

**ASSESSMENT OF TREATMENT COMPLIANCE AMONGST ADULT PATIENTS
WITH TYPE TWO DIABETES MELLITUS AT KENYATTA NATIONAL HOSPITAL**

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DECLARATION

I, Esther Asenahabi, declare that this is my original work and has not been presented for award of a degree in any other university or institution of higher learning.

Signature

Date

APPROVAL

We the undersigned certify that this dissertation is submitted for partial fulfillment of the award of degree of Master of Science in Nursing (Medical Surgical Nursing) of the University of Nairobi with our approval as internal supervisors.

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DEDICATION

I would like to dedicate this work to my parents Ruth and the late Paul Asenahabi for having taken the initiative of educating me.

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ABBREVIATIONS AND ACRONYMS

BP	: Blood pressure
CDC	: Centres for Disease Control and prevention
CVS	: Cardio-Vascular System
DKA	: Diabetes ketoacidosis
DM	: Diabetes Mellitus
GDM	: Gestational diabetes mellitus
DSMQ	: Diabetes self-management questionnaire
HbA1c	: Glycosylated hemoglobin
KNH	: Kenyatta National Hospital
OHAs	: Oral Hypoglycemic Agents
R	: Coefficient correlation
SMBG	: Self-Monitoring of Blood Glucose
SPSS	: Statistical package for social scientists
T1DM	: Type 1 diabetes mellitus
T2DM	: Type 2 Diabetes Mellitus
UK	: United-Kingdom

USA : United States of America

WHO : World Health Organization

OPERATIONAL DEFINITIONS

Adult: An individual who is above 20 years of age.

Diet regimen: Prescribed nutritional plan that the patient is advised to follow consistently.

Exercise regimen: Set exercise program that a diabetic patient is advised to maintain.

Glycemic control: Maintenance of blood glucose levels constantly between 3 mmols/lit to 10mmols/lit, and having a HbA1c below 6.5.

Treatment compliance: Ability of persons diagnosed with diabetes mellitus to follow both medical and non-medical treatment modalities as prescribed by medical team members.

ABSTARCT

Diabetes mellitus is a clinical syndrome characterized by hyperglycemia caused by absolute or relative deficiency of insulin in the body. Type 2 diabetes mellitus (T2DM) accounts for more than 90% of all the diabetic patients (CDC, 2003). Compliance to prescribed therapy is key to glycemic control, which plays an important role in reducing chronic complications of T2DM to include chronic renal failure, cardiovascular complications, neuropathy and erectile dysfunction. Until recently diabetes mellitus (DM) was believed to be a disease occurring in the developed countries. Recent findings reveal that there is a rise in the number of new cases of type 2 diabetes mellitus with an earlier onset and associated complications in developing countries (Saurabh et al, 2013). The main objective of this cross-sectional study was to assess the treatment compliance among T2DM adult patients attending Kenyatta national hospital. The study mainly evaluated compliance to drug therapy, nutrition, physical activities and self-monitoring of blood glucose levels. A total of 199 participants were selected and interviewed. This sample size was calculated using Fisher's formula and the participants were selected using systematic sampling method. A structured questionnaire was used to collect data from the participants. These questionnaires were analyzed using SPSS computer soft-ware version 20. Statistical methods used included chi-square, coefficient correlations, P- values, and percentages. The study found out that 58.3% of the participants had HbA1c levels below 6.5%, while 41.7% had HbA1c above 6.5%. The study also showed that 61.8% had latest random blood sugar level below 10mmols/lit while 38.2% was above 10mmols/l. Only 6.5% of the participants had their cholesterol levels recorded in their files. Majority of the participants, 58.8% had their BP above 130/85 mmHg. This study revealed that 73.36% of the respondents reported high compliance to pharmacological treatment while 72.3% reported high compliance to nutrition. There was sub-optimal compliance to SMBG and nutritional management. Only 35.6% n=71 reported high compliance to SMBG, while 40.7% reported high compliance to physical activities. From the findings of the study, it was noted that there's no significant relationship between age, gender, marital status, education level of T2DM patients at KNH and compliance to pharmacological treatment, SMBG, physical activities, and nutrition ($p > 0.1$). In conclusion, a holistic approach needs to be embraced in managing T2DM patients at KNH so as to have high scores of optimal glycemic control among these patients. Health care providers need to encourage T2DM patients to adhere to all treatment modalities because compliance to a few modalities alone nullifies any efforts put in care of the diabetic patient. This leads to sub-optimal levels of glycemic control and DM complications in the long run. As it is evident, majority of the participants have elevated blood pressure that is likely to be accompanied by other silent complications. The researchers recommend that the health care providers need to improve monitoring of cholesterol levels and re-educate T2DM patients to monitor their blood glucose levels on a daily basis. Emphasis should be laid on compliance to all modalities of DM treatment.

CHAPTER ONE: INTRODUCTION

1.1 Background of the study

Diabetes Mellitus is a chronic metabolic disorder that occurs when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces. This results in elevated blood sugar (hyperglycemia) which over time leads to multiple organ damage (Kenya demographic survey, 2003). There is breakdown of body proteins and fats and poor utilization of glucose obtained from food. These factors lead to hyperglycemia, excessive micturition, increased thirst and dehydration. Types of DM include T1DM, T2DM, GDM, and DM due to other medical conditions. T2DM accounts for over 90% of all forms of DM (CDC, 2008). In order to achieve glycemic control, diet, lifestyle, and medication are the main modes of treatment. Treatment compliance is the ability of persons diagnosed with diabetes mellitus to follow both medical and non-medical treatment modalities as prescribed by medical team members. The patient should also avoid risk factors such as smoking and excessive alcohol consumption. Self-monitoring of blood glucose levels enables people with DM to adjust their treatment regimen. Realizing the multifaceted nature of the problem, a multi-pronged and integrated approach is required to promote self-care practices among diabetic patients to avert long term complications (Rambiharilal et al, 2013).

Diabetes mellitus is a chronic disease that is on the rise in our current society. The current estimate of DM prevalence world-wide stands at a scaring 347 million people. (WHO 2013 diabetes report.) In the year 2011, about 14 million people were estimated to have diabetes mellitus in Africa. This number is estimated to rise to 28 million by the year 2030 (Manouk et al, 2013). According to WHO, it is estimated that by the year 2030, diabetes prevalence in the

developing countries will increase by 82.5%. DM is estimated to cause 4.8 million deaths every year and it accounts for 8.2% of global all-cause mortality (KDHS, 2003).

1.2. Statement of the Problem.

Treatment compliance is very crucial in effective management of all forms of DM. Lack of compliance to prescribed pharmacological and non-pharmacological therapy predisposes the patient to acute and chronic complications. It was presumed that DM was for the affluent and developed world. Today there seem to be an epidemic of DM and other non-communicable diseases like cardiovascular diseases in low and medium income countries. Recent findings reveal that there is a rise in the number of new cases of T2DM with an earlier onset and associated complications in developing countries (Saurabh et al, 2013). A study that was done in France to determine medication adherence in type 2 diabetes mellitus patients, 39% of the participants reported good compliance, 49% moderate compliance and 12% poor compliance (Michel et al, 2012).

A study that was done in Ethiopia revealed that for every 10% increase in adherence, HbA1c decreased significantly by 0.14 to 0.16%. Non adherence to medication among diabetic patients resulted in poor glycemic control and hence increased risk of developing chronic complications as well as increased hospitalization (Nasir et al, 2010). In another study that was conducted by Shams et al, 2010 in Egypt to measure therapeutic adherence among out-patient patients with T2DM, the adherence rate to medication, dietary and exercise regimen, and appointments were observed to be sub-optimal. The adherence levels in this study were as follow: Drugs: 38% good adherence, 45% fair adherence and 16% poor adherence. Exercises and diet: 21% good compliance, 50.4 fair and 28% poor adherence.

Masoud (2012), conducted a study at Kenyatta national hospital to assess glycemic control among insulin treated ambulatory patients. 64 % of the respondents reported that they were adherent to insulin and only 5.2% monitored their blood sugar at least once a day. In this same study, the mean HbA1c was 9.4%. Considering this results it is evident that majority of patients have poor glycemic control. It is therefore crucial to assess the clients' practice on self-medication to understand why there is poor glycemic control. So far there are scanty documented research findings on compliance to OHA and non-pharmacological management at KNH. It is against this backdrop that this study is designed to assess compliance to both pharmacological and non-pharmacological therapy; mainly diet, exercises and self-monitoring of blood glucose levels. There are other non-pharmacological measures of managing T2DM but this research was contained around these three factors because they are seen as the main strategies of controlling blood sugar levels.

1.3. Justification of the study

The studies conducted at KNH among adult T2DM patients mainly focus on non-compliance to insulin therapy. Management of T2DM should emphasize on lifestyle modification like exercises and diet, self-monitoring of blood glucose, compliance to OHAs and where applicable insulin, in that order. There are no documented studies on compliance rates to these main ways of T2DM management at KNH. Therefore it was important to conduct this study and assess the compliance level to these main modalities of managing T2DM in KNH. The study findings will go a long way in determining the success rate or the failure rate of T2DM management. This will inform the care givers at KNH diabetic clinic on the areas that they should emphasize on when treating these patients. This in-turn will reduce T2DM complications amongst the patients. The national

policy makers will also be alerted on the areas that need to be given priority when planning for management of T2DM in the country. The results will assist in allocation of resources to priority areas in management of T2DM both at KNH clinic and nation-wide. The findings will also inform Curriculum developers so that they design it to promote evidence based practice in nursing and related medical fields.

1.4. Research Objectives

1.4.1. Broad Objective

To determine the level of treatment compliance among adult T2DM patients attending Kenyatta National Hospital

1.4.2. Specific Objectives

1. To determine physiological and anthropometric measures of T2DM patients at KNH.
2. To determine the level of pharmacological adherence of T2DM patients at KNH
3. To evaluate blood sugar monitoring among T2DM patients at KNH
4. To determine the extent of nutritional adherence among T2DM patients at KNH
5. To evaluate compliance to physical activity of T2DM patients at KNH

1.5. Research Variables

1.5.1. Independent variables

- i. Age
- ii. Gender

iii. Marital status

iv. Level of education

1.5.2. Dependent variable

Compliance to;

- a. Pharmacological treatment
- b. Physical activities
- c. Prescribed nutrition
- d. Self-monitoring of blood glucose levels.

