COMPLIANCE TO GUIDELINES AND ROLE OF PATIENTS IN MANAGEMENT OF TYPE 2 DIABETES AMONG PATIENTS IN VIHIGA COUNTY REFERRAL HOSPITAL, KENYA

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A Research thesis submitted in partial fulfilment of the requirements for the award of Master of Pharmacy in Pharmacoepidemiology and Pharmacovigilance

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November 2016

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ACKNOWLEDGEMENTS

I would like to thank the Almighty God for the day to day guidance, strength and protection.

For the creation of this thesis, I want to sincerely thank my supervisors for their invaluable assistance, motivation and technical support; Dr. Eric M. Guantai, Dr. Beatrice M. Amugune and Dr. Mercy N. Mulaku, who worked with me to ensure completion of this work.

I convey my deepest gratitude to my beloved parents, Mr. and Mrs. Ernest Kaitany, for always praying for me and for constantly encouraging me to work hard all my life, most specifically as I pursued my studies.

My thanks to my siblings Joan, Joram, Oscar and Fridah and their respective families for lighting up my life every single day and for their never ending love and support through the good times as well as the challenging moments of life.

Special thanks to my best friend Daniel Kasika for the non-reluctant support, encouragement and assistance he offered me whenever I called upon him. Thanks to Anne Mueni who supported me all through with my work. Thanks to Caroline Muhati who eoncouraged me to pursue higher learning and walked me through it.

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LIST OF ACRONYMS AND ABBREVIATIONS

BMI Body Mass Index

DSME Diabetes self-management education

ESMON Efficacy of Self-Monitoring of Blood Glucose

FBG Fasting Blood Glucose

GRADE Grading of Recommendations Assessment, Development and Evaluation

HbA1c Glycated Haemoglobin

HDL-C High Density Lipoprotein Cholesterol

IDF International Diabetic Federation

ICSI Institute for Clinical Systems Improvement

KNH Kenyatta National Hospital

LDL-C Low Density Lipoprotein Cholesterol

MOPC Medical Outpatient Clinic

OGTT Oral Glucose Tolerance Test

RBS Random Blood Sugar

SBP Systolic Blood Pressure

T2DM Type 2 Diabetes Mellitus

UON University Of Nairobi

VCRH Vihiga County Referral Hospital

ABSTRACT

Introduction: The incidence of diabetes is increasing in Kenya, and poor diabetic related outcomes such as complications, high blood sugar levels have resulted due to inadequate management of the condition. However, the majority of the rural population in Kenya are highly ignorant of the common aetiologies and risk factors for diabetes. Patient awareness and involvement in self-care is very critical in improving outcomes and this should be part of treatment plan offered to them. The health care team should adopt standard treatment guidelines that are practical, evidence based, valid and up-to date in management of diabetic patients.

Objective: To asses' compliance to guidelines, prevalence of diabetic complications and role of patients in management of Type 2 diabetes at a rural set up in Kenya.

Methods: Two cross-sectional studies consisting of a retrospective audit of prescribing and monitoring practices and a prospective patient survey on self-practice were conducted. The target population was Type 2 diabetic patients attending medical outpatient clinic at Vihiga County Referral Hospital. Inferential statistics using t-test and Mann-Whitney test was done and bivariable logistic regression analysis carried out. Model building was done to come up with a parsimonious model using IBM SPSS^R Statistics version 22 database.

Results and Discussion: A total of 212 patient files were retrieved. The participants aged 50 – 69 years were 60% and females were the most in the study at 70.3%. Most (39.6%) had had diabetes for 1 to 5 years. Random blood Sugar test was the most used method of diagnosis (58.5%) whilst FBG was performed in 34% of the participants tested. Metformin was part of first line therapy with a compliance rate of 72.2%. Compliance to ICSI recommendations with regard to blood pressure, weight and cholesterol monitoring at initiation was 96.7, 1.4 and 6.1% respectively. Of the 141 patients that had their fasting blood sugar monitored, 113 (80.1%) had uncontrolled blood sugar levels. The median blood glucose for all patients tested with FBG was significantly higher than the target threshold of 7 mmol/L (median blood sugar = 8.9(IQR.7.4, 12.75) mmol/L; P=0.741). The prevalence of the major diabetic complications: neuropathy, retinopathy and nephropathy were 41, 33 and 0.9% respectively. There was an association between fasting blood glucose level and retinopathy and neuropathy. Total of 25 participants were recruited into the survey and most of them did not experiencing challenges in executing

self-care behaviours to managing their condition. Use of treatment guidelines will help improve the quality of clinical decision made by healthcare workers, improve health outcomes. Diabetic patient education should also be encouraged to enhance and improve patient self-care behaviours.

Conclusion: Patients were not adequately being diagnosed, managed and monitored as per the ICSI treatment guideline recommendations. There was high prevalence of retinopathy and neuropathy. Uncontrolled hypertension and fasting glucose levels were significant risk factors for complications. Patients lack on knowledge on nutritional interventions. Hence there is need to strengthen capacity to manage type 2 diabetes in this facilty.

CHAPTER ONE

1. INTRODUCTION

1.1 BACKGROUND

In 2013, global estimates showed that almost 382 million people suffered from diabetes indicating a prevalence of 8.3%. The African diabetic prevalence in the same year was 4.9% representing an approximate population of 19.8 million adults. The prevalence of diabetes in The Island of Réunion, Seychelles, Gabon and Zimbabwe are 15.4, 12.1, 10.7 and 9.7% respectively. The most populous African countries with the highest numbers of diabetics include Nigeria, South Africa, Ethiopia and the United Republic of Tanzania with a diabetic population of 3.9, 2.6, 1.9, 1.7 million respectively [1]. In Kenya, diabetic epidemiology has not been studied to a far extent. Although the prevalence as at 2013 is from an opportunity sample of an urban and rural population that reported value of 4.2% [2].

Diabetes is a long term condition that develops when the body insufficiently produces enough insulin or cannot effectively use it. Insulin is a hormone produced in the pancreas that allows glucose from food to enter the body's cells. It is converted into energy required by muscles and tissues to function. Diabetics do not absorb glucose properly resulting to excess glucose circulating in the blood. This leads to damaging of body tissues over time culminating to disabling and life-threatening health complications [1].

Type 2 diabetes has frequently been seen in adults, although more incidences have risen in children and adolescents. Diabetics either cannot produce enough insulin or develop insulin resistance which results from excess build-up of glucose in the blood [1].

Diabetics must receive care from an intergrated team of diabetes experts constituting of pharmacists, phycisians, nurses and nutritionists. Diabetics must also participate actively in their care. A diabetes management plan should be formulated by incorporating all the ideas from the patient and family and the healthcare team. The plan should also include continous program of patient support and diabetes education on self management. Treatment goals and plans should as much as possible be specific to individual patient. Amongst factors to be considered when developing the plan are the age of patient, daily routine timetable, social and cultural factors, diabetic complications, and other co-morbidities [3].

Lifestyle change remains an integral part of treatment of type 2 diabetes. The most important choices affecting the health of an individual are instituted by that person and not by the health professionals [4]. Diabetic outcomes can thus be improved by increased involvement of diabetic patient in making decisions surrounding their care. Healthcare providors may face challenges such as limited time while engaging in a participatory way with people with Type 2 diabetes [5].

Acknowledging the important roles played by health practitioners and the patients, this study therefore set out to assess the outpatient management of Type 2 diabetes as well as explore the opinions of the patients on practices regarding taking responsibility for their condition.

1.2 PROBLEM STATEMENT

The occurrence of diabetes is on the rise in Kenya [2], and poor diabetic related outcomes such as complications, high blood sugar levels and being overweight have resulted due to inadequate management of the condition. However, the majority of the rural population in Kenya are highly ignorant of the common aetiologies and risk factors for diabetes [15].

In Vihiga County Referral Hospital, diabetes mellitus is estimated to be the 6th most common cause of mortality and 7th highest cause of morbidity (injury or disease) in hierarchy of conditions most commonly managed. From July to December 2014, 974 patient visits were recorded at the clinic while 1,483 were for January to June 2015. Diabetic patients in Vihiga County Hospital attend a medical outpatient clinic held once a week and a review scheduled every after 2-3 months. For most part, the patients are expected to take responsibility for the management of their condition in between the periodic visits. Type 2 Diabetes remains a chronic illness that extensively affects the quality of life of patients if not properly managed, whereby both the healthcare practitioners and patients have important roles to play.

Diabetes treatment guidelines are intended to provide clinicians, patients, researchers and other interested individuals with the components of diabetes care, general treatment goals, and tools to evaluate the quality of care. It is, therefore necessary to uphold compliance to these guidelines. Patient awareness and involvement in self-care is very critical in improving outcomes and this should be part of treatment plan offered to them.

Compliance to T2DM treatment guidelines by clinicians as well as patient awareness and involvement in self-care are inadequately studied in our setting. This study intended to address this knowledge gap by establishing the extent to which guidelines are adhered to and exploring patient adoption of self-care activities at a county referral hospital in Kenya. The lack of adherence to guidelines leads to a high prevalence of complications. The prevalence of diabetic compliations in rural outpatient setting like Vihiga County is unknown. Hence this study sought to measure the prevalence of diabetic complications and patient engagement in disease management.

1.3 RESEARCH QUESTIONS

- i. What is the proportion of adult Type 2 diabetic cases that are diagnosed, managed and monitored in accordance with ICSI treatment guidelines?
- ii. What proportion of type 2 diabetic patients achieve the standard treatment targets for adequate disease control for HbA1c/FBG/OGTT, blood pressure, cholesterol and weight/BMI as outlined in the ICSI treatment guidelines?
- iii. What is the prevalence and risk factors for diabetic complications?
- iv. What are the patients' opinions and practices with regards to taking responsibility for management of diabetes through consuming healthy food, engaging in physical activity, self-tracking of blood glucose levels and compliance with medication?

1.4 OBJECTIVES OF THE STUDY

1.4.1 **Main objective**

The main objective was to determine if outpatient management of Type 2 diabetes mellitus complies with the treatment guidelines and explore patients' opinions on their roles to self care behaviours at Vihiga County Referral Hospital.

1.4.2 Specific objectives

The specific objectives were to:

- i. Determine the proportion of adult Type 2 diabetes cases diagnosed, managed and monitored in accordance with ICSI treatment guidelines.
- ii. Establish the proportion of type 2 diabetic patients who achieve the standard treatment targets for adequate disease control.
- iii. Determine the prevalence and risk factors for diabetic complications
- iv. Explore patients' opinions and practices with regard to taking responsibility for management of diabetes through consuming healthy food, engaging in physical activity, self-tracking of blood glucose levels and compliance with medication.

1.5 JUSTIFICATION OF THE STUDY

This study set to identify the gaps in the adherence of clinical treatment guidelines by clinicians in management of type 2 diabetes. The findings from the study will enable the policy makers identify the areas where improvement should be emphasised on terms of utilization of treatment guidelines. If these gaps are addressed, hopefully this would lead to reduced incidence of diabetic related complications. The study also sought to provide baseline data on the prevalence of diabetic complications in an understudied rural setting. This data can be used as a reference point against which the effectiveness of any future intervention to improve diabetic management can be measured. Lastly, gaps in patient driven intervetions were identified and these will form the basis of impetus to improve non pharmacological interventions.

CHAPTER TWO

2. LITERATURE REVIEW

2.1 Treatment Guidelines in management of Diabetes

In management of Diabetes Mellitus, it is important that health practitioners use an evidence-based, clear, valid and up to date document as a reference guide. It has been shown in rigorous evaluations that the greatest benefit of using clinical practice guidelines is to improve the quality of care received by patients. However, this may not be adequately achieved in daily practice proably because stakeholders in healthcare sector have varying definitions of quality and little is known on the effectiveness of guidelines [6].

The organizations that supported developing of The Kenya National Clinical Guidelines for Management of Diabetes Mellitus first edition (2009) were Kenya Diabetes Management and Information centre, Diabetes Kenya Association, Ministry of Public Health and Sanitation, World Diabetes Foundation and the International Diabetes Federation.

The Guidelines were developed on basis of the Clinical guidelines for Management of Diabetes in Sub Sahara started by the International Diabetes Federation Africa. It was anticipated that regular reviews of the guidelines would be important to add in any new development as it becomes available from time to time[7]. Up to the time of this research, there has not been any update and review of the document.

The Institute for Clinical Systems Improvement (ICSI) Healthcare guideline for Diagnosis and Management of Type 2 Diabetes Mellitus[8] was used in this study. This guideline was developed by ICSI member working groups on basis of a systematic evidence review assessing literature produced on type 2 diabetes mellitus (T2DM). The databases looked into included PubMed and Cochrane with only studies done in the English language considered in the search. Amongst the searches carried out and used to come up with the document were on screening, diagnosis, diagnostic testing, risk factors, blood pressure, and lipid management. Review of several evidence rating and recommendation writing systems, led to ICSI's decision to adopt to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology [8]. The Kenya National Clinical Guidelines for

Management of Diabetes Mellitus was used in areas where the ICSI guideline was not applicable.

