ASSESSMENT OF MEDICATION NON-ADHERENCE AND ASSOCIATED FACTORS AMONG TYPE 2 DIABETES MELLITUS PATIENTS ATTENDING THE DIABETIC CLINIC AT KENYATTA NATIONAL HOSPITAL

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Assessment of medication non-adherence and associated factors among type 2 diabetes mellitus patients attending the diabetic clinic at Kenyatta National Hospital

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DECLARATION

This thesis is my original work and has not been presented for a degree or diploma in any other University.

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DEDICATION

I dedicate this thesis to my beloved parents; Mr. Patrick Waari and Mrs. Esther Waari for their time, encouragement and generous financial support in the course of my education.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

ABBREVIATIONS/ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
ADA	American Diabetes Association
BMI	Body Mass Index
DCCT	Diabetes Control and Complications Trial
DM	Diabetes Mellitus
DMI	Diabetes Management Information
ERC	Ethics Review Committee
HbA$_{1C}$	Glycosylated haemoglobin
HBSM	Home Blood Sugar Monitoring
IDDM	Insulin Dependent Diabetes Mellitus
IDF	International Diabetes Federation
KEMRI	Kenya Medical Research Institute
KNH	Kenyatta National Hospital
MEMS	Medication Event Monitoring System
MMAS	Morisky Medication Adherence Scale
MOH	Ministry of Health
MOPHS	Ministry of Public Health and Sanitation
NCDs	Non-Communicable Diseases
NIDDM	Non-insulin Dependent Diabetes Mellitus
OGLA	Oral Glucose Lowering Agents
OHA	Oral Hypoglycemic Agents
UON	University of Nairobi
SMBG	Self-Monitoring Blood Glucose
SSA	Sub-Saharan Africa
T2DM	Type-2 Diabetes Mellitus
WDF	World Diabetes Federation
WHO	World Health Organization

DEFINITION OF OPERATIONAL TERMS

Adherence: This is extent to which a person's behaviour (taking medication, following a diet, and/ or executing lifestyle changes) corresponds with agreed recommendations from a healthcare provider (WHO, 2003)

Diabetes Mellitus: A group of heterogeneous disorders with the common elements of chronic high blood sugar and glucose intolerance due to insulin deficiency, impaired effectiveness of insulin action or both.

Glycaemic Control: This refers to the typical levels of blood sugar in a person with diabetes mellitus in whom HbA_{1C} value is 7% or less for the past three months.

HbA_{1C}: This refers to the level of glycosylated haemoglobin in the blood as a means of determination of average blood sugar concentrations for the preceding three months.

Glucose: A six carbon sugar that can be linked through glycosidic bonds to form a carbohydrate that serves as a primary source of energy.

Type 2 diabetes: Form of diabetes mellitus when the body loses the ability to produce and/or utilize insulin properly and it is sometimes combined with an absolute insulin deficiency.

ABSTRACT

Medication non-adherence is a global problem facing health care providers treating adult Type 2 diabetes mellitus patients. It results in disease progression, development of complications, premature disability and death. As the prevalence of diabetes mellitus continues to increase in Kenya, there is need for clear definition of factors that lead to medication non-adherence. The objective of this study was to assess the prevalence and factors associated with medication non-adherence among Type 2 diabetes mellitus patients. This study adopted a cross-sectional study design and was conducted at the diabetic clinic at Kenyatta National Hospital from November 2015 to January 2016. The sample size used was two hundred and ninety Type 2 diabetes patients. A questionnaire was used to collect information on patients' demographic and clinical characteristics and challenges relating to diabetes treatment. Adherence levels were determined by the patients' self-report scored on the Morisky Medication Adherence Scale-8(MMAS-8) and glycaemic control by blood sample assay for glycosylated haemoglobin (HbA_{1C}). Data was analysed using STATA statistical software. Logistic regression was used to determine the association between medication non-adherence and various patient, disease and treatment variables. Ethical approval was obtained from the ethics and research committee at the hospital. The prevalence of medication non-adherence was 54.5 %. Glycaemic control was good for 107 (36.9%) of the study participants. A significant association was found between medication adherence and glycaemic control. Factors found to be associated with non-adherence were; dissatisfaction with family members support in regard to diabetes mellitus management, patients with duration disease between 2 – 10 years, ever being admitted for diabetes mellitus, presence of a challenge in drug access and dissatisfaction with attending clinicians. In conclusion, a majority of Type 2 diabetes mellitus patients are non-adherent to medication which was associated with poor blood sugar control. Family support, affordability of medications and good healthcare provider-patient communication are important in curbing medication non-adherence. This study recommends the hospital management seeks to identify patients that are poorly adhering to medication for prompt interventions, including determination of HbA_{1C}. The MMAS-8 can screen for these patients. Further, family members should be facilitated to participate in the diabetic patient care process, insurance schemes can improve medication affordability and regular health provider communication skills trainings should be conducted.

CHAPTER ONE

INTRODUCTION

1.1 Background Information

Diabetes mellitus (DM) is a group of heterogeneous disorders with the common elements of chronic hyperglycaemia and glucose intolerance due to insulin deficiency, impaired effectiveness of insulin action, or both (Davidson, 2005). It is a chronic disease which requires life-long therapy (Nathan *et al.,* 2009). Diabetes mellitus, especially Type 2 diabetes mellitus (T2DM) is a major global health problem covering approximately 347 million people worldwide (Danaei *et al.,* 2011). It is predicted that the global prevalence of diabetes will increase by 65% over the next 20 years (Brunton *et al.,* 2011). Approximately 80% of DM related mortality occurs in the low-and middle-income countries (WHO, 2012). In Kenya, the prevalence of DM was 3.3% in 2007 and is projected to rise to 4.5% in 2025; urban areas have been shown to have a prevalence of up to 10% (Dirk *et al.,* 2009).

Glycaemic control plays the main role in diabetes management (Selvin *et al.,* 2006). Studies have emphasized the importance of achieving optimal glucose control through strict adherence to medications, diet, and exercise in order to minimize serious long term complications (Barnes *et al.,* 2004). In Kenya, studies have shown low levels of glycemic control (Mwavua *et al*., 2016). These complications affect the patient's quality of life, increase mortality, morbidity and economic cost of disease to society (Ciechanowski *et al.,* 2001). It is imperative that patients adhere to their prescribed regimens to minimize the burden of the disease on the health systems (Blanca *et al.,* 2001). However, non-adherence

to prescribed drugs schedule has been and continues to be a major problem globally. Diabetes is considered to be one of the most psychologically and behaviourally demanding of the chronic diseases. It requires frequent self-monitoring of blood glucose and administration of medication on schedule (Hernandez-Ronquillo *et al.,* 2003).

Factors associated with non-adherence to prescribed medications in type 2 diabetic patients have been described as a product of interaction between patient related factors, disease-related factors, treatment-related factors and health care provider-related factors (Delamater, 2006). In a study conducted on adherence to anti-diabetic drugs, the most common reasons behind the non-adherence to the drugs were found to be forgetfulness, financial constraints, being busy with work, too many medicines being prescribed, feeling of well-being and cure, frequent side effects, trying alternative medicines and having no knowledge on the complications of diabetes (Shuvankar *et al.,* 2013). In another study, factors such as poor relationship with health care provider, few symptoms, concomitant chronic illness, perceived lack of effect, real or perceived side-effects, unclear instructions or purpose of treatment, missed appointments, inadequate follow-up, swallowing difficulties and travel to place of treatment were associated with poor adherence to anti-diabetic medications (Caraceni, 2009).

In Kenya, many diabetics are diagnosed with irreversible complications (MOPHS, 2010). Foot ulcers are frequently seen at many tertiary clinics in Kenya and are associated with poor glycemic control and poor self-care (Nyamu *et al.,* 2003). Diabetes mellitus threatens Kenya's healthcare system and the wider economy with loss of productive workforce (Maina, 2011). A study conducted at Kenyatta National Hospital (KNH) found that

diabetic ketoacidosis occurred in 8% of the hospitalized diabetic patients, and almost 29.8% of the patients died within 48 hours of presentation (Mbugua *et al.,* 2005). Studies have shown that the complications and associated morbidity, as well as mortality, can be lowered by strict glycemic control (Otieno *et al.,* 2003; Skyler, 2004). To stem the rising tide of uncontrolled diabetes and improve medication adherence and it is important to understand drivers of medication non- adherence, few of these studies have been carried out in Africa.

1.2 Problem statement

Diabetes mellitus affects the metabolism and regulation of blood glucose within the human body which is governed by insulin production. To maintain blood glucose within the normal levels it is important for diabetes mellitus patients to strictly adhere to prescribed medications, in addition to carrying out other self-management measures such as proper diet and exercise. Poor control of blood sugar due to non-adherence to medication and lifestyle interventions is responsible of over a quarter of all hospital admissions in Kenya (DMIC, 2012). According to the World Health Organization, about 1% of deaths in Kenya were directly attributable to diabetes in 2012 (WHO, 2014).

A global report on medication non-adherence for diabetes and other chronic conditions states that, increasing effectiveness of adherence interventions may have greater impact on the health of populations than improvements in specific medical treatments (WHO, 2003). As the incidence and prevalence of diabetes mellitus continues to increase in Kenya, clear

definition of factors that contribute to medication non-adherence among these patients is essential in developing effective and targetted interventions.

1.3 Justification

Most of the studies on medication non-adherence among Type 2 diabetic patients have been carried out in developed countries, leaving a gap in knowledge about the prevalence and factors that are associated with non-adherence to diabetic treatment in sub Saharan Africa including Kenya. To improve patient outcomes, it is important to determine the magnitude of medication non-adherence and to understand the reasons why non-adherence occurs. Few studies have been conducted on the status of Type 2 DM patients' non-adherence to diabetic medications and associated factors in Kenya. Therefore, this research aims to determine the prevalence of non-adherence to diabetic medication and associated factors among type 2 diabetes mellitus patients attending Kenyatta National Hospital diabetic clinic. Kenyatta National Hospital is a regional referral facility that follows up on over three hundred Type 2 diabetic patients weekly.

Determination of the factors that are associated with medication non-adherence will assist health providers at the hospital develop appropriate patient-centered strategies to support medication adherence among Type 2 diabetic patients. The findings will also justify allocation of resources by the Kenyatta National Hospital management for implementation of interventions. More broadly, at the national level; these findings will contribute in

informing the Ministry of Health policy guidelines on supporting diabetic patients adhere to medication.

1.4 Research questions

This study is expected to answer the following questions:

1. What is the prevalence of non-adherence to recommended medication among Type 2 diabetes mellitus patients?

2. What is the level of glycemic control among Type 2 diabetes mellitus patients?

3. What is the association between self-reported medication non-adherence scored on the MMAS-8 and glycaemic control among Type 2 diabetes mellitus patients?

4. What are the factors associated with non-adherence to recommended medication among Type 2 diabetes mellitus patients?

1.5 Objectives

1.5.1 General objective

To assess medication non-adherence and associated factors among Type 2 diabetes mellitus patients attending the diabetic clinic at Kenyatta National Hospital.

1.5.2 Specific objectives

1. To determine the prevalence of non-adherence to recommended medication among Type 2 diabetes mellitus patients attending the diabetic clinic at Kenyatta National Hospital.

2. To determine the level of glycemic control among Type 2 diabetes mellitus patients attending the diabetic clinic at Kenyatta National Hospital.

3. To determine the association between self-reported medication non-adherence scored on the MMAS-8 and glycaemic control among Type 2 diabetes mellitus patients attending the diabetic clinic at Kenyatta National Hospital.

4. To establish factors associated with non-adherence to recommended medication among Type 2 diabetes mellitus patients attending the diabetic clinic at Kenyatta National Hospital.

CHAPTER TWO

LITERATURE REVIEW

2.1 Diabetes Mellitus – Disease and global overview

Diabetes mellitus is a chronic metabolic disorder in which a person has high blood glucose, either the body does not produce enough insulin or the cells do not respond to the insulin that is produced. There are three main types of diabetes: Type 1 diabetes, Type 2 diabetes, and gestational diabetes (Mahan *et al.,* 2008). Type 2 diabetes (T2DM) is when the body loses the ability to produce and/or utilize insulin properly, and it is sometimes combined with an absolute insulin deficiency. It is often called "adult-onset" diabetes representing 90-95% of all cases of diabetes and it is related to an individual's lifestyle habits that include poor diet and physical inactivity (lack of exercise). However, the underlying cause is still unknown, although genetic and environmental factors (obesity, physical inactivity) are important risk factors (Al-Ajlan, 2009).

Diabetes mellitus is one of the most common non-communicable diseases and is one of the major public health challenges faced at present all over the world. About 194 million adults worldwide or 5.1% in the age group 20-79 years was estimated to have diabetes in 2003 (International Diabetes Federation, 2006). There has been a rapid increase in the incidence of diabetes mellitus. Much of this increase occurs in developing countries and results from aging, an unhealthy diet, obesity, and a sedentary lifestyle. Despite the advances in understanding the disease and its management, the morbidity and mortality rate continues to rise (Rickles *et al.,* 2010). Individuals with poor management of diabetes

are at a greater risk of developing long-term microvascular and macrovascular complications that lead to damage of end organs such as kidney, heart, brain, and eyes and affect direct and indirect healthcare costs and overall quality of life (Maddigan *et al.,* 2005). The burden of diabetes is disproportionately high in low-middle income countries (WHO, 2012; Azevedo, 2008). Diabetes requires long-term follow up, with uninterrupted access to medication and specialist care (Beran, 2006). Many health workers lack adequate knowledge and training (Mcferran, 2008; WDF, 2010) thus exposing diabetics to suboptimal management.

Optimal glucose control can be achieved through strict compliance to medications, diet, and lifestyle modifications, which in turn minimize long-term complications (Rickles *et al.,* 2010).

Medication compliance is defined as the extent to which an individual's medication use behaviour coincides with medical advice, and persistence as the duration of time from initiation to discontinuation of therapy (Cramer *et al.,* 2008). For patients with diabetes mellitus, medication use 'behaviour' includes taking oral hypoglycaemic agents and/or insulin injections, following diets, blood glucose monitoring, and making several lifestyle changes (Odegard *et al.,* 2007).

There are several types of noncompliance. Therapeutic or medication noncompliance includes failure to have prescription medications dispensed or renewed, omission of doses, and premature discontinuation of the drug regimen. A second type of noncompliance is dietary/exercise noncompliance in which the patient fails to follow the diet and exercise recommendations. A third type is the appointment noncompliance in which the patient fails

to show up at the clinics for the scheduled check-up (Hughes *et al.,* 2000). Several methods are used to measure therapeutic compliance. Indirect methods, such as self-reports and interviews with the patient, are the simplest and most common methods for measuring medication compliance (Girerd *et al.,* 2001).

2.2   Diabetes in Sub Saharan Africa and Kenya

The average number of visits for patient care among the diabetic population of Sub Saharan Africa (SSA) is low and usually occurs only when complications are imminent (Otieno *et al.*, 2003; Gning *et al.,* 2007). There is need in SSA to intensify efforts to ensure follow-up of patients whenever treatment has been commenced in order to reduce and/or prevent the high morbidity and mortality rates arising from this chronic disease. The potential severity of increasing prevalence of diabetes in African continent may be translated into severe economic burden, high morbidity and mortality rates that will surpass the ravages of HIV and AIDS in the near future (Azevedo *et al.,* 2008).

In SSA, most people diagnosed with diabetes extremely find it difficult to achieve and maintain the desired glycemic level of control ($HbA_{1C} < 7\%$). Chronic shortages of drugs (including insulin) and their high cost are the major factors for poor glycemic control (Otieno *et al*, 2003, Skyler, 2004). There is great need to establish effective and sustainable strategies to curb diabetes mellitus related morbidity and mortality, considering that the public health system resources in SSA are invested mostly in control of communicable diseases namely HIV/AIDS, malaria and tuberculosis (Kaushik, 2004; Unwin and Marlin, 2005).

The prevalence of diabetes varies from country to country in SSA. The number of diabetes mellitus patients is projected to rise dramatically in the near future in most developing and intermediate societies, affecting particularly urbanizing societies and the middle-aged population (Kenya Society for the Blind, 2008). Developing countries contribute three quarters of the global burden of diabetes mellitus (King, 1998).

In Kenya, the prevalence of DM was 3.3% in 2007 and is projected to get to 4.5% in 2025. The prevalence is up to 10% in some urban areas (Dirk *et al.,* 2009, MOPHS, 2010). T2DM is the more prevalent, and Kenyans are developing it at a younger age than people in developed countries. Kenyans are also at higher risk for crippling or life-threatening complications, because they report to health centres when the disease is advanced (The East African, 2007).

2.3   Management of Diabetes Mellitus and Glycaemic control

Diabetes self-care behaviors are essential for patients to practice and maintain on a daily basis in order to improve their health. They are made up of four components: 1) Oral Hypoglycemic Agents (OHA) medication and/or insulin use, 2) following a meal plan, 3) regular exercise and physical activity, and 4) self-monitoring blood glucose. These behaviors impose daily demands on diabetic patients' and successful performance of these behaviors is likely to be influenced by their sense of competence (Al-Jasem *et al.,* 2001). Patients' adherence to diabetes self-care behaviors plays a major role in improving their

overall quality of life. It often represents a great challenge for patients as well as for healthcare professionals.

Proper management of diabetic condition would allow the patient to live a completely normal life, to remain symptoms free with good health, to achieve a near normal metabolic state and perhaps, to escape most of the long-term complications of diabetes. Successful management of diabetes requires proper evaluation and understanding of the patient's lifestyles (including perceived barriers), perceptions, beliefs, and family and social networks (Bradley and Gamsu, 1994). People with diagnosed type 2 diabetes must be managed through intensive medical therapy with a tailored, stepwise approach of lifestyle modification recommendations and oral hypoglycaemic agent and insulin.

Glycemic control is a medical term that refers to the typical levels of blood sugar in a person with type 2 diabetes (Adams, 2008). Good glycemic control is defined as an HbA_{1C} value of 7 % or less for the past three months and little or no glycosuria, fasting plasma glucose of 80 – 110 mg/dl (Davidson, 2005). Poor glycemic control is defined as an HbA_{1C} value of more than 7 % for the past three months (ADA, 2000; MOPHS 2010). Obesity is determined by body mass index (BMI) and can be classified as overweight (BMI $\geq$ 25 kg/m2), obesity (BMI $\geq$ 30 kg/m$^{2)}$ and normal (18 < BMI $\geq$ 24) (WHO, 1998).

2.4   Diabetes medication non-adherence and its consequences

According to the World Health Organization, adherence is defined as "the extent to which a person's behaviour (taking medication, following a diet, and/ or executing lifestyle

changes) corresponds with agreed recommendations from a health care provider (WHO, 2003). Medication adherence can also be defined as "the extent to which patients take medications as prescribed by their health care providers (Osterberg *et al*., 2005).

The World Health Organization in its landmark report on non-adherence globally estimated that adherence to medication among patients with chronic diseases including diabetes was 50%, it further stated that adherence levels were likely to lower in developing countries owing to resource limitations (WHO, 2003). In the Eastern Africa region, a medication adherence study done in Uganda among Type 2 diabetic patients found that adherence to diabetic medication was 28.9 % (Kalyango *et al*., 2008). Further studies in Ethiopia among diabetic patients found only 45.9% of patients fully adhering to treatment (Abebe *et al*., 2014). In Tanzania, a study using self-reported questionnaires revealed only 17.5% of patient were fully adhering to medication (Kamuhabwa *et al*., 2014)

Non-adherence to oral hypoglycemic agents (OHAs) may lead to suboptimal therapeutic goals and also associated with increased risk of hospitalization (Lau *et al*., 2004*;* De Geest *et al*., 2003). Although medication adherence is very important for reaching glycemic control and reducing complications, previous studies have shown that people with diabetes do not use their medications as prescribed (Donnan *et al.,* 2002). Adherence to the multi-component diabetic treatment regimen requires daily care. Diabetics can live a relatively normal life but chronic complications (neuropathy, myocardial and foot ischemia, renal disease, retinopathy) can result in a substantial decline in quality of life. The Diabetes Control and Complications Trial (DCCT) confirmed that improved metabolic control was significantly associated with delayed onset and progression of microvascular complication,

with a clear increasing risk related to poorer metabolic control (The Diabetes Control and Complications Trial (DCCT) Research Group, 1993).