1.5.3. Confounders

Co-morbidity

Client's attitude

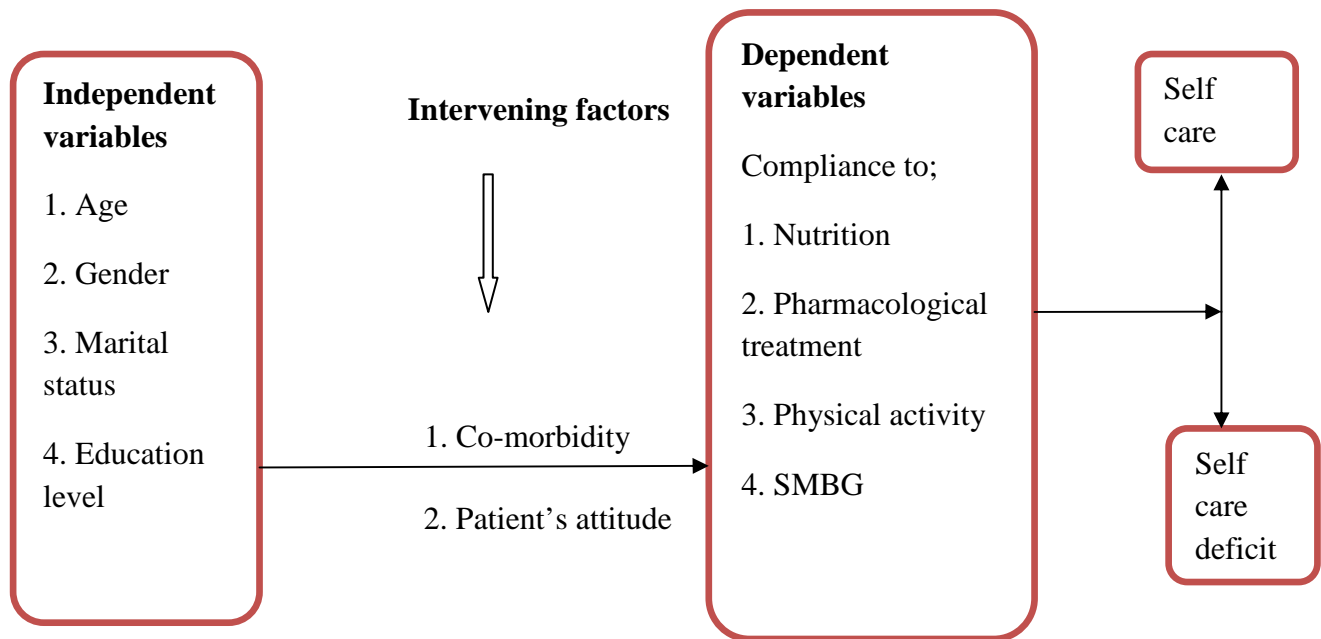
1.6. Research Question.

Do T2DM adult patients attending Kenyatta national hospital comply with prescribed medication regimen, exercises, nutrition, and self-monitoring of blood glucose levels?

1.7. Hypothesis

There is no significant relationship between compliance to pharmacological treatment, exercises, nutrition, self-monitoring of blood glucose levels and levels of education, age, gender, and marital status of T2DM patients at KNH

1.8. Conceptual Framework



Source (authors), 2014.

Figure 1: conceptual framework

1.9. Theoretical Framework.

Orem's theory of self-care was applied in this study. This theory contains three theories;

- Theory of self-care
- Theory of self-care deficit
- Theory of nursing system.

Type 2 diabetes mellitus patients live with the condition for a lifetime. They are expected to learn and participate in care of their own health. Using this theory the study evaluated;

- 1) Patient self-care ability which is basically the compliance to prescribed therapy. Where the patients were compliant to treatment and their glycemic control was good then recommendations are made to reinforce the self-care agencies.
- 2) Self-care deficit. This was demonstrated when the patient was not compliant to prescribed treatment, both pharmacological and non-pharmacological therapy. Self-care-deficit was verified using HbA1c levels among the patients. If self-care agency could not take care of self-care demands then self-care deficit existed. In this case the research recommendations emphasized on the most appropriate nursing system to employ in improving compliance to diabetes treatment.

CHAPTER TWO: LITERATURE REVIEW

2.1. Introduction

T2DM is associated with poor utilization of insulin by peripheral tissues or overproduction of glucose in the body. T2DM is the most common type of diabetes accounting for over 90 % of total cases of DM (Jamieson et al, 2009).

In the year 1901, Albert Cook, a medical missionary in Uganda reported that diabetes mellitus was rather uncommon and very fatal in Africa (Cook 1901). Over the next 50 to 60 years diabetes mellitus continued to be regarded as rare in sub-Saharan Africa, with communicable diseases making the greatest disease burden. But by the year 2020, non-communicable diseases including hypertension and diabetes mellitus will outstrip communicable diseases as the main cause of death (Murray and Lopez, 2010).

2.2. Epidemiology of diabetes mellitus

Diabetes mellitus is on the increase at a very fast rate. WHO estimated that in 2003, 177 million people had diabetes mellitus globally. In the year 2013 this number has almost doubled to 347 million people. (WHO 2013 diabetes report). In the year 2011, about 14 million people were estimated to have diabetes mellitus in Africa. This number is estimated to rise to 28 million by the year 2030 (Manouk et al). Eighty percent (80%) of people with diabetes mellitus live in low and middle income countries (WHO 2013).

The world prevalence rate of DM is projected to be 7.7% (Ayah R et al, 2013). The prevalence of pre-diabetics in sub-Saharan Africa is approximately 5.3% among women and 5.7% among men (Glover et al, 2011). Every year it is predicted that 5 to 10% of pre-diabetics will develop

DM (Glover et al, 2011). In a recent study done in Kibera slum, Kenya, it was demonstrated that the prevalence rate of DM is at 5.3 (95% C.I 4.2 to 6.4) peaking at 10.5% (95 % C.I 6.4 to 14.3 %) in the 45-54 years age category (Aya et al, 2013), correlating with studies done in other parts of sub-Saharan Africa.

2.3. Management of T2DM.

Since DM is a chronic condition, the patient has a great role to play in management of their own health. Individuals with T2DM have been shown to make a dramatic impact on the progression and development of the disease by participating in their own care. Despite this fact, compliance or adherence to these activities has been found to be low especially when looking at long term changes (Saurabh et al, 2011). Effective management of DM largely depends on the clients' individual commitment to follow the prescribed management regimen, both pharmacological and non-pharmacological.

Evidence suggests that empowerment is an important factor to address everyday aspects of dealing with chronic disease. Melbar et al (2012) conducted a study to determine empowerment, medication adherence and self-care behaviors in adults with T2DM in USA. It was shown that diabetes empowerment was associated with medication adherence, increased knowledge and effective care behaviors including diet, physical activity, self-bloods sugar monitoring and foot care. Individuals' knowledge on diabetes mellitus management is crucial to management. Patients must be educated on the different aspects T2DM management.

In a study that was done to determine knowledge, attitudes and practices among community members in Kenya, it was demonstrated that 74% of the respondents in Nairobi had poor knowledge of DM, and 25% had fair knowledge (Maina et al, 2011). However, this study

considered the population in general. Most individuals gain more knowledge on DM once they are diagnosed to be diabetic. This should translate to higher compliance to prescribed modalities diabetes management. In a study that was done in South Korea after health education was offered to the participants and compliance was at 73.6%. Glycosylated hemoglobin (HbA1c) decreased greatly in the compliant group from 7.8 +/- 1.54 at baseline to 6.79 +/- 1.06 at three months versus from 7.74 +/- 1.02 to 7.14+/-0.02 in the non-compliant group (Kim et al, 2012). Management of T2DM should be comprehensive and the patient should be made aware of his management plan. Upon diagnosis of T2DM it is crucial to perform a thorough examination on the patient and involve the patient and significant others in planning the care.

2.3.1. Drug Therapy in T2DM Management.

T2DM is managed by oral hypoglycemic agents (OHAs) like metformin and glibenclamide. These drugs improve insulin utilization at peripheral tissues and reduce glucose production in the body. When T2DM is not controlled by OHAs then insulin replacement therapy is initiated in the patients' regimen. In administration of all these drugs it is important that the patient takes the drugs as prescribed, at the right time and the right dose. In a study that was done in New Zealand, 86% of patients prescribed insulin reported that they were adherent all the time. A study was done in Ethiopia to assess medication adherence in T2DM and self-management practices, and 41.9% of the respondents on OHAs and insulin had adequate glycemic control. Among those who missed their medication, the most common reasons were; forgetfulness at 50.2%, being busy at 34%, other reasons to include disappearance of symptoms, perceived inefficiency of prescribed drug at 33.8% (Mulugeta et al, 2011). Glycemic control is an indicator to compliance to prescribed drugs. A study conducted at the diabetic clinic in Sri Davaraj Urs medical college

and hospital, 68% of respondents had inadequate knowledge on insulin self-administration while 32% had moderate knowledge and none had adequate knowledge. Average mean score of this knowledge was 46.9%. In this study, 72% of respondents had poor practices in insulin self-administration while 28% had moderate practice while none had good practice. Mulugeta et al, 2013 conducted a study in south west Ethiopia, on determinants of glycemic control among insulin treated diabetic patients. In this study, 18.3% of the participants achieved glycemic control while 81.7% had poor glycemic control, 95 % reported re-use of disposable syringe-needle (Broadbent et al, 2011). Compliance to drug therapy involves how well the patient carries out the self-drug administration. This study is designed to identify what patients know about their medication and how well they take their medication. In another study that was done in south western Nigeria on the adherence to anti-diabetic drug therapy among T2DM patients, it was shown that only 1/3 of the patients adhered to their treatment (Yussuf et al, 2010).

2.3.2. Exercises in management of T2DM.

Physical activity and exercises are crucial in maintaining optimal glucose levels in patients who are already diagnosed with T2DM. Exercises enhance utilization of glucose in the body, and this helps to avoid peaks and troughs in blood sugar levels. According to WHO the biggest increase in DM is in the urban areas. Changing patterns of diet, physical activity and ageing population are thought to be the major drivers of increasing prevalence in Africa (WHO diabetes report, 2013). Exercises are important in preventing onset of T2DM and controlling blood sugar levels in patients already diagnosed with T2DM. A study that was conducted in New Zealand reported that only 17% of the participants achieved complete compliance to exercise regimen (Broadbent , et al, 2011). In a study that was conducted at the university of California, it was concluded that

DM is prevented by increasing overall activity and that vigorous activities like swimming, tennis, and running have a more stronger protective effect than the less vigorous activities (Helmrich et al, 2010). In our current setup in Kenya many communities have abandoned their traditional practices that involved vigorous physical activities like walking for long distances. Many have shifted to western lifestyle, resulting in over-reliance on motorized transport. (Maina et al, 2011). This study is designed to evaluate T2DM patients' compliance to exercises in relation to the physical activity levels.

American diabetes association has stipulated standards of exercises that have been adopted by many countries including Kenya. The exercise program is; more than 150 minutes per week of moderate intensity with 50 to 70% of minimum heart rate, spread over more than or equal to three days per week with no more than two days without exercise (American diabetes association, 2013). This study will evaluate all aspects relating to compliance to exercises and correlate this with levels of blood sugar for the participants.

