FACTORS AFFECTING TREATMENT COMPLIANCE AMONG TYPE 2 DIABETES PATIENTS ON FOLLOW-UP AT MOI TEACHING AND REFERRAL HOSPITAL

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A Thesis submitted in partial fulfillment of the requirements for the Degree of Masters of Science in Advanced Nursing Practice (Medical Surgical Nursing) of Masinde Muliro University of Science and Technology

AUGUST, 2020

DECLARATION

This thesis is my original work and has not been presented for a degree or an award in any other university Signature...... Caleb K. Koech Reg. No. HNR/G/26/2014

CERTIFICATION

This	thesis	has	been	submitted	for	examination	with	our	approval	as	university
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DEDICATION

I dedicate this thesis to my dear parents and dear family for their immense support and love throughout the study period. I acknowledge their support and encouragement of all including who contributed positively towards this thesis.

ACKNOWLEDGEMENT

I thank the Almighty God for this far he has brought me. I would like to appreciate my supervisors Prof. A. J. Oloo and Dr Gordon Nguka and the entire School of Graduate Studies. I also acknowledge my lecturers, friends and classmates from the School of Nursing who contributed positively towards my project. Finally, I wish to convey my sincere appreciation to Mable Wakoli for typesetting, editing and printing this research work.

May God bless you all.

ABSTRACT

Best practice in management of chronic diseases including diabetes, requires long duration of treatment, multiple therapies and remains a major challenge in primary health care settings worldwide. Factors such as internal/external environment, healthcare system factors and factors related to medication use system are believed to affect or cause changes in the way patients take their medicine. The main objective was to document the factors affecting treatment compliance for diabetic patients at Moi Teaching and Referral Hospital, Eldoret Kenya. Analytic cross-sectional study design was used in which data was collected from 137 diabetic patients. Data collection tools including a structured questionnaire with Morisky's eight question instrument was used, questionnaires were given out to them by a trained research assistant after which data was entered, cleaned and analyzed using Statistical Package for Social Sciences (SPSS) version 21.0 and Generalized linear model (GLM) and Multiple linear regression. The study found out that occupation had statistically significant difference (p = 0.03), there were no significant differences between patients with low and medium/high adherence for the remaining sociodemographic variables. Results show that the difference in mean adherence to treatment is not statistically significantly for each of the socio-demographic variables except for occupation where the difference between the mean MMAS-8 treatment for the unemployed patients was statistically significantly higher than that of those who were either self-employed or employed with a p value of 0.011. Results show a statistically significant difference between MMAS-8 mean score for external environment suggesting that external environment significantly influences treatment adherence by increasing levels of adherence. Health care system (p=0.12) is marginally significantly (p = 0.08) associated with adherence to treatment. In conclusion, the research findings suggest that the study participants had at least one perception that hindered them from adhering to their oral diabetic medication and there is also significant evidence that these perceptions could as well encourage them to take anti-diabetic medicine.

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LIST OF ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immunodeficiency Disease
CI	Confidence Level
DM	Diabetes Mellitus
DNA	Deoxyribonucleic Acid
DNCD	Division of Non-Communicable Diseases
GLM	Generalized Linear Model
HB1AC	Glycated Hemoglobin
IERC	Institutional Ethics and Research Committee
HIV	Human Immunodeficiency Virus
KNH	Kenyatta National Hospital
MAPS	Morisky Adherence Predictor Scale
MMAS	Morisky Medication Adherence Scale
MOH	Ministry of Health
MTRH	Moi Teaching and Referral Hospital
NHS	National Health Strategy
NICE	National Institute for Health and Care Excellence
SPSS	Statistical Package for the Social Sciences
STATA	Statistics and Data
T2DM	Type 2 Diabetes Mellitus
WHO	World Health Organization

WDF World Diabetes Foundation

CHAPTER ONE

INTRODUCTION

1.0 Overview

This chapter covers the study background, statement of the problem and objectives including the research questions, justification and scope.

The chapter also provides the definition of operational terms used and the conceptual framework of the study.

1.1 Background of the Study

Diabetes type two occurs when the body is not able to produce enough insulin to enable it function properly, or the body's cells do not react to insulin. This means that glucose remains in the blood and is not used as fuel for energy. By the year 2014 global prevalence of diabetes was estimated to be 9% among adults aged 18 years and above (WHO, 2014).

Internationally in 2012, an estimated 1.5 million deaths were directly caused by diabetes whereas more than 80% of diabetes deaths occur in low- and middle-income countries. According to WHO, 2014 it is projected that diabetes will be the seventh leading cause of death in 2030.

The incidence of diabetes, especially type 2, is rapidly growing in the world. In 1985, an estimated 30 million people suffered with this chronic disease, which, by the end of 2006, had increased to 230 million, representing 6% of the world population. Of this number, 80% is found in the developing world of which 4% had diabetes mellitus. It is estimated that, during the next 35 years, diabetic world-wide prevalence will reach 25%, with India being the hardest hit. For a long time, Africa

was considered safe from many of the diseases that are called "diseases of affluence," which plague the Western world.

Similarly, there was a time when Africa was thought to be a continent, relatively free of diabetes mellitus. Today, however, diabetes is very common in Africa, a situation that seemed to have remained virtually static until the 1990s and more recently. From 1959 to the mid-1980s, medical statistics showed that the prevalence rate of diabetes in Africa was equal to or less than 1.4%, with the exception of South Africa, where the rate was estimated to be as high as 3.6% in 2001.

In Kenya, diabetes accounted for 2% of deaths in 2010 and it is estimated that the prevalence of diabetes in Kenya is at 3.3% and predicted to rise to 4.5% by 2025 (World Health Organization, 2010).

Diabetes is a lifelong disease which requires several activities to be performed by the patient e.g., self-blood glucose monitoring, exercise and taking medications as required (American Diabetes association, 2010) it is for this reason that this research study was done in the aim to provide an answer. Adherence becomes a problem when the patient does not meet the required levels of compliance and hence leading to poor treatment outcomes.

Most studies on diabetes management have taken place in Kenya's teaching and national referral hospitals, Moi Teaching and Referral Hospital in Eldoret and Kenyatta National Hospital (KNH) in Nairobi (Chege, 2010). These studies have focused mainly on the complications of diabetes.

It is against this background that the researcher aimed to determine factors affecting treatment compliance among type 2 diabetes patients on follow-up at Moi Teaching & Referral Hospital, Eldoret

1.2 Problem statement

Management of diabetes mellitus and its complications presents an increasing challenge to healthcare systems throughout the world despite the fact that substantial resources have been invested in Diabetes mellitus in several developed and developing countries (Fitzsimons *et al.*, 2012). Diabetes management and outcomes remain unsatisfactory and Kenya as a developing country is not an exception.

