood sugar of ≤ 7.0mmol/L.

Diabetes mellitus duration: -The time interval in years between the diabetes mellitus diagnosis date and the date of the present study.

Fasting blood sugar: Blood glucose measured from venous blood after 8hours of overnight fasting or longer.

Hypertension: -A self-reported history of physician diagnosis or subjects who were receiving drug treatment for hypertension or systolic blood pressure of ≥140 mmHg and/or diastolic blood pressure of ≥ 90 mm Hg.

Adherence to medication: if the study participant took all his/her anti diabetic medication in the last seven days

Regular follow up: a type 2 diabetic patient registered at KNH outpatient unit of the hospital for follow up.

Non-modifiable risk factors: -These are factors that predispose one to develop diabetic retinopathy but no interventions are available to tame them. They include genetic factors, gender, and duration of diabetes. In this study male gender and duration of diabetes mellitus >5years are considered risk factors.

Modifiable risk factors: -These are factors that predispose one to develop diabetic retinopathy and various forms of intervention to treat them are available. They include hyperglycemia, hypertension, cigarette smoking and hypercholesterolemia.

ABSTRACT

Background of the study: Type II Diabetes Mellitus is globally with roughly 80% of those affected being found in developing countries. Glycemic control is the main forecaster of diabetes-related complications, morbidity and mortality. Poor glycaemic control is associated with disastrous complications such as foot complications, renal and heart failure, which are expensive to treat and lead to poor quality of life. There is a paucity of literature in the characterization of determinants of poor glycemic control in Kenya.

Objective: The primary objective of this study was to establish determinants of glycemic control among Type II diabetic patients attending the Kenyatta national hospital outpatient clinic.

Methodology: This was a hospital-based analytic cross-sectional survey design done at the Kenyatta National Hospital diabetes outpatient clinic. The study population was patients diagnosed with Type II diabetes mellitus and seeking treatment at the diabetic clinic. The sample size was 308 participants. Systematic random sampling method was used to select 308 participants. Data was collected using three tools, that is the questionnaire, observation guide, and physical measurements tool. Data from the research tool was entered into the statistical package for social sciences version 25 (SPSS) data editor, cleaned and analyzed. Descriptive statistics, frequency distribution tables and graphs have been used to present the data. The Pearson chi-squared test for independence was used to test the significance of the relationship between variables. Variables found significant at p-value <0.05 analysis. Statistical significance was placed at $p< 0.05$. Multivariate analysis was used to evaluate the association between predictor variables and glycemic control.

CHAPTER 1: INTRODUCTION

1.1 BACKGROUND INFORMATION

Diabetes mellitus (DM) is a metabolic disorder characterized by persistent hyperglycemia as a result of either insulin deficiency, insulin resistance, or both (1,2). Diabetes is one of the major public health apprehensions to impose a heavy global burden on public health as well as socio-economic development (3). The World Health Organization (WHO) in 2017, reported that the global prevalence of DM was estimated to be 9.3% (463 million people) and is expected to rise to 10.2% (578 million) by 2030 and 10.9% (700 million) by 2045 (4,5). In urban areas the prevalence of DM is higher at (10.8%) and highly developed nations (10.4%) compared to the rural (7.2%) areas and low-income countries (4.0%)(6). Globally there has been an increase in cases of Type 2 diabetes mellitus (T2DM) and it contributes to approximately 90% of diabetes cases (7).

In Africa and other developing countries, the number of diabetes patients has increased considerably. In 2017 around 15.5 million adults in the age group of 20 to 79 had diabetes illustrating a regional proportion of 6%. The number of adults with T2DM increased with the proximity of 170% between 1995 and 2017 in developing countries(4). In Africa there's a large proportion undiagnosed diabetes. This in turn raises their risk for morbidity and mortality due to uncontrolled chronic complications (8).

Factors associated with poor glycemic control are multifactorial and complex, they include family history, obesity, chronic physical inactivation, ethnicity or race, history of fasting glucose impairment, impaired-glucose tolerance, HbA1c 5.7%to 6.4% (38.8mmol/mole to 46.4 mmol/mole). Factors like Lifestyle, diabetes self-management (DSM), education status, age, adherence to treatment, drug compliance, morbidity, socioeconomic status, and insurance coverage are risks that affect glycaemic control (9).

Poor glycaemic control among T2DM patients remains to be a major public health concern and a significant contributor to cases of diabetic complications (10). The primary clinical goal for reducing organ damage and other diabetes-related complications remains proper glycaemic control (11). The achievement of optimum long-term Glycaemic Control is challenging in clinical practice

(12). Therefore, for optimum glycaemic control both the patients and the health care providers play a significant role in ensuring blood sugars remain within required limits(13).

T2DM is highly prevalent globally, and in Kenya as well. Studies conducted in Nairobi revealed that 57% of admissions were due to non-communicable diseases and that 27.3% of those were also from T2DM (14). T2DM in Kenya is a significant public health burden (15). Both families and communities are affected by increasing rates of morbidity and mortality from diabetes-related complications. T2DM is linked to multiple life-threatening complications that are difficult to manage. These complications affect the quality of life, morbidity, and mortality (16).

CHAPTER 2: LITERATURE REVIEW

2.1 INTRODUCTION:

The prevalence of non-communicable diseases such as diabetes is on the rise in many developing countries. Kenya is not spared from this scourge. The complications related to these diseases are disastrous and expensive to manage (17). Prevention and control are therefore the main modes of management of such conditions (4). The control of T2DM is affected by glycemic control. Poor glycemic control has been reported in many epidemiological surveys within Kenya (18). These surveys have however not elucidated the common predictors of glycemic control in our setting (19).

T2DM is a chronic metabolic condition that is caused by a combination of insulin resistance in the peripheral cells and relative insulin insufficiency (20). The signs and symptoms of T2DM include excessive thirst and dry mouth, frequent urination, lack of energy, tiredness, slow healing wounds, recurrent infections in the skin, blurred vision, and tingling or numbness in hands and feet (21). These symptoms can be mild or absent and people with type 2 diabetes may live several years with the condition before being diagnosed.

The management of T2DM aims at maintaining acceptable plasma glucose levels between 4.4mmol/L and 7.8mmol/L to prevent diabetes-related complications (22). The cornerstone of glycemic control includes lifestyle modification, medical nutrition therapy (MNT), physical activity, smoking cessation counseling, and psychosocial care that contribute to the management of T2DM (23). Failure to adhere to the treatment guidelines may increase diabetic-related complications, morbidity or mortality. These complications can be microvascular i.e., damage to small blood vessels and microvascular i.e., damage to larger blood vessels. Microvascular complications include damage to; the eyes (retinopathy) that lead to blindness, to the kidneys (nephropathy) leading to renal failure, and to the nerves (neuropathy) leading to impotence and diabetic foot disorders (which include severe infections leading to lower limb amputation). Microvascular complications include cardiovascular diseases such as heart attacks, strokes, and insufficiency in blood flow to the legs (24).

There is evidence from randomized -controlled trials, illustrating that proper control of metabolism in both type 1 and 2 diabetes could cause a delay in the onset and progression of these complications (25). Proper adherence to management modalities has been shown to result in proper glycemic control and the reduced occurrence of complications and deaths associated with T2DM. Available scientific evidence, such as that from the Diabetes Complications Control Trial, shows that the prevalence of T2DM, its complications, and associated morbidity and mortality have been on the rise (26).

Currently, the global prevalence of diabetes is 425 million people, with T2DM accounting for 85%- 95% of the cases. In Kenya, the national prevalence of T2DM is estimated to be at 3.3% (27) The prevalence of various diabetes-related complications has also been on the rise (26). Diabetes is the leading cause of non-traumatic lower-limb amputations in the world (28). According to the world health organization, as cited by Mwangi, (2016), the prevalence of limb amputation associated with T2DM on a global scale stands at about 65% while the national prevalence stands at 25% to 56%. An increase in these complications is due to an increase in the prevalence of T2DM with poor glycemic control. According to the Socio-ecological model, the factors associated with the poor outcomes of T2DM includes both social and environmental. The treatment of T2DM at KNH is guided by the current management guidelines; however, there is the persistence of poor glycemic control.

2.2 GLYCEMIC CONTROL (GLYCATED HAEMOGLOBIN A1c(Hba1c))

Glycemic control is the appropriate control of blood sugar. The specific targets for glycemic control in patients with T2DM patients include Fasting (pre-prandial) plasma glucose levels between 5mmol/L and 7.2mmol/L and HbA1c levels of less than 7% with the normal range being between 4% and 6% (29).

Patients with improper glucose management are approximately 40-60% across the globe. In the African continent, a study done in sub-Saharan Africa showed that 74.0% of these patients exhibited poor glycemic control. In Ethiopia a greater number of diabetic patients could not achieve good glycemic control (30). Locally, the situation is no different. A study conducted at the Mathari National Teaching and Referral hospital highlighted the high burden of poor glycemic

control among T2DM patients and with the burden of diabetes increasing emphasis on diabetes awareness and education to fill the practice gap in glycemic control(31). 81.6% of participants from this study had poor glycemic control with the majority of those affected being women. A study carried out in Machakos county, identified that the odds of poor glycemic control were 5 times higher in patients with inappropriate diet, low physical activity, and poor blood glucose monitoring (19).

The Glycated Haemoglobin (HbA1c) test is recommended as a standard of care (SOC) for testing and monitoring diabetes, specifically T2DM (32). HbA1c is a test that measures the average amount of diabetic control over about three months (the average red blood cell lifetime) and is used as a significant indicator and marker of glycemic control. Diabetics who manage to keep their HbA1c levels of 4.5- 6.0% are considered to have ideal glycemic control, those with HbA1c levels between 6.5% and 7.0% are considered to have optimal glycemic control, while those with HbA1c levels of more than 7.1-8.0% are considered to have sub-optimal glycemic control and above 8% have unacceptable or poor glycemic control. (33). Optimal glycemic control at KNH diabetes outpatient clinic ranges between 5.9-6.7% (41-49mmol/mol) as per the MOH guidelines (34).

Poor glycemic control is highly correlated with the high burden of diabetes complications. However, a study carried out in Ethiopia shows that this type of data is scanty in the region, particularly in Gondar, regarding factors associated with poor glycemic control and the relationship between glycemic control and complications in T2DM (1). Glycemic control i.e., lowering blood glucose to normal range remains the primary therapeutic objective for diabetes management and prevention of target organ damage and other diabetes-related complications. Glycemic control is fundamental to the management of diabetes.

The main challenge of modern diabetes management is how to achieve glycemic control (4). Plasma glucose or HbA1c, and patient self-monitoring of blood glucose (SMBG) remain the two primary techniques for patients and health care providers to assess the effectiveness in the management of glycemic control (35).

The HbA1c is an accurate and easy-to-administer test with on-the-spot results availability and can be an effective tool in establishing the diagnosis of diabetes, especially in low- and middle-income countries and hard-to-reach populations. As the epidemic of diabetes continues to grow worldwide, the HbA1c test may continue to be implemented as part of the diagnostic and prognostic tool, leading to better patient care and successful clinical outcomes (32).

Self-monitoring blood glucose (SMBG) is an essential component of diabetes self-care in obtaining glycemic control (36). There has been a great controversy on whether self-monitoring of blood glucose is appropriate for patients with T2DM. Studies suggest that the use of glucometers can be useful in providing information on a person's blood glucose patterns over time (37). People with T2DM should self-monitor their blood glucose anywhere from 1 to 2 times per day to once every few hours. It is recommended for patients to check not only in the morning fasting condition but at various times of day to be aware of whether their blood glucose levels are much higher or lower than normal (at bedtime). Also, it is recommended for people with pre-diabetes or mild T2DM to self-monitor their postprandial (after meal) glycemic levels (36,38).

2.3 SOCIODEMOGRAPHIC FEATURES OF TYPE 2 DM PATIENTS

2.3.1 Age

A study identified age as one of the factors that are associated with poor glycemic control(39). The ratio of patients with poor glycemic control was higher with age and a notably high proportion of poor glycemic control was observed in patients who had diabetes for a long period. This is echoed in a study by (40) which found that the majority of younger patients under the age of 45 were more likely to adhere to insulin therapy compared to older patients.

In a study on theoccurence of diabetes, the age of T2DM individuals influences self-management and blood sugar control. Adherence to insulin treatment was poorer in older people relative to younger patients. Furthermore, older patients were less able to cope with lifestyle changes compared to younger patients (40). Another study revealed that age tends to be linked to enforcement and various abilities in self-management. Older people with type II diabetes handle

their oral hypoglycemic drugs more efficiently than younger people. Nevertheless, the impact of age on other aspects of self-management has not been published (41).

2.3.2 Sex

A study on glycemic control showed that sex plays a significant role in glycemic control (42). Male diabetics have been observed to be living more effectively with diabetes, less depression, and anxiety but more energy and better positive wellbeing. They are more satisfied with their management of the disease and experience lesser social worry. Gender differences become crucial when one has to learn to live effectively with diabetes. Female diabetics need to develop a more positive attitude towards the disease and its management (43).

Male patients are more likely to cope with lifestyle adjustments such as diet and exercise. Studies further showed that in the case of there is a difference in how the sexes perceive dietary changes, women tend to view dietary change as a personal matter, while men view it as a family issue. Women get less support from husbands than men received from their wives. This may extend to other self-management practices (35). Similarly, Issa in a study done in 2018 showed that gender plays a major role in influencing diabetic patients on self-management. Men were likely to adhere to the modalities of treating diabetes compared to their female counterparts. Male patients can easily modify their lifestyles to prevent diabetic complications.

