FACTORS AFFECTING GLYCEMIC CONTROL AMONG TYPE II DIABETICS ATTENDING MACHAKOS LEVEL FIVE OUTPATIENT CLINIC

By

DR. WANJOHI MILKA MUTHONI

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DECLARATION OF ORIGINALITY FORM

Name of student:	MILKA MUTHONI WANJOHI
Registration Number:	H57/81248/2015
College:	HEALTH SCIENCES
Faculty/School/Institute:	SCHOOL OF PUBLIC HEALTH
Department:	PUBLIC HEALTH
Course Name:	MASTER OF PUBLIC HEALTH
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APPROVALS:

This dissertation has been submitted with the approval of:

Academic supervisors

1. Dr. Rose Okoyo Opiyo, PhD, MSC, B.Ed

   Lecturer

   School of Public Health

   Signature_____ Date_____

2. Dr. Simeon Ochanda Mbuya, MMed, MBCHB, CTM

   Lecturer

   Department of Clinical Medicine and Therapeutics

   Signature_____ Date_____

Director:

Prof. Mutuku Mwanthi, PhD, MSEH, BSc

Director, School of Public Health

College of Health Sciences, University of Nairobi

Signature_____ Date_____

DEDICATION

This research project is dedicated to my husband, Andrew, my son, Nathan, and my entire family. Your support, motivation and encouragement were truly an inspiration.

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LIST OF ABBREVIATIONS

ADA	American Diabetes Association
aOR	Adjusted Odds Ratio
BMI	Body Mass Index
BP	Blood Pressure
CI	Confidence Interval
CVD	Cardiovascular Disease
DM	Diabetes Mellitus
EPI INFO	Epidemiological Information
ERC	Ethics and Research Committee
FBG	Fasting Blood Glucose
HbA1c	Glycated Hemoglobin
IDF	International Diabetes Federation
IQR	Inter-Quartile Range
KDHS	Kenya Demographic Health Survey
KNBS	Kenya National Bureau of Statistics
KNH	Kenyatta National Hospital
LRT	Likelihood Ratio Test
ML5H	Machakos Level Five Hospital
mmol/l	millimoles per litre
NCDs	Non-Communicable Diseases
OGTT	Oral Glucose Tolerance Test
OHA	Oral Hypoglycemic Agents
OR	Odds Ratio

PI	Principal Investigator
PPBS	Post-Prandial Blood Sugar
RBS	Random Blood Sugar
SES	Social Economic Status
SMBG	Self-Monitoring of Blood Glucose
UON	University Of Nairobi
US	United States
UK	United Kingdom
WHO	World Health Organization

DEFINITION OF OPERATIONAL TERMS

Cases	Patients with Type 2 diabetes in the study population with poor glycemic control over a period exceeding six months
Controls	Patients with Type 2 diabetes in the study population with good glycemic control over a period exceeding six months
Diet	Appropriate diet for diabetics in this study was assessed based on weekly balanced diets taken, daily servings of fruits and vegetables, and daily portions consumed
Fasting blood glucose	Blood glucose levels recorded following an overnight or 8 hours fast
Glycemic control	The Regulation and maintenance of blood glucose levels within a normal range. The aim for good glycemic control should be at HbA_{1c} of <7% or a fasting blood glucose of ≤ 7.0 mmol/l or random blood sugar measurements of ≤ 11.0mmol/l
Good glycemic control	Fasting blood glucose ≤7.0mmol/l (average of the last two consecutive readings)
Physical activity	This include exercises such as aerobics, walking, running, cycling, games and work done at home
Poor glycemic control	Fasting blood glucose > 7.0mmol/l (average of the last two consecutive readings)
Self-care activities	Behaviors aimed at attaining optimal glycemic control such as appropriate diet, physical activity, self-monitoring of blood glucose and foot care
Self-monitoring of blood glucose	Measurement of blood glucose levels done by the patients mostly at home using a glucometer
Type II Diabetes	Chronic metabolic disorder of blood sugar control which results from the body's ineffective use of insulin

ABSTRACT

Introduction

Glycemic control refers to the regulation and maintenance of blood glucose levels within a normal range in diabetic patients. Up to 40% of Kenyan Type II diabetic patients on treatment and clinical follow-up have poor glycemic control which is directly associated with the development of diabetes-related complications, morbidity, and mortality. There is however paucity of literature in the characterization of factors affecting glycemic control in Kenya and particularly Machakos County.

Objective

The primary objective of this study was to assess factors affecting glycemic control among Type II diabetic patients attending the Machakos Level Five Outpatient Diabetic Clinic, during the period December 2017-February 2018.

Methodology

The study was an unmatched case-control design, where cases were Type II diabetics with poor glycemic control (average of the last two consecutive fasting blood glucose readings of more than 7.0mmol/l) while controls were Type II diabetics with good glycemic control (average of the last two consecutive fasting blood glucose readings of at least 7.0mmol/l). Structured questionnaires were used to collect data from informed consenting Type II diabetic patients who were selected through simple random sampling. The sample size was 84 patients in each study arm. Multivariable logistic regression was used to evaluate the relationship of the predictors with glycemic control.

Results

From the multivariable analysis, inappropriate diet (odds ratio: 5.98; 95% confidence interval 1.97-18.10), low physical activity (odds ratio: 2.71; 95% confidence interval 1.05-7.04), and inadequate self-monitoring of blood glucose (odds ratio: 5.35; 95% confidence interval 2.09-13.72) were identified as significant factors associated with poor glycemic control. The absence of diabetes complications was associated with good glycemic control (odds ratio: 0.4; 95% confidence interval 0.17-0.96).

Conclusion

This study concluded that diabetes complications, adherence to recommended diet, physical activity and self-monitoring of blood glucose are significantly associated with glycemic control. These findings call for the need to strengthen advocacy on adherence to dietary recommendations, regular physical exercise, and blood glucose monitoring among Type II diabetics to mitigate the effects of poor glycemic control. Emphasis should be placed on self-care activities in the different age-groups to minimize the occurrence of diabetes complications. Further studies such as a cross-sectional study can be carried out in the study area to determine the prevalence of poor glycemic control.

CHAPTER 1: INTRODUCTION

1.1: Background

Diabetes mellitus is a chronic metabolic disorder of blood sugar control that occurs when the pancreas does not produce enough insulin or when the body cells fail to respond to circulating insulin. Type II diabetes affects the majority of people in the world (American Diabetes Association, 2014).

Global prevalence of diabetes has been on the rise, and statistics show a threefold increase in diabetes prevalence between the year 2000 and 2014. In 2017, approximately 451 million people around the world had diabetes, and this figure was expected to rise to 693 million people by the year 2045 (Cho *et al.*, 2018). This is as demonstrated in figure 1.

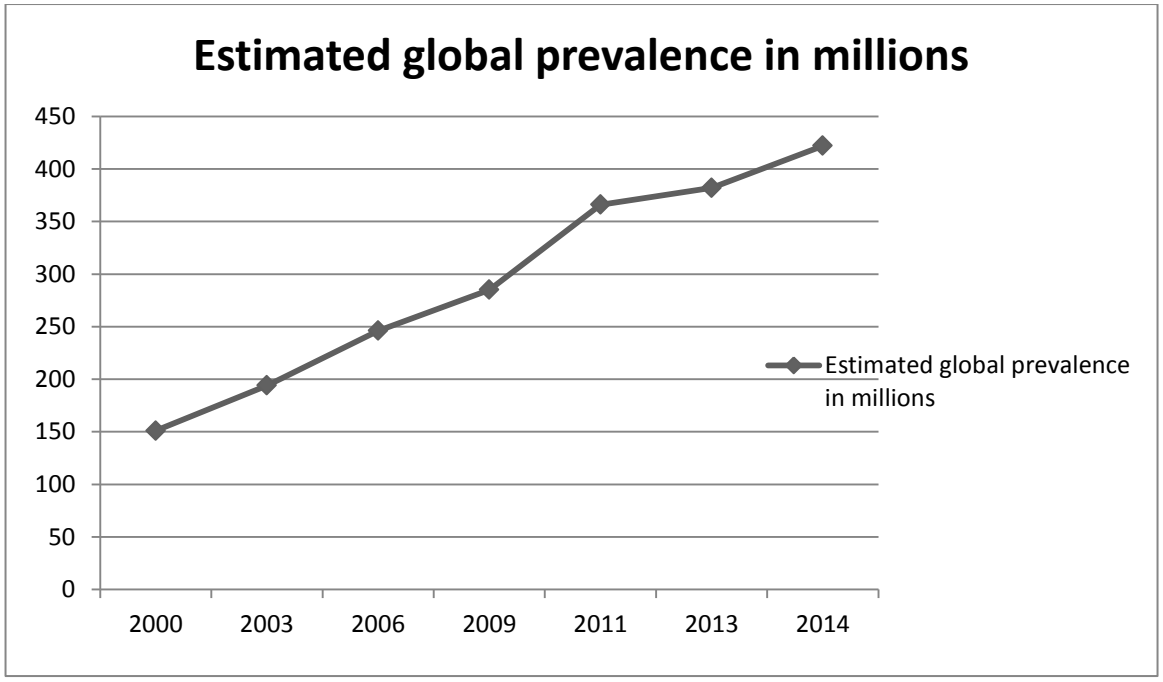

Figure 1: Global prevalence of diabetes (Cho *et al.*, 2018)

In Africa, there is a large and growing burden of diabetes. Rapid urbanization and changes in lifestyle with rising population are the major drivers of this epidemic. With the limited resources in Africa, the diabetes burden presents a substantial public health and socio-economic burden according to a review done on diabetes in Africa (Mbanya *et al.*, 2010). In 2017, around 15.5 million adults in the age group of 20 to79 years in Africa had diabetes, representing a regional prevalence of 6%. By 2045, it is projected that about 40.7 million adults will have diabetes. Moreover, Africa has a high percentage of people with undiagnosed diabetes. Most people are unaware they have diabetes which raises the risk of chronic complications leading to increased morbidity and mortality as reported on the global estimates of diabetes prevalence (Cho *et al.*, 2018).

In Kenya, diabetes prevalence is equally on the rise, and there is an urgent need for the government to tackle this problem to counter the increasing burden of disease. The estimated diabetes prevalence is 3.3% and is predicted to rise to 4.5% by 2025 (WHO, 2014). The high burden has been attributed to rapid urbanization which has resulted in behavioral changes that are risk factors for diabetes and other non-communicable diseases. In a cross-sectional study done in Mathare slums, Nairobi, these behavioral factors include physical inactivity, over-consumption of alcohol, inappropriate diet and smoking (Ayah *et al.*, 2013). Diabetes negatively impacts on the quality of life of affected individuals due to increased rates of morbidity and mortality. The high financial cost associated with its management impacts on the individual, family and the country's economy (Ministry of Public Health and Sanitation, 2010). Therefore, there is need for more resource allocation towards prevention and health promotion to alleviate the diabetes burden.

1.2: Research problem

Optimal glucose control leads to reduced diabetes-related complications according to various cross-sectional studies carried out on Type II diabetics (Chuang *et al.*, 2006; Huang *et al.*, 2011; Mullugeta *et al.*, 2012). Control of hyperglycemia can reduce the incidence of acute diabetic complications which result in morbidity and even death. This reduces the burden of diabetes on the individual, community and the economy (Diabetes UK, 2015).

Diabetes remains a public health problem affecting approximately 451 million people globally (Cho *et al.*, 2018). Several descriptive cross-sectional studies have revealed a high prevalence of poor glycemic control globally and in Kenya (Sasi Sekhar *et al.*, 2013; Ahmad, Islahudin and Paraidathathu, 2014; Musenge *et al.*, 2016; Nduati *et al.*, 2016). According to the hospital records from Machakos Level Five Hospital, about 200 Type II diabetics are enrolled monthly, with about 50 patients having uncontrolled blood sugars. Therefore, there is need to assess factors affecting glycemic control in the study population to alleviate the disease burden.

1.3: Justification

High rates of poor blood glucose control among Type II diabetics have been reported in several exploratory studies globally and in Africa (Angamo, Melese and Ayen, 2013; Sasi Sekhar *et al.*, 2013; Ahmad, Islahudin and Paraidathathu, 2014; Musenge *et al.*, 2016). In Kenya, a cross-sectional study done in Mathari hospital reported that about 82% of Type II diabetics had poor glycemic control (Nduati *et al.*, 2016). These studies are observational in nature and most of them conclude that the management of diabetic patients should take into consideration the patient different characteristics so as to enhance quality care. By identifying factors that improve the care of diabetic patients, this study provided a basis for quality improvement programs in a bid to reduce the rising burden of diabetes.

This study provided insight into the various socio-demographic, clinical and behavioral factors that influence glycemic control among Type II diabetics attending Machakos Level 5 Outpatient Clinic. These findings form a basis for the formulation of strategies and policies that enable the hospital health-care workers as well as the County Health Committee to formulate and implement specific interventions aimed at decreasing the burden of disease.

The study is of public health benefit since it identified risk factors for poor glycemic control and gave appropriate recommendations. The research findings will also form a basis for future similar studies and add to the limited body of literature on the subject.

1.4: Research question

Do socio-demographic, clinical and behavioral factors affect glycemic control among patients with Type II diabetes attending Machakos Level Five Outpatient Clinic?