2.2 Roles of clinicians, pharmacists, nurses and nutritionists in patient care

Health care professionals should educate patients on the essence of good diabetic management including provision of knowledge on lifestyle changes. However, various societal factors influence the ablity of diabetics to manage their conditions and this poses a great challenge.

A coordinated interaction between patients and healthcare providers to achieve equitable, safe, effective and high-quality care for patients across the spectrum of type 2 diabetes is therefore required. In addition, there must be a healthcare system that focuses on improving the patient experience and outcomes throughout the continuum of care. There is need for adequate systems and support, resources and proper communication strategies for healthcare providers to effect change in patients' lifestyles [9]

2.3 PATIENTS RESPONSIBILITY IN MANAGING DIABETES

Self-care in diabetes is a process by which diabetics develop awareness through learning to pull through with the complicated nature of the condition in a social setting. Diabetes daily care activities are overseen by patients themselves and/or family, therefore authentic measures for self-management should be provided to them [10].

2.3.1 Nutrition management by patients

The most demanding section of the treatment schedule for several diabetics is to know what to eat. Nutrition remedy is a fundamental element of diabetes prevention, control, and education on self-management. A trained nutritionist who has the knowledge and skills to provide diabetes management should provide each patient with individualized medical nutrition therapy [3].

The goals of nutrition therapy in adult diabetic patients are to eat healthy and, taking variety of foods in appropriate portions. Second is to deal with each ones' nutritional requirements with focus on individual and cultural priorities, health competence and access to healthy food option, readiness and capacity to make behavioural changes. Finally is to maintain

pleasurable eating and provide the individual with practical tools for daily meal planning rather than focusing on individual macronutrients, micro- nutrients, or single foods.

2.3.2 Patient involvement in physical activity

Exercise is an intergral issue in a management schedule for diabetes. Routine exercise has proven to enhance blood sugar management, bring down cardiovascular uncertainities, contribute to weight loss, and upgrade well-being[10]. The World Health Organisation 2010 recommended that adults over 18 years perform at least 150 minutes per week of moderate-intensity or 75 minutes per week of vigorous-intensity aerobic physical activity. If possible, both activities can be done. In addition, adults should perform activities that strengthen muscles twice or more a week. Adults 65 years of age and over are advised to abide by these recommendations or be physically active as much as possible. Studies in a meta-analysis of effects of exercise interventions on glycaemic control had a mean of 3.4 sessions per week, with a mean of 49 minutes per session[11]. The study showed that exercise training brings down glycated haemoglobin (HbA(1c)) by an amount that should reduce the danger of diabetic complications; but no significantly difference in body mass was found when exercise groups were compared with control groups.

The uptake of exercise in presence of long term specific diabetic complications has also been investigated. Caution is however necessary when a patient has retinopathy, peripheral neuropathy, autonomic neuropathy, albuminuria and nephropathy. Vigorous aerobic or resistance exercise may be contraindicated when proliferative diabetic retinopathy or severe non proliferative diabetic retinopathy is present. This is because there is high risk of triggering vitreous haemorrhage or retinal detachment[12].

For peripheral neuropathy, some exercises lead to reduced pain sensation and higher pain threshold in the extremities, which may result to increased risk of skin infection and Charcot joint destruction. However, some studies show that walking with average-intensity may not result to more danger of developing foot ulcers. In addition, patients with milder forms of neuropathy reported improved outcomes when they got involved in moderate exercise lasting 150 minutes per week [13]. Wearing proper footwear and daily feet examination to detect lesions should be done by all people with peripheral neuropathy. Similarly, those with a foot injury or open sore must be restricted to non–weight-bearing activities[14].

Reduced cardiac receptiveness to exercise, impaired night vision, altered body temperature regulation, postural hypotension, and altered papillary reaction can result to increased risk of exercise-induced injury in people with autonomic neuropathy [13]. Autonomic neuropathy in the cardiovascular system is a sole risk factor for silent myocardial ischemia and cardiovascular death[11]. Therefore, those with this type of neuropathy should be taken through cardiac examination before the start of physical activity which may be more vigorous than that they are used to.

It has been reported that labor intensive activities can sharply increase urinary protein elimination. On contrary, no proof has shown that hard exercise increases the rate of advancement of diabetic kidney disease, and therefore no need to prescribe specific restrictive exercises to diabetics with kidney disease[14].

2.3.3 Home based Self-monitoring of blood glucose

Self-monitoring of blood glucose is the cornerstone of diabetic care that can ensure patient participation in achieving and maintaining specific glycaemic targets. Self-monitoring provides information about current glycaemic status and allows assessment of therapy and guiding adjustments in diet, exercise and medication in order to achieve optimal glycaemic controls[10]. Self-monitoring should only be considered when the person with diabetes is prepared to learn the skills, record the findings, understand the data and act appropriately on the data [3]. However, personal monitoring of blood sugars in those diagnosed for the first time with type 2 diabetes was found to have no advantage in improving glycaemic control compared to non-monitoring[15].

2.3.4 Compliance with anti-diabetic medication

Noncompliance to prescribed anti-diabetic medication is a significant problem and a common occurrence which leads to unnecessary distress and reduced drug efficacy. It was reported in Cramer's review on adherence in the treatment of diabetes, hypertension and dyslipidaemia that 30% of days 'on therapy' are not covered by medication. Only 59% of patients were taking medication for more than 80% of their days 'on therapy' in a year. Diabetes management may be enhanced by enhancing patient compliance because it is evident that good medication compliance has a useful effect on clinical outcomes[16]. Two studies showed 53 and 67% oral medications adherence levels in type 2 diabetics when determined

by electronic tracking. In a more recent study of elderly type 2 diabetic patients' sulfonylureas compliance levels, determined by pill counts was at 104% to a once daily regimen and 87% to a two- or three times daily regimens. In this however, electronic tracking revealed lower adherence rates of 94 and 57% for once a daily and two or three times daily regimens, respectively[17].

2.4 DIABETES ASSOCIATED COMPLICATIONS

Diabetics can survive for many years without exhibiting any signs. Contrary, during then hyperglycemia is slowly destroying the body and diabetic related complications may be developing. The direct and indirect effects on the human vascular tree are the major source of morbidity and mortality in diabetes. Generally, the harmful effects of hyperglycemia are divided into macrovascular complications (coronary artery disease, peripheral arterial disease, and stroke) and microvascular complications (diabetic nephropathy, neuropathy, and retinopathy)[18].

In a study by Litwak *et al*, diabetes complication rates were high with 27.2% for macrovascular complications and 53.5% for microvascular complications and use of vascular disease preventative drugs lower than expected. Predictor variables to complications including age, body mass index (BMI), diabetes duration, low density lipoprotein cholesterol (LDL-C), and systolic bloodpressure (SBP) were positively associated, while high density lipoprotein cholesterol (HDL-C) was negatively associated, with macro- and microvascular complications. Glycated haemoglobin and fasting plasma glucose (FPG) were negatively associated with macrovascular complications[19].

Approximately 10,000 incidences of blindness occur yearly in the United States alone are as a result of retinopathy and may develop 7 years before diagnosis of diabetes. Nephropathy accounts for 7% of type 2 diabetes patients as at the time of diagnosis. Development of diabetic neuropathy is proportional to both the magnitude and duration of hyperglycemia[18].

2.5 TREATMENT TARGET RECOMMENDATIONS FOR DIAGNOSIS AND MONITORING

In management of type 2 diabetes, it is important to select specific improvement measures and goals which involve focusing on glucose, lipid and blood pressure regulation. This

strategy has proven to be successful in stopping up to 53% of heart attacks and strokes which are the main causes of death and excess costs in diabetics.

Type 2 diabetes should be diagnosed using glycated haemoglobin test, fasting glucose levels or Oral glucose tolerance test. Glycated Hemoglobin levels greater than 6.5% and fasting plasma glucose levels greater than 126 mg/dL, are indicative of diabetes. Similarly two hour plasma glucose greater than 200 mg/dl on a 75 g Oral Glucose Tolerance Test are indicative of diabetes [8]. Additionally, a person with symptoms of hyperglycemia and casual plasma glucose or random blood sugar (RBS) greater than 200 mg/dL (≥ 11.1 mmol/L), diabetes may be diagnostic [7].

Diabetic patients' glucose levels should be monitored to achieve glycemic control with glycated haemoglobin of less than 53 mmol/mol or less than 7%. Due to normal variation in test accuracy, HbA1c results ranging between 6.5 and 7.5% or 4–6.7 mmol/L fasting and 8–10 mmol/L postprandial would reflect this goal[8].

Table 1 shows the corresponding equivalences of glycated haemoglobin values to that of fasting blood glucose and post prandial glucose values in mg/dL.

Table 1: Ranges of self-monitored blood glucose values for various Glycated haemoglobin goals [7]

Glycated haemoglobin goal	Fasting blood glucose* (mg/dL)	Post- prandial blood glucose (mg/dL)	
< 6%	< 100	< 140	126
< 7%	90-130	<180	154
< 8%	120-160	<210	182
< 9%	160-190	<240	211

^{*} It is not adviced to achieve fasting sugars values targeted below 70 mg/dL.

Overweight diabetic patients should be counselled on the need to maintain healthful eating pattern to promote weight loss. Patients should be given the necessary support in event of their weight loss program [8].

Poorly controlled high blood pressure is a crucial cardiovascular risk consideration that increases the advancement of diabetic nephropathy. Upon diagnosis of hypertension,

^{**} This mean uses both fasting and post-prandial blood sugar recordings from regular glucose monitors or from 7-point daily testing.

treatment should be started immediately with the aim of attaining blood pressure levels less than 140/90 mmHg[8]. A clinician should recommend moderate- or high-intensity statin therapy for all type 2 diabetics between the ages of 40-75 with a LDL \geq 70 mg/dL[8].

Table 2 shows the equivalent values of average blood glucose measurements in mmol/L to that of HbA1c in percentage and mmol/mol.

Table 2: Glycated haemoglobin and corresponding blood glucose levels

Glycated haemoglobin (%)	Glycated haemoglobin (mmol/mol)	Average blood glucose (mmol/L)
13	119	18
12	108	17
11	97	15
10	86	13
9	75	12
8	64	10
7	53	8
6	42	7

2.6 CONCEPTUAL FRAMEWORK

Figure 1 shows the relationship between patient factors and health outcomes, and the association between self-care behaviours, access to primary care centre, standard treatment targets and improved health outcomes.

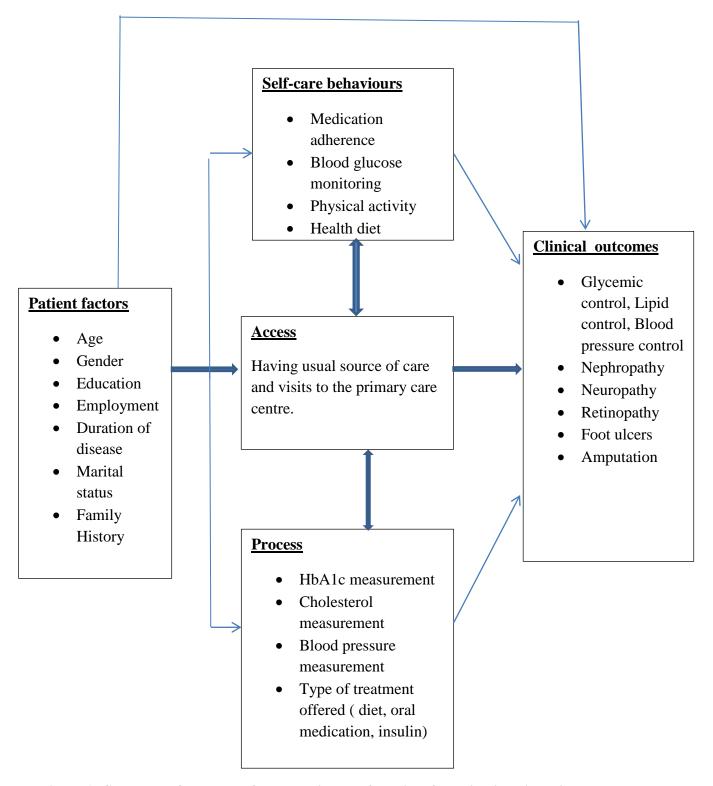


Figure 1: Conceptual framework for determinants of quality of care in diabetic patients

CHAPTER THREE

3. METHODS

Two separate quantitative studies were conduted. The first was a retrospective audit of prescribing and monitoring practices. The second was a prospective survey of patient self care practices.

3.1 STUDY SITE

The study site was Vihiga County Referral Hospital, the largest public hospital in Vihiga County that is located along Kisumu-Kakamega Highway in Mbale town. The hospital has a bed capacity of 160 beds. According to Kenya County Data Sheets 2014, the county has an adult population of approximately 246,000 persons.

The study was carried out at the hospital registry office and at the medical outpatient clinic. The hospital registry office where the entire inpatient and outpatient records are stored is located in the first floor of the hospital building near the administration block and is under the control of a qualified health records officer in-charge.