2.3.3 Residence

The residence of a patient can easily influence self-management and sugar control among T2DM patients as the rate of knowledgeable diabetic urban residents was seen to be significantly higher(44). According to the report, it is typically ascribed to better access to information among urban residents. Significant positive relationships between knowledge level and education, working status, and income were noticed. Similar findings were reported in studies by (35) where knowledge improved with an increase in the level of education and socioeconomic status. The general rate of compliance to prescribed medications was noticed among two-thirds of participants but this rate varied according to socio-demographic conditions where patients <30 years, urban

residents, educated and working patients with higher income were significantly more compliant (45).

2.3.4 Level of education

According to the survey by (12), most of the diabetic patients that developed diabetic complications due to poor glycemic control had a lower level of education. This could be a reason that most of the patients that had less educational background had little information regarding blood sugar control and self-care thus contributing to cases of complications. In Ethiopia, a study indicated that most of the diabetic individuals who developed diabetic complications did not have formal education (46). Health education is therefore a very important aspect of care among diabetic patients. In a study on determinants of glycemic control it was found that educated patients who were more knowledgeable of their disease were more successful in performing self-management practice, thus were less likely to develop poor glycemic control(46). The study also indicated that compliance behavior increased with the amount of knowledge that the patients acquired. According to the survey in Lagos Nigeria, it showed the majority of the patients that developed diabetic complications had a lower educational background and also had little information on self-care management(35,47).

2.3.5 Socioeconomic status

2.4.5.1 Occupation

There is little research concentrated on the relationship between occupation and glycemic function. Findings from a cross-sectional data from the Korea National Health and Nutrition Examination Survey (KNHANES) found that jobs with long hours of work contribute to sub-optimal glycemic regulation for those with diabetes (44). It was attributed to rising stress levels resulting in unhealthy habits such as over-eating. The study also suggested that workers in blue-collar employment are more likely to have low blood glucose regulation than those working in offices due to insufficient knowledge of self-care activities and inadequate social support (48). In the Brazil Qualitative Sectional Analysis on Type II Diabetes, those with an occupation had poor self-care activities due to insufficient free time for disease management (3).

2.4.5.2 Income levels

In previous studies on the impact of socioeconomic status on the control of blood sugars revealed that the level significantly influences cases of uncontrolled blood sugars. The majority of patients that had uncontrolled sugars were of low-income levels (12). Income rates Minority groups and those without insurance in the United States study have a higher rate of low glycemic control. Due to lack of insurance, there is a reduction in access to health care and thus a greater risk of impaired glycemic regulation (49).

2.4 KNOWLEDGE OF GLYCEMIC CONTROL

2.4.1 Knowledge of Diabetes

A survey (45), revealed that knowledge of diabetes was significant in self-care and glycemic control. The study pointed out that the estimation of the baseline knowledge about diabetes among the population has significant public health applications as it helps in developing targeted educational programs (45). Most diabetic patients in Australia pointed out that if left untreated, diabetes can cause many complications (27). The finding is in line with as study that showed most of the T2DM patients in the United States are knowledgeable about diabetes and related complications thus most of them know the required management (9).

A study on Diabetes Attitudes, Wishes and Needs (DAWN) show that most of the respondents had low knowledge of diabetes and related complications and were unaware that the T2DM complication could occur to any diabetic patient, in turn influencing glycaemic control and self-management (50). However, showed that two-fifths of the study participants were not aware of any diabetic symptoms, and only 8.5% could identify all symptoms (51). In contrast, a higher knowledge was reported by previous studies from North Ireland, Canada, Iran, and Jordan, where partial blindness was known by the majority of respondents as complications related to untreated diabetes (Hipwell, 2014; Anon., n.d.)(49).

In a study done in Nigeria illustrated that most of the patients in public hospitals had low knowledge on diabetic symptoms, about half of respondents were not aware of any symptoms and approximately 10.4% could identify all symptoms (33). The most common symptoms recognized by respondents were confusion, trouble speaking or understanding others followed by numbness, weakness of the face, arm, or legs (34.7%), dizziness, trouble walking, and loss of balance or coordination (32.2%).

In a Kenyan study, most of the younger T2DM patients have little knowledge on glycemic control as they cannot define or mention symptoms related to the condition (48). According to the study, many diabetic patients in Kenyans are not aware of the factors that contribute to cases of diabetic complications. Most people were not aware that a disease like diabetes mellitus can predispose one to diabetic retinopathy (52).

2.4.2 Knowledge of lifestyle modification

Knowledge of lifestyle modification measures is paramount in reducing the incidences of diabetes. The majority of the general population in developing countries like India have little knowledge of lifestyle modification measures thus contributing to high incidences of diabetic complications (27).

In turn, Deepa revealed that most of the patients in Singapore have little knowledge of ways of modifying lifestyle (53). A cohort study conducted in Japan among type 2 diabetic patients was conducted at Tokyo Women's Medical University also pointed out that most of the young populations have a high level of knowledge on ways of preventing diabetic complications compared to the older population through lifestyle modification (36). In a study conducted in Singapore, most of the young population pointed out that exercise and a healthy diet is important in the prevention of diabetic complications. This was echoed by Ghazanfari, (Ghazanfari, 2017) who showed most of the older population have little knowledge of preventive measures to diabetic complications as they mentioned exercise as the only way to prevent diabetic complications (35). A study by IDF showed that most of the populations working in the United Kingdom have a high level of knowledge concerning ways of preventing diabetic complications (54). Most of these populations identified that quitting cigarette smoking, engaging in physical activity, weight loss, and reduced sugar intake were measures for preventing and reducing diabetes complications. This

was echoed in a study in the United States, adults aged 18–26 years identified similar benefits (55). In a study done on native American women with previous gestational diabetes, the majority were aware of the roles of physical activity, diet, cholesterol, and family history related to the risk of diabetic complications (56). In another study conducted in French West Indies, women identified physical exercise or sports activity as a precaution to avoid T2DM complications, followed by eating less fat, drinking less alcohol, and not smoking (Engelgau, 2014)(13). A study conducted a study in Taiwan and found that middle and older aged people have only limited knowledge regarding diabetic complications prevention, although many are likely to have risk factors for diabetic complications. An unhealthy diet, obesity, and family history were the most mentioned risk factors for poor glycaemic control by participants of the study (52). These are fairly dissimilar from the factors generally concerned by health professionals, such as hypertension, hyperlipidaemia, and hyperglycaemia (56).

2.4.3 Knowledge on Importance of Medical Follow-ups

Studies on poor glycemic control showed most of the diabetic patients were aware of the benefits of seeking medical help when they present with any symptoms related to diabetes (57). Most of the patients stated that it is beneficial to seek medical help when symptoms appear and to visit the clinic for follow-ups (12). Most of the patients stated that with medical check-ups medical practitioners will be able to identify any anomalies and appropriate intervention be done. Therefore, knowledge of the benefits of health-seeking behaviors helps to improve self-management and ways to control sugars levels (58).

Most of the patients aged 45 years in the United States were aware of the importance of seeking medicals helps and frequent check-ups. However, the younger population had little knowledge in regards to medical check-ups as they stated that they feel to be healthy and they will only seek medical help when they will feel sick and have symptoms of diabetic complications (59). Scanlon showed that most young diabetic patients in Tanzania had little knowledge about seeking medical help and frequent medical examination (58). Most of the respondents pointed out seeking frequent medical examination and check-ups are expensive and they find it not necessary. Correspondingly the finding in Sweden showed that most of the youths had little information on the benefits of

frequent medical examination, as they stated that there is no need to visit the hospital if there is no symptom (60).

Most diabetic patients in Nigeria were found to have adequate knowledge on the benefits of having good health-seeking behaviors as most of the diagnosed patients stated that visiting health facilities during the appointment will help to identify any problem. However, most of the patients that had not been diagnosed with diabetes were found to be having little knowledge toward health-seeking behavior as most of them stated that frequent visiting for health care services and check-ups can lead to discovering problems that will affect their quality of life (33).

2.4.4 Knowledge towards the self-care of diabetes

A study by Borah in 2017 showed that most of the diabetic patients are knowledgeable on the care of diabetic retinopathy as most of the patients reported that diabetic retinopathy can be minimized with a combination of strict blood sugar control and routine screening with though even with optimal medical care. A strict adherent to medications will prevent cases of diabetic complications(1). The study further stated that maintaining near-normal blood sugar can decrease your chance of developing diabetic complications such as diabetic retinopathy and can help keep existing retinopathy from getting worse. Most of the patients stated that the best treatment for diabetic complications is to prevent them. The strict control of your blood sugar will significantly reduce the long-term risk of diabetic complications. They further pointed out that treatment usually will not cure diabetic complications nor does it restore complications, but it may slow the progression of complications and without treatment, diabetic complications progress steadily from minimal to severe stages.

In india a study reported that only 10% of the persons with diabetes knew about the treatment of diabetes while others were unaware of the methods of treating cases of diabetes (61). Therefore, the divergence in knowledge on diabetic complications and modes of prevention and treatment ought be taken into consideration while preparing health promotion strategies for the better impact of education materials (62). Earlier studies, in both developed and developing countries, it was established that knowledge on care and management of diabetic is generally poor among patients

with diabetes. This agrees with the findings that 53% of participants believed diabetic complications could be controlled by reducing sweet and sugar (34,52).

A study by Njenga in 2014 showed that most of the diabetic patients have little knowledge on the care of diabetics as most of them pointed out that it cannot be controlled while some had misconceptions about the nutritional advice for people with diabetes (53). They stated that the reduction of sugar and carbohydrate controls diabetes. Rather, the key aim is to lessen sum weight through the change of lifestyle and behavioural such as the increased sum of exercise, reduction on the intake of extremely refined foods, consuming more legumes, vegetables, whole grains, and fruits, and less or smoking cessation. Similarly, Waari, again showed in 2015 that most of the diabetic patients in Kenyatta national hospital had little knowledge in the management of diabetic retinopathy as most of the patients stated that the condition cannot be controlled once it occurs, nothing can be done (63).

2.5 CLINICAL FACTORS

2.5.1 Diabetes Medication Period

A study on self-care among type II diabetes revealed that there was an important relationship between duration of taking T2DM treatment and poor blood sugar control (16). There was a higher number of patients with prolonged medication period that were having cases of uncontrolled blood sugar (16). Long-term diabetes therapy patients have poor blood sugar regulation as per some cross-sectional diabetic studies (36). A multi cross-section survey of glycaemic control in China reported that longer-term diabetics are more likely to have complications from diabetes. This results in a lower beta-cell function that necessitates intensive treatment (35).

2.5.2 Trends in drug use

The trend in drugs use in T2DM defines the glycaemic levels (64). Patients with a high pill burden appear to have poor glycaemic control due to the heavy pill pressure that can be linked to non-adherence (65). It is according to a cross-sectional study performed on diabetics of type II (43).

Patients with oral hypoglycaemic agents (OHA) have poor glycaemic regulation due to progressive beta-cell loss compared with patients on diet only. Sub-optimal dosages and the use of sub-standard medications may also lead to poor glycaemic regulation (38). A higher body mass index (BMI) leads to poor glycaemic control. Also, glycaemic levels are influenced by under-dose and varying total daily doses. Also, OHAs have impaired glycaemic regulation compared to insulin therapy patients. This makes it difficult to regulate OHAs in combination with insulin in a China multi-centre report (66).

2.5.3 Diabetes Complications

DM complications are found to be higher among patients with poor glycemic control and type 2 DM (67). According to a cross-sectional study conducted in Ethiopia, it revealed that a higher number of patients with diabetic complications had poor glycemic control (56). Diabetes complications due to poor glycemic control were major concern as was associated with high rates of morbidity and mortality in affected patients. The complications may be macro-vascular or micro-vascular and affect the quality of life of patients, in addition to the high pill burden imposed (63). A cross-sectional study among diabetics in Kenya found that people with diabetes complications have low blood glucose regulation due to the complications and sugar levels management pressure. An analysis of risk factors for impaired glycaemic regulation has also shown that the more complications of diabetes, the poorer the glycaemic control level (40).

2.5.4 Cases of High blood pressure

There have been a higher number of individuals treated for diabetes that developed hypertension. A study done among primary healthcare outpatients in Al Ahsa Saudi Arabia illustrated the highest number of uncontrolled BP and poor glycemic control was among the age group of 45 and 49 years. A significant number (84%) had uncontrolled hypertension, and uncontrolled T2DM 67.3% (65). Depending on obesity, race, and age, hypertension affects 20–60% of diabetic patients (49). According to Ghana cross, sectional research showed that the co-management of diabetes through glycaemic control and hypertension by blood pressure regulation is crucial in the treatment and prevention of diabetes.

2.5.5 Body Mass Index

Obesity (BMI) is associated with poor glycaemic control (67). Studies have confirmed very strong relationships between obesity, the insulin resistance of tissues, and poor glycemic control. Elevated BMI in diabetic patients generates a high risk of diabetes complications, including cardiovascular, cerebral vessel, kidney, and lower limb diseases, which has been confirmed among elderly people in the USA(13,38). Any increase in BMI above the normative value is associated with an increased risk of the occurrence of poor glycemic control (53). Meta-analysis reveales, a strong non-linear relationship between BMI and the overall mortality rate in patients with type 2 diabetes. The body mass index proved to be a risk factor for many diseases and impaired glycaemic control. The overweight or obese are named for patients with high BMI. There are more and more overweight and obese people due to lifestyle changes (23).