1.5: Statement of the research hypothesis

It is hypothesized that $H_{0:}$

1. There is no association between socio-demographic factors and poor glycemic control levels among patients with Type II diabetes in Machakos Level 5 Hospital.

2. There is no association between clinical factors and poor glycemic control levels among patients with Type II diabetes in Machakos Level 5 Hospital.

3. There is no association between behavioral factors and poor glycemic control levels among patients with Type II diabetics in Machakos Level 5 Hospital.

1.6: Objectives

1.6.1: General objective

To assess the factors associated with glycemic control among patients with Type II diabetes attending Machakos Level Five Hospital Outpatient Clinic.

1.6.2: Specific objectives

1. To assess socio-demographic factors associated with glycemic control among patients with Type II diabetes attending Machakos Level Five Outpatient Clinic.
2. To assess clinical factors associated with glycemic control among patients with Type II diabetes attending Machakos Level Five Outpatient Clinic.
3. To assess behavioral factors associated with glycemic control among patients with Type II diabetes attending Machakos Level Five Outpatient Clinic.

1.7: Conceptual framework

The conceptual framework in figure 2 shows glycemic control as the main outcome. Predictor variables were grouped into socio-demographic, clinical and behavioral factors. Socio-demographic factors which are mostly non-modifiable have been shown to have a direct association with both clinical and behavioral factors (Gjonca and Calderwood, 2004). Clinical and behavioral factors are interdependent, and the three factors have a direct association with glycemic control (Timothy, 2010).

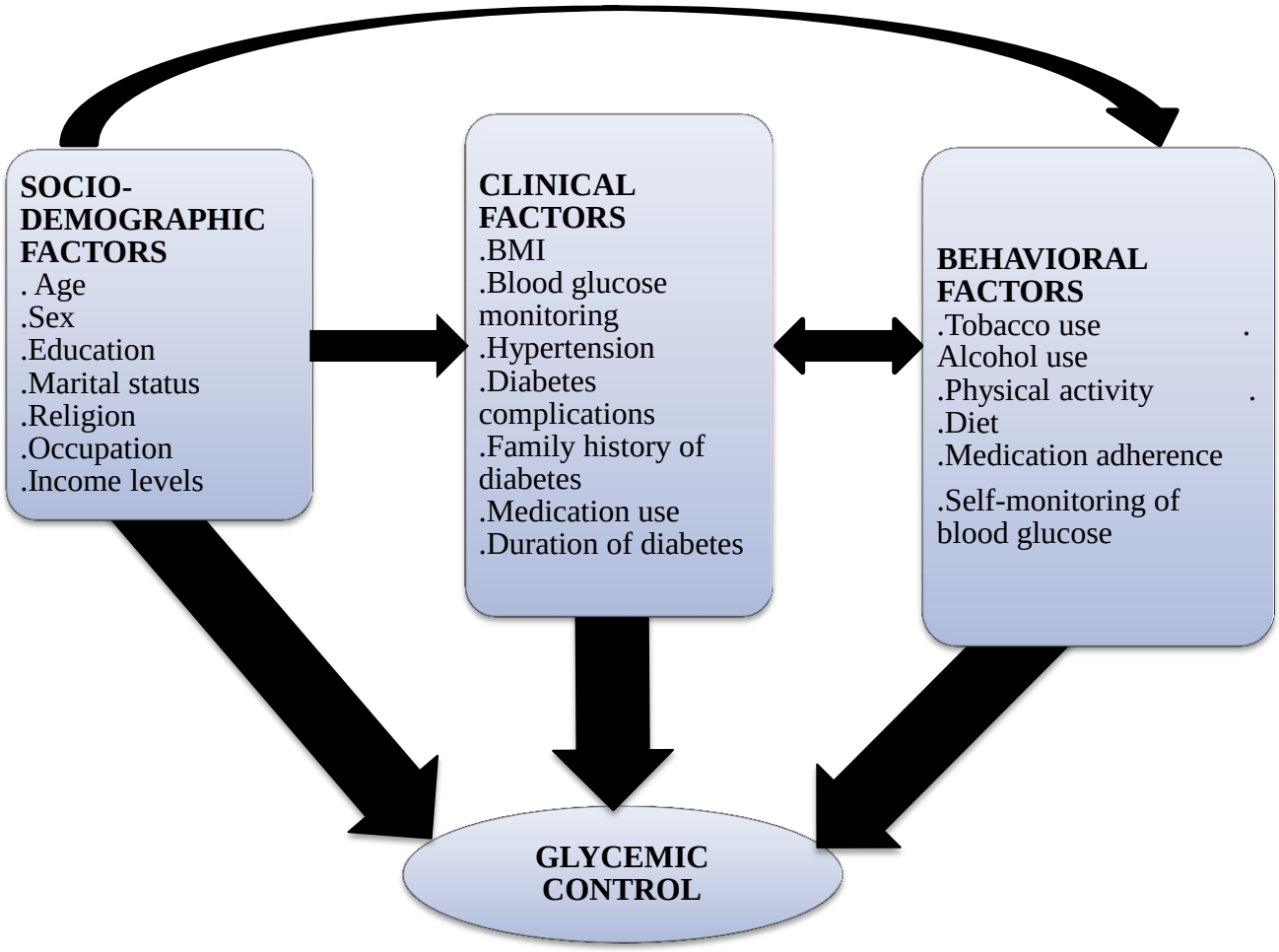

Figure 2: Conceptual framework showing factors affecting glycemic control (Timothy, 2010)

CHAPTER 2: LITERATURE REVIEW

2.1: Introduction

The prevalence of diabetes mellitus is on the rise worldwide. The estimated prevalence of diabetes prevalence for people aged between 20 and 70 years around the world in 2015 was 415 million people and is estimated to be at 642 million people by 2040 (Diabetes UK, 2015). In middle and low-income countries, individuals having diabetes are on the rise (World Health Organization, 2016). According to reports, diabetes will affect approximately 24 million people in sub-Saharan Africa in 2030. In addition, estimates showed that mortality attributable to diabetes in sub-Saharan Africa was at 6% of total mortality in 2010 (International Diabetes Federation, 2015). The diabetes epidemic is on the rise in Kenya with the prevalence being at 3.3% in 2010 and projected to increase to 4.5% by 2025 (Ministry of Public Health and Sanitation, 2010).

2.1.1 Glycemic control

Glycemic control refers to the regulation and maintenance of blood glucose levels within a normal range in diabetic patients. Good blood glucose control is the main target in diabetes care since it reduces long-term complications associated with diabetes. Failure to tackle hyperglycemia increases the risk of chronic complications, acute metabolic occurrences, and death (Huang *et al.*, 2011).

According to different studies with varying designs and study populations, many diabetes patients have poor blood glucose control. In a prevalence study conducted in Malaysia, 72% of the patients had poor blood sugar control (Firouzi, Barakatun-Nisak and Azmi, 2015). Another cross-sectional study carried out in Ethiopia showed that 70.9% of diabetic patients

had poor glycemic control (Kassahun, Eshetie and Gesesew, 2016). In addition, a descriptive cross-sectional study on Type II diabetics conducted in Mathare referral hospital, Kenya revealed that 80% of the patients had inadequate blood glucose control (Nduati *et al.*, 2016). Several other cross-sectional studies on the prevalence of Type II diabetes have reported poor blood sugar control among Type II diabetics (Angamo, Melese and Ayen, 2013; Sasi Sekhar *et al.*, 2013; Ahmad, Islahudin and Paraidathathu, 2014; Musenge *et al.*, 2014; Mwavua *et al.*, 2016).

2.1.2 Measurement of glycemic control

The gold standard measure for glycemic control is HbA1c (WHO, 2006). However, a cross-sectional study conducted in Karnataka showed a direct correlation between FBG, post-prandial blood sugar (PPBS) and HbA1c, in controlled and uncontrolled diabetic patients. PPBS showed better sensitivity (79% vs 74%) than FBG, whereas FBG showed higher specificity (84% vs 74%) and positive predictive value (87% vs 80%) compared to PPBS (Swetha, 2014). Cross-sectional studies conducted in Ghana (Tengey, 2012), Tanzania (Mwera, 2013) and Ethiopia (Angamo, Melese and Ayen, 2013) also used FBG as a measure of glycemic control due to the resource-poor setting.

The study assessed glycemic control using the average of the last two consecutive FBG readings as opposed to glycated hemoglobin measurements. This is because in resource-constrained areas the HbA1c test is not routinely used, and the use of FBG is recommended (Swetha, 2014). Patients are not able to afford the HbA1c test which goes for approximately one thousand shillings (10 US Dollars) but the FBG test is readily available and affordable (McFerran, 2008).

2.2: Factors affecting glycemic control

It is difficult to attain optimal glycemic control, and several exploratory studies have assessed the factors associated with sub-optimal glycemic levels (Angamo, Melese and Ayen, 2013; Sasi Sekhar *et al.*, 2013; Nduati *et al.*, 2016). Factors that affect glycemic control according to various cross-sectional studies include carried out on Type II diabetics include; the duration of treatment, adherence to medication (Ashur *et al.*, 2016) and type of drugs (Otieno, Kariuki and Ng'ang'a, 2003). Physical activity levels, compliance with dietary advice, diabetes education(Kassahun, Eshetie and Gesesew, 2016), existing co-morbidities, sex, and age (Sasi Sekhar *et al.*, 2013) additionally affect glycemic levels.

2.2.1: Socio-demographic factors

Several socio-demographic factors influence glycemic control in regards to age, sex, level of education, marital status, religion, occupation, and income levels.

Age

Age has an association with glycemic control, according to various exploratory studies on risk factors for wide glycemic variability among Type II diabetics. In a survey carried out among diabetics treated at primary health facilities, every one year rise in age increased the probability of having good glycemic control. Patients older than 65 years had better blood glucose control than the other age groups due to the fact that Asian communities had caretakers for the elderly (Ahmad, Islahudin and Paraidathathu, 2014). A retrospective cross-sectional Singapore study showed that younger type II DM patients had poorer cholesterol and

sugar control than elderly patients. This poor control was as a result of the older patients having increased awareness of the disease and its complications compared to younger patients (Paul *et al.*, 2011). Higher HbA1c among younger patients was due to high sugar and fat diets (Juarez *et al.*, 2012; Naranjo *et al.*, 2013). Demographic factors and clinical conditions affect glycemic control in the middle-aged adults while treatment modality was the primary influence on glycemic control in older adults in a China study (Chiu and Wray, 2010). Other cross-sectional studies also showed that age was related to glycemic levels (Ali *et al.*, 2012; Juarez *et al.*, 2012; Sasi Sekhar *et al.*, 2013). In a Kenyan descriptive study carried out on Type II diabetics, patients aged over 56 years had better blood sugar control than those aged between 41 and 55 years (Nduati *et al.*, 2016). This was attributed to the high level of awareness of the disease among older patients. Another cross-sectional Kenyan study carried out on ambulatory Type II diabetics showed no relationship between patient's age and glycemic levels (Otieno, Kariuki and Ng'ang'a, 2003). This could have been due to the high variation in age among the patients studied which ranged from 14-92 years.

Sex

There is conflicting literature on the effect of gender on glycemic control. Some studies have shown that women have poor glycemic control compared to men. A Libyan cross-sectional study on Type II diabetics glycemic control status, findings revealed that a possible explanation to this is that women have a higher body mass index, which leads to poor glycemic control (Ashur *et al.*, 2016). This survey was in concurrence with a Saudi exploratory study on gender differences in glycemic control, which attributed high HbA1c among females to high rates of obesity (Habib, 2013). An Indian cross-sectional study that explored the effect of self-care activities on glycemic control, attributed the poor glycemic

control among women to the fact that diabetes was a social stigma for women leading to low level of awareness and poor self-care practices (Sasi Sekhar *et al.*, 2013). A Kenyan study on Type II diabetics also showed poor glycemic control among women which was due to their high BMI and poor self-care activities (Nduati *et al.*, 2016). On the contrary, females were found to have better glycemic control than males in an Oman descriptive cross-sectional study that explored factors affecting glycemic levels (Dsouza *et al.*, 2015). This was as a result of lower BMI and more support for the women which enhanced their awareness. In a US and Kenyan exploratory study on diabetics, there was no association between sex and blood glucose control (Otieno, Kariuki and Ng'ang'a, 2003; Ali *et al.*, 2012).

Education

Different studies show varying effects of education and literacy levels on glycemic control. A study which used poverty and education levels as indicators for social-economic status (SES) showed that poor coping behavior, as well as depressive symptoms significantly, contributed to poor glycemic control (Houle *et al.*, 2016). In another cross-sectional study that set to evaluate the impact of Type II diabetes patient's education on care outcomes, the findings demonstrated that educated patients had better self-management practices which lowered the rate of complications (Gagliardino *et al.*, 2012). With higher literacy levels, there was improved awareness of diabetes management leading to good glycemic outcomes. This is as shown by a cross-sectional study carried out in a tertiary care teaching hospital in India (Sasi Sekhar *et al.*, 2013). However, knowledge and skill deficit significantly contribute to poor glycemic control. This shortfall is due to limited time, insufficient human resources and inadequate guidelines for diabetes education in an Ethiopian study on the prevalence of poor glycemic control (Angamo, Melese and Ayen, 2013). A Kenyan exploratory study done in

Nairobi showed no association between education and glycemic levels (Nduati *et al.*, 2016). This could be as a result of the study population being from Nairobi where literacy levels are generally high.