According to WHO report on burden, morbidity of disease, mortality and risk factors , people with insufficient physical activity have a 20 to 30% increased risk of all-cause mortality compared to those who engage in at least 30 minutes moderate intensity physical activity on most days of the week. Since exercises are important in controlling blood sugar levels it is important to evaluate how the diabetic patients comply with exercises as part of their treatment. In a study done to determine knowledge, attitudes and practices among communities in Kenya, reasons for non-adherence to exercises were; lack of information 65.7%, exercises potentially exacerbating the illness 16% and specific location away from home at 18% (Maina et al, 2011).

This study however was done among the general population, so this current proposed study is designed to evaluate compliance to exercises among T2DM.

2.3.3. Nutritional therapy in management of T2DM

The type of diet that a diabetic patient takes determines blood sugar levels. High carbohydrate diet translates to hyperglycemia whereas low carbohydrate diet for a diabetic patient on insulin will lead to hypoglycemia. A dietician should be included in planning and educating the diabetic patient on the appropriate diet that they should take. Two important changes that primary care practitioners must recognize are medical nutritional therapy and physical activity. Both can be very effective in reducing glucose levels, increasing energy consumption and contributing to weight loss for overweight patients (Parkin et al, 2010). Broadbent et al 2011 demonstrated in their study that only 22% of the participants reported complete compliance to diet recommendations. There is a shift in feeding habits of many communities. People have shifted from consuming traditional foods that were whole grain based, high fiber, rich in vegetables and fruits. Majority are now consuming high calorie, low fiber, diet rich in fats, salts and sugar (Maina et al, 2011). It is important to assess whether diabetic patients attending KNH diabetic clinic have changed their feeding habits to control blood sugar levels or not. A study done in rural India concluded that tobacco, alcohol use, low fruit and vegetable diet were more common in low socioeconomic groups whereas obesity, dyslipidemia, DM in men and hypertension in women were more common in higher socio-economic groups (Surendath et al, 2012). The American diabetes association stipulates that, all overweight and obese patients should lose weight to attain BMI below 25, encourage low carbohydrate low fat diet and limit intake of

saturated fat to less than 7% of their caloric intake. It also recommends less than one alcohol drink per day for women and less than two alcoholic drinks per day for men.

2.3.4. Self-Monitoring of Blood Glucose Levels.

Blood sugar fluctuations are the main reason behind development of diabetes mellitus complications. In the UK prospective DM study, it was shown that a continuous relationship exists between glycemic control and micro-vascular complications. There was 35% reduction in risk for developing micro-vascular complications with every 1% decrease in HbA1c. (Romes. et al, 2013). The patient can only control his /her blood sugar levels if he/she can monitor the blood sugar levels on a regular basis. Diabetic patients on insulin should monitor their sugar levels prior to meals, at bedtime, prior to exercises and when low blood sugar levels are suspected (American diabetes association). The diabetic patient should monitor their blood sugar levels frequently so that they can know when to adjust their insulin dose, exercises and diet. Diabetic patients should provide their primary care practitioner with their glucose monitoring records so that evaluation can be made and adjustments are made as needed (Parkin et al, 2010).

As the patient monitors their blood sugar levels at home they should be encouraged to keep record of the glucose levels. On the other hand, the health care provider should monitor glycosylated hemoglobin levels. This will help to evaluate if the patient's glycemic control has been kept at optimal levels over a long period. HbA1c is therefore a good measure of how well the patient is complying to prescribed treatment.

According to WHO guidelines on diagnosis of DM and monitoring of blood glucose levels, an HbA1c of 6.5% is recommended as the cut point for diagnosis of DM. A value less than 6.5% does not exclude DM diagnosed by glucose test. HbA1c reflects average plasma glucose over

the previous 8 to 12 weeks (WHO diabetes guidelines 2013). HbA1c should be conducted every three months until the patient is stable then every 6 months. (Parkin et al, 2010). In this study the patients' last HbA1c will be evaluated to be able to correlate the patients self-report of compliance and the HbA1c levels as a means of verifying the patient's self-evaluation.

2.3.5. Complications of T2DM.

Since prevalence of DM is on the increase and specifically T2DM, it is important to confirm the compliance levels to prescribed treatment. Complications of T2DM are life threatening and expensive to treat. According to the national chronic kidney disease fact sheet 2010, more than 35% of people aged 20 years and above with DM have chronic kidney disease. In-adequately controlled DM increases the risk of progression from chronic kidney disease to kidney failure.

DM causes 4.8 million deaths per year accounting for 8.2% of global all-cause mortality (WHO global burden of disease, 2010). A study was done to determine prevalence of diabetic retinopathy, cataract and visual impairment in diabetic patients in sub-Saharan Africa identified that 32.5% of any retinopathy was associated with diabetic retinopathy and that it was also associated with albuminuria and neuropathy (Glover et al, 2011). Other complications of DM type 2 include hypertension, heart failure, lower limb amputation and neuropathy.

A study that was done in Boston USA revealed that patients who are adherent to treatment at baseline of the study and remained adherent had the lowest rate of hospitalization and emergency department visits at 27%. In the analysis of potential benefits of improving adherence it was estimated that approximately 699,000 emergency department visits and 341,000 hospitalizations would have been averted annually if all non-adherent patients with DM became adherent. It was also estimated that the USA would have saved \$3.95 billion in hospitalization and \$735 million

in emergency department visits each year (Ashish et al, 2012). Compliance to diabetes mellitus type 2 treatment will definitely reduce morbidity and mortality related to the disease process. The prevalence of T2DM and its complications is on the increase. In order to maintain optimal blood glucose levels and minimize complications, T2DM patients should comply with prescribed therapy. A high prevalence of diabetes complications indicates sub-optimal complications to DM treatment. According to WHO 2013, DM is the leading cause of renal failure in both developed and developing countries. Lower limb amputations are at least 10 times more common among diabetics than non-diabetics world-wide. A study that was done at Kikuyu hospital revealed that 11.4 % of limb amputation at this hospital was accounted for by diabetic vasculopathy (Ogeng'o et al, 2009). T2DM is also a leading cause of renal failure. The prevalence of diabetic nephropathy is estimated to be 6 to 16 % in South Africa (Naicker, 2010). A study that was done on diabetes out-patients in new Zealand, both T1DM and T2DM patients ranked medication significantly more important than diet and exercises for controlling DM, p less than 0.001 (Broadbent, et al, 2011)

CHAPTER THREE: METHODOLOGY

3.1. Study design

This was a cross-sectional descriptive study that was conducted among adult T2DM attending KNH out-patient diabetic clinic and medical wards.

3.2 Area of Study

The study was conducted at Kenyatta national hospital (KNH), which is the largest referral and teaching hospital in Kenya and East Africa, located in the capital city Nairobi. KNH has a bed capacity of 1800 and several out-patient clinics where patients are followed up for management of chronic conditions. The hospital is located in upper hill area and it occupies an area of 45.7 hectares. There are two diabetic clinics at KNH; the main and mini clinics operated every Friday from 8am to 12 noon and every day same time respectively. This study focused on T2DM adult patients attending the main out-patient diabetic clinic located in the medical clinic number 17 of KNH and T2DM patients admitted in the medical wards on level 7 and 8, that is ward 7A, 7B, 7D, 8A, 8B, 8C and 8D.

3.3. Study Population

The study population was T2DM patients attending KNH diabetic out-patient clinic for follow up care and old T2DM patients admitted in the medical wards. The average number of old patients who attend the clinic on a monthly basis was approximately 263 (health information statistics, KNH, 2013). Each medical ward admits an average of 20 patients per month. Therefore in total the medical wards admit an average of 140 diabetic patients. The patients seen in the clinic and those admitted in the wards formed the study population.

3.4. Sampling and Sample Size.

3.4.1. Sample Size calculation.

The sample size was calculated using Fischer's formula

$$SS = Z^2 * P * (1 - P) / C^2$$

Where;

SS= sample size

Z=Z value at 1.96 for 95% confidence interval.

P= Percentage picking choice expressed as a decimal (0.5). Prevalence of DM at 50%.

C= confidence interval expressed as a decimal. +/- 0.05 or 5%

Therefore;

$$SS = 1.96 * 1.96 * (0.5) * (1 - 0.05) / 0.05^2$$

384.16

Given that the population was less than 10,000;

The new SS was given by:

$$SS / 1 + [SS - 1 / \text{pop}]$$

Where pop = Population.

$$\text{New SS} = 384.16 / 1 + [384.16 - 1 / 413]$$

199 Patients

Therefore 199 patients were selected for the study.

3.4.1 Inclusion Criteria

Adult diabetic patients(above 20 years) who had had the diagnosis for 6 months and above, whether they had been admitted in the past or not, either on oral hypoglycemic agents or on both oral hypoglycemic agents and insulin. All the participants were old patients at the clinic or in the wards.

3.4.2. Exclusion Criteria

Adults above 20 years who were on insulin alone will be excluded. These are likely to be T1DM patients. Adults below 20 years and those who had had the diagnosis for less than six months were excluded. All new T2DM patients were excluded. All known T1DM patients were also excluded.

3.4.3. Selection of Study Subjects

The sample was selected using systematic random sampling method. Since there were approximately 263 patients seen per month in the clinic and 140 patients admitted in the wards in a month, then the ratio of patients in the clinic to that of patients in the medical wards was approximately 2:1. Participants from these areas were selected in this proportion. That is 132 participants from the clinic and 66 patients from the medical wards.

3.4.4. Determination of selection interval

In total 263 patients are seen at the main diabetes clinic monthly. On average therefore, the number of patients who visit the clinic every clinic day; $263/4=66$ patients. Since the investigator intends to interview 132 participants in four weeks, then every Friday the participants that were interviewed were: $132/4=33$. The first client was selected randomly. Then every 2nd patient was included in the study.

Sample in the medical wards: 140 patients admitted in a month, each ward admits 20 patients in a month. The sample required was 66 participants from the 7 wards. Therefore each ward had 9 patients participating in the study in a month. Week 1, 2 and 3 each 2 participants were interviewed and 3 participants on the 4th week from every ward. The first patient was selected randomly then every second patient was included.

3.5. Study Instruments

3.5.1. Questionnaire.

The data was collected using a structured questionnaire which was the main tool. The questionnaire was in two parts. The first part elicited information on the demographic data of the participants. The second part of the questionnaire was an adopted diabetes self-management questionnaire i.e. DSMQ (Schmitt A, Gahr A et al, 2013). It has 16 items that are easy for the participants to understand. This is a validated tool that evaluated the patients' compliance to prescribed medication, exercises and physical activities, diet, clinic visits and self-monitoring of blood glucose levels. This tool has an advantage over other tools because it is able to assess diabetes self-care activities associated with glycemic control. DSMQ also has a psychometric evaluation. Other tools that are available include summary of diabetes self-care activities

(SDSCA). This tool is commonly used but it demonstrates weak correlation between self-care activities and glycemic control. Another tool is diabetes self-management profile (DSMP), which is mainly used to evaluate compliance among adolescents. Therefore DSMQ was used because it was the most appropriate tool that was consistent with the study title in this research. A validated tool is has a high reliability and validity. The questionnaire was self-administered for participants who could read and write. Respondent who could not read and write were given a questionnaire guided interview using the same tool.