2.6 STATEMENT OF RESEARCH PROBLEM

Up to 40% of Kenyan Type II diabetic patients on treatment and clinical follow-up have poor glycemic control(19). T2DM is a chronic metabolic condition that is caused by a combination of insulin resistance in the peripheral cells and relative insulin insufficiency (20). The signs and symptoms of T2DM include excessive thirst and dry mouth, frequent urination, lack of energy, tiredness, slow healing wounds, recurrent infections in the skin, blurred vision and tingling or numbness in hands and feet. These symptoms can be mild or absent and people with type 2 diabetes may live several years with the condition before being diagnosed. The management of T2DM aims at maintaining proper glycemic levels between 4.4mmol/L and 7.8mmol/L. (22) to prevent diabetes-related complications. The cornerstone in the management of T2DM is lifestyle management as a fundamental aspect of diabetes care and includes diabetes self-management education and support (DSMES), medical nutrition therapy (MNT), physical activity, smoking cessation counseling, and psychosocial care (23). Failure to adhere to the treatment guidelines may increase diabetic-related complications, morbidity, and mortality. These complications can be microvascular i.e., damage to small blood vessels and macrovascular i.e., damage to larger blood vessels. Microvascular complications include damage to; the eyes (retinopathy) that lead to blindness, to the kidneys (nephropathy) leading to renal failure, and to the nerves (neuropathy) leading to impotence and diabetic foot disorders (which include severe infections leading to lower limb amputation). Macrovascular complications include cardiovascular diseases such as heart attacks, strokes, and insufficiency in blood flow to the legs (68). There is evidence from large randomized-controlled trials that good metabolic control in both type 1 and 2 diabetes can delay the onset and progression of these complications (21,69). Lack of proper adherence to management modalities has been shown to result in proper glycemic control and the reduced occurrence of complications and deaths associated with T2DM (23).

Available scientific data, such as that from the Diabetes Complications Control Trial, show that the prevalence of T2DM, its complications, and associated morbidity and mortality have been on the increase, both nationally and globally(26). Currently, the global prevalence of diabetes is 425 million people, with T2DM accounting for 85%- 95% of the cases. In Kenya, the national prevalence of T2DM is estimated to be at 3.3% (27) The prevalence of various diabetes-related complications has also been on the rise (70). Diabetes is the leading cause of non-traumatic lower-

limb amputations in the world (28). The prevalence of limb amputation associated with T2DM on a global scale stands at about 65% while the national prevalence stands at 25% to 56%. An increase in these complications is due to an increase in the prevalence of T2DM with poor glycemic control. According to the Socio-ecological model, the factors associated with the poor outcomes of T2DM are both social and environmental. Even though the treatment of T2DM at KNH is guided by the current management guidelines, there is the persistence of poor glycemic control. It is, therefore, necessary to determine the factors associated with the increasing prevalence of poor glycemic control if the prevalence of complications associated with T2DM is to be reduced.

Diabetes is one of the costly chronic diseases and imposes a substantial economic burden on the health sector, society, and individuals. The current global healthcare expenditures due to diabetes are about US$376 billion and the figure is expected to increase to US$490 billion by 2030 (35). Also, T2DM accounted for $245 billion in economic costs in 2012 alone for diagnosed cases in the United States and accounted for $69 billion in reduced productivity (71). Poor glycemic control in T2DM is highly correlated with a high burden of chronic diabetes complications, psychiatric events that lead to poor quality of life, and increased levels of morbidity and mortality (1). The cost associated with diabetes-related complications represents the most exorbitant part of the national healthcare expenditure for diabetes and is higher than the costs of managing diabetes itself (72). This affects government funding to other health projects such as Maternal and Child Health projects and causes diversion of resources to the treating of diabetes complications (23). The cost of diabetes on the society is both direct (opportunity cost of resources used for treatment) and indirect (measures the value of resources lost due to the illness), and leads to loss of productivity due to an increase in morbidity and mortality (measured in lost earnings) (58). This will also result in funds being used to; recruit specialized personnel to provide a holistic care approach to patients with complications, procure pharmaceuticals for managing complications, transport costs to hospitals, laboratory visits, and more. If the situation remains uncontrolled, opportunity cost effects will affect the countries health expenditure and gross domestic product (GDP). To prevent these consequences, we must establish the determinants of poor glycemic control in T2DM patients with the aim to mitigate the gaps that are identified in the study.

2.7 JUSTIFICATION OF THE STUDY

Despite the efforts of promoting and improving the quality of life among patients with diabetes, there is still an increased number of patients presenting with diabetic complications due to poor glycemic control. Kenyatta National referral hospital has recorded a high number of diabetic complications and mortality related to diabetes and the hospital's diabetic clinic being one of the largest clinics in the country, therefore, serves as the perfect study area to ascertain determinants to poor glycemic control. Addressing the issue of non-communicable diseases such as T2DM would help towards achieving the Sustainable development goal (SDG) three (3) as glycemic control would reduce morbidity and mortality.

Through identifying factors that influence poor glycemic control, the study will provide a basis for quality improvement programs to reduce the rising burden of poor glycemic control in diabetes. The study is of public health benefit since it highlights factors associated with poor glycemic control and will give appropriate recommendations. The study finding will help the stakeholders develop policies and guidelines for the management of diabetic patients. The research findings will also form a basis for future similar studies and add to the limited body of literature on the subject.

Diabetes mellitus is both a National and Global burden that requires rigorous management to avert diabetes complications and mortality attributable to diabetes. The majority of Kenyans living with T2DM are elderly with limited knowledge about diabetes, negative attitudes, and poor management practices about the disease (3). Poor glycemic control may lead to early onset of irreversible diabetes complications which include retinopathy leading to blindness; nephropathy leading to renal failure; peripheral neuropathy with risk of foot ulcers, amputations, and autonomic neuropathy causing gastrointestinal, genitourinary, and cardiovascular symptoms and sexual dysfunction (35). Correct dietary intake is crucial in the management of T2DM. Studies have shown that health workers disseminate knowledge on dietary recommendations in the management of T2DM to diabetic patients, but compliance is still a challenge to many. Studies on diabetes in Kenya majorly focus on overall knowledge, attitudes, and practices in the management of T2DM as well as other aspects of diabetes mellitus (43).

The trend of type 2 diabetes patients is on the rise and this calls for more similar studies to support Mathari National, Teaching and Referral Hospital achieve its standard of care to diabetes patients (29). Determination of factors that influence compliance with these recommendations is also not well documented. This study, therefore, will assess the determinants of glycemic control in T2DM patients at the Kenyatta National Hospital.

2.8 RESEARCH QUESTIONS.

1. What is the prevalence of patients with poor glycemic control among patients with Type II diabetes attending the KNH DM clinic?
2. What are the socio-demographic factors associated with glycemic control among patients with Type II diabetes attending the KNH DM clinic?
3. What is the knowledge on self-care-related factors associated with glycemic control among patients with Type II diabetes attending the KNH DM clinic?
4. What are the clinical related factors associated with glycemic control among patients with Type II diabetes attending the KNH DM clinic?

2.9 OBJECTIVES

2.9.1 BROAD OBJECTIVES

The study aimed to ascertain the determinants of glycemic control in type 2 diabetes patients at Kenyatta National Hospital

2.9.2 SPECIFIC OBJECTIVES

1. To estimate the prevalence of patients with poor glycemic control among patients with Type II diabetes attending KNH DM clinic
2. To assess the socio-demographic factors associated with glycemic control among patients with Type II diabetes attending KNH DM clinic
3. To assess knowledge on self-care related factors associated with glycemic control among patients with Type II diabetes attending KNH DM clinic
4. To identify clinical factors associated with glycemic control among patients with Type II diabetes attending KNH DM clinic.

2.10 CONCEPTUAL FRAMEWORK

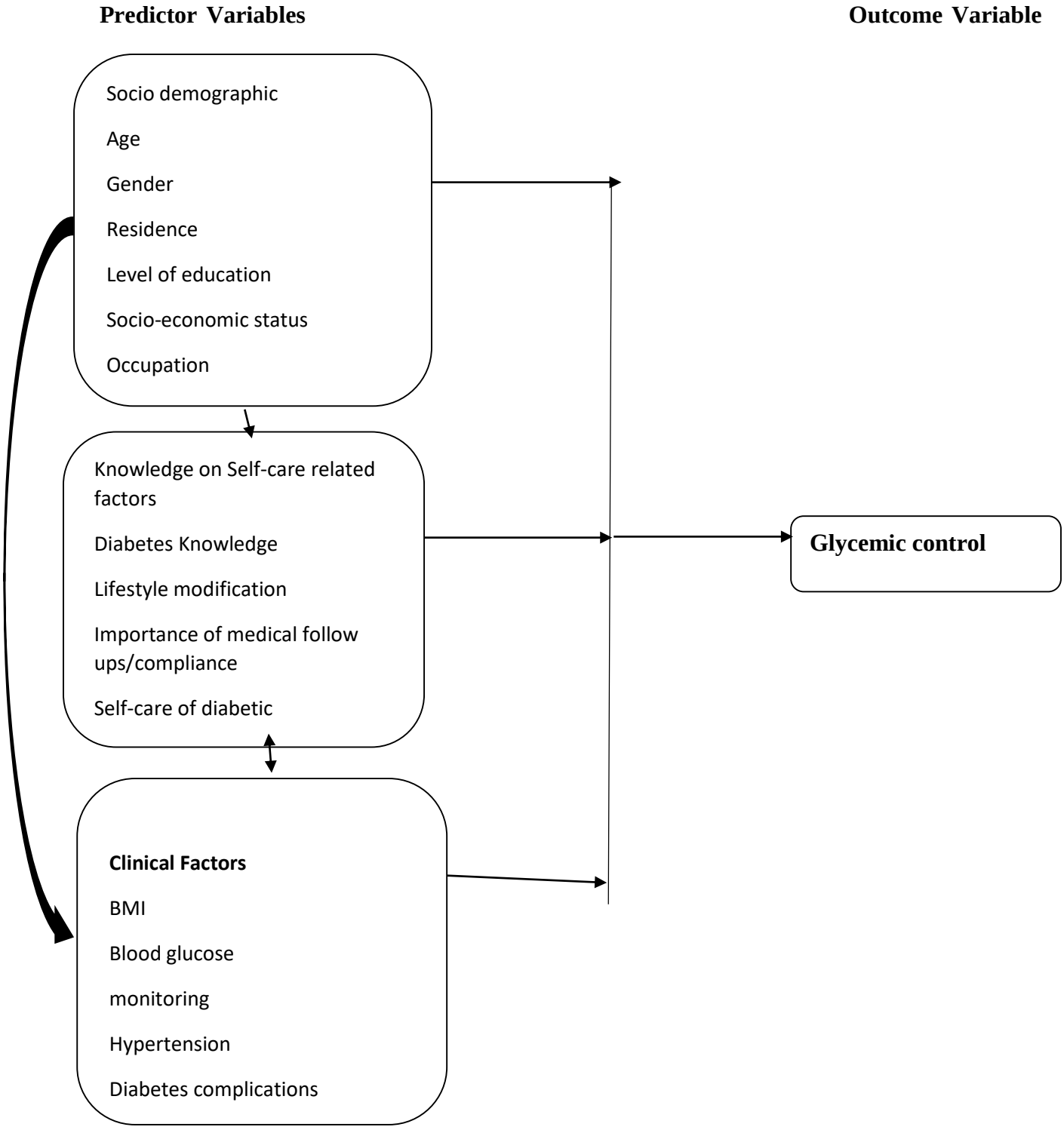


Figure 2. Conceptual Framework

CHAPTER 3: METHODS AND MATERIALS

3.1 STUDY DESIGN

This was a hospital-based analytic cross-sectional survey design.

3.2 STUDY SETTING:

Kenyatta National Hospital (KNH) diabetic clinic, Nairobi.

KNH is the largest public, a tertiary referral hospital in Kenya and is located in Nairobi County which is coterminous with the city of Nairobi, the countries capital and largest city of Kenya. It is located 3.5 kilometers west of the city's central business district. As the largest public hospital in the East African region, KNH has a bed capacity of 1800 beds and a staff of over 6000 health workers under the Ministry of Health (MOH).

KNH has a specialized diabetic clinic located in the diabetic and endocrinology center and is managed by a team of diabetologists, interns, graduate resident doctors, nutritional doctors, nutritional assistants, and nurses (both qualified and in training). The diabetic outpatient clinic attends to about 400 patients per week from Monday to Friday and receives referrals from all over the country many from the middle working class and low-income population. It has a steady flow of patients with diabetic complications and accounts for approximately 11.4% of all admissions.