Poor adherence to prescribed medications has been related to an increase in disease progression, development of complications, preventable hospitalizations and emergency department visits, ambulatory care, increased visits to Doctors and other healthcare providers, premature disability, death, and increased health care costs (Shenolikar *et al*., 2008). In the United States, 33 to 69 per cent of medication related hospital admissions are due to poor adherence and these have been reported to account for about $100 billion a year. Generally, patients with chronic conditions (especially after the first six months of therapy) have been reported to present with lower adherence rates when compared to those with acute conditions (Osterberg *et al*, 2005).

2.5   Factors Related to Medication Non-Adherence in Type 2 Diabetes

Non-adherence to prescribed medications in type 2 diabetic patients have been described as a product of the interaction between patient-related factors (for example, demographic, psychological and social factors), disease-related factors (for example, diseases severity, presence of comorbidities and complications), treatment-related factors (for example, number of medications, side effects of medications, dosage frequency of medications, and cost of medications), medical system and health care provider-related factors (Delamater, 2006).

2.5.1 Patient Related Factors

Demographic factors commonly associated with non-adherence include age, gender, race, socioeconomic status, and education level. The effect of age on medication adherence in type 2 diabetic patients seems to be inconsistent. Certain studies reported better adherence with older patients while others reported younger patients as being more adherent with medications (Donnan *et al.,* 2002). There are also conflicting results with respect to the effect of race and gender on adherence to oral anti-diabetic medications. While some studies reported a non-statistically significant effect, others reported poor medication adherence with males and minority groups. Low education levels and low socioeconomic status have been related with poor medication adherence and greater diabetes related morbidity (Delamater *et al.,* 2001; Delamater, 2006).

Psychological factors associated with non-adherence include health beliefs (how the patient perceives the seriousness of his/her disease condition, how vulnerable the patient views his/her likelihood of developing complications, how the patient perceives the efficacy of prescribed medications), patient's past behaviours, stress levels, anxiety, depression, and eating disorders (Gonzalez *et al.,* 2007). Diabetic patients with poor psychological wellbeing have problems adhering to their medications (Peyrot *et al.,* 2005). In addition, poor social support (especially from family members) negatively affects patients' adherence to their diabetic medication regimen (Delamater *et al.,* 2001). Family relationships play an important role in diabetes management. Studies have shown that low levels of conflict, high levels of cohesion and organization, and good communication patterns are associated with better regimen adherence. Greater levels of social support,

particularly diabetes-related support from spouses and other family members are associated with better regimen adherence (Peyrot *et al.,* 1999).

Barriers and health beliefs such as positive health beliefs regarding adherence to medication taking have been found to be associated with good medication adherence (Garcia and Cote, 2003). Decreases in patients' numbers of perceived barriers have also been identified as contributing to patient adherence (Rubin and Peyrot, 2001). Pertaining to diabetics, treatment-related barriers and negative emotions contribute to lack of success in reducing HbA_{1C} (Weinger and Jacobson, 2001). The authors suggest that problems with adherence are cyclical in that poor adherence may lead to poor glycaemic control, which creates treatment-oriented frustration (for the patient and the health care provider). This cycle perpetuates itself while creating greater problems with glycaemic control and adherence.

2.5.2   Disease Related Factors

Type 2 diabetic patients presenting with co-morbid condition(s) (for example, depression, musculoskeletal diseases, and obesity) and/or complications of diabetes (for example, hypertension, dyslipidaemia, painful diabetic peripheral neuropathy) will require additional medications to treat these conditions (Benner *et al.,* 2002; Jackevicius *et al.,* 2002).

2.5.3   Treatment Related Factors

Treatment related factors associated with non-adherence in the management of type 2 diabetes include the number of medications (pill burden), side effects, dosage frequency,

and cost. Increased side effects of medications have been shown to negatively impact patients' medication adherence. Side effects of diabetes and other diabetes-related medications (for example, dyslipidemics, antihypertensives) are a major cause of medication non-adherence in diabetic patients (Grant *et al.,* 2003).

Studies have reported an inverse relationship between the complexity of dosage regimen (number of doses per day) and medication adherence in patients (Dailey *et al.,* 2002). Studies reported significant differences between patients' adherence rates and dosage regimens; simpler dosage regimens were associated with better adherence rates (Dezii *et al.,* 2002). Higher medication cost has been shown to be associated with decreased medication adherence (Piette *et al.,* 2004).

2.5.4   Health Care Provider Related Factors

The quality of a patient's relationship with his/her health care provider has been shown to have a considerable effect on patient medication adherence. Patients who are more satisfied with their healthcare provider have better adherence. Availability of support from healthcare providers has been shown to be related to achieving adequate glycaemic control in patients (Delamater, 2006).

Social support provided by nurse case managers has been shown to promote adherence of diabetic patients to diet, medications and weight loss. Another study showed that having regular, frequent contact with patients by telephone promoted regimen adherence and achieved improvements in glycemic control, as well as in lipid and blood pressure levels (Sherbourne *et al.,* 1992). It was observed in the Diabetes Control and Complications Trial

that one of the key elements to success in achieving good glycemic control was the availability of support provided to patients by the health care team (The Diabetes Control and Complications Trial (DCCT) Research Group, 1993; Aubert *et al.,* 1998).

2.6   Conceptual Framework

| Independent Variables |

Patient related factors:

- Age
- Sex
- Education level
- Marital status
- Family support
- Smoking
- Alcohol abuse
- Home blood sugar monitoring

Disease related factors:

- Duration of disease
- Complications/ Comorbidities

Treatment related factors:

- Injection/Insulin medication
- No. of medications
- Route of administration
- Delay in medication initiation
- DM-related admissions

Healthcare system and provider related factors:

- Clinic Frequency
- DM education sessions
- Satisfaction with attending clinician
- Attitude of attending clinician
- Overall clinic/health service satisfaction

| Dependent variable |

Non-adherence to medication

Figure 2.1: Conceptual Framework

18

2.7   Measures of Medication Non-adherence

Various methods have been devised to assess medication adherence. Objective measures that are used include simple pill counts to sophisticated methods that involve an electronic monitoring cap that records timing of pill bottle opening for example MEMS (Medication Events Monitoring System) (Cramer *et al.,* 1989) and MedTracker device (Tamara *et al.,* 2006). Subjective measures include several patient self-reported medication questionnaire for example the Morisky Medication Adherence Scale – 4(Morisky *et al*., 1986), Morisky Medication Adherence Scale - 8 (Morisky *et al.,* 2008) and Brief Medication Questionnaire (Svarstad *et al.,* 1999). Whereas the objective measures may be more preferable to the patient self-reports, they are often expensive and not practical in the daily clinical experience. Furthermore, it has been shown that self-reports that assess one month periods and have percentage based ratings of adherence have the strong associations with MEMS and HbA_{1C} (Gonzalez *et al.,* 2013).

The Morisky Medication Adherence Scale (MMAS) is one of the most commonly used medication adherence assessments worldwide and has been used for several disease conditions including hypertension (Oliveira- Filho *et al.,*2012), diabetes (Abebe *et al.,* 2014), asthma (Hinchanjeri *et al.,*2012) , chronic myeloid leukaemia(CML) (Kapoor *et al.,* 2015) and HIV/AIDS (Ministry of Health, 2016). The eight-item MMAS had an alpha reliability of 0.83 (n= 1367) among patients diagnosed with essential hypertension attending an outpatient clinic of a large teaching hospital (Morisky *et al.,* 2008). It also shown significant association with antihypertensive medication pharmacy refill records;

patients who had a low adherence score by MMAS were 5-6 times more likely to exhibit non-persistence in medication refill rates by pharmacy data (Krousel-Wood *et al.,* 2009).

Among Type 2 diabetes mellitus patients, scores on the Morisky scale reflecting good adherence have been associated with lower HbA_{1C} levels indicative of better glycaemic control (Krapek *et al.,* 2004, Aikens et al., 2013). However some studies have also shown good adherence scores on the Morisky scale correlating weakly or negatively associated with HbA_{1C} levels (Wong *et al.,* 2014). Despites such contradiction, the Morisky scale has been judged as the near gold standard in a review of available medication adherence scales (Culig *et al.,* 2014). The scale has also been demonstrated to have a predictive capability to detect patients whose glycaemic control will likely subsequently deteriorate on longer term follow-up (Aikens *et al.,* 2013).

2.8 Summary of Literature

According to reviewed literature, there an alarming and increasing burden of diabetes mellitus globally and in Kenya. There also exist effective treatment therapies for diabetes mellitus, which if properly utilised can result in significant reduction in disease related morbidity, mortality and financial costs. Various researchers have developed various models to try and explain non- adherence to medication. These models have been largely validated by empirical research

There also exist effective and practical methods of measuring medication adherence. These methods have also been validated in large cohort studies in various parts of the world. None of the studies however have been conducted in Kenya despite the rapid increase in

diabetes prevalence and population effects. This study sought to address the dearth of information on extent of medication non- adherence and factors that influence this behaviour among Kenyan patients attending the largest referral hospital in country.

CHAPTER THREE

MATERIALS AND METHODS

3.1   Study site

The study was conducted at the Diabetic Clinic at Kenyatta National Hospital. Kenyatta National Hospital was founded in 1901 and serves a national referral hospital for the entire country. The hospital is located 3.5 kilometers from the Nairobi city's central business district (CBD); along Ngong Road. The coordinates of its physical location are 1.3010º S, 36.8072º E.
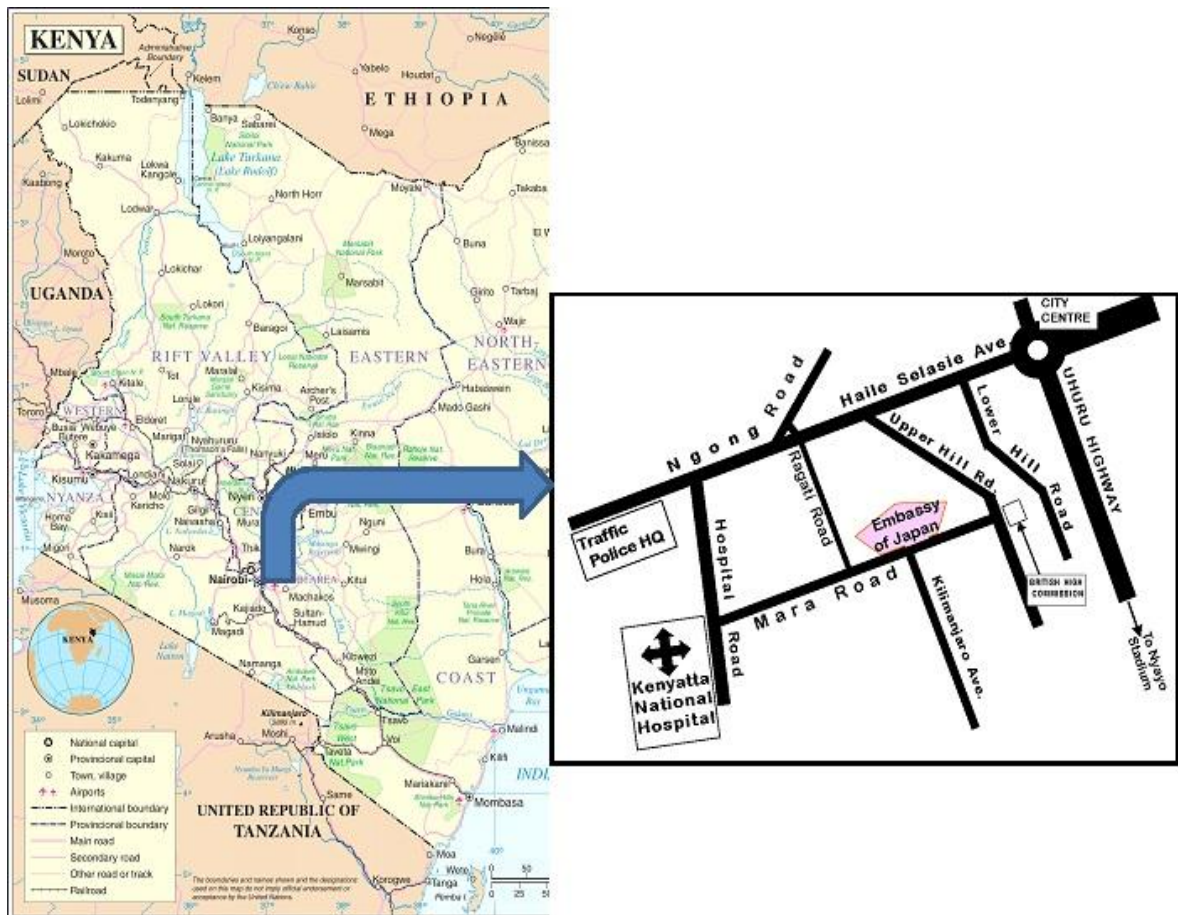
Figure 3.1: Location Map of Kenyatta National Hospital.

The diabetic clinic at Kenyatta National Hospital is operational five days a week; from 0800 hours to 1700 hours. It serves to initiate treatment and follow-up on diabetes patients through a booking and appointment system. The clinic attends to an average of 60 Type 2 diabetes patients for four days a week i.e. Mondays, Tuesdays, Thursdays and Fridays. Wednesdays are designated for education sessions on diabetes care for new patients. Patients on a typical clinic day are attended to by a consultant physician who is assisted by registrars (internal medicine), two clinical officers and nurses.

3.2   Study design

This was a cross-sectional study which utilized quantitative techniques. A structured questionnaire was utilized to collect data from November 2015 to January 2016.

3.3   Study population

The study population comprised of Type 2 diabetes mellitus patients (males and females) enrolled at the diabetes clinic of Kenyatta National Hospital and on oral or injection medication or both.

3.3.1   Inclusion criteria

Participants recruited into the study had to satisfy the following criteria;

1. Patients with Type 2 diabetes with at least one previous visit to the clinic.

2. Patients who were 18 years of age or older.

3. Patients who consented.

3.3.2   Exclusion criteria

Participants were disallowed into the study based on the following criteria;

1. Patients who are diagnosed with Type 2 diabetes mellitus attending their first clinic visit.

2. Patients who are less than 18 years of age.

3. Patients with Type 1 diabetes mellitus.

4. Patients who were seriously ill (unable to speak).

5. Patients who refused to give consent.

3.4   Sample size determination

In a similar study conducted in India, a developing country with comparable socio-economic characteristics to Kenya and evaluating non-adherence to treatment prescriptions among Type 2 diabetes mellitus patients and associated reasons for non-adherence, the prevalence of the adherence to anti-diabetic medication was found to be 25% (Shobhana *et al.,* 1999). Factoring this prevalence into the single population proportion formula (Gorstein *et al.,* 2007) and considering the following;

- Margin of error =5%

- Confidence level = 95%

The desired sample size was calculated to be:

$$n = \frac{Z^2 \, p \, (1-p)}{d^2} \qquad = \frac{(1.96)(1.96)\,0.25\,(1-0.25)}{(0.05)(0.05)}$$

= 289 participants

In this equation;

n denotes the desired sample size

Z denotes critical value for confidence level 95%

p denotes known prevalence of adherence

d denotes the set margin of error(5%)

3.5   Sampling technique

The participants for this study were recruited from the weekly diabetic clinic conducted at the Kenyatta National Hospital. On the day of the diabetic clinic, patients seated in waiting bay awaiting health worker consultation were recruited into the study through systematic sampling technique. The first participant into the study was selected by writing down the names of the first two patients in separate papers and thereafter choosing one randomly. Thereafter, every other patient who met the selection criteria was enrolled into the study.

3.6 Research variables

The research variables for this study were as follows;

3.6.1 Dependent variable

- Non-adherence to diabetes medication

3.6.2   Independent variables

- Glycemic control

- Factors related to medication non-adherence in Type 2 diabetes mellitus grouped into patient related factors (these include; age, sex, education level, marital status, family support, smoking, alcohol abuse and home blood sugar monitoring). Secondly into disease-related factors (these include; presence of comorbidities and complications and duration of disease). Thirdly into treatment-related factors (for example, number of medications (pill burden), route of administration and cost of medications) and fourthly into healthcare system and provider related factors (these include; frequency of clinic appointments and follow-up; patient health education, quality of relationship between the physician and the patient and health service quality).

3.7   Data collection

On each diabetic clinic day, for each of the patients selected for participation in the study, consent was sought for and documented. A structured questionnaire was then administered; either the English or Kiswahili version was used as per comfort of the participant (Appendix 3 and 4) by the principal investigator. The questionnaire captured information regarding socio-demographic characteristics such as age, residence, occupation, education level, marital status, sources of medication, satisfaction with family

members, satisfaction with health care providers and performance of home based blood sugar monitoring.

The principal investigator secondly reviewed the participant's clinic file to obtain information regarding the medication regimen including the number of medications, route of administration and dosing frequency of each medication and known comorbid/complication states for each study participant.

Adherence was assessed using the participant's self-report on how they have been taking prescribed medication. Evaluation of adherence and medication challenges was done using the updated Morisky Medication Adherence Scale-8 (Morisky *et al.,* 2008, Morisky *et al.,* 2011, Krousel-Wood *et al.,* 2009). A score of 8 indicates high adherence, a score of 6-7 indicates medium adherence whilst a score of less than 6 indicates poor adherence.

The study participants had two anthropometric measurements taken; these were height and weight. Height was measured without shoes to the nearest of 0.1 centimeter (cm) using a stand-meter. Weight was measured to the nearest of 0.1 kg on a hospital scale, with the participant wearing one-layer of clothes and with no shoes. Body Mass Index (BMI) was calculated as weight (kg) divided by the square of the height (m^2). The cut-offs for BMI will be based on the World Health Organization (WHO) criteria, where underweight is defined as BMI < 18.5 kg/m^2, normal weight as BMI between 18.5 kg/m^2 and 24.99 kg/m^2, overweight is defined as a BMI ≥ 25 kg/m^2, and obesity is defined as a BMI ≥ 30 kg/m^2 (WHO, 1995).

Upon completion of the questionnaire administration; the principal investigator drew finger-prick blood for assay of glycosylated hemoglobin (HbA_{1C}). The portable A1cNow® point of care system (PTS Diagnostics, IN, USA) was used determine the level of HbA_{1C}. This is a compact and portable device that uses about 5 microliters of blood from a finger prick to determine glycosylated hemoglobin level and display result on a digital screen in 5 minutes. Values obtained from this point of care system have demonstrated good correlation with standard reference laboratory systems (Amarbir *et al*., 2007, Knaebel *et al.*, 2013). Anthropometric measures and biochemical values were recorded in last section of the questionnaire for each participant by the principal investigator (Appendix 3; section L and Appendix 4; sehemu L).

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3.8 Data management

Data from the questionnaires including participants' anthropometric measures and glycosylated hemoglobin values were entered into a computer spreadsheet designed using MS-Excel application. Data cleaning was done by daily checking of the completed questionnaires prior to computer entry in order to achieve a clean dataset. Regular file back-up was done to avoid any loss or tampering. Back up files were stored in a designated study flash disk. This was stored in a locked cabinet.