Marital status

Social relationships such as social networks and support are associated with better disease management outcomes. They can arise from the family, friends and the health-care provider. Good treatment outcomes occur when there is positive support given, which encourages better self-care activities leading to improved quality of life. Findings from cross-sectional studies on partner relations and diabetes outcomes have shown that having a partner is associated with more support leading to enhanced diabetes-related outcomes (Mayberry and Osborn, 2014; Trief *et al.*, 2015). Partners who provided support led to improved regimen adherence and lifestyle satisfaction according to a study done on Type II diabetics (Fincham *et al.*, 2018). However, partner criticism, hostility, and overprotection were found to be a negative form of social support which was associated with poor glycemic control, in a qualitative study done to assess how couples manage diabetes (Houston-Barrett and Wilson, 2014).

Religion

People have different systems of faith and worship, which pose a challenge in inferring an association between religion and treatment outcomes. There are limited studies on religion and blood glucose control, with most of them showing an association between the two. A cross-sectional, descriptive, correlational study done in the USA showed that spiritual wellness was related to good blood sugar control (Newlin *et al.*, 2008). This was concurrent with other exploratory studies on Type II diabetics where many couples stated that spirituality helped them to endure diabetes stress (Houston-Barrett and Wilson, 2014). Descriptive cross-

sectional studies conducted on African Americans found that spiritual care was linked to improved self-care management behavior leading to better glycemic outcomes (L. Polzer, 2007; Houston-Barrett and Wilson, 2014). On the contrary, a Thailand descriptive qualitative study showed that Buddhist and Muslim women had self-management practices associated with their religions, but many of them had poor glycemic control due to inappropriate lifestyle habits (Lundberg and Thrakul, 2013).

Occupation

Limited studies have focused on the association between occupation and glycemic control. Findings from a US cross-sectional study showed that occupations with long working hours lead to sub-optimal glycemic control for those with diabetes. This was due to elevated stress levels resulting in undesirable habits like overeating. The study also indicated that those in blue collar jobs were more likely to have poor blood glucose control than people working in offices due to limited knowledge on self-care practices and inadequate social support (Davila *et al.*, 2011). In a Brazil qualitative sectional study on Type II diabetics, those who with an occupation had poor self-care practices due to the limited free time to manage the disease (Lima *et al.*, 2016).

Income levels

Minority groups (Non-Hispanic blacks and Hispanics) and those lacking insurance in a survey conducted in the United States had a higher prevalence of poor glycemic control. Due to lack of insurance, there is a decrease in accessibility to health services and hence a higher probability of poor glycemic control. However, in the same study, there was no association between education levels, poverty-income ratio and poor glycemic control (Ali *et al.*, 2012). Native Americans and African-American men had poor glycemic control in a cross-sectional

study conducted in North Carolina. Low-income levels, being married and lacking Medicaid had an association with poor glycemic control (Quandt *et al.,* 2005).

2.2.2: Clinical factors

BMI

The body mass index has been shown to be a risk factor for many illnesses and poor glycemic control. Patients with a high BMI are termed as overweight or obese. There is an increasing number of individuals who are overweight and obese, due to lifestyle changes (American Diabetes Association, 2016). Diabetic patients with high BMI have an increased occurrence of poor glycemic control which is attributed to increased insulin resistance due to high body fat. This is according to a cross-sectional study conducted on diabetics and secondary research carried out (Timothy, 2010; Bae *et al.*, 2016). A cohort study with a five-year follow-up on diabetics showed that the high BMI subjects patients to other co-morbidities leading to unfavorable health outcomes (Luijks *et al.*, 2015). Some descriptive cross-sectional studies, however, showed no relationship between elevated BMI and poor blood glucose control, which could have been attributed to the study population used (Vazquez *et al.,* 2014; Mut-Vitcu *et al.,* 2017).

Blood glucose monitoring

Blood sugar monitoring is important because it allows for timely identification of high glycemic levels, which is the key strategy in reducing acute and chronic diabetes complications. This finding is as per a facility based cross-sectional survey done in Ethiopia (Kassahun, Eshetie and Gesesew, 2016). Additionally, according to a cross-sectional study done in three community health centers in South Africa, it allows patients and health care

providers to monitor therapeutic response and gauge whether the desired glycemic targets are being achieved (Timothy, 2010). Frequent blood glucose monitoring, whether at home or in health facilities contributes to better glycemic control (American Diabetes Association, 2016).

Hypertension

In a cross-sectional study on treatment of Type II diabetics with hypertension, it is a common co-morbidity in diabetics. Hypertension affects 20-60% of diabetic patients depending on obesity, ethnicity, and age (Arauz-Pacheco, Parrott and Raskin, 2002). Patients who have both conditions face increased macro-vascular and micro-vascular complications risks and should be optimally managed, according to a cross-sectional study done in Ghana (Tengey, 2012). Co-management of diabetes through glycemic control and hypertension through blood pressure control is central to the treatment and prevention of diabetes and cardiovascular complications (Mancia, 2007).

Presence of diabetes complications

The occurrence of diabetes complications due to poor blood sugar control is a major concern since they increase the rates of morbidity and mortality in affected patients. The complications can be macro-vascular or micro-vascular and they affect the patients quality of life, in addition to the high pill burden imposed (Luijks *et al.*, 2015). Cross-sectional studies conducted in Malaysia (Almutairi, Said and Zainuddin, 2013) and Turkey (Kayar *et al.*, 2017) on Type II diabetics showed that people with complications arising from diabetes had poor blood glucose control which was attributed to the burden of managing the complications and the sugar levels. A Turkey sectional observational study risk factors for poor glycemic control (Kayar *et al.*, 2017) also showed that the more the diabetes complications, the higher the rate of poor glycemic control.

Family history of diabetes

Patients with a familial history of diabetes have an earlier onset of diabetes and poorer glycemic control compared to those without a history of diabetes in the family, according to various exploratory studies on Type II diabetics (Kayar *et al.*, 2017; Wu *et al.*, 2017; De, Banu and Muthukumar, 2018)**.** Having a history of diabetes in the family is associated with an early onset of the disease which may predispose patients to uncontrolled hyperglycemia with time. A study conducted among urban African Americans demonstrated that a positive parental history was associated with worse glycemic control and early diagnosis (Gong *et al.*, 2008). However, no significant association was found in a population-based cross-sectional study done in Saudi Arabia (Veghari *et al.*, 2010) which could have been due to the study population used.

Drug utilization pattern

The type of medication in use determines the glycemic levels in Type II diabetics. Patients taking many medications tend to have poor glycemic control which can be attributed to non-adherence due to the high pill burden. This is according to various cross-sectional studies carried on Type II diabetics (Chiu and Wray, 2010; Kamuhabwa and Charles, 2014). Compared to patients on diet only, patients on oral hypoglycemic agents (OHA) have poor glycemic control due to progressive beta-cell failure. Sub-optimal dosages, as well as the use of sub-standard medication, could also contribute to poor glycemic control (Otieno, Kariuki and Ng'ang'a, 2003). Among patients on insulin therapy, a higher body mass index contributes to poor glycemic control. In addition, under-dosing and varying the total daily doses affects glycemic levels (Angamo, Melese and Ayen, 2013). Moreover, patients on

insulin therapy have poorer glycemic control in comparison to those on OHAs as shown by different exploratory descriptive studies (Ali *et al.,* 2012; Ashur *et al.,* 2016). This poor control could be as a result of these patients having a more advanced disease, making it difficult to control the sugar levels (Musenge *et al.,* 2016). In a China multi-center study, glycemic control was better in patients treated with only OHAs compared to those on OHAs in combination with insulin. This finding was due to the fact that those on combination therapy had the disease for a longer period predisposing them to poor blood glucose control (Ji *et al.,* 2013).

Duration of diabetes treatment

Patients on a long duration of treatment for diabetes tend to have poor blood sugar control according to various cross-sectional studies on diabetics (Juarez *et al.,* 2012; Sasi Sekhar *et al.,* 2013; Madani, Ei-hadiyah and Abdelrahim, 2014). This long duration of diabetes, results in reduced beta-cell function, necessitating intensive therapy. A multi-center cross-sectional survey on glycemic control in China reported that long-term diabetics are more likely to have complications due to advancing diabetes (Ji *et al.,* 2013). A duration of five years and below in a Kenyan cross-sectional study was associated with poor glycemic control due to reduced awareness about disease management and complications (Nduati *et al.,* 2016).

2.2.3: Behavioral factors

Tobacco and alcohol use

Tobacco use decreases absorption of insulin subcutaneously, leading to increased dosing requirements for patients on insulin and poor glycemic control (Tengey, 2012)**.** This finding is concurrent with other exploratory studies which found that non-tobacco users had better

glycemic control than tobacco users (Vlassopoulos, Lean and Combet, 2013; Melba S. D'Souza, Subrahmanya N. Karkada, Ramesh Venkatesaperumal, 2015). However, no association was found between smoking and glycemic control in an Ethiopian prospective cross-sectional study (Woldu *et al.*, 2014).

Alcohol use was not linked to poor glycemic controls in a cross-sectional study conducted on diabetics, and occasional drinking was linked to beneficial health effects (Ahmed *et al.*, 2008).

Exercise

Physical activity is a low-cost intervention that helps prevent most non-communicable diseases. A cross-sectional study conducted in Libya in Type II diabetics showed that medication adherence was the most significant predictor of glycemic control followed by exercise (Ashur *et al.*, 2016). Structured exercise training that entails resistance training and aerobics contributes to a HbA1c reduction in Type II diabetics. Physical activity advice contributes to reduced sugar levels when implemented with dietary recommendations (Umpierre *et al.*, 2011). A United States survey showed that exercise among other lifestyle behaviors, significantly affect HbA1c levels independent of other factors such as demographics, clinical conditions, and treatment modalities (Chiu and Wray, 2010).

Diet

The likelihood of poor glycemic control is lower in patients on diet-only therapy because they tend to have a better endogenous insulin production as per the finding from a cross-sectional study done in KNH, Nairobi on Type II diabetics (Otieno, Kariuki and Ng'ang'a, 2003). Appropriate dietary intake is essential in diabetes care and reduction in the occurrence of complications (Steyn, Lambert and Tabana, 2009; Angamo, Melese and Ayen, 2013). However, patients' adherence to the recommended dietary regime is sub-optimal which poses

a problem in diabetes care. In a Nepal analytical cross-sectional study, this high rate of non-adherence to diet was as a result of increasing age, poor knowledge about diabetes and a long duration of disease (Parajuli *et al.*, 2014). In a Kenyan cross-sectional study on dietary adherence pattern in Type II diabetics, patients preferred taking medications to control their blood sugar than following recommended diet regimes (Musee, Omondi and Odiwuor, 2016). A diet lower in carbohydrates is suitable for improvements in glycemic control according to a community based randomized study (Westman *et al.*, 2008). Very low-calorie diets of < 800 calories daily are ideal for weight loss and for improving glycemia and lipemia in Type 2 diabetics. There should be a reduction in the intake of energy, sodium, saturated fats and cholesterol (American Diabetes Association, 2007). A randomized behavioral trial study done on Type II diabetics showed that intensive dietary advice is also key to improving dietary intake outcomes (Gutschall *et al.*, 2009).

Medication adherence

Adherence to medication leads to improved glycemic control (Ali *et al.*, 2012; Aikens and Piette, 2013; Ahmad, Islahudin and Paraidathathu, 2014). Patients may not adhere to their medication due to cost and unavailability of drugs, long distances to health facilities as well as side effects of the medication and use of alternative medicine (Kamuhabwa and Charles, 2014). In a retrospective observational study, aging patients and those with co-morbidities had higher adherence rates, due to increased knowledge about diabetes and its complications (Rozenfeld *et al.*, 2008). A Tanzania cross-sectional study done on Type II diabetics, the aging population had low adherence rates due to forgetfulness in taking their medication and high pill burden since they normally have other comorbidities (Mwera, 2013). A Zambian hospital-based observational study showed that there was a relationship between poor

medication adherence and poor blood sugar control. In the study, insufficient resources in the area and inadequate capacity to manage the disease led to poor medication adherence (Musenge *et al.,* 2016).

Self-monitoring of blood glucose

Blood glucose monitoring at home is recommended as an effective way of ensuring good glycemic control since patients can easily and conveniently assess their response to therapy (American Diabetes Association, 2016). Most cross-sectional studies on factors affecting blood glucose levels have shown that patients who regularly monitor their blood sugars have better glycemic control (Ji *et al.,* 2013; Miller *et al.,* 2013; Musenge *et al.,* 2016). On the contrary, a Malaysian exploratory study done at primary health clinics showed that self-management practices had no effect on glycemic control, but emphasized on the need of ensuring that patients observe self-management behaviors (Ahmad, Islahudin and Paraidathathu, 2014).