The Kenyatta National Hospital diabetes unit provides a daily diabetes clinic (Monday to Thursday) and a consultant diabetes clinic every Friday, which runs from 8 am to 5 pm daily. The clinic sees an average of 50 patients per day. Services such as screening for diabetes, hypertension, high cholesterol, obesity and diabetes education sessions are offered to patients attending the clinic daily. Newly diagnosed patients and follow-up patients are seen in the clinic. Screening of patients' glycated hemoglobin (HbA1c) is done routinely and used to monitor long-term glycemic control in diabetic patients attending the clinic. Services of screening for diabetic retinopathy, diabetic neuropathy, and other diabetic complications are also done at the diabetic

clinic. A patient review involves triage and daily glucose monitoring history taking and clinical examination as well as surveillance for complications of diabetes.

3.3 STUDY DURATION

This study was conducted between July 2021 and September 2021.

3.4 STUDY POPULATION

The study population included T2DM patients seeking treatment at the KNH and attending the diabetes outpatient clinic within the duration of the study.

3.5 SELECTION CRITERIA

3.5.1 Inclusion criteria:

Patients that were included are those;

1. Above the ages of 18years
2. Had been clinically diagnosed with T2DM
3. Attending the KNH diabetes outpatient clinic with at least 1 reading of HbA1c.

3.5.2 Exclusion Criteria:

1. Non-consenting patients.
2. Were Newly diagnosed type II DM
3. Patients unable to adequately give responses due to mental health concerns.
4. Patients on drugs known to interfere with glucose metabolism such as steroids.

3.6 SAMPLE SIZE ESTIMATION:

Fisher's formula will be used to estimate the sample size.

$$\mathbf{n} = \frac{Z^2 P(1-P)}{d^2}$$

Where: -

n= is the desired sample size to be determined,

Z^2 = the critical value at 95% level of significance (1.96)

P= the expected prevalence that can be obtained from similar studies (31).

d= precision, corresponding to effect size (for our case 0.05), and the desired statistical power (0.8 for this study) respectively. With the above assumptions from previous workers studying similar parameters (impaired glycemic control), in substitution:

$$n0 = \frac{1.96\text{^}2*0.761(1-0.761)}{0.05^2} = 280$$

Estimating a 10%nonresponce = 0.1*280 = 28

280+28 = 308

The calculated sample size is 308 patients diagnosed with diabetes. The outcome was then analysed as those with adequate glycaemic control and those with poor glycaemic control.

3.7 SAMPLING METHOD

Study method used was systematic random sampling.

3.8 SAMPLING TECHNIQUE

A sampling frame included all T2DM adult patients attending the KNH diabetes outpatient clinic. Simple random sampling using a random number generator was used to select the first participant. Subsequent participants were recruited by stratified random sampling at regular intervals to minimize selection bias. Participants were selected at steady intervals i.e., every K^{th} patient

Where K = S/N

S is the total number of patients in the sampling frame

N is the sample size

K^{th} =S/N

K=1800/308=5.6

$K^{th}=6^{th}$

A systematic random sample of 308 T2DM patients seeking care at the diabetes center at the KNH was collected over 3 months.

With 6 being constant, the researcher selected the first participant using a random number generator to select the first respondent and systematically selected every 6^{th} respondent. The researcher administered the questionnaire to the participants that accepted to participate in the study by giving consent. Those who chose to withdraw from the study were allowed to do so without replacement. The data was collected regularly from Monday to Friday until the sample size was achieved.

3.9 VARIABLES:

3.9.1 Outcome variable:

1. Glycemic control

3.9.2 Explanatory variables:

- **Socio-demographic factors**
  - Age
  - Sex
  - Marital status
  - Residence
  - Level of education
  - Socioeconomic status
    - Occupation
    - Income levels
- **Knowledge related factors** (73)
  - Knowledge of Diabetes
  - Knowledge of Lifestyle modification
  - Knowledge on Importance of medical follow-ups
  - Knowledge on Self-care of diabetics
- **Clinical related factors**
  - Duration of disease
  - Diabetes Medication Period
  - Diabetic related Complications
  - Cases of High blood pressure
  - Body mass index (BMI)

Explanatory variables and their measurements in the study are as shown in table 1 below:

Explanatory Variables	**Measurement**
Sociodemographic Factors Age	Measured in years
Sex	Assessed as male or female
Marital Status	Assessed as Married, Single, Widow/widower divorced/separated
Level of education	Classified as primary education, secondary education, college/university education, informal education and none
Religion	Captured as Christian, Muslim or other
Occupation	Captured as employed or unemployed
Income	Categorized as <=5000, 5001-20000, 20001-40,000
Knowledge on self-care related Factors Knowledge on Diabetes	Categorized as adequate or poor knowledge
Lifestyle modification	Categorized as yes or no
Regular medical follow-ups	Categorized as yes or no
Self-care of diabetics	Categorized as yes or no
Clinical factors BMI	Computed as weight (kgs) / height in meters squared
Blood glucose measurement	Assessed using Random Blood Sugar
Duration of diabetes	Assessed in years
Diabetes Treatment	Categorized as oral medication, injectable or both
Hypertension	Assessed as being present or absent
Hypertension treatment	Assessed as yes or no
Diabetic Complications	Assessed as being present or absent

***Outcome Variable*:** Glycemic control- HbA1c levels was used to assess glycemic control. Adequate glycemic control- HbA1c level being less than 7%, Poor glycemic control- HbA1c levels equal to or above 7%.

3.10 DATA COLLECTION TOOLS

Data was collected using three tools, that is a pre-structured questionnaire, observation guide, and physical measurements tool. A researcher-administered questionnaire consisting of open and closed-ended questions will be used to collect data. The questionnaire was subdivided into three sections to address research questions. The section included socio-demographic data, clinical characteristics, knowledge on self-care management data, medication adherence, barriers to adherence, and attitude towards diabetes. The other tools used include the weighing scale which will be used to collect participants' weight and tape measure to collect their height and waist circumference. All available readings of participants' hemoglobin A1c (HbA1c) and fasting blood sugar (FBS) were abstracted from patients' records. Their last three fasting blood glucose and charts of their HbA1c to assess their level of glycemic control, as well as the type of treatment regimen the patient, will be receiving. Poor glycemic control was defined as HbA1c level >7%.

3.11 DATA COLLECTION STRATEGIES

3.11.1 DATA COLLECTION PROCEDURES

A sampling frame was made using the patients' register. Simple random sampling was used to select the first participant using a computer random number generator. Subsequent participants were recruited at intervals by use of the systematic random sampling technique to minimize selection bias. Participants were selected from the sampling frame at steady intervals of every K^{th} participant where K was 6.

After recruitment and attainment of consent from participants, structured questionnaires were administered through one-on-one interviews and other necessary information obtained from participants. Clinical records were reviewed for medications in use; any complications suffered

and the last two HbA1c readings. All collected data will remain anonymous and coded to ensure confidentiality. Data was coded, entered and managed in a Microsoft Access Windows 10 database and at the end of data collection exported to SPSS V27 2020 version for analysis. The baseline characteristics were summarized and presented as means, medians and proportions.

3.11.2 RECRUITMENT OF STUDY ASSISTANTS

The study assistants were registered Nursing officers from the diabetic outpatient department and hold a degree in Nursing from the school of Nursing; University of Nairobi college of health sciences.

None of the participants had a direct relationship with the researcher or the research assistants, to avoid conflict of interest such as contract, reporting affiliation, or any connection that could inform study bias. The research assistants were trained in the skills to enable them to conduct the designed study.

3.11.3 QUALITY CONTROL MEASURES OF DATA COLLECTION

a. Training of research assistants

The principal investigator together with the statistician will conduct relevant training in the clinical area that will involve questionnaire administration, patient interviews and file perusal for relevant HbA1c data.

Research assistants will also be trained on research ethics and monitored to ensure that they obtain informed consent from all participants before conducting any interviews (Appendix II: research participation consent form.)

The principal investigator and the research assistants interviewed the participants after they had been reviewed by the clinicians and administered the questionnaire and anthropometric measurements as required.

b. Pre-testing of data collection tools

A 10% (n=10) of the questionnaires were administered for pretesting purposes. According to Chaudhary, 2018, a good pretesting should be composed of 10-25 questionnaires or 10% of the total participants (74). The pretesting was done at Mbagathi county hospital. Pretesting helps to check the reliability of answers, estimated amount of time taken to fill the questionnaire, and the common flow of the questionnaire (75). Mbagathi county referral hospital is within the same administrative locality as KNH.

3.12 DATA ANALYSIS

Data from the research tool was coded and entered into the statistical package for social sciences (SPSS) version 25. Double data entry was done along with data cleaning to ensure accuracy. Continuous variables were summarized using mean, range and standard deviation. The prevalence of poor glycemic control was computed by proportion and presented using frequency distribution tables and graphs. Knowledge of study participants was categorized. If a respondent managed to correctly identify 10 of the listed responses, that respondent was deemed to have good knowledge. From this assumption, the maximum possible score per respondent was 8 points. A cumulative score was computed for each of the respondents. Using the median score, the cut-off point the individual knowledge scores were then categorized as good knowledge of causes, symptoms and complications of diabetes. Those who scored 5 and below were classified as having poor knowledge, while those who had scored below were classified as having good/adequate knowledge.

The Pearson's chi-squared test of significance was used to test the relationship between the predictor and outcome variables. Multivariate correlation analysis was used to explain the relationship between random blood sugar and significant predictor variables. The odds ratio was used to assess the association between glycemic control and predictor categorical variables. Variables found significant in the statistical analysis were included in multivariate logistic regression analysis. Statistical significance will be at $p< 0.05$.

3.13 DATA STORAGE AND MANAGEMENT

Filled questionnaires and filled forms were locked in a cabinet accessible only, to the Principal Researcher, and Research Supervisors. Back up of soft copy of the data was stored in password-protected hard drives. The computers in which the data will be stored will have passwords that and were only accessible to the principal researcher. The data will be stored for 10 years after which the hardcopy papers will be shredded into pieces and the soft copy data will be deleted and passwords removed from the computers.

3.14 ETHICAL CONSIDERATIONS

Ethical approval was sought from the Kenyatta National Hospital - the University of Nairobi Ethics and Research Committee under the reference number Ref: KNH-UoN ERC/A/269 and all appropriate legal and ethical regulations concerning the use of human volunteers in a study were adhered during to the whole duration of the study. Data collection was initiated only after ethical approval was obtained. Participants or their next of kin were requested to give written informed consent during recruitment. Patients who will be involved in the study will sign a consent form (Appendix I and II). Participants were informed of the theoretical framework of the research and unwilling participants were free to opt-out even after consent was given. Participants were informed that such withdrawal will have not in any way impact the care due to them. All information obtained will remain confidential. All the voluntary participants were accorded a coded study identification number, linking them to their bio-data to avoid using actual names and ensure confidentiality of data extracted. The database access is limited to the principal investigator. All the data sheets were stored appropriately and after a certain period will be appropriately disposed of.

The information sheet was prepared to explain the aim of the study was prepared and explained to all eligible participants. This was a hospital-based cross-sectional analytic study; therefore, no experiments (interventions) were performed on the patients. Patients received care as provided for in the hospital, the outcome of which was described in this study. The research assistants were trained on research ethics to ensure they obtained informed consent from all participants prior to conducting the interviews and maintain patient integrity through the study period.

3.15 LIMITATIONS OF THE STUDY.

It is required that patients remember the history of their disease. This may introduce recall bias. This was mitigated by the use of a patient's well-kept records that represent the full account of the patient's treatment such as HbA1c readings, treatments and complications.

The respondents may have given information that the researcher would have wanted to hear. This was lessened by reassuring the participants that the researcher was unbiased and there were no penalties for being honest.

Being a cross-sectional stud, the results from the study may not be used to establish causality; however, the data obtained may be used in future research projects.

CHAPTER 4: RESULTS.

4.0 INTRODUCTION

This chapter illustrates the study findings and results using frequency tables, graphs and charts to describe crucial data of all study participants.

The variables were described as follows: -

Outcome variable: - Adequate glycemic control- Participants with T2DM with their HbA1c level being less than 7% attending the KNH diabetes outpatient clinic.

- Poor glycemic control- Participants with T2DM with HbA1c levels equal to or above 7% attending the KNH diabetes outpatient clinic.

Explanatory Variables: - data was collected from participants using questionnaires and patient records and information on socio-demographic, clinical and knowledge-related factors were captured. These variables were classified as categorical and numerical for analysis.

4.0.1 RESPONSE RATE

During the study period, a total of 308 participants were recruited from the KNH diabetes outpatient clinic. Complete data was obtained from 302 of the participants setting the response rate at 98.1%.