3.9   Data analysis

Descriptive statistics such means, proportions and frequencies were used to express participant socio-demographic, clinical and anthropometric characteristics such as age, sex, level of education, occupation, smoking status, alcohol usage, duration of disease medication regimens and body mass indices. Medication adherence prevalence was determined by proportion of patients who obtain a score of 8 on the Morisky Medication Adherence Scale. HbA_{1C} values determined by blood assay were categorized to either good control for patients whose values were less than 7% and poor control for patients whose values were 7% or more. Alcoholism screening was done using the CAGE test (Ewing, 1984). The CAGE questionnaire asks the following questions: 1) Have you ever felt you needed to Cut down on your drinking? 2) Have people annoyed you by criticizing your drinking? 3) Have you ever felt Guilty about drinking? 4) Have you ever felt you needed a drink first thing in the morning (Eye-opener)? Item responses on the four-item CAGE test are scored 0 or 1; with a higher score indicating alcohol problems. A total score of 2 or greater is considered clinically significant.

Analysis of the quantitative data was done using STATA 11.0 program (Release 11. College Station, TX: StataCorp LP). Chi-square test analysis was carried out to determine the statistical significance of the association between the three medication adherence categories and two glycemic control categories and secondly between suboptimal adherence and the different independent categorical variables such as sex, marital status, level of education and route of administration of diabetic medication, presence of comorbid states and complications. All independent variables whose p-values did not

exceed 0.2 were selected for inclusion in the multivariable analysis model. Logistic regression was used for multivariable analysis. Odds ratios (ORs), 95% confidence intervals and p-values were calculated. A p-value of less than 0.05 was considered statistically significant.

3.10   Ethical considerations

Authority to conduct research at Kenyatta National Hospital was sought from the Research and Programs department and ethical approval was sought from the Ethics and Research committee of Kenyatta National Hospital/University of Nairobi (Appendix 5). Prior permission to use the Morisky Medication Adherence Scale had been sought and a license agreement signed with the copyright owner (Appendix 6).

The participants were informed that their participation is voluntary and they could withdraw from the study at any time without giving any reason. The consent of the respondents was sought and obtained before the administration of the questionnaire by requesting them to sign an informed consent form (Appendix 1 and 2). The findings were treated with utmost confidentiality and were used the purpose of this research only. The objective and findings of the study was explained to the participants of the study. The participants were informed that a blood sample shall be required and on the procedure for drawing blood and counselled on the anticipated pain and that the sample shall be for the determination of HbA_{1C} levels only. The participants were also informed that they shall incur no costs for this test. The recorded data on flash disks was stored in a lockable

cabinet till presentation of findings and recommendations and the materials will be erased

after publication of the research.

CHAPTER FOUR

RESULTS

4.1   Characteristics of study participants

A total of two hundred and ninety Type 2 diabetes mellitus participants were recruited from the diabetic clinic at Kenyatta National Hospital were recruited into the study.

 The mean age of the participants was 56.6 (SD ±11.86) years. The majority of participants were female (67.6%). 16.9% participants had never received any formal education; whilst the rest were stratified over three levels of formal education. 26.9 % participants were not engage in any form of employment. The bulk of the participants were Christians; constituting 97.6 % of the enrolled patients.

Socio-demographic characteristics of the participants are summarized in Table 4.1.

Table 4.1 Socio-demographic characteristics of study participants

Characteristic	Participants [N (%)]
Age(years), Mean(S.D.)=56.6(11.86)	
Sex	
Male	
Female	94 (32.4)
	196 (67.6)
Marital status	
Single	31 (10.7)
Married	222 (76.6)
Divorced	14 (4.8)
Widower/Widow	23 (7.9)
Education Level	
No formal education	49 (16.9)
Primary	85 (29.3)
Secondary	104 (35.9)
Higher/university	52 (17.9)
Occupation	
Unemployed	114 (39.3)
Civil servant	60 (20.7)
Farmer	33 (11.4)
Small scale business	62 (21.4)
Casual laborer	15 (5.2)
Other	6 (2.1)
Religion	
Christian	283 (97.6)
Muslim	6 (2.1)
Alcohol consumption	
Yes	12 (4.2)
No	276 (95.8)
Smoking habits	
Yes	5 (1.7)
Never	231 (79.7)
Used to but stopped	54 (18.6)

4.2 Prevalence of medication non-adherence

The prevalence of medication non-adherence was 54.5%, representing 158 study participants. The distribution as categorised on the MMAS-8 was low for 28.3 % [95% CI: 23.1, 33.5], medium for 26.2% [95% CI: 21.1, 31.3], and high for 45.5% [95% CI: 39.6, 51.3] of the study participants (Figure 4.1).
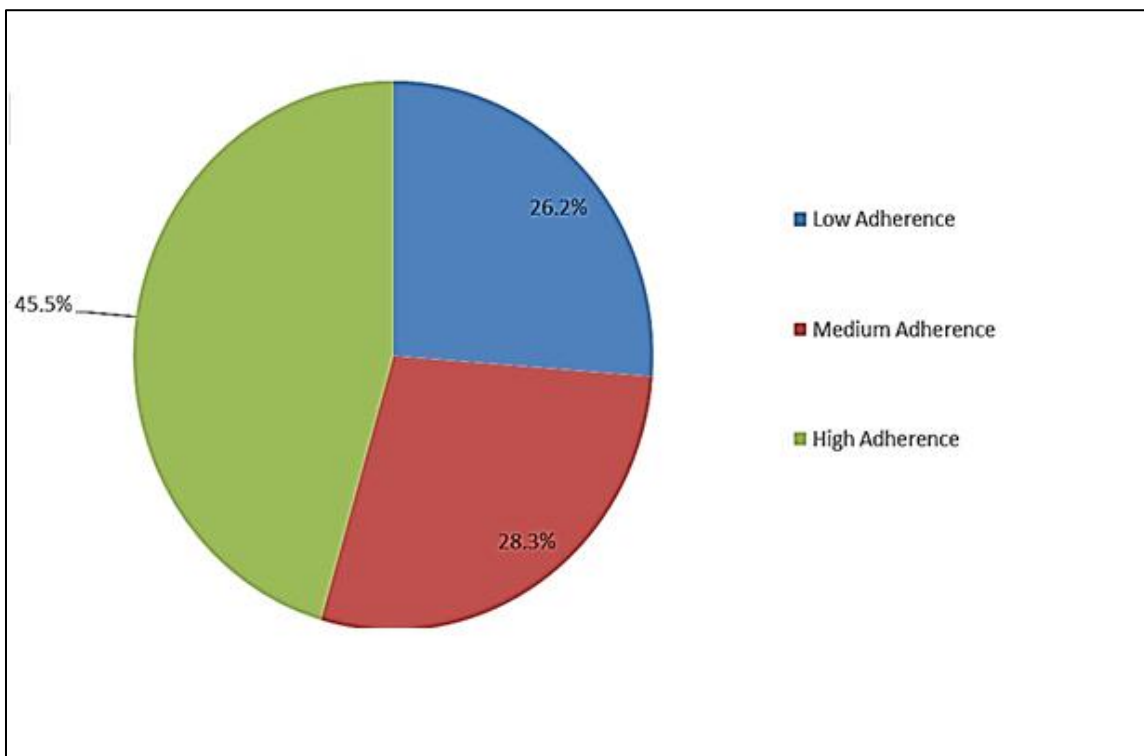
Figure 4.1: Prevalence of medication non-adherence according to MMAS-8 categories.

4.3 Level of glycemic control

Glycemic control as determined by glycosylated hemoglobin (HbA$_{1C)}$ was good (<7.0%) for 107 (36.9 %) participants. The mean HbA$_{1C}$ for all study participants was 7.9 (SD ±1.97). Figure 4.2 shows the mean HbA$_{1C}$ values for each for the three medication adherence categories.
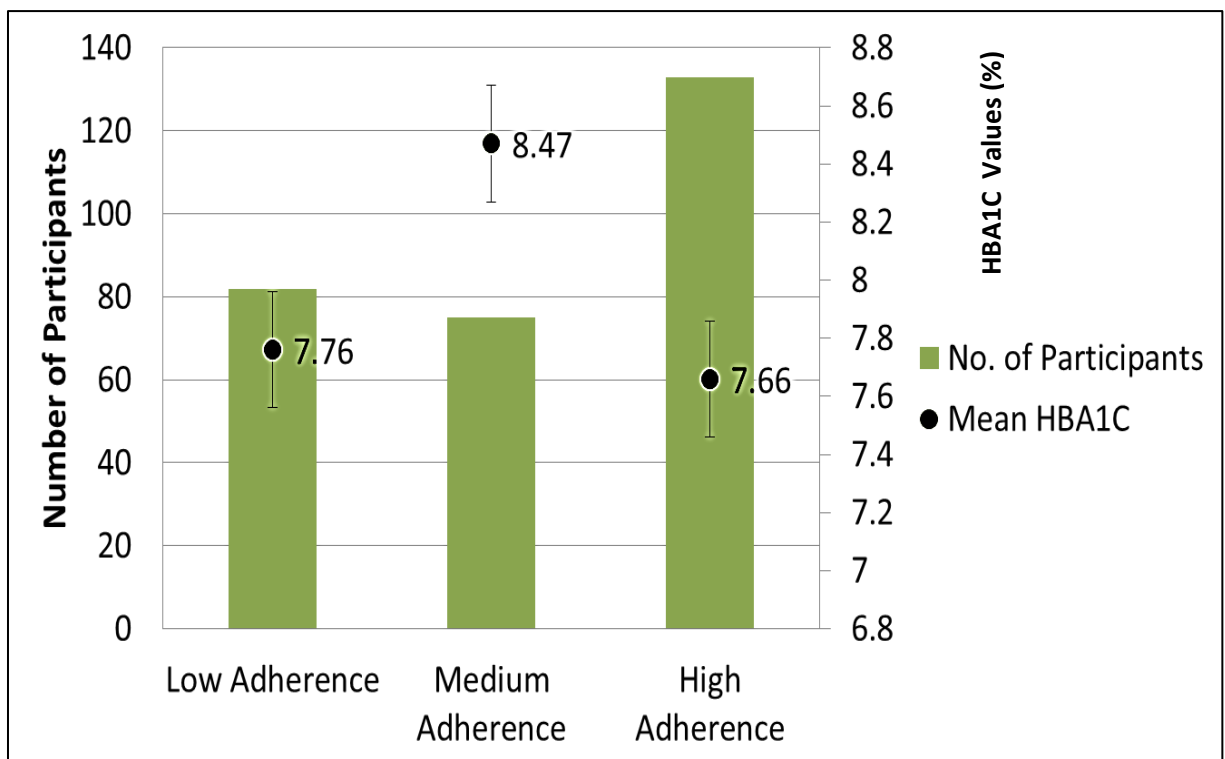
Figure 4.2: Mean HbA1C values according to adherence category.

4.4   Association between medication non-adherence with glycemic control

A significant association (p=0.019) was found between medication non-adherence and glycaemic control i.e. poorer glycaemic control with low levels of medication adherence and vice versa (Table 4.2).

Table 4.2: Relationship between Morisky Medication Adherence Scale (MMAS) categories and glycaemic control

Glycaemic control	Low Adherence	Medium Adherence	High Adherence	p-value
Good (HBA1C ≤ 7%)	26 (24.3%)	21 (19.6%)	60 (56.1%)	0.019
Poor (HBA1C >7%)	56 (30.6%)	55 (30.1%)	72 (39.3%)	
Total	82 (28.3%)	76 (26.2%)	132 (45.5%)	

4.5   Factors associated with medication non-adherence

4.5.1   Anthropometric and clinical profiles of study participants

The average duration of diabetes mellitus for the participants enrolled for this study was 8 (SD ±7.82) years. There was a delay in commencement of medications following diagnosis for 13.1% of the participants. The majority of the study participants (44.5%) were on oral glucose lowering medications (OGLAs) only with no injections. 51.4% were taking two medications for blood sugar control. Most of the participants (63.1%) had never been admitted because of diabetes mellitus since diagnosis.

A summary of the participants' anthropometric and clinical profiles is given in Table 4.3.

Table 4.3 Participants' anthropometric and clinical profiles

Characteristic	Participants [N (%)]
BMI (kg/m2), Mean(S.D.)= 30.03(7.04)	
Normal	60 (21)
Overweight	107 (37.4)
Obese	119 (41.6)
Glycosylated Hemoglobin(HBA1C), Mean(S.D.)=	
7.9 (1.97)	107 (36.9)
Good (< 7%)	183 (63.1)
Poor (>7%)	
Duration of Disease(years), Mean (S.D.) =8 (7.82)	
< 2	66 (22.8)
2 – 10	141 (48.6)
11+	83 (28.6)
Delay in medication start following diagnosis (years), Mean (S.D.)= 0.5 (1.76)	
Yes	38 (13.1)
No	252 (86.9)
Type of medication	
Oral Glucose Lowering Agents(OGLA)	129 (44.5)
Insulin	44 (15.2)
Combination therapy (Insulin + OGLA)	117 (40.3)
Number of diabetes medications	
1	110 (37.9)
2	149 (51.4)
3	29 (10)
4 +	2 (0.7)
Number of diabetes –related admissions	
0	183 (63.1)
1	71 (26.2)
2	15 (5.2)
3	9 (3.1)
4	2 (0.7)
5+	5 (1.7)
Presence of diabetes complications	
Yes	139 (47.9)
No	151 (52.1)
Presence of co-morbid states	
Yes	217 (74.8)
No	73 (25.2)

Study participants having documented presence of diabetes related complications in their clinic file were 47.9%. The majority of them (27.6%) had eye complications (Figure 4.3).
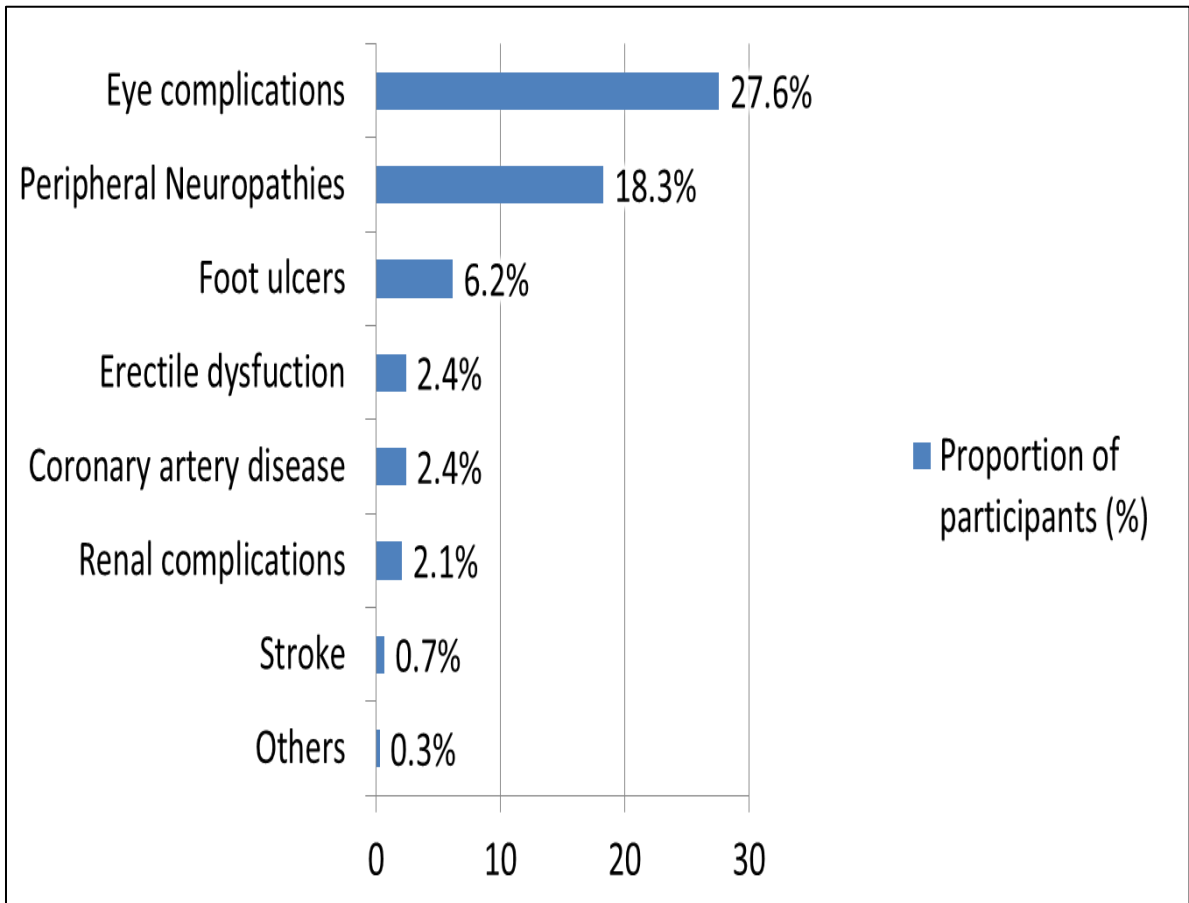
Figure 4.3: Diabetes related complications present among study participants

Participants having a comorbid state besides Type 2 diabetes mellitus were 74.8%. The most frequent comorbid state encountered among them was hypertension (68.3%). (Figure 4.4)
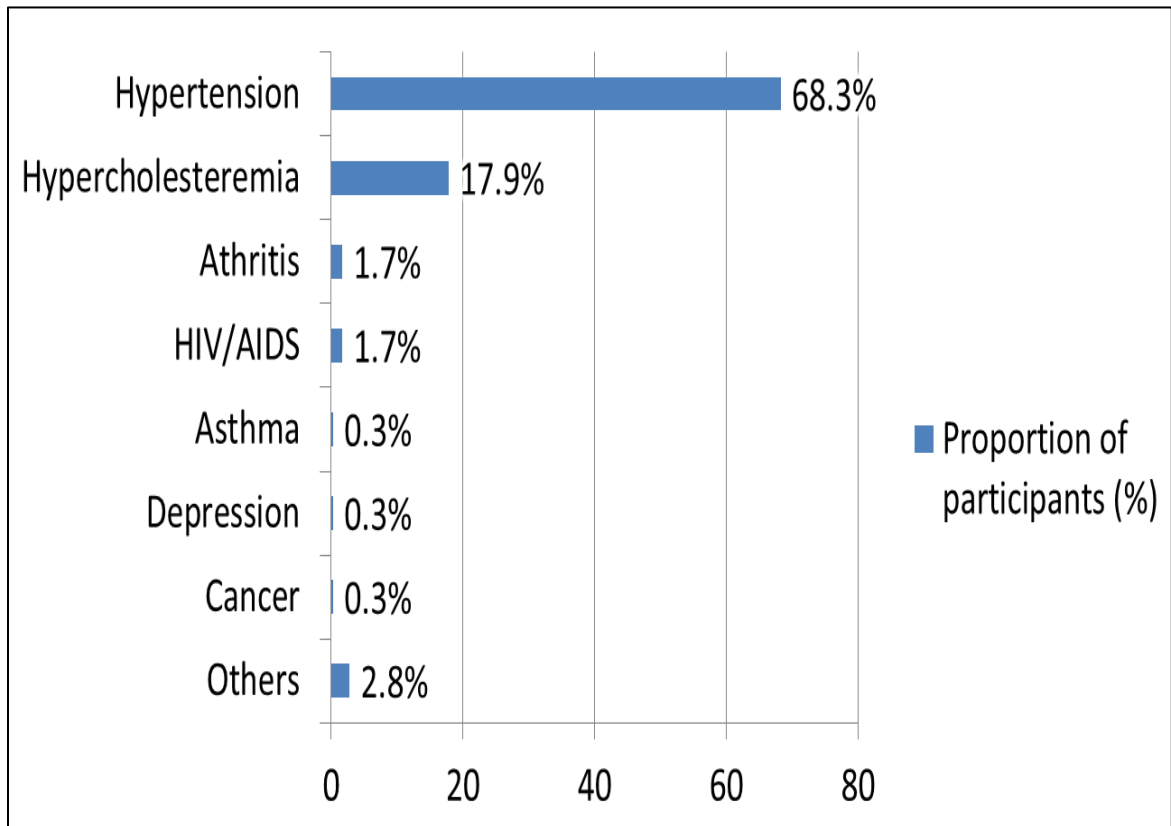
Figure 4.4: Comorbid states present among study participants

