

**FACTORS ASSOCIATED WITH NON-ADHERENCE  
TO ORAL HYPOGLYCEMIC MEDICATIONS  
AMONG ADULT TYPE 2 DIABETES MELLITUS  
OUTPATIENTS ATTENDING MBAGATHI DISTRICT  
HOSPITAL NAIROBI, KENYA**

**EVANGELINE WAIRIMU MAINA**

**MASTER OF SCIENCE**

**(Public Health)**

**JOMO KENYATTA UNIVERSITY OF  
AGRICULTURE AND TECHNOLOGY**

**2016**

**Factors Associated with Non-adherence to Oral Hypoglycemic Medications among Adult Type 2 Diabetes Mellitus outpatients attending Mbagathi District Hospital Nairobi, Kenya**

**Evangeline Wairimu Maina**

**A thesis submitted in partial fulfillment for the degree of Master of Science in Public Health in the Jomo Kenyatta University of Agriculture and Technology**

**2016**

## DECLARATION

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

1) Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Evangeline Wairimu Maina**

This thesis has been submitted for examination with our approval as University supervisors

1) Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Dr Gideon Kikuvi,**

**JKUAT, Kenya**

2) Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Mr Lawrence Muthami,**

**KEMRI, Kenya**

3) Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Dr Lucia Keter,**

**KEMRI, Kenya**

## **DEDICATION**

This thesis is dedicated to my parents for their hard work in raising and educating me. To my husband Francis, for supporting me throughout the long journey of writing this thesis. Our beloved children, Ann and Joseph for their patience. To my family members who were a constant source of love and encouragement and to my friends from whom I got the motivation to soldier on.

## **ACKNOWLEDGEMENT**

Special thanks goes to almighty God for giving me the ability, knowledge and wisdom to come this far. Many thanks to my supervisors Dr. Gideon Kikuvi, Mr Lawrence Muthami, and Dr. Lucia Keter for their guidance, support and motivation during the period of research work. I am also grateful to Dr. Francis Ngotho and my research assistant Doreen Lusike whose contribution during data collection was invaluable.

My gratitude goes to KEMRI for providing a conducive environment for learning as well as to JKUAT for making the course accessible. Thanks to the teaching and non teaching staff from KEMRI and JKUAT for preparing me to undertake this research work.

My special thanks to my employer Ministry of Health Kenya, for giving me time off to undertake this course. I deeply appreciate my friends and fellow students, for their moral support and encouragement

To those who assisted me in this research work in one way or the other and have not been mentioned I am grateful to you all.

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## LIST OF ABBREVIATIONS AND ACRONYMS

<b>ADA</b>	America Diabetic Association
<b>AIDS</b>	Acquired Immuno Deficiency Syndrome
<b>AOR</b>	Adjusted Odds Ratio
<b>ASA</b>	American Society on Aging
<b>ASCPF</b>	American Society Consultant Pharmacist Foundation
<b>B</b>	Logistic Coefficient
<b>BMI</b>	Body Mass Index
<b>CDC</b>	Centre for Disease Control
<b>CI</b>	Confidence Interval
<b>DF</b>	Degrees of Freedom
<b>HbA<sub>1C</sub></b>	Glycosylated Haemoglobin
<b>HIV</b>	Human Immunodeficiency Virus
<b>IDF</b>	International Diabetes Federation
<b>IFG</b>	Impaired Fasting Glucose
<b>IGT</b>	Impaired Glucose Tolerance
<b>JKUAT</b>	Jomo Kenyatta University of Agriculture and Technology

<b>KEMRI</b>	Kenya Medical Research Institute
<b>KNBS</b>	Kenya National Bureau of Statistics
<b>LDL</b>	Low Density Lipoprotein
<b>MNT</b>	Medical Nutritional Therapy
<b>OGTT</b>	Oral Glucose Tolerance Test
<b>OR</b>	Odds Ratio
<b>S.E.</b>	Standard Error
<b>SD</b>	Standard Deviation
<b>SPSS</b>	Statistical Package for Social Scientists
<b>WHO</b>	World Health Organization

## DEFINITION OF TERMS

<b>Adherence</b>	Taking not less than 80% and not more than 110% of the prescribed oral diabetic medication (Abella <i>et al.</i> , 2011)
<b>Lifestyle modification</b>	Having healthy diet and regular physical exercises.
<b>Non-adherence</b>	Taking less than 80% or more than 110% of the prescribed oral diabetic medication (Abella <i>et al.</i> , 2011)
<b>Oral hypoglycemic agents</b>	Oral medications used to manage type 2 diabetes mellitus by lowering the blood sugar.

## ABSTRACT

Non-adherence to diabetic medication has been shown to contribute to poor glycemic control leading to development of complications. Given that patients' adherence to prescribed oral diabetic medication assessment is rare in routine clinical practice, the study aimed at determining the factors associated with non-adherence to oral diabetic medication among adult type 2 diabetes mellitus outpatients at Mbagathi Hospital. A descriptive cross-sectional study was carried out after getting administrative clearance from the hospital medical superintendent and ethical approval from KEMRI scientific and ethics committee. A systematic random sampling method was used to recruit study participants and informed consent was obtained. Data was collected using pretested semi structured questionnaire and key informant interviews. Pearson's chi square ( $X^2$ ) was used to assess the association between dependent and independent categorical variables and binary logistic regression for independent association. Factors associated with non-adherence to oral hypoglycemic agents were considered statistically significant at  $P \leq 0.05$ . Among the 113 study participants recruited 61.9% were females and their mean age was  $53.4 \pm 11$  years. The prevalence of non-adherence to oral diabetic medication(s) was 45.1%. Twenty-seven percent of the study participants had at least one perception that hindered them from adhering to their oral diabetic medication(s). Non-adherence was significantly associated with taking two or more types of oral diabetic medication(s) (AOR = 6.51; 95% CI: 1.63 -25.03;  $P < 0.006$ ) and forgetfulness (AOR = 3.12; 95% CI: 1.26 – 7.73  $P < 0.014$ ). Non-adherence to oral hypoglycemic agents among type 2 diabetic outpatients at Mbagathi Hospital is associated with use of multiple oral diabetic medications and forgetfulness. Treatment should be simplified and health education enhanced in the area of diabetic medication adherence. In addition, ways should be devised for reminding patients to take their diabetic medications.

## **CHAPTER ONE**

### **INTRODUCTION**

#### **1.1 Background Information**

Diabetes mellitus is a chronic disease characterized by high blood sugar levels. It occurs when there is inadequate production of insulin by the pancreas or when the insulin produced is not effectively used by the body. There are three main types of diabetes mellitus; type 1, 2 and gestational. Type 1 is associated with lack of insulin production and type 2 is caused by ineffective use of insulin by the body as a result of excess body weight and lack of exercises (WHO, 2012). Type 2 diabetes accounts for approximately 90 - 95% of diabetic cases globally while type 1 accounts for 5 -10% of those with diabetes (ADA, 2015). Gestational diabetes is a temporary metabolic disorder that any previously non-diabetic woman can develop during pregnancy usually in the third trimester and normally disappears after pregnancy. Hormonal changes, excess weight and family history contribute to the development of this disease (Riaz, 2009). Its prevalence ranges from 2% - 5% of all pregnancies (Mwangi & Gitonga, 2014).

The burden of type 2 diabetes is escalating worldwide especially in middle income countries. This has been suggested to be due to obesity and physical inactivity brought about by lifestyle changes that occur in newly industrialized and developing countries. The incidence and the prevalence of type 2 diabetes show major differences between countries and ethnic groups (WHO, 2012). The global diabetes mellitus prevalence was estimated to be 387 million (8.3 %) in 2014, 22 million (5.1%) in Africa and 775,200 (3.6%) in Kenya (IDF, 2014a) which is likely to be an underestimation as two thirds of diabetics in Kenya may be undiagnosed (Jones, 2013). Diabetes prevalence is projected to rise to 592 million in 2035 globally (IDF, 2014a). More than 80% of diabetes deaths occur in low and middle income countries (WHO, 2012). Over 50% of all hospital admissions and 55% of hospital deaths in Kenya are due to non-communicable diseases,



diabetes being among the leading (El-busaidy *et al.*, 2014). Deaths attributable to all types of diabetes in Kenya were 15,523 in 2014 but this is an underestimation as deaths arising from undiagnosed cases go unreported (IDF, 2014b). Diabetes awareness among Kenyan population is very low (27%) which explains its poor attitude and practices towards diabetes (Maina *et al.*, 2010). The knowledge differs according to level of education and region (Jones, 2013). Indeed the awareness is still demanding in rural Kenya (El-busaidy *et al.*, 2014). Most diabetic patients suffer from diabetes complications because of lack of diabetes awareness (Kisokanth *et al.*, 2013).

Management of type 1 diabetes requires administration of exogenous insulin. Type 2 diabetes requires initially medical nutritional therapy (MNT) and physical activity to increase insulin sensitivity and promote weight loss followed by oral hypoglycemic agents if glycemic targets are not achieved, with insulin being indicated as the last option (Kasper *et al.*, 2005). Type 2 diabetes mellitus complications can be prevented or delayed by use of total lifestyle modification and oral hypoglycemic agents (Sabate, 2003) and therefore patients' adherence to therapies remains key to achieving good health outcomes (Charity *et al.*, 2016). Adherence is the extent to which a person's behavior; taking medication following a prescribed diet/ or executing lifestyle corresponds with the agreed recommendation from a health care provider according to World Health Organization. Adherence to long term therapy for chronic illnesses is approximately 50% in developed countries and even lower in developing countries (Sabate, 2003) while adherence to oral hypoglycemic agents has been reported to range between 36% to 93% (Cramer, 2004). Patient's adherence to oral hypoglycemic agents is important for adequate glycemic control (Lee & Taira, 2005). Non-adherence to the treatment of diabetes is one of the main causes of development of diabetes complications and is associated with increased patient morbidity, premature disability, death (WHO, 2012) and excess cost to the health care system (Bagonza *et al.*, 2015). Many diabetics in Kenya are diagnosed with irreversible complications (Jones, 2013). Diabetes and its complication have a significant economic impact on individuals' families, health system

and countries (WHO, 2012). The cumulative global expenditure on treatment of diabetes and management of complications in 2013 was US\$ 548 billion. In Africa the cost per person with diabetes was US\$ 208.07 while in Kenya it was US\$ 81.79 (IDF, 2014a). Diabetes threatens Kenya health care system and wider economy with loss of productive workforce (Jones, 2013). The heavy economic burden underscores the urgent need for increased investment in prevention and management of diabetes (Kirigia *et al.*, 2009).

Illness perception is associated with self management effectiveness among diabetic patients; someone with poor diabetic control has different perception as compared to one with good diabetic control (Yuniarti *et al.*, 2013). Illness perception is based on self regulatory model theory whose dimensions are perceived disease identity, cause, duration, consequences and control (Mahajan & Padvi, 2013). Patients' health perceptions are strongly under the influence of culture and the environment in which one is raised (Pourghaznein *et al.*, 2013) and are important determinants of health seeking behavior, treatment engagement and adherence which may impact on disease outcome (Mahajan & Padvi, 2013). It has been reported that patients' perceptions about diabetes and its therapy can potentially influence non-adherence to oral hypoglycemic agents (Shiyanbola & Nelson, 2011). Though important, illness perception is rarely used in quantitative and clinical assessment as well as management of patients (Thongsai, 2015).

In view of the above, the study aimed at determining the factors associated with non-adherence to oral hypoglycemic agents in the management of type 2 diabetes in-order to reduce morbidity and mortality among diabetic patients and help improve their social economic status.

## **1.2 Statement of the Problem**

Non-adherence to long term therapy in chronic illness including diabetes mellitus is of great magnitude worldwide (Sabate, 2003) and the degree of adherence to oral hypoglycemic agent's ranges from 36% to 93% (Cramer, 2004). Non-adherence to

medications among diabetic patients have been shown to result to poor glycaemic control leading to treatment ineffectiveness, increased incidences of diabetic mellitus complications and increased health care cost (Rozenfeld *et al.*, 2008). Infact a multinational study revealed the prevalence of macrovascular and microvascular complications associated with suboptimal diabetes therapy to be 53.5% and 27.2% respectively in type 2 diabetic patients (Litwak *et al.*, 2013). On the other hand, adherence to antidiabetic medications was found to be associated with a decrease in glycosylated haemoglobin (Pladevall *et al.*, 2004) and reduced incidences of diabetes complications (Kalsekar *et al.*, 2006). Since assessment of patients' adherence to prescribed oral hypoglycemic agents and use of interventions to improve adherence are rare in routine clinical practice (Adisa *et al.*, 2009; Michael *et al.*, 2006) hence there was need to identify the factors associated with non-adherence to oral hypoglycemic agents in type 2 diabetes.

### **1.3 Justification of the study**

Non-adherence to oral hypoglycemic agents has been reported in several countries and it is among the factors reported that contribute to suboptimal glycaemic control which is a major risk factor for developing diabetes mellitus complications. Non-adherence to oral hypoglycemic agents has been shown to reduce the treatment effectiveness and increase the health care cost (Rozenfeld *et al.*, 2008). Since the information on level of non-adherence to oral hypoglycemic agents and the associated factors lacks in Kenya, it was necessary to establish the factors with th view of informing policy, improve practice and eventually reducing the incidences of diabetes complications leading to reduced morbidity, early disability and mortality among type 2 diabetic patients.

### **1.4 Research Questions**

- i. What is the prevalence of non-adherence to oral hypoglycemic agents among adult type 2 diabetes mellitus outpatients attending Mbagathi District Hospital?

ii. What are the social perceptions associated with diabetes mellitus and its treatment?

iii. What are the factors associated with non-adherence to oral hypoglycemic agents?

## **1.5 Study Objective**

### **1.5.1 General Objective**

To determine the social perceptions associated with diabetes mellitus and its treatment, prevalence of non-adherence to oral hypoglycemic agents and factors associated with non-adherence to oral hypoglycemic agents among adult type 2 diabetes mellitus outpatients attending Mbagathi District Hospital.

### **1.5.2 Specific Objectives**

- i. To determine the prevalence of non-adherence to oral hypoglycemic agents among type 2 diabetes mellitus outpatients attending Mbagathi District Hospital.
- ii. To determine the social perceptions associated with diabetes mellitus and its treatment among type 2 diabetes mellitus outpatients attending Mbagathi District Hospital.
- iii. To determine the factors associated with non-adherence to oral hypoglycemic agents among type 2 diabetes mellitus outpatients attending Mbagathi District Hospital.

## CHAPTER TWO

### LITERATURE REVIEW

#### 2.1 Background Information

Diabetes mellitus is a metabolic disorder characterized by high blood glucose level resulting from defective insulin production by the pancreas, insulin resistance or both (Goldenberg & Punthakee, 2013). Insulin maintains normal blood glucose levels by facilitating cellular uptake of glucose (Wilcox, 2005). Diabetes mellitus occurs in numerous distinct types and are caused by a complex interaction of genetics, environmental factors and lifestyle choices. With increasing incidence worldwide, diabetes mellitus will be a leading cause of morbidity and mortality in the foreseeable future (Kasper *et al.*, 2005)

#### 2.2 Types of Diabetes Mellitus

There are three main types of diabetes mellitus type 1, type 2 and gestational. Type 1 is further categorized into type 1A and 1B. Type 1A occurs due to autoimmune beta cell destruction which leads to insulin deficiency. Type 1B lack immunological markers indicative of autoimmune destruction process of the beta cells; hence the mechanism for development of insulin deficiency is unknown. Relatively, few patients in type 1 are in type1B and are of African, American or Asian heritage. Type 1 usually develops before 30 years of age. However, autoimmune beta cell destruction can occur at any age and this account for 5-10% of type 1 diabetes development after 30 years of age (Kasper *et al.*, 2005). Type 1 diabetes mellitus accounts for 5 to 10% of diabetes cases (ADA, 2015).

Type 2 diabetes mellitus is characterized by degree of insulin resistance, impaired insulin secretion and increased glucose production. It is preceded by abnormal glucose homeostasis classified as impaired fasting glucose (IFG) or impaired glucose tolerance (IGT). Type 2 diabetes develops with increasing age and occurs in children particularly

in obese adolescent (Kasper *et al.*, 2005) and it accounts for approximately 90 to 95% of those with diabetes (ADA, 2015).

Gestational diabetes mellitus is defined as any level of glucose intolerance first recognized during pregnancy. For most mothers glucose intolerance resolves after delivery however there is up to 50% likelihood of developing type 2 diabetes within 5 years after giving birth (Hirst *et al.*, 2012). The prevalence of gestational diabetes ranges from 2% - 5% of all pregnancies (Mwangi & Gitonga, 2014).

### **2.3 Risk Factors for Developing Diabetes Mellitus**

Type 1 develops as a result of synergistic effects of genetics, environmental and immunological factors that end up destroying the pancreatic cells (Kasper *et al.*, 2005). Type 2 is associated with a number of risk factors which includes obesity, unhealthy diet and physical inactivity, increasing age, insulin resistance, family history and ethnicity (Steyn *et al.*, 2004). Type 2 diabetes prevalence increases with age though the age of onset has moved to young adults and adolescent where there is a major imbalance between energy intake and expenditure (Alberti *et al.*, 2007).

### **2.4 Signs of Diabetes Mellitus**

Type 1 diabetes mellitus develops suddenly and the most commonly experienced symptoms include frequent urination, excessive thirst, increased hunger, weight loss, tiredness, slow-healing wounds, recurrent infections, and blurred vision whereas the onset of type 2 is gradual and difficult to detect as the symptoms are mild (Ramachandran, 2014); in fact, 50% of individuals with type 2 have one or more diabetes specific complication(s) at the time of their diagnosis (Kasper *et al.*, 2005).