Studies have been conducted in various countries and have been used in various clinical settings and the results have identified inappropriate drug therapy and gaps in adherence to clinical guidelines (Elliot *et al.*, 2013). There is no clear certainty however, regarding the extent to which these guidelines are adhered to. With the devolution of Kenya's Ministry of Health (MOH) there should be clear guidelines on standards of diabetes care in the delivery of health services and the interventions need to be laid down according to evidence-based guidelines and best practices to improve outcomes of diabetic patients. This study will evaluate the factors affecting treatment compliance among type 2 diabetes patients on follow-up at Moi Teaching and Referral Hospital.

1.3 Main objective

The main objective of this study is to determine the factors affecting treatment compliance among type 2 diabetes patients on follow-up at Moi Teaching & Referral Hospital, Eldoret.

1.4 Specific objectives

 To establish the association between individual factors and mean adherence levels.

- ii) To determine the mean effect of factors on anti diabetic drug compliance.
- iii) To determine the factors influencing adherence to anti diabetic treatment.

1.5 Research questions

- i) What is the association between individual factors and mean adherence level?
- ii) What is the mean effect of factors on anti-diabetic drug compliance?
- iii) What are the factors influencing adherence to anti diabetic treatment?

1.6 Justification of the Study

Diabetes Mellitus (DM) is a widespread disease which has affected both young and the old worldwide and is one of the major causes of morbidity and mortality. Its chronic nature and constantly increasing prevalence as well as its complications, remains a major medical and social problem. It puts a heavy burden on the individuals affected, their families and society as a whole, not only financially but also in psychological and social terms. Generally, the goals of diabetes management are to extend the periods of wellness that patients experience, improve the overall quality of their lives and prevent occurrence of complications. Clinical guidelines are therefore an important element in the management of diabetics because it provides a basis for screening, treatment, evaluation, and pharmacological management of patients with diabetes.

According to previous studies from the literature, polypharmacy (prescription of several drugs to be used by a patient at ago) is associated with a higher cost, increased risk of side effects, drug interactions and non-compliance (Bailey and Kodack, 2011). It is important to assess the prescribing patterns to obtain information about usage and cost of drugs, which are of economic interest in a resource limited setting. There is no existing data on treatment compliance in management of diabetes

mellitus in Kenya. However, a study in the neighboring Eastern Uganda indicates that about four in five patients adhere to anti-diabetic treatment (Joan N *et al.*, 2008). Strategies aimed at improving anti diabetic drug availability and providing health education could improve adherence.

This study aims to provide information concerning compliance to anti-diabetic drugs which may be useful to policy makers in development of protocols governing prescribing, patient education, and ways to eliminate the factors hindering drug compliance for diabetes patients.

1.7 Scope of the Study

The study was conducted in Moi Teaching and Referral Hospital (MTRH), Eldoret of Uasin Gishu County. Patients attending the diabetic outpatient clinic at Chandaria Centre were included in the study. The study focused on treatment compliance for the patients who had been on treatment at least for more than a month prior to the study within MTRH.

1.8 Limitations of the Study

In this study the researcher identified that most patients selected were in a hurry either to go to the laboratory or see the clinician due to long queues and therefore did not have adequate time for filling the questionnaire.

Small sample size of 137 patients was used from a total population of 180 patients seen per month translating to about 2160 patients per year, this could have affected the findings negatively.

Some of the limitations of this study were the possibility of inaccuracies from the respondents/ patients that could be found in any self-administered questionnaire. There was always a chance of over-reporting of adherence.

1.9 Conceptual framework of the study

The conceptual framework below indicates the independent and dependent variables of the study which are believed to have influence on the outcome of the treatment compliance.

This framework was adopted from WHO 2015 guidelines and modified by the researcher to suit this study. It has several domains including socioeconomic, internal factors, external factors, healthcare system socio-demographic and medication use factors. The framework helped the researcher in guiding data collection, organization and analysis.



Figure 1.1 Conceptual framework on factors affecting treatment compliance among type 2 Diabetes patients Source: Researcher, 2019

1.10 Operational definition of terms

Adherence - Faithful attachment; devotion to the treatment regimen.

Compliance - the act of conforming, acquiescing, or yielding. In this study it is the Willingness to follow a prescribed course of treatment.

Diabetes Mellitus (type 2) - a group of metabolic diseases in which there are high blood sugar levels over a prolonged period.

Factors- a Latin word meaning "who/which acts". In this study it means those things that affect another and cause a noticeable change.

In this study patients who will take 80% and above of the prescribed doses over the last seven days will be considered adherent to anti diabetic drugs.

NB: For the purpose of this study compliance and adherence are used interchangeably

Polypharmacy- the concurrent use of multiple medication/ drugs. It can be associated with the prescription and use of too many or unnecessary medicines at dosages or frequencies higher than therapeutically essential.

Treatment- the manner in which someone behaves toward or deals with someone or something. It may also mean medical care given to a patient for an illness or injury.

CHAPTER TWO

LITERATURE REVIEW

2.1 Overview

This chapter presents an overview of type 2 diabetes and the literature related to its treatment compliance as per the following objectives:

- To establish the association between individual factors and mean adherence levels.
- ii) To determine the mean effect of factors on anti diabetic drug compliance.
- iii) To determine the factors influencing adherence to anti diabetic treatment.

2.1.1 Diabetes in Kenya

According to Lewis, 2011 diabetes is a lifelong disease that requires careful monitoring and control. Without proper management it can cause high blood sugars which can result in long term damage to various organs and tissues which include micro and macro vascular complications.

Pancreas makes a hormone called insulin which lets cells turn glucose from the food we eat into energy. People with type 2 diabetes produce insulin but their cells do not use it as well as they should. This is situation called insulin resistance (http://www.webmd.com/diabetes/guide/type-2-diabetes/2011).

Usually the pancreas makes a lot of insulin which will try to get glucose into the cells. But eventually it can't keep up, and the sugar builds up in the blood instead.

According to American Diabetes Association, there are several factors that make a combination of things causing type 2 diabetes, including: Genetic factors, obesity, and metabolic syndrome/insulin resistance, too much glucose from the liver and worn out beta cells (NICE clinical guidelines, December 2009). A patient can have one or a combination of these factors to be said to have developed diabetes mellitus.

Diabetic patients do more than 95% of their own care, notes authors Martha Funnell and Robert Anderson in their article, 'The Problem With Compliance in Diabetes,' published in the October 2010 issue of The Journal of the American Medical Association. The authors recommend that physicians and health care workers create a collaborative relationship in which the responsibilities and roles of clinicians and patients are clearly defined. Furthermore, when patients as the main decision-makers for their diabetic care, establish their own goals, they act more responsibly about controlling their diabetes. This is a fact that will be determined at the end of this study.

There is clear evidence that complications resulting from late diagnosis, late presentation, and lack of access to essential medication and services, and poor management of diabetes are common and all these combine to create a heavy socioeconomic burden for Africa and the developing countries. A recent study suggested that direct costs such as medical care and treatment of diabetes are usually met by the patients, family and healthy sector (Motala *et al.*, 2010).