4.5.2 Diabetes health education

The vast majority of study participants (94.8%) had attended at least one health education session on diabetes mellitus since diagnosis (Figure 4.5).
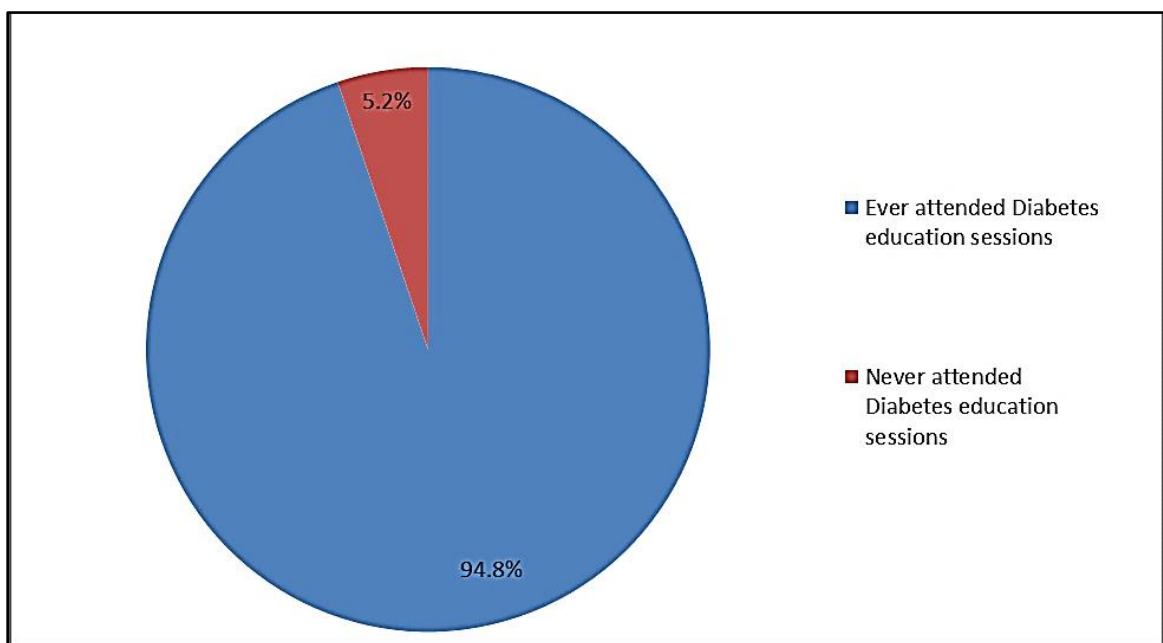
Figure 4.5: Attendance of diabetes education sessions among study participants.

The most reported source of information on diabetes among the cadres of health personnel were the nurses and followed by mass media sources (90.3% and 28.3% respectively) (Figure 4.6).
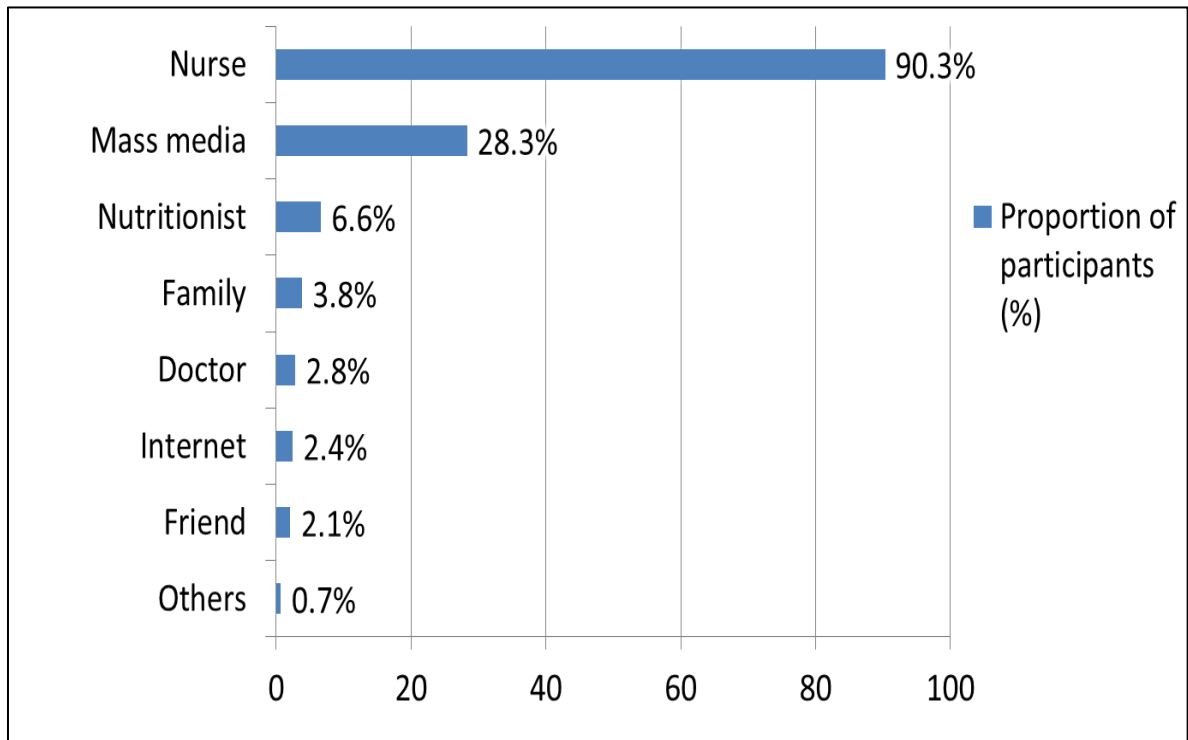
Figure 4.6: Sources of diabetes information among study participants

4.5.3 Family members' attitude and support

Most participants (83.8%) reported that their family members' attitude towards them in regard to diabetes mellitus was supportive (Figure 4.7).
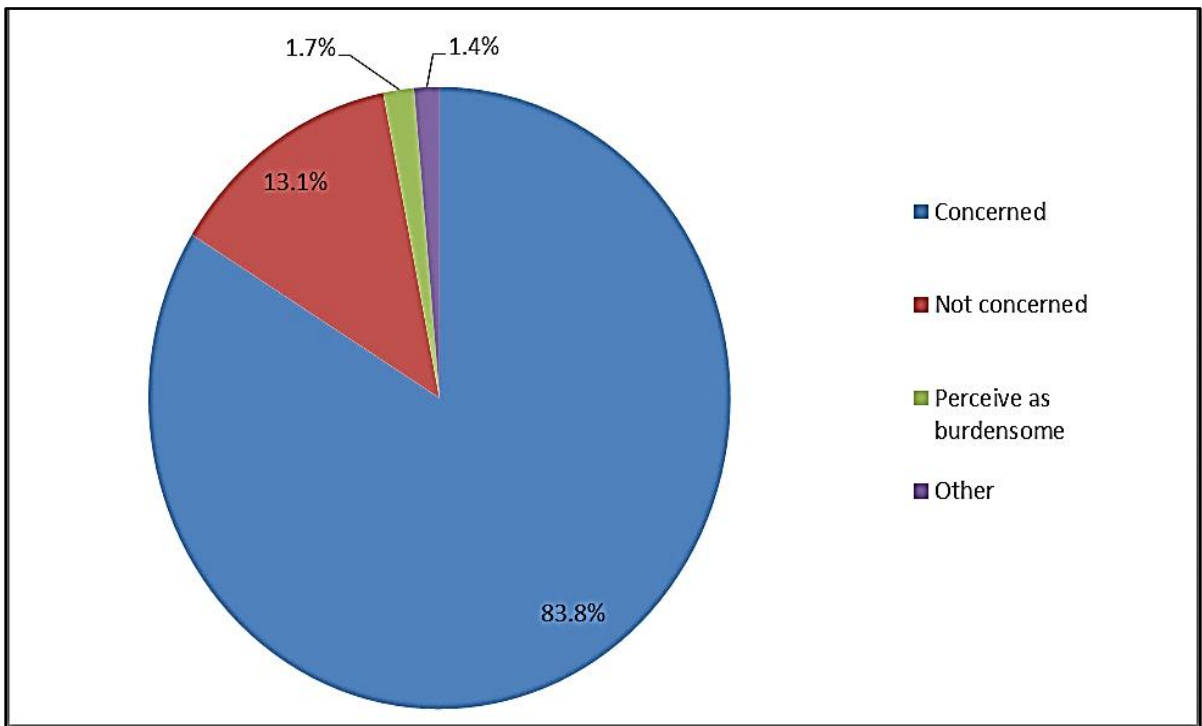
Figure 4.7: Attitudes of family members towards diabetes mellitus among study participants

When queried if they felt satisfied with the support they received in their family most of them (88.5%) reported in the affirmative (Figure 4.8).
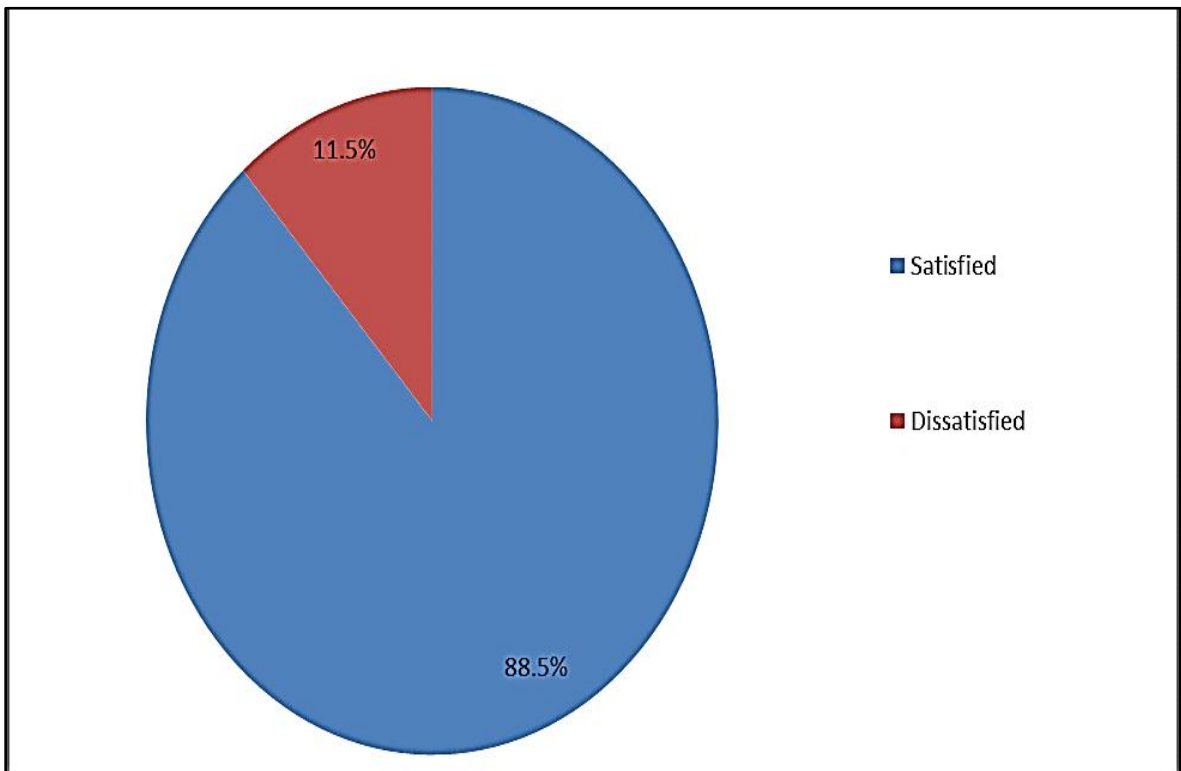
Figure 4.8: Satisfaction with family support among study participants.

Figure 4.9 shows the forms of support family members were reported to given to the participants in regard to diabetes mellitus management. The most common form of support cited (from 70% of the participants) was of reminding them of medications.
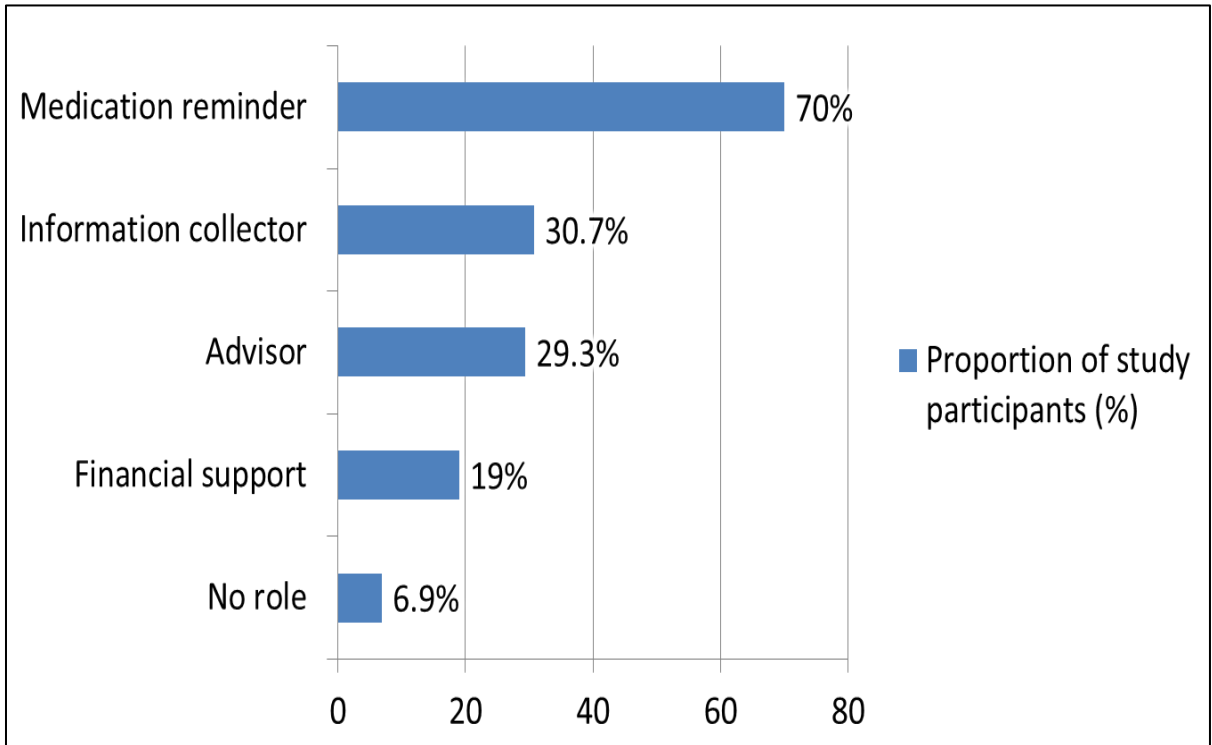
Figure 4.9: Forms of family support accorded to study participants

4.5.4 Health care system

The diabetic clinic operates on an appointment and booking system in order to effectively manage the patient workload. Patients are stratified into different schedules depending on clinician assessment of a patients' competency in diabetes self-management. A majority of the patients studied were on a six-monthly schedule (38.3%); followed by those on a three-monthly schedule (35.9%). Figure 4.10 shows the proportion of study participants in each schedule.
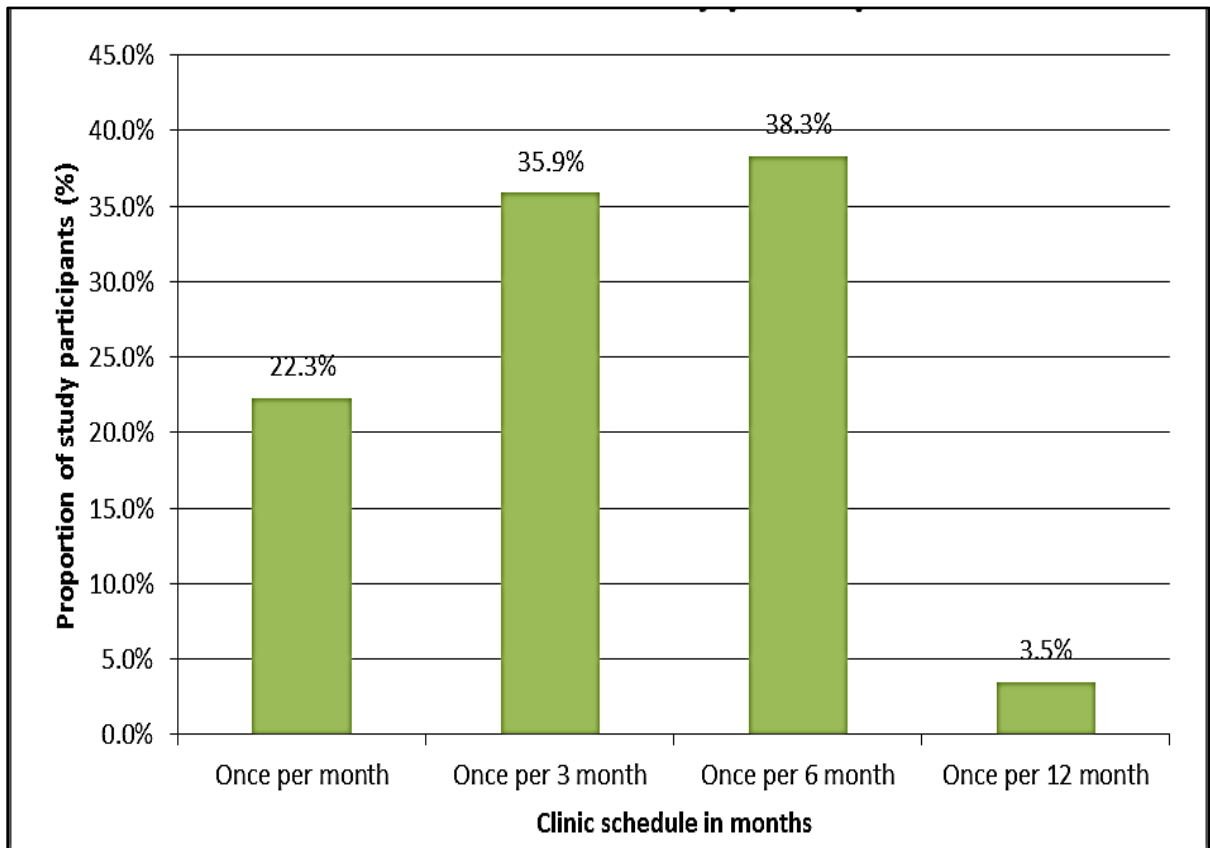
Figure 4.10: Clinic schedule appointments among study participants.