### **2.5 Diagnosis of Diabetes Mellitus**

Diagnosis is demonstrated and confirmed by a random blood glucose concentration greater or equal to 11.1 mmol/l (200 mg/dl) for patients with classic symptoms of

hyperglycemia, fasting plasma glucose concentration greater or equal to 7 mmol/l, glycosylated hemoglobin (HbA<sub>1C</sub>) greater or equal to 6.5% or blood glucose concentration equal to 11.1 mmol/l two hours after 75 g glucose drink during an oral glucose tolerance test (OGTT) (ADA 2015). In asymptomatic subjects, performing the test on one occasion is not sufficient to make a diagnosis. This must be confirmed by carrying out at least one more test the following day (Yach & Alberti, 2003).

## **2.6 Diabetes Mellitus Complications**

Diabetes mellitus if not properly managed can result in long term damage to organs and tissues. The chronic complications of diabetes mellitus cause most of the morbidity and mortality associated with the disease. The microvascular complications include retinopathy, neuropathy, and nephropathy while macrovascular complications include artery and peripheral arterial diseases and cerebral vascular diseases. Non vascular complications include gastroparesis, infections and skin changes (Kasper *et al.*, 2005). The main pathological mechanism in macrovascular complications is the process of atherosclerosis which causes the narrowing of arterial walls. Diabetes is a strong independent predictor of risk of stroke, cerebrovascular and cardiovascular diseases. Diabetic nephropathy is the leading cause of kidney failure in USA (Fowler, 2008). It occurs in 50% of patients with long standing diabetes mellitus and correlates with duration of diabetes mellitus and glycemic control (Kasper *et al.*, 2005). Diabetes accounted for 44% new cases of kidney failure in USA in 2008 (CDC, 2011). The nerves damage causes impaired sensation or pain in the feet or hands leading to lower extremity amputations (CDC, 2011). Ophthalmic complication of diabetes mellitus is the leading cause of blindness between the ages of 20 and 74 years in USA and it is as a result of progressive retinopathy and macular edema. Duration of diabetes mellitus and degree of glycemic control are predictors of development of retinopathy (Kasper *et al.*, 2005). In 2005-2008 in USA, 28.5% of the people with diabetes aged 40 years and above had diabetic retinopathy (CDC, 2011). Since the prevalence of type 2 diabetes

mellitus is higher than type 1 and is expected to rise more rapidly in future due to increasing obesity and reduced activity levels (Kasper *et al.*, 2005), it is of utmost importance to focus on the management of type 2 diabetes mellitus.

## **2.7 Management of Type 2 Diabetes Mellitus**

The key components of management of diabetes mellitus are regular physical activity, healthy eating patterns and pharmacotherapy (Evert *et al.*, 2013). The initial treatment of type 2 diabetes should be based on dietary therapy combined with increased physical activity if possible, however pharmacotherapy may be considered in case of marked hyperglycemia. Insulin is indicated when diet and oral hypoglycemic agents fail to control hyperglycemia and achieve targets (Nathan, 2002). Support for lifestyle measures should be maintained throughout disease management plan (Brunetti & Kabalik, 2012). The optimal targets for glycemic control for diabetic patients are < 7% glycosylated haemoglobin (HbA<sub>1c</sub>), < 7.75 mmol/l two hours post prandial capillary blood glucose values and 3.9 -7.2 mmol/l fasting capillary blood glucose values (Monnier & Colette, 2009).

### **2.7.1 Lifestyle Modification**

Lifestyle interventions are useful in the management of type 2 diabetes. Lifestyle intervention programs address the total lifestyle of an individual with the goals of decreasing excess weight, increasing physical activity and improving the quality of the diet (Weber *et al.*, 2010). The main environmental factors that raise cardiovascular risk in type 2 diabetes mellitus are sedentary lifestyle and overfeeding resulting to obesity (Binu *et al.*, 2011). Physical activity along with healthy eating and medication are the cornerstone of effective diabetes management (Sigal *et al.*, 2006). Type 2 diabetic patients receiving lifestyle interventions; increased physical activity and dietary modification shows improvement in resting energy expenditure, low density lipoprotein (LDL) Cholesterol, insulin sensitivity, weight loss, decrease in glycosylated



Haemoglobin (HbA<sub>1C</sub>), Body Mass Index (BMI), blood pressure and fasting glucose (Weber *et al.*, 2010).

### **2.7.1.1 Physical Activity**

Sedentary lifestyle is a main risk factor for development of type 2 diabetes mellitus (Esteghamati *et al.*, 2008) while physical activity plays a key role in the management of type 2 diabetes. Regular exercise reduces hyperglycemia in all forms of diabetes and also improves Insulin sensitivity by reducing the free fatty acid load to the liver and hence reduction in obesity. Exercise reduces hepatic glucose output, increase uptake of glucose by the skeletal muscles. It also increases insulin sensitivity of skeletal muscles (Binu *et al.*, 2011). Physical activity reduces glycosylated hemoglobin (HbA<sub>1C</sub>) to a level associated with reduced risk of diabetic complications (Plotnikoff, 2006). The recommended physical activity program for type 2 diabetic patients should consist of aerobic training of moderate intensity performed at least 3 days per week, a minimum of 150 minutes per week. Resistance training should be undertaken twice weekly and flexibility training should also be undertaken (Colberg *et al.*, 2010).

### **2.7.1.2 Diet**

Dietary management of type 2 diabetes among patients is one way of preventing or delaying diabetes complications (Omondi *et al.*, 2011). There is no standard meal plan that works universally for all diabetic patients. Dietary therapy should be individualized as needed to achieve treatment goals (Evert *et al.*, 2013). It is aimed at ensuring weight control, providing nutritional requirements, correcting blood lipids and allowing good glycemic control with blood glucose level as close to normal as possible. The dietary fat should provide less than 35% of total energy intake with saturated fat not exceeding 10% of total energy; cholesterol should be limited to 300mg or less daily. Protein should be from both animals and plants sources and its intake should range between 10-20% of total energy and high intake for children and during pregnancy is recommended.

Carbohydrates should provide 45-60% of total energy of the diet with fibre not less than 40gm per day; added sugar should be less than 10% of energy intake. Excessive salt and alcohol intake should be avoided and nutritive sweeteners restricted (Aas *et al.*, 2013)).

Medical nutritional therapy (MNT) is important in treating diabetes and preventing its complications. MNT for type 2 diabetes mellitus should stress on modest caloric reduction, reduced fat intake, increased physical activity and modification of hyperlipidemia and hypertension. Increased intake of soluble dietary fibre can improve glycemic control in type 2 diabetic patients. Dietary modification addresses both energy restriction and quality of food especially fat intake (Kasper *et al.*, 2005).

### **2.7.2 Oral Hypoglycemic Agents**

These are medicines which lowers the blood sugar. They are considered only after a regimen of dietary treatment combined with exercise has failed to achieve the therapy targets (Nathan, 2002). There are five classes of hypoglycemic agents with unique pharmacological properties. They are sulfonylureas, biguanides, thiazolidinediones, alpha-glycosidase inhibitors and meglitinides. Monotherapy with metformin is the first line treatment of type 2 diabetes however, combination therapy should be considered as initial choice if HbA<sub>1C</sub> is greater than 7.5% (Brunetti & Kabalik, 2012).

Sulfonylureas include acetohexamide, chlorpropamide, gliclazide, glipizide, glibenclamide, tolbutamide and tolazamide (Brunetti & Kalabalik, 2012). Their mode of action is by stimulating release of insulin from the beta cell of the pancreas and slightly improves insulin resistance in peripheral target tissues, muscles and fat. One of the side effects of sulfonylureas is hypoglycemia associated with chlorpropamide and glyburide (glibenclamide) that are metabolized to active metabolites. The other side effect of sulfonylureas is weight gain (Luna & Feinglos, 2001).

Biguanides comprises of phenformin, buformin and metformin. Phenformin and buformin were withdrawn from the market due to associated lactic acidosis (Mkele,

2013). Metformin is the only biguanide that is in clinical use and its mode of action is by reducing hepatic glucose output and to a lesser extent improves peripheral glucose utilization. It reduces fasting plasma glucose and insulin levels and improves lipid profile (Kasper *et al.*, 2005). Metformin is used in obese patients not responding to dietary therapy (Golay, 2007). The drug's side effects include lactic acidosis, diarrhoea, nausea, anorexia and metallic taste (Kasper *et al.*, 2005). Metformin can be given in combination with other hypoglycemic agents when therapy targets are not met (Mkele, 2013).

Thiazolidinediones mode of action is through enhancing insulin sensitivity in both muscles and adipose tissues and to a lesser extent by inhibiting production of glucose by the liver. They improve insulin resistance when used in combination with other hypoglycemic agents however; they have no effect on Insulin secretion. Rosiglitazone and pioglitazone are some of the thiazolidinediones (Luna & Feinglos, 2001). They are associated with slight weight gain, peripheral edema and congestive heart failure and liver disease (Kasper *et al.*, 2005).

Alpha-glycosidase inhibitors consist of acarbose, miglitol and voglibose. Their mode of action is by reducing postprandial hyperglycemia (Laar *et al.*, 2005). They delay glucose absorption through inhibition of the enzyme that breaks down oligosaccharides to simple sugars in the intestine. Side effects associated with this class include abdominal distention, flatulence and diarrhea (Kasper *et al.*, 2005).

Meglitinides acts by stimulating the release of insulin from pancreatic beta cells. They decrease the postprandial glucose and have decreased risk of hypoglycemia. Repaglinide and nateglinide are some of the examples of meglitinides (Kasper *et al.*, 2005; Luna & Feinglos, 2001).

## **2.8 Non-adherence to Oral Hypoglycemic Agents**

### **2.8.1 Importance of Adherence**

Adherence is active voluntary involvement of the patient in management of his or her disease by following a mutually agreed course of treatment and sharing responsibility between the patient and health care provider. With regards to long term therapy, it is defined as the extent to which a person's behavior, following a diet and / or executing lifestyle changes corresponds with agreed recommendation from a health care provider (Sabate, 2003). Adherence to medication is the extent to which a patient takes medication as prescribed by the health care provider (Osterberg & Blaschke, 2005) while non-adherence is failure to take medication as prescribed (ASA & ASCPF, 2006) and affects not only the patient but also the health care system (Jimmy & Rose, 2005). Oral hypoglycemic agents are effective in controlling glucose levels among type 2 diabetic patients thus lowering their risk of developing microvascular and macrovascular complications (Lau & Nau, 2004). Hence patient's adherence to oral hypoglycemic agents is important for adequate glycemic control, reducing poor health outcomes, reducing health care cost and prevention of future complications in type 2 diabetic patients (Kalsekar *et al.*, 2006; Lee & Taira, 2005).

### **2.8.2 Consequences of Non-adherence**

Non-adherence to medication is potentially one of the most serious problems facing diabetes care delivery particularly in type 2 diabetes mellitus (Clark, 2004). It has been shown that Type 2 diabetic patients, who fail to take at least 80% of their oral hypoglycemic agents across one year time frame, are at risk of hospitalization during the following year (Lau & Nau, 2004). Non-adherence to oral hypoglycemic agents leads to increased glycosylated haemoglobin in type 2 diabetic patients (Michael *et al.*, 2006). Other consequences of medication non-adherence are waste of medication, worsening of

the disease, treatment failure, reduced functional abilities, lower quality of life, death and increased healthcare cost (Jimmy & Rose, 2011).

### **2.8.3 Rates of Non-adherence**

Patients' adherence to prescribed oral hypoglycemic agents is generally low and difficult to maintain even in a population with adequate access to health care and drug coverage (Lee & Taira, 2005). According to WHO, the adherence to long term therapy for chronic diseases on average is 50% in developed countries and is even lower in developing countries (Sabate, 2003) while adherence to oral hypoglycemic agents treatment ranges from 36-93% (Cramer, 2004). This shows that patients experiences problems sticking to recommended therapies (Sabate, 2003) and therefore interventions are needed to increase medication adherence so that patients can realize the full benefits of prescribed therapies (Michael *et al.*, 2006).

### **2.8.4 Predictors of Non-adherence**

Studies have reported that the major predictors of medication non-adherence are side effects of the medication, patients' lack of insight into the illness and belief in the benefit of treatment. Other predictors reported are complexity of treatment, missed appointments, cost of medication and treatment of asymptomatic disease. Inadequate follow up, presence of cognitive impairment, substance abuse, presence of psychological problems particularly depression, presence of barriers to care or medications and poor provider patient relationship have also been reported as major predictors (ASA & ASCPF, 2006; Osterberg & Blaschke, 2005).

### **2.8.5 Strategies for Improving Adherence**

Studies have proposed strategies for improving adherence to medication such as emphasizing the importance of the regimen and the effect of adherence, providing simple and clear instructions and simplified regimen. Other strategies proposed are customizing the regimen according to the patient wishes, finding out the patient's feeling

about his or her ability to follow the regimen and if need be design support to encourage adherence. Studies have also proposed involving family members, friends and community services in promoting adherence by the patient and identifying poor adherence by looking for markers of non-adherence such as missed appointments, missed refills, and lack of response to medication can also improve adherence (Osterberg & Blaschke, 2005).

### **2.8.6 Measurement of Medicine Non-adherence**

There are many methods for measuring medicine non-adherence, direct and indirect (Jimmy and Rose, 2011) however; there is no gold-standard method (Clark, 2004). The direct methods are directly observed therapy, measurement of level of medicine or its metabolite in the blood or urine including detection or measurement of biological marker added to drug formulation. Direct approaches are more accurate but are expensive. The indirect methods are patient questionnaire, self reports and pill count. Others are use of patients' diaries, electronic medication monitor and measurement of physiological markers including assessment of patient's clinical response and rate of prescription refills. The simplest way of measuring non-adherence is from patient self report (Jimmy & Rose, 2011; Osterberg & Blaschke, 2005).

## **2.9 Social Perceptions Associated with Diabetes and its Treatment**

Illness perception is individuals' response to ill health and is formed through individuals organized beliefs and conception of their illness based on experience and environment (Yuniarti *et al.*, 2013). Illness perception is based on self regulatory model theory whose dimensions are identity, cause of illness, duration, consequences and self control. Patients' perception of their diabetes illness has been found to influence self management behavior which may impact on glycemic control (Mahajan & Padvi, 2013). Diabetes mellitus is perceived to be caused by genetics, poor eating habits and physical inactivity in various studies (Liani *et al.*, 2014, Yuniarti *et al.*, 2013 and Irene *et al.*,

2005). In a study conducted in Kenya (Liani *et al.*, 2014), witchcraft and punishment from God for past sins were perceived as causes of diabetes. Other perceived causes were obesity (Jijomon *et al.*, 2013; Irene *et al.*, 2005) and transmission from one person to the other (Jijomon *et al.*, 2013). In regards to treatment, eating healthy diets, physical exercise and medication were perceived as cure for diabetes. Prayers, use of herbal medicine and home remedies such as drinking a lot of water and eating raw chicken liver were also perceived as cure for diabetes (Liani *et al.*, 2014).

## **2.10 Factors Associated with Non-adherence to Diabetic Therapy**

### **2.10.1 Factors Associated with Non-adherence to Lifestyle Modification**

Adherence to lifestyle modification measures is very poor among type 2 diabetic patients (Binu *et al.*, 2011). Studies carried out in Zimbabwe, Saudi Arabia, Mexico and Hungary showed that 26% - 85% of the study subjects did not follow the physician's advice on exercise however, the instructions on diet were followed by 38% - 76.8% of them (Mandewo *et al.*, 2014; Adewale *et al.*, 2013; Khan *et al.*, 2012; Serour *et al.*, 2007; Hanko *et al.*, 2007; Ronquillo *et al.*, 2003).

Diet is a lifestyle behavior that has been reported to have poor compliance among diabetics (Omondi *et al.*, 2011). Among the reasons reported for non-adherence to diet recommendation were lack of information, economic reasons and being away from home (Mandewo *et al.*, 2014; Adewale *et al.*, 2013; Ronquillo *et al.*, 2003). Difficulty of changing previous habits was cited as reason for not changing the diet adequately (Ronquillo *et al.*, 2003). Other reasons cited were granting self permission, eating out and poor self control (Adewale *et al.*, 2013). A study carried out in Kuwait cited difficulty adhering to diets different from the rest of the family, social gathering and willingness as reasons for non-adherence to diet (Serour *et al.*, 2007).

With regards to exercise, studies conducted in Mexico, Botswana and Kuwait reported coexisting diseases (Adewale, 2013; Serour *et al.*, 2007; Ronquillo *et al.*, 2003), weather

(Adewale *et al.*, 2013; Serour *et al.*, 2007), lack of time (Serour *et al.*, 2007; Ronquillo *et al.*, 2003), associated diseases (arthritis), lack of motivation, idiosyncrasy and change in their habits (Ronquillo *et al.*, 2003) as reasons for non-adherence to physical activity. Other reasons cited were lack of information, exercise as potentially exacerbating illness, lack of exercise partner and specific locations away from home (Adewale *et al.*, 2013). Studies in the field of obesity and diabetes have shown that, adherence remains an issue of concern when treatment involved diet and or exercise (Fappa *et al.*, 2007). Studies have reported that patients aged over 25 years have difficulties in adherence to physical activity recommendations and females have poor adherence to physical activity as compared to men (Sabate, 2003).

### **2.10.2 Factors Associated with Non-adherence to Diabetic Medication**

Medication non-adherence is prevalent among patients with diabetes mellitus and is associated with poor treatment outcomes (Michael *et al.*, 2006) resulting to increased morbidity and mortality. Studies have reported that medication non-adherence is associated with socio-economic, health care system, therapy, patient and condition related factors.

Studies have shown that socio-economic factors with significant effect on medication adherence in general are poor socio-economic status; illiteracy, unemployment and poor social support network. Others factors reported are unstable living conditions, long distant from health facility, high transport cost and high medicine prices. Changing environmental situations, cultural and lay beliefs about illness and treatment and family dysfunction are also other factors (ASA & ASCPF, 2006; Sabate, 2003). For control of diabetes mellitus, the socio economic factors that have been shown to affect therapy adherence are cost of medicine and poverty (Wabe *et al.*, 2011; Adisa *et al.*, 2009; Kalyango *et al.*, 2008; Sabate, 2003; Donnon *et al.*, 2002). It has been reported that social and family support improves adherence to diabetic therapies (Sabate, 2003).