The Medical outpatient clinic (MOPC) at the hospital is a physician based clinic designed to meet the needs of diabetics and hypertensives who require initial and continuing treatment and care. In addition to the physician, there is a complement of a multidisciplinary team of healthcare professionals who provide the required service at the clinic. The team serves the needs of patients who require follow up care, monthly check-ups or treatment for medical problems associated with diabetes and hypertension.

Vihiga County Referral Hospital is the most well equipped hospital in the region, with several specialist consultants and was selected for this study because majority of patients from the general community who are on therapy access care from this facility as their major primary care centre.

3.2 RETROSPECTIVE CROSS SECTIONAL AUDIT

3.2.1 Study design and Population

This was a retrospective descriptive audit of prescribing and monitoring practices. The study

population comprised of Type 2 diabetes patients attending the medical outpatient clinic.

3.2.2 Inclusion and exclusion criteria for the clinical audit

Patient files included were those for patients who had type 2 diabetes as the primary

diagnosis, attended routine MOPC between January and June, 2015 and were either male or

female adults age 18 years and above.

Patient files for those patients with any other type of diabetes and attended MOPC with

Hypertension as the primary diagnosis without diabetes were excluded from the study.

3.2.3 Sample size for the clinical audit

The Cochran formula [20] was used to calculate the sample size. The formula for the sample

size is as presented in equation one. The calculated sample size was based on previous

reported prevalence of how often practising physicians claim to use guidelines when treating

patients. A study done in the United States estimated a prevalence 27% according to the New

England Healthcare Institute[21].

Equation 1: $n = (Z^2 \times P(1 - P))/e^2$

Where,

Z = value from standard normal distribution corresponding to desired confidence level

(Z=1.96 for 95% CI)

P is expected true proportion

e is desired precision.

Thus, the estimated sample size was 303 patient files.

Cochran's finite population correction formula used to calculate the final sample size. The

formula is presented in equation two:

14

Equation 2:
$$n = \frac{n_0}{(1 + n_0 / Population)}$$

Where:

Population size = 709, n_0 = Sample size according to Cochran's formula= 303 n = Sample size

The sample size obtained after correcting for finite population was 212.

3.2.4 Sampling method

A systematic random sampling method was used to obtain the sample files. A list of the 709 type 2 diabetes patients who attended clinic from January 2015 to June 2015 was obtained. From the list, the researcher randomly selected the first sample element from the first 709 elements on the population list. Thereafter, every third element on the list was selected, where 3 is the appropriate sampling interval that allowed for the achievement of the target sample size. This was done until the calculated sample size of 212 was obtained.

3.2.5 **Data collection**

Data collection for this study phase was conducted on any other day of the week than the clinic day to minimize interruption of clinic activities. The sampled files were retrieved and data on the variables and outcomes of interest extracted. The data collection also included details on patient's demographics. The data collected was entered into a predesigned data collection form (Appendix 1).

Review of the individual patient files was carried out to identify the cases that had been diagnosed and managed at the institution. In addition, records of patients who developed complication amongst the cases were noted. The individual recent recorded measurements of HbA1c/FBG/OGTT, blood pressure, cholesterol and weight/BMI recorded within the study period were also retrieved.

3.3 PROPECTIVE PATIENT SURVEY

3.3.1 Study design and Population

This was a prospective descriptive survey of diabetic patients on self monitoring practices. The study population comprised of Type 2 diabetes patients attending the medical outpatient clinic.

3.3.2 Inclusion and exclusion criteria for the clinical audit

Participants included were those for patients who had type 2 diabetes as the primary diagnosis, attended routine MOPC between January and June, 2015 and were either male and female adults age 18 years and above. Similarly, those woth outpatient booklets and gave volunatary consent were included.

Participants with any other type of diabetes and attended MOPC with Hypertension as the primary diagnosis without without diabetes were excluded from the study.

3.3.3 Sample size

Because this was a pilot study, as sample size of 25 participants was used.

3.3.4 Sampling method

For every clinic day, approximately 50 clients were seen. This was usually conducted once in a week. The first client was approached, requested and if he/she accepted then were considered for recruitment. Upon completion of the interview with the client, the procedure was repeated on the next available clients until a sample of 5 participants was achieved per day. This was repeated on subsequent clinic days until the target sample size of 25 respondents was attained.

3.3.5 Participant recruitment and Data collection

The patient was approached at the pharmacy dispensing window after collecting their drugs and invited into the pharmacy office where he/she was briefed about the study and requested

to participate in it. Informed consent (Appendix 2) was sought and obtained prior to start of the administration of the questionnaire.

The structured questionnaire was administered by the researcher (data collection form Appendix 3). Information about participants' medicine use, recent eating habits, physical activity and blood glucose testing was collected. In addition, socio-demographic data including age, sex, education, marital status, and employment was obtained, as well as their opinions regarding all these activities collected. Patients were then requested for their outpatient booklets that aided extraction patients' personal demographic data. Data obtained was recorded in the data collection sheets (Appendix 2). The interview for those who consented lasted approximately 20-30 minutes.

3.4 DATA MANAGEMENT

To ensure confidentiality, unique patient identifiers rather than patient names or outpatient numbers were used in the data capture forms. All the data from retrieved files was extracted at the hospital registry office. Any document linking the collected data to the patient files or identity in hardcopy were kept under lock and key and was only accessible by the principal investigator. The soft copy raw data was password protected by the principal investigator. Data was entered in the Microsoft Excel worksheet 2010 and counterchecked for completeness and accuracy by the principal investigator on the same day of data entry.

3.5 QUALITY ASSURANCE

The data collection form (questionnaire, Appendix 3) was pre-tested on a pilot sample of five patients, to estimate the time needed for the administration and assess the clarity and suitability of the questions. Accordingly, modifications were done to make the questions shorter, clearer and easier to understand. This pilot sample was excluded from the study sample.

3.5.1 **STUDY VARIABLES**

The primary outcome variable was adherence by health care workers to the ICSI guideline for management of diabetes. The outcome was measured using the following indicators: the

cases diagnosed, managed and monitored in accordance with ICSI treatment guidelines, proportions of patient who attained treatment targets.

The secondary objective of the study was to relate the presence of complications with attainment of therapeutic targets and socio-demographics characteristic of the patients. For this analysis, the main outcome of interest was presence of any complication which included retinopathy and neuropathy. The independent variables that are known risk factors for these complications include age, gender, cadre, blood glucose, blood pressure, duration of disease, methods of diagnosis, and prescribed drug therapy for diabetes. The achievement of standard treatment targets for HbA1c, FBG, OGTT, RBS, blood pressure, cholesterol and weight/BMI was also used as independent variables.

3.6 DATA ANALYSIS

The collected data was entered to IBM SPSS^R Statistics version 22 database. P-P normality plots were generated to determine if the continuous were normally distributed. The continuous variables were summarised as means and the standard deviation of the mean if they were normally distributed. Continuous variable that were not normally distributed were summarised as the median and interquartle range. Catergorical data was summarised as proportions. The results were expressed graphically.

Inferential data analysis was done using the Student t-test, chi square test and the Mann Whitney non parametric tests. Bivariable analysis was used to determine any relationship between compliance to diagnosis and management as per ICSI treatment guidelines and the other variables under study. Odds ratios with 95% confidence interval were computed.

Binary logistic regression was conducted to identify risk factors of diabetic complications. Model building to come up with a parsimonious model was done using forward stepwise model building. All variables that were significant on the bivariable logistic regression were considered for the model building. The level of significance was set at 0.05.

3.7 ETHICAL CONSIDERATIONS

Ethical approval was sought and obtained from the KNH-UoN Ethics and Research Committee (P641/10/2015) as study involved human subjects and identifiable health information data was accessed. See Appendix 4.

Informed consent was sought from the anticipated participants in the survey, prior to data collection. The informed consent form (Appendix 2) was used for this purpose. Study tools and the consent process information and form were translated from English version to Kiswahili version to facilitate comprehension.

Patient records were anonymised and any patient identifiers removed to assure confidentiality of patient information (See section 3.6)

Participants were informed that they were free to leave the study at any time without having to give any reason. Any withdrawal from the study would not jeopardize their access to their usual services at the hospital.

There was no compensation in this study. Patients were informed that they are likely to benefit from future interventions that may improve practices of care and treatment being offered at the facility. Any case encountered that required further management was referred back to the physician in-charge.

CHAPTER FOUR

4. RESULTS

4.1 RETROSPECTIVE CROSS SECTIONAL AUDIT OF COMPLIANCE TO TREATMENT GUIDELINES

A total of 212 patient files were retrieved and data on patient's demographics and information on compliance to ICSI treatment guidelines obtained and captured in the data collection form.

4.1.1 Patient demographics and clinical characteristics

The largest proportion of the participant tswere aged between 50 - 59 years (31.1%) with majority female (70.3%). Duration of illness was between 1 to 5 years in 39.6% of the respondents. However, information on duration of illness was available for 54.3% (115) of the respondents. Table 3 presents a summary of the patient demographic characteristics.

Table 3: Distribution of patients as per the Age, sex and duration of illness

Demographics	n	%
Age(years)		
20 - 29	4	1.9
30 - 39	7	3.3
40 - 49	23	10.8
50 - 59	66	31.1
60 - 69	63	29.7
70 - 79	41	19.3
≥80 years	8	3.8
Sex		
Male	63	29.7
Female	149	70.3
Duration of Illness(ye	ears)	
≤5	84	39.6
6 - 10	16	7.5
11 - 15	12	5.7
16 - 20	1	.5
≥21	2	.9
Not indicated	97	45.8

For those participants whose duration of illness was reported, analysis showed that majority of those who had the disease for duration of 6 years and above were aged 50 years and above.

4.1.2 **Prescriber information**

The respondents had been attended to by various cadres of healthcare personnel within the health facility at the time of diabetes diagnosis. A greater majority had their illness diagnosed by a medical officer (48.1%) while medical officers on internship diagnosed 22.2% of the patients. Only 1 of the respondents had their condition diagnosed by a Registered Clinical Officer. Prescriber information was unavailable in 9% of the patient files as depicted in

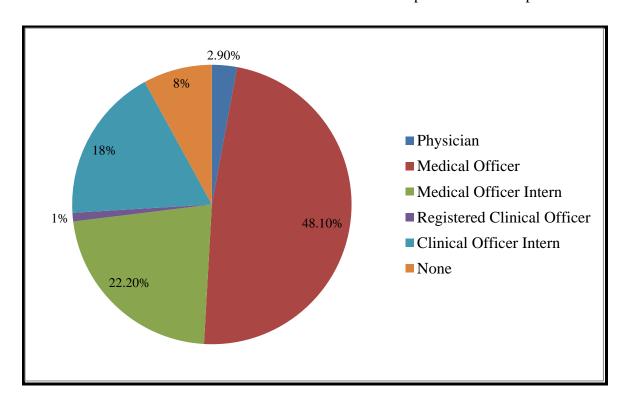


Figure 2: Healthcare providors at initiation of therapy

4.1.3 Complaince to guidelines on diagnosis, drug selection and monitoring of diabetis

Table 4 summarises the rates of the compliance treatment guideline by Health care workers. Each the key indicators will be described.

Table 4: Compliance to guidelines on diagnosis, management and monitoring of diabetic therapy

METHOD OF DIAGNOSIS	OF DIAGNOSIS COMPLIANCE COMMENT	
	RATE	
Random Blood Sugar	58.5%	There was good compliance
Fasting Blood Glucose	34.0%	although glyacted haemoglobin test
Glycated Haemoglobin	1%	was underutilized.
No test indicated	6.5%	
DRUGS USED AT INITIATIO	ON	
Metformin	15.6%	There was good compliance
Glibenclamide	8.5%	although patients should be initiated
Metformin and Glibenclamide	56.6%	on metformin alone before
Insulin	12.3%	combining with other antidiabetics.
TESTS DONE AT INITIATIO		
Blood pressure checked	96.7%	Non compliance with monitoring
Cholesterol levels checked	6.1%	cholesterol and weight was very
Weight measurement	1.4%	high
BLOOD GLUCOSE TESTS DONE ON FOLLOW UP		
Fasting Blood Glucose	66.5%	The use of Random blood sugar test
Random Blood sugar	31.6%	in not recommended on follow up
Glycated Haemoglobin	0%	thus being non compliant.
Not indicated	1.9%	

4.1.4 Method of diagnosis and medication selection at treatment initiation

The ICSI guidelines recommend that diagnosis should be based on measurements of glycated haemoglobin(HbA1c), Fasting Blood Glucose(FBG) and Random Blood Sugar(RBS)[8]. Measurements of RBS was the most used method of diagnosis with 58.5% of the patients having been diagnosed using this method. The FBG test was used in 34% of the respondents. Only 1% of the patients were diagnosed using HbA1c tests while 6.5% patients lacked details on method of diagnosis (Table 4). The ICSI treatment guidelines

recommend that patients on follow up be monitored for their blood sugar levels using Hb1Ac or FBG test [8]. The use of RBS is not explicitly recommended for monitoring of blood sugar levels by the guidelines.

A majority of the partcipants (66.5%) had their blood sugar monitored using the FBG test compared to those using RBS (31.6%); none were monitored using Hb1Ac. Some 1.9% of patients' records had no details on blood sugar monitoring. Table 4 depicts the use of different types of blood sugar tests for monitoring treatment targets.