In regard to barriers in access to medication; 55.5% of the participants reported a challenge in accessing drugs and medical supplies. The cost was the most frequent barrier mentioned (45.9% of study participants); followed by drug availability (7.8%). This is depicted in figure 4.11 below.
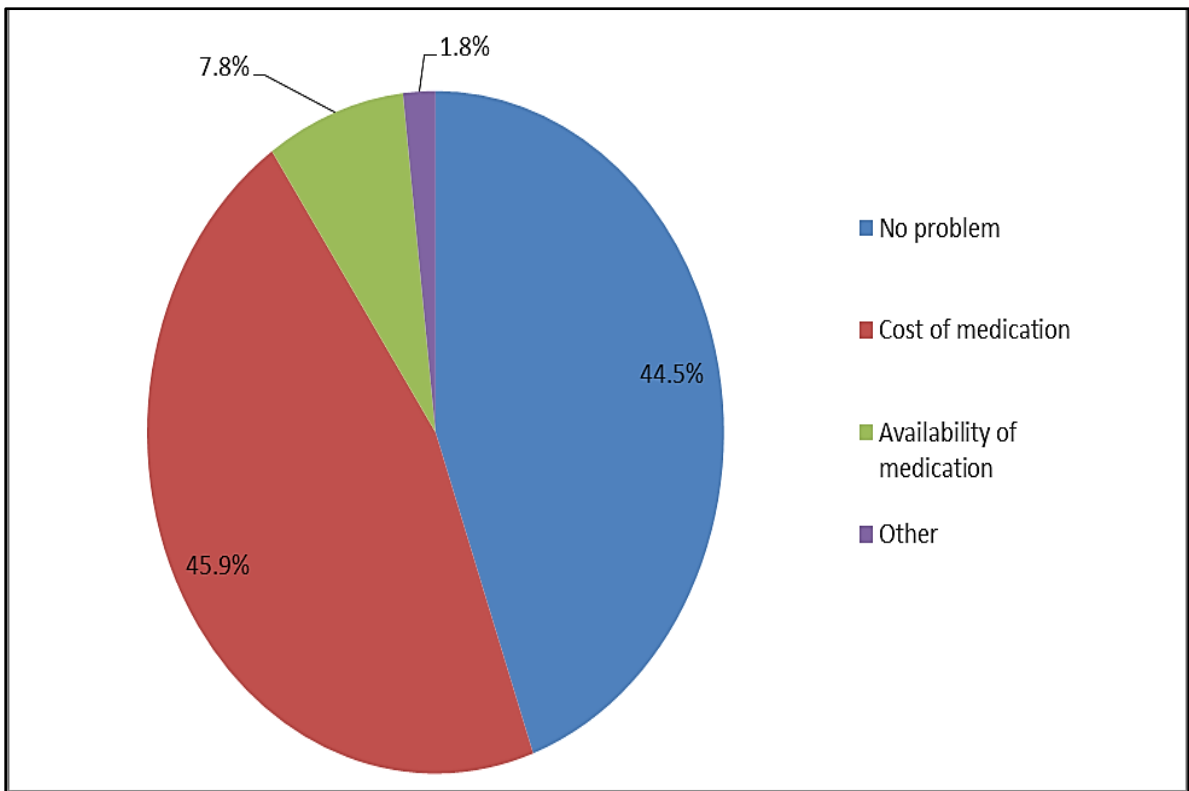
Figure 4.11: Medication challenges encountered by study participants

4.5.5   Patient healthcare satisfaction

Among the factors queried in regard to a patient satisfaction with healthcare provided at the diabetic clinic included satisfaction with the attending clinician, satisfaction with other staff cadres and overall clinic experience. Satisfaction with the attending clinician and other health staff cadre was score in a 5-point likert scale.

Most participants (52.6%) were rated their relationship with the attending clinician as very satisfying. A similar trend was observed in regard to satisfaction with other health cadres at the clinic. A majority of the participants (51.2%) reported to be very satisfied with the care they received. Figure 4.12 depicts the healthcare satisfaction that study participants reported with health care staff at the clinic.
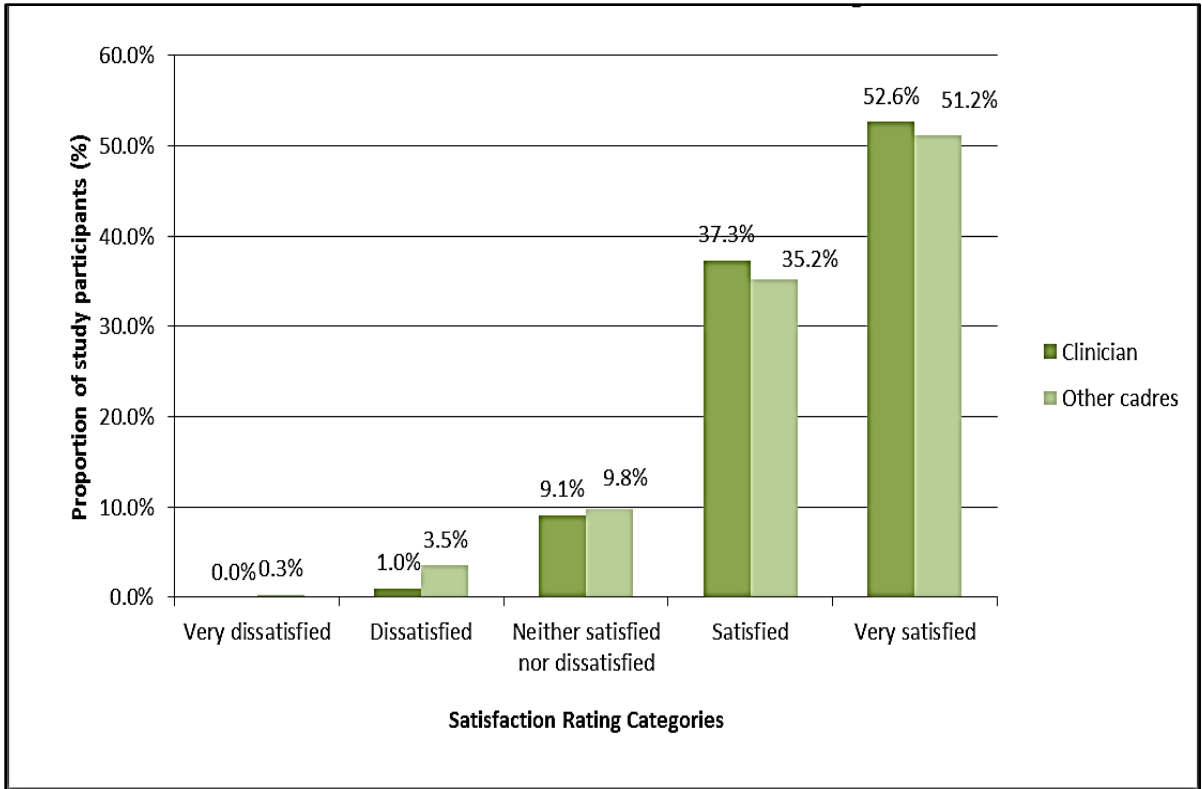
Figure 4.12: Satisfaction ratings for clinicians and other health cadres by study participants

The overall clinic experience including human and physical facilities reflecting health service quality was also rated. Most patients rated their experience as excellent (45.9%); only two patients (0.7%) rated their experience as being poor. Figure 4.13 shows the distribution of overall rating scores.
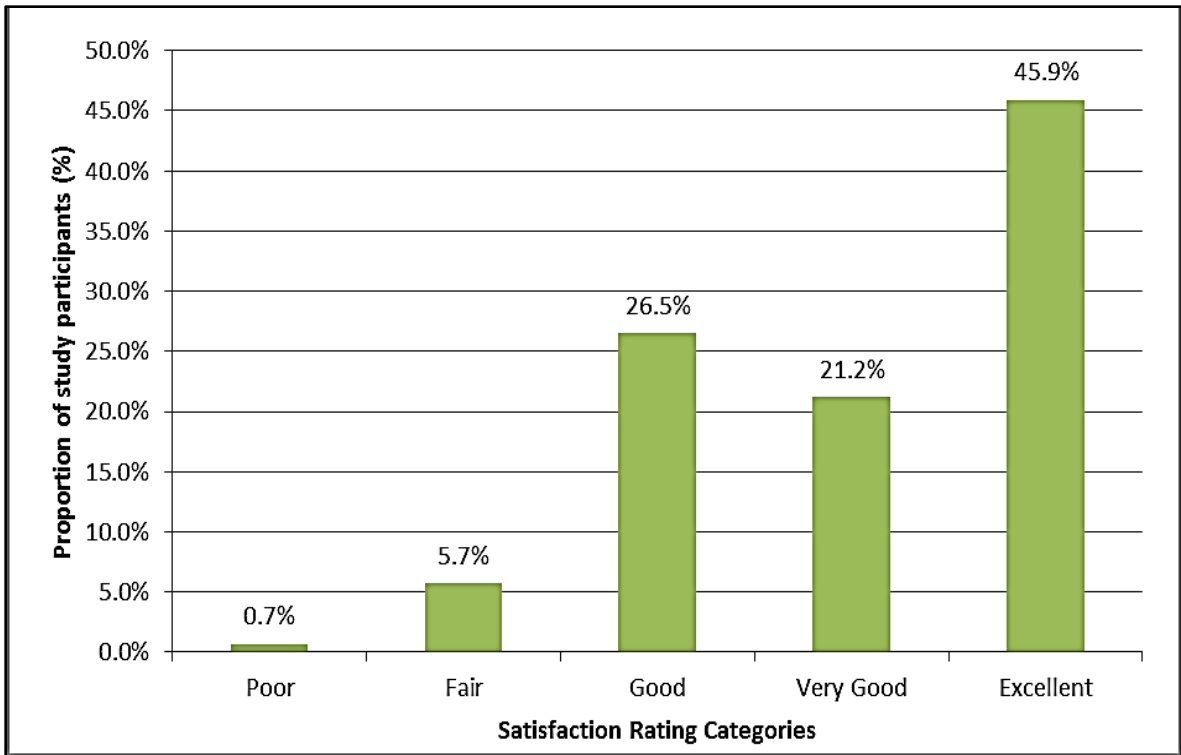
Figure 4.13: Satisfaction ratings for the overall clinic experience

4.5.6 Home blood sugar monitoring

Majority of the participants (92.7%) believed that home blood sugar monitoring (HBSM) was important. However 44.1% of the participants actually practiced HBSM (Figure 4.14).
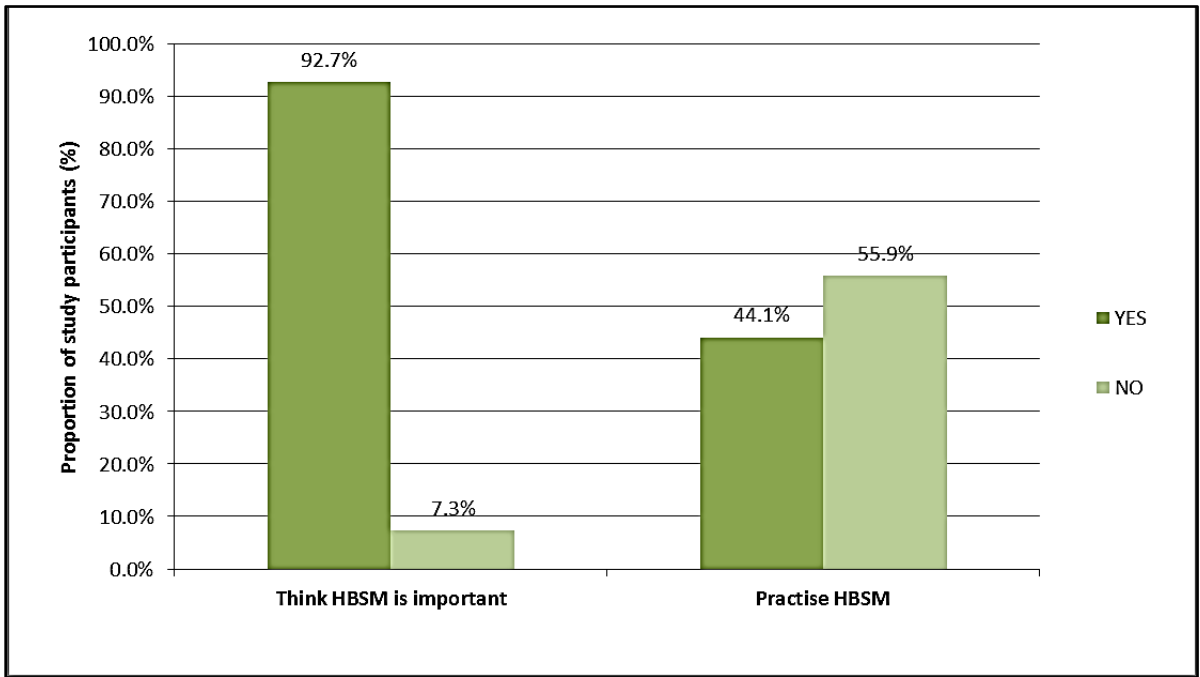
Figure 4.14: Perception and practice of HBSM among study participants.

The majority (79.4%) of those who did not practice HBSM cited not having a glucometer as the reason for not practicing HBSM. The second frequent reason cited was that glucometer strips had ran out (10.3%). Figure 4.15 shows the reasons for not practicing HBSM.
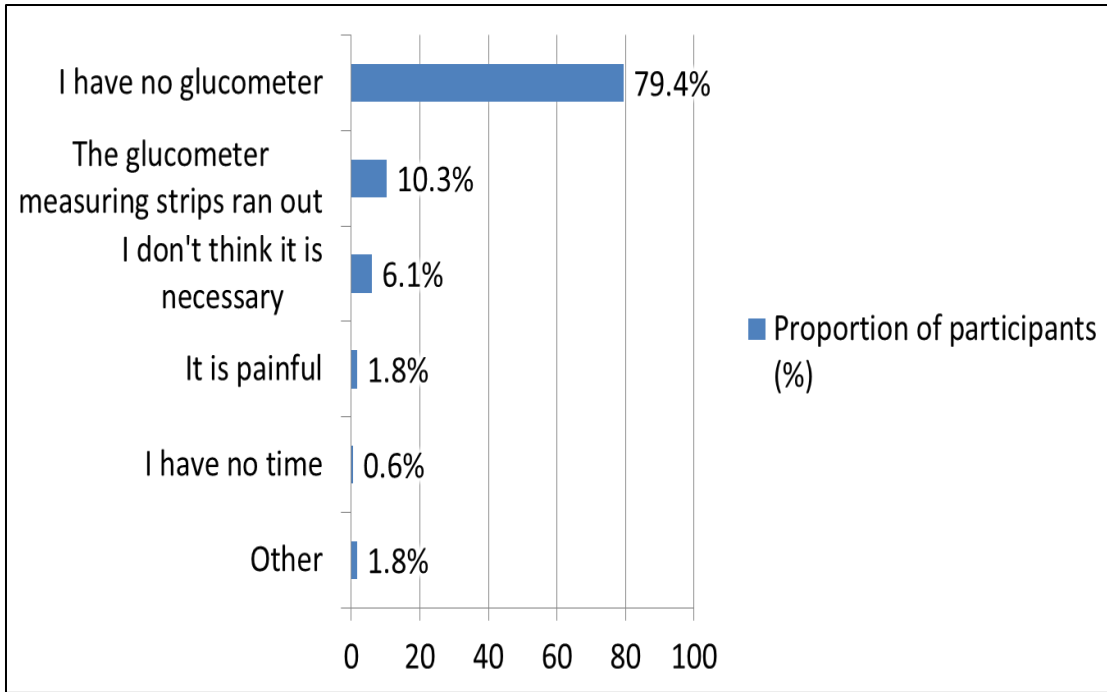
Figure 4.15: Reasons cited for non-performance of HBSM

Among the participants that practiced HBSM (43.8% of all study participants); only 19.7% adjusted their diabetes medication according to their blood sugar; thus reducing the utility of the procedure (Figure 4.16).
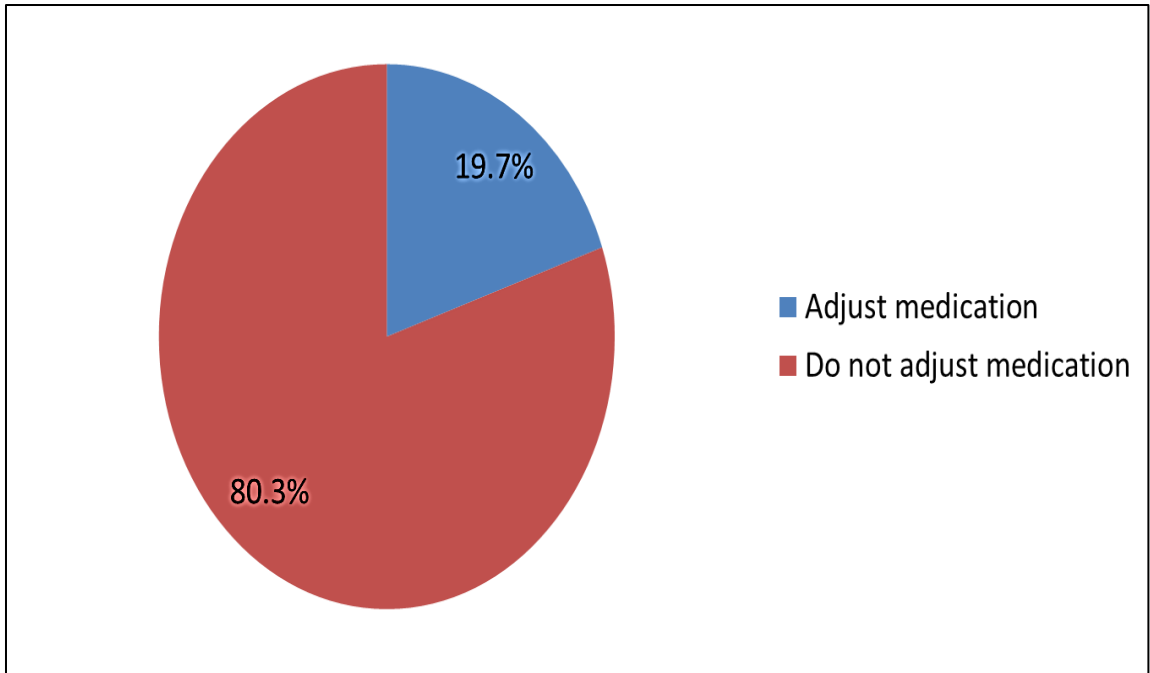
Figure 4.16: HBSM medication adjustment among study participants.