3.5.2. Medical Records.

Records of those who consented to participate in the study were reviewed to check for the latest HbA1c, cholesterol and the latest blood sugar level.

3.5.3. Pre-Testing the questionnaire.

The questionnaire was pretested among T2DM patients attending Mbagathi district hospital diabetic clinic. Mbagathi district hospital is one of the government hospitals within the capital city, Nairobi. Pre-testing the questionnaire enabled the researcher to evaluate clarity of questions asked, the general flow and the sensitivity of the tool.

3.6. Personnel.

The data was collected with the assistance of two research assistants. Kenya registered community health nurses were chosen as research assistants. The principle investigator worked with the assistants in data collection, data cleaning and data entry. The researcher analyzed the data with the assistance of a statistician.

3.7. Ethical Considerations

The proposal was subjected to the KNH/ UON research and ethics committee for approval. Permission was sought from KNH diabetic clinic and records department to access patient's files.

Informed consent was sought from the respondents before collecting data from them at their own free will. The participants were allowed to give information at their own free will without coercion from the researcher. The questionnaires were coded and no names were written on the questionnaire. Participants who could not read or write were interviewed in privacy away from the other patients. The participants were assured of total confidentiality concerning the collected information.

3.8. Data Management (data collection, cleaning and entry).

3.8.1. Data collection procedure.

After systematic random sampling was done, the selected participants were explained to the aim of the study and expectations. The respondents were asked to consent voluntarily and those who did not consent were not included in the study. Literate participants were given the questionnaire to fill in. Those who could not read nor write were taken through a questionnaire guided interview by the researcher and research assistants. After filling the questionnaires the participants' weight, height and blood pressure were taken and filled in the questionnaires. The researcher then reviewed each of the patients' files for the latest random blood sugar, HbA1c and cholesterol levels. These parameters were filled in the relevant questionnaires.

3.8.2. Data entry and cleaning.

Questionnaires filled by the participants were collected and checked for completeness and consistency. Inconsistent information was eliminated and the unclear responses were clarified from the respondents.

Data from the completed questionnaires was entered using epi-data and the password was protected.

The researcher and the research assistants administered the questionnaires and participants who were able to read and write filled in the questionnaire. Those participants who could not read and/or write were asked to participate in a questionnaire guided interview, using the same questionnaire. Questionnaires filled by the respondents were collected and checked for completeness and consistency. Data from the completed questionnaires was entered using SPSS version 20 and the pass word was protected.

3.9. Data Analysis

Data was analyzed using SPSS computer soft-ware, version 20. The data was summarized using descriptive statistics like percentages and inferential statistics including chi square, p values and Pearson correlations. Results were presented in frequency tables, pie charts and bar graphs. Scientific conclusions were drawn from the findings.

3.10. Minimizing errors and bias

- i. The questionnaire was pretested and reviewed to ensure consistency.
- ii. Participants were selected randomly from the eligible study population.

- iii. All eligible subjects were allowed to participate (whether literate or illiterate), whether admitted in the medical wards or visiting the clinic.

CHAPTER FOUR: RESULTS

4.1. Introduction

This chapter presents the results of the study on treatment compliance amongst adult patients with type two diabetes mellitus at Kenyatta National Hospital. The questionnaires were completed by 199 participants. A total of 132 participants were drawn from the diabetes clinic and 66 participants from the medical wards.

4.2. Socio-demographic characteristics of the participants.

4.2.1 Age Distribution of the participants

The proportion of respondents above 40 years was 88.5% (n=176) significantly higher ($p=0.021$) than the proportion of participants in the younger age groups. Only 4.5% (n= 9) of the participants were aged 20-29 years. Seven percent of the respondents (n=14) were aged 30-39(fig 2). Mean age of the participants was 48 years.

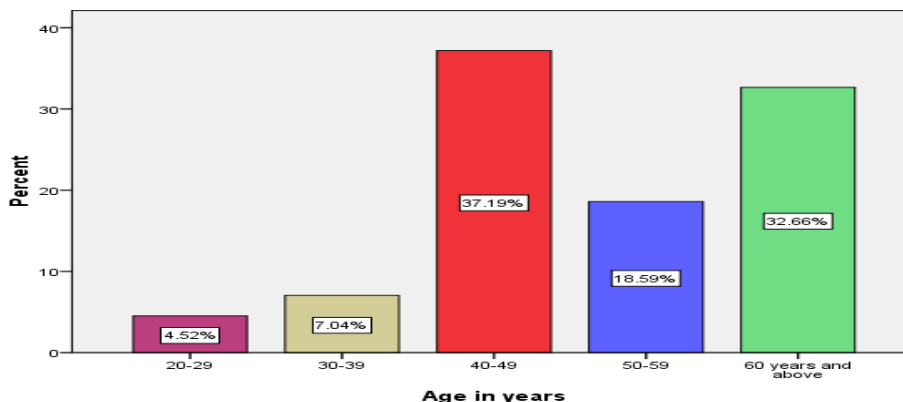


Figure 2: Bar Graph showing age distribution

4.2.2 Gender of the participants

More than half of the participants 72.4%(144) were female compared to men 27.6%(55). The difference between the proportion of women to men was statistically significant ($p=0.03$) (table 1).

Table 1: Gender of the participants

Gender	No. of patients	%	P value
Male	55	22.6	0.03
female	144	72.4	
Total	199	100	

4.2.3 Marital status of the participants.

Majority 77% ($n=155$) of the participants were married ($p<0.01$), compared to single,9% ($n=18$), widowed 12% ($n=24$) and 1%, ($n=2$) separated (figure 3)

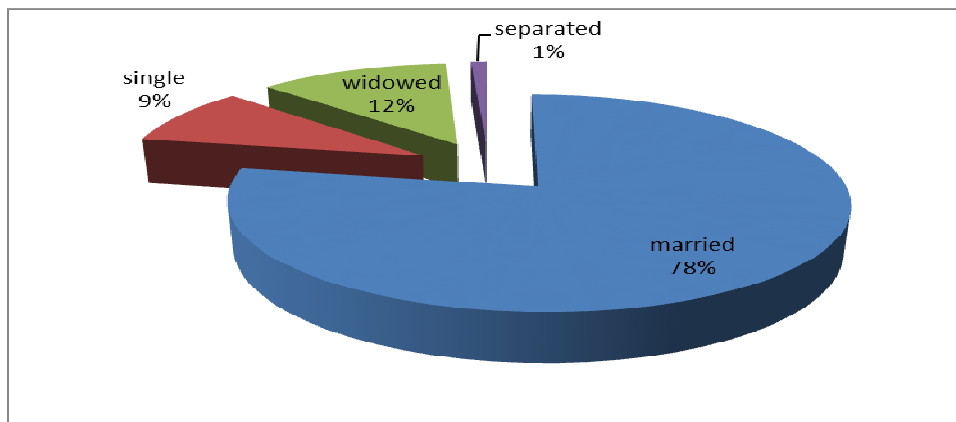


Figure 3: Marital status of the participants.

4.2.3. Education level of the participants

Majority of the respondents, 55.3% (n=110) had attained secondary education , 24.6% (n= 49) primary education, 14.1% (n=28) college/university education and 6.0% (n=12) no education respectively. No statistical difference was yielded between those participants with secondary education and the other levels of education (p=0.622)

Table 2: Education level of the participants

Level of education	No. of patients	Percentage
No education	12	6.0
Primary education	49	24.6
Secondary education	110	55.3
College/university education	28	14.1
Total	199	100

4.2.4. Alcohol consumption.

Participants who did not consume alcohol were statistically significant different, 77.4% (n=154) (p<0.01). Only 22.6% (n=45) consumed alcohol. Majority of those who consumed alcohol, 95.5% (n=43) were men.

Table 3. Alcohol consumption

Alcohol consumption	No. of participants	P value
Yes	22.6%(n=45)	< 0.01
No	77.4 (n=154)	
Total	100%(n=199)	

Out of those who consumed alcohol 80.9% (n= 38) had taken alcohol for more than two years, while 19.1% (n=9) had taken alcohol for two years. Of those who consumed alcohol, 73.7% (n=28) reported that they took beers, 21.1% (n= 8) spirits and 5.3% (n=2) combined the above types of alcohol. A significant majority (p=0.002) of the participants who consumed alcohol, 80.6 % (n=31) consume the alcohol in social clubs while 11.1% (n=4) took the alcohol at home.

A higher proportion of those who consume alcohol, 81.6% (n= 31) (p<0.001) take more than two drinks per occasion compared to 18.4% (n=14) who take two drinks per occasion

Table 4: Alcohol consumption per occasion

Amount consumed per occasion	No. of patients	Percentage
Two drinks	7	18.4
More than two drinks	31	81.6
Total	38	100

The participants who consume alcohol reported their consumption frequency as follows; 52.6% (n=20) on alternate days, 36.8% (n= 14) on weekly basis and 10.5% (n=4) daily.

4.2.5. Smoking

A majority 87.7% (n=175) (p<0.001), did not smoke tobacco. Only 7.2% (n=14) reported to smoke tobacco and 5.1% (n=10) stopped smoking. All the smokers 100% (n=14) were men. Of those who smoke tobacco, 68.4% (n=9) reported to have been smoking for more than two years, while 31.6% (n=5) reported to have smoked for less than one year. Out of the smokers, a significant (p<0.05) 66.7% (n= 8) smoke cigarettes, 19% (n= 4) smoked pipe and 14.3% (n= 2) smoked E cigars. Majority of the smokers 88% (n=12) smoked less than one packet per day

compared to 18% (n=2) who smoked more than one packet per day. A majority of the smokers, 97.7 % (n=195) of the participants did not take any other drug while 2.3% (n=4) took other drugs in addition to tobacco.

4.3. Physiological and anthropometric measurements

4.3.1. Blood pressure

Majority of the participants, 57.8% (n=115) of the participants had a blood pressure of 131/86 mmHg and above while 42.2% (n= 84) had a blood pressure of 130/85 and below. This difference was statistically significant $p = 0.05$

Table 5: Blood pressure

BP level	No. of patients	Percentage
130/85mmHg and below	84	42.2
131/86mmHg and above	115	57.8
Total	199	100

4.3.2 Body mass index.

Eighty three percent (n=166) of the participants had a body mass index (BMI) above 25kg/m². The mean BMI was 29kg/m², (95% confidence interval 25.4-33.5). Female participants were four times more likely to be obese than their male counterparts, (odds ratio 4.33, 95% confidence interval 26-34.5). Specifically, 58.3% (n=115) had a BMI above 30 while 26.63% (n=51) had BMI between 25 and 29.9 kg/m². Only 16.1% (n=55) were within the normal BMI of 20 to 25 kg/m². The difference between the obese and the normal BMI was statistically significant

($p < 0.05$). Among the participants with BMI above 25 kg/m^2 , a significant majority 75% (125) ($p < 0.05$) were aged 40 years and above.