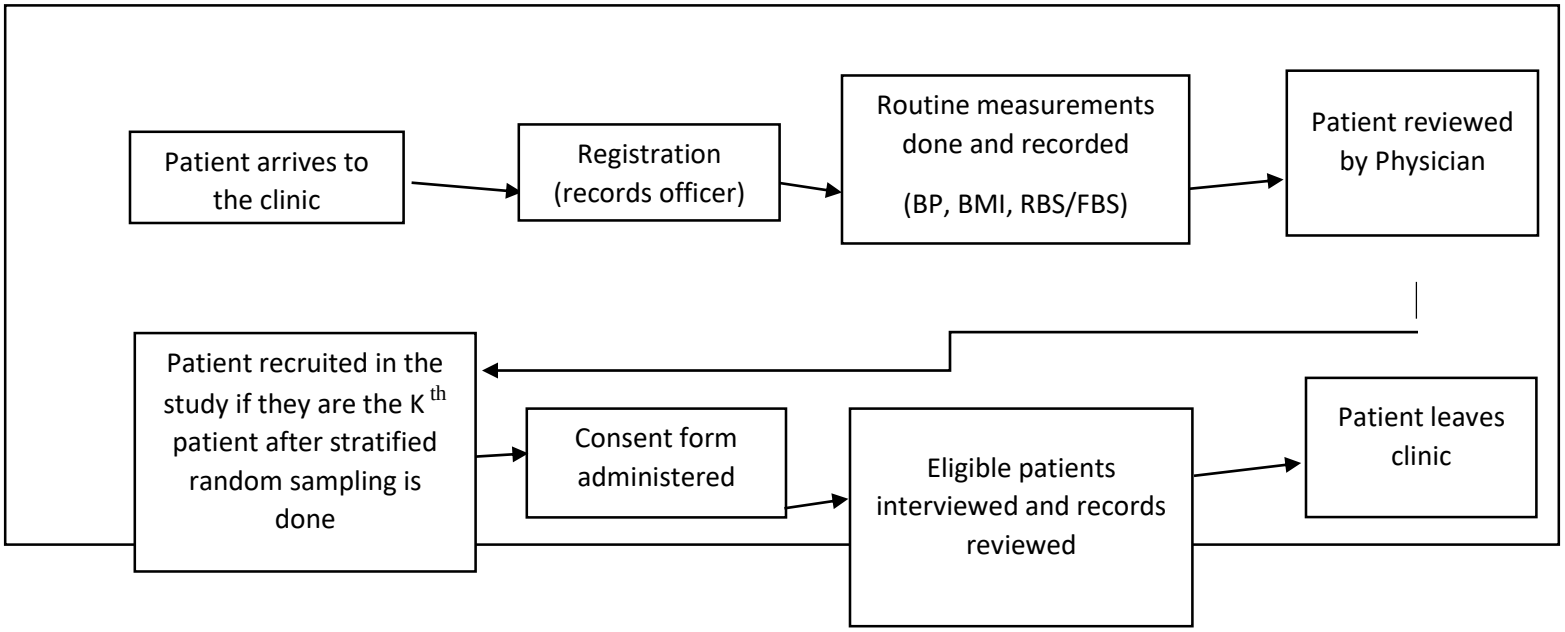


Figure 3. Flow diagram of patients' movement through the clinic and recruitment process.

4.1 SOCIO-DEMOGRAPHIC CHARACTERISTICS OF THE STUDY PARTICIPANTS

Most participants were over 60 years of age and were of the female gender 191 (63.2%, n = 302). Table 2, below summarizes socio-demographic characteristics of the study participants, with the mean age observed being 57 years (SD±12.9; median 56). The youngest respondent was 27 years while the oldest was 94 years. About seventy-four percent (74.8%, n = 302) of the respondents were married, 12.6% (n = 302) were widowed and 11.3% (n = 302) were single at the time of the study. Furthermore, among the participants, 66 (21.9%, n = 302) attained college education, 118

(39.1%, n = 302) secondary school education and 99 (32.8%, n = 302) primary school education. 49 (16.2%, n = 302) of the study participants were employed, 69 (22.8%, n = 302) were unemployed, while 130 (43.0 %, n = 302) were self-employed. The levels of income showed a fairly low income with 39 (12.9%, n = 302) earning less than a dollar a day and 168 (55.6 %, n = 302) reported earnings between 5001 – 10000 Ksh per month.

Table 2: Descriptive statistics of Socio-demographic Characteristics of T2DM Patients at KNH

Variable	**Values**	**n=302; Frequency (%)**
Age (years)		
	Mean (SD)	57.0 (12.9)
	Range	27.0-94.0
	<30	1 (0.3)
	30-39	25 (8.3)
	40-49	61 (20.2)
	50-59	96 (31.8)
	60+	**119 (39.4)**
Sex	Male	118 (39.1)
	Female	**184 (60.9)**
Marital status	**Married**	**226 (74.8)**
	Single	34 (11.3)
	Divorced/separated	4 (1.3)
	Widowed	38 (12.6)
Occupation	Employed	118(39.1)
	Self-employed	**130 (43.0)**
	Unemployed	54 (17.9)

Level of education	Primary **Secondary** College/university Informal education None	99 (32.8) **118 (39.1)** 66 (21.9) 11 (3.6) 8 (2.6)
Level of income	Above 20,000 15001-20,000 10001-15000 **5001-10000** Below 5000	7 (2.3) 12 (4.0) 76 (25.2) **168 (55.6**) 39 (12.9)
Religion	**Christian** Muslim Others	**287 (95.0)** 12 (4.0) 3 (1.0)

4.3 KNOWLEDGE RELATED FACTORS OF STUDY PARTICIPANTS

Knowledge on T2DM was assessed adopting the DSCK-30 Item Performance tool on patients' understanding of T2DM is and its symptoms, genetic association of T2DM, diabetes self-care, glucose monitoring practices, knowledge on the appropriate diet, need for physical activity (73). Figure 2 shows the knowledge score from the listed responses per category. Knowledge of study participants was categorized as illustrated. If a respondent managed to correctly identify 10 of the listed responses, that respondent was deemed to have good knowledge. From this assumption, the maximum possible score per respondent was 8 points. A cumulative score was computed for each of the respondents. Using the mean score as the cut-off point the individual

knowledge scores were then categorized as good knowledge or poor knowledge. The mean knowledge score was 5.2 (SD±1.6; median 4.2). The minimum score was 0 while the maximum score was 8. 219 (72.5%, n = 302) of the patients had a good knowledge score while 83 (27.5%, n = 302) had poor knowledge.

Figure 4: Knowledge level of study participants.

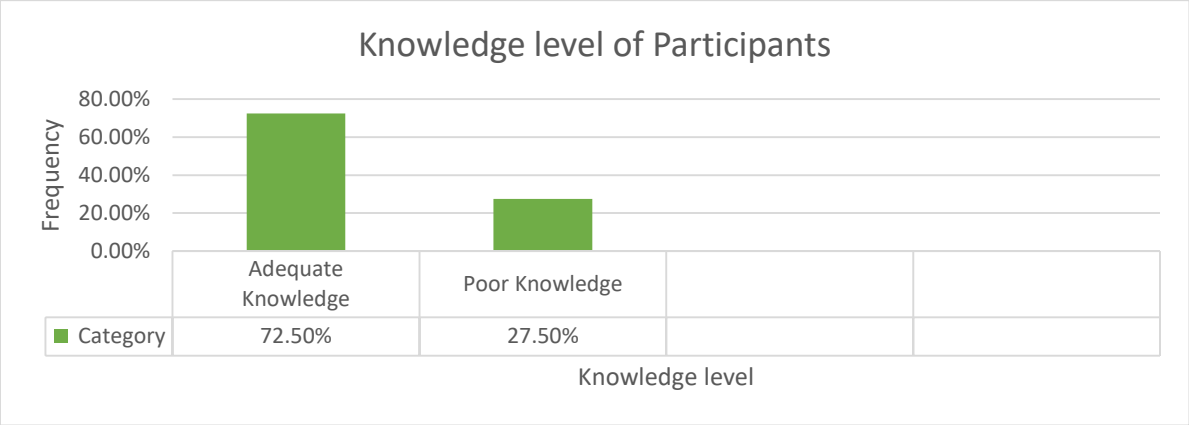


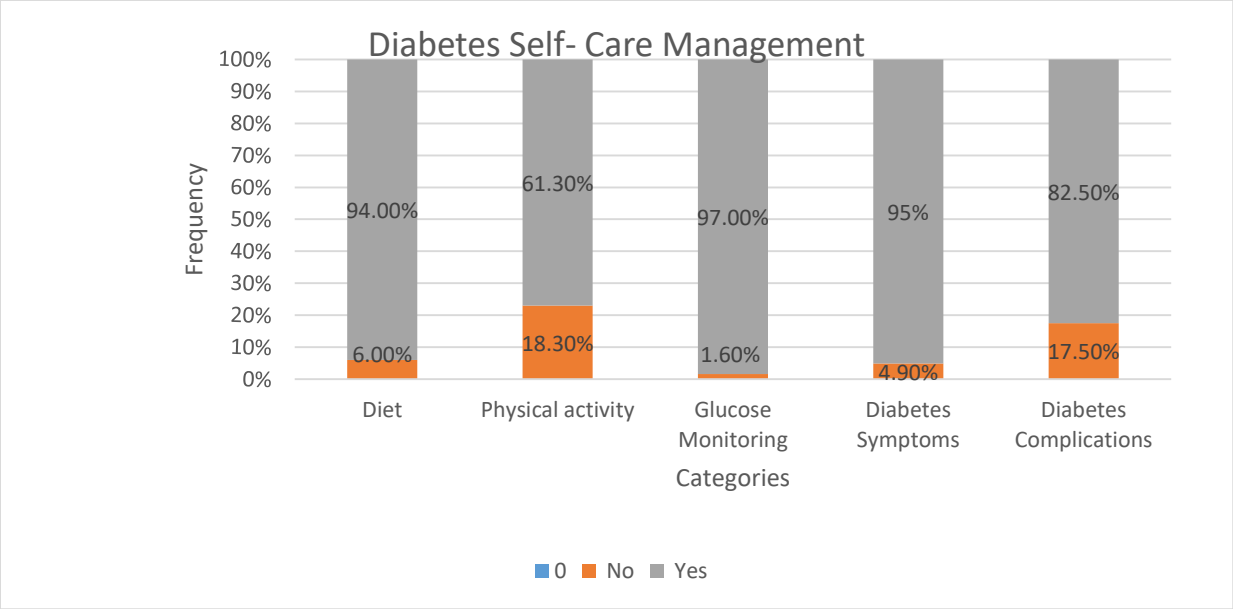
Table 2: Diabetes Knowledge among T2DM patients

KNOWLEDGE LEVEL	
Mean score (SD)	5.2 (1.6)
Min-Max	0-8
Category, n (%)	
Good Knowledge	**219 (72.5)**
Poor Knowledge	**83 (27.5)**

Figure:5 below indicates the overall knowledge score on a list of responses on self-care management, symptoms and complications. Participants selected the most correct response on the various categories on knowledge on diabetes management and self-care practices. Participants who selected the best response gained a score of 1 and those who could not identify the correct response obtained a score of zero. Diet illustrated patient's ability to adhere to recommended healthy diet that involves low calorie, low saturated fat, high fiber and high vegetable diet. Physical activity

that involves at least 30 minutes of aerobic activity daily for five days a week. Adequate self-monitoring of blood glucose using a glucometer at least twice every fortnight. In addition, assessment of Patient knowledge to recognize symptoms of hyperglycemia that include polyuria, polydipsia, polyphagia, fatigue, excessive unintended weight loss as well as assessment of patients' knowledge to recognize microvascular, macrovascular and non-vascular complications of T2DM.

Figure 5: Knowledge on Diabetes complications and Self-Care Behaviors of T2DM Patients at KNH

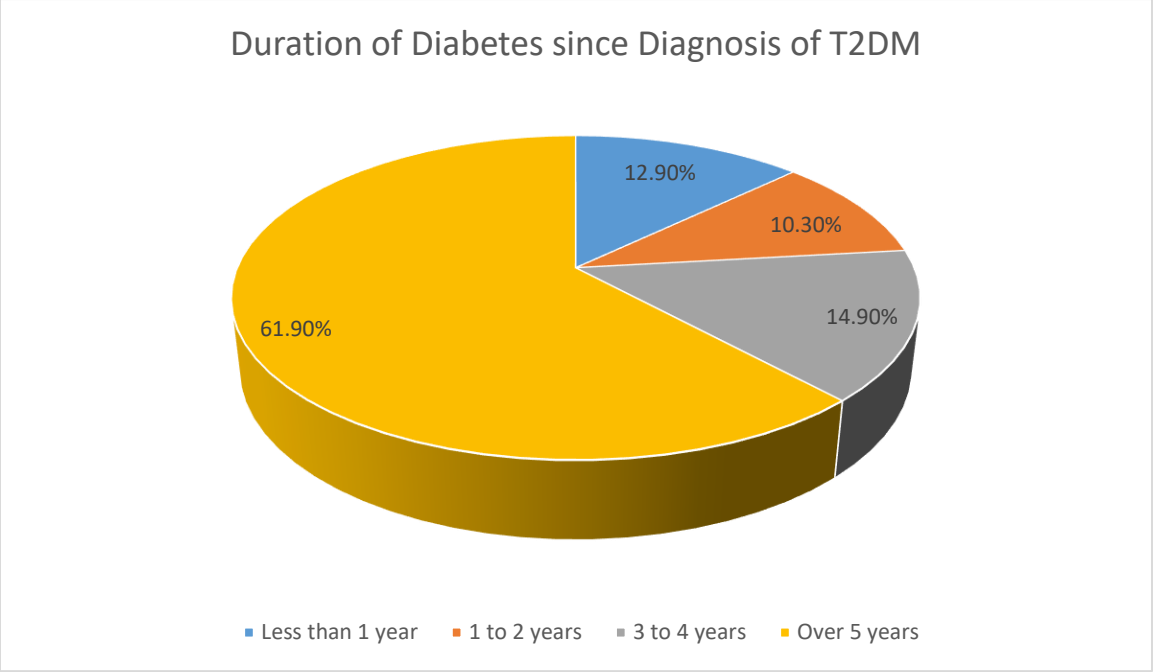


4.4 CLINICAL FACTORS AMONG STUDY PARTICIPANTS

4.4.1 Duration of diabetes since diagnosis of the study participants

The results in figure 6 indicate that 61.9% (187) of the participants had been diagnosed with diabetes for periods longer than five years and 38.1% (115) of the participants had been diagnosed with diabetes for a period less than five years.