The pattern of HBSM was also not predictable for most of those who practiced it. 40.2% of

HBSM practitioners did it irregularly; only when they had symptoms (Figure 4.17).
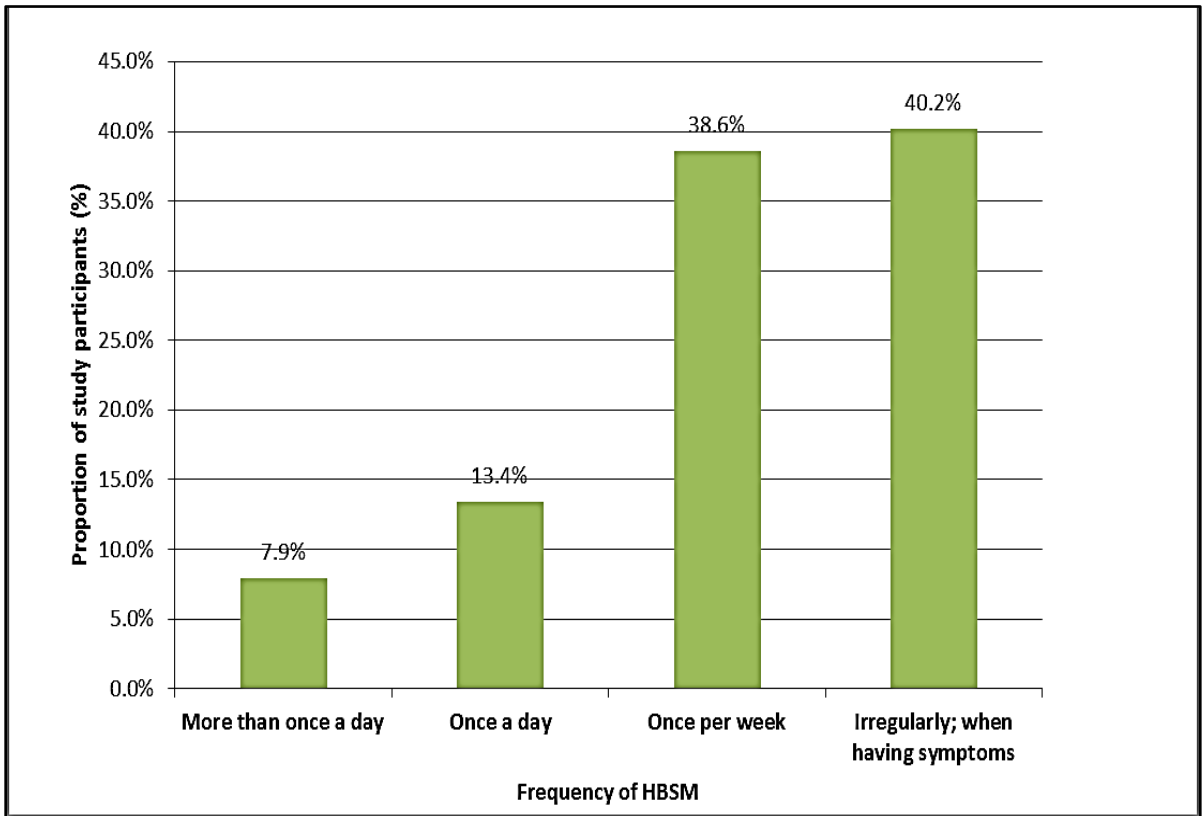
Figure 4.17: Patterns of HBSM among study participants

4.5.7 CAGE scores for alcohol usage

Twelve participants (4.2%) of this study affirmed to be current users of alcohol. They underwent the CAGE assessment (Ewing, 1984) to identify alcoholism. Only two of the current alcohol users attained the clinical significant threshold score of ≥ 2 points. Table 4.4 shows the results of this assessment.

Table 4.4: CAGE assessment scores for alcohol consuming study participants

Total Cage Score	Participants [N (%)]
0	9 (3.1)
1	1 (0.3)
2	1 (0.3)
3	1 (0.3)
4	0 (0)

4.5.8   Patient-related factors and non-adherence

The study sought to find out if there were significant associations between patient related factors (these include; age, sex, education level, marital status, family support, smoking, alcohol abuse and home blood sugar monitoring) and non-adherence. Chi-square analysis was carried out to determine the statistical significance of association between each independent categorical variable and non-adherence. Table 4.5 shows the results of this analysis.

Table 4.5: Relationship between patient related factors and non-adherence

Characteristic	Total	Low-Medium Adherence [N (%)]	p-value
Age			0.715
18 -54	122	68 (55.7)	
55+	168	90 (53.6)	
Sex			0.760
Male	94	5 (53.2)	
Female	196	108 (55.1)	
Marital status			0.168
Married	222	116 (52.3)	
Not married	68	42 (61.8)	
Education level			0.236
None or Primary	134	68 (50.7)	
Secondary or Tertiary	156	90 (57.7)	
Occupation			0.911
Formal	122	66 (54.1)	
Informal	168	92 (54.8)	
Alcohol consumption			0.145
No	276	148 (53.6)	
Yes	12	9 (75.0)	
Smoking habits			0.357
Ever smoked	59	29 (49.2)	
Never Smoked	231	129 (55.8)	
Satisfaction with family support?			0.024
Satisfied	254	132 (52.0)	
Dissatisfied	33	24 (72.7)	
Attitude of family members in regard to patient's illness	243	126 (51.9)	0.03
Positive	43	30 (69.8)	
Negative			
Do Home Blood Sugar monitoring (HBSM)?			0.506
Yes	127	66 (52.0)	
No	161	90 (55.9)	

4.5.9   Disease, treatment and health system/provider factors and non-adherence

The study sought to find out if there were significant associations between disease-related factors (these include; presence of comorbidities and complications and duration of disease), treatment-related factors (for example, number of medications (pill burden), route of administration and cost of medications) and healthcare system and provider related factors (these include; frequency of clinic appointments and follow-up; patient health education, quality of relationship between the physician and the patient and health service quality). Chi-square analysis was carried out to determine the statistical significance of association between each independent categorical variable and non-adherence. Table 4.6 shows the results of this analysis.

Table 4.6: Relationship between diabetes treatment factors and non-adherence among study participants

Variable	Total	Non- Adherence [N (%)]	p-value
Injection/insulin medication			0.049
No	129	62 (48.1)	
Yes	161	96 (59.6)	
Duration of Disease			0.004
< 2 year	66	25 (37.9)	
2 – 10 years	141	88 (62.4)	
11+	83	45 (54.2)	
Number of Diabetes Medications			0.052
1	110	52 (47.3)	
2	149	84 (56.4)	
3+	31	22 (71.0)	
Delay in medication start following diagnosis?			0.011
No	252	130 (51.6)	
Yes	38	28 (73.7)	
Ever DM related admission?			0.004
No	183	88 (48.1)	
Yes	107	70 (65.4)	
Presence of complication or comorbidity?			0.193
No	42	19 (45.2)	
Yes	248	139 (56.0)	
Frequency of DM clinic			0.664
3 monthly or less	167	92 (55.1)	
4 monthly or more	120	63 (52.5)	
Attendance of diabetes education session			0.739
No	14	7 (50.0)	
Yes	275	150 (54.5)	
Challenge in drug access?			0.069
No	141	85 (60.3)	
Yes	126	62 (49.2)	
Satisfaction with attending clinician?			0.096
Satisfied	258	136 (52.7)	
Dissatisfied	29	20 (69.0)	
Overall clinic experience			0.104
Poor	18	10 (55.6)	
Average	75	33 (44.0)	
Good	190	111 (58.4)	

4.5.10 Logistic regression analysis

All independent variables whose p-values did not exceed 0.2 were selected for inclusion in the multivariable analysis model. On bivariate analysis, the following factors attained this cut-off level of association required to be included in multivariable analysis; number of diabetes mellitus medications (p=0.052), ever having being admitted for diabetes mellitus (p=0.004), category of diabetes medications (p=0.049), presence of complication or comorbidity(p=0.051),duration of disease (p=0.004), patient satisfaction with family members support in regard to diabetes mellitus management (p=0.024), family members attitude towards patient's illness (p= 0.03), presence of a challenge in drug access (p=0.069), patient's satisfaction with attending physician (p=0.096), patient's overall experience at the clinic (p=0.104), marital status (p=0.168), alcohol usage (p=0.145) and whether there was a delay in commencement of medication upon diagnosis (p=0.011).

Significant collinearity was observed between patient satisfaction with family members support in regard to diabetes mellitus management and family members' attitude towards patient's illness and also between patient satisfaction with attending clinician and patient's overall experience at the clinic. The independent variable in each of the two cases which exhibited greater association to non-adherence i.e. lower p- value was selected for inclusion in the final logistic regression model (Patient's satisfaction with family member support in regard to diabetes mellitus was selected in the first case and patient's satisfaction with attending clinician in the latter).

Results of the logistic regression are depicted on Table 4.7. Five factors emerged significantly associated with poor medication adherence in this analysis; patients with duration disease between 2 − 10 years (OR=2.07, CI= 1.01-4.22), ever being admitted for diabetes mellitus (OR = 2.94, CI=1.60-5.41), dissatisfaction with family members support in regard to diabetes mellitus management (OR = 2.99, CI=1.12-7.98), presence of a challenge to drug access(OR=1.76, CI=1.01-3.05) and satisfaction with attending clinician (OR= 3.58, CI= 1.36 - 9.43).

Table 4.7: Logistic regression analysis of factors associated with medication non- adherence.

Variable	OR	95%CI	p-value
Injection/insulin medication			
No	1		
Yes	1.46	0.80-2.68	0.216
Duration of Disease			
< 2 year	1		
2 – 10 years	2.07	1.01-4.22	0.047
11+	0.99	0.43-2.28	0.983
Number of Diabetes Medications			
1	1		
2	1.16	0.63-2.12	0.631
3+	2.26	0.80-6.41	0.125
Ever DM related admission?			
No	1		
Yes	2.94	1.60-5.41	<0.0001
Satisfaction with family support?			
Satisfied	1		
Dissatisfied	2.99	1.12-7.98	0.029
Presence of complication or comorbidity?			
No	1		
Yes	1.85	0.84-4.06	0.125
Satisfaction with attending clinician?			
Satisfied	1		
Dissatisfied	3.58	1.36-9.43	0.01
Alcohol consumption			
No	1		
Yes	0.22	0.05-1.05	0.057
Delay in medication start following diagnosis?			
No	1		
Yes	2.28	0.96-5.39	0.061
Marital status			
Married	1		
Not married	1.20	0.60-2.37	0.609
Challenge in drug access?			
No	1		
Yes	1.76	1.01-3.05	0.046

CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1   Discussion

Non-adherence to treatment of chronic diseases is a worldwide problem of striking magnitude. The resultant consequences are poor health outcomes and increased health care costs (WHO, 2003). This study found a high prevalence of medication non-adherence among Type 2 diabetic mellitus patients and this is associated with poor glycaemic control.

5.2   Prevalence of medication non-adherence

This study found more than one in every two patients (55.5%) was not fully adhering to the prescribed medications. This proportion of medication non- adherence is comparable to other studies done among Type 2 diabetic patients in clinic settings done in Kenya and in the Eastern Africa region. (Kalyango *et al*., 2008, Abebe *et al*., 2014, Kamuhabwa *et al*., 2014, Ministry of Health, 2015).

This is a very worrying trend given that the incidence of diabetes in Kenya and other developing countries is expected to increase driven by uncontrolled urbanisation and unhealthy lifestyle (Mbanya *et al*, 2010). Currently in sub-Saharan Africa there are about 14.2 million people living with diabetes; it is projected that in 2040 this number will increase to 34.2 million people (International Diabetes Federation, 2015). This epidemiological shift to increasing non-communicable diseases has created a double disease burden in this region; on one side the traditional communicable diseases which are

still highly prevalent and the other and increasing incidence of non-communicable diseases. National health systems are poorly coping with the increasing burden of non-communicable diseases owing to underdeveloped public health systems and inadequate funding (Hall *et al*., 2011). According to the 2003 World Health organisation report on medication adherence; increasing effectiveness of adherence interventions may have greater impact on the health of populations than improvements in specific medical treatments (WHO, 2003). This is because however efficacious novel treatments are, if patients do not take them correctly, then the expected benefits such as averted morbidity, disability and mortality may not be realised. Indeed among Type 2 diabetic patients; a study demonstrated that all-cause hospitalisation increased by 58% and all-cause mortality increased by 81% among diabetic patients who were poorly adhering to their medications (Ho *et al*., 2006). Medication non-adherence is preventable and there is great need to support patients adhere to their prescriptions.

5.2. Level of glycemic control

According to the 2010 Kenya clinical guidelines for the management of diabetes mellitus; good control is indicated by a glycosylated hemoglobin level of less than 7 % (MOPHS, 2010). In this study one hundred and seven (36.9%) of the patients who participated in the study achieved this cut-off of blood sugar control. Studies done in Kenya and other parts of Africa region have shown similar low levels of glycemic control ranging from 17% to 38% (Mwavua *et al*., 2016, Abebe *et al*., 2014, Odume *et al.,* 2015)

Chronically raised blood sugar and associated metabolic disturbances related to insufficiency in insulin production or/ and insulin action is the underlying pathology in diabetes mellitus. Glycemic control is hence the ultimate objective of any diabetes mellitus therapy. Good glycaemic control among type 2 diabetes mellitus patients involves interplay of self-management measures including physical activity, diet and adherence to medication (WHO, 2003). Low levels of good glycaemic control in Kenya and Africa in general lead to high rates of diabetes related morbidity and mortality. Globally diabetes is a leading cause of blindness, kidney failure, heart attacks, stroke and lower limb amputation (WHO, 2016). In some parts of Africa, the five year mortality for diabetic patients is over 50% (Hall *et al*., 2011).

The commonest complication type encountered among participants in this study was eye complications. Diabetic retinopathy and subsequent visual loss has been shown to be largely preventable in settings where a multidisciplinary approach is utilized in the care of diabetic patients (Burgess *et al*., 2013). In this study we found a retinopathy prevalence of 27.6 %; other studies done in peripheral health facilities in eastern Africa have shown a prevalence of over 40% (Njambi, 2012, Stanifer *et al*, 2016). This reflects the discrepancies in the care received by patients in tertiary referral hospitals and what is available to patients receiving care at primary or secondary care facilities. Low levels of community awareness and access to diagnostic and treatment facilities has been shown to impede glycemic control among diabetic patients (Avezedo *et al*., 2008)

 In this study the commonest comorbid states encountered were hypertension and hypercholesteremia. In the Kenya the prevalence of hypertension and hypercholesteremia

in the general population is 23.8% and 10% respectively (MOH, 2015). However in this study, higher prevalence was observed for hypertension and hypercholesteremia; 68.3% and 17.9% respectively. This higher prevalence of the above two disease entities is consistent with development of a metabolic derangement syndrome among the type 2 diabetic patients, who underlying pathophysiology is insulin resistance (Okafor, 2012). The implication for the presence of complications and comorbid states is that there is additional pill burden and dosage frequency which has been shown to have a deleterious effect on medication adherence (Farrell *et al*, 2013).

5.3 Medication non-adherence and glycemic control among Type 2 diabetes mellitus patients

This study found a significant relationship between adherence scores and assayed values of glycosylated haemoglobin (HbA$_{1C}$). The patients with low scores in the MMAS-8 reflecting medication non-adherence were also likely to have lower and optimal glycosylated haemoglobin values. This finding demonstrates that medication adherence plays an important role in maintaining blood sugar levels within normal ranges. This finding is similar to other studies which have demonstrated significant association between self-reported medication adherence and better glycaemic control (Kamuhabwa *et al*., 2014, Abebe *et al*., 2014),

This finding is also important because it supports the use of quick to administer and self-reported medication adherence scales such as the MMAS-8 in busy clinical practices as a

means of quickly filtering patients who are poorly adhering to medication for intensified counselling to reinforce medication adherence.

5.4 Factors associated with non-adherence

5.4.1 Patient related factors

Among the patient related factors; dissatisfaction with close family members' support in regard to diabetes mellitus management emerged significantly associated with non-adherence. Poor social support has been shown in several studies to be associated with inadequate management of diabetes mellitus (Odume *et al.*, 2015). Most patients enrolled in this study reported that the family members played the role of encouraging and reminding them of their medication, this is important for patients suffering chronic illnesses who tend to feel isolated in their daily struggle to contain their disease. Strategies to strengthen the role of family members may include encouraging their participation in diabetes self-care education sessions to ensure that they are well informed and able provide appropriate advice and support for their kin who are diabetic. The role of a treatment supporter usually a close family member in diabetes mellitus management has often been neglected; this is in contrast with care provision for chronic communicable illness such as HIV/AIDS and tuberculosis (TB) that have long periods of medication use (Stubbs *et al.*, 2009, Wandwalo *et al.*, 2004). In these two conditions patients' registration into care usually involves engaging the patient in identification of a suitable treatment supporter. The identified treatment supporter is informed of the patient's diagnosis, educated on the

healthy lifestyle modifications, importance of medication adherence and clinic attendance in order that he/she may encourage the patient towards these goals.

Age was not found to be significantly associated with non-adherence in this study. Whereas it has been shown that the prevalence of diabetes mellitus increases with age in Kenya (Ayah *et al*., 2013); medication adherence has been shown to either not be affected by the patient's age (Abebe *et al*., 2014) or actually improve with age (Rwegerera, 2014). The majority of participants in this study was over fifty-five years of age and may likely be living with children or relatives; the protective effect of family noted above is likely to facilitate adherence with medication. In contrast younger patients who are professionally active have been shown to be more likely to skip or forget their medication (Tiv *et al*., 2012); hence poorer adherence. Sex was also found not to be significantly associated with adherence in this study. Some studies have found that females were more likely not to adhere to medications. (Kalyango *et al*., 2008, Kirkman *et al.*, 2015). Due to the relative minority of males (32.4%) in the clinic attendance, we may have been unable to demonstrate this association. Level of education in this study was found not to be significantly associated with medication adherence. Several studies have also shown similar findings (Awodele *et al.,* 2015, Bagonza *et al.,* 2015). The crucial aspect as regards to medication adherence as demonstrated in qualitative studies is whether a patient understands their prescribed medication (Borgsteede *et al*., 2011). This lays great importance on patient education and counseling at diagnosis and during follow-up in simple language within the patient's level of understanding.

Alcohol usage has been show in other studies to be associated with non-adherence (Ahmed *et al*., 2006), however due to the small number of alcohol users in this study we may have been unable to demonstrate this association. Home blood sugar monitoring (HBSM) is an important part of diabetes self-management and provides the patient with an ongoing feedback on effectiveness of his/her diabetes management efforts i.e. whether blood sugar levels are within target ranges (WHO, 2003). However in our study; there was no association between the HBSM and medication non-adherence. This finding is consistent with findings from another study conducted in western Kenya that demonstrated low levels of blood glucose monitoring and no association with glycemic control (Wambui *et al*., 2015). In this study, this finding can be explained by a majority of patients lacking personal glucometers thus not practicing HBSM and for those who have glucometers not adjusting their medication based on blood sugar values obtained.

5.4.2 Disease and treatment factors

Among the patients enrolled for this study; ever having been admitted for diabetes mellitus was shown to be significantly associated with of non-adherence. This finding of higher hospitalisation rates among poorly adherent patients agrees with several studies carried out among diabetic patients (Liebl *et al*., 2002; Mwendwa *et al*., 2005). Physiologically poor adherence is associated with uncontrolled blood sugar levels that result in accelerated end organ damage (UKPDS, 1998; DCCT, 1993). Frequent admissions have economic impacts at the personal level and public health level. At the personal level costs accrue from direct loss in productivity and income. Furthermore in a country such as Kenya where the bulk of health care costs are paid out of pocket (OOP); this increased expenditure can result in

catastrophic impoverisation of individuals and their families especially if the breadwinner is affected (Ministry of Health, Government of Kenya, 2014; Wamai, 2009). At the public or national health level; increased resources need to be invested in caring for these patients including health personnel; medications and physical facilities. The annual cost of diabetes in the sub-Saharan Africa region has been estimated at over 8000 United States dollars per patient (Hall *et al.,* 2011). This aggravates the strain placed on public health resources by the growing non-communicable disease burden on sub-Saharan economies already bearing the brunt of communicable or infectious disease (Azevedo *et al.*, 2008; WHO, 2014).

Patients who have had diabetes for a period of 2 to 10 years were found in this study to have less adherence to the diabetes mellitus medication than newly diagnosed patients(duration of disease <2 years). This finding could be associated with the progressive Beta-cell failure in diabetes mellitus which results in progressive increase in the number and dosage of medications required to achieve optimal glycaemic control. This additional pill burden and increased complexity of a patient's regimen are a possible explanation of this observation. Regimen complexity is also associated with an increase in medication side effects which limits the willingness of patients to take their medicines. Similar findings have been observed by other workers among Type 2 diabetic patients (Blaum *et al.*, 1997; Benoit *et al.*, 2005; Khattab *et al* 2010). In a cohort of Type 1 diabetic patients; forgetfulness was another reason that has been observed to contribute to poor medication adherence among those with longer duration of disease (Jarosz-Chobot *et al.,* 2000). Longer time periods between clinic appointments for these experienced patients has also been shown to contribute to poor medication adherence (Kalyango *et al.*, 2008).