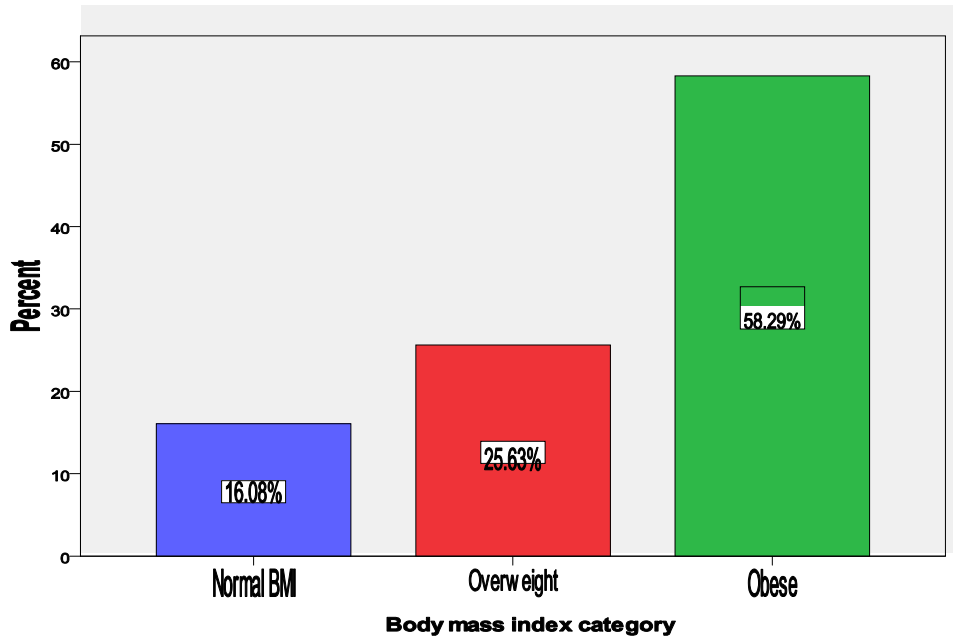


Figure 4; body mass index

4.3.3. Glycosylated hemoglobin

Majority of the respondents 58.3% ($n = 116$) had HbA1c below the recommended level of 6.5%. There was no statistical significance ($p > 0.05$) between those with HbA1c below and above 6.5%. Further statistical analysis did not yield significant difference between those with poor glycemic control versus those with normal values (Table 6).

Table 6: HbA1c

HbA1c levels	No of patients	Percentage	P-value
6.5% and below	116	58.3	>0.05
Above 6.5%	83	41.7	
Total	199	100	

4.3.5. Latest random blood glucose levels.

Majority 61.8% (n=123) of the respondents had random blood glucose of <10 mmols/lit compared to 38.2% Random blood glucose >10mmols/lit. The difference was statistically significant (p<0.05).

Table 7. Latest Random blood glucose levels

Latest random blood glucose(mmols/lit)	No. of participants	percentage	P value
<10	123	61.8	0.05
>10	76	38.2	
Total	199	100%	

4.4. Compliance levels.**4.4.1. Compliance to pharmacological treatment.**

Majority of the respondents 73.4% (n=146) p<0.001 reported compliance to pharmacological therapy. Only 26.1% (n=52) had moderate compliance. There was only 1% (n=1) participant who reported low compliance to pharmacological treatment (figure 5)

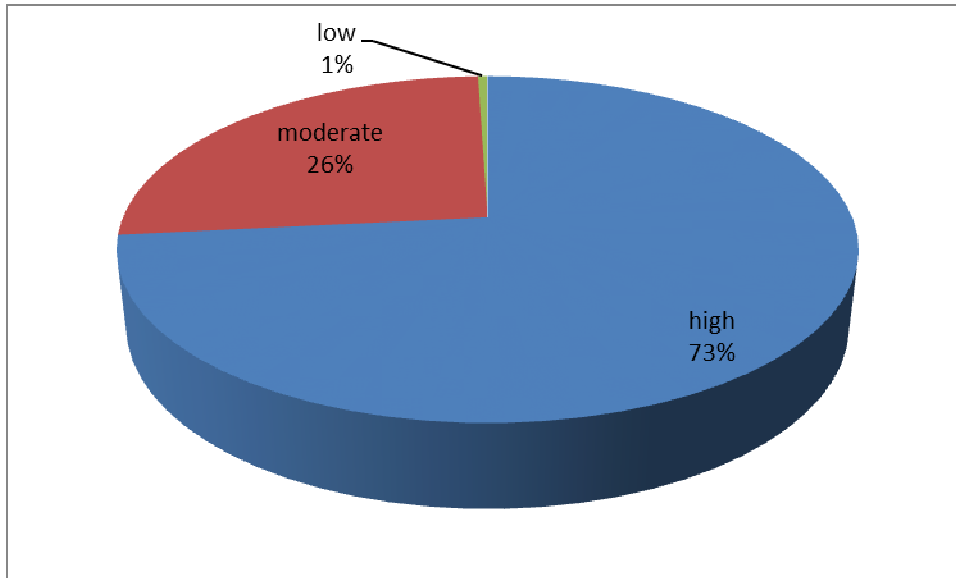


Figure 5: Compliance to pharmacological treatment

There was no statistical significance between compliance to pharmacological treatment and the age of the participants, ($p= 0.310$). Participants aged 40 to 49 years had the highest score in the category that reported high compliance to pharmacological therapy, 36.9%, ($n= 54$), (table 8). The proportion of women who reported high compliance to pharmacological treatment, 76.7% ($n=112$), ($p=0.01$) was statistically significant, compared to 23.28% ($n= 34$) men. Among the married participants, 74.19% ($n=115$) ($p=0.010$) had high compliance to drug treatment, while the remaining 25.80 ($n= 40$) had moderate compliance to pharmacological therapy.

The relationship between compliance to pharmacological treatment and highest level of education was statistically significant. Majority (60.95%) of the participants with high compliance to pharmacological treatment had secondary education.

Table 8: Relationship between participant characteristics and compliance to pharmacological treatment

Independent variables	categories	Low n (%)	Moderat n (%)	High n (%)	Total n (%)	Chi squam e	P value
Gender	Male	0(0)	21(40.38)	34(23.28)	55(27.63)	5.988	0.01
	female	1(0.5)	31(59.6)	112(76.7)	144(72.36)		
Age	20-29	0(0)	2(3.8)	7(4.7)	9(4.5)	19.17	0.31
	30-39	0(0)	9(17.3)	5(3.4)	14(7%)		
	40-49	0(0)	20(38.4)	54(36.9)	74(37.1)		
	50-59	1(0.5)	4(7.6)	32(21.9)	37(18.5)		
	Above 60	0(0)	17(32.6)	48(32.8)	65(32.6)		
Education level	None	0(0)	0(0)	12(8.2)	12(6)	14.89	0.05
	Primary completed	0(0)	17(32.69)	32(21.9)	49(24.6)		
	Secondary completed	1(100)	22(42.30)	87(60.95)	110(55.2)		
	College/university	0(0)	13(25)	15(10.27)	28(14.07)		
Marital status	Married	0(0)	40(76.92)	115(78.7)	155(77.8)	8.631	0.01
	Single	0	6(11.53)	12(8.2)	18(9)		
	Widowed	1(100)	5(9.6)	18(12.32)	24(12)		
	separated	0(0)	1(1.92)	1(0.6)	2(1)		

4.4.2. Compliance to self- monitoring of blood glucose

More than half of the participants, 55.27% (n= 110) (p<0.05) had moderate compliance to SMBG while 35.67% (n= 71) reported high compliance to blood glucose monitoring, and 9%

(n=18) low compliance. There was a significant statistical difference ($p < 0.05$) among those who reported moderate compliance and low compliance to SMBG.

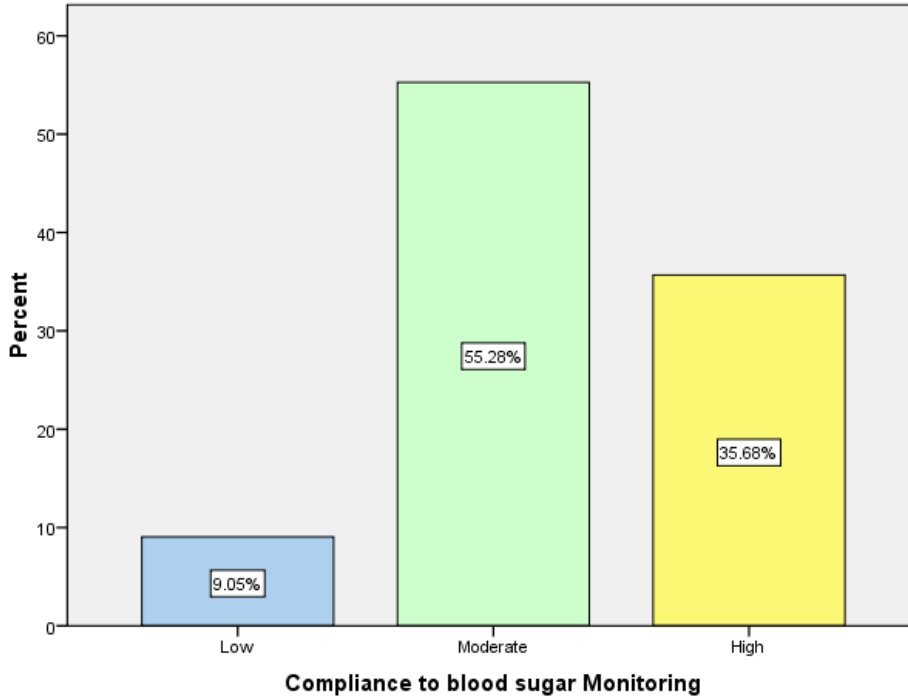


Figure 6: Compliance to SMBG

Among those who reported high compliance, 69% (n=49) were females compared to 31% (n=22) men. The female participants were three (3) times more likely to comply highly to SMB (Odds ratio 3.45 95% confidence interval 1.22- 3.9). There was no statistical significance between age and education of the participants and compliance to SMBG ($p > 0.1$). Among the respondents with no education and those with college/university education, 11.1% reported low compliance. The highest compliance to SMBG was reported among clients with secondary education where 57.7% (n=41) had high compliance to SMBG. There was a significant statistical association between marital status and compliance to SMBG, $p = 0.034$. Among the respondents who reported high compliance, 73% were married.