The ICSI treatment guidelines recommend that patients with Type 2 diabetes mellitus should be initiated on metformin as first-line pharmacotherapy, or metformin in combination with other glucose-lowering agents, unless medically contraindicated[8].

Paticipants were initiated on different kinds of medications as either monotherapy or dual therapy. Monotherapy medications were metformin, glibenclamide, gliclazide, chlorpropramide or insulin. Metformin with glibenclamide or insulin with glibenclamide combinations were used as dual therapy. About 57 % of patients were initiated on metformin in a combination therapy while 15.6% were on metformin alone as their first line therapy. Table 4 details the drugs at initiation of treatment for the respondents.

4.1.5 Blood pressure, cholesterol and weight monitoring at initiation

The ICSI treatment guidelines recommend that a protocol should in detail set out the indicators to be checked at first visit, routine follow-up visits, and at the periodic yearly review[7]. In this case, individual patient risk assessment should be carried out for blood pressure, cholesterol levels and weight at initial visit[8].

Based on the patient records, almost all the patients (96.7%) had their blood pressure checked. Only 6.1% of the patients had their cholesterol levels checked and even fewer, (1.4%) had their weight measurements taken. Table 4 presents the findings.

4.1.6 Monitoring and Attainment of treatment therapeutic targets for Sugar, Blood pressure, lipid levels, weight and renal function on follow up

Table 5 summarises follow up therapeutic treatment targets for the paarticipants.

Table 5: Attainment of treatment targets on follow up between January and June, 2015

PARAMETER	THRESHOL D VALUE	% WITHIN TARGETS RANGE	% OUTSIDE TARGET RANGE	MEAN (SD) ¹ or MEDIAN (IQR) ² VALUES
Have hypertension	-	188 (97.2%)	24 (2.8%)	-
Controlled systolic blood pressure (mmHg)	140 mmHg	110 (51.1%)	92 (48.9%)	139.56 ±20.94 mmHg ^a
Controlled diastolic blood pressure	90 mmHg	186 (86.2%)	26 (13.8%)	79.81 ±11.03 mmHg ^b
Fasting blood glucose test (n=141)	7 mmol/L	28 (20%)	113 (80%)	8.9 (IQR 7.40 to 12.75 mmol/L ^c
Cholesterol	-	No records	No records	-
Weight	-	No records	No records	-
Renal function tests	-	No records	No records	-

^a The mean systolic blood pressure was not statisfially higher than the target (p=0.638)

The median blood sugar for all the participants tested with FBG was 8.9 (IQR 7.40, 12.75) mmol/L (Table 5). Amongst the 141 participants tested using the FBG, 80% did not have their blood sugars controlled adequately as per the guidelines. The guidelines recommend that the blood sugars should be maintained below7 mmol/L. The median blood sugar for the participants tested with FBG was compared against the threshold value (7 mmol/L) to find out if they were significantly higher than this recommended threshold. The independent sample Mann Whitney result showed the median blood sugar was not significantly higher than the target threshold of 7mmol/L (p=741),(Table 5).

Blood pressure monitoring data was available for the 212 patients. Overall, the mean systolic blood pressure for these patients was 139.56±20.94 mmHg while mean diastolic blood pressure was 79.81±11.03 mmHg during this follow up period. Amongst the 212 patients

^b The mean diastolic blood pressure was not statiscally higher than the target (p=0.000)

^cThe median fasting glucose was not statisfally higher than the target (p=0.741)

¹ Standard deviation

² Interquartile ranges

with follow-up blood pressure monitoring data, 188 (97.2%) had hypertension as comorbidity and were on antihypertensive treatment.

The ICSI guidelines recommend that diabetics with a blood pressure ≥ 140/90 mmHg should be started on antihypertensive therapy and blood pressure should be maintained below these levels.

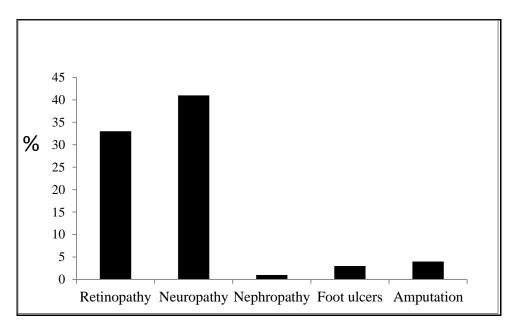
The mean systolic blood pressure (139.56±20.94 mmHg) was compared against the recommended threshold value (140 mmHg). Results show it was not significantly higher than the target maximum value (p=0.638). Similarly, the mean systolic blood pressure (79.81±11.03 mmHg) was compared against the recommended threshold value (90 mmHg) and this was found to be significantly higher than the target maximum value (p=0.000).

4.1.6.1 Cholesterol levels, weight, BMI and renal function tests on follow up

Only 6 (2.8%) patients had their cholesterol levels checked and recorded during the follow-up study period. None of the patients had their weight nor BMI recorded during follow up. Of the 2.8% whose cholesterol levels were taken, there was incomplete information regarding the test values and corresponding reference values. It was only indicated as high or normal. Those indicated as normal were five whilst one was high. There was no evidence of renal function tests request or results forms in all the patient files reviewed.

4.3 PREVALENCE AND RISK FACTORS FOR COMPLICATIONS ASSOCIATED WITH TYPE 2 DIABETES

The proportions of participants presenting with various microvascular complications are as presented in Figure 3. The most common complication experienced by the patients was neuropathy (41%) followed by retinopathy (33%). The least frequent complication was nephropathy in only 0.9% of the patients. Under-reporting of nephropathy may be attributed to lack of records on renal function tests that would have ascertained the presence of nephropathy. The patients were also checked for foot ulcers and amputations.



 $Figure\ 3\ Prevalence\ of\ micro-vascular\ and\ other\ complications\ of\ Type\ 2\ diabetes$

4.3.1 Risk factors of Retinopathy

Table 6 presents the findings of logistic regression analysis to identify determinants for retinopathy.

Table 6: Summary of the risk factors for retinopathy

Variable on follow up	Crude odds ratio (95% CI)	P value
Age at initiation	1.011 (1.007, 1.016)	0.000
Female Gender	1.577 (1.331, 1.866)	0.000
Cadre	1.223 (1.118, 1.338)	0.001
Duration of illness (n=113)	1.072 (1.005, 1.114)	0.034
Blood pressure at initiation	2.44 (1.545, 2.703)	0.000
Method used for diagnosis	1.234 (1.135,1.341)	0.000
Antidiabetic drugs initiated	1.228 (1.118, 1.349)	0.000
Controlled Systolic pressure	1.744 (1.199, 2.538)	0.004
Controlled Diastolic pressure	2.889 (1.354, 6.165)	0.006
Fasting blood glucose test (n=141)	2.382 (1.596, 3.556)	0.000
Random blood sugar (n=64)	1.500 (0.674, 3.339)	0.321

For the known risk factors assessed, all were positively associated with retinopathy (Table 6). Females had higher risk compared to males' crude OR 1.577 (95% CI1.331, 1.866). As expected, increase in age increased the risk of retinopathy. Participants who had their blood pressure taken at initiation had an increased risk of having retinopathy. Participants initiated on metformin had lowest prevalence of retinopathy at 21%. On the other hand, 40% initiated on glibenclamide developed retinopathy. These findings seem to suggest that initiating patients on metformin reduces the risk of retinopathy while patients initiated on sulphonylureas had high risk of retinopathy. Patients initiated on combined therapy of glibenclamide and metformin also had higher risk compared to those on metformin alone. There was no statistically significant association between systolic blood pressure and retinopathy while on other hand there was a statisticall significant association with well controlled diastolic blood pressure and retinopathy. This seems to suggest that it is more important to control diastolic blood pressure as opposed to systolic blood pressure to prevent retinopathy. The only variable not associated with retinopathy was the controlled random blood sugars at follow up. Patients with poorly controlled fasting blood glucose on follow up had a two-fold odd of developing retinopathy compared to those with well controlled fasting blood glucose levels (Table 6). On model building, having high blood pressure was the most significant predictors of retinopathy.

4.3.2 Risk factors for neuropathy

Unlike retinopathy, gender was not a risk factor for neuropathy (Table 7). Similarly, increased duaration of illness did not increase the risk of neuropathy. Uncontrolled Systolic blood pressure was positively associated with neuropathy unlike uncontrolled diastolic blood pressure that was not associated with neuropathy.

As seen previously in the case of retinopathy, well controlled random blood sugars had no association with neuropathy. Before adjusting for cofounding, there was a very weak association between fasting blood glucose and neuropathy, although it was almost significant (p=0.078) (Table 7). On model building, fasting blood glucose was the most powerful predictor of neuropathy compared to other variables, adjusted odds ratio 1.018 (95 C.I 1.006, 1.029)

Patients on insulin had the lowest prevalence of neuropathy at 27%. The risk of neuropathy in those on metformin was 33%. Those initiated on combined therapy of glibenclamide and

metformin had prevalence 47%. This seems to suggest that patients treated with sulphonylureas may have a higher risk of neuropathy. The effect of drug therapy was significant when adjusting for confounding crude OR 1.228 (95% CI 1.096, 1.370). It lost significance when adjusted for confounding by systolic blood pressure, adjusted OR 0.839 (95% C.I.0714, 1.116)

Table 7: Summary of risk factors to neuropathy

Variable on follow up	Crude odds ratio	P value
	(standard deviation)	
Age	1.005(1.000, 1.009)	0.040
Female Gender	1.087 (0.952, 1.241)	0.217
Cadre	1.126 (1.035, 1.226)	0.006
Duration of illness (n=113)	1.27 (0.970, 1.088)	0.363
Blood pressure at initiation	1.449 (1.112, 1.887)	0.006
Method used for diagnosis	1.112 (1.028,1.203)	0.008
Antidiabetic drug initiated on.	1.079 (0.988, 1.178)	0.090
Controlled systolic levels	1.744 (1.199, 2.538)	0.004
Controlled diastolic levels	1.059 (.0546, 2.054)	0.866
Fasting blood glucose test (n=141)	1.396 (0.964, 2.022)	0.078
Random blood sugar test (n=64)	0.923 (0.421, 2.023)	0.842

4.4 PROSPECTIVE SURVEY OF PARTICIPANTS ON SELF-CARE BEHAVIOURS IN TYPE TWO DIABETES

4.4.1 Patient demographic characteristics

A total of 25 patients were interviewed and their responses were received and analysed for perceptions regarding diabetes and its management. Slightly more than half of the participants were male (52%). Most of them were unemployed (88%) and almost all were married (92%). Most of the respondents had secondary level of education (41.7%). Slightly less than half of the respondents had family history of diabetes (40%). The mean age of the participants was 58.36 years with a range of 37 to 81 years while their mean weight was 78.5 kgs with a range of 42 to 111 kgs.

4.4.2 Participant perceived adequacy of glycemic control

Patients were asked how satisfied they were with their overall blood glucose control. Approximately half of the respondents (52%) considered themselves to have good control of their glucose levels; 8% claimed they had very good control, while 12% had excellent satisfaction with their glucose control. However, 28% were experiencing problems with glucose control.

Majority of the respondents (68%) maintained the targeted range for their blood glucose as agreed upon with their doctor compared to 32% who were not cautious on maintaining a target range. The blood sugar levels for most of the respondents (68%) were never too high whilst 28% had high blood sugars occasionally a month. On the other hand, the blood sugar for 84% of the respondents was never too low whilst 12% had low blood sugars occasionally a month. Figure 4 summarises patients' perception of blood glucose control.

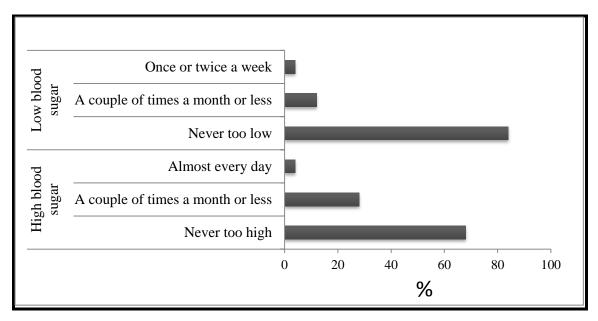


Figure 4: Patient perception on blood glucose control

4.4.3 Knowledge and practice of dietary control of diabetes

Patients were asked about their eating habits. All the respondents reported using sugar free products at least one or more times a day. Most of the respondents (80%) reported to never having used information on calories, carbohydrates or fat content in food labels to make decisions on what food to eat. Amongst the respondents, 56% reported to never have skipped a meal deliberately in order to reduce on calories or fat while 24% reported to skip meals at least one or more times a day. Amongst the respondents, 60% knowingly took less portions of food to cut on calories, while 24% never considered taking small portions of food at all. Regarding the use of a written meal plan to know what foods to eat, 64% reported to use it one or more times a day while 28% never used it. Figure 5 presents the findings.