In our study patients reporting a challenge in drug access were significantly less likely to be adherent to their medication. A majority of the study participants (45.9 %) cited the cost of drugs as their greatest hindrance. This finding is correlated by other studies conducted in developing countries. Studies in Uganda, Tanzania and Ethiopia have demonstrated that high costs of medication or patients that report inability to afford some of their medications or had a poor wealth index were significantly less likely to adhere to medication (Kalyango *et al.,* 2008; Rwegerera, 2014; Abebe *et al.,* 2014; Ijeoma *et al.,* 2015). Furthermore a study done in the United States of America demonstrated that even the perception of financial access barriers or worrying about the potential costs among diabetic patients limited their medication adherence (Piette, 2000).

Disease and treatment factors such as number of diabetes mellitus medication, presence of injectable medication and presence of comorbidities and complications were on bivariate analysis significantly associated with poor adherence. However the significance in association was lost when they were placed in multivariable analysis. This could have been due to association of these factors with other factors associated with medication adherence that when controlled for were able cater for their confounding effects. These findings suggest that these factors do not predict medication adherence behaviour among this cohort of patients. Similar findings have been found in studies involving Type 2 diabetes mellitus patients (Kalyango *et al* 2008; Grant *et al*., 2003).

5.4.3 Health system and health provider factors

Attendance of health education sessions was not significantly associated with good medication adherence. Furthermore majority of the patients had not been taught how to adjust medication based on blood sugar readings. This finding differs from a similar study conducted in Uganda which demonstrated that ever attending a health education session lowered the odds of non-adherence (Bagonza *et al.,* 2015) Whereas the classroom or group approach utilised at the clinic is effective when many patients need to be educated; the information disseminated is generalised and may not satisfy the individual needs of each patient. It has been shown that diabetic patients consider obtaining information regarding their prescribed medication as their foremost need towards medication adherence (Borgsteede *et al.,* 2011). Towards improving medication adherence, supplementary personalised counselling and education sessions targeted at uncovering the particular adherence barriers pertaining to each patient would be of great value. Indeed studies have shown that patients receiving care from specialists who are typically busy and have less time per individual patient are less likely to adhere to their medication (Tiv *et al*., 2012; Kirkman *et al*., 2015). Similarly in this study, nurses were reported to be the commonest source of diabetes health information and not the attending doctors.

Satisfaction with the attending clinician emerged as a significant contributor to good medication adherence. Patients who were dissatisfied in their clinician were three times more likely to be non- adherent to their diabetic medication compared to those who were. In a similar study, patients reporting poor patient –provider communication and dismissing attachment were significantly less likely to adhere to their medication and consequently

had poorer glycaemic control (Ciechanowski *et al*., 2001). General dissatisfaction with the quality of health services provided at a health facility is also a recognised barrier to medication adherence in patients who received care there (Abebe *et al*., 2014). Dissatisfied patients are also less likely to attend follow-up clinics or attend education sessions. They also have little trust in the medication prescribed.

5.5   Study limitations

Limitations of this study included that it was conducted in a single clinic setting; so the findings may not be necessarily generalizable across all type 2 diabetes mellitus patient groups. However the location of the clinic at the national referral hospital means that it serves a very diverse population of patients drawn from different geographical locations and social strata. Another limitation was reliance of participants' self-reported medication adherence. This was however mitigated in this study by assuring the participants of anonymity and confidentiality to facilitate truthful disclosure of medication adherence. The MMAS-8 Scale used in this study is validated and has been extensively used in assessment of medication adherence. The findings are thus unlikely to have been greatly overestimated

5.6   Conclusions

This study found a majority of type 2 diabetic patients have poor medication adherence and consequently high levels of poor glycaemic control.

The linkage between medication non-adherence and poor glycaemic control has been well demonstrated in this study. The significant association demonstrated between self-reported

medication adherence and glycosylated haemoglobin levels, reflecting glycaemic control; presents an opportunity for the incorporation into the clinic routines of easy to administer adherence scales such as the MMAS-8; to quickly identify poorly adhering patients for focused interventions.

The importance of family and social support in enhancing adherence among type 2 diabetes mellitus patients has been highlighted. It is important that adherence counselling and education be sustained at diagnosis and on follow-up. In this study the more experienced patients were found to be having poorer medication adherence levels than the newly diagnosed patients. The assumption that the more experienced patients are more efficacious in their diabetes management is erroneous as they may be challenged by more complex regimens.

A key limitation in medication adherence among Type 2 diabetic patients in our health system is affordability of the medication. A majority of the patients experience financial challenges in accessing medication which compromises their ability to adhere to their prescriptions. Further research is required to determine appropriate access solutions for these patients.

The quality of the relationship between the patient and clinician plays a great role in facilitating adherence. Patients that have positive experiences at the health facility including their interaction with the non-clinical staff are more likely to adhere to their prescribed medications leading to better glycaemic control and better health outcomes.

5.7   Recommendations

In order to help Type 2 diabetic patients at the hospital adhere to medication; it is important to implement the following strategies;

1. Identification of patients that have suboptimal medication adherence for intensified adherence counselling is of prime importance. In the setting of busy clinic environments and resource limitations, the MMAS-8 can be adopted as a practical tool for this purpose.

2. Comprehensive and practical training sessions on appropriate use of diabetes management aids such as glucometers and appropriate medication adjustment criteria should be offered to all patients at the clinic.

3. Create awareness among the clinical staff of the need to identify treatment supporters' preferably family members, who should be adequately educated on diabetes mellitus; who then can support the patients in medication adherence. Formation of patient support groups should also be encouraged. Meeting areas or rooms in the vicinity of the diabetic clinic should be created. Trained facilitators for these sessions should be provided by the hospital administration to moderate and enrich group meetings. This will cater for the need for sustained adherence counselling and motivation targeting the more experienced patients who could easily become neglected by programs targeting the newly diagnosed.

4. A scheme for free or subsidised medication and glucometer provision would also help improve medication adherence and treatment outcomes. The hospital administration can approach manufacturers to enter in preferential pricing

agreements for diabetes medication and commodity owing to the large patient volumes handled within the clinic. The Ministry of Health should lobby the National Treasury and Kenya Revenue Authority for tax-waivers or rebates for diabetes medication and commodities. Ensuring comprehensive coverage of diabetes treatment and medication in national and private insurance schemes would facilitate higher adherence rates.

5. Clinician patient communication plays an important role in sustaining medication adherence. Clinicians need to be taught on counselling techniques to ensure effective and positive communication with patients. Non-clinical staff should also be included in these trainings as they are the first interface into the health system that the patient interacts with during the registration and subsequent procedures such as laboratory testing. The clinic structural facilities also play an important role in patient satisfaction; guaranteeing clean, well labelled and well-lit rooms for patient interaction will indirectly improve patient medication adherence.

6. Further research needs to be done to understand which models of social support and medication access support is both effective and sustainable in the context of lifelong disease and how to improve clinician communication skills and engagement strategies with patients especially in busy public health facilities to achieve optimal medication adherence including the use of electronic technology and mobile telephony.

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APPENDICES

Appendix I: Informed Consent in English

Study title:

Assessment of medication adherence and associated factors among type 2 diabetes mellitus patients attending the diabetic clinic at Kenyatta National Hospital

Institutions and Investigators:

Researcher	Institution	Contact
Gabriel Waari	Jomo Kenyatta University of Agriculture and Technology	0720289209

Introduction

My name is Gabriel Waari, a Master's student at Jomo Kenyatta University of Agriculture and Technology. I am the principal investigator in this study that aims at assessing adherence and associated factors to treatment among Type 2 diabetic patients attending the diabetic clinic at Kenyatta National Hospital.

You are invited to participate in this study. This is a consent form that gives you information about the purpose, procedure, risks, benefits, confidentiality/privacy and the process that will be expected during the study. If you agree to take part, please sign your name at the bottom of this form. You can ask any questions you have at any time.

Purpose of the study

The purpose of this study is to determine medication adherence and associated factors among type 2 diabetic patients attending the diabetic clinic at Kenyatta National Hospital.

Procedure of Study

If you decide to join the study, you will be asked questions regarding your personal socio-demographic characteristics, adherence to medication, reasons for not adhering to prescribed medications and knowledge regarding diabetes, complications, and different management strategies, your satisfaction/attitude towards care provided by the diabetic clinic. The interview will last approximately 20 minutes only.

Two body parameters of weight and height will be measured and thereafter a blood sample for determination of glycosylated haemoglobin; which is a measure of blood sugar control for the past three months will be drawn. Two drops of blood sample shall be drawn from a fingertip that will have been cleaned and a sterile lancet will be used. During the procedure you shall experience pain, but it will only be for a short time. You will press a piece of clean cotton wool over the puncture site for a minute or so until the bleeding stops.

Voluntariness

Participation in this study is voluntary. Your decision to or not to participate in this research study will not affect your current or future relations with this Diabetic Clinic. If you choose not to participate in this study or to leave the study during the interview process, you may do so freely by informing the researcher, without any consequences against you.

Risks of study participation

Your clinical file will be reviewed for medications prescribed; however the information gathered will be anonymously recorded and cannot be identified as yours. During the blood drawing procedure you will experience pain on your finger but this will be transient and blood loss from the procedure is expected to be minimal subsequently a clean piece of cotton wool shall be applied to the puncture site temporarily to avoid unnecessary blood loss. All equipment used to draw blood is sterile and will not cause contamination or infection.

Benefits of participating in the study

You may get no direct benefit from the information you provide for this study. However, the information you provide will help improve local diabetes care for the future.

Study Costs

There will be no costs to you for participating in this study apart from your precious time. The costs for the blood tests will be covered by the principal investigator.

Research related injury

It is unlikely that any form of injury could happen to you as a result of being part in this study. It is important that you tell the principal investigator if you have any problem arising from taking part in this study.

Confidentiality

Every effort will be made to keep the information you provide confidential. You will only be identified by a code and the personal information from the interview will not be released without your written permission. The information in the questionnaire cannot be identified as belonging to you. You will not be personally identified in any publication about this study.

Contacts and questions

This research has been approved and reviewed by the Kenyatta Hospital Ethics and Research Review Committee. This committee has reviewed this study in order to help protect participants. If you have any questions about your right as research participant you may contact to:

    KNH/UoN ERC,

    Kenyatta National Hospital,

    P.O. Box 20723-00202, Nairobi.

    Tel: +254 -020-2726300

OR

    The Principal;

    College of Health Sciences

    Jomo Kenyatta University of Agriculture and Technology

    P.O. Box 62200-00200; Nairobi

    Tel: 254-67-52711/52181-4

    Fax: 254-67-52161

    director@itromid.jkuat.ac.ke

Your statement of consent and signature:

If you have read the informed consent, or have had it read and explained to you, and you understand the information and voluntarily agree to join this study, please carefully read the statements below and think about your choice before signing your name:

- I have been given the chance to ask any questions I may have and I am content with the answers to all my questions.
- I know that any information I give will be kept confidential and that I may leave this study at any time.
- If I leave or refuse to be in the study, I understand that there will be no repercussions.
- The name , phone number and address of whom to contact in case of an emergency has been told to me and has also been given to me in writing.
- I agree to take part in this study as a volunteer, and will be given a copy of this informed consent form to keep.

…………………………………

………………………………………..

Participant's name   Signature/thumb print and date

…………………………………

………………………………………..

Researcher's name   Researcher's signature and date

Appendix II: Informed Consent in Kiswahili.

Kiabatanisho 2: Ombi la ridhaa.

Tathmini ya uzingatifu wa matumizi ya dawa za kisukari na sababu ambatanishi kati ya wagonjwa wa kisukari aina ya pili katika kliniki ya kisukari katika hospitali ya kitaifa ya Kenyatta.

Taasisi na wakaguzi

Mtafiti	Taasisi	Mawasiliano
Gabriel Waari	Jomo Kenyatta University of Agriculture and Technology	0720289209

Utangulizi

Jina langu ni Gabriel Waari, mimi ni mwanafunzi katika chuo kikuu cha Jomo Kenyatta. Mimi ndiye mtafiti mkuu katika Tathmini hii ya uzingatiaji matumizi ya dawa na sababu ambatanishi kati ya wagonjwa wa kisukari katika hospitali kuu ya Kenyatta. Kabla ya kuamua kama unataka kuwa katika utafiti huu, unahitaji kujua kuhusu jambo lolote nzuri au mbaya linaloweza kutokea ukiamua kuwa katika utafiti huu. Fomu hii anaelezea kuhusu utafiti huu; madhumuni, matarajio, athari na hatari ambazo huwenda zikatokea na usiri wa habari utakazo zitoa. Unaweza kuuliza swali lolote wakati wowote. Baada ya kuelezewa na kuelewa utafiti, kama utakubali kujihusisha na utafiti huu, utaulizwa kuweka ishara ya jina lako au kufanya alama yako juu ya fomu hii.

Madhumuni ya utafiti:

Madhumuni ya utafiti huu nikutathmini kutozingatia matumizi ya dawa za ugonjwa wa kisukari na sababu zinazoambatanishwa na hali hio kati ya wagonjwa wa kisukari wanaohudumiwa katika hospitali kuu ya Kenyatta.

Nini cha kutarajia:

Ukikubali kushiriki utafiti huu, utaulizwa maswali kuhusu habari zako za kibinafsi na kijamii, aina na matumizi yako ya dawa za ugonjwa wa kisukari, sababu zinazozuia matumizi mazuri ya dawa na elimu uliyonayo kuhusu ugonjwa wa kisurikari, madhara,

93

mbimu tofauti za kuukabili ugonjwa huo na maoni yako kuhusu matibabi unayoyapata kwenye kliniki hii ya kisukari. Mahojiano haya yanatarajiwa kuchukua dakikia 20.

Vipimo mbili za mwili vitapimwa; uzani na urefu wako. Baadaye utatolewa damu ili kupima kiwango cha uthibiti wa kisukari katika miezi mitatu iliyopita. Matone mawill ya damu ya tatolewa kutoka kwa kidole anapopamepanguswa safi and kichomi safi kitatumiwa. Wakati wa kutoa damu, utahisi uchungu lakini huu utakuwa kwa muda mfupi. Utatupewa pamba safi ilikufinya juu ya palipodungwa kwa dakika moja hivi hadi damu iache kuvuja.

Kuwa katika utafiti huo ni uchaguzi wako:
Una uhuru wa kutoshiriki katika huu utafiti. Ukiamua kutoshiriki au kuondoka kenye utafiti wakati wa mahojiano, unaweza kufanya hivyo kwa uhuru bila madhara dhidi yako.

Uwezekano wa Hatari
Faili yako itaangaliwa ilikuthibitisha dawa unazotumia, hakuna habari zitahifadhiwa ambazo zitakuwa na jina lako.Kila juhudi zitafanywa kulinda faragha yako na usiri wakati wewe unashiriki katika utafiti. Wakati wa kutoa damu utahisi uchungu lakini hii itakuwa kwa muda mfupi tuu. Uvujaji wa damu unatarajiwa kuwa mdogo na kipande kisafi kitatumiwa kuzuia uvujaji wa damu usiohitajika. Vifaa vyote vya kutoa damu vimekaguliwa na havina athari ya viini.

Faida zinazoweza kutokana na utafiti huu:
Hakuna faida ya moja kwa moja kutokana na habari utataoa kwa ajili ya utafiti huu. Hata hivyo, matokeo yatatumika kusaidia katika kutunga sera zitawafaidi wagonjwa wa kisukari hospitalini katika siku zijazo.

Gharama:
Hakuna gharama kwako kwa ajili ya kushiriki katika utafiti huu mbali na wakati wako. Gharama za upimaji damu zimechukuliwa na mfafiti mkuu.

Rekodi yako itakuwa siri:

Kila juhudi zitafanywa kuweka habari utakazotoa siri. Hauhitaji kuandika jina lako na taarifa za kibinafsi ambazo utatoa katika mahojiano hazitatolewa bila idhini yako iliyoandikwa. Habari katika dodoso haiwezi kutambuliwa kama ni yako. Habari zozote binafsi hazitatolewa katika uchapishaji wowote kuhusu utafiti huu.

Kuumia kwa sababu ya kushiriki katika utafiti huu:
Uwezekano wa kuumia inaweza kutokea kutokana na utafiti huu ni mdogo. Ni muhimu kumweleza mtafiti mkuu kama wewe umehisi kuathirka kwa sababu ya kushiriki katika utafiti huu.

Matatizo na maswali:
Utafiti huu umepitishwa na kupitiwa na Kamati ya Utafiti na Mapitio ya Hospital ya Kenyatta. Kamati hii imepitia huu utafiti ili kusaidia kulinda haki za washiriki. Kama una maswali yoyote kuhusu haki yako kama mshiriki wa utafiti unaweza kuwasiliana na:

KNH/UoN ERC,
Kenyatta National Hospital,
P.O. Box 20723-00202, Nairobi.
Tel: +254 -020-2726300

Au;
The Principal;
College of Health Sciences
Jomo Kenyatta University of Agriculture and Technology
P.O. Box 62200-00200; Nairobi
Tel: 254-67-52711/52181-4 Fax: 254-67-52161
director@itromid.jkuat.ac.ke 29

Kauli yako ya ridhaa na saini:

Kama umesoma ridhaa, au kama imesomwa na ukaelezewa, na umeelewa habari na hiari na umekubali kujiunga na utafiti huu, tafadhali kusoma kwa makini maelezo ya hapa chini kabla ya kusaini jina lako:

- Nimepewa nafasi ya kuuliza maswali yoyote na nina uhakika kuhusu majibu ambayo nimepeana.
- Najua kwamba taarifa yoyote nimetoa itakuwa siri na kwamba mimi ninaweza kuondoka kwenye utafiti huu wakati wowote.
- Nikiamua kuondoka au kukataa kuwa katika utafiti, naelewa kwamba hakutakuwa na madhara.
- Jina, namba ya simu na anuani ya kuwasiliana katika kesi ya dharika kuandika.
- Mimi kukubaliana na kuchukua sehemu katika utafiti huu kama kujitolea, na nimepewa nakala ya fomu hii ya ridhaa ya kutunza.

…………………………………

………………………………………..

Jina la mhojiwa   Saini ya mhojiwa na tarehe

………………………………

………………………………………..

Jina la mtafiti   Saini ya mtafiti na tarehe

Appendix III: Questionnaire in English

Study title:

Assessment of medication adherence and associated factors among type 2 diabetes mellitus patients attending the diabetic clinic at Kenyatta National Hospital

Section A: Basic Information

1. Date of interview   _____
2. Questionnaire serial number   _____
3. Data collector's name and signature   _____

Section B: Background Information (Circle the correct response)

No	Questions	Coding categories	
1.	Sex	M/F: _____	
2.	Age	_____(Years)	
3.	What is your area of residence/ location?	_____	
4.	What is your level of attained education?	No formal education	1
		Primary	2
		Secondary	3
		Higher/University	4
5.	What is your occupation?	Unemployed	1
		Civil servant	2
		Farmer	3
		Small-scale business	4
		Casual labourer	5
		Student	6
		Other (specify)_____	77
6.	What is your religion?	Christian	1
		Muslim	2
		Hindu	3
		Traditional	4
		Other (specify):_____	77
7.	What is your marital status?	Single	1
		Married	2
		Divorced	3
		Widower/Widow	4
		No response	99
8.	Do you smoke cigarettes currently?	Yes	1

		Never	2
		Used to but stopped	3

Section C: Patient diabetes disease status

1. When do you know or were informed that you had diabetes? -

   _____ (month and year).

2. When did you start using any diabetic medication after diagnosis?

   _____ _____(month and year).

3. What type of medications do you take for diabetes?

        i.   Diet   [ ]

        ii.   OGLAs   [ ]

        iii.   Insulin   [ ]

        iv.   Insulin and OGLA   [ ]

        v.   Herbal treatment   [ ]

        vi.   Insulin/OGLAS + herbal preparations   [ ]

4. How many types of medicines do you take for diabetes? _____ medicine(s).

5. What types of medications do you take for diabetes? (Please list – correlate with patient's file)

        i.   Drug Name:_____

        ii.   Drug Name:_____

        iii.   Drug Name:_____

        iv.   Drug Name:_____

        v.   Drug Name:_____

6. Have you been admitted in the past for diabetes?

        i.   Yes

        ii.   No

7. If yes in Question 6 above, how many times and when?

        _____ (times)   When (month and year)_____

                                      When (month and year)_____

                                      When (month and year)_____

                                      When (month and year)_____

Section D: Adherence to diabetic medication scale

You indicated that you are taking medication(s) for diabetes. Individuals have identified several issues regarding their medication-taking behavior and we are interested in your experiences. There is no right or wrong answer. Please answer each question based on your personal experience with your diabetes medication

Items	Yes (1)	No (0)
1. Do you sometimes forget to take your diabetes pills?		
2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your diabetes medicine?		
3. Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?		
4. When you travel or leave home, do you sometimes forget to bring along your diabetes medication?		
5. Did you take your diabetes medicine yesterday?		
6. When you feel like your diabetes is under control, do you sometimes stop taking your medicine?		
7. Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your diabetes treatment plan?		