Health care system related factors with negative effect on medication adherence are inefficient medicine distribution systems, short consultation time, overworked health care provider and weak capacity of the system to educate the patient and provide follow up according to studies. Other factors reported are inability to provide community support, lack of knowledge on adherence and effective interventions to improve it. In addition, lack of knowledge and training of health care providers on managing chronic diseases and lack of health insurance plans including poor provider communication skills have also been reported to have negative effects on medication adherence (Sabate, 2003; ASA & ASCPF, 2006). In the management of diabetes mellitus, it has been shown that the main health care related factor of significance is the poor patient-service provider relationship and has adverse effect on treatment adherence (Sabate, 2003, longer time since last visit to a health worker (Kalyango *et al.*, 2008) and long distance from health facility (Mandewo *et al.*, 2014; Fredrick & Temu, 2012)

Adherence to therapies is reported to be affected by many factors such as chronic conditions requiring long term administration of drugs, lack of symptoms and severity of symptoms. Others factors reported are depression, mental disorders, degree of disability and availability of effective medicines (Kalogianni, 2011; ASA & ASCPF, 2006 and Sabate, 2003). It has been shown that medications requiring indefinite administration, adherence to such treatments decline with time; this is so for diseases with few or no symptoms (ASA & ASCPF, 2006). Duration of disease and co-morbidities like hypertension, obesity and depression has been reported to have a negative impact on adherence to diabetic therapies (Sabate, 2003, Ronquillo *et al* 2003).

Therapy related factors of significance that affect adherence according to studies are duration of treatment, complexity of medication regimen, previous treatment failure and frequent changes in treatment. Othe factors like side effects, medication that are slow to produce beneficial effect and therapies that are inconvenient or interfere with one's lifestyle were also shown to affect adherence (Kalogianni, 2011; ASA & ASCPF, 2006;

Sabate, 2003). In addition, complicated treatment regimens, multiple drug therapy, and side effects are reported to be associated with poor adherence to diabetic medicines (Fredrick & Temu, 2012; Wabe *et al.*, 2011; Gimenes *et al.*, 2009; Tiv *et al.*, 2012; Sabate, 2003). Single drug therapy and fixed dose combination with simple dosing have been reported to have a positive effect on adherence (Hustchins *et al.*, 2011; Sabate, 2003) and duration of treatment longer than ten years (Mandewo *et al.*, 2014).

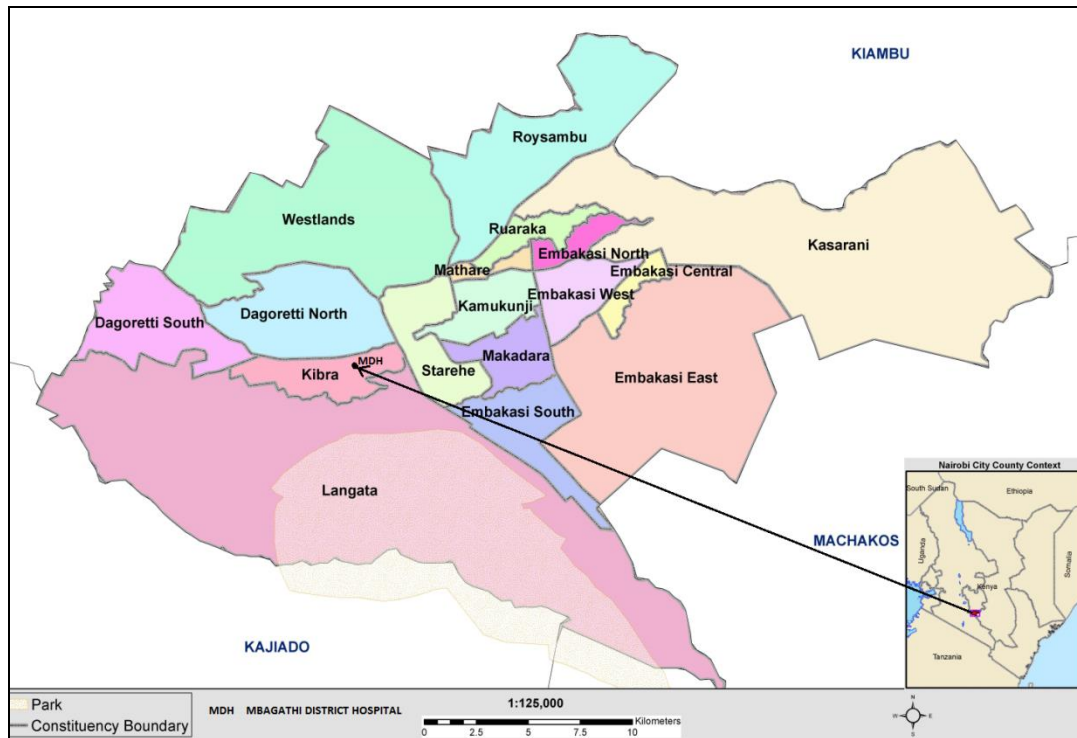
Studies have shown that physical impairments like visual, hearing, swallowing, mobility and cognitive/memory problems negatively affects adherence. Others factors reported are lack of knowledge about the disease, the importance of medication and non-adherence outcome, lack of motivation, and low self esteem. Further alcohol and substance abuse, fears about possible side effects, disease condition denial, frustration with health care provider, psychosocio stress, anxiety and anger have also been reported to affect adherence (Kalogianni, 2011; ASA & ASCPF, 2006; Sabate, 2003). In addition, alcohol abuse by the patient, stress, emotional problems, being away from home, change of habits, stopping to take medicine when they feel better, perceived lack of efficacy of the prescribed medicine, concomitant self medication with traditional medicine, not understanding drug regimen well, forgetfulness and depression have been reported to have negative effects on adherence on diabetic therapies (Wabe *et al.*, 2011; Adisa *et al.*, 2009; Kalyango *et al.*, 2008; Tiv *et al.*, 2012; Sabate, 2003; Ronquillo *et al.*, 2003)

## CHAPTER THREE

### MATERIALS AND METHODS

#### 3.1 Study Site

The study was conducted at Mbagathi District Hospital situated at Kenyatta golf course location, Kibra sub-county in Nairobi City County (Figure 3.1). The county occupies 695.1 sq.km and has a population of 3,138,376 as per 2009 population census (KNBS, 2013). Mbagathi Hospital is a well established government district hospital in Nairobi City County. In addition, its diabetic clinic is well established in terms of number of skilled staffs, space, facilities and the number of diabetic patients enrolled thus enhancing access to the target population. It has a large catchment population of three hundred and eighty thousand seven hundred and thirty nine (380,739) people and has a capacity of 200 beds. Patients attending diabetic clinic at Mbagathi District Hospital come from all the 17 sub-counties of Nairobi City County mainly from Kibra, Lang'ata, Starehe, Dagoretti North and Embakasi South according to the attendance register and therefore they are representative of type 2 diabetic patients in Nairobi. Its location in urban area provides easy access to target population for the study as type 2 diabetes is more prevalent in urban population due to their lifestyle of eating unhealthy diets and inadequate physical activity relative to rural population (Maina *et al.*, 2010).



**Figure 3.1: Location of Mbagathi District Hospital in Nairobi City County.** (Source: Google maps accessed on 4<sup>th</sup> January 2015).

### 3.2 Study Design

This was a descriptive cross-sectional study.

### 3.3 Study Period

The study was conducted for duration of three months, between 14<sup>th</sup> April, 2014 and 14<sup>th</sup> July, 2014

### 3.4 Study Population

The study population consisted of adult type 2 diabetes outpatients attending diabetic clinic at Mbagathi District Hospital and had been on oral hypoglycemic medications for at least one month including doctors and nurses working at the clinic.

### **3.4.1 Inclusion Criteria**

The identification of type 2 diabetic patients was based on the diabetic medications that the patients were on. Type 2 diabetic patients were identified as those on oral hypoglycemic agents only or both oral hypoglycemic agents and insulin. Included in the study were:-

- i. Type 2 diabetic out patients both males and females who attended Mbagathi District Hospital.
- ii. Type 2 diabetic out patients aged 18 years and above.
- iii. Type 2 diabetic out patients on oral hypoglycemic agents for at least 1 month (Kalyango *et al.*, 2008).
- iv. Type 2 diabetic out patients on oral hypoglycemic agents only or on both oral hypoglycemic agents and insulin.
- v. Type 2 diabetic out patients with or without other chronic conditions who attended the diabetic clinic.
- vi. Type 2 diabetic out patients who gave consent to participate in the study.

### **3.4.2 Exclusion Criteria**

- i. Type 1 diabetic out patients who attended diabetic clinic at Mbagathi District Hospital.
- ii. Individuals under 18 years of age.
- iii. Type 2 diabetic out patients who did not consent to participate in the study.
- iv. Type 2 diabetic out patients who were on oral hypoglycemic agents for less than one month.

- v. Type 2 diabetic out patients who were controlled on lifestyle modifications (diet and exercise) alone.
- vi. Type 2 diabetic out patients who had cognitive / memory problems.

### 3.5 Sample Size Determination

According to the statistics obtained from diabetic clinic attendance register at Mbagathi District Hospital from 1<sup>st</sup> September 2011 to 30<sup>th</sup> August 2012, the hospital served 156 patients per month. The appointments for review of diabetic patients are done every one month hence; the registered numbers of patients who actively attend outpatient diabetic clinic at Mbagathi District Hospital was 156 patients of which 140 were type 2 diabetic patients. Therefore the study population was 140.

Currently there is no data on the prevalence of non-adherence to oral hypoglycemic agents in Kenya. Hence, based on a study that was carried out in Uganda (Kalyango *et al.*, 2008), prevalence was estimated at 28.9%

Using Cochran's formula (Cochran, 1977), the minimum estimated sample size at 95% confidence interval and 5% level of significance was given as:-

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

- Where;
- n= Expected sample size
  - Z= Degree of confidence at 95% that corresponds to 1.96
  - P= estimated prevalence of non-adherence to oral hypoglycemic therapy
  - $\delta$  = Acceptance error at 0.05 (5% precision)

$$n = \frac{1.96^2 \times 0.289 \times 0.711}{0.05^2}$$

$$n = 316$$

Since the target population was less than 10,000 the finite population correction factor was applied to the calculated sample size.

$$n_c = \frac{Nn}{(N+n-1)} \text{ (Cochran, 1977)}$$

Where,  $n_c$  = sample size after finite population correction factor

$N$  = Target population size of 140

$n$  = calculated sample size before adjustment

The sample size after finite population correction factor ( $n_c$ ) =  $\frac{140 \times 316}{(140+316-1)} = 97$  patients.

The sample size after finite population correction factor was 97 patients; this was inflated for refusals to participate in the study by 10%. The adjusted sample size was given by:-

$$n(\text{new}) = \frac{n(\text{calculated})}{1-\lambda}$$

Where;  $n(\text{new})$  = Adjusted sample size

$n(\text{calculated})$  = Calculated sample size

$\lambda$  = Adjustment for refusal to participate (10%)

$n(\text{new}) = 97/0.9$

The adjusted sample size = 108 study participants.

### 3.6 Sampling Procedures

Mbagathi District Hospital diabetic clinic runs from 8:00 a.m to 1:00 p.m. once in a week on Monday's and serves 39 patients per week on average of which about 35 are type 2 diabetic patients. Due to limited clinic operating hours and the lengthy questionnaire which took approximately 30 minutes to administer, 10 study participants were scheduled to be interviewed per week for over a period of 3 months. The study

participants were recruited as they came for the clinic using a systematic random sampling technique with a sampling interval of 3 (35 ÷ 10). The sampling was done until 113 study participants were recruited. The choice of the first study participant was identified through random sampling by picking either the 1<sup>st</sup> or the 2<sup>nd</sup> patient by way of tossing a coin. Only those who had met the inclusion criteria and had consented to participate in the study were recruited. Purposive sampling was used to select 3 nurses and 3 doctors as key informants from among 3 nurses and 4 doctors working at the diabetic clinic.

### **3.7 Data Collection**

In-order to improve data validity and reliability, the questionnaire and the key informant interview guide were pretested by administering the questionnaire to five study participants and the interview guide to key informants; a nurse and a doctor at Mathare Hospital diabetic clinic and the tools were modified. The research assistants were also trained on how to administer the tools.

#### **3.7.1 Quantitative Data Collection**

The quantitative data was collected using a pretested semi-structured questionnaire which was in English and translated to Kiswahili (Appendices 1 and 2). It was serialized and administered to the study participants with the help of 3 trained research assistants and the principal investigator. The data collected included demographic characteristics, assessment of non-adherence, social perceptions associated with diabetes and reasons for non-adherence; the socio economic, health care system, condition, therapy and patient related reasons. Single and multiple responses were allowed in data collection. It took approximately 30 minutes to administer the questionnaire.

A self reported therapeutic non-adherence test (Kalyango *et al.*, 2008) was used to evaluate non-adherence to oral hypoglycemic agents. The study participants were asked to recall whether they had missed any doses of oral diabetic medications on day to day



basis over the last one week. To increase accuracy on the number of pills prescribed the study participants' hospital files and previous prescriptions were reviewed. Study participants were probed for reasons for non-adherence to oral diabetic medications

The assessment of social perception was based on self-regulatory model of illness behaviour and treatment beliefs. The dimensions of illness perception evaluated were causes of diabetes, control, timeline and consequences (Shiyanbola & Nelson, 2011). The evaluation on treatment perception was based on cultural, religious and lay beliefs that hindered treatment adherence (Mandewo *et al.*, 2014).

### **3.7.2 Qualitative Data Collection**

The qualitative data was collected using pretested key informant interview guide (Appendix 3). The key informants were interviewed on patients' non-adherence to oral hypoglycemic agents, their social perceptions associated with diabetes its treatment and reasons for non-adherence to oral hypoglycemic agents. The discussions were audio recorded and the interviews lasted between 20-30 minutes.

## **3.8 Data Management**

### **3.8.1 Data Storage**

The filled questionnaires were locked in a cabinet. The data collected from each study participant was entered twice into Microsoft excel spread sheets in password protected computers. Each entry was assigned a unique study participant identifier which could not be linked to study participant's personal data. A back up was created and updated as data entry progressed and this was stored in a different site away from the computer containing the original data. The backed-up copy was tested from time to time and was archived for future use. The audio recorded data obtained from key informant interviews, interview transcripts and any identifying information were encrypted.

## **3.9 Data Analysis**

### **3.9.1 Quantitative Data Analysis**

The quantitative data was validated and exported from Microsoft excel to SPSS software version 20 for analysis. Descriptive statistics were computed for characteristics of the study participants, their opinions and prevalence of non-adherence to oral hypoglycemic agents. Bivariate analysis to assess the association between independent and dependent categorical variables was carried out using Chi square ( $\chi^2$ ). To test for independent association, factors with  $P < 0.15$  were included in the binary logistic regression model and stepwise forward likelihood ratio procedure was used to select variables associated with non-adherence to oral hypoglycemic agents. Non-adherence to oral hypoglycemic agents was assessed using study participants self reports of how they took their oral diabetic medication in the previous seven days preceeding the interview and was measured by the number of tablets missed divided by number of pills prescribed and then expressed as a percentage (Khan *et al.*, 2012; Kalyango *et al.*, 2008). Those who reported taking less than 80% or more than 110% of their prescribed oral diabetic medication were considered non-adherent (Guirado *et al.*, 2011; Abella *et al.*, 2011; Fonseca *et al.*, 2011). The prevalence of non-adherence was computed as a percentage of the study participants who were non-adherent. The factors associated with non-adherence to oral hypoglycemic agents were considered statistically significant at  $P \leq 0.05$ . The data was presented in form of tables and figures

### **3.9.2 Qualitative Data Analysis**

The qualitative data was analyzed manually. The audio recorded data from all the key informant interviews was transcribed and all identifying materials were removed from the transcripts. Each interview transcript was assigned a unique key informant identifier. The transcripts were sent back to the key informants for validation purposes. The key issues in all the transcripts were coded and grouped into similar concepts. The concepts

were then categorized into themes and a short report was produced for each discussion topic. The qualitative data was presented in form of quotes.

### **3.10 Ethical Consideration**

The study ethical clearance was sought from KEMRI Scientific Steering Committee and Ethics Review Committee (Appendices 4 and 5). Clearance from the medical superintendent Mbagathi district hospital was sought as well (Appendix 6). The study participants were given time to attend the clinic first then on exit they were requested to participate in the study. The study participants including the key informants were informed of the purpose of the research and the potential benefits and risks of the study. They were also informed that participation was voluntary and that they were free to withdraw from the study at any time (Appendices 7, 8 and 9), after which the informed consent was obtained from them in writing.

To safeguard on privacy and confidentiality, study participants who consented were interviewed in a private room which was set aside for that purpose. The study participants' information was kept in a secure place and it was never divulged to a third party except for the purpose of the study. The questionnaires containing the study participants' data, the audio recorded data and interview transcripts were assigned unique numbers. They did not bear the names of the study participants or any form of identity which could be linked to the study participants. At the end of the interview, the study participants were individually educated about diabetes and importance of adherence to diabetic treatment.

## CHAPTER FOUR

### RESULTS

#### **4.1 Socio-demographic and Economic Characteristics of Study Participants**

Among the 113 study participants, females were 61.9% and males 38.1%. Protestant was the most predominant religious affiliation (75.2%) followed by catholic (22.1%). The mean age of the study participants was 53.4 years, sd  $\pm 11$  (95% CI 31 – 75 years). Most (60.2%) of the study participants were aged between 40- 59 years and a few (11.5%) were aged less than 40 years. More than 70% of the study participants were married and 21.2% were either widowed or divorced. A relatively high proportion of the study participants were in the informal employment (46.0%), 23.9% were not employed while 17.7% had out patient medical cover. More than 58% of the study participants earned less than ten thousand Kenya shillings per month and approximately 48% had attained primary education while (18.6%) did not have social support in medication taking (Table 4.1).