Adherence has been and can be defined as the extent to which individuals follow the instructions they are given for prescribed treatments (Haynes *et al.*, 2012). Therefore, if a person is prescribed for a drug to be taken as one tablet four times a day for a week for a condition, but takes only two tablets a day for five days, their adherence would be 10/28=36%, (Haynes, 2012)

According to the World Health Organization, non-compliance occurs with long-term medication for conditions such as hypertension, dyslipidemia and diabetes as a common problem that leads to poor health outcomes and serious economic consequences in terms of wasted time, money and uncured disease (WHO, 2013).

Compliance with medication has become a topic of much research, and various interventions have been proposed to improve patient drug compliance. However, Cramer states that it has proved difficult to compare studies of compliance because of a lack of standard terminology and methodology (Cramer, 2010). The ultimate aim of any prescribed medical therapy is to achieve certain desired requirements or outcomes in the patients concerned. These desired outcomes are part and parcel of the objectives in the management of the diseases or conditions. However, despite all the best intention and efforts on the part of the healthcare professionals, those outcomes might not be achievable if the patients are non-compliant to treatment. This shortfall may also have serious and negative effects from the perspective of disease management (Jin *et al.*, 2010).

Kenya, like other developing countries is experiencing an increase in diabetes and other non-communicable diseases. The true prevalence of diabetes in the country is unknown due to lack of population-based studies. According to the Ministry of health, division of non-communicable diseases (DNCD) current prevalence is estimated to be 10% (DNCD, 2012) which the World Diabetes Foundation (WDF) claims to be an underestimate.

About 1% of deaths in Kenya were directly attributable to diabetes in 2012, according to WHO data. But this is likely an under-estimate, says Gojka Roglic, who leads WHO's global work on diabetes. "Most people with diabetes do not die of causes uniquely related to diabetes, but of associated cardiovascular complications, like a heart attack," she notes.

In a study by Clark and Fowel, (2015) 'non-compliance is believed to be the most common cause of treatment failure. Non-compliance leads to lack of metabolic control, which contributes to development and acceleration of diabetic complications.' This is one of the main reasons why this study is important

2.1.2 Management of Diabetes

Although lifestyle modifications play an important role in diabetes management, drugs become unavoidable in many patients (Ellis *et al.*, 2000). Modern approaches to diabetes primarily rely upon dietary and lifestyle management, often combined with regular ongoing blood glucose level monitoring (Tuomilehto *et al.*, 2001). Treatment of diabetes is aimed at reducing elevated blood glucose levels.

Management of type 2 diabetes includes regular exercise, adherence to diabetes medication i.e., insulin therapy and blood sugar monitoring (http://www.mayoclinic.org Feb, 2016).

Monitoring of blood glucose levels is very important in management of diabetes. A Cochrane review (Deakin, 2009) concluded group-based training for selfmanagement strategies in people with T2DM is effective by improving fasting blood glucose levels, glycated hemoglobin and diabetes knowledge, and reducing systolic blood pressure levels, body weight and the requirement for diabetes medication. In diabetes mellitus the higher amounts of glycated hemoglobin is an indicator of poor control of blood glucose levels (ibid).

Glycated hemoglobin (HbA1c) readings higher than 7% indicate higher than normal amounts of glucose circulating in blood stream in the past 120 days (https://en.wikipedia.org/wiki/Glycated_hemoglobin).

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2.2 Effects of socio-demographic factors on treatment compliance

Socio demographic factors such as age, sex, marital status, occupation, belief system, religion among others have been associated with drug compliance. Adisa (2009) states as follows: "significant association exists between sex, occupation and patients' tendencies to forget doses of prescribed oral medications" (Adisa *et al.*, 2009).

In a study by Kirkman *et al.*, (2015) they found that some patient demographic and clinical factors were associated with higher adherence to noninsulin antidiabetic medications: older age, male sex, higher education level, higher income, and presence of comorbid chronic conditions.

According to Kirkman Sue *et al.*, (2015) his study found few meaningful differences in patient adherence according to prescriber factors. There were no differences in patient adherence by sex of the prescriber. Although there was a statistically significant association of adherence with prescriber age, the effect size was very small (for each additional year of prescriber age, the odds of adherence increased by 0.2%.

It has been shown that an increase in the number and dose of drugs is one of the main factors for non-compliance, mainly because of 'forgetfulness' in the older age group patients and may also be associated with it being a burden by the patient. A statistically significant association was found between non-compliance and frequent dosing and multiple drugs in a study done by Sharma T *et al.*, (2014).

In yet another study done by Divya *et al.*, (2015) showed that an economic problem to buy medicines is one the main factors for non-adherence.

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This study will determine therefore the effects of these socio demographic factors on treatment compliance.

2.3 Effects of external environment on compliance to Treatment

One of the factors affecting the care of diabetic patients is external environment. According to Suzanne Wait of SHW Health (2014), "Added to the complexity inherent to diabetes are pressures facing the external environment within which diabetes management is evolving". (<u>http://www.ecdiabetes.eu/documents</u>). Such an environment implies money, support from significant others and distance from hospitals.

Suzanne further states that health care systems are under constant financial pressure and health care reforms are bound to change roles which will eventually impact service delivery to diabetes patients. The challenge in this case is therefore to ensure that diabetes policies, the programs put in place by the government and other stakeholders and the models of care built to deliver services, are not compromised in their ability to serve patient needs within the dynamic context of their surrounding health care environment.

2.4 Health care system factors that affect treatment

Apart from the environmental factors we also have other factors which affect compliance to treatment. In this instance, health care system factors that affect treatment these include Lack of accessibility to hospital or drugs, Long waiting time, Difficulty in getting prescriptions filled and unhappy clinic visits (http://www.ncbi.nlm.nih.gov/pmc/articles)

Patient centered factors have also been identified which can affect compliance negatively and they include age, gender, education, beliefs, knowledge, alcohol,

tobacco, physical disabilities and history of compliance (http://www.ncbi.nlm.nih.gov/pmc/articles).

Patient centered, in this context, means treating patients as partners, involving them in planning their health care and encouraging them to take responsibility for their own health. Research shows that patients are more likely to take their pills and show up for appointments when allowed to help shape their treatment plans (http://www.aafp.org/fpm/2015/0300).

This research study will be able to determine whether these factors truly contribute to treatment compliance by patients with type 2 diabetes.

2.5 Influence of internal environment on treatment compliance

Green & Kreuter, (2009), defines cues as "precipitating force that makes the person feels the need to take action" cue to action and can be internal or external factors. Internal factors may be the appearance of the signs and symptoms of a disease (Glanz et al, 2012). Internal factors include age, genetics, physical, spiritual, cognition, attitude and personality can influence a patient to have an urge to take medicine or to comply with treatment.