In conclusion, diabetes is on the rise globally, and this poses a significant financial burden on the individual, the health-care system and to a country's economy. From the literature review, various socio-demographic, clinical and behavioral factors influence glycemic control. There is conflicting information on the effect of different factors on diabetes control depending on the study design, study population and the sample size. Therefore, there is a need for the study in Machakos County since the study population has varying characteristics that may affect glycemic levels.

CHAPTER 3: METHODOLOGY

3.1: Study design

The study was an unmatched retrospective hospital-based case-control which applied a quantitative methodological approach. Cases were respondents with poor glycemic control, while controls were those with good glycemic control. The total sample size was 168 respondents, comprising eighty-four cases and eighty-four controls. This study design enabled an efficient sampling technique for assessing the association between various exposures and glycemic control. The study was carried out from December 2017 to February 2018.

3.2: Study area

The study was conducted at Machakos Level Five Hospital, which is the main referral hospital in Machakos County.

Machakos County is in Kenya, and its largest town is Machakos town. The County area covers 6,208 square kilometers with a population of 1,098,584. There are eight sub-counties namely Masinga, Matungulu, Mwala, Athi River, Kangundo, Kathiani, Machakos, and Yatta.

The area is semi-arid and has an altitude of 1000 to 2100 meters above sea level. Maize and drought-resistant crops such as sorghum and millet are the main food crops in the area. The County has open-air markets with major market days where trading of goods such as fruits, vegetables and other foodstuffs like maize and beans takes place.

Machakos Level Five Hospital was the ideal study area since it is the main referral hospital in Machakos County. It serves a large population from the eight sub-counties and the

neighboring counties that include Kitui and Makueni. Type II diabetics attending the outpatient clinic, as per the hospital registry, were approximately 700 at the beginning of the study period, which provided a good base population to choose the cases and controls from. The location of Machakos County in the map of Kenya is as shown in figure 3.

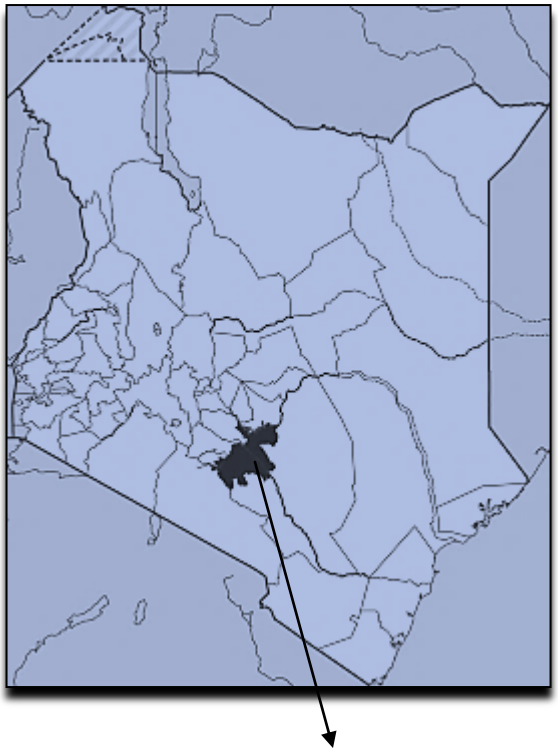

Figure 3: Map of Kenya showing Machakos County (Wiesmann, Boniface and Mwangi, 2016)

3.3: Study population

The study population comprised Type II diabetics attending the outpatient clinic in Machakos Level 5 Hospital. Cases were those with poor glycemic control while the controls were those with good glycemic control.

3.4: Case-control classification

Case definition

Cases were patients with Type II diabetes in the study population with poorly controlled glycemic levels. An average of the last two consecutive fasting blood glucose readings was used and if it was >7.0mmol/l, then the individual was considered a case.

Controls definition

Controls were patients with Type II diabetes in the study population with well-controlled glycemic levels. An average of the last two consecutive fasting blood glucose readings was used and if it was ≤7.0mmol/l, then the individual was considered a control.

Inclusion criteria:

For both cases and controls, individuals that were included were those aged over 18 years, Type II Diabetics attending Machakos Level 5 Diabetes Clinic for at least six months, and those willing to give informed consent.

Exclusion criteria:

In both cases and control arms, patients excluded were those attending Machakos diabetes clinic for less than six months, who declined to give informed consent, requiring immediate medical attention and expectant plus lactating mothers.

3.5: Study variables

Predictor variables included socio-demographic, clinical and behavioral factors.

a. Socio-demographic factors

These included age, sex, education, income levels, marital status, and occupation.

b. Clinical factors

These included BMI, monitoring of blood glucose, medication use, hypertension, diabetic complications, family history of diabetes and duration of diabetes.

c. Behavioral factors

These included tobacco use, alcohol use, physical activity, diet, self-monitoring of blood glucose and adherence to medication.

Predictor variables and their measurements in the study are as shown in table 1.

Table 1: Predictor variables and their measurements	
Predictor variable	**Measurement of the predictor variable**
Socio-demographic factors	
Age	Measured in years
Sex	Assessed as male or female
Level of education	Classified into primary education, secondary education, tertiary education, and no formal education
Marital status	Assessed as single, married, widow/widower
Religion	This was captured as Christian, Muslim or other
Occupation	Assessed as either employed, not-employed or retired
Income levels	Income levels were categorized as no income, <=5000, 5001-20000, >20001
Clinical factors	
BMI	Computed as weight (kgs) / height in meters squared
Blood glucose measurements	Assessed using fasting blood glucose.
Hypertension	Determined using systolic and diastolic measurements.
Diabetes complications	Assessed as being absent or present
Family history of diabetes	Assessed as being absent or present
Diabetes medication use	Categorized into oral medication, injectable or both
Duration of diabetes	Assessed in years
Behavioral factors	
Tobacco use	Categorized as tobacco users or non-users
Alcohol use	Categorized as alcohol consumers or non-consumers
Physical activity	Classified into low, moderate or high-intensity exercise.
Appropriate diet	Classified as either adherent or non-adherent
Medication adherence	Categorized as being adherent or non-adherent.
Self-monitoring of blood glucose	Grouped into SMBG done or not done.

Outcome Variable- Glycemic control

Glycemic control –Fasting blood glucose was used to assess glycemic control. Good glycemic control was at a fasting blood glucose of ≤7.0mmol/l, obtained from the average of the last two consecutive FBG readings and poor glycemic control was at a fasting blood glucose of >7.0mmol/l, obtained from the average of the last two consecutive FBG readings.

3.6: Sampling and recruitment criteria

The sampling frame included all Type II diabetic patients aged 18 years and above attending Machakos Level 5 diabetes clinic. Patient records of those who had clinic bookings during the study period were used to identify cases and controls at the beginning of the study period. Those who met the inclusion criteria were identified and classified as either a case or a control, and simple random sampling was used to obtain 84 cases and 84 controls. A simple flow diagram of patient movement through the clinic and recruitment is as illustrated in figure 4.

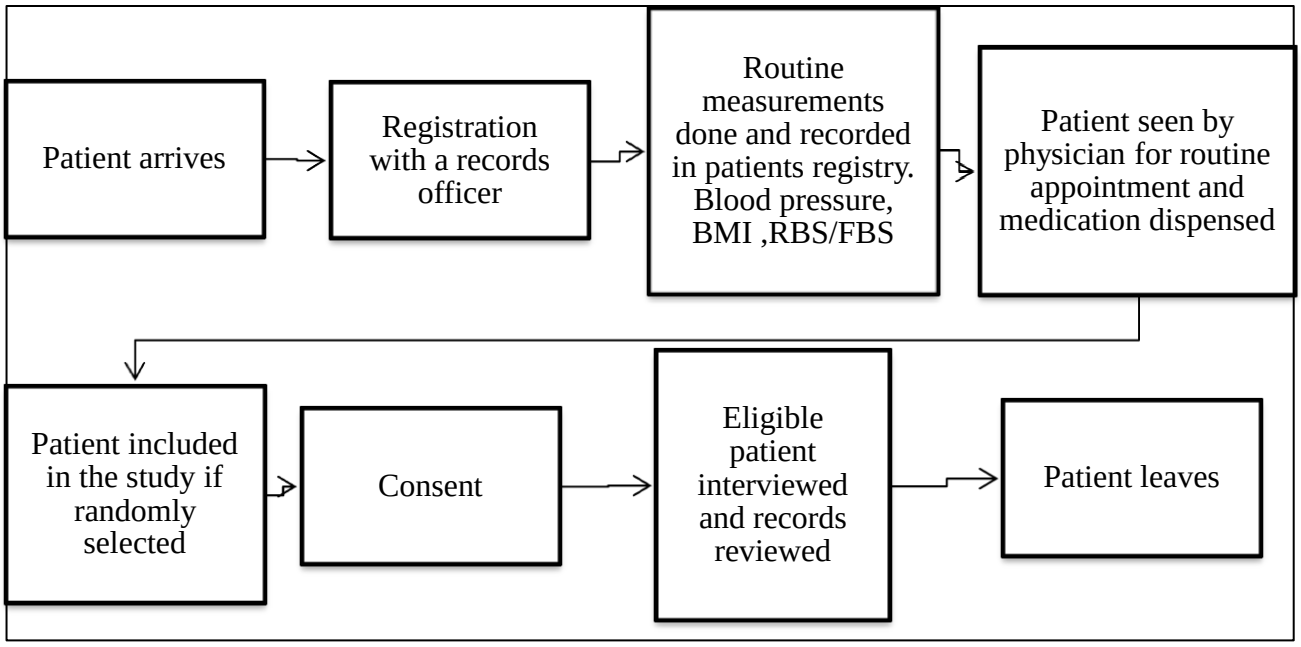

Figure 4: Flow diagram of patient movement through the clinic and recruitment process

3.7: Sample size

The standard statistical approach to determining sample size for a case-control study was applied (Kesley et al., 1996).

$$n_1 = \frac{(Z_\alpha + Z_\beta)^2 \bar{p}\bar{q}(r+1)}{r(p_1 - p_2)^2} \qquad n_2 = rn_1$$

$$\bar{p} = \frac{p_1 + \mathrm{r}p_2}{\mathrm{r}+1} \qquad p_1 = \frac{p_2 \mathrm{OR}}{1 + p_2(\mathrm{OR}-1)} \qquad \bar{q} = 1 - \bar{p}$$

$\mathbf{Z_{\alpha/2}}$ (1.96) and $\mathbf{Z_{1-\beta}}$ (0.84) represent the 2-tailed confidence level (95%) and statistical power (80%) desired respectively. $\mathbf{p_1}$ is the proportion of individuals with poor glycemic control who

do not adhere to medication and $\mathbf{p_2}$ is the proportion of individuals with good glycemic control who do not adhere to medication and is set at 31% with an odds ratio (OR) of 2.4 (Akotey, 2012). **r** = 1, is the ratio of controls to cases. Given the figures, a total sample size of **168** subjects, (84 cases and 84controls) were selected.

3.8: Data collection procedure

After recruitment and signing of informed consent, the interviewer administered a structured questionnaire in a private room. The questionnaire consisted of socio-demographic data, behavioral and clinical factors. Clinical records were reviewed for medications in use, complications suffered and the last two consecutive fasting blood glucose readings. All collected data were anonymized and availed by code only to the principal investigator to ensure confidentiality.

3.9: Data processing and analysis

Each question was coded and the data was entered into an Epi-Data spreadsheet, version 3.1 (Epi-data association, Denmark). Double entry of data was done and data cleaning to ensure accuracy. The validated dataset was exported to STATA version 13 (Stata Corporation, Texas, USA) for analysis.

For descriptive statistics, continuous variables were summarized using the median and interquartile range (IQR). For qualitative variables, the proportions (percentages) were computed. Initial analysis was carried out based on a series of univariable comparisons to evaluate the effect of each predictor variable on the outcome variable. The significance of each predictor variable was evaluated by using a likelihood ratio test at $p<0.20$, which is a liberal p-value, to rule out negative confounding (Dohoo, Martin and Stryhn, 2012).

Significant variables in the univariable analysis were then included in the multivariable model. The significant variables at $p \leq 0.05$ (Dohoo, Martin and Stryhn, 2012) were considered to be associated with the outcome variable.

4.0: Minimization of errors and bias

The study was prone to recall bias, interviewer bias, and incomplete questionnaires. To minimize errors and bias, a pre-tested standard questionnaire was used and conducting interviews was limited to the researcher. Recall bias was minimized by collecting information about the exposure for the twelve months before the study. Double checking of questionnaires was done to avoid omissions and in case of incomplete questionnaires, the participants were re-interviewed.

4.1: Ethical considerations

The Kenyatta National Hospital KNH-UoN Ethics and Research Committee provided clearance for the study under protocol number P329/06/2017. Machakos Level Five Hospital also gave approval for the study to be conducted in the facility. Subjects who agreed to participate in the study signed a written consent form and they were free to leave the study at will. Data collected was kept confidential through the anonymity of the questionnaires and no information obtained was shared out.

The participants were not remunerated in any way and they were made to understand the benefits of the study.

4.2: Pilot study

The data collection tool which was an interview administered structured questionnaire was pre-tested in Machakos Level Five Hospital. The pilot study was essential to test the tool and

amend it accordingly. Pre-test of the tool did not interfere with the collection of the main data. This was ensured by not including data and participants from the pilot study in the main study. A sample of twenty participants from the study population was involved in the pilot study. From the pilot study, the questionnaires were found to be in order and no amendments were done.