**Table 4.1: Socio-demographic and economic characteristics of study participants**

<b>Characteristics</b>	<b>Frequency</b>	<b>Percent</b>
<b>Gender</b>		
Male	43	38.1
Female	70	61.9
<b>Age (Years)</b>		
<40	13	11.5
40 -49	29	25.7
50 -59	39	34.5
≥60	32	28.3
<b>Religion</b>		
No religion	1	0.9
Muslims	2	1.8
Protestant	85	75.2
Catholic	25	22.1
<b>Marital status</b>		
Single	8	7.1
Married	81	71.7
Widowed/divorced	24	21.2
<b>Employment</b>		
Not employed	27	23.9
Informal employment	52	46.0
Formal employment	22	19.5
Retired	6	5.3
Other	6	5.3
<b>Income (Ksh per month)</b>		
≤ 9,999	66	58.4
10,000 -19,999	21	18.6
20,000 -29,999	14	12.4
≥30,000	12	10.6
<b>Highest level of education</b>		
No formal education	7	6.2
Primary school	54	47.8
Secondary school	43	38.0
Tertiary college and university	9	8.0
<b>Medical cover</b>		
Yes	20	17.7
No	93	82.3
<b>Social support</b>		
Available	92	81.4

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#### 4.2 Prevalence of Non-adherence to Oral Hypoglycemic Agents

The overall prevalence of non-adherence to oral hypoglycemic agents among the study participants was 45.1%

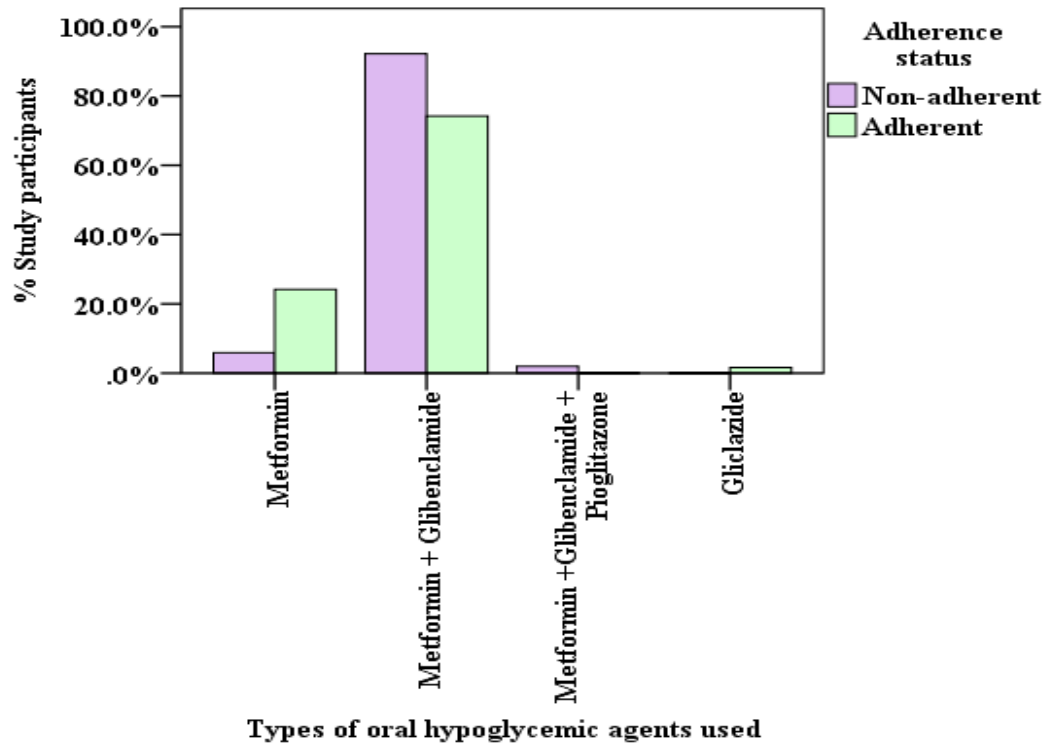
Adherence to oral hypoglycemic medications was viewed by the key informants to be unsatisfactory. Between 25% and 50% of the target population was said to be non-adherent.

*“Adherence is unsatisfactory among patients attending my diabetic clinic. I would say 50% adhere and 50% do not adhere.” (Key informant 1- doctor)*

*“I can say adherence is not a hundred percent. Those who adhere are 70% and those who don't are 30 %.”(Key informant 4 - nurse)*

Majority (82.3%) of the study participants were on a loose combination therapy of metformin and glibenclamide, 15.9% were on metformin only, 0.9% on gliclazide only and 0.9% on loose combination therapy of metformin, glibenclamide and pioglitazone.

Among those who were non-adherent to oral hypoglycemic agents, majority (92.2 %) were on loose combination therapy of metformin and glibenclamide and a few (5.9%) were on metformin mono therapy (Figure 4.1).

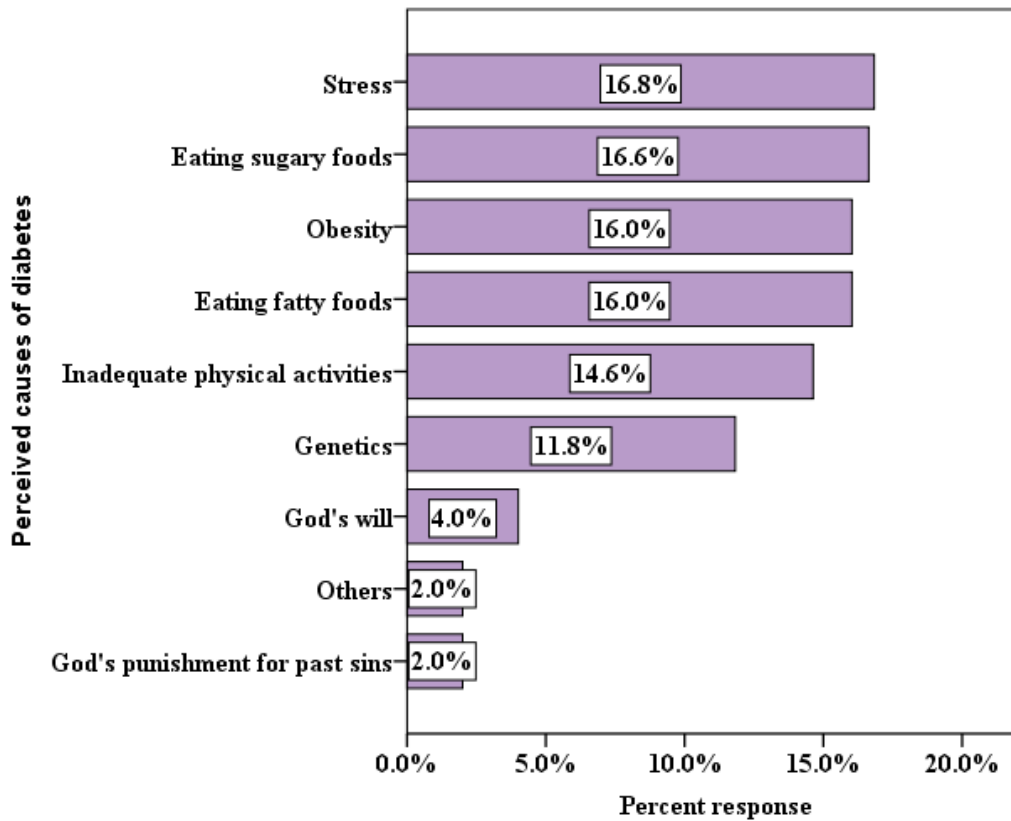


**Figure 4.1: Adherence status to various diabetic regimens**

### **4.3 Social Perceptions associated with Diabetes Mellitus and its Treatment**

#### **4.3.1 Perceived Causes of Diabetes Mellitus**

The most commonly reported social perceptions on causes of diabetes were stress (16.8%), consuming sugary diets (16.6%), eating fatty foods (16.0%), being overweight or obese (16.0%), inadequate physical activity (14.6%) and genetics (11.8%) (Figure 4.2)



**Figure 4.2: Perceived causes of diabetes mellitus**

According to key informants, some study participants perceived their diabetes mellitus to be inherited, others as a result of witchcraft, or due to stress while others did not know the cause. Some blamed the disease on the type of food they used to eat before they were diagnosed.

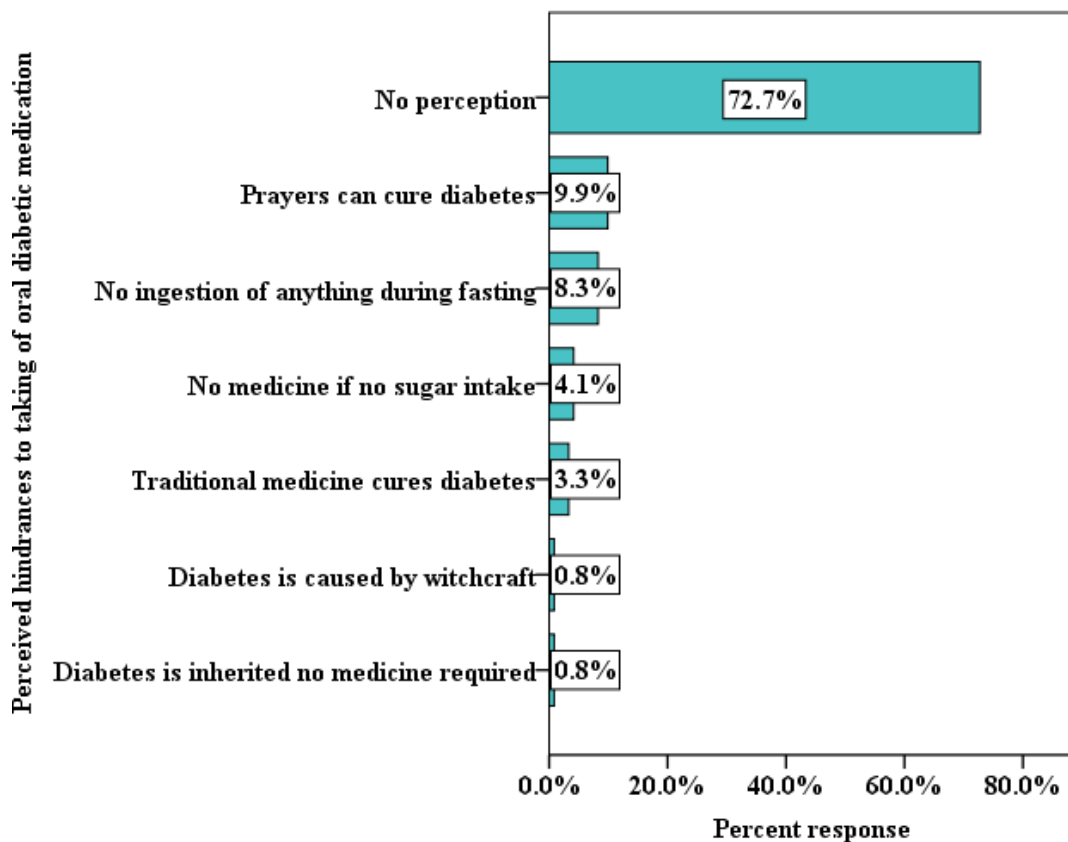
*“Some patients relate it to witchcraft especially the old generation but most of them don’t know what caused their illness.” (Key informant 5 – doctor)*

*“Quite a lot of the patients actually know and will tell you my dad has it, my mum has it. So they know it is hereditary factor, genetic factor that contributes.” (Key informant 6 - doctor)*



### 4.3.2 Perceived Hindrances to Taking Oral Diabetic Medication

The most common perceptions that hindered study participants from using their oral diabetic medications were that prayers could cure diabetes (9.9%), that nothing should be swallowed during fasting period (8.3%), medicine was not necessary if sugary diets were not consumed (4.1%) and traditional medicine cured diabetes (3.3%) (Figure 4.3).



**Figure 4.3: Perceived hinderances to taking of oral hypoglycemic agents**

According to key informants, some of the patients believed in total cure of diabetes mellitus. There are those who take traditional medicines for cure and some believed prayers that cures diabetes.

*“Some believe in prayers.” Another patient told me, “You know me I decided to go to Kakamega and Prophet X prayed for me and I got well that’s why I stayed for long without coming to the clinic but since the problem has come back that’s why I have come back.” (Key informant 2 – nurse)*

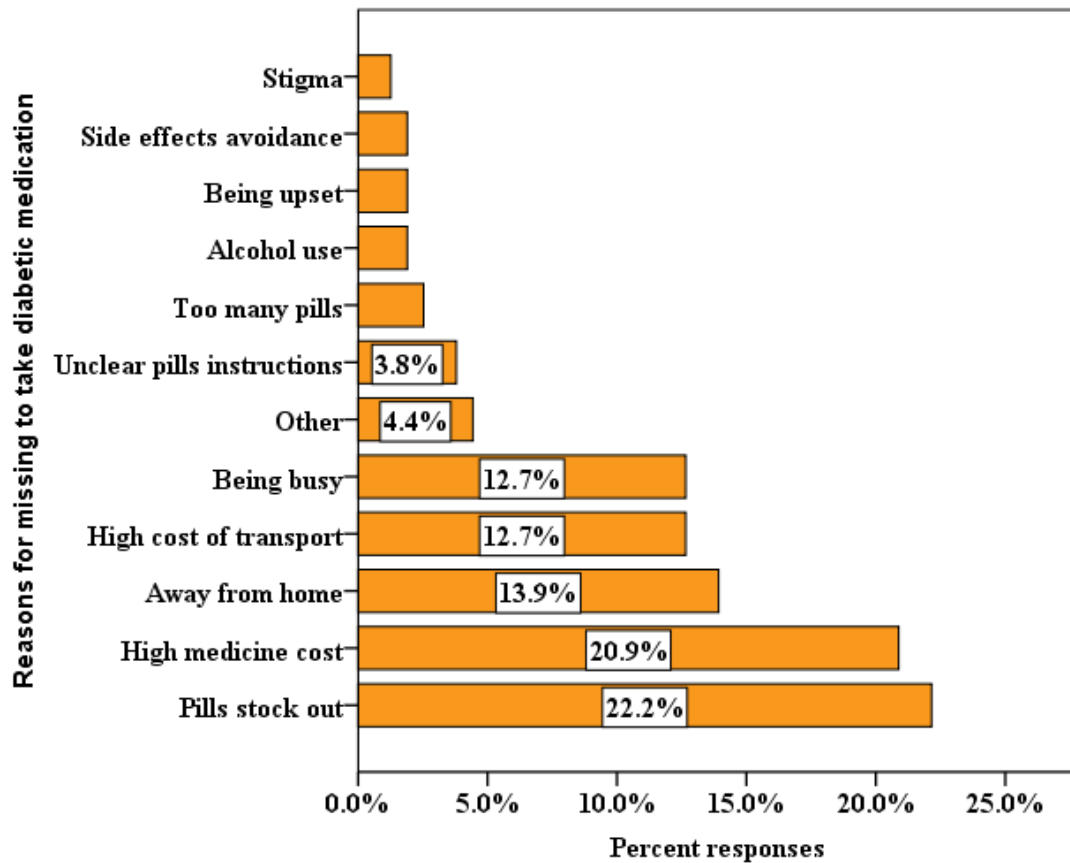
*“Some believe in herbal medicine and they really take them for long and they end up coming to you with complications.”(Key informant 3 – nurse)*

### **4.3.3 Other Perceptions Associated with Diabetes**

A majority (97.3%) of the study participants were of the opinion that oral diabetic medication was necessary and a similar proportion (92.9%) perceived that taking best care of diabetes delays or prevents diabetes complications. A few (20.4%) of the study participants perceived that diabetes illness lasts forever while 10.6% were optimistic that it can last for a specific duration.

### **4.4 Patient Related Reasons for Non-adherence to Oral Hypoglycemic Agents**

The most commonly reported reasons for missing to take oral diabetic medication(s) were, pills stock out (22.2%), high cost of medication (20.9%), being away from home (13.9%) (Figure 4.4).



**Figure 4.4: Reasons for missing to take oral hypoglycemic agents**

**Other Patient Related Reasons for Missing to take Oral Diabetic Medication**

Slightly more than half (54%) of the study participants reported poor dose timing as reason for missing to take oral hypoglycemic agents and more than a quarter (28.3%) cited forgetfulness. A few (11.5%) mentioned feeling worse after taking diabetic medication while 3.5% cited feeling better as reasons for missing to take their oral diabetic medication.

Most of the key informants cited financial problems and inadequate knowledge on diabetes mellitus as reasons given by the patients for not adhering to oral diabetic medication. Few mentioned forgetfulness, side effects of diabetic medication and being

away from home upon travelling. Others cited long duration of the treatment and thinking that one is cured.