In a study done in Gaza Strip, Palestine by Elsous *et al.*, (2017), the information on adherence was based on patients' recall, and therefore the actual and true prevalence of compliance could be lesser than the presented findings in this study. In addition, patients might have difficulties in remembering their habits and medications taking practices, but this was diminished by asking patients to memorize within a period of 2 weeks only. Their study also found that the level of adherence to medications was associated with patients' belief about the severity of disease, which reflects the feelings concerning the seriousness of contracting an illness or leaving it untreated,

(ibid). This is in line with the findings of this study where negative believes about treatment resulted on non adherence.

2.6 Medication use system effects on treatment compliance

Medication use system comprise of factors such as storage methods of anti-diabetic drugs, method of use, knowledge of drugs, side effects as well as patient care giver relationships. 'Promoting adherence involves a good clinician-patient relationship, as well as provision of personalized, practical, and repeated education' (Fish and Lung, 2001). In other words these factors can affect drug compliance negatively.

There is emerging evidence that the clinician-patient relationship may also be associated with patient adherence to HIV medication. Martini *et al.*, (2012) found that patient satisfaction with the clinician-patient relationship was related to adherence.

in another study by Bakken *et al.*, (2012) found that patients who were more engaged with their providers evidenced better adherence to medications and appointments and better immune health than their less-engaged peers.

2.7 Morisky instrument

In 2008, a modified eight item Morisky Medication Adherence Scale (MMAS-8) developed from the original four item Morisky scale was published. The first seven items are dichotomous response categories with yes or no and the last item was a five point Likert response (Morisky DE *et al.*, 2013).

The Morisky eight item instrument has much better psychometric properties: sensitivity and specificity are 93% and 53%, respectively and Cronbach's alpha value is 0.83 that is above the acceptance threshold (Morisky DE *et al.*, 2013).

A study by Al-Qazaz *et al.*, (2010) indicate that Malaysian version of the Morisky Medication Adherence Scale (MMAS) is a reliable and valid measure of medication adherence. (See appendix II for the Morisky's instrument).

CHAPTER THREE

METHODOLOGY

3.0 Overview

This chapter will cover the methodology used in the study. The study design, study area, target population, sampling method and procedures are described. It also includes sample size calculation, inclusive/ exclusive criteria, research instruments, data collection tools, data analysis procedures and ethical considerations.

3.1 Research Design

Analytic cross-sectional design was used in this study. Data was collected from patients who had type 2 diabetes mellitus on factors affecting treatment compliance. Information on both the independent and dependent variables were collected at the same point in time after approval by the Institutional Review Board.

3.2 Study Area

The study was conducted at Moi Teaching and Referral Hospital. This government hospital that is located 310 km North West of Nairobi in Uasin Gishu County (Eldoret). A number of specialist clinics are run at the hospital and the diabetic outpatient clinic is one of these clinics. Average number of patients seen per clinic day is 15; that is on Tuesdays, Thursdays and Friday. This brings to a total of 180 patients per month and 2160 per year.

The clinics are run by endocrinologists, physicians, nurses, clinical officers, nutritionists and records personnel.

Uasin Gishu County is one of the 47 counties of Kenya, located in the former Rift Valley Province. The town of Eldoret is the County's largest population center as well as its administrative and commercial center.

Uasin Gishu is located on a plateau and has a cool and temperate climate. The county borders Trans-Nzoia County to the north, Elgeyo-Marakwet and Baringo counties to the east, Kericho county to the south, Nandi county to the south, south-west and Kakamega county to the west.

This study area was chosen because majority of patients in this region come to seek medical care here because of the available facilities and the advantage of serving the neighboring counties.

3.3 Target Population

All patients with a diagnosis of diabetes type 2 who presented at Moi Teaching and Referral Hospital diabetic clinic during the period of study constituted the study population.

3.4 Inclusion and Exclusion Criteria

3.4.1 Inclusion criteria

1) Patients of age 18 years and above

2) Participants with a diagnosis of diabetes type 2 for at least one month with or without other co-existing medical conditions.

4) Patients who agreed and consented to participate in the study

3.4.2 Exclusion criteria

1) Newly diagnosed patients who are less than one month on treatment

2) Patients who could not respond e.g., too sick to be interviewed

3) Patients on anti-diabetic medication who could not consent to participate in the study.

3.5 Sample Size Determination and Calculation

Sample size calculations were made based on Fischer's formula of the total target population of patients attending the diabetic clinic (Mugenda, 2003). The proportion of the population having the required characteristics is estimated at 50% (p=0.5). Sample size was calculated using the following formula:

 $n = Z^2 pq/n$

Where by n = the required minimum sample size

p = estimated proportion of the target population who have the characteristics being measured.

q= 1-p

d= the level of statistical significance set at + or -5% or 0.05

z = standard normal deviate corresponding to 95% confidence level=1.96

The target population being less than 10,000, then the final sample estimate (nf) will be:

nf=n/1+n/N

N= the estimate of the population size which is 180

In this study, the proportion of the population with the desired characteristics is 50 the z statistic is 1.96 and the error margin assuming 95% Confidence level (CI) is 0.05 therefore the sample size is:

$$n= \frac{(1.96)^2 (0.5) (0.5)}{(0.5)^2}$$

n=384

Therefore n= 384 divide by 1+n divided by the estimate of the population nf=384 divide by 1+384/180 nf=384/1+2.13 nf=384/3.13 nf=124 The researcher added 10% of the population to cater for non-responsive cases. Therefore, 124x10% = 12.4 participants

124+12.4=137

The sample size is therefore 137 participants.

The researcher obtained consent from the participants in the study and gave full information about the study clarifying all issues that would concern the respondents. The participants therefore signed an informed consent form (Appendix I).

3.6 Sampling Procedure

Convenience sampling procedure was used. In this case subjects are selected from the MTRH diabetic clinic, because it was easily accessible to the researcher. Patients who were attending the diabetic clinic at MTRH were picked continuously as they tripled in to the clinic from 8:00am through 2:00pm on Monday, Thursday and Friday for the period of study. The sample size was achieved after on the fourth week and a total of 137 participants filled the questionnaire.

All the patients had equal chance of being selected to participate in the study except where they did not meet the inclusion criteria.

3.7 Development of Research Instrument

The researcher developed a questionnaire which would be used to collect data from the respondents. In addition to the questionnaire was the eight question Morisky instrument (MMAS-8).

The following sections formed part of the questionnaire: Demographic data and factors affecting treatment compliance. The research assistants were health records personnel and had been trained on how to collect data/ administer the questionnaire. All the research tools were piloted at a different hospital's Out Patient Clinic to ascertain their validity and reliability in the study.