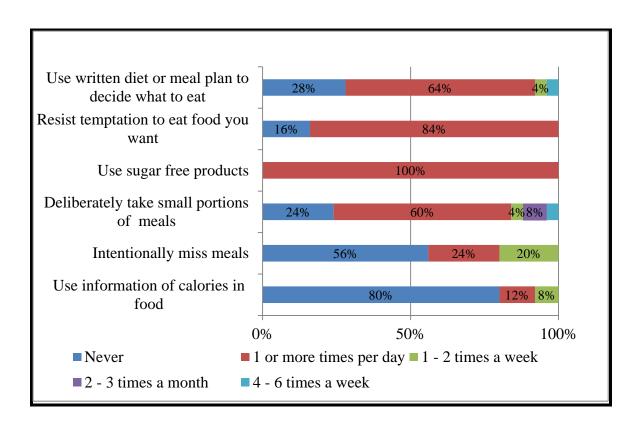


Figure 5: Participant dietary knowledge and practices

4.4.4 Barriers to dietary practices

Participants were asked about overeating, unplanned snacking, or poor food choices. Majority of the respondents reported to never have had any problem with diet. However, 14% reported to have had eating problems because of hunger or craving for specific foods at least one to two times a week while another 14% had hunger or craving for specific foods once a month. Another 13 and 9% had eating problems once a month and at least one or more times per day respectively, because either family or some friends did not support them in the efforts to eat right (Figure 6).

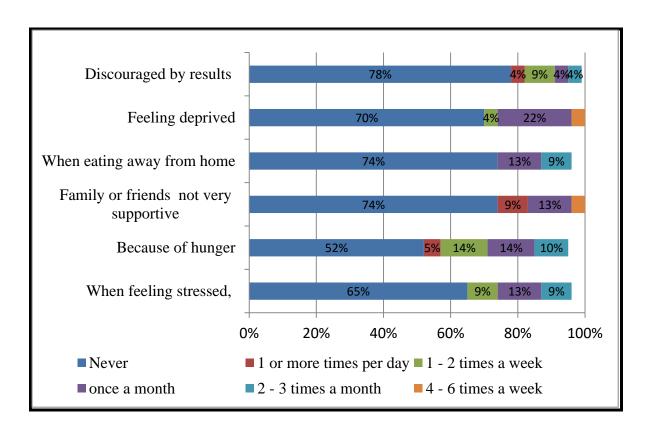


Figure 6: Barriers on adherence to dietary instructions

4.4.5 Participant reported adherence to medication

Patients were asked about their use of medication to treat diabetes. About 88% of respondents had their antidiabetic tablets at the time of the interview. About 72% were taking their tablets twice a day, while 16% took them three times daily. The proportion of respondents on insulin was 17%. All of these respondents were injecting insulin twice a day. None of these respondents reported to ever miss taking a dose of either the tablets or insulin shots.

4.4.6 Particpant barriers to medication use

Participants' opinions were sought on barriers to taking medications (either tablets or insulin shot). Most expected barriers such as cost and low mood or depression did not have much influence on medication use as shown in Figure 7. Only 12% of the respondents stated that low mood and cost of medicines were barriers to adherence once per month. Lack of support from family and friends hindered 8% from effectively taking their medication (see Figure 7).

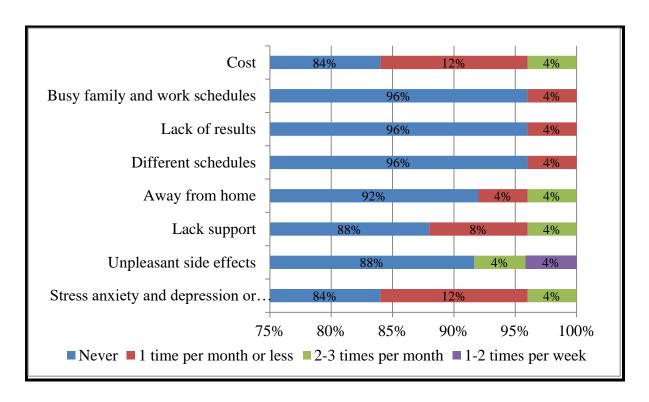


Figure 7: Factors hindering effective medication use.

4.4.7 Participant blood glucose monitoring practices

Respondents' opinions were also sought on patterns of testing their blood glucose levels. Amongst the respondents, 48% had not been told to test their blood glucose while 20 and 24% were told to test occasionally as needed and one or two times a week respectively.

Majority of the respondents (68%) tested their blood glucose only on their clinic appointment days. Another 20% tested their blood sugars more frequently than this, with 8% testing their level at least once a day. One respondent tested his blood sugar three or four times a day. Most of the expected barriers (depression, hates pricking, lack of social support, busy schedules) did not seem to hinder respondents from monitoring their blood glucose. The mostimportant barrier to glucose monitoring was the cost of supplies. Nine (36%), of the respondents felt that the cost of blood sugar monitoring machines and supplies was a key barrier.

4.4.8 Engaging in routine physical activity

Respondents were asked about the levels of physical activity they engaged in. Twenty (80%) respondents had been advised by their doctor to exercise while 5(20%) did not receive any advice.

Respondents were asked the extent of physical activity they benefit from as a result of routine work like going on shopping, perfoming housework, engaging in yard work or other daily activities. Amongst them, 18(76%) were very active while 4(16%) were inactive. Nearlly all, 23(92%), engaged in activities like walking, running, cycling at least once a day, or more. None of them were going to the gym or participating in sports.

4.4.9 Factors hindering participants from engaging in exercises

Participants' responses were sought on why it was difficult to begin exercising or abide by an exercise schedule. Many (24%) claimed that exercise and physical activity caused pain and discomfort once or twice week. A smaller number (12%) claimed that exercise caused and discomfort twice or thrice a month). Majority of them, (56%) reported that pain and discomfort was as a barrier. Generally, most of the other expected the barriers (depression, lack of social support, when away for vacation, preoccupied with other responsibilities) did not seem to cause a problem in respondents executing physical activities.

4.4.10 Overall assessment on patient self care behaviour

Generally, it was observed that medication use and engagement with physical activity were well adhered to with least number of barriers appearing to hinder participants from effectively executing these two activities. Problems were observed with dietary knowledge and practices because some patients never understood the importance of obtaining or following a prescribed meal plan. Self-monitoring of blood glucose levels was not evident because most of the patients had their blood sugar tests done only at the hospital with majority indicating lack of testing supplies as hindrance to frequent monitoring of their sugar levels.

CHAPTER FIVE

5. DISCUSSION

From the findings, patients were diagnosed according to the recommendation of the ISCI treatment guidelines with regards to the diagnostic methods used in testing for blood glucose levels. Random Blood Sugar and FBG were the most commonly used methods of diagnosis compared to HbA1c. This can be attributed to unavailability of technical resources (laboratory testing materials and equipment) and inadequate financial resources necessary to support the use of HbA1c as a primary diagnostic procedure at the facility[7]. A study on laboratory medicine in Africa indicated that allocation of resources to diagnostic laboratory testing has not been a priority for resource-limited health care systems. In addition, unreliable and inaccurate laboratory diagnostic testing leads to unnecessary expenditures [22]. Compared to FBG, OGTT and RBS tests, glycated haemoglobin (HbA1c) test is the most preferable for measuring blood glucose levels because it detects long term glucose vulnerabilty over a period of two to three months. It also is less affected by internal considerations like anxiety or illness [8]. Nonetheless, adherence to guidelines with regards to diagnosis of diabetes was followed, which was a positive impact on practise by clinicians.

Oral drug therapy is a preferred when one's glucose targets are not achieved by both diet modifications and vigorous exercise. Metformin is the ICSI guidelines' first line oral pharmacotherapy recommendation and most of the diabetic patients were initiated either on metformin as single therapy or in combination with other hypoglycaemic drugs. A satisfactory compliance of 72% to the ICSI guidelines with regards to first line therapy use of metformin was achieved, though there is much room for improvement. Non-compliance to these guidelines recommendations' may lead to suboptimal therapeutic goals and also associated with increased risk of hospitalization of diabetic patients due to complications.

Early detection and prevention of complications are secondary preventive measures of diabetes. Similarly, early monitoring of blood pressure, cholesterol levels and weight measurements in management of diabetes enhances individuals' quality of life. Type 2 diabetes frequently occur simultenously with hypertension, obesity and dyslipidaemias whereby the occurrence of all three of these components in a type 2 diabetic patient constitute of metabolic syndrome[7]. Almost all the patients were monitored for their blood pressure levels and it was discovered that 89% were hypertensive. These findings are consistent with other studies which indicate that diabetes and hypertension coexist in approximately 40 to

60% of patients with type 2 diabetes. In addition, diabetics subjects have a 1.5 - 3 times increased prevalence of hypertension compared to non-diabetics, with 50% of adults with diabetes having hypertension at the time of diagnosis[23].

Obesity is a vital element of the metabolic syndrome. It is evaluated through measurement of weight and height that's used to calculate the BMI of an individual. Monitoring of neither BMI nor weight measurements were rarely being done contrary to the recommendation by the ICSI treatment guidelines that indicates all patients' weight and BMI should be monitored. Literature suggests that over 70% of Type 2 diabetics are either overweight or obese[7]. Due to this inconsistency in taking weight measurements, it was not clear what proportions of patients had excess weight or were obese. Having excess weight or being obese can drastically increase the risk of morbidity and death from Type 2 diabetes and its co-morbidities.

For those patients with some degree of dyslipidaemia, the dangers of developing coronary artery disease and other macro-vascular complications is 2 to 5 times higher in diabetics compared to those without diabetes [7]. Measurement of fasting lipids should be done annually if lipids levels are normal whilst every 3-6 months if abnormal or on treatment. Over the study period, it was noted that very few patients had their lipid profile measured. The data obtained was not sufficient to ascertain extent of dyslipidaemia amongst these patients. Therefore, inconsistent follow up on lipids levels would expose the patients to higher risks of mortality and morbidity due to complications associated with diabetes.

The ICSI treatment guidelines recommend HbA1c, FBG and post prandial glucose tests as ideal methods of follow up glycaemic control. The treatment guideline was not adhered to because not all patients were monitored for their blood glucose levels as per the recommendation. Almost 32% of the patients were monitored using RBS test. Random blood sugar test is only recommended for purposes of diagnosis. Random blood sugar test might have been used as an alternative monitoring test rather than FBG because the patients had probably taken a meal in between the fasting period of six to eight hours required before performing FBG test. For the 67% of patients who were tested with FBG test on follow up, 80% did not have their blood sugar levels controlled adequately. The benefits of achieving near-normal glycaemic control can lower the risk of diabetes micro-vascular complications such as retinopathy, nephropathy and amputations.

Low rates of nephropathy (1%) reported may be attributed to unavailability of laboratory resources for screening nephropathy, negligence by the clinician to request for some specific tests to be done or lack of skills and knowledge by the clinicians in treating diabetic patients. The prevalence of neuropathy (41%) and retinopathy (33%) are comparable to that of a study done in Malawi which revealed micro-vascular complications as being common with prevalence of retinopathy (34.7%), neuropathy (46.4%) and nephropathy (34.7%). This shows the risk of type 2 diabetic patients developing these micro-vascular complications[24].

Diabetic self-care activities are undertaken in order to successfully manage the condition. The activities assessed included healthy eating, being physically active, personal-monitoring of blood sugar levels and adherence to medication.

Majority of participants were not keen on specific information on quantity of calories, carbohydrates and fat that was contained in the food they consumed. These findings may be attributed to individuals' ignorance, lack of knowledge/awareness or age factor since majority of the participants were elderly. This may result to patients consuming particular food nutrients in excess of what is required of them to adequately control the levels of sugars and calories. However, some studies have revealed controversy that surrounds the optimal ratio of carbohydrate-to-fat in the diet with respect to the prevention of type 2 diabetes. The association between dietary fat consumption and the proportion of the overweight population was positive. This therefore supports the notion of a reduced fat with increased carbohydrate intake as a preventative measure for chronic diseases [25]. Findings also showed that majority of the participants avoided binge eating which is characterised by exorbitant consumption of food without purging. Avoiding binge eating reduces the chances of developing obesity. Majority of the participants alluded to using a written diabetic meal plan which is a positive attribute and a good idea for diabetic patient. To promote adherence, a diabetic written meal plan should fit in an individual's schedule and eating habits because the meal plan helps patients in determining how much to eat and what kinds of food one can choose to eat at meals and snack time.

The self-reported adherence to the use of medication amongst the participants in this study, either on twice a day regimen or three times a day regimen was 100%. Contrary to the findings, several studies compared cohorts with different medication adherence regimen and found that once a day regimen had higher rates of adherence than twice a day regimen (61%).

vs. 52%) [25]. High medication adherence observed could be attributed to patients' positive attitudes and beliefs about the benefits of use of diabetes medications in the improvement of quality of life. Findings also revealed that the cost of medication and depression were major barriers to the use of medication. This is consistent with other studies that indicate that cost of treatment may be a significant barrier to diabetes treatment particularly for patients with low socioeconomic status and limited to no health insurance cover [26].