*” Some patients say the drugs are expensive and others complain that they do not have money for transport and even for food.” (Key informant 2 - nurse)*

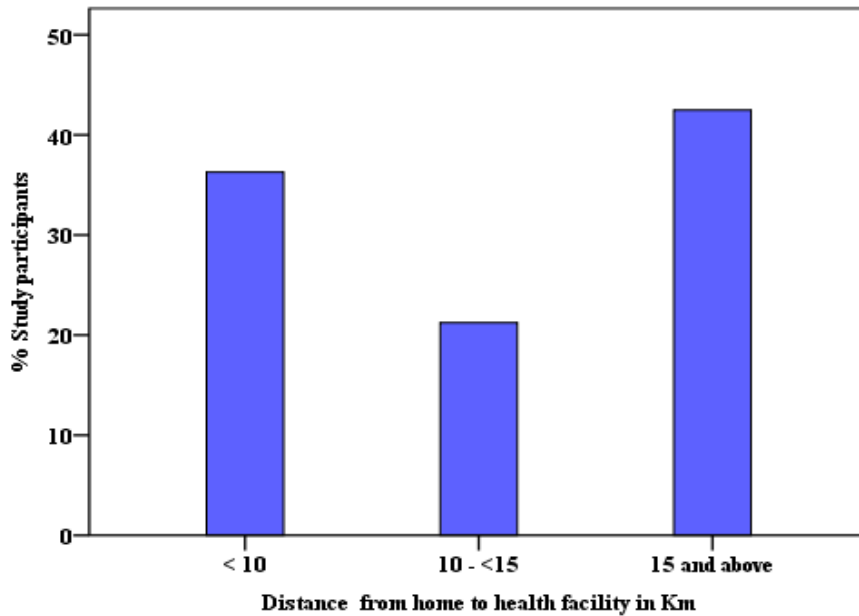
*“There are some who do not adhere because of side effects of the drugs. They say when they take the drugs they feel bloated and dizziness.” (Key informant 6 - doctor)*

*“Few patients say their drugs got finished and were waiting for the next clinic, others say they had travelled up country while others think they are okay.” (Key informant 5 – doctor)*

#### **4.5 Health care system, Disease and Therapy Information**

About half of the study participants (50.4%) obtained their diabetic medication(s) from Mbagathi Hospital pharmacy and a few (18.6%) had strained relationship with health care providers. Approximately 90% knew the benefits of taking diabetic medicine and more than half (68.1%) were on co-medication for long term illnesses such as anti-hypertensives. A relatively high proportion (78.8%) of study participants had at least one diabetes complication, a few (8.0%) reported that they sometimes used traditional medicine for managing diabetes and majority (83.2%) were on more than one type of oral diabetic medications.

Majority (63.7%) of the study participants resided at least 10 km away from the facility (Figure 4.5)



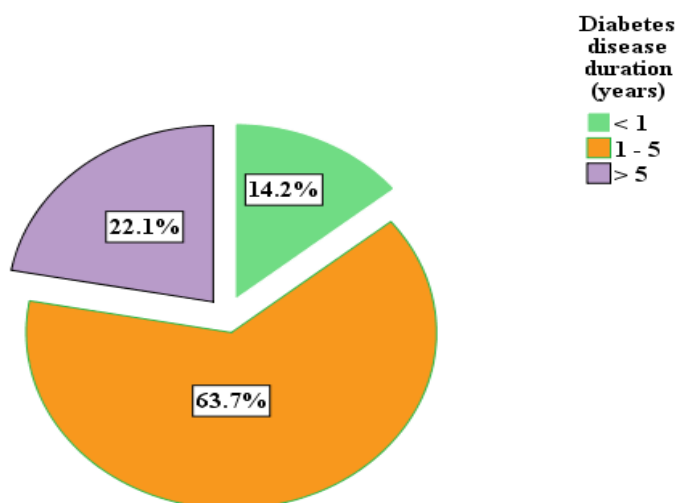
**Figure 4.5: Study participants distribution by distance from home to health facility**

A relatively high proportion (44.2%) of the study participants were on oral hypoglycemic agents for more than 36 months (Table 4. 2).

**Table 4.2: Distribution of study participants by duration of oral diabetic medication use**

Demographic characteristics	Descriptive	
	Frequency	Percent
Duration of oral diabetic medicine use (Months)		
1 – 12	29	25.7
13 – 24	14	12.4
25 – 36	20	17.7
>36	50	44.2

Most (63.7%) of the study participants had been diagnosed with diabetes for 1- 5 years (Figure 4.6)



**Figure 4.6: Distribution of study participants by duration of diabetes disease**

Majority (83.2%) of the study participants had received education on diabetic management and care with (71.3%) having received education less than 1 year previously, 13.8% received diabetic education in the last 1- < 2 years while 14.9% received at least 2 years earlier from the date of patients' interview.

Most of the key informants viewed long waiting time, high charges for services and occasional stock out of diabetic medication including inadequate diabetes education as major health system related factors contributing to non-adherence to oral hypoglycemic medication.

*“Long waiting time; patients come as early as 7:00 a.m and they stay until 11:a.m before the doctors can start seeing them. There are many times you get patient files, you call them and the patients left, they gave up and they miss the appointment.”(Key informant 1- doctor)*

*“Cost sharing contributes to non-adherence because majority of our patients are not in employment and they really strain to get the little money to buy drugs.”  
(Key informant 5- doctor)*

*“Health education on diabetes and importance of adhering to medication to patients is not adequately done and this can contribute to non-adherence to oral hypoglycemic medications.”(Key informant 4- nurse)*

#### **4.6 Factors Associated with Non- adherence to Oral Hypoglycemic Agents**

##### **4.6.1 Socio-demographic and Economic Factors**

None of the socio-demographic and socio-economic characteristics was significantly associated with non-adherence to oral hypoglycemic agents ( $P > 0.05$ ) (Table 4.3).

**Table 4.3: Socio-demographic and economic characteristics associated with non-adherence to oral hypoglycemic agents**

Characteristics	$X^2$ (df)	OR	95% CI		P Value
			Lower	Upper	
Gender	0.05 (1)	0.91	0.43	1.96	0.817
Age	3.10 (3)				0.377
Religion	0.93 (3)				0.818
Marital status	3.64 (2)				0.162
Employment status	2.95 (4)				0.566
Income	2.00 (3)				0.572
Medical cover	0.23 (1)	1.27	0.48	3.34	0.630
Education level	4.58 (3)				0.205
Social support	0.55 (1)	0.70	0.27	1.81	0.459

#### 4.6.2 Social Perception Factors Associated with Non-adherence to Oral Hypoglycemic Agents

None of the social perception on causes of diabetes mellitus was significantly associated with non-adherence to oral hypoglycemic agents ( $P > 0.05$ ) (Table 4.4).

**Table 4.4: Association between perceived causes of diabetes mellitus and non-adherence to oral hypoglycemic agents**

Variables	$X^2$ (df)	OR	95% CI		P Value
			Lower	Upper	
God's will	0.96 (1)	1.62	0.61	4.28	0.328
Punishment for past sins	0.11 (1)	1.24	0.34	4.54	0.746
Stress	0.001 (1)	1.02	0.44	2.38	0.959
Eating sugary foods	0.39 (1)	0.77	0.33	1.77	0.532
Genetics	0.38 (1)	0.79	0.38	1.66	0.538
Eating fatty foods	0.002 (1)	0.98	0.44	2.22	0.965
Physical inactivity	0.14 (1)	0.86	0.40	1.87	0.708
Obesity	1.67 (1)	0.59	0.26	1.33	0.197

The perception that oral hypoglycemic agents are not necessary if sugary diets are not consumed was significantly associated with non-adherence to oral hypoglycemic agents ( $P = 0.045$ ). Those who were of the opinion that oral hypoglycemic agents were not necessary if sugary diets were not consumed had 2-fold risk of non-adherence (Table 4.5).

**Table 4.5: Association between perceived hindrances to taking oral diabetic medication and non-adherence to oral hypoglycemic agents**

Variables	$X^2$ (df)	OR	95% CI		P Value
			Lower	Upper	
Diabetes timeline	0.56(2)				0.756
Diabetic medicine necessity	2.54 (1)	0.952	0.90	1.01	0.250
Diabetic care prevents complications	0.08 (1)	0.81	0.19	3.41	1.000
Prayers can cure	2.51 (1)	2.70	0.76	9.54	0.134
Traditional medicine cures	0.68 (1)	0.39	0.04	3.90	0.626
No sugary foods no medicine	4.89 (1)	2.01	1.40	2.90	<b>0.045*</b>
No perceived hindrance	1.53 (1)	0.57	0.23	1.40	0.216

\*Statistically significant at  $P \leq 0.05$



### 4.6.3 Patient Related Factors Associated with Non-adherence to Oral Hypoglycemic Agents

Feeling better, being busy and forgetfulness were significantly associated with non-adherence to oral hypoglycemic agents with 4.8, 3.5 and 2.7 fold risk respectively ( $P \leq 0.05$ ) (Table 4.6).

**Table 4.6: Association between patient related factors and non-adherence to oral hypoglycemic agents**

Variables	X <sup>2</sup> (df)	OR	95% CI		P Value
			Lower	Upper	
Forgetfulness	5.44(1)	2.69	1.16	6.25	<b>0.02*</b>
Poor dose timing	0.88 (1)	1.43	0.68	3.02	0.349
Feeling better	6.00 (1)	4.80	1.24	18.51	<b>0.014*</b>
Feeling worse	1.49 (1)	3.81	0.38	37.82	0.326
Being busy	6.07 (1)	3.53	1.25	10.02	<b>0.014*</b>
Too many pills	0.68 (1)	0.39	0.04	3.90	0.626
Side effects avoidance	0.17 (1)	0.60	0.05	6.81	1.000
Being upset	0.58 (1)	2.49	0.22	28.27	0.588
Pills stock out	1.72 (1)	1.71	0.76	3.81	0.19
High medicine cost	0.21 (1)	1.21	0.54	2.73	0.646
Being away from home	2.15 (1)	2.02	0.78	5.19	0.143
Alcohol use	0.17 (1)	0.60	0.05	6.81	1.000
High transport cost to the clinic	0.96 (1)	0.62	0.61	4.28	0.328
Unclear medicine instructions	0.36 (1)	0.59	0.10	3.37	0.688
Stigma	0.02 (1)	1.22	0.07	20.00	1.000

\*Statistically significant at  $P \leq 0.05$

### 4.6.4 Health care system, Disease and Therapy Related Factors Associated with Non-adherence to Oral Hypoglycemic Agents

Use of two or more types of oral diabetic medication was significantly associated with non-adherence to oral hypoglycemic agents with 5.6 fold risk ( $P = 0.005$ ). The rest of the health care system, disease and therapy related factors were not significantly associated with non-adherence to oral hypoglycemic agents ( $P > 0.05$ ) (Table 4.7).

**Table 4.7: Association between health care system, disease, therapy related factors and non-adherence to oral hypoglycemic agents**

Variables	$X^2$ (df)	OR	95% CI Lower Upper	P Value
Diabetic pills availability at the hospital	0.74(1)	1.39	0.66 – 2.91	0.390
Distance from participants home to hospital	0.46(2)			0.794
Strained patient -provider relationship	1.50 (1)	1.81	0.70 – 4.72	0.220
Ever received diabetic education	0.94 (1)	0.61	0.22 – 1.68	0.332
Time since last diabetic education	0.36 (2)			0.837
Knows medication benefits	0.56 (1)	1.25	0.20 – 7.76	1.000
Co-morbidity	1.25 (1)	0.64	0.29– 1.46	0.264
Have diabetes complications	0.01(1)	0.97	0.39 – 2.39	0.938
Use of traditional medicines	0.55 (1)	0.58	0.14 – 2.46	0.510
Diabetes duration since diagnosis	1.66 (2)			0.437
Duration of oral diabetic medication use	0.16 (3)			0.984
Number of types of oral diabetic medication used	7.94 (1)	5.57	1.52 – 20.37	<b>0.005*</b>

\*Statistically significant at  $P \leq 0.05$

#### 4.7 Multivariate Analysis of Factors Associated with Non-adherence to Oral Hypoglycemic Agents

Variables from bivariate analysis with  $P \leq 0.15$  were fitted into the binary logistic regression model to identify factors independently associated with non-adherence to oral hypoglycemic agents. The variables included were being away from home, prayers and faith can cure diabetes, forgetfulness, feeling better, being busy, taking oral diabetic medicine was not necessary if sugary diets were not consumed and number of types of oral diabetic medication used. Using stepwise forward likelihood ratio method, the variables number of types of oral hypoglycemic agents used and forgetfulness were identified as the predictors of non-adherence to oral hypoglycemic agents. Use of two or more types of oral diabetic medications was significantly associated with non-adherence to oral hypoglycemic agents (AOR = 6.51; 95% CI: 1.63 – 25.03;  $P < 0.006$ ). Being forgetful was significantly associated with non-adherence to oral hypoglycemic agents (AOR = 3.12; 95% CI: 1.26 – 7.73;  $P < 0.014$ ) (Table 4.8).

**Table 4.8: Predictors of non-adherence to oral hypoglycemic agents on logistic regression**

Predictor variable	B	S.E.	df	P value	AOR	95% C.I.for AOR	
						Lower	Upper
Forgetfulness(1)	1.139	.462	1	<b>.014</b>	3.124	1.262	7.731
Number of types of oral diabetic medication (1)	1.873	.687	1	<b>.006</b>	6.509	1.693	25.028
Constant	-2.132	.682	1	.002	.119		

Where B is the Logistic coefficient, S.E is Standard Error; DF is the degrees of freedom and AOR is the Adjusted Odds Ratio

## CHAPTER FIVE

### DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

#### 5.1 Discussion

##### 5.1.1 Prevalence of Non-adherence to Oral Hypoglycemic Medications

Non-adherence to medication is common not only among diabetic patients but also among those suffering from chronic conditions (Kasznicki *et al.*, 2007; Sabate, 2003). In the current study among type 2 diabetic patients interviewed, 45.1% were non-adherent to oral hypoglycemic medications. This was in agreement with reports by other researchers (Sweileh *et al.*, 2014; Chua *et al.*, 2011; Nelson *et al.*, 2007) and different from the results of other studies (Unni *et al.*, 2014; Kalyango *et al.*, 2008; Rozenfeld *et al.*, 2008; Michael *et al.*, 2006; Lee & Taira, 2005; Lau & Nau, 2004). The difference in non-adherence rates could have been due to free treatment and medical insurance provided to comparison study populations making diabetic medication accessible to them; but in the current study, patients had to pay for treatment and very few had out patient medical insurance thus limiting their access to medication. This could have been attributed to differences in cut off points in the assessment of medication non-adherence. In comparison to other chronic diseases, non-adherence rate to oral hypoglycemic medication in the current study is higher than non-adherence rate to antiretroviral therapy in HIV/AIDS patients (Wakibi *et al.*, 2011) and antihypertensive medication (Ali *et al.*, 2014). However it is lower than non-adherence rate for antihypertensive medication for a study carried out in Kinshasa, Democratic Republic of Congo (Aimee *et al.*, 2015).

##### 5.1.2 Social Perceptions Associated with Diabetes Mellitus and its Treatment

Health perception of diabetic patients is considered as one of the most influential factors on health behaviours which help control complications (Pourghaznein *et al.*, 2013).

Most of the study participants perceived that diabetes was caused by stress, consuming sugary diets and eating fatty foods, being overweight or obese, physical inactivity and genetics. The findings are consistent with those of other studies (Jansiraninatarajan, 2013; Shiyabola & Nelson, 2011; Yuniarti *et al.*, 2013; Grace *et al* 2008; Irene *et al.*, 2005). A greater majority (97.3%) of the study participants were of the opinion that oral diabetic medication was necessary. A similar proportion (92.9%) perceived that taking best care of diabetes delays or prevents diabetes complications while a few (20.4%) perceived that diabetes illness lasted forever. These findings are similar to those of a study carried out in South Asia among people of Pakistan and Indian origin (Lawton *et al.*, 2005), most of the study participants perceived oral hypoglycemic agents as important part of their diabetic regimen.

In the current study some of the participants perceived diabetes to be caused by God's will, others as punishment from God for past sins while others viewed it was as a result of witchcraft. These findings are supported by Liani *et al.*, (2014) and Jijomon *et al.*, (2013) who also found similar perceptions. The current study further revealed that a few of the study participants were of the opinion that they only needed prayers to get better, others had the idea that one should abstain from ingesting anything including medicine from morning to evening during fasting period, still others thought that oral diabetic medication was not necessary if one does not eat sugary foods while others perceived that traditional medicine cured diabetes. The findings are consistent with those of a study carried out in India by Rai *et al.*, (2009). Since a person's behavior is dictated by ones perceptions, hence therefore religious and cultural perceptions held by some of the study participants could prevent them from seeking health services for diabetes. They could even abstain from taking diabetic medication resulting in development of diabetes complications. It is therefore important to empower patients through health education. In comparison to a study carried out in Nigeria (Iyalomhe G. & Iyalomhe S. 2010) among hypertensive patients, high blood pressure was perceived to be caused by hereditary and witchcraft which was similar to the findings of the current study.

### **5.1.3 Factors Associated with Non-adherence to Oral Hypoglycemic Agents**

The study revealed that, none of the social demographic and economic characteristics namely gender, age, religion, marital status, employment, income, level of education, medical insurance and social support were significantly associated with non-adherence to oral hypoglycemic agents. The findings are consistent with results from other studies (Mandewo *et al.*, 2014; Faria *et al.*, 2013; Mahfouz *et al.*, 2011; Gimenes *et al.*, 2009; Ronquillo *et al.*, 2003). The findings contrasts with studies carried out in Uganda (Kalyango *et al.*, 2008) in which female gender was significantly associated with non-adherence to oral hypoglycemic agents and in Nigeria (Adisa *et al.*, 2009) where gender and occupation were significantly associated with non-adherence to oral hypoglycemic medications. This could have been as a result of not adjusting for confounding factors for the Nigerian study. The findings also differed from those studies carried out in Hawaii (Lee & Taira, 2005) and France (Tiv *et al.*, 2012) where adherence was strongly associated with age. Perhaps this could have been due to differences in sample sizes. Lack of health insurance was reported to be significantly associated with non-adherence to oral hypoglycemic agents in a study carried out in United Arab Emirates (Koprulu *et al.*, 2013) while lower education level was observed to be significantly associated with non-adherence to oral hypoglycemic agents for studies done in Iran (Farsaei *et al.*, 2011) and United Arab Emirates (Koprulu *et al.*, 2013) which is not the case in the current study. Various studies (Mandewo *et al.*, 2014; Kalyango *et al.*, 2008; Tiv *et al.*, 2007) reported social support to be significantly associated with adherence to oral diabetic medication. The findings do not correspond to those of the current study. This could be due to differences in lifestyles among populations in various countries whereby some could be more cohesive and supportive than others. Populations in Uganda embrace strong extended family system where other relatives and distant relations live in the same house (Karimli *et al.*, 2012) consequently more social support would be expected in extended family way of life than the nuclear family system which is common in Kenya (Kimani & Kombo, 2010). In comparison to a study involving hypertensive study

participants, non-adherence to antihypertensive medication was significantly associated with age and education attainment level; younger and lower education attainment groups were more likely to be non-adherent (Cho *et al.*, 2014). The findings do not correspond to those of the current study.