4.3: Study limitations

The study being a case-control study was able to capture the association between the predictor and outcome variables, but could not estimate the prevalence of poor glycemic control in the study population. Therefore, a cross-sectional study can be carried out in future studies within the population to determine the prevalence of poor glycemic control.

Being a retrospective study, only a limited number of variables could be assessed for association with glycemic control. Health-care system factors also need to be explored because they have been shown to affect glycemic levels. More so, the information on variables assessed was obtained by self-report which may have been limited by recall bias, especially behavioral factors.

The study used FBG readings as opposed to HbA1c to monitor and assess glycemic control. HbA1c test is the gold standard test for glycemic control but the test is not available in Machakos Level Five Hospital and patients are not able to afford it. FBG is routinely used on all patients and is affordable. Moreover, studies have shown that the morning FBG can be used to measure glycemic control. The study used an average of the last two consecutive FBG readings for more accurate results.

CHAPTER 4: RESULTS

During the study period December 2017-February 2018, one hundred and sixty eight (168) participants were recruited in the study; 84 cases and 84 controls. Three cases and two controls declined to participate in the study. Complete data from one hundred and sixty three (163) participants, 81 cases and 82 controls, were considered for analysis.

From the data obtained, descriptive statistics was carried out for continuous variables and proportions obtained for qualitative variables. Univariable analysis was then conducted for each factor, and significant factors were subjected to the multivariable model.

The flow diagram of study participants is as shown in figure 5.

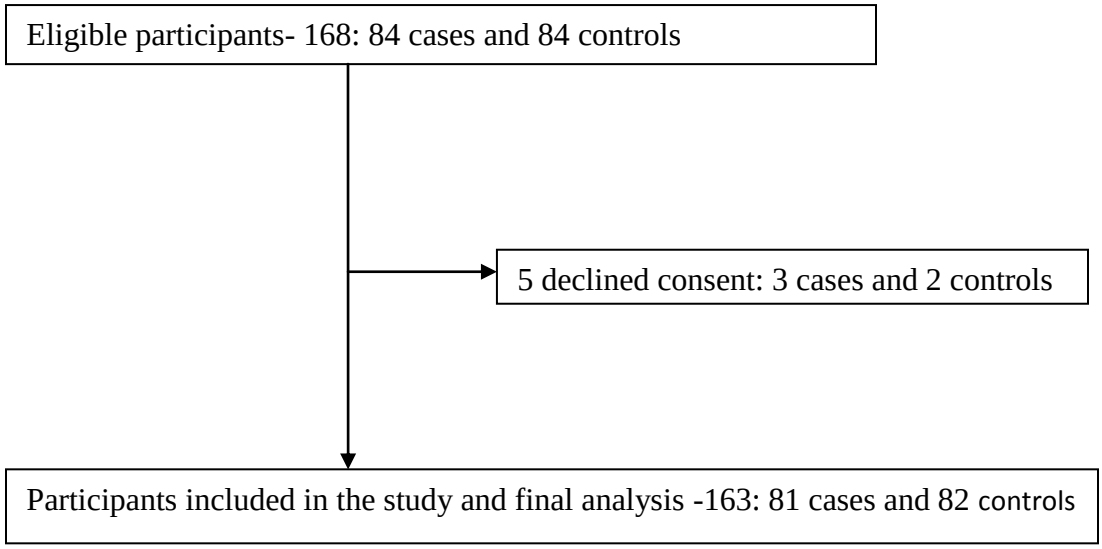

Figure 5: Flow diagram of recruited participants

Descriptive statistics

A total of 163 participants were included in the final analysis comprising 81 cases and 82 controls. Notably, a majority of the patients were female (65.6%) who made up 71.6% of the cases and 59.8% of the controls. The age of the study participants ranged from 28-90 years with a median of 62 years. Cases had a median age of 65 years while controls had a median age of 59 years. Most of the cases (42.3%) and controls (44.4%) had primary level education, were married, cases (85.2%) and controls (84.2%); and had income levels of between 5,001 and 20,000, cases (33.3%) &controls (35.4%). Majority of the participants were in employment, 38.3% of the cases and 58.5% of the controls. This is as portrayed in table 2.

Table 2: Descriptive statistics of socio-demographic factors affecting glycemic control among Type II diabetics attending Machakos Level Five Hospital (n=163: cases=81, controls=82)

Variable	Values	Cases Frequency n (%)	Controls Frequency n (%)	Total Frequency n (%)
Sex	Male	23 (28.4)	33 (40.2)	56 (34.4)
	Female	**58 (71.6)**	**49 (59.8)**	**107 (65.6)**
Age (years)	28.0 – 90.0	**Median** 65	59	62
		IQR 18	17	19
Level of education	No formal education	6 (7.4)	8 (9.8)	14 (8.6)
	Primary education	**36 (44.4)**	**33 (40.2)**	**69 (42.3)**
	Secondary education	30 (37.0)	29 (35.4)	59 (36.2)
	Tertiary education	9 (11.1)	12 (14.6)	21 (12.9)
Marital status	Single	7 (8.6)	6 (7.3)	13 (8.0)
	Married	**69 (85.2)**	**69 (84.2)**	**138 (84.7)**
	Widow/widower	5 (6.2)	7 (8.5)	12 (7.4)
Occupation	Not employed	**35 (43.2)**	27 (32.9)	62 (38.0)
	Employed	31 (38.3)	**48 (58.5)**	**79 (48.5)**
	Retired	15 (18.5)	7 (8.5)	22 (13.5)
Income Levels	No income	26 (32.1)	24 (29.3)	50 (30.7)
	≤5000	24 (29.6)	17 (20.7)	41 (25.2)
	5001-20000	**27 (33.3)**	**29 (35.4)**	**56 (34.4)**
	≥20001	4 (4.9)	11 (13.4)	15 (9.2)
	Not indicated	-	1 (1.2)	1 (0.6)
Religion	Christian	81 (100)	82 (100)	163 (100)
	Muslim	-	-	
	Other	-	-	

In both groups, the duration of diabetes was between 1-40 years, with the cases having a median of 9 years and controls 5 years. Moreover, both cases (77.8%) and controls (82.9%) were mostly on oral medication and had a family history of diabetes, cases (54%) and controls (56%). Majority of the controls (57.3%) did not have diabetes complications but 58% of the cases had diabetes complications. The systolic blood pressure (BP) in both groups ranged from 101-195 mmHg, with the cases having a median of 139 mmHg and controls 138 mmHg.

Diastolic BP was in the range of 56-116 mmHg, with a median of 84 mmHg for cases and 85mmHg for controls. BMI ranged from 17- 43.5 kg/$m^2$for both groups, with the median for cases being at 26.3 kg/m^2 and 25.7 kg/m^2 for controls. This is as seen in table 3.

Table 3: Descriptive statistics of clinical factors affecting glycemic control among Type II diabetics attending Machakos Level Five Hospital (n=163: cases=81, controls=82)

Variable	Values	Cases	Controls	Total
		Frequency n (%)	Frequency n (%)	Frequency n (%)
Duration of disease (years)	1.0 -40.0	**Median** 9 **IQR** 8	5 7	7 7
Type of treatment	Oral medication Injectable Combination of both	**63 (77.8)** 10 (12.4) 8 (9.9)	**68 (82.9)** 5 (6.1) 9 (11.0)	**131 (80.4)** 15 (9.2) 17 (10.4)
Diabetes history	Absent Present	37 (45.7) **44 (54.3)**	36 (43.9) **46 (56.1)**	73 (44.8) **90 (55.2)**
Diabetes complications	Absent Present	34 (42.0) 47 **(58.0)**	**47 (57.3)** 35 (42.7)	81 (49.7) **82 (50.3)**
Systolic BP	101 - 195	**Median** 139 **IQR** 28	138 22	139 24
Diastolic BP	56 - 116	**Median** 84 **IQR** 11	85 16	84 13
BMI	17 – 43.5	**Median** 26.3 **IQR** 6.5	25.7 5.7	25.8 5.7

Descriptive statistics on behavioral factors is as displayed in table 4.

Majority of the cases (97.5%) and controls (97.6%) did not use tobacco and alcohol. About 50.6% of the cases and 90.2% of the controls adhered to the appropriate diet. Most of the controls (77%) engaged in moderate physical activity, while majority of the cases (58%) did

not engage in enough physical activity. Self-monitoring of blood glucose (SMBG) was done by most of the controls (57.3%) but not by the cases (85.2%). Majority of the cases (69%) and controls (88%) adhered to the prescribed medications

Table 4: Descriptive statistics of behavioral factors affecting glycemic control among Type II diabetics attending Machakos Level Five Hospital (n=163: cases=81, controls=82)

Variable	Values	Cases Frequency n (%)	Controls Frequency n (%)	Total Frequency n (%)
Alcohol use	Non-consumer	**79 (97.5**)	**80 (97.6)**	**159 (97.6)**
	Consumer	2 (2.5)	2 (2.4)	4 (2.4)
Tobacco use	Non-user	**80 (98.8**)	**82 (100**)	**162 (99.4)**
	User	1 (1.2)	-	1 (0.6)
Appropriate diet	Non-adherent	40 (49.4)	8 (9.8)	48 (29.5)
	Adherent	**41 (50.6**)	**74 (90.2)**	**115 (70.6)**
Physical activity	Low	**47 (58.0)**	17 (20.7)	64 (39.3)
	Moderate	34 (42.0)	**63 (76.8)**	**97 (59.5)**
	High	-	2 (2.4)	2 (1.2)
Self-monitoring of blood glucose	Not done	**69 (85.2)**	35 (42.7)	**104 (63.8)**
	Done	12 (14.8)	**47 (57.3)**	59 (36.2)
Medication adherence	Non-adherent	25 (30.9**)**	10 (12.2)	35 (21.5)
	Adherent	**56 (69.1)**	**72 (87.8)**	**128 (78.5)**

Logistic regression analyses

Based on logistic regression analyses, socio-demographic factors that were significantly associated with poor glycemic control at p≤0.20 were; sex, age, occupation and income-levels as seen in table 5.

Table 5: Logistic regression analysis of socio-demographic factors affecting glycemic control among Type II diabetics attending Machakos Level Five Hospital

Variable	Values	Cases (n=81) n	Controls (n=82) n	Crude OR	95% CI Lower- Upper	p-value
Sex	Male	23	33	1.0	-	
	Female	58	49	1.70	0.88 – 3.27	**0.111***
Age group	18-39 years	7	4	1.0	-	
	40-59 years	21	38	3.17	0.83 – 12.08	
	≥60years	53	40	1.32	0.36 – 4.82	**0.022***
Level of education	No formal education	6	8	1.0	-	
	Primary education	36	33	0.69	0.22 – 2.19	
	Secondary education	30	29	0.73	0.22 – 2.35	0.836
	Tertiary education	9	12	1.00	0.25 – 3.92	
Marital status	Single	7	6	1.0	-	
	Married	69	69	1.17	0.37 – 3.65	0.816
	Widow/widower	5	7	1.63	0.34 – 7.95	
Occupation	Not employed	35	27	1.0	-	
	Employed	31	48	2.01	1.02 – 3.94	**0.021***
	Retired	15	7	0.60	0.22 – 1.69	
Income Levels	No income	26	24	1.0	-	
	≤5000	24	17	0.77	0.33 – 1.77	
	5001-20000	27	29	1.16	0.54 – 2.50	
	≥20001	4	11	2.98	0.84 – 10.63	**0.191***
	Not indicated		1	-	-	

Clinical factors that were significantly associated with glycemic control at p≤0.20 were the duration of disease and presence of diabetes complications. This is as portrayed in table 6.

Table 6: Logistic regression analysis of clinical factors affecting glycemic control among Type II diabetics attending Machakos Level Five Hospital

Variable	Values	Cases (n=81) n	Controls (n=82) n	Crude OR	95% CI Lower- Upper	p-value
Duration of disease (years)	≤5	27	44	1.0	-	
	6-10	28	24	0.53	0.25 – 1.09	**0.018***
	≥ 11	26	14	0.33	0.15 – 0.74	
Type of treatment	Oral medication	63	68	1.0	-	
	Injectable	10	5	0.46	0.15 – 1.43	0.379
	Combination of both	8	9	1.04	0.38– 2.87	
Diabetes history	Absent	37	36	1.0	-	
	Present	44	46	1.07	0.58 – 1.99	0.820
Diabetes complications	Absent	34	47	0.54	0.29 – 1.00	**0.050***
	Present	47	35	1.0	-	
Systolic BP (mmHg)	≤139.9	41	43	1.0	-	
	140-159.9	25	28	1.07	0.54 – 2.13	0.661
	≥160	15	11	0.70	0.29 – 1.70	
Diastolic BP (mmHg)	≤79.9	22	25	1.0	-	
	80-89.9	37	33	0.78	0.37 – 1.65	0.778
	≥90	22	24	0.96	0.43 – 2.17	
BMI (Kg/m^2)	Normal weight	33	34	1.0	-	
	Over-weight	32	35	1.06	0.54 – 2.09	0.797
	Obese	16	13	0.79	0.33 – 1.89	

Behavioral factors that were significantly associated with glycemic control at p≤0.20 were; diet, physical activity, self-monitoring of blood glucose and medication adherence. This is as demonstrated in table 7.