3.8 Pre-test of Research Instrument

This is a trial administration of an instrument to identify flaws. When a study tool is used as a data gathering instrument, it is used to determine whether questions and directions are clear to study participants and whether they understand what is required from them. The questionnaire and the Morisky's eight question Instrument were administered for piloting at the Uasin Gishu County Hospital, which is a different but public hospital other than the one identified for the study. The pilot study was conducted to clarify instructions, check the appropriateness of the language used in the research instruments and to determine the difficulty of the items in the instruments in order to make adjustments in the study tool.

Before the study, some precautions were taken into consideration including ensuring short, clear and straightforward questions in order to eliminate ambiguity. The researcher also had a discussion with the participants prior to presentation of the tool for the purposes of the study and this was to motivate the respondents to own up to the process by filling in the items required in the tool.

3.9 Validity and Reliability of the Instruments

3.9.1 Validity of the Instrument

This was achieved by providing a pretested self-reported questionnaire with the statements based on the content from the literature review and the study objectives.

3.9.2 Reliability of the Instrument

This was achieved by consistency in the administration of the research tool during data collection period and on individual basis.

3.10 Data Collection Tool

Data was collected by the researcher and one assistant trained on data instruments. A questionnaire consisting of closed ended questions was used during the interviews together with Morisky's eight question instrument (MMAS-8) was used. The structured data collection instrument information regarding patient's social demographic characteristics was used. The estimated time used to complete one form was approximately 15 minutes; data was collected within a period of one month at MTRH diabetic clinic during clinic days i.e., Tuesdays, Wednesdays and Fridays.

Structured questionnaire (Appendix II): a questionnaire, containing the Morisky Adherence Predictor Scale (MAPS) was utilized to collect information necessary to assess anti diabetic medication adherence. The questionnaire has two parts: Part I collected information on basic socio-demographic variables. Part II consisted of questions required to gather information on factors affecting anti diabetic treatment compliance.

The other part was the eight question Morisky scale which was used to assess the levels of anti-diabetic medication adherence.

The data collection tools were personally distributed to the respondents by the researcher and his assistant. Data collection started with self-introduction and overview of the research including the study objectives. Explanations were given to respondents as required and the questionnaires were administered after signing the consent form.

3.10.1 Data Quality Control

The questionnaires were pre-tested and research assistant was trained for two days on the objectives of the study, sampling procedure and checking for the completeness of questionnaires. Furthermore, data were checked for completeness during entry into the computer before analysis.

3.11 Data Analysis

The raw data was cleaned to ensure completeness, consistency, coded and checked for normality. After entry into a data base, SPSS was used to analyze the data. Descriptive statistics i.e., mean, mode, median, range, standard deviation and frequency distributions were used to summarize the data. Generalized linear model (GLM) was used for categorical independent variable (with two or more categories) and a normally distributed interval dependent variable (calculated mean of adherence to treatment). Student t test for independent samples was used to compare mean difference in treatment adherence for each of the four domains that were likely to influence treatment compliance. Multiple linear regression was used to identify the relationship between a dependent variable (adherence to treatment) and effects of medication system, influence of internal environment, influence of health care system and influence of external environment. A p- value of ≤ 0.05 was used to test the null hypothesis of no relationship between the independent variables and treatment compliance. All the items except item 6 are reverse-coded (no, 0; yes, 1). The total scale has a range of 0–8, including low adherence (6), medium adherence (6–7), and high adherence (8). The MMAS-8 scale is reliable (Cronbach's α =0.83), with a sensitivity of 93% and a specificity of 53% respectively.

HbA1c of >7% was considered as uncontrolled Diabetes Mellitus.

Data analysis was done as per the objectives. Analyzed data were presented in tables. Data security was achieved by use of passwords kept by the researcher only.

3.12 Ethical Consideration

Prior to conducting the study, approval was sought from the Institutional Ethical Review Committee (IERC) of Masinde Muliro University of Science and Technology, where logistical and ethical considerations were included, as well as from the Administration of Moi Teaching and Referral Hospital in which the study was conducted. In compliance with the outlined regulations brought forth by the facility, the principal investigator provided contact information to each participant in lieu of questions regarding participation in the study. The participants were assured of anonymity in joining the study; they were also informed that the exercise was voluntary to those willing to take part and that there was no penalty for those not willing to participate. The respondents were informed that should they were free to withdraw from the exercise should they wish.

The researcher avoided strategies that would compromise the participants' values or put them at risk. Informed consent and maintaining confidentiality were the ethical issues considered in this study. The researcher accurately represented what the respondents reported without bias.

3.12.1 Informed Consent

This refers to the process of giving respondents an opportunity to decide whether to participate in a particular study or not. Adequate information and opportunity to enquire was availed before respondents were asked to fill in the informed consent forms. The respondents in this study were patients who were on follow-up at the diabetic out-patient clinic of Moi Teaching and Referral Hospital.

The patients were given all the relevant information about the study that was to be undertaken as this was important for them to give consent without coercion, pressure or undue enticement. The researcher ensured that the respondents' anonymity was maintained, and this was to allow them to choose to either participate in the study or not.

3.12.2 Confidentiality

The material and information provided by the respondents would be destroyed upon completion of the study period to protect their confidentiality. The researcher had no intention whatsoever to use the patients' names in any publication.

3.11.3 Privacy

This was achieved where no disclosure of information was done by researchers to others at any point during the study. No identification of participants involved in the study was done during data collection and coding.

3.12.4 Beneficence

In this study the respondents involved were given all information on what the study was about, and a debriefing after the study. This gave them room to ask questions and get clarifications about the study before participating. This was to ensure that the potential risks incurred will not be greater than acceptable levels.

3.12.5 Non- Maleficence

This entails the duty to benefit others and prevent any harm in the study.

3.12.6 Justice

In this research fairness and equity was observed, where the same procedure was used in selecting patients to be involved in the study was done using an inclusive criteria.

CHAPTER FOUR

RESULTS

4.0 Overview

This chapter presents the findings in line with the study objectives and themes in the form of response rate, demographic data and patient characteristics according to medication adherence categories.

The objective of the study was to determine the factors affecting treatment compliance among type 2 diabetes patients on follow-up at Moi Teaching & Referral Hospital in Uasin Gishu County. The results of this study have been presented in this chapter and were analyzed using Statistical Package for Social Sciences (SPSS) version 20.0.

4.1 Response Rate

A total of 137 self-administered questionnaires were given to patients who were on follow-up at MTRH diabetic clinic during the study period. All the questionnaires were filled completely giving 100% response rate. The response rate was sufficient and represents the whole population and this conforms to what Mugenda (2003) stipulates: "a response rate of 50% is sufficient for analysis and reporting; a rate of 60% is good and a response rate of 70% and above is excellent". This therefore indicates that the response rate of 100% in this study was quite and reliable.