Patients' disease and treatment related perceptions influence treatment engagement and adherence (Sweileh *et al.*, 2014; Horne *et al.*, 2013). In the current study, none of the social perceptions on diabetes mellitus and its treatment were significantly ( $P > 0.05$ ) associated with non-adherence to oral hypoglycemic agents. Despite majority having the perception that oral diabetic medication was necessary for them and that taking best care of diabetes prevented or delayed diabetes complications in the current study, there was no significant difference between the adherent and non-adherent groups. The findings are similar to those reported in South Dakota (Shiyanbola & Nelson, 2011) where there were no differences in illness perceptions and beliefs in medicine between adherent and non-adherent participants. However the findings differ from those of other studies (Sweileh *et al.*, 2014; Horne *et al.*, 2013) where high adherence rate was significantly associated with stronger perceptions of treatment necessity. This could have been due to differences in their socio-economic status. The findings in the current study also differs from those of a study conducted in United Kingdom (Ross *et al.*, 2004), in that study participants who believed in the necessity of medication were significantly associated with adherence to antihypertensive medication.

Having at least one perception either cultural, religious or lay perceptions which hindered study participants from using their oral diabetic medication was not significantly associated with non-adherence to oral hypoglycemic agents in the current study. The findings are in line with those of a study carried out in Zimbabwe (Mandewo *et al.*, 2014) which observed that religion, culture and consulting of traditional healers were not significantly associated with non-adherence ( $P > 0.05$ ).

In the current study, the most commonly mentioned reasons for missing diabetic medication were poor dose time keeping, stock out and high cost of the medication, forgetfulness, being away from home, busy, high cost of transport to the clinic and feeling well. These findings are consistent with those of studies carried out in other countries (Shrestha *et al.*, 2013a; Mukherjee *et al.*, 2013; Okoro & Ngong, 2012; Wabe *et al.*, 2011; Farsaei *et al.*, 2011; Chua *et al.*, 2011; Adisa *et al.*, 2009). Forgetfulness, feeling better and being busy were significantly associated with non-adherence to oral hypoglycemic agents in the bivariate analysis. The findings are consistent with those of studies conducted in Zimbabwe (Mandewo *et al.*, 2014) and United Arab Emirates (Koprulu *et al.*, 2013) in regard to having significant association between forgetfulness and non-adherence. In a study carried out in Kenya (Wakibi *et al.*, 2011), the main reasons given for missing antiretroviral therapy in HIV/AIDS patients were being busy and forgetting. In another study conducted in Nigeria (Olowookere *et al.*, 2008), forgetfulness was significantly associated with non-adherence to antiretroviral therapy. The findings in the two studies were similar to those of the current study.

None of disease related factors namely existing diabetes complications, duration of having diabetes and co-morbidity were significantly associated with non-adherence to oral hypoglycemic agents in the current study. The findings are similar to those of previous investigations (Teklay *et al.*, 2013; Khan *et al.*, 2012). A study conducted in the United Arab Emirates (Koprulu *et al.*, 2014), reported lack of significant association between disease duration and non-adherence which was similar to the current study; however co-morbidities was reported to be significantly associated with non-adherence which contrasted with the current study. The findings also differs from those of studies conducted in India (Mukherjee *et al.*, 2013) and Mexico (Ronquillo *et al.*, 2003) where there was a significantly higher risk of non-adherence among those who had diabetes for 5 or more years and co-morbidity related to hypertension and obesity respectively. Existing diabetes complication was significantly associated with non-adherence for a study carried out in France (Tiv *et al.*, 2012) which was different from the current study.



In a study conducted in Ethiopia (Ali *et al.*, 2014) among hypertensive study participants, hypertension related complications were found to be strongly associated with treatment non-adherence. The findings differ from those of the current study.

Therapy related factors that is, duration of using oral diabetic medication, taking of traditional medicine, co-medication for other long term illness and side effects of the drugs were not significantly associated with non-adherence to oral hypoglycemic agents. The only drug related factor found to be significantly associated with non-adherence to oral hypoglycemic agents in the current study was the use of two or more types of oral diabetic medication by the study participants. The findings are in agreement with the views of Koprulu *et al.*, (2014), Shams *et al.*, (2010), Melikian *et al.*, (2002) and Dailey *et al.*, (2001) where loose combination therapy was significantly associated with non-adherence as compared to monotherapy or fixed dose combination. The findings contrasts with those of a study conducted in Uganda (Kalyango *et al.*, 2008) where no significant association was observed between the number of types of drugs and non-adherence. This could have been due to use of different assessment methods whereby the current study assessed the association with non-adherence against those taking one type of drug and those taking two types of drugs and above; while the Ugandan study assessed the association against those taking two types of drugs or less and those taking more than two types of drugs. In another study carried out in Nepal (Shrestha *et al.*, 2013a) no significant difference was found among single, two and more than two drug users which contradicted the current study. Perhaps it could be due to differences in health care settings. In view of the fact that Nepal study site (Dhulikhel hospital) is a non-government, tertiary care University hospital (Shrestha *et al.*, 2013b) better healthcare services would be expected in terms of medication adherence counseling as opposed to Mbagathi which is only a government district hospital. In other studies done in United Arab Emirates (Koprulu *et al.*, 2014; Ethiopia (Abebe *et al.*, 2014) use of traditional medicine was associated with non-adherence to diabetic medication. These findings contrasted with those of the current study and could have been due to

differences in cultures in which they belonged. Ninety percent of the population in Ethiopian use herbal remedies for their primary health care (Mahomoodally, 2013) while in contemporary United Arab Emirates society, herbs and plants are still widely used for diabetes (Hurriez, 2002) unlike Kenya where use of traditional medicine is low (8%) going by the findings of the current study. The cultural beliefs and preference of traditional medicines in Ethiopia and United Arab Emirates would impact negatively on adherence to conventional medicines. The long duration of diabetes treatment greater than ten years was found to be significantly associated with non-adherence to oral hypoglycemic medications in a study conducted in Zimbabwe (Mandewo *et al.*, 2014) which did not agree with the current study. This could have been due to differences in levels of diabetes awareness. In Kenya, 27.2% of diabetic patients were reported to have good knowledge of diabetes (Maina *et al.*, 2010) and 20.7% in Zimbabwe (Mufunda *et al.*, 2012). This shows that a bigger proportion of people in Zimbabwe than Kenya may not have known that diabetes is not curable and that its treatment is life-long and therefore they were more likely to default treatment. A study involving study participants on antihypertensive therapy revealed that the experience of adverse drug effects was significantly associated with non-adherence to antihypertensive medication (Jokisalo *et al.*, 2002). The findings differed from those of the current study.

In the current study, none of the health care system related factors specifically the availability of diabetic medication, distance from health facility, patient-health care provider relationship, diabetic education and high medication cost was significantly associated with non-adherence to oral hypoglycemic agents. The findings are consistent with those of a study carried out in Ethiopia (Teklay *et al.*, 2013) in regard to the distance from the health facility. However the findings do not agree with those of a study done in Zimbabwe (Mandewo *et al.*, 2014) where distance from health facility, having attended two or more sessions of health education in the past 6 months and non affordability of drugs were significantly associated with non-adherence. The differences could have been due to the fact that a higher population (72.3 %) lives below poverty

line in Zimbabwe as compared to Kenya (45.9 %) (World Bank, 2015) where the current study was conducted. Therefore few people in the Zimbabwe study could afford the cost of their medication as well as transport cost to the health facility. In comparison to a study carried out in Democratic Republic of Congo (Aimee *et al.*, 2015) among hypertensive study participants, unavailability of antihypertensive drugs in health facilities and lack of hypertensive patient's education in health care facilities were significantly associated with non-adherence to antihypertensive medications. The findings were not consistent with those of the current study with regards to similar variables.

**Study limitation:** The use of subjective self reporting method of measuring non-adherence to oral hypoglycemic agents in this study had potential recall bias and underestimation of non-adherence to medication. This was minimized by asking the study participants to recount how they took their oral diabetic medications for the last one week preceding the interview and explaining the importance of honest reporting.

## **5.2 Conclusions**

1. Type 2 diabetes mellitus outpatients at Mbagathi District Hospital have a high (45.1%) prevalence of non-adherence to oral hypoglycemic medication(s).
2. The commonest social perceptions by study participants on causes of diabetes were stress, consuming sugary diets, eating fatty foods, obesity, physical inactivity and genetics. Twenty seven percent of the study participants had at least one perception that hindered them from using their oral diabetic medication(s).
3. Use of two or more types of oral hypoglycemic medications by the study participants and forgetfulness are factors associated with non-adherence to oral hypoglycemic medication(s) among type 2 outpatients at Mbagathi District Hospital.

### **5.3 Recommendations**

1. Continuous education of the patients on the importance of adherence to diabetic medication and the consequences of non-adherence whenever they go for clinic appointments and assessment of the level of non-adherence to oral hypoglycemic medications should be done from time to time.
2. The health care workers should dispel negative perceptions surrounding diabetes mellitus and its treatment by giving health talks to patients during diabetic clinic days.
3. The clinicians should simplify the medication regimen by using monotherapy as much as possible otherwise the patients should be put on fixed dose combination therapy with the view of reducing pill burden and improving adherence. The government should therefore introduce fixed dose combination of oral hypoglycemic agents in public health facilities.
4. A reminder system should be devised in-order to assist the patients in taking their oral diabetic medications on daily basis in a timely manner.

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**APPENDICES**

**Appendix 1: Questionnaire**

Questionnaire Number      \_\_ \_\_ \_\_

Date of interview dd/mm/yy   \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_

Interviewer's initials   \_\_ \_\_

**Please Tick Only One Response Unless Instructed**

**Part A: Demographic Data**

1. Gender

Male..... 1      Female.... 2

2. What is your age in years? \_\_\_\_\_ Years

3. What is your religion?

No religion ..... 0      Muslim ...1    Protestant/Other Christian...2  
Roman catholic..3      Other (Please specify)\_\_\_\_\_4

4. What is your marital status?

Never married...1      Married .....2  
Widowed .....3      Divorced or separated .....4

5. What is your employment status?

Not working .....0      House work .....1  
Informal employment ...2      Formal employment .....3

Retired.....4                      Other (Please specify) \_\_\_5

6. How much is your monthly income in Kenya shillings?

< 9,999.....1                      10,000 - 19,999.....2  
 20,000 - 29,999.....3                      30,000 - 39,999.....4  
 40,000 - 49,999.....5                      ≥ 50,000.....6

7. Do you have an out patient medical cover / medical insurance?

No .....0                      Yes.....1

8. What is your highest level of education?

No formal education.....0                      Primary school not completed.....1  
 Primary school completed ..2                      Secondary school not completed...3  
 Secondary school completed ...4                      College .....5  
 University .....6                      Other (Please specify) \_\_\_\_\_7

**Part B: Social perceptions on diabetes mellitus and its treatment**

9. What reasons do you believe causes diabetes illness?

**You can tick more than one response**

	Reasons	No = 0	Yes = 1
A	Gods will		
B	It is punishment from God for past sins		
C	It is caused by evil spirit or witchcraft		
D	Stress		

E	Eating too much sugary foods and sodas		
F	Genetics (hereditary) / Diabetes runs in the family		
G	Eating fatty foods		
H	Not doing enough physical exercises		
I	Being overweight or obese		
J	Others(please specify)		

10. How long do you think your diabetes illness will continue?

< 3months .....1    3- 6 months .....2  
7 – 11 months....3    1- 3 years.....4  
>3 years.....5    Forever.....6  
Others (Please specify)\_\_\_\_\_7

11a. Are you on oral diabetic medication?

No .....0                      —————> Terminate the interview  
Yes .....1

11b. **IF YES**, do you think oral diabetic medication is necessary for you?

No .....0                      Yes .....1

12. Do you believe taking best care of diabetes (taking medication, eating healthy diet, exercise etc) will delay or prevent, heart disease, high blood pressure, kidney, eye, and foot problems?

No .....0                      Yes .....1

13. Some beliefs hinder people from using their medications; what beliefs (religious, cultural practices and lay beliefs) about diabetes and its treatment may hinder you from using your diabetic medication?

**You can tick more than one response**

	<b>Beliefs</b>	<b>No = 0</b>	<b>Yes = 1</b>
a	Prayers is enough to get better		
b	Doctors practice witchcraft		
c	One should not swallow anything from sunrise to sunset during fasting period		
d	Traditional / herbal medicines cures diabetes		
E	Diabetes is caused by witchcraft & only traditional healers can cure it		
E	No need of taking diabetic medicine if one does not eat sugary foods		
G	None		
H	Others (Please specify)		

**Part C: Oral Hypoglycemic Use adherence/Non-adherence**

14. How many types of oral diabetic medication are you currently on?

One .....1                      Two.....2  
 Three.....3                      More than three...4

15. Thinking over the past one week, for each of the oral diabetic medication that you are currently on, please answer each of the questions in the boxes below

Type of Medication	How many days did you take it that week?	How many times per day did you take it?	How many tablets did you take each time?	How many times did you miss taking it that week?	How many times did you take fewer tablets per dose that week	Total number of tablets taken divided by Number required to be taken that week x 100% (entry by officials)

Type 1						
Type 2						
Type 3						

**Part C: Factors associated with non-adherence to oral hypoglycemic agents**

16. How long ago were you told you had diabetes? \_\_\_\_\_ Years

17. How long have you been on oral diabetic medication? \_\_\_\_\_ Months

18. Sometimes people have difficulty taking their medicines for one reason or another. Do you sometimes forget to take your diabetes pills?

No .....0                      Yes .....1

19. Do you sometimes have problems remembering to take your diabetic medication at the assigned / right time?

No .....0                      Yes.....1

20. When you feel better, do you sometimes stop taking your diabetic medication?

No.....0                      Yes.....1

21. Sometimes when you feel worse when you take diabetic medication, do you stop taking it?

No.....0                      Yes.....1

22. People miss taking their medication for various reasons. What reasons sometimes make you miss taking your diabetic medication as prescribed?

**You can tick more than one response)**

	Possible Reasons	No = 0	Yes =1
A	When you are busy with other things?		
B	When you have too many pills to take?		
C	When you want to avoid side effects?		
D	When you are upset/ depressed or overwhelmed?		
E	When you ran out of pills?		
F	When you cannot afford the drugs?		
G	When you are away from home?		
H	When you take alcohol?		
I	When you do not have money for transport to go to the clinic?		
J	When you do not understand how to take diabetic medication?		
K	When you do not want others to notice that you are taking diabetic medication?		
L	Other (Please specify)		

23a. Did you get **all** the diabetic medication(s) that you are currently on from Mbagathi Hospital pharmacy?

No .....0

Yes .....1 → Go to Q24

23b. **IF NO**, why? \_\_\_\_\_

24. How far do you live from the health facility where you collect your diabetic medication in kilometers? \_\_\_\_\_ Kilometers

25. Do you find it difficult asking health care providers (Doctors, nurses, pharmacists) questions about diabetes and its treatment?



No.....0      Yes .....1

26a. Have you ever received diabetic education?

No.....0      —→      Go to Q27  
Yes.....1

26b. **IF YES**, how long ago did you receive the last diabetic education?  
\_\_\_\_\_Months

27. Do you know the benefits of taking your diabetic medicine as told to you by health care provider?

No.....0      Yes .....1

28. Are you on any other medication for other long term illnesses? (Illnesses lasting for more than 3 months)

No.....0      Yes.....1

29. Have you ever been told by a health care provider that you have any of the following problems, eye, heart, high blood pressure, kidney or feet problem?

No .....0      Yes .....1

30. Do those around you and your family encourage you to take your diabetes medication?

No.....0      Yes .....1

31. Do you sometimes take traditional medicine for managing diabetes?

No .....0      Yes ....1

**Thank you for your time and for participating in this study**

## **Appendix 2: Fomu la Hoji**

Nambari ya fomu la hoji \_\_\_ \_\_ \_\_

Tarehe ya mahojiano siku/mwezi/mwaka \_\_\_ \_\_ / \_\_\_ \_\_ / \_\_\_ \_\_

Herufi za mwanzo za majina ya mhoji \_\_\_ \_\_

**Tafadhali weka tick kwa jibu moja tu isipokuwa pale utakapoagizwa vinginevyo.**

### **Sehemu ya A. Demografia**

#### **1. Jinsia**

Mwanamume.....1 Mwanamke.....2

#### **2. Una miaka mingapi? \_\_\_\_\_**

#### **3. Dini yako ni gani?**

Sina dini...0 Muislamu.....1 Protestanti/mkristomwingine...2

Mkatoliki...3 Nyingineyo (Tafadhali eleza).....4

#### **4. Hali yako ya ndoa ni gani?**

Sijawahi kuolewa au kuowa...1 Nimeoa/kuolewa.....2

Nimefiwa .....3 Nimetalikiwa/kutengana...4

#### **5. Hali yako ya ajira ni gani?**

Sifanyi kazi.....0 Kazi ya nyumba.....1

Ajira ya vibarua....2 Ajira ya mshahara.....3

Nimestaafu.....4 Nyingineyo (Tafadhali eleza).....5

#### **6. Je, pato lako la mwezi ni la kiwango gani?(Kshs)**

≤9,999.....1 10,000- 19,999.....2

20,000-29,999.....3 30,000-39,999.....4

40,000-49,999.....5 ≥50,000. ....6

#### **7. Je una bima ya matibabu kwa wagonjwa wasiolazwa?**

La.....0                      Ndiyo.....1

8. Je, kiwango chako cha juu cha masomo ni kipi?

Sina elimu yoyote.....0                      Shule ya msingi lakini sikukamilisha.....1

Shule ya msingi nilikamilisha...2                      Shule ya upili lakini sikukamilisha...3

Shule ya upili nilikamilisha...4                      Chuo anuwai.....5

Chuo Kikuu.....6                      Nyingineyo(Tafadhali eleza)\_\_\_7

**Sehemu ya B. Mtazamo wa Kijamii Kuhusu Ugonjwa wa Kisukari na Tiba Yake.**

9. Ni sababu gani unazoamini husababisha ugonjwa wa kisukari?

**Unaweza kuweka tick kwa zaidi ya jibu moja**

	<b>Sababu</b>	<b>La = 0</b>	<b>Ndio = 1</b>
a	Mapenzi ya Mungu		
b	Ni adhabu kutoka kwa Mungu kwa ajili ya dhambi za zamani		
c	Inatokana na roho mbaya au kurogwa		
d	Matatizo ya dunia		
e	Kukula vyakula vyenye sukari nyingi na soda		
f	Una rithiwa / ugonjwa wa kisukari uko katika familia		
g	Kukula chakula chenye mafuta nyingi		
h	Kutofanya mazoezi ya kimwili ya kutosha		
i	Kuwa na uzito unaozidi au unene wa kupindukia		
j	Nyingineo ( Tafadhali eleza)		

10. Unadhani hali yako ya ugonjwa wa kisukari itadumu kwa muda gani?

Chini ya miezi mitatu.....1

Miezi 3-6.....2

Miezi 7-11 .....3                      Mwaka 1-3.....4  
 Zaidi ya miaka tatu.....5              Itadumu milele.....6  
 Nyingineo (Tafadhali eleza) \_\_\_\_\_7

11. a. Je, unatumia dawa za kumeza za ugonjwa wa kisukari?