Table 7: Logistic regression analysis of behavioral factors affecting glycemic control among Type II diabetics attending Machakos Level Five Hospital

Variable	Values	Cases (n=81) n	Controls (n=82) n	Crude OR	95% CI Lower- Upper	p-value
Alcohol use	Non-consumer Consumer	79 2	80 2	1.0 0.99	- 0.14 – 7.18	0.990
Tobacco use	Non-user User	80 01	82 00	1.0 -	- -	-
Appropriate diet	Non-adherent Adherent	40 41	8 74	9.02 1.0	3.86 – 21.11 -	**0.000***
Physical activity	Low Moderate High	47 34 -	17 63 2	5.12 1.0 -	2.56 – 10.25 - -	**0.000***
Self-monitoring of blood glucose	Not done Done	69 12	35 47	7.72 1.0	3.64 - 16.40 -	**0.000***
Medication adherence	Non-adherent Adherent	25 56	10 72	3.21 1.0	1.43 – 7.24	**0.003***

***Significant variables eligible for inclusion in the multivariable model (p ≤0.20)**

The significant factors from the logistic regression analyses were subjected to the multivariable model, diabetes complications, diet, physical activity and self-monitoring of blood glucose were significantly associated with glycemic control.

Those who did not adhere to the recommended diet had about six times (aOR:5.98; 95% CI; 1.97-18.10) the odds of poor glycemic control compared to those who adhered to the appropriate diet, controlling for age, co-morbidities, physical activity, SMBG, and medication

adherence. Compared to those who moderately exercised, respondents who did low physical activity had about three (aOR: 2.71; 95% CI; 1.05-7.04) times the odds of poor glycemic control, controlling for age, diabetes complications, diet, SMBG, and medication adherence.

Respondents who did not carry out SMBG had about five times (aOR: 5.35; 95% CI; 2.09-13.72) the odds of poor glycemic control, compared to those who self-monitored their blood glucose levels, controlling for age, diabetes complications, diet, physical activity, and medication adherence. Multivariable analysis results are as displayed in table 8.

Table 8: Multivariable logistic regression analysis of the factors affecting glycemic control among Type II diabetics attending Machakos Level Five Hospital

Variable	Values	aOR[a]	95% CI Lower Upper	LRT p-value
Sex	Male Female	1.0 1.85	- 0.71 – 4.86	0.205
Age group	18-39 years 40-59 years ≥60years	1.0 7.29 2.19	- 0.98 – 54.18 0.33 – 14.69	0.023
Occupation	Not employed Employed Retired	1.0 4.11 0.95	- 0.77 – 21.90 0.16 – 5.53	0.067
Income levels	No income ≤5000 5001-20000 ≥20001 Not indicated	1.0 0.55 0.18 0.60 -	- 0.12 – 2.47 0.03 – 1.18 0.05 – 6.67 -	0.169
Duration of disease (years)	≤5 6-10 ≥ 11	1.0 0.66 0.44	- 0.24 – 1.83 0.15– 1.34	0.344
Diabetes complications	Absent Present	0.40 1.0	0.17 – 0.96 -	**0.037***
Appropriate Diet	Non-adherent Adherent	5.98 1.0	1.97 – 18.10 -	**0.000***
Physical Activity	Low Moderate High	2.71 1.0 -	1.05 – 7.04 - -	**0.039***
Self-monitoring of blood glucose	Not-Done Done	5.35 1.0	2.09 – 13.72 -	**0.000***
Medication adherence	Non-adherent Adherent	1.88 1.0	0.58 – 6.16	0.293

[a]Adjusted odds ratio

[*]Significant variables that affect glycemic control in the study population ($p \leq 0.05$)

CHAPTER 5: DISCUSSION

5.1: Introduction

The main objective of this study was to assess factors affecting glycemic control among Type II diabetics attending Machakos Level Five Outpatient Clinic. The predictor variables assessed were categorized into socio-demographic, clinical and behavioral factors. The response rate was 97% and the 3% non-response did not have any effect on the validity of the data obtained from the final analysis.

This study demonstrated that diet, physical activity, diabetes complications and self-monitoring of blood glucose are significant in attaining optimal glycemic control in the study population.

These findings are important because knowledge of these factors is essential in the formulation of appropriate health actions centered on the patient to obtain adequate glycemic control and improve patient outcomes. Targeted interventions also reduce socio-economic cost and enhance the patients' quality of life leading to a decreased burden of disease.

5.2: Review and discussion of key findings

Key findings according to the research objectives of this study are as summarized in table 9.

Table 9: Key findings from the study research objectives

Research objective	Key finding
1.To assess Socio demographic factors affecting glycemic control in the study population	None of the variables under socio-demographic factors had a significant association with glycemic control
2.To assess clinical factors affecting glycemic control in the study population	The absence of diabetes complications was associated with good glycemic control
3. To assess behavioral factors affecting glycemic control in the study population	• Diet- The type of diet consumed in the study population was associated with glycemic control. • Physical activity – Those who undertook low physical activity had about three times the odds of poor glycemic control compared to those who moderately exercised. • Self-monitoring of blood glucose – Patients who did not regularly monitor their blood glucose levels had an increased risk of poor glycemic control compared to those who did.

5.2.1: Socio-demographic factors

There was no association between age and glycemic control in this study. This could have been as a result of most respondents being in the same age group, with the median age for both cases and controls being 62 years. This finding is consistent with exploratory study

results obtained from Type II diabetics conducted in Brazil (Mendes et al., 2010), Tanzania (Mwera, 2013) and Kenya (Nduati et al., 2016). However, some cross-sectional studies done showed that old age was associated with good glycemic control. This was attributed to the elderly patients having a better knowledge on how to manage their sugar levels having lived with the condition for a long time (Paul *et al.*, 2011; Nduati *et al.*, 2016). The observed differences in the association between age and glycemic control can be explained by the variation in population characteristics, study designs and age distribution in different studies.

The study finding showed no association between sex and glycemic control. This could be as a result of females comprising a majority of the study participants. This is expected in the study area because men have poor health-seeking behaviors. This finding is similar to that reported in a Portugal, Ghana and Ethiopian prevalence study on Type II diabetics (Tengey, 2012; Kassahun, Eshetie and Gesesew, 2016; Lima *et al.*, 2016). However, cross-sectional studies done in Libya (Ashur *et al.*, 2016), Saudi (Habib, 2013) and Kenya (Nduati *et al.*, 2016), showed that women had poor glycemic control compared to men. This was linked to the high rates of obesity in women which contributed to high blood glucose levels. On the contrary, men had poor glycemic control compared to women, in an Oman study on Type II diabetics due to poor health-seeking behaviors in males (D *et al.*, 2013). The different study methods could also contribute to differing conclusions.

The level of education was not associated with glycemic control. The lack of association in this study could be due to the fact that most study participants had about the same level of education which was primary education. This finding was expected because the poverty levels are at 59.6% which contributes to the poor socio-economic background (Kenya National

Beaureu of statistics, 2005). This finding is concurrent with observations in made in Niger (Ufuoma *et al.*, 2016), Ethiopia (Angamo, Melese and Ayen, 2013), Tanzania (Mwera, 2013) and Kenya (Nduati *et al.*, 2016), which were mainly observational studies. On the contrary, higher education was associated with good glycemic control in an Oman prevalence study due to increased awareness on diabetes management and blood glucose control (D *et al.*, 2013).

Marital status, occupation, income levels, and religion had no association with glycemic control. This finding might be explained by the fact that there was no major variation between the cases and controls in terms of the stated factors. This is as reported in cross-sectional studies done in India (Sasi Sekhar *et al.*, 2013) and Portugal(Lima *et al.*, 2016). It was however expected that income levels would affect glycemic control since those with higher incomes could afford medications and appropriate diets, hence better self-care than those with a low income. In a USA observational study, high-income levels were linked to good glycemic control due to enhanced access to insurance leading to better disease management (Shani *et al.*, 2008).

5.2.2: Clinical factors

In this study, the absence of diabetes complications was associated with good glycemic control. This observation was expected in the study area because there are inadequate health facilities and few medical personnel (Machakos County Government, 2013). This limits accessibility for patients and reduces the health-seeking behavior. Consequently, there is a high risk of developing diabetes complications which impact negatively on glycemic control. They are also a barrier to adequate patient self-care because they affect medication compliance due to the high pill burden and associated costs. This finding was consistent with

previous prevalence studies done in Malaysia (Mafauzy, Hussein and Chan, 2011), Turkey (Kayar *et al.*, 2017) and Ethiopia (Angamo, Melese and Ayen, 2013).

The duration of diabetes was not associated with glycemic control in this study. This is because the proportion of respondents with a short duration of diabetes was high, and majority of them had good glycemic control. This finding is concurrent with observations in a Ghana case-control study (Tengey, 2012). Other cross-sectional studies on diabetics have shown a positive association between diabetes duration and glycemic control in India (De, Banu and Muthukumar, 2018), Iran (Janghorbani and Amini, 2012), Ethiopia (Yigazu and Desse, 2017) and South Africa(Timothy, 2010). This was attributed to progressive impairment of insulin secretion due to B-cell failure. Consequently, patients tend to have a poor response to diet alone or medication (Ji *et al.*, 2013).

Drug utilization pattern in this study had no significant association with glycemic control. This is because most respondents were on oral anti-diabetics for both cases and controls. Few patients were on insulin and combination therapy. This finding was as expected because oral anti-diabetics are readily available and affordable in the study area. This observation is concurrent with a study done in India on factors affecting glycemic control (B. Gopinath *et al.*, 2013). Other cross-sectional studies have shown a positive association between the type of anti-diabetic used and glycemic control in Malaysia (Ahmad, Islahudin and Paraidathathu, 2014) and Ethiopia (Kassahun, Eshetie and Gesesew, 2016). Patients on only oral medication had better glycemic control than those on insulin and combination therapy (Ali *et al.*, 2012; Angamo, Melese and Ayen, 2013; Ashur *et al.*, 2016). This was attributed to poor adherence

as a result of combination therapy and inadequate dosages and injection techniques for those on insulin therapy (Ji *et al.*, 2013).

Having a family history of diabetes was not significantly associated with glycemic control in the study. Diabetes history in this study may not have shown any association since both cases and controls had an equal proportion of familial diabetes history. However, with a family history of diabetes, it is expected that patients may have an earlier onset of diabetes which pre-disposes them to hyperglycemia with time (Gong *et al.*, 2008). This study finding is consistent with the results of a Ghana study (Tengey, 2012) where having a family history of diabetes and support was not associated with blood glucose levels. However, exploratory studies conducted in India (De, Banu and Muthukumar, 2018), Turkey (Kayar *et al.*, 2017) and Malaysia (Almutairi, Said and Zainuddin, 2013) showed a significant association between having a family history of diabetes and glycemic control. Having a familial history of diabetes was a risk factor for poor glycemic control in susceptible patients, according to a China prevalence study (Wu *et al.*, 2017).

Both systolic and diastolic blood pressures showed no significant association with glycemic control. This is because the study showed a median systolic blood pressure of 139mmHg and diastolic BP 89mmHg which was within normal range in both groups, hence no association with glycemic control. This is concurrent with a study on Type II diabetics conducted in India (De, Banu and Muthukumar, 2018). On the contrary, most diabetic patients have been found to have high blood pressure, which is a co-morbidity that contributes to poor glycemic control in Ghana (Tengey, 2012), Australia (Luijks *et al.*, 2015) and Kenya (Nduati *et al.*, 2016).

BMI in the study was not significantly associated with glycemic control. This observation could have been as a result of the median BMI being relatively normal for both cases and controls. This finding was expected because most people in the region have low BMI. This is concurrent with a Kenyan cross-sectional study on diabetics (Nduati *et al.*, 2016). However, other studies on risk factors for poor glycemic control have shown a positive association between being obese or overweight and poor glycemic control in the USA (Bae *et al.*, 2016), India (De, Banu and Muthukumar, 2018) and Ghana (Tengey, 2012). This was attributed to insulin resistance among those with high BMI leading to poor glycemic control (Al-Rasheedi, 2015).

5.2.3: Behavioral factors

The type of diet consumed in the study population was significantly associated with glycemic control. Those who did not adhere to the recommended diet had about six times the odds of poor glycemic control compared to those who adhered. Low adherence to a diabetic meal plan in this study could be due to poor dietary habits. The primary staple food in the study population comprised of maize mixed with beans and peas ('isyo') which is not a well-balanced diet for diabetics. Additionally, most households consume one big portion of food, while approximately 40% of the households lack food or money to purchase food (Kenya National Bureau of Statistics (KNBS); ICF Macro, 2014). This predisposes them to uncontrolled blood glucose levels. These findings are concurrent with results from cross-sectional studies conducted in Turkey (Kayar *et al.*, 2017), Libya (Ashur *et al.*, 2016), Jordan (Khattab *et al.*, 2010) and Ethiopia (Angamo et al. 2013).