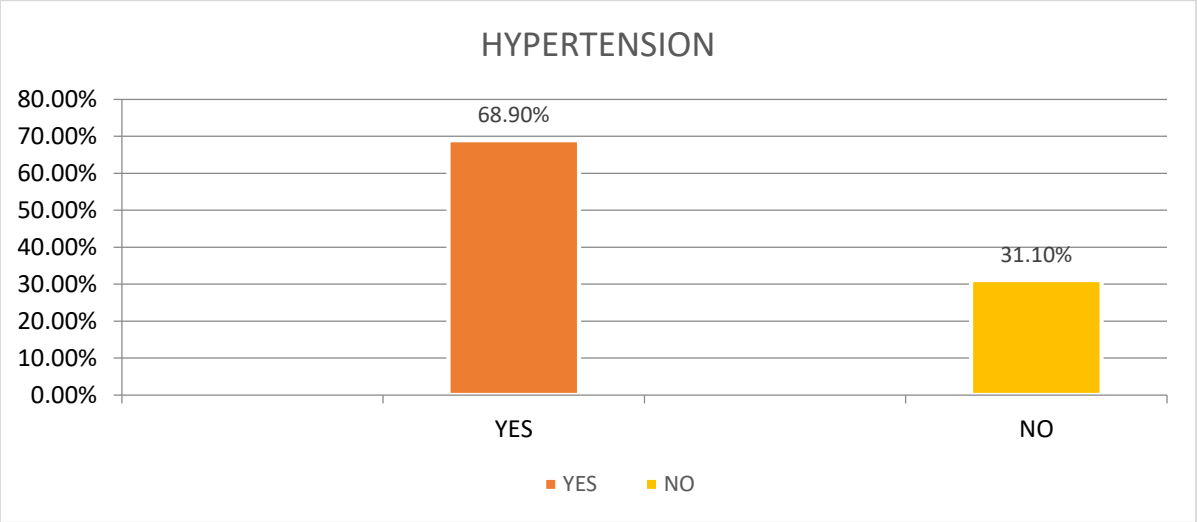
Figure 6: Duration of Diabetes of Participants since Diagnosis



4.4.2 Hypertension among T2DM Patients at KNH

Systemic hypertension was observed to be at 68.9% (Blood pressure above 140/90mmHg).

Figure 7: Proportion of patients with Hypertension among T2DM patients at the KNH

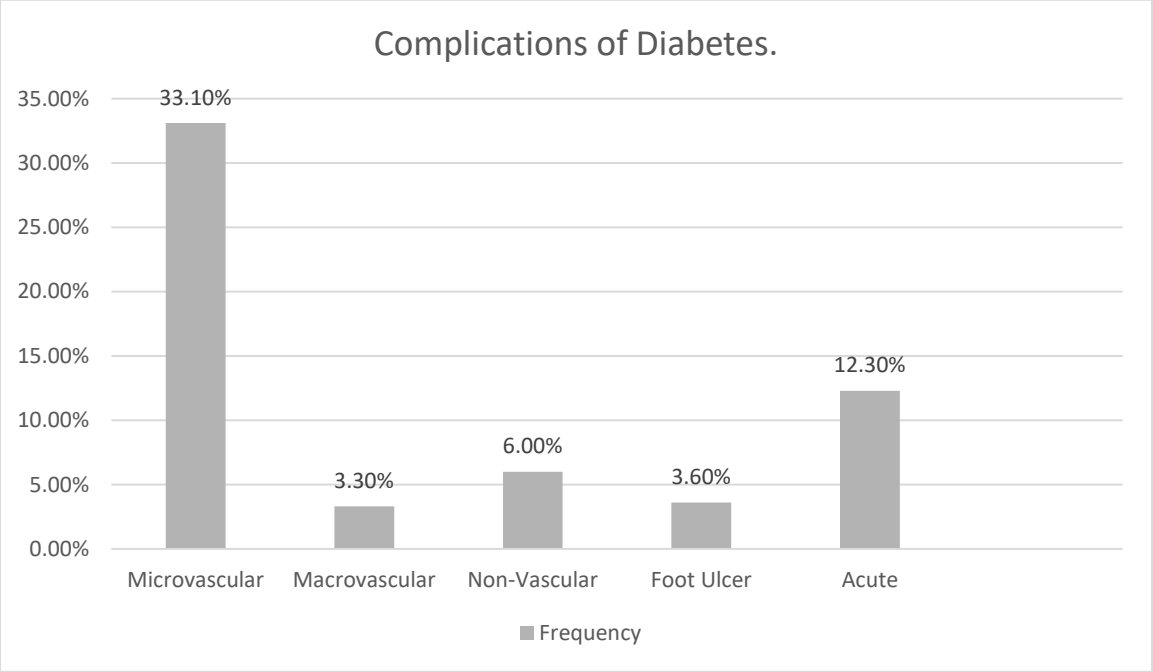


4.4.3 Diabetes related complications

The study showed that 58.3% (n = 302) of patients had experienced at least one complication of diabetes. Figure 7 below shows diabetes complications categorized as

- microvascular complications which are retinopathy, neuropathy and nephropathy;
- macrovascular complications that include coronary artery disease, ischemic cerebral vascular accident (CVA), peripheral arterial disease (PAD);
- non-vascular complications which are increased risk of infections and cataracts.
- acute complications namely diabetic ketoacidosis, hyperglycemic hyperosmolar state and hypoglycemia.

Figure 8: Proportion of patients with Diabetes Complications among T2DM Patients at KNH



About sixty-seven percent (67.5%, n = 302) of the patients were on antihypertensive treatment and 45% of patients at KNH were on combination treatment for T2DM. Patient's body mass index (BMI) range was from 20 kg/m^2 to 41 kg/m^2. The mean RBS was 8.1mmol/L (SD±1.4).

Table 3: Clinical Factors among T2DM patients at KNH

Variable	Value	n=302 Frequency (%)
Duration of Diabetes	>1year	39 (12.9)
	1-2years	31 (10.3)
	3-4years	45 (14.9)
	<5years	187 (61.9)
Duration of follow-up	>1year	49 (16.2)
	1-2years	32 (10.6)
	3-4years	41 (13.6)
	<5years	180 (59.6)
Hypertension	Present	208 (68.9)
	Absent	94 (31.1)
Currently on HTN treatment	Yes	204 (67.5)
	No	98 (32.5)
Diabetes Complications	Present	176 (58.3)
	Absent	126 (41.7)
Treatment	Yes	180 (59.6)
	No	122 (40.4)
BMI	Normal weight (18.5-24.9 kg/m^2)	55 (18.2)
	Overweight (25-29.0 kg/m^2)	127 (42.1)
	Obese (>30 kg/m^2)	120 (39.7)
RBS	Hypoglycemia (<4mmol/L)	17 (5.6)

	Euglycemia (4.1-7.7mmol/L)	125 (41.5)
	Sub-optimal (7.8-11.0mmol/L)	82 (27.2)
	Hyperglycemia(>11.1mmol/L)	77 (25.6)
Glycemic control (HbA1c)	Good control (HbAlc <6.0%)	61 (20.0)
	Fair control (HbA1c 6.0-7.0%)	55 (18.2)
	Poor control (HbAlc > 7.0%)	186 (61.6)

The mean score of BMI, RBS and HbA1c Levels were established and presented as shown in table 4 below.

Table 4: Table showing mean scores of clinical factors of T2DM patients at KNH

Variable	Mean	SD	Median	IQR	Range
BMI	29.9	3.4	29.5	28.7-34.2	20.0-41.0
Glycemic control (HbA1c)	8.1	2.7	7.8	-	0.4-19
RBS	8.9	4.1	7.9	5.8-11.4	2.5-24.1

4.5 PREVALENCE OF POOR GLYCEMIC CONTROL

Glycemic control in this study was defined by the HbA1c level. Respondents with HbA1C levels above 7% were classified as having poor glycemic control. The prevalence of poor glycemic control was 63.2% (n = 302), as presented in Table 5 below.

Table 5: Prevalence of poor glycemic control among patients with Type II Diabetes Mellitus

Variable	**n=302; Frequency (%)**
Glycemic control (HbA1c) Mean HbAlc (SD**)**	 8.1 (2.9)
Category, n (%) Good control (HbAlc <7%) Poor control (HbAlc >=7%)	 105 (34.8) 197 (65.2)

4.6 STATISTICAL ANALYSIS ESTABLISHING THE RELATIONSHIP BETWEEN GLYCEMIC CONTROL AND SELECTED VARIABLES

The variables were grouped into 3 main categories, socio-demographic factors, knowledge-related factors and clinical factors. They were then analyzed to determine the relationship between the explanatory variables and outcome variables.

Age was a continuous variable and was presented as a mean with SD. The comparison between patients with good glycemic control versus those with poor glycemic control was tested using the independent T-test. The independent t-test is a statistical test used for comparing the differences in means between two independent groups in a population.

Sex, marital status, education level, occupation and religion were categorical variables. The chi-square test was used to test the ssociation between categorical variables and glycemic control. The test was appropriate for comparing the distribution of various socio-demographic characteristics of the population in the two separate groups (of good and poor glycemic control). For associations where the expected count was less than 5, the fisher's exact test was used in place of the chi-square test. 95% confidence interval was presented to show the precision of the test in estimating the risk. Socio-demographic characteristics were associated with glycemic control as shown in table 6.

Table 6: Statistical Analysis to establish association of glycemic control and socio-demographic variables

Variable	**Values**	**Glycemic Control (HbA1c)**		**Degree of Freedom (df)**	**Statistical Test**	**P-VALUE**
		Good >7%	**Poor <=7%**			
Age (Years)	**Mean (SD)**	56.9 (12.9)		300	T-Test	.686
	<30	1	1			
	30-39	9 (8.1)	15 (8.4)			
	40-49	22 (19.8)	39 (20.4)		Fisher's	.891
	50-59	39 (35.1)	57 (29.8)			

	60+	40 (36.9)	78 (40.8)			
Sex	**Female**	62 (37.8)	102 (62.1)	1	X^2	.007
	Male	43 (31.2)	95 (68.8)			
Occupation	**Employed**	49 (44.1)	69 (36.1)	2	X^2	.358
	Self-employed	45 (40.5)	85 (44.5)			
	Unemployed	17 (15.3)	37 (19.4)			

Marital status	**Married**	88 (79.3)	138 (72.3)			
	Single	13 (11.7)	21 (11)		Fisher's	.070
	Separated	1 (0.9)	3 (1.6)			
	Widowed	9 (8.1)	29 (15.2)			
Education Level	**Primary**	35 (31.5)	64 (33.5)			
	Secondary	47 (42.3)	71 (37.2)			
	College/ University	23 (20.7)	43 (22.5)		Fisher's	.901
	Informal education					

	Illiterate	3 (2.7) 3 (2.7)	8 (4.2) 5 (2.6)			
Income Level	**>20,000** **15001-20,000** **10001-15000** **5001-10000** **< 5000**	13 (12.5) 8 (9.3) 22 (14.6) 61 (60.1) 18 (10.4)	24 (15.9) 19 (11.2) 20 (13.0) 98 (62.9) 19 (11.2)	4	X^2	.040
Religion	**Christian** **Muslim**	105(94.6) 6 (5.4)	182 (95.3) 6 (3.1)	-	Fisher's	.295

	Others	0	3 (1.6)			

Statistical tests: *Comparison of means were tested using independent T-test, p-values for categorical variables were generated using Chi-square test and the Fishers exact test when the expected values were less than 5.*

Knowledge-related factors were scored and presented as a continuous variable and as a mean with SD. The comparison between patients with good glycemic control versus those with poor glycemic control was tested using the independent T-test. Knowledge-related factors were also classified as categorical variables. The chi-square test was used to establish the association between categorical variables of the knowledge-related factors and glycemic control. Binary logistic regression was used to generate an odds ratio. The odds ratio was calculated for all categorical variables and presented as estimates of the risk of poor glycemic control. 95% confidence interval for the odds ratio was presented to show the precision of the test in estimating the risk. The p-values generated showed no statistical significance between knowledge-related factors and glycemic control.

Table 7: Statistical analysis and association of Glycemic control and knowledge on self-care variables

Variable	**Values**	**Glycemic Control (HbA1c)**		**Degree of freedom (df)**	**Test**	**P-VALUE**
		Good	**Poor**			
Knowledge level	**Mean**	5.1 (1.4)	5.3 (1.7)		T-test	.140
	Adequate	81 (73.0)	138 (72.3)	0.02 (1df)	X^2	.892
	Poor	30 (27.0)	53 (27.7)			

Statistical tests: *comparison of means were tested using independent T-test, p values for categorical variables were generated using Chi-square.*

Duration of diabetes, duration of follow-up, mode of treatment, hypertension, treatment for hypertension and diabetes complications were categorical variables. The chi-square test was used to test the association between these categorical variables and glycemic control. The test was appropriate for comparing the distribution of various clinical characteristics of the population in the two separate groups (good and poor glycemic control).