La..... 0      —————>      sitisha mahojiano  
 Ndiyo.....1

12b. **KAMA NDIYO**, je, unadhani tiba ya ugonjwa wa kisukari kwa kutumia dawa za kumeza ni muhimu kwako?

La.....0                      Ndiyo.....1

12. Je, unaamini kwamba uthibiti bora wa kisukari (kumeza dawa, kula chakula bora, kufanya mazoezi na kadhalika) utasaidia kuchelewesha au kuzuia ugonjwa wa moyo, shinikizo la damu mwilini, matatizo ya figo, macho na mguu?

La.....0                      Ndiyo.....1

13. Baadhi ya imani huzuia watu kutumia dawa zao; Je ni imani gani (ya dini, mila, au imani fulani) kuhusu ugonjwa wa kisukari na matibabu yake, ambayo inaweza kukuzuia kumeza dawa zako za kisukari?

**Unaweza kuweka tick kwa zaidi ya jibu moja**

	<b>Imani</b>	<b>La = 0</b>	<b>Ndio= 1</b>
A	Maombi na imani inatosha ili kuhisi nafuu		
B	Madaktari hutumia uchawi		
C	Mtu hapaswi kumeza kitu chochote kuanzia asubuhi hadi jioni wakati wa kufunga.		
D	Dawa za kitamaduni na mitishamba zinaweza kutibu kisukari		
E	Ugonjwa wa kisukari husababishwa na uchawi na waganga wa kitamaduni ndio wanaweza kuutibu		

<i>F</i>	<i>Hakuna haja ya kutumia dawa kama mtu hakuli vyakula vyenye sukari mwingi</i>		
<i>G</i>	<i>Hakuna Imani yoyote</i>		
<i>H</i>	<i>Nyingineo (tafadhali eleza)</i>		

***Sehemu ya C: Kuzingatia/ Kutozingatia Matumizi ya Dawa za Kumeza za Tiba ya Kisukari.***

*14. Je, kwa sasa unatumia aina ngapi za dawa za kumeza za ugonjwa wa kisukari?*

*Moja .....1                      Mbili.....2*

*Tatu.....3                      Zaidi ya tatu.....4*

*15. Ukiwa na fikra za wiki moja iliyopita, kwa kila aina ya dawa za kumeza za ugonjwa wa kisukari unazotumia sasa, tafadhali jibu kila swali kwa vijisanduku vya hapo chini.*

<i>Aina ya dawa</i>	<i>Ulimeza dawa kwa siku ngapi (wiki hiyo)?</i>	<i>Ulimeza dawa mara ngapi kwa siku?</i>	<i>Ulimeza tembe ngapi kila wakati ulipomeza?</i>	<i>Je, ni mara ngapi ulikosa kumeza dawa wiki hiyo?</i>	<i>Ulimeza tembe chache kuliko kipimo mara ngapi wiki hiyo?</i>	<i>Jumla ya dawa zilizomezwa gawa na idadi ya dawa zinazofaa kumezwa kwa wiki hilo x 100% (Hii itafanywa na maafisa)</i>
<i>Aina ya kwanza</i>						
<i>Aina ya pili</i>						
<i>Aina ya tatu</i>						

***Sehemu ya D: Sababu Zinazohusishwa na Kutozingatia kwa Matumizi ya Dawa za Kumeza za Ugonjwa wa Kisukari***

16. Imepita miaka mingapi tangu ulipoambiwa kuwa una kisukari? \_\_\_\_\_

17. Je, umetumia dawa za kumeza za ugonjwa wa kisukari kwa muda wa miezi ngapi? \_\_\_

18. Mara kwa mara, watu huwa na ugumu wa kutumia dawa zao kwa sababu moja au nyingine. Je, wakati mwingine wewe husahau kumeza dawa zako za ugonjwa wa kisukari?

La.....0                      Ndiyo.....1

19. Je, wakati mwingine wewe huwa na matatizo ya kusahau kumeza dawa zako za ugonjwa wa kisukari kwa wakati ufaao?

La.....0                      Ndiyo.....1

20. Je, wakati mwingine wewe huacha kumeza dawa zako za ugonjwa wa kisukari unapohisi nafuu?

La.....0                      Ndiyo.....1

21. Wakati mwingine ukihisi vibaya mno unapomeza dawa za ugonjwa wa kisukari; je, wewe huacha kutumia dawa hizo?

La.....0                      Ndiyo.....1

22. Watu hukosa kutumia dawa zao kwa sababu mbalimbali. Je, ni sababu gani wakati mwingine hukufanya ukose kumeza dawa zako za ugonjwa wa kisukari kama ulivyoshauriwa?

**Unaweza kuweka tick kwa zaidi ya jibu moja**

	<i>Sababu zinazowezezana</i>	<i>La = 0</i>	<i>Ndiyo = 1</i>
<i>A</i>	<i>Wakati wewe uko na shughuli zingine?</i>		
<i>B</i>	<i>Wakati uko na dawa nyingi za kumeza?</i>		
<i>C</i>	<i>Wakati unataka kuepuka madhara ya dawa?</i>		
<i>D</i>	<i>Wakati umekasirika au kuhuzunika kupita kiasi?</i>		
<i>E</i>	<i>Ukiishiwa na dawa?</i>		
<i>F</i>	<i>Ukiwa huna uwezo wa kununua dawa?</i>		
<i>G</i>	<i>Ukiwa mbali na nyumbani?</i>		
<i>H</i>	<i>Ukiwa umelewa pombe?</i>		
<i>I</i>	<i>Ukiwa huna na nauli ya kwenda kliniki au kituo cha afya?</i>		
<i>J</i>	<i>Wakati hujaelewa namna ya kumeza dawa?</i>		
<i>K</i>	<i>Wakati hutaki watu wengine watambue kuwa unatumia dawa za kisukari?</i>		
<i>L</i>	<i>Nyingineo (Tafadhali eleza)</i>		

23a. Je, ulipata dawa **zote** za ugonjwa wa kisukari **unazotumia kwa wakati huu** kutoka kwa famasia ya hospitali ya Mbagathi?

*La.....0*

*Ndiyo.....1*      **—————>** *Nenda kwa swali la 24*

23b. **KAMA LA**, kwa nini? \_\_\_\_\_

24. Je, unaishi umbali wa kilomita ngapi kutoka kwa kituo cha afya ambako wewe huchukua dawa zako za ugonjwa kisukari? \_\_\_\_\_

25. Je, wewe huona ugumu wa kuwauliza wahudumu wa afya (madaktari, wauguzi, wafamasia) maswali kuhusu ugonjwa wa kisukari na tiba yake?

La.....0                      Ndiyo.....1

26a. Je, umewahi kupata mafunzo kuhusu ugonjwa wa kisukari?

La.....0                      —————> Nenda kwa swali la 27

Ndiyo.....1

26b. **KAMA NDIYO**, ni miezi ngapi iliyopita tangu upokee mafunzo ya mwisho? \_\_

27. Je, unajua umuhimu wa kutumia dawa zako za ugonjwa wa kisukari kama unavyoambiwa na wahudumu wa afya?

La.....0                      Ndiyo.....1

28. Je, unatumia dawa ya kumeza yoyote ya magonjwa mengine sugu? (Ugonjwa uliodumu kwa zaidi ya miezi mitatu)

La.....0                      Ndiyo.....1

29. Je, umewahi kuambiwa na mhudumu wa afya kuwa una tatizo lolote la ifuatayo: tatizo ya macho, moyo, shinikizo la damu mwilini, figo au miguu?

La.....0                      Ndiyo.....1

30. Je, wale walio karibu nawe, na familia yako hukuhimiza moyo kumeza dawa zako za ugonjwa wa kisukari?

La.....0                      Ndiyo.....1

31. Je, wakati mwingine wewe hunywa dawa za kienyeji ili kudhibiti ugonjwa wa kisukari?

La.....0                      Ndiyo.....1

**Asante kwa muda wako na kwa kushiriki katika utafiti huu.**



### **Appendix 3: Key Informant Interview Guide**

Interview Guide Number \_\_ \_\_ \_\_

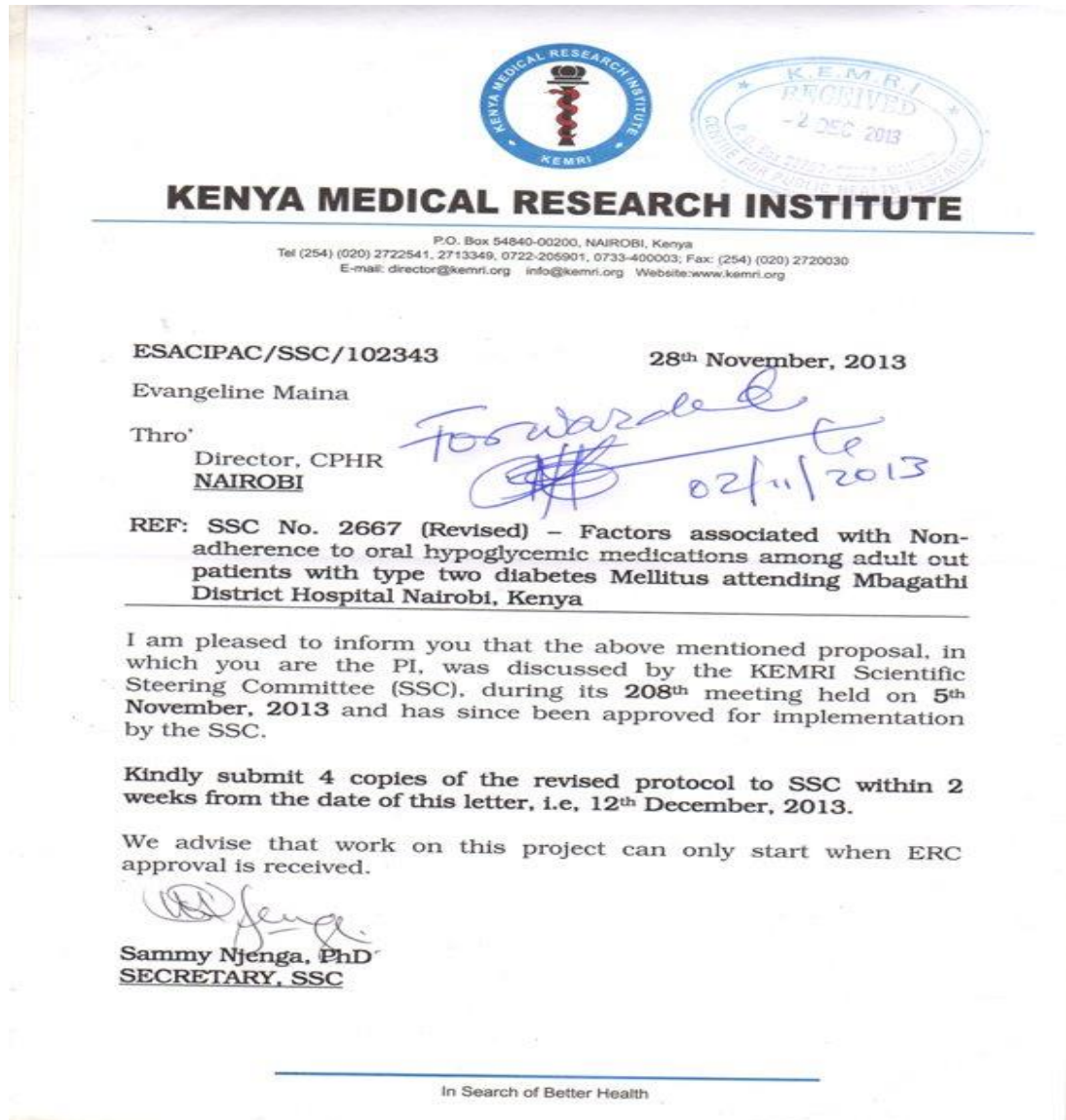
Respondent Title \_\_\_\_\_

Date of interview \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_



- Q1. Please tell me about adherence to oral hypoglycemic agents among type 2 diabetic patients attending your clinic?
- Q2. How does non-adherence to oral hypoglycemic agents, seem apparent in type 2 diabetic out patients attending your clinic?
- Q3. Approximately, what is the proportion of those who do not adhere to oral hypoglycemic agents?
- Q4. What are the patients' social perceptions surrounding diabetes mellitus and its treatment?
- Q5. What are the reasons for not adhering to oral hypoglycemic medication as reported to you by the patients?
- Q6. In your view, how does health system within which you operate, contributes to non-adherence to oral hypoglycemic agents among type 2 diabetic patients attending your clinic?
- Q7. What else would you like bring up in relation to non-adherence to oral hypoglycemic agents among type 2 diabetic out patients attending your clinic?

**Thank you for taking time to participate in this interview**

**Appendix 4: Scientific Steering Committee Approval**



## Appendix 5: Ethics Review Committee Approval



**KENYA MEDICAL RESEARCH INSTITUTE**

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P.O. Box 54840-00200, NAIROBI, Kenya  
Tel (254) (020) 2722541, 2713349, 0722-205901, 0733-400003; Fax: (254) (020) 2720030  
E-mail: [director@kemri.org](mailto:director@kemri.org) [info@kemri.org](mailto:info@kemri.org) Website: [www.kemri.org](http://www.kemri.org)

**KEMRI/RES/7/3/1** **March 11, 2014**

**TO:** **EVANGELINE W. MAINA (PRINCIPAL INVESTIGATOR)**

**THROUGH:** **DR. CHARLES MBAKAYA** *Forwarded and Congratulations*  
*for* **ACTING DIRECTOR, CPHR**  
**NAIROBI** *13-3-2014*

Dear Madam,

**RE: SSC NO. 2667 (RESUBMISSION 3): FACTORS ASSOCIATED WITH NON ADHERENCE TO ORAL HYPOGLYCEMIC MEDICATIONS AMONG ADULT OUT PATIENTS WITH TYPE TWO DIABETES MELLITUS ATTENDING MBAGATHI DISTRICT HOSPITAL NAIROBI, KENYA**

Reference is made to your letter dated 24<sup>th</sup> February 2014. The ERC Secretariat acknowledges receipt of the revised document on 4<sup>th</sup> March 2014

This is to inform you that the Ethics Review Committee (ERC) reviewed the document submitted, and is satisfied that the issue raised at the 223<sup>rd</sup> meeting, has been adequately addressed.

This study is granted approval implementation effective this **March 11, 2014**. Please note that authorization to conduct this study will automatically expire on **March 10, 2015**. If you plan to continue with data collection or analysis beyond this date please submit an application for continuing approval to the ERC secretariat by **January 27, 2015**.

You are required to submit any amendments to this protocol and other information pertinent to human participation in this study to the SSC and ERC for review prior to initiation.

You may embark on the study.

Yours faithfully,  
*EAB*

**DR. ELIZABETH BUKUSI,**  
**ACTING SECRETARY,**  
**KEMRI/ETHICS REVIEW COMMITTEE**

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In Search of Better Health

## Appendix 6: Mbagathi District Hospital Research Authorization Letter

### MINISTRY OF HEALTH

Tel: 2724712, 2725791, 0721 311 808  
www.mbagathihospital.org  
info@mbagathi.org,  
mdhnaïrobi@yahoo.co.uk  
Our Ref: MS/VOL.1/2013/14



Mbagathi District Hospital  
P.O. Box 20725- 00202  
Nairobi

24<sup>th</sup> March 2014

**Evangeline W. Maina**  
Institute of Tropical Medicine and Infectious Diseases  
Jomo Kenyatta University of Agriculture and Technology

Dear Madam,

**RE: RESEARCH AUTHORIZATION**

This is in reference to your application for authority to carry out a research on "*Factors associated with non – adherence to oral hypoglycemic agents among adult outpatients with type 2 diabetes mellitus attending Mbagathi District Hospital, Nairobi*"

I am pleased to inform you that your request to undertake the research in the hospital has been granted.

On completion of the research you are expected to submit one hard copy and one soft copy of the research report / thesis to this office.

MEDICAL SUPERINTENDENT  
MBAGATHI DISTRICT HOSPITAL  
P. O. BOX 20725  
NAIROBI, KENYA  
TEL. 2728532 / 2724712  
**Dr. A. J. Suleh**  
Medical Superintendent  
Mbagathi District Hospital

## **Appendix 7: The Informed Consent Form**

**Title of the research study:** Factors associated with non-adherence to oral diabetic medication among adult out patients with type 2 diabetes mellitus attending Mbagathi district hospital Nairobi, Kenya.

### **Principal Investigator and Institutional affiliation**

Evangeline Maina, Masters of Science in Public Health, Institute of tropical Medicine and Infectious diseases, Jomo Kenyatta University of Agriculture and Technology.