Self-monitoring of glycaemic control is considered the cornerstone of diabetes care that can ensure patient participations in achieving and maintaining specific glycaemic targets. On the contrary, it was observed that very few participants practised personal tracking of blood sugar levels. Majority of the participants' blood glucose tests were carried out only at the hospital during the clinic appointment days that's scheduled at a frequency interval of two to three months. This observation may be attributed to the lack of knowledge or awareness by participants on the importance of self-monitoring of glucose levels in management of the disease. On the contrary, evidence suggest that type 2 diabetic patients not on insulin therapy do not benefit clinically from self-monitoring of blood sugar. Decreased incidences of hospital admissions and morbidity are amongst the positive effects of self-monitoring of blood glucose levels[27], whereas negative results include no improvement in glycaemic control especially if the glycaemic control is not well sustained.

Majority of participants reported to actively engage in exercises like aerobic exercises that included walking, running, cycling and little of resistance exercise like yard work or housework. Engaging in either resistance or aerobic exercises reduces body fat and improves weight control, improves glucose tolerance, reduces insulin resistance, lowers resting systolic blood pressure (SBP) and diastolic blood pressure (DBP) in people with high BP amongst other benefits. A few of them reported pain and discomfort as a major barrier in executing physical activity.

The findings can be generalized to other primary care facilities which offer the same services in rural set up. The limitations which included poor quality of documentation in records that may have resulted in under reporting (or over-reporting) of treatment target indicators and presence of severe complications associated with diabetes. Also, a few prospective participants may have opted to leave the facility after doctors' consultation without passing through the pharmacy for issuance of drugs. This might have created bias in data (for example clients who obtain medicines outside the hospital pharmacy did not have the opportunity to be interviewed) collected in the qualitative arm of the study.

CHAPTER SIX

6. CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

There were low levels of adherence to the following ICSI treatment recommendations: monitoring of weight, renal function, lipid levels and fasting blood sugar level. A few patients were wrongly initiated on sulphonylyureas. There was lack of edequate labaratory supplies that aid diagnosis and monitoring. There was high prevalence of retinopathy and neuropathy. Eighty percent of the participants did not achieve the targeted fasting blood glucose levels. Uncontrolled hypertension and fasting glucose levels were significant risk factors for complications. Patients lack on knowledge on nutritional interventions. Hence there is need to strengthen capacity to manage type 2 diabetes in this facilty.

6.2 Recommendations

6.2.1 **Recommendation for practice**

There is need to either re-orient or train healthcare providers at Vihiga county referral hospital on the importance and use of diabetes clinical treatment guidelines as well as adherence to these guidelines in practice are emphasised.

The hospital administration can avail and adopt a health information technology system that will aid electronic medical recording and e-prescribing with a component of a prescribed diabetic-specific outpatient form inclusive. The system will enable healthcare providers readily access the guidelines at the point of care, keep track of complete individual patient history and offer support for clinical decision making.

There is need for the hospital administration to provide adequate resources to support the health information system technology adoption, healthcare provider training and maintenance of the information technology systems.

6.2.2 Recommendation for future research

Further studies can be done on exploration of factors affecting adherence to clinical treatment guidelines by healthcare providers' in Vihiga County.

A study is needed to find out if the use sulphonylureas may increase the risk of neuropathy and retinopathy.

REFERRENCES

- Aguiree F, Brown A, Cho N, Dahlquist Dodd S, Dunning T, Hirst M, Hwang C,
 Magliano D, Patterson C. IDF Diabetes Atlas. IDF diabetes Atlas. 6th ed. Brussels,
 Belgium: International Diabetes Federation; 2013. 155 p. [cited 2015 September 12]
- 2. Ayah R, Joshi MD, Wanjiru R, Njau EK, Otieno CF, Njeru EK. A population-based survey of prevalence of diabetes and correlates in an urban slum community in Nairobi , Kenya. 2013;
- 3. American Diabetes Association; Standards of Medical Care in Diabetes: The Journal of Clinical and Applied Research and Education. Diabetes care. Supplement 1, 2015;38(January). [cited 2015 September 12]
- 4. Gorter KJ, Tuytel GJ, De Leeuw RR, Bensing JM, Rutten GEHM. Opinions of patients with type 2 diabetes about responsibility, setting targets and willingness to take medication. A cross-sectional survey. Patient Education Counselling. 2011;84(1):56–61.
- 5. Beresford C. Patients' perspectives of type 2 diabetes care by practice nurses: A qualitative study. Journal of Diabetes Nursing. 2011;15(10):391–7.
- 6. Woolf SH, Grol R, Hutchinson A, Eccles M, Grimshaw J. Potential benefits, limitations, and harms of clinical guidelines. Bmj. 1999;318:527–30.
- 7. Ministry of Public Health and Sanitation, Republic of Kenya; The National Clinical Guidelines for Management of Diabetes Mellitus July 2010, First edition.
- 8. Redmon B, Caccamo D, Flavin P, Michels R, O'Connor P, Roberts J, Smith S, Sperl-Hillen J. Institute for Clinical Systems Improvement. Diagnosis and Management of Type 2 Diabetes Mellitus in Adults. Updated July 2014
- 9. General practice management of type 2 diabetes 2014–15. Melbourne: The Royal Australian College of General Practitioners and Diabetes Australia, 2014.
- Shrivastava SR, Shrivastava PS, Ramasamy J. Role of self-care in management of diabetes mellitus. Journal of Diabetes Metabolic Disorders [Internet]. BioMed Central Ltd; 2013 Jan 5 [cited 2015 Aug 5];12(1):14. Available from: http://www.jdmdonline.com/content/12/1/14
- 11. Boule NG, Haddad E, Kenny GP, Wells GA, Sigal RJ. Effects of Exercise on Glycemic Control and Body Mass in Type 2 Diabetes Mellitus A Meta-analysis of

- Controlled Clinical Trials. 2008;286(10):11–5.
- 12. Shahjamal khan, Assistant Professor, Department of Endocrinology, Journal of Enam Medical College & Hospital, Savar, Dhaka; Exercise for the Management of Diabetes Mellitus: A Review of the Evidence. 2013;3(2):99–108.
- Exercise Prescription for Other Clinical Populations. In Walter Thompson; Neil F
 Gordon; Linda S Pescatello; ACSM's guidelines for exercise testing and prescription.
 8th ed. American College of Sports Medicine, 2010, P. 226
- 14. Colberg SR, Sigal RJ, Fernhall B, Regensteiner JG, Blissmer BJ, Rubin RR. Exercise and type 2 diabetes: The American College of Sports Medicine and the American Diabetes Association: Joint position statement. Diabetes Care. 2010;33(12).
- 15. Davidson MB. Evaluation of Self Monitoring of Blood Glucose in Non-Insulin-Treated Diabetic Patients by Randomized Controlled Trials: Little Bang for the Buck. 2010;(323):1–5.
- 16. Delamater M. Improving Patient Adherence. Clinic Diabetes, American Diabetes Association 2006;24(2):71–7.
- 17. Koçkaya G, Ministry T, Directorate G. An estimation of the effect of 100 % Compliance with Diabetes Treatment: Can we reduce cost of illness with higher compliance rates? Artccle 45, Innovations in Pharmacy. 2011;2(2):1–8.
- 18. Fowler MJ. Microvascular and Macrovascular Complications of Diabetes. Clinical Diabetes journal, 2008;26(2):77–82.
- 19. Litwak L, Goh S-Y, Hussein Z, Malek R, Prusty V, Khamseh ME. Prevalence of diabetes complications in people with type 2 diabetes mellitus and its association with baseline characteristics in the multinational A1chieve study. Diabetology Metabolic Syndrome [Internet]. Diabetology & Metabolic Syndrome; 2013;5(1):57. Available from:
 - http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3854020&tool=pmcentrez &rendertype=abstract[Cited 2015 October 7]
- 20. Bartlett JE, Kotrlik JWKJW, Higgins C. Organizational research: Determining appropriate sample size in survey research appropriate sample size in survey research. *Information Technology, Learning* and *Performance* Journal. 2001;19(1):43.
- 21. Hope Kenefick, Jason Lee, Valerie Fleishman: Improving Physician Adherence to

- Clinical Practice Guidelines; Barriers and Strategies for Change. 2008;63.
- 22. Petti CA, Polage CR, Quinn TC, Ronald AR, Sande MA. Laboratory Medicine in Africa: A Barrier to Effective Health Care. Clinical Infectious Diseases; 2006;42:377–82.
- 23. Palacio A, Temponi D, Luster K, Chapman A. Diabetes Care In Press, published online April 11, 2007. 2007;(January):1–12. Available in http://care.diabetesjournals.org/content/30/7/1699. [Cited 2016 April 20]
- 24. Msyamboza KP, Mvula CJ, Kathyola D. Prevalence and correlates of diabetes mellitus in Malawi: population-based national NCD STEPS survey. BMC Endocrine Disorder, 2014;14(1):1–6.
- 25. Steyn NP, Mann J, Bennett PH, Temple N, Zimmet P, Tuomilehto J. Diet, nutrition and the prevention of type 2 diabetes. Public Health Nutrition Journal, 2004;7:147–65.
- 26. Chesla CA, Stotts NA, Janson SL, Nam S, Chesla C, Stotts NA. Barriers to diabetes management: Patient and provider factors Barriers to diabetes management: Patient and provider factors. Diabetes research and clinical practice, 2011;(March).
- 27. Saia G, Giorgino R. Population of Diabetes. High Prevalence of Hypovitaminosis D in. Diabetes care, 2001;24(8).

APPENDIX 1: DATA COLLECTION FORM FOR PATIENT'S DEMOGRAPHICS AND INFROMATION ON COMPLIANCE TO ICSI TREATMENT GUIDELINES

STUDY TITLE: COMPLIANCE WITH GUIDELINES AND THE ROLE OF PATIENTS IN MANAGEMENT OF TYPE 2 DIABETIC PATIENTS AT VIHIGA COUNTY REFERRAL HOSPITAL, KENYA.

Serial	Serial Number		Date of Collection			Vers	ion: 01	AUGUST 2015	
A.	BIODA	ГА							
1.	Patient	initials:							
2.	Age:								
3.	Gender:	Male □	Femal	е 🗆					
4.	Marital	status: Married	Single	e 🗆	Widowed	□ Di	vorced □	Not Indicated □	
5.	Employ	ment: E	Employed □	Self-en	ployed □ N	Not indic	ated □		
В.	PRESCI	RIBER INFORMA	ATION AT IN	ITIATIO!	N				
6.		Physician □				Me	edical Of	fficer Intern	
		Registered Clini	cal Officer	Clinic	al Officer Ir	ntern 🗆		Not Indicated	
C.	PATIEN	NT MEDICAL RE	CORD ON DI	[AGNOSI:	S				
7.		first diagnosis: □_				Not avai	lable		
		-							
	n not av	ailable, then whic	en earnest dat	e or visit	is available	in the iii	le?		
8.	Duratio	n of the disease: _							
0	Mathad	of Diognosis on t	oot domo on th	a indicate	ad applicated	oto of vi	ait.		
9.	Method	of Diagnosis or to	est done on u	ie maicaie	ed earnest d	ate of vi	sit:		
	HbA1c	□ FBG □ OG7	TT □ RBS □	None i					
10	. Anti-dia	betes drug therap	y initiated or	or put or	n at that ear	liest indi	cated da	te of visit:	
			-						
			_						
11.	. Other pa	arameters measure	ed at initiation	n or at tha	t earliest in	dicated o	late of v	isit :	
	I.	Blood pressure le	vels		YES 🗆 🗎	NO 🗆			
	II.	Cholesterol levels	S		YES 🗆 N	1O 🗆			
	III.	Weight			YES □ N	IO 🗆			
	IV.	Body Mass Index			YES □ N	1O 🗆			

D. PATIENT MEASUREMENTS OF TREATMENT TARGETS MONITORED ON EVERY FOLLOW-UP VISIT AT THE FACILITY DURING THE 6 MONTHS OF THE STUDY PERIOD

12.	Blood glucose levels: HbA1c □ FBG □ OGTT □ RBS □	None []	
	Measurement value:			
	Mean value:			
13.	Blood Pressure levels : YES \Box	NO □		
	Measurement value:			
	Mean value:			
14.	Cholesterol levels : Measurement value:	YES 🗆		
	Mean value:			
15.	Weight (kgs): Measurement value:	YES 🗆		
	Mean value:			
16.	Body Mass Index : Measurement value:	YES 🗆		·
	Mean value:			
Е.	Anti-diabetic Drug therapy as at the e	end study	y period (June 2	2015)
F.	Complications associated with Diabete	es, ident	ified since the t	ime of diagnosis of the
	condition to the time of the study period	od.		
17.	Retinopathy/Eye problems		YES □	NO □
18.	Neuropathy/Nerve problems		YES □	NO □
	Nephropathy/Kidney problems		YES □	NO □
	Foot ulcers		YES □	NO □
21.	Amputation		YES □	NO □
	High Blood Pressure/Hypertension		YES □	NO □

APPENDIX 2: INFORMED CONSENT PROCESS INFORMATION AND CONSENT FORM

Serial Number Version: 01 March 2015

STUDY TITLE: MANAGEMENT OF TYPE 2 DIABETIC PATIENTS AS PER PROTOCOLS AND ASSESMENT OF PATIENTS' OPINIONS ON PRACTICES WITH REGARD TO TAKING RESPONSIBILITY AT VIHIGA COUNTY REFERRAL HOSPITAL

A. CONSENT EXPLANATION INFROMATION

(for face to face Interview with adult type 2 diabetic patients)

Title of Study: Management of type 2 diabetic patients as per protocols and assessment of patients' opinions, practices on responsibility at Vihiga County Referral Hospital

Institution: Department of Pharmacology and Pharmacognosy, School of Pharmacy, University of Nairobi, P.O. BOX 30197-00400, Nairobi.