4.2 Demographic Characteristics of the Respondents

This section identifies the demographic information of the respondents which include age, gender, marital status, level of education, occupation and income. These characteristics are important for the fact that they are known to influence the variables of any given study. The gender of the participants should be considered because diabetes can cause erectile dysfunction in men. Age is an important factor since the young see themselves as still productive and need to do more in the society hence positive adherence. Marital status is also important factor since a spouse can remind the partner to take medicine and to attend clinics when needed.

Level of education and income can influence medication adherence since it informs the respondent's suitability to answer questions, knowledge on diabetes and prevention of complications and ability to purchase prescribed drugs.

Table 4.1 below shows patient characteristics by medication adherence. The participant response rate was 100% (137/137). All the participants completed MMAS-8 questionnaires. Slightly more than half (51.8%) were females compared to 48.2%) males. Most of the participants were aged 25 - 39 years (48.2%). Almost two-thirds (65%) were single. This was followed by 22.6% who were married. According to patient's level of education, the majority had attained diploma level (46%) closely followed degree level (40.9%). Regarding their occupation, about half (48.2%) were unemployed while 40.9% were employed. Results on the range of income indicates that 43.1% were earning between KSh. 10,000 – 49,999.

Except for occupation that was with statistically significant difference (χ^2 =7.0; p = 0.03), there were no significant differences between patients with low and medium/high adherence for the remaining socio-demographic variables. Majority of those who were employed (89.3%) were categorized under low adherence in contrast to 10% with medium/high adherence for the same category.

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Patient characteristics	Total number of	Medication adherence score (%)		χ^2	p value	
	patients (%)	Low (MMAS-8) <6	Medium and High (MMAS-8) >6		vulue	
Gender						
Male	66 (48.2)	52 (78.8)	14 (21.2)	0.0001	0.99	
Female	71 (51.8)	56 (78.9)	15 (21.1)			
Age group (years)						
18 - 24	35 (25.6)	28 (80.0)	7 (20.0)	0.05	0.97	
25 - 39	66 (48.2)	52 (78.8)	14 (21.2)			
≥40	36 (26.3)	28 (77.8)	8 (22.2)			
Marital status						
Single	89 (65.0)	67 (75.3)	22 (24.7)	2.0	0.36	
Married	31 (22.6)	26 (83.9)	5 (16.1)			
Other (Widow,	17 (12.4)	15 (88.2)	2 (11.8)			
divorced)						
Level of						
education						
Secondary	18 (13.1)	15 (83.3)	3 (16.7)	0.26	0.88	
Diploma	63 (46.0)	49 (77.8)	14 (22.2)			
Degree	56 (40.9)	44 (78.6)	12 (21.4)			
Occupation						
Unemployed	66 (48.2	46 (69.7)	20 (30.3)	7.0	0.03	
Self-employed	15 (10.9)	12 (80.0)	3 (20.0)			
Employed	56 (40.9)	50 (89.3)	6 (10.7)			
Income (KSh.)						
<5000	26 (19.0)	19 (73.1)	7 (26.9)	2.4	0.5	
5000 - 9999	29 (21.2)	21 (72.4)	8 (27.6)			
10000 - 49999	59 (43.1)	48 (81.4)	11 (18.6)			
≥50000	23 (16.8)	20 (87.0)	3 (13.0)			

Table 4.1 Patient characteristics according to medication adherence categories

4.3 Relationship between socio-demographic characteristics and mean adherence levels

Mean adherence measurement was calculated by adding up all the eight (8) items in the Morisky's Measurement questionnaire and the total figure was divided by eight. A mean of 0.0 was considered as high adherence while a mean of 1 or 2 was considered as medium level of adherence and a mean greater than 2 was considered as low adherence. Results show that the difference in mean adherence to treatment is not statistically significant for each of the socio-demographic variables except for occupation where the difference between the mean MMAS-8 treatment for the unemployed patients was statistically significantly higher than that of those who were either self-employed or employed with a p value of 0.011. Although significantly higher, the MMAS-8 adherence level is still low.

Table4.2GeneralizedLinearModelanalysesonsocio-demographiccharacteristics and mean adherence levels

Patient characteristics	Total number of patients	Mean MMAS-8	SD	F	p value
Gender					
Male	66	0.47	0.24	0.8	0.37
Female	71	0.43	0.26		
Age group (years)					
18 - 39	101	0.44	0.24	0.02	0.88
≥ 40	36	0.45	0.27		
Marital status					
Single	89	0.41	0.25	1.44	0.23
Others (Married, Widow,	48	0.46	0.24		
divorced					
Level of education					
Secondary or Diploma	81	0.45	0.27	0.07	0.79
Degree	56	0.44	0.22		
Occupation					
Unemployed	56	0.49	0.22	6.59	0.011
Others (Self-employed or	81	0.38	0.26		
Employed					
Income (KSh.)					
< 10000	55	0.47	0.27	0.71	0.40
≥10000	82	0.43	0.23		

4.4 Generalized Linear Model analysis on treatment factors and blood sugar levels and MMAS-8

Generalized linear models were used with MMAS-8 total score as the outcome variable. There was no significant difference in the mean MMAS-8 treatment score for duration of diabetes mellitus, type of treatment, glycated hemoglobin level. Notably, all the mean score for each of the dichotomous variables on treatment factors suggest low level of adherence as the means are all below 0.6.

Treatment factors	Total number of patients	Mean MMAS-8	SD	F	p value
Duration with DM					
<1 year	58	0.47	0.24	0.6	0.44
≥1 year	79	0.43	0.26		
Type of treatment					
Pills	78	0.44	0.24	0.09	0.77
Injectable or both	59	0.45	0.26		
Glycated					
Hemoglobin Level					
(mmol/L)					
≥ 10.2 (uncontrolled)	20	0.51	0.20	1.36	0.24
<10.2 (controlled)	117	0.43	0.26		

 Table 4.3 Generalized Linear Model analyses on treatment factors and blood

 sugar levels and MMAS-8

4.5 Comparison of mean values of low and medium/high treatment adherence by domains

Results show a statistically significant difference between MMAS-8 mean score for external environment. This suggests that external environment significantly influences treatment adherence by increasing levels of adherence. On the contrary, health care system (p = 0.51), internal environment (p = 0.48) and medication system (p = 0.70) resulted in non-statistically significant difference between the mean MMAS-8 score. Thus, there is insufficient evidence to suggest that health care system, internal environment and medication system do change the mean MMAS-8 score on treatment adherence.