Binary logistic regression was used to generate the odds ratio. The test is appropriate as glycemic control was a categorical variable and had two possible outcomes either good or poor. The odds ratio was calculated for all categorical variables and presented as estimates of the risk of poor glycemic control. The 95% confidence interval for the odds ratio was also presented to show the precision of the test in estimating the risk.

Clinical variables that showed statistically significant association with glycemic control were co-morbidities, in this case, hypertension, treatment for hypertension, BMI, RBS and diabetes complications. Poor glycemic control was associated with patients who were hypertensive 74.5% (p=0.012, 195% CI; 0.3-1.0) and were on anti-hypertensive treatment 71.7% (p=0.042, 95% CI; 0.4-1.0) as well as patients who had experienced diabetes-related complications 74.5% p=0.011, 95% CI; 0.3-0.9). The mean BMI was seen to be at 31.8 kg/m2 (SD ±4.1 p=0.028) and the mean RBS was 10.0mmol/L (SD±4.4, p=<0.001) among patients with poor glycemic control. While the duration of diabetes was not statistically significant, the proportion of participants who had diabetes for 2 years and below showed to have poor glycemic control at 11.2% (p=0.549, OR=0.7) unlike those who had diabetes for 5 years and above, with 66.7% having good glycemic control (p=0.740, OR=1.2, 95% CI 0.5-2.7).

Table 8: Statistical analysis of clinical variables associated with Glycemic control in T2DM patients

Variable	Values	Glycemic Control (HbA1c)		Degree of freedom (df)	p-VALUE
		Good >7%	Poor <=7%		
Duration of disease	>1year	15 (13.5)	24 (12.6)		
	1-2years	9 (8.1)	22 (1.5)		
	3-4years	16 (14.4)	29 (15.2)	3	.804
	<5years	71 (64.0)	116 (60.7)		
Duration of follow-up	>1year	18 (16.2)	31 (16.2)		
	1-2years	10 (9.0)	22 (11.5)		
	3-4years	15 (13.5)	26 (13.6)	3	.910
	<5years	68 (61.3)	112 (58.6)		

Forms of treatment	Oral Injectable Combination	40 (36.0) 15 (13.5) 56 (50.5)	81 (42.4) 30 (15.7) 80 (41.9)	1	.353

Hypertension	Yes No	71 (64.0) 40 (36.0)	137 (71.7) 54 (28.3)	1	.162
Hypertension treatment	Yes No	67 (60.4) 44 (39.6)	137 (71.7) 54 (28.3)	1	.042*
Diabetes complications	Present Absent	66 (59.5) 45 (40.5)	110 (57.6) 81 (42.4)	1	.011*

BMI	Normal	3 (2.7)	2 (1.0)		
	Overweight	56 (50.5)	71 (37.2)		
	Obese	52 (46.8)	118 (61.8)	1	.028*
	Hypoglycemia	9 (8.2)	8 (4.2)		
RBS	Euglycemia				
	Sub-optimal	64 (58.2)	61 (31.9)	3	<.001*
	Hyperglycemia	28 (25.5)	54 (28.3)		
		9 (8.2)	68 (35.6)		

Statistical tests: *P- values for categorical variables were generated using Chi-square test. Mean scores were compared using independent t test.*

Variables that were found to be significant from the Chi-square, fishers and t test analysis were subjected to the multivariate analysis model. Sex, diabetes complications, treatment for hypertension, BMI and RBS were seen to be significantly associated with glycemic control. Those who were obese were three times more likely to have poor glycemic control than those who had normal BMI. Those on antihypertensive treatment were five times more likely to have poor glycemic control than those not on antihypertensive treatment. Results are presented in Table 9 below.

Table 9: Multivariate logistic regression analysis for determinants of glycemic control among T2DM

Variable	**Values**	**OR**	**95% CI**	**p-Value**
Sex	Male Female	1.0 1.7	0.7-1.8	**0.04**
Hypertension	Present Absent	1.2 0.95	0.77-5.53	**0.364**
Hypertension treatment	Yes No	5.1 1.0	0.17-1.96	**0.005**
Diabetes complications	Absent Present	0.40 1.0	0.17- 7.04	**0.036**

BMI	Normal Overweight Obese	1.0 1.9 2.9	0.9-12.70	**0.004**
RBS	Hypoglycemia Euglycemia Sub-optimal Hyperglycemia	1.0 0.2 1.1 1.6	0.18-1.34	**0.001**

CHAPTER 5: DISCUSSION

The proportion of patients found to have poor glycemic control was 65.2%. These findings are comparable to various studies done in Kenya. A cross-sectional study done by Ngoyo et al, found the prevalence of poor glycemic control to be at 81.9% at the Mathari teaching and referral hospital (29), while Wanjohi et al, in a case-control study at Machakos level 5 referral hospital found the majority of the patients had poor glycemic control (19).

There was no significant association between age and glycemic control in this study. The majority of the participants were above the age of 50 years with the mean age being 57 years. It was however observed that in 35.1% of patients between the age of 50-59 years had a 1.3 odds of adequate glycemic control than those of younger age groups. This is consistent with a case-control study carried out at the Machakos Level 5 hospital (19). It is also seen to be comparable to the findings of a study done in Australia. The the findings showed the adjusted OR (AOR) of HbA1c above >7.0% was 1.5 times higher (95% CI 1.22 to 1.84) for younger patients compared to older patients (76). Similarly, a study done in Northern Iran found that glycemic control was better among the middle and older age groups in comparison to younger age groups (77). When implementing the diabetes management programs while applying the belief model, the needs assessment component targets the elderly when determining at-risk groups for T2DM and thus the younger age groups are less considered when advocating for lifestyle and behavior change.

There was an association observed between sex and glycemic control. The majority of patients with poor glycemic control were women, compared to men. This may be attributed to the fact that our population comprises more of females than males. Men have also been shown to have delayed health seeking behavior accounting to their fewer numbers in hospitals. In addition, the higher economic status among men results in their higher purchasing power and control of resources in households that influence affordability and accessibility to diabetes healthcare. In a cross-sectional study carried out in Brazil and Venezuela, the outcome was similar with women having worse glycemic control than men (42). This was computed to be attributed to possible differences in glucose homeostasis, treatment response and psychological factors (18). In a local study, they found there was a high burden of the prevalence of poor glycemic control among females (29). This can also be attributed to a higher prevalence of obesity among women compared to men, that is associated with insulin resistance and poor glycemic control. We require gender main streaming

programs to equalize the genders. The socio-cultural issues on how men and women view diabetes needs to be researched and addressed as well as optimize patient care through sex-based and gender based analysis in diabetes and endocrinology research (78)

There was no association observed between the level of education and glycemic control in this study. This has been demonstrated in a study carried out at King Khalid University hospital (79) which stipulated that formal education has not been proven to be a predictor of better therapeutic compliance. Occupation and level of income did not have any significant association with glycemic control in this study. However, education level and living in poverty are indirectly associated with worse glycemic control through avoidance coping and depressive symptoms among patients with T2DM (80). The health belief model can be applied in designing interventions through skill development and providing support that enhances self-efficacy that leads to better glycemic control practices. The representation that diabetes is unpredictable shows there is a relationship between living in poverty and poor glycemic control.

Marital status and religion did not have an association with glycemic control in this study. A higher proportion of those with poor glycemic control was married and self-employed. This could be because they made up a majority of the respondents. Religious individuals were found to have better glycemic control in a study done in an urban university-based teaching outpatient clinic (81). There are limited studies on marital status association with glycemic control and this area requires further study.

Knowledge on self-care related factors assessed in this study were knowledge of diabetes, genetic association of diabetes, symptoms, lifestyle changes such as need for physical activity, appropriate diet, proper self-care monitoring practices and diabetes related complications.

There was no association between knowledge and glycemic control in this study. This could be attributed to a majority of the patients obtaining health education on diabetes and self-care practices within the clinic with patients receiving similar information regarding diabetes and diabetes care. Many of the patients had the disease for a long period bringing about a better level of awareness of the illness. This is in line with the study done at Mathari teaching and referral

hospital where patients had adequate knowledge, however, many had poor self-care practices with 99% (31), having poor glycemic control. Various studies demonstrate that despite the tremendous advances in knowledge on healthcare, social factors are more powerful determinants of health. Therefore, social and genetic causes of disease cannot be seen as mutually exclusive (82). The socio-cognitive theory illustrates the influence of social determinants of health among diabetes patients.

There was a statistical association between clinical factors and poor glycemic control. Diabetes complications, hypertension treatment, BMI and RBS were observed to be associated with poor glycemic control among T2DM patients.

There is an association between diabetes complications and poor glycemic control. There was a high proportion of poor glycemic control among patients with diabetes-related complications 74.5%. Diabetes-related complications are interrelated, and poor glycemic control aggravates the diabetes complications. T2DM patients are still susceptible to further complications after experiencing previous complications, this results to compromised self-care abilities (34). This not only affects the patients' therapeutic goals but may also hamper their health-related quality of life (HRQoL) and their financial status. This leads to depression, impaired cognition, poor physical functioning, frailty, malnutrition, chronic pain, and poor self-care behavior (80). Stricter guidelines are required to look at diabetes complications and simpler protocols need to be put in place to encourage patient adherence in implementing diabetes management self-care actions (83).

Glycemic control in T2DM was found to be poor among patients on antihypertensive treatment. The type of medication strongly influences glycemic control. This findings are supported by Al-Amin, Md et al, in a study carried out in Bangladesh (80). Treatment for hypertension was significantly related to poor glycemic control in this study. The mean HbA1c recorded among patients on antihypertensives was higher compared to those who were not (18). Some antihypertensive medications for instance thiazide diuretics, beta- blockers as well as statins may have negative effects on glucose metabolism and are seen to promote and worsen T2DM. This might also be associated with the duration of disease as many patients develop hypertension due

to atherosclerosis. Patients on a combination treatment of oral antidiabetics, insulin, and antihypertensives had a high proportion of poor glycemic control. The poor glycemic control may be a consequence of the high pill burden which may result in non-adherence to medication.

5.5 Study limitations

- This being a cross-sectional descriptive study, it does not determine causality and only determines factors associated with poor glycemic control
- This study was conducted in a tertiary healthcare facility, consequently, our conclusions cannot be generalized to patients with T2DM who do not seek medical care or who have not yet been diagnosed.
- The study population largely represents a specialist referred patient group receiving treatment in a tertiary facility.

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

6.1 CONCLUSIONS

Based on the findings of this study on T2DM patients at the KNH diabetes outpatient clinic the conclusions can be derived:-

The majority of the participants were aged above 60 years, were female, married, attained a secondary level of education, were self-employed, earned between 5001 and 10000ksh a month, and were Christians.

There was a high prevalence of poor glycemic control (63.2%) among T2DM patients attending diabetes outpatient clinics with a mean HbA1c level of 8.1%. Females were more affected than their male counterparts.

In regards to co-morbidities, the majority of the participants were on treatment for hypertension (67.5%) and had poor glycemic control (74.5%). The factors that were found to be statistically associated with poor glycemic control were sex, hypertension as a co-morbidity and its treatment, high blood glucose, obesity, and pre-existing diabetes complications. These were observed to be the main factors that negatively influence glycemic control in this study population. These factors affect self-care activities and add to the already existing burden of diabetes that leads to poor patient outcomes as well as impaired quality of life.

Obesity and elevated blood sugars emphasize the social cognitive theory's impact on behavior in glycemic control and hence the emphasis on lifestyle modification as a major contributor to preventing and managing non-communicable diseases.

6.2 RECOMMENDATIONS

Based on the findings from this study, our recommendation to reduce the burden of poor glycemic control among T2DM patients include:

- Intensive glycemic control to prevent further complications by identifying and reducing barriers that hinder patient action among T2DM patients. This can be addressed through needs assessment and better communication among various age groups and individuals on level of risk for poor glycemic control and diabetes complications.
- Provide health care providers and facilities with capacity building to improve care of patients with diabetes. There is need to empower patients with knowledge and resources to enhance their individual participation in diabetes self-care, example weight control and management through nutrition programs to aid curb the complications of diabetes among diabetic patients.
- Targeted interventions that will help reduce the socio-economic cost as well as enhance patients' quality of life leading to a decreased burden of disease.
- Further studies on different antihypertensive medications to determine their direct impact on glycemic control.
- Further studies to evaluate other socio-cultural factors beyond the scope of this study that may have an impact on glycemic control.
- Enacting health care policies that provide resources that facilitate self-monitoring of blood glucose and other self-care practices among T2DM patients.

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APPENDIX I: CONSENT FORM

UNIVERSITY OF NAIROBI (UoN)

COLLEGE OF HEALTH SCIENCES KNH-UoN ERC KENYATTA NATIONAL HOSPITAL (KNH)

P O BOX 19676 Code 00202 Email: uonknh_erc@uonbi.ac.ke P O BOX 20723 Code 00202

Telegrams: varsity Website: http://www.erc.uonbi.ac.ke Tel: 726300-9

(254-020) 2726300 Ext 44355 Facebook: ttps://www.facebook.com/uonknh.erc Fax: 725272

Twitter: @UONKNH_ERC

ttps://twitter.com/UONKNH_ERC Telegrams: MEDSUP, Nairobi

PARTICIPANT INFORMATION AND CONSENT FORM

SAMPLE ADULT CONSENT

FOR ENROLLMENT IN THE STUDY

(To be administered in English or any other appropriate language e.g. Kiswahili translation)

Title of Study: DETERMINANTS OF GLYCEMIC CONTROL IN TYPE 2 DIABETES PATIENTS AT KENYATTA NATIONAL HOSPITAL OUTPATIENT CLINIC

Principal Investigator\and institutional affiliation: WAWERU ANNYUSTAR MUGURE; UNIVERSITY OF NAIROBI

Co-Investigators and institutional affiliation: N/A

Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: I) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol no. _____

WHAT IS THIS STUDY ABOUT?