Investigator: Dr. Kaitany Benjamin, P.O. Box 5603-00506, Nairobi. Mobile +254 710339864

Supervisors: E.M. Guantai, Dr. M.N. Mulaku and Dr. B. Amugune. School of Pharmacy, University of Nairobi

Ethics Approval: Kenyatta National Hospital/ University of Nairobi Ethical Research Committee, P.O.BOX 20723-00100, Nairobi. Tel 2726300 / 2716450 Ext 44102.

Permission is requested from you to consider enrolling in this medical research as part of my degree; Master of Pharmacy in Pharmacoepidemiology and Pharmacovigilance work. You should understand the following general principles, which apply to all participants in a medical research:

- i. Your agreement to participate in this study is voluntary.
- ii. You may withdraw from the study at any time without necessarily giving a reason for your withdrawal.
- iii. After you have read the explanation, please feel free to ask any questions that will enable you to understand clearly the nature of the study.
- iv. The interview is anticipated to last 20-30 minutes.

Introduction: In this study, I am assessing the management of type 2 diabetic patients at Vihiga County Referral Hospital as per some official protocols and exploring patients' opinions on practices regarding their responsibilities.

Purpose of the study: The purpose of this study is to determine the proportions of type 2 diabetic patients at Vihiga County Referral Hospital treated as per some official protocols and exploring patients' opinions on practices regarding their responsibilities. You have been approached to participate because you have type 2 diabetes and have been managed at this hospital.

Procedure: With your permission I will engage you in a discussion about your opinions on practices regarding your responsibility to manage this condition through healthy eating, physical activity, self-monitoring of blood glucose and drug compliance. I will take notes of the discussion by pen and paper. All information will be handled with confidentiality.

Risks: This is a minimal risk study and there will be no physical or otherwise harm to you during the study. However, there may be some psychological and emotional risk associated with information disclosure by you during the interview. This will be minimized or completely eradicated by the investigator upholding effective confidentiality strategies. Only the principal investigator will handle the primary data that may have some elements of your direct identifiers. However no information collected will bear your name in it. Any other research assistants involved in data entry and analysis will handle the secondary data that will be delinked from the primary data.

Benefits: There will be no financial incentives or other direct benefits to you. However, the study findings may be useful later in improving the quality of care provided to type 2 diabetes patients, through clinician compliance to treatment guidelines in diagnosis, management and monitoring of such patients.

Assurance of confidentiality: All information obtained from you will be kept in confidence. At no point will your name be mentioned or used during data handling or in any resulting publications. Codes will be used instead. Your hospital number will be removed from the primary data we collect but codes used instead. The data will be stored under lock and key accessed only by the principal investigator. The electronic records will be password protected.

Contacts: In case you need to contact me or the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee that has given ethical approval to this study

regarding your rights as a participant in this study please feel free to use the contacts provided on the consent form.

B. PARTICIPANT CONSENT FORM

I, the undersigned willingly agree to participate in the study. I have been explained and understood the nature of the study, my responsibilities as a study participant, the inconveniences associated with voluntary participation in the study and that all my questions and concerns relating to the study have been answered satisfactorily. I understand that I may choose to leave the study at any time and will not be penalized or prejudiced in any way. I understand that the information gathered will be used for the purpose of this study only and maximum confidentiality will be maintained.

will receive a copy of this signed consent document to take away and keep.					
Name and signature of study participant	Date				
INVESTIGATOR DECLARATION					

I have explained the information in this document to this participant and encouraged them to ask questions which I took time to answer. I am satisfied that the participant adequately understands all aspects of the research as discussed in the consent process information document above.

Name and Signature of Person Obtaining Consent	
Date	

Contacts:

INVESTIGATOR: DR. KAITANY BENJAMIN, P.O. BOX 5603-00506, NAIROBI.MOBILE +254 710339864

SECRETARY, KENYATTA NATIONAL HOSPITAL/ UNIVERSITY OF NAIROBI ETHICAL RESEARCH COMMITTEE, P.O. BOX 20723-00100, NAIROBI. TEL 2726300 / 2716450 EXT 44102

APPENDIX 3: DATA COLLECTION FORM (QUESTIONNAIRE) FOR PATIENTS' DEMOGRAPHICS AND INFROMATION ON OPINIONS WITH REGARD TO PRACTICES ON SELF CARE BEHAVIOURS

Individ	ual Diabetes Question Sheet
Patient	initials Date
pattern	vide you with the best possible care, we need to know about your current eating s, medication, blood glucose testing, and your physical exercise. We need some formation about you and your diabetes.
1.	Are you (check one) Male Female
2.	Are you employed : Yes No
3.	Are you (check one) Married Single Widowed Divorced
4.	How old are you? years old
5.	Any family history of diabetes : Yes No
6.	How long have you had the disease :years
7.	Education level: primary Secondary College
8.	How much do you weigh? kgs
9.	What is your desired weight? What do you think would be a good, realistic weight for you?
A. Perc	eived Blood Glucose Control
1.	How satisfied are you with your overall blood glucose control
	I have excellent controlI have a few problemsI have pretty good controlI have poor controlI have good controlI have very poor control
2.	Do you have a target range for your blood glucose? That is, do you try to keep your blood sugar from getting lower or higher than certain values that you and your doctor or nurse have agreed on? Yes No Not sure
3.	Sometimes when you test your blood sugar, it can be too high. How often is this a problem for you?

	My blood sugar is never too high A couple times a month or less Once or twice a week	Three to five times a week Almost every day
4.	Sometimes blood sugar can be too lo reaction). How often is this a problem for	
	My blood sugar is never too low A couple times a month or less Once or twice a week	Three to five times a week Almost every day

B. Knowledge and Skills on diet

During the past 3 months, how often did you:

1. Use the information on the number of calories, carbohydrates or grams of fat in foods to decide what to eat?	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily
2. Intentionally miss a meal or snack to cut calories or fat?	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily
3. Intentionally take small amounts to cut calories, sugar or fat?	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily
4. Use sugar free or reduced sugar products?	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more a day
5. Resist the desire to eat a food you want because it is too high in fat, sugar, or calories?	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times

						daily
6. Use a written meal procedure to decide what foods to eat?	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily

C. Diet Barriers

During the past 3 months, how often have you had eating problems with each of the following?

1.When feeling stressed, anxious depressed, angry, or bored.	Never	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	2 to 3 times/month	1 or more times daily
2. Because of having hunger or food cravings.	Never	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	2 to 3 times/month	1 or more times daily
3. Because family or friends tempt you or are not very supportive of your efforts to eat right.	Never	2 to 3 times/month	1 to 2 times/week	4 to 6 times/week	2 to 3 times/month	1 or more times daily
4. When eating away from home (restaurants)	Never	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	2 to 3 times/month	1or more
5. Because you feel deprived due to trying to follow a diet.	Never	2 to 3 times/month	1 to 2 times/week	4 to 6 times/week	2 to 3 times/month	1 or more times daily
6. Because you	Never	2 to 3	1 to 2	4 to 6	2 to 3	1 or

feel discouraged due to lack of results (e.g.no weight loss, high blood sugars).		times/month	times/ week	times/week	times/month	more times daily
7. Because you are to busy with family, work, or other responsibilities.	Never	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	2 to 3 times/month	1 or more times daily

D. Use of Medicine

This section focuses on your use of medicines to treat diabetes.

1. Has your doctor prescribed tablets for your diabete	s?
Yes No	
2. How many times are you supposed to take these to	ablets?
I do not take tablets	Twice daily
often as needed	Three or more times daily
Once daily	
3. How many times do you end up taking these tablet	ts?
I do not take the tablets I miss	a dose three to five times weekly
I never miss a dose I miss a	a dose almost every day
I miss a dose a several times a month or less	I never take my prescribed pills
I miss a dose one or two times a week	
4. Has the doctor prescribed insulin injection for you	r diabetes?
Yes No	
5. How many times are you supposed to take insuling	n?
I do not take insulin	_ Twice a day
Often as needed	Three or more times a day

Once daily	
6. How many times do you end up taki	ng your insulin?
I haven't been prescribed for insulin	I never miss an injection
I miss three to five times weekly	I miss almost every day
I miss several times a month	I never take my prescribed insulin
I miss once or twice a week	

E. Medication Barriers

During the past 3 months, how often has each of the following caused a problem in taking your prescribed medicine?

1. Feeling stressed, anxious depressed, angry, or bored.	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily
2. The medication has unpleasant side effects.	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more a day
3. Family or friends are not very Supportive.	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/week	4 to 6 times/week	1 or more times daily
4. When away from home (e.g., on vacation, business trips, at restaurants, parties).	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/week	4 to 6 times/week	1 or more times daily
5. My daily program (waking, going to bed, eat, work, etc.) is different from one day to the other.	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily

6. Feel discouraged due to lack of results (e.g., no weight loss, high blood sugars).	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily
7. Too much occupied with family, work, or other responsibilities.	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily
8. The medicines are too costly	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily

F. Monitoring of blood glucose

The following questions have to do with testing your blood glucose

1. How many times have you been asked to test you	our blood glucose?
I have not been asked	Once a day
Often as needed	Twice a day
Several times a month	3 or 4 times a day
1 or 2 times a week	5 or more times a day
3 to 6 times a week	
2. How many times do you actually test your block	od glucose?
I have not been asked to test	Once a day
Often as needed	Twice a day
Several times a month	3 or 4 times a day
1 or 2 times a week	5 or more times a day
3 to 6 times a week	

Other comments:

G. Barriers to Blood Glucose Monitoring

In the past 3 months, how many times has each of the following caused a problem in testing blood glucose?

1. Feeling stressed, anxious depressed, angry, or bored.	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily
2. I hate to prick myself.	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily
3. Family or friends are not very supportive.	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily
4. When away from home (e.g., on vacation, business trips, at restaurants, relatives).	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily
5. My daily program (waking, going to bed, eat, work, etc.) is different from one day to the other.	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/week	4 to 6 times/week	1 or more times daily
6. Feel discouraged due to lack of results (e.g., no weight loss, high blood sugars).	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/week	4 to 6 times/week	1 or more times daily
7. Too much occupied with family, work, or other responsibilities.	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily

8. The testing supplies are too costly e,g glucometer	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily
Other comments:						
H. Physical Exercise						
The following questions	s are abo	ut your leve	el of physical ac	tivity.		
1. Has the doctor to	old you to	get more e	exercise?			
Yes	No		Don't know			
2. How active is yo of going to work, yard v	•					s a result
Very inactive			A moder	ate amour	nt of activity	
Inactive			Active			
A little activity	Very active					
3. How many time something physically ac in sports?	•				•	•
I never exercise			5	to 6 time	s a week	
A couple times a	month		C	nce a day	7	
1 or 2 times a we	ek		N	Nore than	once a day	
3 to 4 times a we	ek					
Other comments:						
I. Barriers to Exercisin	ng					
In the past 3 months, lof the following?		ny times ha	ve you had tro	uble exer	cising because	e of each
1. Feeling stressed, anxious depressed, angry, or bored.	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times

						daily
2. Exercise and physical activity cause pain and discomfort for me.	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily
3. Feeling that Family and friends are not very supportive.	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily
4. When away from home (e.g., on Vacation, business trips, at relatives).	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times daily
5. Felt discouraged because of lack of results (e.g., no weight loss, high blood sugars).	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/week	4 to 6 times/week	1 or more times daily
6. Too much occupied with family, work, or other responsibilities.	Never	1 time monthly or less	2 to 3 times/month	1 to 2 times/ week	4 to 6 times/week	1 or more times

APPENDIX 4: FOMU YAKUIDHINISHA UTARATIBU WA KUKUSANYA UJUMBE NA MAAFIKIANO

Nambari ya usajilimtindo:01	Tarehe: Machi, 2015
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MADA YA UTAFITI: UTHIBITISHAJI WA UGONJWA WA KISUKARI AINA YA PILI KULINGANA NA UTARATIBU NA TATHMINI, MAONI NA MASUALA YA RUFAA YA KAUNTI YA VIHIGA.

A. Ujumbe wa kuidhinisha maelezo

(Kwa usaili wa ana kwa ana na mgonjwa wa ugonjwa wa kisukari aina ya pili)

Mada ya utafiti: kudhibiti wagonjwa wa kisukari aina ya pili kulingana na itafiki na tathmini ya wagonjwa, maoni na mazoezi kulingana na majukumu ya hospitali ya rufaa ya kaunti ya Vihiga.