## **PART A**

### **Introduction:**

You are invited to participate in this study because the number of people suffering from diabetes mellitus is increasing in our country Kenya and non-adherence to oral diabetic medication has been shown to worsen the disease condition leading to heart attack, stroke, kidney failure, nerve damage and blindness.

### **Purpose of the Study:**

The aim of this study is to determine the proportion of people who do not adhere to oral diabetic medication as well as identifying the reasons for non-adherence to oral diabetic medication in adult out patients with type 2 diabetes mellitus attending Mbagathi district hospital. The information gathered will assist the government to design programmes and policies to enhance adherence to oral diabetic medication.

### **Study Procedure**

You must be at least 18 years old to participate in this research. If you agree to take part in this study, you will be interviewed on age, gender, marital status, occupation, level of

education, use of diabetic medicine and reasons for not adhering to oral diabetic medication. It will take about 20- 30 minutes to answer these questions.

### **Risk of Study Participation**

We do not anticipate any risks or discomforts to you. You will be requested to avail yourself for interview. We will protect your privacy and confidentiality during your participation in the study. The interview will take place in private and it is unlikely any harm will happen to you as a result of being in the study.

### **Research Benefits:**

Your participation in this study will improve your knowledge on diabetes mellitus and the importance of adherence to therapies also, you and the Hospital management will be informed of the research findings for immediate interventions to be put in place to improve adherence. By answering our questions, you will help increase our understanding of the reasons behind non-adherence to oral diabetic medication among adult type 2 diabetic out patients. In future, you and others may benefit from this study as the results will be used to assist the Ministry of Health (MOH) to take the necessary steps to enhance adherence to oral diabetic medication and to formulate policies and programmes to improve the services given to diabetic patients in our health facilities and thus prevent them from developing complications of diabetes mellitus.

### **Study Cost**

There is no cost that will be incurred by you for participating in this study and no payment will be made to you for participation.

### **Confidentiality**

All the information collected from you will be kept confidential. It will only be used for research purposes. The questionnaire will not bear your name but will have a number thus your identity will not be revealed. Your names will not be used in any report of this

study or in any publication or presentations. However, your records may be reviewed by KEMRI Ethics Review Committee or JKUAT officials.

### **Participation Information**

Participation is voluntary; it is your decision to participate or not to participate in this study. If at any time you wish to withdraw from participating from the study, you can do so without fear of being penalized and this will not affect any future participation or relation with anyone or any institution.

### **Contacts and Questions**

If you have any question regarding this study, you can contact

Evangeline Maina, P.O Box 1306 - 00900 Kiambu, Mobile No. 0710725472 or on e-mail address [evangelinemaina@yahoo.co.uk](mailto:evangelinemaina@yahoo.co.uk)

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), you are encouraged to contact the

Director, Kenya Medical Research Institute (KEMRI) or the Secretary, KEMRI Ethics Review committee,

P.O. Box 54840 – 00200, NAIROBI

Tel: (020) 2722541; (020) 2713349

E-mail: [erc@kemri.org](mailto:erc@kemri.org)

or

Director, ITROMID,

JKUAT,

P.O Box 62000 -00200, NAIROBI

Tel 067 52711

E-mail [itromid@nairobi.mimcom.net](mailto:itromid@nairobi.mimcom.net)

### **PART B: Participant Consent Form**

Please read the information in PART A or have it read to you carefully before completing this consent form. If you have any question, please ask the investigator prior to signing the consent form.

**Participant Statement**

I Mr/Miss/Mrs....., do hereby give consent to Evangeline W. Maina to include me in the proposed study “**Factors associated with non-adherence to oral diabetic medication among adult out patients with type 2 diabetes mellitus attending Mbagathi District Hospital Nairobi, Kenya**”. I have read the information sheet, I understand the objectives of the study and what is required of me if I take part in the study. The risks and benefits if any have been explained to me. Any questions I have concerning the study have been adequately answered. I understand that I can withdraw from the study at any time if I so wish without any consequences. I realize I will be interviewed once. I consent voluntarily to participate in this study.

Study subject Signature or Thumb print

\_\_\_\_\_

Date \_\_\_\_\_

Name of person taking consent \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_



**Appendix 8: Fomu ya Kukubali Kushiriki kwa Hiari.**

*Mada ya Utafiti: Sababu zinazohusishwa na kutozingatia tiba ya ugonjwa wa kisukari kwa kumeza dawa miongoni mwa wagonjwa wa umri mkubwa, wenye ugonjwa wa kisukari aina ya 2 wanaotibiwa na wasiolazwa katika hospitali ya wilaya ya Mbagathi Nairobi, Kenya.*

***Mtafiti Mkuu na Ushirika wa Kitaasisi.***

*Evangeline Maina, Shahada ya Uzamili ya Sayansi ya Afya ya Umma, Taasisi ya Dawa za Tropiki na Magonjwa Ambukizi, Chuo Kikuu cha Kilimo na Teknolojia cha Jomo Kenyatta.*

**SEHEMU YA A.**

***Utangulizi:***

*Unaulizwa kushiriki katika utafiti huu kwa sababu idadi ya watu wanaougua kisukari katika nchi yetu ya Kenya inaendelea kuongezeka na hali ya kutozingatia tiba ya ugonjwa wa kisukari kwa kutumia dawa za kumeza imeonekana kuchangia pakubwa hali ya ugonjwa huu kua mbaya zaidi na husababisha mshtuko wa moyo, kiharusi, kufeli kwa figo, kuharibika kwa neva na upofu.*

***Madhumuni ya Utafiti.***

*Lengo ya utafiti huu ni kutaka kujua kiwango cha watu ambao hawazingatii tiba ya ugonjwa wa kisukari kwa kutumia dawa za kumeza na pia kubaini sababu za kutozingatia tiba ya ugonjwa wa kisukari aina ya 2 kwa kutumia dawa za kumeza miongoni mwa wanaotibiwa katika hospitali ya wilaya ya Mbagathi. Taarifa itakayokusanywa itaisaidia serikali kubuni mipango na sera za kuzingatia tiba ya ugonjwa wa kisukari aina ya 2 kwa kutumia dawa za kumeza.*

***Mbinu Zitakazotumiwa Katika Utafiti***

*Unahitajika kuwa na umri wa miaka kumi na nane au zaidi ili kushiriki katika utafiti huu. Ikiwa utakubali kushiriki katika utafiti huu, utahojiwa kuhusu umri, jinsia, hali ya ndoa, kazi, kiwango cha elimu, matumizi ya dawa za ugonjwa wa kisukari na sababu za kutozingatia tiba ya ugonjwa wa kisukari kwa kutumia dawa za kumeza. Itakuchukua dakika 20-30 kuyajibu maswali haya.*

***Hatari za Kushiriki Katika Utafiti Huu.***

*Hatutarajii hatari au kutoridhika kwokwote kutokana na kushiriki kwako. Utaombwa kushiriki katika mahojiano. Tutailinda siri yako wakati wa kushiriki kwako katika utafiti. Mahojiano haya yatafanyika mahali faraghani na hakuna chochote kibaya kinachoweza kufanyika kwako kutokana na wewe kushiriki katika utafiti huu.*

***Faida za Utafiti Huu.***

*Kushiriki kwako katika utafiti huu kutaboresha maarifa yako kuhusu ugonjwa wa kisukari na umuhimu wa kuzingatia matibabu yake pia, wewe na wasimamizi wa Hospitali mtapewa taarifa ya matokeo ya utafiti huu na hatua za haraka zitachukuliwa za kuboresha uzingatiaji. Kwa kujibu maswali yetu, utachangia pakubwa kuelewa sababu za kutozingatia tiba ya ugonjwa wa kisukari aina ya 2 kwa kutumia dawa za kumeza kwa wagonjwa wasiolazwa. Siku za baadaye, wewe na wengine mtafaidika kutokana na utafiti huu kwani matokeo ya utafiti huu yatasaidia Wizara ya Afya kuchukua hatua zitakazoboresha tiba ya ugonjwa wa kisukari kwa kutumia dawa za kumeza na pia kubuni sera na mipango ili kuboresha huduma inayotolewa kwa wagonjwa wa kisukari katika vituo vyetu vya afya na hivyo kuwazuia kutokana na matatizo ya kisukari.*

***Gharama ya Utafiti.***

*Hautagharamika kwa kushiriki kwako katika utafiti huu na pia hautalipwa kwa kushiriki.*

### ***Usiri.***

*Habari yote itakayokusanywa kwako itawekwa kuwa siri. Itatumika tu kwa shughuli za utafiti. Fomu la hoji haitakuwa na jina lako lakini itakuwa na nambari na hivyo basi hautatambulika. Majina yako hayatumika kwa ripoti yoyote katika utafiti huu au katika machapisho au mawasilisho ya aina yoyote. Hata hivyo, rekodi yako inaweza kukaguliwa na wakuu wa kamati ya ukaguzi wa maadili ya KEMRI au Maafisa wa JKUAT.*

### ***Habari ya Kushiriki kwa Utafiti.***

*Kushiriki kwako ni kwa hiari. Uamuzi ni wako wa kushiriki au kutoshiriki katika utafiti huu. Pia una uhuru wa kujiondoa katika utafiti huu wakati wowote utakaopenda. Unaweza kufanya hivyo bila kuhofia kuadhibiwa na kujiondoa huku hakutaathiri ushiriki au uhusiano wako wa baadaye na yeyote au taasisi.*

### ***Mawasiliano na Maswali.***

*Ikiwa una swali lolote kuhusu utafiti huu, unaweza kuwasiliana na:*

*Evangeline Maina. Sanduku la posta 1306-00900 Kiambu, Simu ya mkononi, 0710725472 au barua pepe [evangelinemaina@yahoo.co.uk](mailto:evangelinemaina@yahoo.co.uk)*

*Ikiwa una maswali au jambo lolote kuhusiana na utafiti na ungependa kuzungumza na mtu mwingine mbali na mtafiti au watafiti, unaombwa kuwasiliana na:*

*Mkurugenzi, Kenya Medical Research Institute (KEMRI) au katibu wa kamati ya ukaguzi wa maadili ya KEMRI,*

*Sanduku la Posta 54840-00200, NAIROBI.*

*Nambari ya Simu: (020) 2722541; (020) 2713349*

*Barua pepe: [erc@kemri.org](mailto:erc@kemri.org),*

*au*

*Mkurugenzi, ITROMID,*

*JKUAT,*

*Sanduku la Posta 62000-00200, NAIROBI.*

*Nambari ya Simu (067) 52711.*

*Barua pepe: [itromid@nairobi.mimcom.net](mailto:itromid@nairobi.mimcom.net)*

***SEHEMU YA B: Fomu ya Kukubali Kushiriki kwa Hiari***

*Tafadhali soma habari katika sehemu ya A au usomewe kwa makini kabla ya kujaza fomu ya kukubali kushiriki. Kama una swali, tafadhali uliza mtafiti kabla ya kutia sahihi.*

***Kauli ya Mshiriki.***

*Mimi Bwana/Bi....., ninamkubalia Evangeline W. Maina kunishirikisha katika utafiti uliopendezwa “Sababu zinazohusishwa na kutozingatia tiba ya ugonjwa wa kisukari kwa kumeza dawa miongoni mwa wagonjwa wa umri mkubwa wenye ugonjwa wa kisukari aina ya 2 wanaotibiwa na wasiolazwa katika hospitali ya wilaya ya Mbagathi Nairobi , Kenya.” Nimesoma taarifa katika fomu ya habari, ninaelewa madhumuni ya utafiti na kile ninachohitajika kufanya iwapo nitashiriki katika utafiti huu. Hatari na faida zozote ikiwa zipo zimefafanuliwa. Maswali yote niliyokuwa naye yamejibiwa. Ninaelewa kwamba ninaweza kujiondoa kwa utafiti huu wakati wowote nikipenda bila athari zozote. Ninafahamu kwamba nitahojiwa mara moja. Ninakubali kwa hiari kushiriki katika utafiti huu.*

*Sahihi au alama ya kidole cha gumba (kushoto) ya mhojiwa.*

.....

*Tarehe.....*

*Jina la anayepewa ruhusa.....*

*Sahihi.....*

*Tarehe.....*

## **Appendix 9: Consent form for Key Informant Interviews**

**Title of the research study:** Factors associated with non-adherence to oral diabetic medication among adult out patients with type 2 diabetes mellitus attending Mbagathi district hospital Nairobi, Kenya.

### **Principal Investigator and Institutional affiliation**

Evangeline Maina, Masters of Science in Public Health, Institute of tropical Medicine and Infectious diseases, Jomo Kenyatta University of Agriculture and Technology

### **Purpose**

The purpose of this study is to determine the proportion of people who do not adhere to oral diabetic medication, social perceptions surrounding diabetes mellitus and its treatment, as well as identifying the reasons for non-adherence to oral diabetic medication in adult out patients with type 2 diabetes mellitus attending Mbagathi district hospital. The information gathered will assist the government to design programmes and policies to enhance adherence to oral diabetic medication.

### **Procedure**

The interview will last for 30 to 45 minutes and will be audio recorded so that none of the important insights and conversations are missed out. The audio tape will not have your name on it and will be kept in a secure place. The audio tape will be destroyed upon completion of the study.

### **Risks**

There is no anticipated or known risk in participating in this study. Your identifying information will not be published.

## **Benefits**

Your participation in this study will contribute to understanding the reasons behind non-adherence to oral diabetic medication among type 2 diabetic out patients. The results of this study will be used to assist the Ministry of Health (MOH) to take the necessary steps to enhance adherence to oral diabetic medication and to formulate policies and programmes to improve the services given to diabetic patients in our health facilities and thus prevent them from developing diabetes mellitus complications.

## **Confidentiality**

The information that you provide will be treated in confidential manner and will be used for research purposes only. Your name will not be used in any research reports and nothing will be published that might identify you.

## **Participation Information**

Participation in this interview is voluntary. If at any time you wish to discontinue participation you may do so without penalty.

## **Contacts and Questions**

For more information or any question regarding this study, please contact Evangeline Maina, P.O Box 1306 - 00900 Kiambu, Mobile No. 0710725472 or on e-mail address [evangelinemaina@yahoo.co.uk](mailto:evangelinemaina@yahoo.co.uk)

For questions regarding your rights as a human subject participating in this study, please contact Director, Kenya Medical Research Institute (KEMRI) or the Secretary, KEMRI Ethics Review committee, P.O. Box 54840 – 00200, NAIROBI. Tel: (020) 2722541; (020) 2713349

E-mail: [erc@kemri.org](mailto:erc@kemri.org)

**Documented Consent**

By signing this form you are indicating that you have read and understood the information provided to you and agree to participate in the interview.

Respondent's initials \_\_\_\_\_ Organization \_\_\_\_\_

Signature \_\_\_\_\_ Title \_\_\_\_\_

Date \_\_\_\_\_

**Appendix 10: Manuscript abstract**  
**Prime Journal of Social Science**

ISSN: 2315-5051

Volume 4, Issue 5, pp. 1058-1066

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*Full Length Research*

**Title**

**Social perceptions surrounding diabetes and prevalence of non-adherence to oral diabetic medication among type 2 diabetes mellitus outpatients at Mbagathi district hospital Nairobi, Kenya**

**Author(s)**

**<sup>1</sup>Evangeline W. Maina , <sup>2</sup>Gideon Kikuvi, <sup>3</sup>Lawrence Muthami, and <sup>4</sup>Lucy Keter**

**Address(es)**

<sup>1</sup>Institute of Tropical Medicine and Infectious diseases, Jomo Kenyatta University of Agriculture and Technology, Kenya. Cell-phone NO. 0710725472

<sup>2</sup>College of Health Sciences, Jomo Kenyatta University of Agriculture and Technology

<sup>3</sup>Centre for Public Health and Research, Kenya Medical Research Institute

<sup>4</sup>Centre for Traditional Medicine and Research, Kenya Medical Research Institute

**Accepted Date**

17th May, 2015

**Citation**



Maina EW, Kikuvi G, Muthami L, Keter L (2015). Social perceptions surrounding diabetes and prevalence of non-adherence to oral diabetic medication among type 2 diabetes mellitus outpatients at Mbagathi district hospital Nairobi, Kenya. *Prim. J. Soc. Sci.* 4(5): 1045-1057.

### Abstract

Patient's health perceptions are influenced by culture and the environment under which one is brought up. Illness perceptions affect health seeking behavior, treatment engagement and adherence to therapy leading to poor disease outcome. The study was carried out to determine the social perceptions surrounding diabetes mellitus and the prevalence of non-adherence to oral hypoglycemic agents among type 2 diabetic patients. A descriptive cross sectional study was carried out at diabetes clinic of Mbagathi hospital after getting administrative approval from the hospital Medical superintendent and ethical approval from KEMRI scientific and ethical committees. Study participants were recruited using systematic random sampling method and informed consent was obtained. A pretested semi structured questionnaire and key informant interviews were used to collect data. The association between independent variables and non-adherence was assessed using Pearson's chi square ( $\chi^2$ ) and Fishers exact test.  $P < 0.05$  was considered significant. Key informant interviews were conducted on staff working at the diabetic clinic and data analyzed manually by themes. A total of 113 study participants were interviewed of which 61% were females. The mean age was 53.4 years. The study established a 45.1% prevalence of non-adherence to oral hypoglycemic agents. The most commonly perceived causes of diabetes were stress (74.3%), consuming sugary diets (73.5%), eating fatty foods (70.8%) and obesity (70.8%). A few (22.1%) of the study participants had at least a perception that hindered them from taking their oral diabetic medications. The findings concurred with the key informants' views. The opinion that use of diabetic

medication was not necessary if sugary diets were not consumed was significantly associated with non-adherence ( $P < 0.05$ ). Negative perception is associated with non-adherence to oral hypoglycemic agents among Mbagathi hospital type 2 diabetic patients. The health care workers should educate the patients on the consequences of non-adherence to oral hypoglycemic agents and dispel perceptions that negatively affects adherence.

**Key words:** Social perception, non-adherence, Type 2 diabetes, oral hypoglycemic agents.