The researchers listed above are interviewing individuals who are diagnosed with Type 2 diabetes mellitus and attend the diabetic outpatient clinic. The purpose of the interview is to find out determinants of glycemic control. Participants in this research study will be asked questions about socio-demographic characteristics, self-care and clinical related factors. Participants will also have the choice to undergo test such as height and weight.

There will be approximately 308 participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen:

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 15 minutes. The interview will cover topics such as lifestyle, diet and treatment.

After the interview has finished***, (explain in details any procedures that are necessary e.g. blood draws, counseling etc.)***

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include:
_____n/a_____

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your

confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.

Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

It may be embarrassing for you to have _____We will do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews. Also, _____ may be stressful (e.g. event recalls).

You may feel some discomfort when _____ and you may have a small bruise or swelling in your _____. In case of an injury, illness or complications related to this study, contact the study staff right away at the number provided at the end of this document. The study staff will treat you for minor conditions or refer you when necessary.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You may benefit by receiving free health information testing, (list e.g. Counseling, health information etc.) .We will refer you to a hospital for care and support where necessary. Also, the information you provide will help us better understand the complications. This information is a contribution to science and public health care protocols.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

(Explain)

_____N/A_____

WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY?

(Enter statement) ___N/A_____

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study:	**Yes**	**No**
I agree to have (define specimen) preserved for later study:	Yes	No

I agree to provide contact information for follow-up: Yes No

Participant printed name:

_____

Participant signature / Thumb stamp _____ Date

_____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: __WAWERU ANNYUSTAR **Date**: _____

Signature

_____

Role in the study: RESEARCHER_____ *[i.e. study staff who explained informed consent form.]*

For more information contact _WAWERU ANNYUSTAR____ at _0725363961_____ from __Monday_____ to Friday_____

Witness Printed Name (*If witness is necessary, a witness is a person mutually acceptable to both the researcher and participant*)

Name _____ Contact information

_____

Signature /Thumb stamp: _____ Date;

_____

For Any Enquiries, please contact:

1. Annyustar Waweru,
Principle investigator
Mobile number: 0725363961
E-mail: starmugure@gmail.com

2. Dr. Tom Olowe
Department of Public and Global Health, University of Nairobi.
Mobile number: 0733940215
Email: tomolewe@gmail.com

3. Prof. Joyce Olenja
Chair, Department of Public and global Health, University of Nairobi.
Mobile number: 0722955230
Email: jolenja@uonbi.ac.ke

4. Kenyatta National Hospital/University of Nairobi Ethics and Research Committee
College of Health Sciences
P.O. Box 19676-00202
Nairobi
Telephone: 020-2726300 Ext 44355/+254202726300-9
Email: uonknh_erc@uonbi.ac.ke

FOMU YA IDHINI

SOMO: UJUZI WA UGONJWA WA KISUKARI KUHISI NA HALI YA SUKARI KWA WANAOUGUA KISUKARI KATIKA HOSPITALI YA KITAIFA YA KENYATTA

Nambari ya kushiriki……..

Utangulizi

Niruhusu nikweleze kuhusu utafiti tunaokusudia kufanya. Nia ya ufafanuzi huu ni kukuelimisha wewe kuhusu utafuti kabla yaw ewe kuamua kama utakubali kuwa mshiriki au la. Haki zako kama mshiriki ni kama zifuatavyo

I) Uko na haki ya kuelewa uhuru wako kukubali ama kukataa kushiriki katika utafiti huu

II) Uko na haki ya kutoka katika utafiti huu hata baada ya kukubali unapogeuza nia

III) Uko na haki ya kupewa matibabu yote bila chuki wala fitina baada ya kukataa kushiriki tena katika utafiti huu

Je umetupa kibali cha kuendelea

Ndio La

Ufafanuzi

Nafanya utafiti kuonyesha vile wagonjwa wa kisukari huenda mwishowe wakapata adhari za vidonda vya miguu na hatimaye wengine hukatwa miguu. Nia yangu ni kuona jinsi tunavyoweza kuzuia mapema hatima hii.

Katika huu utafiti tunasaka washiriki 255 watakaochuguliwa bila kwa mpangilio bila mwelekezo. Tungetaka uzingatie kuwa mshiriki pia.

Taratibu

Ukikubali kushiriki tutakuuliza maswali kama vile umri na jinsi unavyohisi miguu. Pia tutakupima uzito , urefu na tupime hali yako ya kuhisi katika miguu tukitumia kifaa mpya – Biothesiometer. . Hii itachukua muda wa takriban robo saa na itafanyika kwa sehemu iliyojitenga kuhakikisha usiri wako haudhulumiwi.

Je kuna adhari gani kushiriki katika utafiti huu?

Utafiti wowote wa kiafya unaweza kuwa na adhari kama vile kuzambaa kimakosa kwa ujumbe wa kibinafsi na pia uchunguzi waweza kuwa na maswali ya kufedhehesha.

Mikakati tuliyoiweka ni ya kuzuia upeperushaji usio wa hiari wa ule ujumbe tutakaokusanya kama vile kutotumia majina ya washiriki. Badala yake tutatumia nambali maalum ya kuwatambulisha itakayojulikana tu ma mtafiti.

Iwapo maswali uoyote ya kuaibisha itakuwepo, mshiriki akona hiari ya kukataa kujibu na pia hiari ya kukataa kuendelea kushiriki hata baada ya kupeana saini.

Je, kuna faida gani kushiriki

Ukishiriki katika huu utafiti, tutakwelezea jinsi hali ya kuhisi ilivyo katika mwili wako.

Na malipo je?

Matumizi yote yauchunguzi katika utafiti huu itagharamiwa kikamilifu na mtafiti mkuu

Maelezo zaidi

Ijapo una maswali, usisite kuwasiliana nasi wakati wowote kwa namna zilizotadhrishwa.
Iwapo ungetaka kujua Zaidi haki zako kama mshiriki, tafadhali wasiliana na mwenyekiti au katibu wa Kamitii ya utafiti ya Hospitali ya Kitaifa ya Kenyatta na Chuo Kikuu cha Nairobi kwa simu 2726300 Ext. 44102 au barua pepe uonknh_erc@uonbi.ac.ke.

Hati ya Ruhusa

Sahihi ya mshiriki.....Tarehe.....
Ninathibitsha yakwamba nimetoa maelezo sahihi kwa mhusika kuhusu huu utafiti na yale yote yaliyomo kwa ustadi, naye mhusika ametoa uamuzi wa kushiriki bila ya kushurutishwa.
Sahihi ya mchunguzi……Tarehe……
Sahihi ya shahidi……...Tarehe……..

1. Mshriki mkuu
   Annyustar Waweru
   Simu ya rununu: 0725363961
   Barua pepe: starmugure@gmail.com

Wasimamizi

2. Prof. Joyce Olenja
   Mkurugenzi, Chuo Kikuu cha Nairobi

Simu ya rununu: 0722955230

Barua pepe: jolenja@uonbi.ac.ke

3. Dr Tom Olewe
   Chuo Kikuu cha Nairobi
   Simu ya rununu: 0733940215
   Barua pepe: tomolewe@gmail.com

4. Hospitali ya kitaifa ya Kenyatta /Chuo Kikuu cha Nairobi,Kamati ya maadili na utafiti .Chuo cha sayansi ya afya
   Sanduku la posta 19676-00202 Nairobi
   simu: +254202726300-9 Ext 44355 barua pepe: uonknh_erc@uonbi.ac.ke

INDEPENDENT CERTIFICATE FORM

I the undersigned have been explained to and have understood the above and willingly accept to participate in the research study.

Signature ……. Date …….

I the investigator, having explained in detail the purpose of this study, hereby submit that confidentiality of the data collected will be maintained and only details relevant to the study will be revealed.

Signature ……. Date …….

APPENDIX II: QUESTIONNAIRE

Do not write your name anywhere on this questionnaire

Answer all the questions

Put a tick (√) against the appropriate response and fill in the blank spaces where appropriate

SECTION A: demographic Information

1. What is your age ……. years
2. What is your marital status?
    a) Married [ ]
    b) Single [ ]
    c) Divorced/separated [ ]
    d) Widowed [ ]
3. What is your Occupation
    a) Employed [ ]
    b) Business [ ]
    c) Housewife [ ]
    d) Others (specify)……
4. What is your highest level of education?
    a) primary [ ]
    b) secondary [ ]
    c) college/university [ ]
    d) informal education [ ]
    e) none
5. The religion of the respondent
    a) Christian
    b) Muslim
    c) Others (specify)…….

Section B: Knowledge of related factors

6. What is diabetes?
    a) A condition people get for not eating well

b) A chronic disease in which blood glucose is too high because insulin is not produced or is insufficient.
c) A condition rich people get because of drinking alcohol and eating nyama choma
d) A condition that causes weight loss
e) Are all the above descriptions
f) Others ……..specify
g) I don‘t know

7. Is diabetes hereditary?
    a) Yes
    b) No
    c) I don‘t know
8. Can diabetes be cured?
    a) Yes
    b) No
    c) I don‘t know
9. Can lifestyle modifications, such as diet and exercise be used to manage diabetic
    a) Yes
    b) No
    c) I don‘t know
10. The major cause of diabetes is?
    a) Lifestyle changes such as reduced physical activity and poor dietary habits
    b) Eating Potatoes
    c) Sin against God
    d) HIV and TB
    e) Vectors such as mosquitoes and jiggers
    f) I don‘t know
    g) Others ……specify
11. The symptoms of diabetes are?
    a) Tiredness, weight loss, increased thirst, frequent urination, blurred vision.
    b) Loss of hair, change in nail color
    c) Frequent coughing and sneezing

d) I don‘t know

e) Others ……..specify

12. Diabetes if not treated, may cause…

a) Tiredness, weight loss, increased thirst, frequent urination, and blurred vision.

b) Loss of hair, change in nail color

c) Serious complications such as amputations, stroke, kidney disease

d) Frequent coughing and sneezing

e) I don‘t know

f) Others ……..specify

13. The most accurate method of monitoring diabetes is

a) Blood glucose monitoring

b) Number of urges for urination

c) Level of tiredness

d) Use of thermometer

e) don‘t know

f) Others ……..specify

14. What effect does fruit juice have on blood glucose?

a) Don‘t Know

b) Lowers it

c) Raises it

d) Has no effect

e) Others ……..specify

15. What are the complications related to diabetic that you are aware of?

……

……

Section c clinical related factors

16. When were you diagnosed with diabetes?
    a) Less than a year
    b) 1 to 2 years ago
    c) 3 to 4 years ago
    d) More than 5 years
17. For how long have you been attending the clinic?
    a) Less than a year
    b) 1 to 2 years ago
    c) 3 to 4 years ago
    d) More than 5 years
18. What type of treatment are you currently on?
    a) Oral medication
    b) Injectable(Insulin)
    c) Combination of both
19. Are you a known Hypertensive?
    a) Yes
    b) No
20. Are you currently receiving treatment for hypertension?
    a) Yes
    b) No
21. Have you been hospitalized because of diabetes-related complications?
    a) Yes
    b) No
22. If Yes in the above question (21), which one(s)? _____

Table illustrating glycemic control among participants

Participant	Glycemic Control	
	Adequate Glycemic Control <7	Poor Glycemic Control >9
1		
2		
3		

APPENDIX 1V: LOGFRAME MATRIX

2021											2022	
Activity	Jan	Feb	Mar	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec
Proposal writing												
Pretesting of collection instrument												
Data collection												
Data analysis and write up research												
Correction revision of write up by the supervisor												

APPENDIX V: BUDGET AND BUDGETARY NOTES

Budgetary Notes

The listed items in the budget provided are essential for this study to be successful. The estimated cost of the consumables, tests and stationery is as per the current pricing in the Kenyan economy in Nairobi. The following are suggested sources of funding; Self-sponsorship

Components	Unit of Measure	Duration/ Number	Cost (Ksh)	Total (Ksh)
Personnel				
Research Assistant	1 Individual	3 Month	15000/Month	45000
Participants	None	None	None	None
Printing				
Consent Form	1 Page	1	10/Page	10
Assent Form	1 Page	1	10/Page	10
Questionnaires	4 Pages	1	10/Page	40
Final Report	50 Pages	1	10/Page	500
Photocopying				
Consent Form	1 Page	300	3/Page	900
Assent Form	1 Page	300	3/Page	900
Questionnaires	4 Page	300	3/Page	3600
Final Report	50 Page	5	3/Page	750
Final Report Binding	Report Books	5	200/Book	5000
Laboratory Cost				
FBS		300	20	6000

Other costs				
ERC Fees	Single	1	2000	2000
Records Access Fee	Single access	1	3000	3000
Miscellaneous				10%
Total				68,350