		Mean of domain						
	MMAS-8			Minimum	Minimum			р
Domain		Ν	Mean	Mean	Mean	SD	t	value
External	Low <6	108	1.8	1.70	1.84	0.4	2.5	0.01
environment	Medium or High	29	2.0	1.83	2.07	0.3	_	
	≥6							
Health care	Low <6	108	1.7	1.64	1.78	0.4	0.7	0.51
system	Medium or High	29	1.8	1.64	1.88	0.3	-	
	≥6							
Internal	Low <6	108	1.8	1.76	1.90	0.4	-	0.48
environment	Medium or High	29	1.8	1.64	1.91	0.3	0.71	
	≥6							
Medication	Low <6	108	1.7	1.64	1.78	0.3	-	0.70
system	Medium or High	29	1.7	1.55	1.81	0.3	0.39	
	≥6							

 Table 4.4 Comparison of mean values of low and medium/high treatment

 adherence by domains

4.6 Multiple linear regression analysis on factors influencing MMAS-8

Regression model was fitted to assess the relationship between external environment, health care system, internal environment, medication system and MMAS-8 score on adherence to treatment. Each predictor was tested while holding other predictors in the model constant. This statistical control that regression provides is important because it isolates the role of one variable from all of the others in the model. The equation shows that the coefficient for external environment is 0.14 which implies that for every additional unit in external environment (being encouraged by family to take medicine, work/home/hospital environmental) adherence level increases by an average of 0.14 with the relationship being statistically significant (p = 0.02). Health care system is not significantly (p = 0.08) associated with adherence to treatment. For every additional unit in health care system mean score (accessibility to hospital, long waiting time, difficulties in getting physician, being not satisfied with clinic visits) adherence level increases by an average of 0.12.

On the other hand, age, level of education, attitude and marital status which are considered as internal environment had no effect on treatment compliance (p = 0.83). Similarly, domain on medication system which includes route of administration of anti-diabetics, storage methods, side effects of medications, duration of treatment and treatment complexity is not a predictor of treatment adherence (p = 0.87).

Independent variables	Estimate	t value	p value
External environment	0.14	2.29	0.02*
Health care system	0.12	1.78	0.08
Internal environment	-0.01	-0.22	0.83
Medication system	0.01	0.17	0.87

Table 4.5 Predictors of treatment adherence among diabetes mellitus type 2

*statistically significant

CHAPTER FIVE

DISCUSSION

5.1 Overview

This chapter provides the findings of the study as per the objectives and research questions as presented below:

5.2 The association between individual factors and mean adherence levels

Individual factors are those which originate from within the person/ patient and they include attitude, forgetfulness, knowledge and motivation.

In this study, the findings indicate that most patients (89.3%) who were employed were categorized under low adherence and only (10.7%) of them were classified as medium to high adherence on the Morisky's eight question Scale. There was no significant difference between patients with low and medium/ high adherence for the remaining socio-demographic factors.

The researcher calculated the mean adherence measurement by adding up all the eight (8) items in the Morisky's Measurement questionnaire and the total number was divided by 8 where a mean of zero was considered as high adherence while a mean of 1-2 was considered as medium adherence and a mean of more than 2 was considered as low level of adherence. Results show that the difference in mean adherence to treatment is not statistically significantly different for each of the socio-demographic variables except for occupation where the difference between the mean MMAS-8 treatment for the unemployed patients was statistically significantly higher than those who were either self-employed or employed with a p value of 0.011. Although significantly higher, the MMAS-8 adherence level is still generally low.

In a research conducted in Nigeria by Senanu (2014) and published online via *ncbi.nlm.nih.gov*, she states that, "being employed (including being self-employed and the nature of job) connotes a busy lifestyle where medication may not fit in." Her study further states the instances where individuals find it difficult to get time off their work to complete medical treatment such as injections for fear of stigmatization or public knowledge of their health may prevent somebody from taking his drugs at work place, the side effects of some medication influence medication non-adherence". The results by Senanu are in agreement with the findings of this study which has indicated that the occupation can significantly affect treatment adherence. In essence, the findings of this study in relation to occupation can be presumed that when people are so busy with their daily chores or activities they end up forgetting to take medication or may not get time to go to the hospital to pick drugs.

In yet another study conducted in Uganda by Bazeyo *et al.*, (2015) he states that several socio-demographic factors that are significantly associated with poor adherence were age, financial difficulties, and occupation. Bazeyo's study therefore is in line with the findings of this research and could then be concluded that the reason for significant compliance among the unemployed in this study could be attributed to several factors including having enough time and less busy schedule.

5.3 The mean effect of socio-demographic factors on anti-diabetic drug compliance

Results in table 4.2 show that the difference in mean adherence to treatment is not statistically significantly for each of the socio-demographic variables except for occupation where the difference between the mean Morisky's eight question treatment for the unemployed patients was statistically significantly higher than that of those who were either self-employed or employed.

Notably, all the mean score for each of the dichotomous variables on treatment factors suggest low level of adherence as the means are all below 0.6.

In a study by Kirkman *et al.*,(2015) they found that some patient demographic and clinical factors were associated with higher adherence to non-insulin anti-diabetic medications for instance; older age, male sex, higher education level, higher income, and presence of comorbid chronic conditions and therefore being new to diabetes therapy was associated with lower adherence.

A study done by Mohammad and Siddiqui (2013) indicates that employment is a factor which significantly is associated with non-compliance. Others include age, gender and marital status. Their results in regard to occupation/ employment are consistent with those of this research study.

5.4 To determine the predictors of adherence to anti diabetic treatment

Regression model was fitted to assess the relationship between external environment, health care system, internal environment, medication system and MMAS-8 score on adherence to treatment. Each predictor was tested while holding other predictors in the model constant. This statistical control that regression provides is important because it isolates the role of one variable from all of the others in the model. The equation shows that the coefficient for external environment is 0.14 which implies that for every additional unit in external environment (being encouraged by family to take medicine, work/home/hospital environmental) adherence level increases by an average of 0.14 with the relationship being statistically significant (p = 0.02).

High risk situations and environmental systems have been linked to poor adherence in patients with diabetes. Self-care behaviors occur in the context of a continually changing series of environmental situations at home, at work, in public etc which are associated with different demands and priorities. Patients are frequently called upon to choose between giving attention to diabetes self-management or to some other life priority. Some of these environmental factors such as money, daily activities and people we live with can have positive or negative consequences in treatment compliance (Schlundt DG, *et al.*, 2009; 21:19–36).

In this study the results indicate that being encouraged by family members and having conducive hospital environment has a positive impact on adherence and are therefore consistent with the above author.

Health care system (b=0.12) is marginally significantly (p = 0.08) associated with adherence to treatment. The study results are marginally significant implying that factors like long waiting time, unhappy clinic visits and difficulty in getting prescriptions can have a negative influence on the compliance. Maina E. W., (2016) in her research study found out that most of the respondents 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.

On the other hand, age, level of education, attitude and marital status which are considered as internal environment (b=-0.01) had no effect on treatment compliance (p = 0.83). These results are inconsistent with the findings of Glanz, *et al.*, (2012) where it states that internal factors including age, genetics, physical, spiritual, cognition, attitude and personality can influence a patient to have an urge to take medicine or to comply with treatment.