Table 9: Relationship between compliance to self-blood glucose monitoring and patient characteristic

Independent variables	categories	Low n (%)	Moderate n (%)	High n (%)	Total n (%)	Chi square	P value
Gender	Male	4(22.2)	29(26.4)	22(31)	55(27.63)	0.751	0.061
	female	18(77.8)	81(73.6)	49(69)	134(67.33)		
Age	20-29	0(0)	3(2.7)	6(8.5)	9(4.5)	5.8	0.171
	30-39	2(11.1)	7(6.7)	5(7.0)	14(7)		
	40-49	8(44.4)	41(37.3)	25(35.2)	94(47.23)		
	50-59	2(11.1)	23(20.9)	12(16.9)	37(18.5)		
	Above 60	6(33.3)	36(32.7)	23(32.4)	65(32.6)		
Education level	None	2(11.1)	7(6.4)	3(4.2)	12(6)	2.672	0.116
	Primary completed	4(22.2)	30(27.3)	15(21.2)	49(24.62)		
	Secondary completed	10(55.6)	59(53.6)	41(57.7)	110(55.27)		
	College/univ.	2(11.1)	14(12)	12(16.9)	28(14)		
Marital status	Married	15(83.3)	88(80)	52(73.2)	155(77.88)	8.072	0.034
	Single	0(0)	7(6.4)	11(15.5)	18(9)		
	Widowed	3(16.7)	13(11.8)	8(11.3)	24(12)		
	separated	0(0)	2(1.8)	0(0)	2(1)		

4.4.3. Compliance to nutrition

Majority of the participants 72.36% (n=144) ($p < 0.05$) reported high compliance to prescribed nutrition, while 23.11% (n=46) moderate compliance and 1.5% (n=3) low compliance to nutrition. A higher proportion of male participants had better compliance to nutritional management 86.7% (n=49), than their female counterparts 70.8% (n=102). There was no statistical significance between compliance to nutritional management and gender, $p = 0.194$. A statistically significant proportion of married respondents 77.88% (n=120), $p = 0.046$ reported high compliance to nutritional management, compared to 9.2% (n=14) single participants and 11.25% (n=17) widowed participants (Table 10).

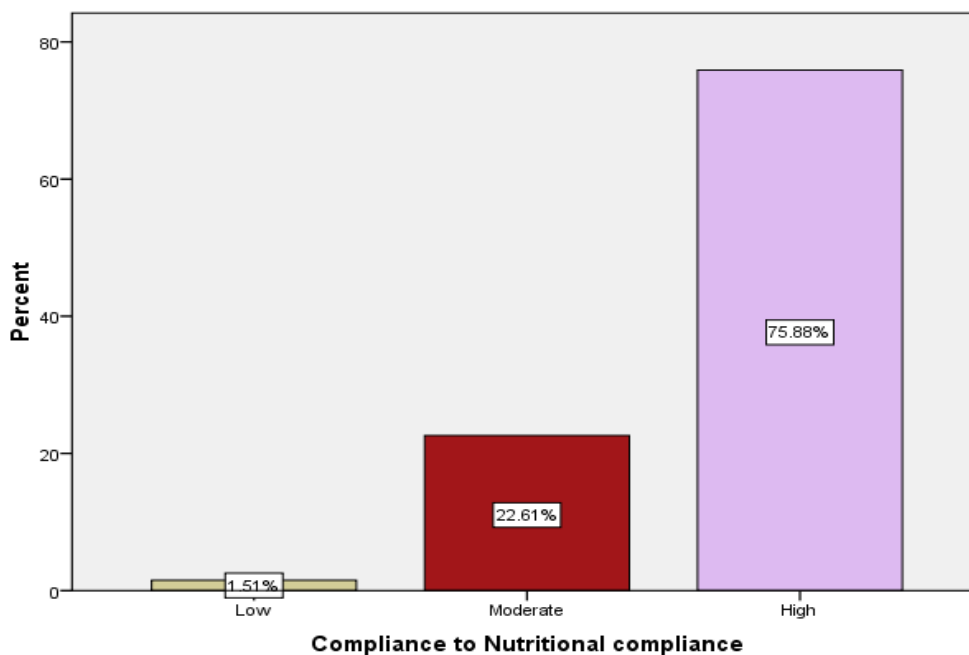


Figure7: Compliance levels of nutrition

Table 10: Relationship between patient characteristics and Compliance to nutrition

Independent variables	Categories	Low n (%)	Moderate n (%)	High n (%)	Total n (%)	Chi square	P value
Gender	Male	0(0)	6(13.3)	49(86.7)	55(27.63)	7.498	0.194
	female	3(2)	39(27)	102(70.8)	144(72.36)		
Age	20-29	0(0)	2(4.3)	7(4.86)	9(4.5)	6.03	0.178
	30-39	0(0)	1(2.15)	13(9)	14(7)		
	40-49	2(66.66)	21(45.65)	51(35.4)	74(37.18)		
	50-59	1(33.33)	7(15.21)	29(20.1)	37(18.59)		
	Above 60	0(0)	14(30.4)	51(35.4)	65(32.66)		
Education level	None	0(0)	3(6.6)	9(5.9)	12(6)	1.576	0.89
	Primary completed	1(33.3)	9(20)	3(1.9)	13(6.5)		
	Secondary completed	2(66.66)	27(60)	81(53.64)	110(52.27)		
	College/univ.	0(0%)	6(13.2%)	22(14.56%)	28(14%)		
Marital status	Married	2(66.6)	33(73.33)	120(77.88)	155(77.88)	8.609	0.046
	Single	0(0)	4(8.8)	14(9.2)	18(9)		
	Widowed	1(33.3)	6(13.33)	17(11.25)	24(12)		
	separated	0(0)	2(4.4)	0(0)	2(1)		

4.4.4 Compliance to physical activities.

Moderate compliance to physical activities was reported by 47.23% (n= 94) of the respondents, compared to 40.7% (n=81) who reported high compliance, and 12% (n=24) low compliance

($p > 0.05$). Although male participants were fewer than their female counterparts, they had a higher proportion, 45% ($n=25$), ($p=0.02$) reporting high compliance to physical activity compared to 38.88% ($n=56$) females. That indicated a statistical significance level.

Statistical analysis between age, education and marital status and compliance to physical activities did not yield significant difference ($p > 0.1$).

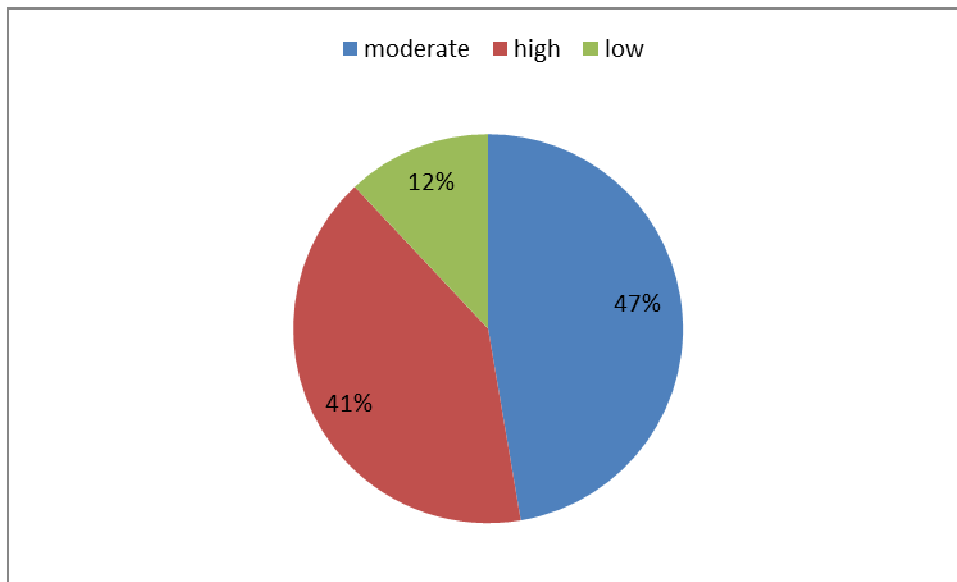


Figure 8: Compliance to physical activity

Table 11: Relationship between patient characteristics and Compliance to physical activities

Independent variables	categories	Low n (%)	Moderate n(%)	High n (%)	Total n (%)	Chi squares	P value
Gender	Male	8(14.54)	22(40)	25(45.45)	55(27.63)	1.65	0.02
	female	16(29)	72(50)	56(38.88)	144(72.36)		
Age	20-29	0(0)	7(7.4)	2(2.5)	9(4.)	13.3	0.259
	30-39	0(0)	6(6.4)	8(9.9)	14(7)		
	40-49	8(33.3)	40(42.6)	26(32)	74(37)		
	50-59	3(12.5)	16(17)	18(22.22)	37(18.5)		
	Above 60	13(54.2)	25(26.5)	27(33.3)	65(32.6)		
Education level	None	2(8.3)	6(6.4)	4(4.9)	14(7)	3.49	0.132
	Primary	8(33.3)	20(21.3)	21(25.9)	49(24.62)		
	Secondary	12(50)	56(59.6)	42(17.3)	110(55.27)		
	College/university.	2(8.3)	12(12.8)	14(17.3)	28(14)		
Marital status	Married	21(87.5)	74(78.72)	60(74)	155(77.88)	3.20	0.124
	Single	2(8.3)	8(8.5)	8(9.8)	18(9)		
	Widowed	1(4.2)	10(10.6)	13(16)	24(12)		
	separated	0(0)	2(2.1)	0(0)	2(1)		

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1. Introduction

T2DM is on the increase at a very fast rate. WHO estimates that the prevalence of T2DM in the year 2013 was 347 million people world-wide (WHO 2013 diabetes report). Individuals with T2DM have a great role to play in management of their own health. However, compliance to management has been found to be low especially when looking at long term changes. The aim of this study was to evaluate treatment compliance amongst adult patients with T2DM attending KNH.

Generally, T2DM patients attending KNH had varied levels of compliance to the different modes of treatment. Participants reported highest compliance to pharmacological treatment and nutrition. Sub-optimal compliance was realized in SMBG and physical activities.

5.2. Socio-demographic characteristics of T2DM patients at KNH.

In this study the proportion of females was higher than that for men. These findings are consistent with the findings by Kalyango et al (2008) in their study on compliance to DM management at Mulago hospital in Uganda. They realized that majority of their study subjects were female. There is likelihood that most men have a lower adherence to clinic appointments. These findings contradict the established prevalence levels of DM. Ayah et al (2013) reported that the prevalence of DM among women and men in Kenya is almost the same. This would have translated to almost an equal ratio of men to women seeking health care services.

The age group that was highly represented in this study was 40 to 49 years. These findings correspond with the results that were realized in a recent study that was done in Kibera slums in

Nairobi Kenya, which demonstrated that DM peaked in the 45 to 54 age group (Ayah et al, 2013). In this study, majority of the participants were age 40 years and above. This is a clear indication that prevalence of DM increases with age.

A high proportion of the participants had secondary education. This is attributed to the fact that people with higher level of education have better lifestyle practices and health seeking behavior which makes them less likely to develop conditions like diabetes mellitus.