Physical activity was significantly associated with glycemic control in the study. Those who undertook low physical activity had about three times the odds of poor glycemic control compared to those who did moderate physical activity. Low physical activity in the study population could have been due to a majority of them being elderly which could interfere with regular exercise. Exercise has been shown to improve glucose control by increasing insulin sensitivity and non-insulin-dependent glucose uptake in skeletal muscles (Holloszy, 2005). This finding is concurrent to exploratory studies carried out in Turkey (Kayar *et al.*, 2017), India (Sasi Sekhar *et al.*, 2013) and Libya (Ashur *et al.*, 2016). On the contrary, studies on diabetics done in Malaysia (Almutairi, Said and Zainuddin, 2013) and South Africa (Timothy, 2010) showed no significant association between physical activity and glycemic control.

Self-monitoring of blood glucose had a significant association with glycemic control. Patients who did not monitor their blood glucose levels regularly had an increased risk of poor glycemic control compared to those who frequently monitored. This finding is expected in the study areas because of the high poverty level which makes glucometers and reagents strips unaffordable for diabetic patients (Pastakia *et al.*, 2015). Patients are thus prone to poor glycemic control and the development of complications. This finding is comparable to study observations made in the USA (Miller *et al.*, 2013), China (Ji *et al.*, 2013) and Tanzania (Mwera, 2013). On the contrary, a Malaysian study done in primary health clinics on Type II diabetics found no significant association (Ahmad, Islahudin and Paraidathathu, 2014). Frequent blood glucose monitoring enhances quick assessment of response to therapy and keeps track of the blood sugar levels. This ensures that glycemic levels are kept under control.

Medication adherence was not associated with glycemic control in the study. This study may have shown no relationship because most of the cases and controls adhered to the prescribed medications. This finding was as expected since diabetes medication was readily available in the diabetes pharmacy hence increasing the rate of compliance. This is contrary to other study observations which have shown poor glycemic outcomes for those who fail to comply with the prescribed medication. These were study findings in the USA (Aikens and Piette, 2013), Jordan (Khattab *et al.*, 2010), Ethiopia (Kassahun, Eshetie and Gesesew, 2016) and Tanzania (Mwera, 2013). However, a South African prevalence study(Timothy, 2010) had the same finding as this study, showing no association between medication compliance and glycemic control.

Alcohol and tobacco use were not subjected to linear regression in the study since almost all of the participants did not consume alcohol or use tobacco. This was because about 70% of the study populations were women, with a median age of 62 making it highly unlikely for them to be users of alcohol and tobacco. The study findings are comparable to those obtained in an Ethiopian cross-sectional study (Woldu *et al.*, 2014). Other studies on factors affecting glycemic levels, however, have shown an association between tobacco use and glycemic control. These are studies conducted in the UK (Vlassopoulos, Lean and Combet, 2013), Oman (D *et al.*, 2013), and Ghana (Tengey, 2012). Alcohol consumption has been shown to have no effect on glycated hemoglobin in a Japan study on non-diabetics consuming alcohol (Inada and Koga, 2017).

5.3: Strengths and weaknesses of the study

The case-control design in this study showed the association between various exposures and the outcome variable, having controlled for potential confounders that gave more accurate results on the factors that affect glycemic control in the study population.

However, the study findings may not be generalized to other populations with diabetes because it was a hospital-based study.

The prevalence of poor glycemic control could not also be determined because of the study design. Future studies should focus on the entire population using a cross-sectional design so as to obtain the prevalence rate.

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.1: Conclusion

According to the objectives and findings of this study, the following conclusions were arrived at;

1. Of the clinical factors analyzed, the presence of diabetes complications was associated with poor glycemic control. Diabetes complications affect self-care activities and add on to the already existing burden of diabetes. This leads to poor patient outcomes and impaired quality of life.

2. Improper diet, physical inactivity and lack of self-monitoring of blood glucose were the behavioral factors significantly associated with poor glycemic control. This highlights the role of behavioral factors in glycemic control and hence the emphasis on lifestyle modification as a major contributor to non-communicable diseases.

6.2: Recommendations

Based on the study findings and conclusions, the following recommendations were made;

1. The healthcare providers should stress on early diagnosis and aggressive management of those with diabetes to alleviate the occurrence and re-occurrence of diabetes complications.

2. The hospital management team should create opportunities for patients to be regularly educated and counseled on the need to take good care of themselves to avoid diabetes complications.

3. The nutritionist and other health care providers should sensitize diabetes patients on the need to adhere to the recommended diet.

4. The nutritionists should assist patients to formulate appropriate diets within their financial affordability and regional availability. Care-takers for the elderly should also be included in the dietary plans so that adherence is enhanced.

5. Health care providers should recommend and encourage diabetic patients to actively engage in different forms of exercises. This can range from at least short walks to simple household chores and basic workouts communicated through individual consultations or talks held during clinic days.

6. The hospital management should seek partnership with Non-Governmental Organizations so as to provide free glucometers and test strips to all diabetic patients for self-monitoring of blood glucose.

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Appendix 1: Consent explanation form (English version)

Patient study number: _____

STUDY TITLE: Factors associated with poor glycemic control among Type II diabetics attending Machakos Level Five Outpatient Clinic

Principal investigator: My name is Dr. Milka Muthoni. I am a senior pharmacist at Machakos Level Five Hospital and I hold a Bachelor of Pharmacy degree. I am currently pursuing a Masters degree in Public Health at the University of Nairobi.

Introduction:

The purpose of this consent form is to give you information that will help you decide whether or not to participate in the study. You are free to ask any questions regarding the study. Once you understand and agree to participate, you will be required to sign your name on the form. Your decision to participate is fully voluntary and you may withdraw from the study at any time. Refusal to participate will not affect the services you are entitled to in this or any other health facility.

May I proceed?

□ Yes □ No

This study has been approved by the Kenyatta National Hospital- University of Nairobi Ethics and Research Committee protocol no_____

Objective of the study:

The researchers listed above will be interviewing patients with Type II diabetes attending Machakos Level Five Hospital Outpatient Clinic.

The study aims to identify factors associated with poor glycemic control amongst Type II diabetics which will be categorized into socio-demographic, clinical and behavioral factors.

There will be approximately 168 participants in this study randomly chosen. We are asking for your consent to consider participating in the study.

Participation in the study:

Once you agree to participate in the study, 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 study will involve responding to a questionnaire which has questions on socio-demographic, clinical and behavioral characteristics. Also, your fasting blood glucose, height and weight measurements will be obtained from your file and used in the study.

After the interview, we will ask for a telephone number which we can contact you with, if necessary. Your contact information will only be used by people working for this study and will not be shared with others. Your contacts will be necessary in case some more information is needed for the study and for giving necessary recommendations once the study is done.

Risks:

One potential risk of being in the study is loss of privacy. We will keep all information gathered as confidential as possible. A code number will be used to identify you in a password protected computer database and all paper records will be kept in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is possible that someone could find out you were in this study.

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.

Benefits:

By taking part in this study, you will know your glucose control as measured by the random blood sugar test, the level will be interpreted for you and you will be able to take appropriate steps to improve the control or maintain if it is within the normal range. Also, the information you provide will help us better understand factors that affect glycemic control among Type II diabetics. The information will be a contribution to Science and Research.

Cost:

You will not be required to make any payments to participating in this study and no payment will be done to you.

For further information, questions or queries you can contact:

The Principle Investigator: Milka Muthoni

School of Public Health, University of Nairobi

Cell no. +254 724849474

Email: milkawanjohi@yahoo.com

Or

The lead supervisor: Dr. Rose Opiyo

School of Public Health, University of Nairobi

Cell no, +254 722473122

Email: roseokoyo@gmail.com

This proposal has been reviewed and approved by Kenyatta National Hospital- University of Nairobi Ethics and Research Committee, which is a committee whose task is to make sure that research participants are protected from harm.

In case of any questions, you can contact them: P.O BOX 20723-00200 Nairobi, Telephone no. (020)726300-9, Email- uonknh-erc@uonbi.ac.ke

Other choices

Your decision to participate in this 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.

Statement of consent

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

I agree to participate in this research study ☐Yes ☐No

I agree to provide contact information for follow up ☐Yes ☐No

Participant/next of kin signature/ thumb stamp_____

Date_____

Researcher's statement

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

Researcher's name _____ Date_____

Signature _____

Role in the study _____

For more information contact_____at_____from_____to_____

Appendix II: Consent explanation form (Kiswahili version)

Nambari ya kujitambulisha _____

Fomu ya Ridhaa ya kushiriki katika utafiti

Jina langu ni Dr. Milka Muthoni Wanjohi. Mimi ni mwanafamasia mwandamizi katika hospitali ya Machakos Level Five na nina shahada ya Pharmacy. Kwa sasa mimi ni mwanafunzi katika faniya Afya ya Umma, Chuo Kikuu cha Nairobi. Ninafanya utafiti kuangalia mambo yanoyohusiana na kiwango cha sukari kwa watu wenye wana ugonjwa wa kisukari katika Hospitali ya Machakos Level Five.

Madhumuni ya utafiti

Utafiti huu unalenga kujua sababu zinazohusiana na kuzidi kwa kiasi cha sukari kwa wagonjwa wa kisukari.Utaangazia mambo ya socio-demographic, kliniki,na tabia za wenye wanaishi na ugonjwa wa kisukari.

Ushiriki katika utafiti

Unaweza kushiriki katika utafiti huu kama una umri wa miaka 18 na zaidi na umekuwa ukipata matibabu kwa angalau miezi sita. Utafiti huu unahusu kujibu maswali wewe mwenyewe. Ukiamua kutoshiriki, utaendelea kupata huduma kama kawaida na hutaaathirika kwa njia yoyote.

Hatari

Hatari moja ya kuwa katika huu utafiti, nikupoteza faragha. Tutaweka taarifa zote zilizokusanywa kwa siri iwezekanavyo.

Kujibu maswali pia inaweza kuwa na wasiwasi kwako. Una haki ya kukataa mahojiano au maswali yoyote yalioulizwa wakati wa mahojiano.

Faida za utafiti

Kwa kushiriki katika utafiti huu, utajua kiwango cha sukari kwa kutumia kipimo cha FBG na hii itakusaidia kuchukua hatua za kuboresha kiwango cha sukari au kuidumisha kama ipo katika ngazi ya kawaida.

Usiri

Taarifa zote zitakazokusanywa katika utafiti huu zitakuwa siri, hivyo ushiriki wako hautajulikana na mtu yeyote ila wenye timu ya utafiti.

Malipo

Kwa kushiriki katika utafiti huu, hautalipwa wala hautalipa chochote

Ukiwa na swali au tatizo lolote,unaweza kuwasiliana na:

Mtafiti mkuu, Milka Muthoni

School of Public Health, University of Nairobi
Cell no. +254 724849474
Email: milkawanjohi@yahoo.com
Ama
Msimamizi mkuu: Dr. Rose Opiyo
School of Public Health, University of Nairobi
Cell no, +254 722473122
Email: roseokoyo@gmail.com

Pendekezo hili limepitishwa na Hospitali yaTaifa ya Kenyatta- Chuo Kikuu cha Nairobi, kamati ya maadiliano utafiti, ambayo kazi yake ni kuhakikisha washiriki wa utafiti hawataadhirika kwa njia yoyote.
Ikiwa kuna maswali yoyote, unaweza kuwasiliana nao: P.O BOX 20723-00200 Nairobi, Telephone no. (020)726300-9, Email- **uonknh-erc@uonbi.ac.ke**

Taarifa ya idhini

Nimesoma fomu ya kibali au nimesomewa maswali kwa lugha ninayoelewa na hatari na faida zimeelezewa kwangu. Ninaelewa kwamba kushiriki kwangu katika utafiti ni kwa hiari na naweza kuchagua kujiondoa wakati wowote. Ninakubali kwa hiari yangu kushiriki katika utafiti huu.

Ninakubali kushiriki katika huu utafiti □ Ndio □ La
Ninakubali kupatiana nambari ya simu kwa mawasiliano zaidi, □ Ndio □ La

Sahihi ya mshiriki/alama ya kidole/pili ya jamaa/_____
Sahihi ya mtafiti_____
Tarehe_____

Appendix III: Questionnaire(English version) Adapted from**:**(Timothy, 2010; Mwera, 2013)

Study number_____ Interviewer I.D_____

Date of Interview_____

A. Socio-demographic factors

1. Sex

□ Female

□ Male

2. Age (Years) _____

3. Level of education

□ Primary school

□ Secondary school

□ Tertiary education

□ No formal education

□ Other

4. Marital status

□ Married

□ Single

□ Widow

□ Widowed

8. Occupation

□ Employed

□ Self employed

□ Retired

□ Not employed

9. Income levels

- □ 0-5000
- □ 5000-10000
- □ 10000-20000
- □ 20000 and above

10. Religion
    - □ Christian
    - □ Muslim
    - □ None
    - □ Other (specify)

B. Clinical factors

1. When were you diagnosed with diabetes?
    - □ 0-2 years
    - □ 3-5 years
    - □ 6-8 years
    - □ 9-10 years
    - □ More than 10 years ago
    - □ Don't remember

2. Where was the diagnosis made?
    - □ Hospital
    - □ Home
    - □ Other

3. How long have you been attending the clinic?
    - □ 0-2 years
    - □ 3-5 years
    - □ 6-8 years
    - □ 9-10 years
    - □ More than 10 years
    - □ Don't know

4. What type of treatment are you currently on?

- □ Oral medication
- □ Injectable
- □ Combination of both

5. Do you have a family history of diabetes?

- □ Yes
- □ No
- □ Don't know

6. When was your last FBG test?

- □ Within the past 3 months
- □ Within the past 6 months
- □ Within the past year
- □ 1-2 years ago
- □ Never

7. What was your last FBG value?

- □ > 7.0mmol/l
- □ ≤7.0mmol/l
- □ Don't remember
- □ Have never had an FBG test

8. Clinic accessibility

i) How long does it take you to get to the clinic?