8. How often do you have difficulty remembering to take all your medications? (Please circle the correct number)

99

Never/Rarely……………………………………….0

Once in a while……………………………………1

Sometimes…………………………………….....2

Usually……………………………………….3

All the time……………………………………..4

Section E; Complications and co-morbidities- Check from patient's clinic file.

1. Are there complications arising from diabetes? (Check all as appropriate)

[ ] Eye complications	[ ] Foot ulcers
[ ] Renal complications	[ ] Coronary artery disease
[ ] Neuropathic complications	[ ] Stroke
[ ] Erectile dysfunction	[]Other(specify)

………………

2. Is there any other chronic disease or conditions present?

[ ] Asthma

[ ] Hypertension

[ ] Cancer

[ ] Tuberculosis

[ ] HIV/AIDS

[   ]   Depression

[ ] Other (specify)………………………..

Section F: Diabetes health education

1. Have you ever received education on diabetes?
    i.   Yes
    ii.   No

2. From whom, did you get the information regarding diabetes? (Check all appropriate).
    i.   Doctors   [ ]

    ii.   Nurses   [ ]

    iii.   Hospital nutritionist   [ ]

    iv.   Family member   [ ]

    v.   Friends   [ ]

    vi.   Internet   [ ]

    vii. Mass media i.e. T.V/Radio   [ ]

    viii. Others (specify)…………………….

Section G: Social determinants of adherence

1. What is your family member's attitude to your illness/diabetes?
    i.   Very concerned
    ii.   Not concerned
    iii.   Feel as a burden
    iv.   Others, specify……………….

2. Which of the following role does your family member play in your self-management of diabetes?
    i.   Reminder
    ii.   Information collector
    iii.   Advisor
    iv.   No role
    v.   Others, specify…………………..

3. Are you satisfied with your family member's action to your diabetes?
    i.   Yes
    ii.   No

4. How does your family member influence your control of diabetes?

       i.   Help me control diabetes
      ii.   Hinder me control diabetes
     iii.   Has no effects on my control of diabetes

5 Do you consistently receive moral and/or emotional supports from your family members towards adhering to anti-diabetic medications?
       i.   Yes
      ii.   No

Section H: Health care system determinants

1. How many times do you go to hospital for diabetes only consultation or clinic?
        i.   Once or more per month
       ii.   Once per three months
      iii.   Once per six months
       iv.   Once per year
        v.   Never

2. Do you have any problem in getting your drugs?
        i.   No problem
       ii.   The cost
      iii.   Others specify…………………….

Section I: Patient care satisfaction.

(Please check the correct response.)

	Strongly Agree (5)	Agree (4)	Neither agree or disagree (3)	Disagree (2)	Stongly disagree (1)
1. Physician					
Listened to you					
Spent enough time with you					
Explained what you need to know					

2. Staff					
Treated you with courtesy and respect					
Explained what you need to know					
3. I understand how to take my medicines when I get home					

4. How would you rate your overall experience

(5)Excellent   (4) Very good   (3) Good   (2) Fair   (1) Poor

Section J: Blood monitoring

1. Do you think it is important to monitor blood glucose level at home?
      i. Yes
      ii. No
2. Do you practice home monitoring for glucose level?
      i. Yes
      ii. No
3. If the answer is 'No' for Question No. 2; what are the reasons?
      i. I have no glucometer.
      ii. The measuring strips for the glucometer have run out.
      iii. I don't think it is necessary.
      iv. I have no time
      v. It is painful
      vi. Other (specify)………………….

4. How do you monitor your glucose level?
      i. Blood
      ii. Urine test
      iii. Other (specify)………………….

5. How often do you home monitor the glucose level?

i.   More than once per day
    ii.   Once per day
    iii.   Once per week
    iv.   Irregularly, when I have symptoms

4. Do you adjust your dose of medication (insulin or drug) according to the result of your own   glucose measurement?
            i.   Yes
            ii.   No

Section K: Alcohol usage

1. Do you take any drinks containing alcohol?
            i.   Yes
            ii.   No
2. Have you ever felt you should cut down on your drinking?
            i.   Yes
            ii.   No
3. Have people annoyed you by critising your drinking
            i.   Yes
            ii.   No
4. Have you ever felt bad or guilty about your drinking?
            i.   Yes
            ii.   No
5. Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hang-   over?
            i.   Yes
            ii.   No

Section L: Biochemical and Anthropometric measures

        1. Height: _____
        2. Weight: _____
        3. Body mass index: _____
        4. HbA_{1C} _____

Appendix IV: Questionnaire in Kiswahili

Kiambatanisho 4: Dodoso

Tathmini ya uzingatifu wa matumizi ya dawa za kisukari na sababu ambatanishi kati ya wagonjwa wa kisukari aina ya pili katika kliniki ya kisukari katika hospitali ya kitaifa ya Kenyatta.

Sehemu A: Habari Msingi

1. Tarehe ya mahojiano   _____
2. Namba ya dodoso   _____
3. Jina la mhojaji na saini   _____

Sehemu B: Habari Asili

Namba	Swali	Vitengo vya uratibu	
1.	Jinsia	Mume/ Mke: _____	
2.	Umri	_____(Miaka)	
3.	Eneo unaloishi/Maskani?	_____	
4.	Kiwango cha elimu?	Hakuna elimu rasmi	1
		Shule ya msingi	2
		Shule ya upili	3
		Chuo Kikuu/Elimu ya juu	4
5.	Unafanya kazi gani?	Huna kazi	1
		Mfanyikazi wa serikali	2
		Mkulima	3
		Mfanyi biashara	4
		Kibarua	5
		Mwanafunzi	6
		Ingine (eleza)_____	77
6.	Unafuata dini ipi?	Mkristo	1
		Muislamu	2
		Mhindu	3
		Kitamaduni	4
		Ingine (eleza):_____	77
7.	Hali ya ndoa?	Hujaoa/Hujaolewa	1
		Umeoa/Umeolewa	2
		Mtalakiwa	3
		Mjane	4
		Hakuna jibu	99

8	Je wewe unavuta sigara kwa sasa?	Ndio	1
		Sijawahi hata kamwe	2
		Mbeleni nimevuta sigara	3

Sehemu B: Hali ya ugonjwa wa kisukari

1. Ulijua lini kwamba una ugonjwa wa kisukari? -

   _____ (mwezi na

   mwaka).

2. Ulianza kutumia madawa lini baada ya ugunduzi huo?

   _____(mwezi na

   mwaka).

3. Unatumia dawa zipi kwa sababu ya kisukari?

   i.   Chakula   [ ]

   ii.   OGLAs   [ ]

   iii. Insulin   [ ]

   iv.   Insulin na OGLA   [ ]

   v.   Mti-shamba   [ ]

   vi.   Insulin/OGLAS na Mti-shamba   [ ]

4. Idadi ya dawa kudhibiti kisukari unazotumia ni ngapi? _____ .

5. Aina ya dawa za kisukari ni zipi? (Tafadhali orodhesha)

   i.   Jina la dawa:_____

   ii.   Jina la dawa:_____

   iii. Jina la dawa:_____

   iv.   Jina la dawa:_____

   v.   Jina la dawa:_____

6. Umewahi lazwa hospitalini kwa sababu ya kisukari?

   i.   Ndio

   ii. La

7. Kama 'ndio' kwa swali namba 6, mara ngapi na lini?

_____ (idadi)   Lini (Mwezi na mwaka)_____

Lini (Mwezi na mwaka)_____

Lini (Mwezi na mwaka)_____

Lini (Mwezi na mwaka)_____

Lini (Mwezi na mwaka)_____

Sehemu C: Kipimo cha kutathmini uzingatifu wa matibabu.

Ulisema kwamba unameza madawa yako ya kisukari. Watu wametambua maswala kadhaa yanayohusu tabia yao ya kumeza madawa, hivyo tungetaka kujua uzoefu wako. Hakuna jibu sahihi au lisilo sahihi. Tafadhali jibu kila swali kwa msingi wa uzoefu wako uliyopitia kibinafsi ukitibi kisukari.

Vipengele	Ndio (0)	Hapana (1)
1. Je, kuna nyakati ambapo wewe husahau kutumia matibabu yako ya kisukari.		
2. Wakati mwingine watu hawamezi dawa zao kwa sababu zingine kando na kusahau. Ukirejelea wiki mbili zilizopita, je, kuna siku ambazo hukumeza dawa zako za kisukari?		
3. Je, ushawahi kupunguza / kusitisha kutumia dawa zako za kisukari bila kumwarifu daktari wako, kwa sababu ulijihisi mgonjwa zaidi ulipokuwa ukizimeza?		
4. Wakati unaposafiri au kuondoka nyumbani je, kuna nyakati ambapo wewe husahau kubeba dawa zako za kisukari?		
5. Je, ulimeza madawa yako ya kisukari jana?		
6. Wakati unapohisi kuwa kisukari kimedhibitiwa, je, kuna wakati mwingine wewe huacha kutumia		

madawa yako?		
7. Baadhi ya watu hutatizika sana kutumia madawa kila siku. Je, ipo nyakati unapohisi kusumbuliwa na kufuatilia mpangilio wako wa matibabu ya kisukari?		

8 . Ni mara ngapi una ugumu wa kukumbuka kutumia dawa zako zote za kisukari?

(Tafadhali tia alama jibu lako hapa chini)

Kamwe/maranadra………………………….0

Mara chache…………………………………1

Wakati mwingine……………………………2

Mara nyingi………………………………….3

Kila mara…………………………………….4

Section D; Matatizo na majongwa shirika – Toa habari kutoka faili ya mgonjwa

1. Matatizo ya kisukari yalionukuliwa? (Weka alama kama ipasavyo)

        [ ] Matatizo ya macho

        [ ] Matatizo ya figo

        [ ] Matatizo ya mishipa ya hisia

         [ ] Vidonda vya miguu

        [ ] Shida ya moyo

        [ ] Stroke

        [ ] Tatizo la ngono   []Ingine(eleza)

    ………………………

2. Magonjwa mengine yakudumu yalionukuliwa?

    [ ] Asthma

[ ] Mshindikizo wa damu mwilini/Presha

[ ] Kansa

[ ] Kifua kikuu

[ ] HIV/AIDS

[ ] Depression

[ ] Ingine (eleza)………………………..

Sehemu D: Elimu kuhusu Kisukari

1. Je umewahi kupata elimu kuhusu kisukari?

     i.   Ndio

    ii.   La

2. Kutoka kwa nani, ulipata habari kuhusu kisukari? (Weka alama kwa zote zinazofaa).

    i.   Daktari   [ ]

    ii.   Muuguzi   [ ]

    iii.   Mtaalamu ya vyakula   [ ]

    iv.   Familia ama jamaa   [ ]

    v.   Rafiki   [ ]

    vi.   Mtandao   [ ]

    vii.   Vyombo vya habari(redio/t.v.)   [ ]

    viii.   Ingine (Eleza)…………………….

Sehemu F: Vigezo vya kijamii za uzingatiaji wa matumizi ya dawa

1. Je familia yako wana mkao/maoni yapi kuhusu ugonjwa wa kisukari?

    i.   Wanajali sana

    ii.   Hawajali kabisa

    iii.   Wanaona ni mzigo

    iv.   Ingine, eleza……………….

2. Je familia yako wanajukumu gani katika harakati zako za kuudhibiti ugonjwa wa kisukari?

i. Wanakukumbusha
 ii. Wanakusanya habari
iii. Washauri
iv. Hawana jukumu
 v. Ingine, eleza…………………..

3. Umetosheka na matendo ya wanafamilia yako juu ya ugonjwa wako wa kisukari?
  i. Ndio
 ii. La

4. Je wana familia yako wana ushawishi upi katika udhibiti wako wa kisukari?
  i. Wananisaidia kudhibiti kisukari
 ii. Wananizuia kudhibiti kisukari
iii. hawana ushawishi wowote

5 Je unapokea mara kwa mara msaada wa kimaadili na hisia kutoka kwa familia yako ili uzingatie matumizi ya dawa zako za kisukari?
  i. Ndio
 ii. La

Sehemu G: Vigezo vya mfumo wa afya

1. Mara ngapi unamuona daktari kwa sababu ya kisukari ama kushiriki kliniki wa kisukari?
  i. Mara moja ama zaidi kwa mwezi.
 ii. Mara moja kila miezi tatu.
iii. Mara moja kila miezi sita.
iv. Mara moja kila mwaka

2. Unashida gani kupata dawa zako?
  i. Hamna shida
 ii. Gharama
iii. Ingine, elezea…………………….

Sehemu K: Kurithika kwa mgonjwa kwa huduma anayopata.

(Tafadhali ainisha jibu sahihi.)

	Kubali kabisa (5)	Kubali (4)	Sikubali wala sikatai (3)	Nakataa (2)	Nakataa kabisa (1)
1. Daktari					
Anakusikiliza					

Anakaa nawe muda wa kutosha				
Alikuwelezea ulichotaka kujua				
2. Wafanyikazi wengine				
Walikuhudumia kwa heshima na nidhamu				
Walikuelezea ulichotaka kujua				
3. Ninaelewa jinsi ya kutumia madawa yangu ninapofika nyumbani				

4. Unaweza tathmini aje huduma ambayo umepata?

(5) Nzuri zaidi (4) Nzuri sana (3) Nzuri (2) Nzuri kiasi (1)

Mbovu

Sehemu H: Upimaji wa damu.

1. Je, unafikiria kwamba kupima kiwango cha sukari nyumbani ni muhimu?
   - i. Ndio
   - ii. La

2. Je, huwa unajipima sukari nyumbani kwako?
   - i. Ndio (Kama ndio nenda Swali 4.)
   - ii. La

3. Kama jibu ni 'La' kwa swali 2; sababu ni zipi?
   - i. Sina kifaa cha kupima.
   - ii. Stripu za kifaa zimeisha.
   - iii. Sidhani ni muhimu.
   - iv. Sina wakati.
   - v. Ni uchungu.
   - vi. Other (Eleza)…………………

4. Unapima kiwango cha sukari mwilini kwa jinsi gani?
   - i. Kupima damu.
   - ii. Kupima mkojoo

iii.   Ingine (Eleza)…………………

5. Je unapima kiwango cha sukari nyumbani mara ngapi?
   i.   Mara mbili ama zaidi kwa siku.
   ii.   Mara moja kwa siku
   iii. Mara moja kwa wiki
   iv.   Nadra, wakati ninapopata maumivu.

4. Je unabadilisha dosi ya dawa zako and insulin kulingana na matokeo ya upimaji wako wa sukari mwilini?
   i.   Ndio
   ii.   La

Sehemu I: Vipimo vya mwili

   1. Urefu: _____

   2. Uzani: _____

   3. Kielezo cha msongano wa mwili(BMI):   _____

   4. HbA_{1C} _____

Appendix V: ERC Approval Letter

UNIVERSITY OF NAIROBI
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Ref: KNH-ERC/A/380

9ᵗʰ September 2015

Gabriel Waari
TM310/0932/2012
JKUAT

Dear Gabriel

RESEARCH PROPOSAL –ASSESSMENT OF MEDICATION ADHERENCE AND ASSOCIATED FACTORS AMONG TYPE 2 DIABETES MELLITUS PATIENTS ATTENDING THE DIABETIC CLINIC AT KENYATTA NATIONAL HOSPITAL (P420/06/2015)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 9ᵗʰ September 2015 – 8ᵗʰ September 2016.

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) 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.
d) 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.
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) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) 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.

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

Protect to discover

113

Appendix VI: Morisky scale license and copyright agreement

MMAS-4 or 8 License Contract and Copyright Agreement

Required citations and copyright acknowledgement for the MMAS-8 item scale are available on the final license contract and copyright agreement.

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6) Rights granted under this Agreement to use the Morisky scales terminate one-year from the date below or on termination of Licensee's study, whichever is shorter. Licensee acknowledges understanding and agreeing to abide by the above requirements regarding use of any Morisky Medication Adherence Scale or other Morisky intellectual property.

7) Further specific requirements, e.g., citations required in publications, may be obtained from the Owner via <dmorisky@ucla.edu>. Additional terms and agreements via hardcopy or email will become a part of and subject to the provisions of this Agreement.

114

MMAS-4 or 8 License Contract and Copyright Agreement

The license agreement is in effect for a one-year period or the duration of the study, whichever is shorter. If your study is longer than one year, a renewal of license is available based upon a brief status report prior to expiration of the waiver of license fee and copyright agreement.

If I am eligible for a waiver of license fee contractual agreement, I agree to provide Dr. Morisky a report of my findings upon completion of this study, cite the required references as noted on this waiver of license fee agreement and will comply with the copyright specification outlined above regarding the use of the Morisky Medication Adherence Scale, 8-Items, MMAS-8 and will abide with its requirements. I also agree to pay Dr. Morisky a fee of $250 if I do not submit a report to him following the completion of my research project.

Please scan and email to: *Donald E. Morisky, ScD, ScM, MSPH, Professor, Department of Community Health Sciences, UCLA Fielding School of Public Health, 650 Charles E. Young Drive South, Los Angeles, CA 90095-1772; email to dmorisky@ucla.edu.*

Please sign and return this contractual agreement in a PDF format, Pages 1 and 2 to Professor Morisky and he will provide you with pages 3 and 4 of the listing of the MMAS-8 items, scoring and re-coding criteria and signature authorizing full use of this copyrighted scale. I agree to use only the English version of the MMAS-8 unless I purchase a validated translation of the MMAS-8 through Professor Morisky. I understand that it is a violation of international copyright laws to either use your own translation and call it the "MMAS-8" or use an existing MMAS-8 scale that has been translated and used for another study. The validated translation is non-transferrable and is linked to a specific license agreement and cannot be reproduced, copied, distributed, placed on the internet, published, or used by another individual.

Name and Contact Info: Name: Gabriel Waari. Postal Address: P. O. Box 2140 - 10100, Nyeri, Kenya. Telephone number: +254 720 289 209

Title of Study: ASSESSMENT OF MEDICATION ADHERENCE AND ASSOCIATED FACTORS AMONG TYPE 2 DIABETES MELLITUS PATIENTS ATTENDING THE DIABETIC CLINIC AT KENYATTA NATIONAL HOSPITAL.

Number of Anticipated Administrations of the MMAS-8:   300

Signature of Licensee:

Date: 29th April, 2015.

Signature of Developer/Owner: *Donald C. Morisky*

Date: May 11, 2015