Similarly, domain on medication system (b=0.01) which includes route of administration of anti-diabetics, storage methods, side effects of medications, duration of treatment and treatment complexity is not a predictor of treatment

adherence (p = 0.87) which are again are not consistent with those of Fish and Lung, 2001. The results suggest that promoting adherence involves a good clinician- patient relationship as well as provision of personalized, practical and repeated health education which all comprise the medication use system.

CHAPTER SIX

CONCLUSION AND RECOMMENDATION

6.1 Conclusion

This study focused on the factors affecting treatment compliance among type 2 diabetes patients on follow-up at Moi Teaching and Referral Hospital, Eldoret.

Majority of the patients (72%) had poor drug compliance. While this might point to lack of attention the patients with diabetes give to their condition, it may also imply limitations in the diabetes care or services in MTRH, and most likely the methods used in patient education and counseling on the importance of strict adherence to their treatment regimen.

The study findings of non-adherence are also most likely to be due to patients being conservative due to the fact that this was based on patient recall which is prone to errors.

Finding on external environment adherence level increases by an average of 0.14 with the relationship being statistically significant (p = 0.02).

6.2 Recommendations

- MTRH doctors, nurses, clinical officers and other officers should target especially the employed patients and enhance health education them on the need for treatment compliance including the effects of non-compliance to the overall health outcomes.
- External factors (being encouraged by family to take medicine, work/home/hospital environmental) should be enhanced since it has shown positive impact on compliance.
- Further studies to be conducted with a much larger sample size in several other hospitals within Uasin Gishu County.

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APPENDICES

APPENDIX I: LETTER OF INTRODUCTION

Greetings! My name is Caleb Koech.

I am a student a student at **Masinde Muliro University of Science and Technology** taking Master's Degree in Nursing. I am carrying out a research on factors affecting treatment compliance among type 2 diabetes patients on follow-up at Moi Teaching and Referral Hospital -Eldoret.

Your participation in this study will help in assessing treatment compliance among the diabetes type 2 patients at MTRH Eldoret. You will be given a questionnaire to fill and it will take you approximately 15 minutes to complete. Your participation will be strictly on voluntary basis and your refusal to participate will not have any effect on your treatment.

The research is being done to help us learn more on the major factors that cause poor treatment compliance amongst type 2 diabetes patients and eventually the ways of mitigating these factors and hence improving the treatment compliance. The questionnaire will ask questions related to your socio-demographic information, factors that cause low treatment compliance and an eight question Morisky tool which also assesses the drug compliance. You will be in the study for the period that the study will be conducted and there is a risk that the information about your confidentiality may be known by others outside the study but there will measures to protect this information and keep it safe in the sense that no names will be used but the researcher shall use coded numbers. Some of the benefits from the study is that there will be increased knowledge about the factors that lead to poor treatment adherence and therefore corrective measures will be put in place. Remember, adherence to drug treatment plans lead to improved quality of life and less complications.

Your answers/responses will therefore remain confidential and will not be shared with anyone during the study period neither is your name.

Patients attending the out- patient clinic will be eligible to participate in the study as long as they meet the criteria.

Informed consent for participants

Your participation in this study is totally voluntary. You can leave the study at any time for any reason. You can choose not to answer questions on the questionnaire and Morisky eight question tool. Do not write your name and signature on the study tools before or after answering the questions. The researcher and the assistant will be observing you from a distance and you will not know when you are being observed you will be evaluated on the treatment compliance for type 2 diabetes mellitus.

Your signature below shows that you have understood the above information and agree to participate in the study.

Participant's name	_signature:	Date
Witness	Date	

Thank you for your participation.

APPENDIX II: QUESTIONNAIRE

Part I: Demographic data

Please tick ($\sqrt{}$) in the appropriate box.

1. What is your age in years?

 \Box 18 - 24 \Box 25 - 39 \Box 40 - 49 \Box 50 and above

2. Please indicate your gender.

 \Box Male \Box Female

- 3. Marital status \Box Married \Box Single \Box Widowed \Box Divorced
- 4. How long (in years) have you had diabetes type 2?

 \Box less than 1 year $\Box 1 - 2$ $\Box 3 - 5$ $\Box 5 - 10$ \Box above 10

5. What is your highest Educational qualification?

□ Other qualifications (please specify)

6. What is your current occupation?

 \Box Employed \Box Unemployed \Box Self employed \Box Other

(specify).....

7. Monthly income (in Kenyan Shillings)

 \Box Less than 5000 \Box 5000- 10000 \Box 10000- 50000 \Box over 50000

8. What kind of medicine do you use?

 \Box Pills \Box Injection \Box Both

 Glycated haemoglobin level (laboratory values to be filled by the researcher/ assistant during the clinic

visit).....

Part II: Factors affecting treatment compliance

i) Influence of external environment on treatment

compliance

No.		Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
10	I get encouraged by family members to take medicine					
11	Work/Home/hospitalenvironmental settings affect mydrug compliance					
12	Lack of money can cause non compliance to medication					

ii) Influence of the healthcare system on compliance

No.		Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
13	Accessibility to the hospital affects drug compliance negatively					
14	Long waiting time at the hospital affects my compliance negatively					
15	Difficulties in getting a physician affects my compliance negatively					
16	Unsatisfied clinic visits affects treatment compliance negatively					

iii) Influence of internal environment on compliance

No.		Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
17	My age affects treatment compliance negatively					
18	My level of education influencescompliancetopositively					
19	My attitude and beliefs can					

	negatively influence treatment compliance			
20	My marital status can influence			
20	treatment compliance positively			

iv) Effects of medication system on treatment compliance

No.		Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
21	Route of administration of antidiabetics influences treatment compliance negatively					
22	Storage methods for anti diabetics influences compliance to treatment negatively					
23	My medication side effects affects compliance to treatment negatively					
24	Duration of treatment can influences compliance negatively					
25	Treatment complexity affects compliance negatively					

Part III: Medication Adherence measurement (Morisky's eight question instrument)

- i. Do you sometimes forget to take your medicine? \Box yes \Box no
- ii. People sometimes miss taking their medicines for reasons other than forgetting.

 \Box yes \Box no

- iii. Thinking over the past 2 weeks, were there any days when you did not take your medicine? \Box yes \Box no
- iv. Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it? \Box yes \Box no
- when you travel or leave home, do you sometimes forget to bring along your medicine? □ yes □ no
- vi. Did you take all your medicines yesterday? \Box yes \Box no
- vii. When you feel like your symptoms are under control, do you sometimes stop taking your medicine? \Box yes \Box no
- viii. Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan? \Box yes \Box no

YES=1, No	= 0 for questions 1 to 8
Scores: >2	= low adherence
1 or 2	= medium adherence
0	= high adherence

How often do you have difficulty remembering to take all your medicine?

- ____A. Never/rarely
- ____B. Once in a while
- ___C. Sometimes
- ___ D. Usually
- ____E. All the time

A = 0; B-E = 1

Thank you for participating.