- □ 0-2 hours
- □ 2-4 hours
- □ 4-6 hours
- □ Over 6 hours

ii) How much does it cost you to and from the Clinic?

- □ 0-50 shillings
- □ 50-100 shillings
- □ 100-200 shillings
- □ Over 200 shillings

iii) Is this your nearest Clinic?

□ Yes

□ No

If not, why do you come here?

9) Presence of co-morbidities

i) Are you a known Hypertensive?

□ Yes

□ No

ii) Are you currently receiving treatment for hypertension?

□ Yes

□ No

iii) When was your BP checked last?

□ 0 to 6 months ago

□ 6-12 months ago

□ Over one year ago

□ Never

□ Don't remember

iv) During the past 1 year have you ever been told that your BP is high?

□ Yes

□ No

v) Have you been hospitalized for diabetes problems?

□ Yes

□ No

If so, which one(s)? _____

vi) Other co-morbidities

C. Behavioral factors

1. Alcohol consumption

i) Have you consumed alcohol within the past one year?

□ Yes

□ No

If yes, how often do you drink in a week?

ii) When you **do** drink, how many standard drinks do you have at one go?

2. Diet

1. How often in a week do you havea healthful eating plan?

2. On average, how many serving of vegetables and fruits do you take per day as advised by your health care provider?

3. How many days in a week do you eat small carbohydrates portions throughout the day?

4. How many days in a week do you eat five or more servings of fruits and vegetables?

5. How many days in a week do you eat high-fat foods such as red meat or full-fat dairy products?

3. Physical Activity

1. In one week, on how many days do you do **vigorous** physical activities like heavy weight lifting, digging, aerobics, or fast bicycling?

No vigorous physical activities ***Skip to question 3***

2. How much time do you usually spend doing **vigorous** physical activities on one of those days?

Think about all the **moderate** activities that you do in a week. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

Think only about those physical activities that you did for at least 10 minutes at a time.

3. How many days in a week do you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ day/s per week

No moderate physical activities ***Skip to question 5***

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ hour/s per day _____ minute/s per day

Don't know/Not sure

Think about the time you spend**walking** in one week. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5. In one week, how many days do you **walk** for at least 10 minutes at a time?

_____ day/s per week

No walking ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

_____ hour/s per day _____ minute/s per day

Don't know/Not sure

The last question is about the time you spend**sitting** on weekdays in one week. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. In one week, how much time do you spend **sitting** on a **week day**?

_____ hour/s per day _____ minute/s per day

Don't know/Not sure

4. Smoking

i) Do you smoke?

□ Yes

□ No

ii) Have you ever smoked?

□ Yes

□ No

If yes, how many sticks of cigarette do you/did you smoke per day?

□ 1-2
□ 3-4
□ 4-6
□ Over 6

If yes but stopped smoking,

i) When did you stop smoking?

□ 0-6 months ago
□ 6-12 months ago
□ Over one year ago
□ Don't remember

ii) For how many years did you smoke?

□ 0-1year
□ 1-3 years
□ Over 3 years
□ Don't remember

5. Medication compliance

1. Do you ever forget to take your medication?

□ Yes

□ No

2. People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past 2 weeks, were there any days when you did not take your medicine?

□ Yes

□ No

3. If the answer is yes to Q2, what were the reasons for missing taking the medicines?

- □ Travelling
- □ Medication side effects
- □ Feeling unwell
- □ Other reasons please specify

4. Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it?

- □ Yes
- □ No

5. When you travel or leave home, do you sometimes forget to bring along your medicine?

- □ Yes
- □ No

6. Did you take all your medicines yesterday as advised by your health care provider?

- □ Yes
- □ No

7. When you feel like your symptoms are under control, do you sometimes stop taking your medicine?

- □ Yes
- □ No

6. Self monitoring of blood glucose

1. On how many of the last SEVEN DAYS did you test your blood sugar?

_____

2. How many times has your health care provider recommended you to test your blood sugar?

_____

3. At what time do you test your blood sugar? _____

D. Patient measurements(Obtained from the hospital register or patient's file)

1. Fasting blood glucose (mmol/l) _____

2. Height (cm) _____

3. Weight (kg) _____

4. Blood Pressure (mm/hg) _____

Appendix IV: Questionnaire (Kiswahili version)

Nambari ya mshiriki _____ Tarehe_____

A. Mambo ya socio-demographia

1. Jinsia
   - □ Kiume
   - □ Kike

2. Umri wa mgonjwa (miaka)_____

3. Kiwango cha elimu
   - □ Elimu ya msingi
   - □ Elimu ya sekondari
   - □ Elimu ya mafunzo ya juu
   - □ Hujaenda shule
   - □ Kiwango kingine

4. Hali ya ndoa
   - □ Umeoa/umeolewa
   - □ Mseja
   - □ Mjane
   - □ Mgane

5. Hali ya kazi
   - □ Umeajiriwa
   - □ Umejiajiri
   - □ Umestaafu
   - □ Haujaajiriwa

6. Kipato chako kwa mwezi
   - □ 0-5000
   - □ 5000-10000
   - □ 10000-20000
   - □ 20000 kwenda juu

7. Dini
   - □ Mkristo

- □ Muislamu
- □ Hakuna
- □ Nyingine (dhihirisha)

B. Mambo ya kikliniki

1. Ulipatikana na ugonjwa wa kisukari lini?
   - □ Miaka 0-2
   - □ Miaka 3-5
   - □ Miaka 6-8
   - □ Miaka 9-10
   - □ Zaidi ya miaka kumi iliyopita
   - □ Sikumbuki

2. Utambuzi wa ugonjwa wa kisukari ulifanyika wapi?
   - □ Hospitali
   - □ Nyumbani
   - □ Kwingine

3. Umekuwa ukija kliniki kwa muda gani?
   - □ Miaka 0-2
   - □ Miaka 3-5
   - □ Miaka 6-8
   - □ Miaka 9-10
   - □ Zaidi ya miaka 10
   - □ Sijui

4. Unatumia dawa gani?
   - □ Tembe
   - □ Sindano
   - □ Tembe na sindano

5. Kuna historia ya familia kuhusu ugonjwa wa kisukari?
   - □ Ndio
   - □ La
   - □ Sijui

6. Kipimo cha mwisho cha FBG kilikuwa lini?

- □ Katika miezi mitatu iliyopita
- □ Katika miezi sita iliyopita
- □ Mwaka moja uliopita
- □ Miaka 1-2 iliyopita
- □ Sijui
- □ Sijawahipimwa

7. Kiwango cha mwisho cha FBG kilikuwa?

- □ Chini ya 7.0mmol/l
- □ Juu ya 7.0mmol/l
- □ Sikumbuki
- □ Sijawahipimwa

8. Umbali na kliniki

i) Unachukua muda gani kufika kliniki?

- □ Saa 0-2
- □ Saa 2-4
- □ Saa 4-6
- □ Zaidi ya saa sita

ii) Inakugharimu pesa ngapi kufika na kurudi kutoka kliniki?

- □ Shillingi 0-50
- □ Shillingi 50-100
- □ Shillingi 100-200
- □ Zaidi ya shilling 200

iii) Hii kliniki ndio iliyo karibu na wewe zaidi?

- □ Ndio
- □ La

Kama la, mbona umechagua hapa?

9. Magonjwa mengine

i) Uko na ugonjwa wa shinikizo la damu?

- □ Ndio
- □ La

ii) Je, unatumia dawa za ugonjwa wa shinikizo la damu?

- □ Ndio
- □ La

iii) Mara ya mwisho kupima BP ilikuwa lini?

- □ Miezi 0-6 iliyopita
- □ Miezi 6-12 iliyopita
- □ Zaidi ya mwaka moja uliopita
- □ Sikumbuki
- □ Sijawahipimwa

iv) Ushawahi kulazwa hospitali juu ya shida za ugonjwa wakisukari?

- □ Ndio
- □ La

Kama ndio, ulilazwa juu ya shida gani?

v) Magonjwa mengine

C. Mambo yakitabia

1. Matumiziyapombe

i) Umetumia pombe kwa mwaka moja uliopita?

- □ Ndio
- □ La

Kama ndio,

a) Unatumia pombe mara ngapi kwa wiki?

b) Unatumia kiasi gani cha pombe ukikunywa?

2. Chakula

1. Ni mara ngapi kwa wiki unafuata utaratibu mzuri wa ulaji wa vyakula bora?

2. Kwa wastani unakula milo ngapi ya mboga na matunda kwa siku kama ulivyoshauriwa na mtaalamu wako wa afya?
3. Ni mara ngapi kwa wiki unakula chakula kwa viwango vidogo?
4. Ni mara ngapi kwa wiki unakula milo tano au zaidi ya mboga na matunda?

5.Ni mara ngapi kwa wiki unakula chakula cha mafuta mengi kama vile nyama nyekundu au jamii ya vyakula vyamafuta vitokanavyo na maziwa?

3. Mazoezi

1. Ni mara ngapi kwa siku saba unajihusisha na mazoezi ya viungo angalau kwa dakika thelathini?

2.Ni mara ngapi kwa wiki unajihusisha na mazoezi maalumu (kama vile kuogelea, kutembea, kuendesha baiskeli)?

3.Unachukua muda gani kujihusisha na mazoezi maalumu kwa siku?

4.Kwa wiki moja, ni siku ngapi unatembea angalau dakika kumi mfululizo?

5.Kwa wiki moja, unakaa chini kwa muda gani mfululizo?

4. Uvutaji sigara

i) Je,unavuta sigara?

- □ Ndio
- □ La

ii) Ushawahi kuvuta sigara

- □ Ndio
- □ La

Kama ndio, unavuta sigara ngapi

- □ 1-2
- □ 3-4
- □ 4-6
- □ Over 6

5. Uaminifu katika kutumia dawa

1. Wakati mwingine unasahau kutumia dawa?

- □ Ndio
- □ La

2.Wakati mwingine watu wanaacha kutumia dawa zao kwa sababu nyingine zaidi ya kusahau. Kwa wiki mbili zilizopita, kulikuwa na siku zozote ambazo haukutumia dawa?

- □ Ndio
- □ La

3. Kama ulisahau kutumia dawa, ni sababu gani haukutumia dawa zako?

- □ Kusafiri
- □ Madhara yatokanayo na dawa
- □ Kujiskia vibaya
- □ Sababu zinginezo. Taja

4. Ushawahi kupunguza au kuacha kutumia dawa bila kumwambia daktari kwa sababu ulijiskia vibaya baada ya kutumia?

- □ Ndio
- □ La

5. Wakati unapo safari au kutoka nyumbani, kuna wakati unasahau kubeba dawa zako?

- □ Ndio
- □ La

6. Je, ulitumia dawa zako jana kama ulivyoshauriwa na mtaalamu wako wa afya?

- □ Ndio
- □ La

7. Wakati unapohisi huna dalili za ugonjwa, je unaacha kutumia dawa?

- □ Ndio
- □ La

6.Kujipima kiwango cha sukari

1. Ni mara ngapi kwa siku saba unajipima kiwango chako cha sukari?

2.Ni mara ngapi kwa wiki wataalamu wa afya wanakushauri upime kiwango chako cha sukari kwenye damu?

3.Ni wakati gani unachukua kipimo chako cha sukari kwenye damu?

7. Vipimo za mgonjwa (Kutoka register au faili ya mgonjwa)

1. Kiwango cha sukari (FBG) mmol/l _____

2. Urefu (cm) _____

3. Uzito (kg) _____

4.Kipimo cha shinikizo la damu (mm/hg) _____

Appendix V: KNH-UoN ERC approval letter

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 30 OCT 2017 KNH/UoN-ERC P.O.BOX 20723-00202 NRB.

Ref: KNH-ERC/A/321

30th October, 2017

Milka Muthoni Wanjohi
Reg. No. H57/81248/2015
School of Public Health
College of Health Sciences
University of Nairobi

Dear Milka,

REVISED RESEARCH PROPOSAL –FACTORS AFFECTING GLYCEMIC CONTROL AMONG TYPE II DIABETICS ATTENDING MACHAKOS LEVEL FIVE OUTPATIENT CLINIC (P329/06/2017)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above proposal. The approval period is from 30th October 2017 –29th October 2018.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
d) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

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For more details consult the KNH- UoN ERC website**http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M.L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Assistant Director, Health Information, KNH
The Chairperson, KNH-UoN ERC
The Director, School of Public Health, UoN
Supervisors: Dr. Rose Okoyo Opiyo (School of Public Health, UoN),
Dr. Simeon Ochanda Mbuya (Dept. of Clinical Medicine and Therapeutics, UoN)

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