Majority of the study participants were married. This was consistent with findings in a study that was conducted in Uganda on adherence to DM treatment, where a greater percentage of the participants were married compared to those that were widowed and single (Kalyango et al, 2008). A higher proportion of married participants is explained by the fact that the population from which the sample was drawn has predominantly married individuals. In this current study, married participants reported high compliance in the different modalities of T2DM treatment. This may be attributed to the fact that married clients receive support from their spouses. Other studies that have shown better compliance to treatment among married patients than single individuals include: Anjuman et al (2004), Koraya et al, (2004), Lemlem et al (2014).

5.3. Physiological and anthropometric measures of T2DM patients at KNH.

The results demonstrated that most of the participants had a blood pressure of 130/85 mmHg and above. These findings are consistent with those of a study that was conducted in Korea on prevalence of cardiovascular complications; half of the diabetic patients had cardiovascular complications (Kim et al, 2011). This may be explained by the fact that cardiovascular complications are a result of prolonged fluctuations in blood glucose levels. Majority of the

participants had suboptimal SMBG, making them have wide fluctuations in blood glucose levels without noticing.

Majority of the respondents were overweight and obese. These results are consistent with findings of a study that was done in north Eastern Kenya on the seriousness of the impact of T2DM in rural Kenya, where majority of the participants were overweight (Busaidy et al, 2014). This finding is associated with change of lifestyle amongst both rural and urban populations in Kenya. Majority of individuals have switched to western lifestyle in nutrition and physical activities. However, these findings contradict the findings of a study that was done in Bangladesh on nutritional status of diabetic patients, where majority of the participants had normal BMI and minority were overweight (Anjuman et al, 2004). This difference may be due to variations in the study populations in their cultural practices, exercise levels and nutritional habits.

More than half of the participants had random blood sugar below 10mmols /lit. A higher percentage of the participants reported that they adhere to prescribed medication. This may explain the high level of normal blood glucose level among the study subjects. Majority of the respondents had HbA1c below the accepted level of 6.5%. This finding contradicts the study that was done at KNH on cardiovascular risk factors associated with T2DM, which revealed that majority of the participants had HbA1c above 6.5% (Vaghela et al, 2001). These results differ from that in a study that was done in Ethiopia to determine glycemic control among insulin treated clients. Majority of the participants in that study had poor glycemic control (Mulugeta et al, 2013). A study done in the United kingdom suggested that glycemic control reduces onset of micro vascular and macro-vascular complications (Carole et al, 1999). Generally, the anthropometric measures give a general picture of long term adverse effects of low compliance

to prescribed treatment. Anthropometric and physiological measures can be used to validate the extent to which the participants are complying to treatment because they give a direct picture of effects of prolonged blood sugar fluctuations on the physic of the client.

5.4. Pharmacological adherence.

Compliance to pharmacological therapy was rated highly by most of the participants. These findings corresponds with the study that was done in Ethiopia to assess medication adherence in T2DM patients and their self-care practices, where majority of the participants reported high level compliance to drug therapy (Nassir et al, 2011). In both of these studies, majority of the participants reported high compliance to drug therapy. The results are also consistent with those of another study conducted by Masoud et al, (2012) at Kenyatta national hospital to assess glycemic control among insulin treated ambulatory patients. Most of the respondents had high compliance to insulin therapy. High compliance treatment in this set-up may be associated to adequate emphasis by health care workers on drug compliance. This indicates that the health care workers at KNH give proper health education on drug treatment to the clients. On the other hand, majority of the clients believe that drugs are the single most important aspect of their treatment as compared to the other modalities of treatment. In a study that was conducted In New Zealand, both T1DM and T2DM patients ranked medication significantly more important than diet, exercises and self- monitoring of blood sugar levels (Broadbent et al, 2011).

However these findings contradict results that were obtained in a French population based study. In this study it was concluded that in a country with high level of access to health care, there was low level of medication adherence among T2DM patients (Michel et al, 2012). This difference may be associated to population characteristic differences. The perception of the French

population about diabetes management may be different from that of Kenyan population. Female gender, married status and secondary education were significantly associated with high compliance to pharmacological treatment. As age of the participants increase, there was minimal increase to pharmacological treatment. This is because many of the patients tend to accept the condition with time. Most of the patients become more efficient in self-care as they receive more health education from time to time. Female respondents had higher pharmacological compliance than men. Married respondents most likely receive support from their spouses while secondary education enables one to have better understanding of drug compliance.

5.5. Compliance to SMBG

More than half of the participants reported moderate compliance to SMBG. Less than half of the participants had high compliance to SMBG. These findings are consistent with those that were obtained by Masoud (2012) in a study that he conducted at KNH to assess glycemic control among insulin treated ambulatory patients. In the Masoud study a very small proportion of the participants complied to SMBG. In both of these studies, majority of the clients reported to monitor their blood glucose levels once a month or once a week. This is way below the recommended daily SMBG. This is associated with knowledge deficit on the appropriate frequency of SMBG. Majority of the participants reported that they do not have personal glucometers at home. They actually monitored their blood glucose in the nearest health centers. These patients lack skills and appropriate devices to carry out SMBG as recommended.

Low level of SMBG is most likely contributing to unnoticed glycemic fluctuations. This in-turn predisposes them to long term complications like cardiovascular conditions. There was marginal significance between the female gender and compliance to SMBG. Generally women keep keen

interest on details than men. This could be probably due to the fact that women have more time with themselves at home and so they can remember to monitor their blood sugar levels than men. According to Parkin et al, (2010), the diabetic patients should provide their primary care practitioner with their blood glucose monitoring records so that proper evaluation can be made. All the participants in this study had a record of the blood sugars that they do mainly once a month. If they are challenged to monitor their blood glucose levels on a daily basis, then they will be able to give a very good impression of their continuous glycemic levels and the health care practitioners would make informed decision on pattern of management for the patients. There was a significant statistical relationship between compliance to SMBG and marital status. The spouse could be reminding their partner to monitor their blood glucose on time and also provides moral support.

5.6. Compliance to nutrition

Majority of the participants had high compliance to nutritional management. This level of high compliance to recommended nutrition in this study did not correlate with the anthropometric and physiological measures. A high proportion of the participants was overweight and had elevated BP. This contradicting picture may be associated with inappropriate reporting by the participants on their true nutritional state. There is a shift in feeding habits of many people in Kenya, from consuming traditional foods that are high in fiber, whole grain based, rich in vegetables and fruits, to high calorie diet, rich in fats, salt and sugar (Maina et al, 2011). However these findings differed from those of Broadbent et al (2011) .They demonstrated in their study that only a minority of the participants adhered to nutritional advice fully.

Minority of the participants consumed alcohol and smoked tobacco. This is associated with proper knowledge on these habits. Generally, Male participants seem to have a slightly better compliance to nutritional management than their female counterparts. Women are more prone to low nutritional compliance due to their roles in food preparation and proximity with food many a times. Married participants reported high compliance to nutritional management compared to the single and the widowed. This is most likely associated with psychological support that the patients receive from their spouses.

5.6. Compliance to physical activities.

A minority of the respondents reported high compliance to physical activities. This is associated to the fact that most people have adopted the western lifestyle which has generally reduced activity levels of individuals. Male participants had a higher proportion of high compliance to physical activity as compared to women .This probably relates to the nature of activities that the two genders engage in on daily basis. Generally men are exposed to more vigorous physical outdoor activities than women. The findings in this study are consistent with results that were achieved in a study that was conducted by Broadbent et al. In their study they concluded that majority of their participants had low compliance to physical activities. However, the findings of this study contradict those that were realized by Maina et al in Kenya. In her study, it was concluded that majority of the participants had high compliance to physical activities. This variation may have been due to differences in study methodology. Differences in the study subjects characteristics may also have contributed to this variations. The patients need to be informed that daily routines may not be adequate especially if the patient has a sedentary lifestyle.

5.7. Conclusion

Majority of T2DM patients attending KNH have high compliance to pharmacological therapy and nutritional management. However, compliance to SMBG and physical activities is sub optimal. Anthropometric and physiological measures are sub-optimal while glycemic control is moderate.

Holistic approach needs to be embraced in managing T2DM patients at KNH so as to have high scores of optimal glycemic control among these patients. Health care providers need to encourage T2DM patients to adhere to all treatment modalities because compliance to few modalities alone nullifies any efforts put in care of the diabetic patient.

Most of the Socio-demographic factors had no statistical significance in relation to compliance to the different aspects of treatment. Therefore the null hypothesis that ‘there is no significant relationship between compliance to OHA and Insulin, exercises, diet, self-monitoring of blood glucose levels and, levels of education, age, gender and marital status of T2DM patients at KNH’ is not rejected.

5.8. Limitations of the Study

Self-reported compliance may not have been accurate. Some participants are likely to have given inaccurate information in the questionnaires. To minimize this, the researcher encouraged the clients to give true information about them-selves. The importance of the study was explained to them before they responded to the questions. Majority of the participants did not have their blood cholesterol levels recorded. This may be associated to financial implications of doing this test. The minority who manage to have the test done may have been able to afford the cost. Alternatively, the health care workers could have put less emphasis on the importance of

monitoring cholesterol levels. During data collection majority of the participants raised concern about financial implications of diabetes management.

There was a challenge in differentiating between T1DM and T2DM. To minimize errors that could arise from this, participants' clinical presentation were considered because T1DM mainly have weight loss, have more acute complications, easily go into diabetes ketoacidosis(DKA), While T2DM are mainly obese or overweight, rarely get DKA, and have slow onset with fewer acute complications. The researcher did not measure the hip /waist ration, that could have been crucial in measuring distribution of body fat.

5.9. RECOMMENDATIONS.

1. Health care providers need to ensure that cholesterol levels are monitored every six months so as to detect patients who are at risk of cardiovascular complications and manage them adequately.
2. Further studies need to be conducted to determine how T2DM patients carry out self-medication and how they handle their drugs at home.
3. Type 2 diabetes mellitus patients consuming alcohol need to be advised to cease
4. Health care providers need to re-educate these patients to monitor their blood glucose levels on a daily basis
5. There is need to emphasis holistic compliance to all forms of treatment that is physical activities, diet, self-monitoring of blood glucose and drugs.

6. The ministry of health needs to increase funding to health care facilities attending to diabetic patients so that patients can receive adequate follow up care and they can also purchase glucometers at subsidized prices

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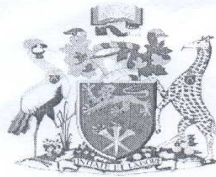
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APPENDICES

APPENDIX 1: RESEARCH BUDGET

<u>Description</u>	<u>Unit</u>	<u>Quantity</u>	<u>Cost per unit</u>	<u>Tot.cost. Ksh.</u>
<u>Proposal writing.</u>				
1.typing and printing	Rims	2	500	1000
2.research note book	Piece	1	900	900
3.biro pens ,pencils and erasers	Pieces	15	@ 20	300
4.photocopy	Rims	4	400	1,600
KNH ethical committee		1	2000	2,000
Preparation of instrument				
1. Typing and printing	Rims	2	500	1,000
2. Photocopy	Rims	2	400	800
Staff cost				
Researcher	Individual	1	40,000	40,000
Research assistants		2	10,000	20,000
Transport.	Trip	10 days	300	3,000
Data processing and binding				
1. Typing and printing preliminary results	Rims	3	500	1500
2. Photocopy for supervisors	Rims	2	400	800
3. Typing and printing final draft	Rims	4	500	2000
4. Printing and binding final copy	Rims	10	2,000	20,000
Subtotal				99,900
Contingencies 10%			10% tot. cost.	9390
Grand Total				101,290

APPENDIX 2; KNH-UON RESEARCH/ETHICS COMMITTEE APPROVAL



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KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

Link: www.uonbi.ac.ke/activities/KNHUoN



KENYATTA NATIONAL HOSPITAL
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4th April 2014

Esther Asenahabi
School of Nursing Sciences
College of Health Sciences
University of Nairobi

Dear Esther

Research proposal; Assessment of Treatment compliance amongst adult patients with Type Two Diabetes mellitus at Kenyatta National Hospital (P29/01/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 4th April 2014 to 3rd April 2015.

This approval is subject to compliance with the following requirements:

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

For more details consult the KNH/UoN ERC website www.uonbi.ac.ke/activities/KNHUoN.

Protect to Discover

APPENDIX 3: KNH REGISTRATION CERTIFICATE

KNH/R&P/FORM/01

KENYATTA NATIONAL HOSPITAL
Hospital Rd. along, Ngong Rd.
P.O. Box 20723, Nairobi.
Tel: 2726300-9 Fax: 2725272
Research & Programs: Ext. 44705
Email: k.research@knh.or.ke

Study Registration Certificate

1. Name of the PI ESTHER ASENAHABI
2. Email address: asenalabesther@yahoo.com Tel No. 0724729453
3. Contact person (if different from PI)..... AS ABOVE
4. Email address: Tel No.
5. Study Title
ASSESSMENT OF TREATMENT COMPLIANCE AMONGST ADULT
PATIENTS WITH TYPE TWO DIABETES MELLITUS AT
KENYATTA NATIONAL HOSPITAL
6. Department where the study will be conducted MEDICINE
7. Endorsed by Head of Department where study conducted
Name: Dr. Mute Signature: [Signature] Date: 22/4/14
H.O.D. Medicine
Kenyatta National Hospital
8. KNH UoN Ethics Research Committee approval number
(Please attach copy of ERC approval)
9. I ESTHER ASENAHABI commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Research and Programs.
Signature: [Signature] Date: 22/4/2014
10. Study Registration number (Dept/Number/Year) MED 1013/2014
(To be completed by Research and Programs Department)
11. Research and Program Stamp _____

All studies conducted at Kenyatta National Hospital must be registered with the Department of Research and Programs and investigators must commit to share results with the hospital.

APPENDIX 4: ACTIVITY TABLE

ACTIVITY	Nov. 2013	Dec 2013	Jan 2014	Feb 2014	Mar 2014	April 2014	May 2014	June 2014	July 2014	Aug 2014	Sept 2014
Proposal Writing	x	x									
Presentation for correction and approval		x	x	x							
Printing questionnaire for pretest				x							
Pretest field work				x							
Analysis and evaluation of pretest				x	X						
Finalization and printing of research instrument					X						
Field data collection					X	X					
Data cleaning					X	X					
Data analysis and report writing							X	x			
Defense of project report									x		
Dissemination; submission and publication.										x	x

APPENDIX 5: RESEARCH INSTRUMENT

The Study Questionnaire.

Treatment compliance amongst adult patients with diabetes mellitus type two at Kenyatta national hospital.

Questionnaire number;

INSTRUCTIONS TO THE INTERVIEWER

- I. Ensure that participants are T2DM adult patients by considering the inclusion and exclusion criteria.
- II. Do not suggest responses to the participant
- III. Do not write the name of the participant on the questionnaire.

1. Socio-demographic Data;

1.1. Age in years ; 20-29 30-39 40-49 50-59 60 and above

1.2. gender:

Male

Female

1.3. Marital status:

married

single

widow/widower

separated

1.4. What is your highest education level?

None

primary completed

secondary completed

college/university completed

1.5. Residence.....estate.....

1.6. Home district.....

1.7. What is your occupation status?

Employed

Not employed

Self employed

1.8. Have you ever used alcohol?

Yes

No

1.8.1. If yes for, for how long have you been drinking?

Six months and below

One year

More than two years

Which type of alcohol do you take?

Spirits

Beers

Wines

Local brews

Where do you drink your beer?

At home

In social clubs

How frequent do you drink alcohol?

Daily

Alternate day

Weekly

How much alcohol do you drink on each occasion?

2 drink

More than 2 drinks

1.9.1. Have you ever smoked tobacco?

Yes

No

Stopped smoking

1.9.2. For how long have been smoking?

Six months and below

One year

More than two years

1.9.3. Which type of tobacco do you smoke?

Cigars

Pipe

E-cigars

1.9.4. do you take any other drugs in addition to smoking?

Yes

No

If yes, indicate type.....

1.10. Anthropometric measures

1.10.1. Blood pressure

Systolic

Diastolic

1.10.2. HbA1c

6.5% and below

Above 6.5%

1.10.3. Latest blood glucose level

1.10.3. Weight

1.10.4. Height

1.10.5. Body mass index

1.10.6. cholesterol level

2.0. Diabetes self-management questionnaire (DSMQ).

The following statements describe self-care activities related to your diabetes. Thinking about your self-care for the last 8 weeks, please specify the extent to which each statement applies to you. Rate your responses using the following scale;

scale	Remarks
4	Applies to me to a very high extend
3	Applies to me to a high extend
2	Applies to me to a moderate extend
1	Applies to me to a low extend
0	Does not apply to me to any extend

2.1. Compliance to pharmacological treatment and follow up care.

Item No.	Question	4	3	2	1	0
1a	I take my diabetes medication e.g. insulin, tablets as prescribed					
1b	Diabetes medication is required as part of my treatment					
2a	I tend to forget or skip my diabetes medication					
2b	Diabetes medication is/ insulin is not required as part of my medication					
3	I keep all doctor's appointments recommended for my diabetes treatment					
4	Regarding my diabetes care, I should see my medical practitioner(s) more often					
5	I tend to avoid diabetes related doctor's appointments					

2.2. Compliance to blood sugar monitoring

Item number	Question	4	3	2	1	0
6a	I check my blood sugar with care and attention					
6b	Blood sugar monitoring is required as part of my treatment					
7a	I do not check my blood sugar levels frequently enough as would be required for achieving good blood glucose control					
7b	Blood sugar measurement is not required as part of my treatment					
8	I record my blood sugar levels regularly.					

2.3. Nutritional compliance.

Item No.	question	4	3	2	1	0
9	I strictly follow dietary recommendations given by my doctor or diabetes specialist					
10	The food I choose to eat makes it easy to achieve optimal blood sugar levels					
11	Occasionally I eat lots of sweets or other foods rich in carbohydrates					
12	Sometimes I have real food overindulgence (not triggered by hypoglycemia)					

2.4. Compliance to physical activity.

Item No.	Question	4	3	2	1	0
13a	I do regular physical activity to achieve optimal blood sugar levels					
13b	I engage in non-programmed physical activities					
14	I tend to skip planned physical activity					
15	I avoid physical activity although it would improve my diabetes					
16	My diabetes self-care is poor					

APPENDIX 6: INFORMED CONSENT

Research information sheet for study participants

Study title; treatment compliance amongst adult patients with T2DM at Kenyatta National Hospital.

Introduction to the research and the researcher

My name is Esther Asenahabi, a post graduate student in MScN, school of nursing sciences The University of Nairobi. I'm conducting a research study at the Kenyatta National Hospital diabetic out-patient clinic and medical wards to assess the compliance to treatment of diabetes mellitus among the adult type two diabetic patients.

In order for this study to be successful, I request you to participate in the study by completing a questionnaire that will be availed to you. You will be required to tick on the most appropriate answer to the best of your knowledge. Since you are already on management of diabetes mellitus, I would like to collect information on how you comply on the prescribed drugs, clinic attendance, exercises, diet and monitoring of your blood glucose levels.

Assurance of Confidentiality

All the information collected from you will be kept confidentially. You will be given a copy of the consent form to fill if you voluntarily consent to participate in the study. Your name or any other form of identification will NOT be included on the questionnaire. Instead you will be accorded an identification number that will remain confidential to the researcher alone.

Participants' Rights

Your participation in this study is voluntary and if you decline to participate, you will not be denied any services that you deserve to receive. You are free to withdraw from the study at any time. There is no monetary incentive to the participants of the study.

Benefits /Risks of the Study

The findings of this study will be used to determine the success rate or the failure rate of T2DM management. This will inform the care givers at KNH diabetic clinic on the areas that they should emphasize on when treating T2DMpatients. This in-turn will reduce complications amongst the patients. The national policy makers will also be alerted on the areas that need to be given priority when planning for management of T2DM in the country. The results will assist in allocation of resources to priority areas in management of T2DM both at KNH clinic and nation-wide. The findings of this study will be used for future research in this field.

You will not be subjected to any invasive procedures during the study. This study will impose minimal risks to you that could be psychological as you realize areas that you did not comply to in management of your health. In-case you encounter psychological challenges, kindly consult the researcher for counseling services. You will not face any punitive measures if you are not compliant to management.

Duration of Participation

This study will require you to fill in a questionnaire if you are able to read and write. If you are not able, the researcher will assist to read out the questions and fill in the responses that you give.

After that, there shall be no further follow-up interviews. This process will take about 30 minutes of your time.

Contact Information

In-case you have any clarifications or questions concerning this study, you may ask or contact Esther Asenahabi, MScN student at the University of Nairobi on cell phone number 0724729453, or chairperson, KNH/UON/ERC. P.O.BOX 20723-00200. Tel: 020-2725272.

Consent form.

The above details about the study have been explained to me and I agree to take part in this study. I understand that I'm free to choose to participate in the study or not. I willfully give my consent to give the required information.

Participant's signature/ thumb mark

Researcher's signature:

Date:

Ridhaa Ya Kushiriki Kwenye Utafiti

Nimeelezwa kuhusu utafiti unaonuiwa kufanwya na nimekubali kuwa mshirika kwa utafiti huu. Nimeelewa kwamba kushiriki au kutoshiriki kwenye zoezi hili kwa hiari yangu. Nakubali kutoa habari zitakazotakikana kwa zoezi hili.

Sahihi/ kidole gumba cha mgonjwa

Sahihi ya mtafiti

Tarehe