Chuo: Idara ya famakolojia na famakognsia, chuo cha famasia behewa la Nairobi, SLP 30197-00400, Nairobi.

Mpelelezi: Dkt. E. Guantai, Dkt M N Mulaku- Idara ya Famasia na Famakognosia, Dkt Amugune – Famasia ya Kemia.

Idhinisho la kimaadili

Hospitali kuu ya Kenyatta/ Chuo Kikuu cha Nairobi, kamati ya utafiti, SLP 20723-00100 Nairobi. Simu 2726300 / 2716450 ext 4410. Tunakuomba ruhusu kwako ili ujisajili katika utafiti huu. Unafaa kuelewa mambo yafuatayo ya kimsingi yanayofaa kuzingatiwa na washiriki wote.

- i. Mwitikio wako wa kushiriki katika utafiti huu ni wa hiari.
- ii. Unaweza kujitoa kutoka kwa utaiti huu wakati wowote pasipo kuhitajika kutoa sababu za kujitoa.
- iii. Baada ya kufanya maelezo tafadhali, una uhuru wa kuuliza maswali yoyote yatakayokuwezesha kuelewa vizuri aina tofauti.
- iv. Usahili huu unakadiriwa kuchukua muda wa dakika 20-30.

Utangulizi: Katika utafiti huu, natathmini njia za kudhibiti wagonjwa wa kisukari aina ya pili kulingana na utaratibu na kukagua maoni ya wagonjwa na majukumu katika hospitali ya rufaa ya kaunti ya Vihiga.

Lengo la utafiti: Lengo la utafiti huu ni kujua kiwango cha wagonjwa wa kisukari aina ya pili kwa mujibu wa utaratibu na ukaguzi wa maoni ya wagonjwa kulingana na majukumu katika hospitali ya rufaa ya kaunti ya vihiga.

Utaratibu: Kwa ruhusa yako, nitakushirikisha katika mjadala kuhusu maoni yako kuhusu mazoezi, kujikagua mwenyewe kiwango cha sukari kwenye damu na matumizi yafaayo ya dawa. Nitaandika tutakayojadiliana kwa kalamu kwenye karatasi. Ujumbe wote itashughulikiwa kwa siri.

Hatari: Hakuna hatari yoyote kwa kuwa atakayeshirikiwa hataumizwa lakini kunaweza kuwa na adhari za kusaikolojia au adhari za kihisia zinazohusiana na ujumbe ambaye anayesaidiwa atatoa wakati wa usajili. Tutapunguza au kumaliza hisia hizi kabisa kwa kuuweka ujumbe gushi na anaweza kuorodhesha baadhi ya vipengee kumwezesha kubaini aliyetoa. Wasaidizi wake wowote watapata ujumbe na maelezo kutoka kwa msajili na ujumbe wenyewe hautakuwa na ushusiano wa moja na ule uliotolewa na aliyesajiliwa.

Umuhimu: Hakutakuwa pesa zozote zitakazotolewa ama faida ya moja kwa moja. Hata hivyo ,matokeo yatasaidia kuboresha utunzaji wa wagonjwa na aina ya pili ya kisukari kupitia utabibu utakaozingatia kutibu kulingana na utabuzi wa wagonjwa, udhibiti na uangalizi bora wa wagonjwa hawa.

Hakikisho la usiri: Ujumbe wote utakaochukuliwa kwako utahifadhiwa kama siri. Hakuna wakati jina lako litatajwa au litumike wakati wa kuwasilisha ujumbe au kuandika nakala ya ujumbe gushi. Nambari za siri zitatumika. Nambari za hospitali/wodi za wagonjwa zitaondolewa kutoka kwenye ujumbe gushi na nambari za siri zitumike kuwatambulisha. Ujumbe huo utafungwa na ufunguo utawekwa na ujumbe utafunguliwa tu na aliyeutafiti.

<u>Mawasiliano</u>: Iwapo ungetaka kuwasiliana nami, ama hospitali kuu ya Kenyatta chuo kikuu cha Nairobi maadili na kamati ambayo imeniruhusu kufanya utafiti huu, kuwa huru na utumie nambari za mawasiliano zilizoorodheshwa kwenye fomu hii.

FOMU YA IDHINI YA MSHIRIKI

Mimi niliyetia sahihi kwa hiari nakubali kushiriki utafiti huu. Nimeelezwa na kuelewa kinachohusiana na utafiti huu, majukumu yangu katika utafiti huu, athari zinazoweza kutokana na kujitolea kwangu na kuwa maswali yote yanayohusiana na utafiti huu nimeyajibu kama inavyotakikana. Naelewa kuwa naweza kuchagua kuacha kushiriki katika utafiti huu wakati wowote bila kupigwa penalti kwa njia yoyote. Naelewa kuwa ujumbe uliokusanywa utatumika kwa lengo la utafiti pekee na usiri wa hali ya juu utadumishwa. Nitapokea nakala ya fomu hii iliyotiwa sahihi.

utanti nuu wakati wowote ona kupigwa penaiti	kwa njia yoyote. Naciewa kuwa ujumbe
uliokusanywa utatumika kwa lengo la utafiti pel	kee na usiri wa hali ya juu utadumishwa.
Nitapokea nakala ya fomu hii iliyotiwa sahihi.	
Jina na sahihi ya mshiriki wa utafiti	tarehe
MIADI YA MTAFITI	
Nimeelewa kuwa ujumbe katika fomu hii kwa n	nshirika huyu na nimewatia wote moyo ili
kuuliza maswali ambayo nilichukua wakati kuya	ajibu. Nimetosheleza kila mshirika kabisa na
naelewa vipengee vyote vya utafiti kama ilivyot	elezwa katika fomu ya kudhibitisha ruhusa
hapo juu.	
Jina na sahihi ya anayeomba ruhusa	Tarehe
A CHI LA NIO	

MAWASILIANO

Mtafiti: Dkt. Kaitany Benjamin SLP 5603-00506, Nairobi. Simu +254 710 339 864 . Sekritari ,Hospitali kuu ya Kenyatta chuo kikuu cha Nairobi kamati ya maadili na utafiti, SLP 20723-00100

Nairobi simu 2726300-2716450 ext 44102.

APPENDIX 2: FOMU YA KUKUSANYA WUMBE(MASWALI)KUHUSU WAGONJWA WA KISUKARI MAONI NA MAZOEZO NA NJIA ZA KUJITUNZA

MASWALI YA KIBINAFSI KUHUSU UGONJWA WA KISUKARI.

Jina la	magonjwa kimkatotarehe
kujipii	tupa utunzaji bora, tunahitaji kujua kuhusu njia zako za hivi punde za kula, dawa ma kiwango cha glukosi katika damu na mazoezi ya misul.jibu kila swali kwa ukweli kabisa.tutatumia majibu yako kutatua shida unazozipata unapodhibiti ugonjwa wa ri .
<u>Tunal</u>	nitaji ujumbe wa kukuhusu wewe na ugonjwa wa kisukari
1.	(Chagua moja) Jinsia yakokiume Kike
2.	Umeajiriwala
3.	(chagua moja)umeolewa/umeoahujaoa/hujadewaumetalikiana
4.	Una umri gani?miaka
5.	Kuna historia ya ugonjwa wa kisukari katika familia yenu?ndiola
6.	Umekuwa na ugonjwa huu kwa muda gani? miaka
7.	Kiwango cha elimu:shule ya msingichuo cha upilichuo
	Una uzito gani? kilo
<i>7.</i>	Ungependelea kuwa na uzito gani? Ni uzito gani unadhani ni mzuri kwako na unakufaa?kilo Njia za kuaminika za kudhibiti za kudhibiti glukosi
1.	Umeridhikaje na kiwango cha glukosi katika damu?
	nimeshibiti kabisanina sjida chache
	nimejabibu sana nimedhabiti vobaya
	nimedhibiti kabisasijadhibiti kabisa
2.	Una lengo la kiwango cha glucose katika damu? Yaani, unajaribu kudhibiti kiwango cha sukari kisipande au kuteremka kuliko kinavyostahili kulingana na ushauri wa daktari? ndiolasina uhakika
	natonasina unakika
3.	Wakati mwingine unapopima kiwango cha sukari kwenye damu, kinaweza kuwa cha juu sana. Hufanyika mara ngapi kwako? kiwango cha sukari katika damu huwa hakipandi sanamara kadhaa kwa mwezi au chini yakemara moja au mbili kwa wiki
	mara tatu hadi tano kwa wiki
	takribani kila siku
4.	Wakati mwingine kwango cha sukari kwenye damu huwa kiko chini sana, hii hutokea

mara ngapi kwako?

 Kiwango changu cha sukari kwenye damu huwa hakiteremki sana
 Mara kadhaa kwa mwezi au mara chache kwa mwezi
 Mara moja au mbili
 _Mara tatu hadi tano kwa wiki
 Takribani Kila siku

B. Maarifa na Ujunzi Kuhusu chakula

Kwa muda wa miezi mitatu iliyopita, ni mara ngapi ulifanya yafuatayo?

1. Utafuata maelezo kuhusu idadi ya viungo, gramu za mafuta ili kutoa uamuzi wa chakula utakacho kila?	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
2. Ulikosa kula kwa hiari (kupenda kwako) chakula ili kupunguza mafuta mwilini?	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
3. Ulikula chakula kidogo kwa hiari ili kupunguza kiwango cha sukari au mafuta?	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
4. Ulitumia vyakula viungo na sukari au vyenye sukari kidogo?	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
5. Ulikwepa jaribio la kula chakula ukipendacho kwa sababu kuna mafuta mengi au sukari nyingi au viungo	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa	Mara nne hadi sita kwa	Mara moja au zaidi kwa

vingi?				wiki.	wiki	siku
6. Unatumia menu au mpangilio wa chakula kabla ya kuamua chakula utakachokula?	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku

C. Vizuizi Vya Chakula Kifaacho

Katika kipindi cha miezi mitatu iliyopita, ni mara ngapi ulikuwa na shida hizi?

1. Shida za kula kutokana na mawazo mengi, kutotulia kiakuli, ama hasira.	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
2. Shida za kula kwa sababu ya njaa au kupenda chakula Fulani zaidi.	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
3. Shida za kula kwa sababu ya familia, au marafiki ambao hawakuungi mkono katika juhudi za chakula kifaacho.	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
4. Shida za kula kwa kuwa hauli nyumbani (hotelini, mikahawaini au shereheni).	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
5. Shida za kula kwa kuhisi kunyanyasika kwa kujaribu kufuata maagizo.	Hakuna	Mara moja kwa mwezi au chini ya mara moja	Mara mbili hadi tatu kwa	Mara moja au mbili	Mara nne hadi sita	Mara moja au zaidi

		kwa wiki.	mwezi.	kwa wiki.	kwa wiki	kwa siku
6. Shida za kula kwa sababu unahisi kuvunjwa moyo kwa kukosa matokeo bora (Kukosa kupunguza uzito, kwango cha juu cha sukari.	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
7. Shida za kula kwa kuwa na shughuli nyingi za familia, kikazi au majukumu.	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku

D. Matumizi ya Dawa:

Sehemu hii inahusiana na matumizi ya matibabu ya ugonjwa wa kisukari.

7.	Daktari wako amekushauri utumie tembe za ugonjwa wa kisukari?
	Ndio La
8.	Unafaa kumeza tembe hizi mara ngapi?
	Huwa simezi tembe hizi Mara Mbili kwa siku
	Mara tu ninapohitajika kumeza Mara tatu au zaidi kwa siku
	Mara Moja kwa siku
9.	Ni mara ngapi unajipata ukitumia tembe hizi?
	Huwa simezi tembe hizi kabisa
	Huwa sikosi dozi
	Nakosa dozi mara kadhaa kwa mwezi au chini ya mwezi
	Huwa nakosa dozi mara moja au mbili kwa siku
	Nakosa dozi mara tatu hadi tano kwa wiki
	Nakosa dozi takribani kila siku.

10.	Je, daktari amekushauri kutumia insulin kudhibiti sukari ya damu?
	Ndio La
11.	Unafaa kutumia insulin mara ngapi?
	Huwa situmii insulini Mara mbili kwa siku
	Mara kadhaa inavyohitajika Mara tatu au zaidi kwa siku
	Mara moja kwa siku
12.	Ni mara ngapi unajipata ukitumia insulin?
	Sijashauriwa kutumia insulin kudhibiti kiwango cha sukari kwenye damu
	Nakosa mara tatu hadi tano kwa wiki
	Nakosa mara kadhaa kwa mwezi
	Nakosa mara moja au mbili kwa wiki
	Nakosa takribani kila siku
	Huwa sikosi kama nilivyolekezwa kutumia

E. Vizuizi Vya Matibabu

Muda wa miezi mitatu iliyopita, ni mara ngai umekuwa na shida zifuatazo na kuadhiri matumizi ya dawa ulizolezewa?

Mawazo mengi au hasira	Hakuna	Mara moja au chini ya mara moja kwa mwezi	Mara moja au mbili kwa mwezi	Mara moja au mbili kwa wiki	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku.
2. Dawa zenyewe zina athari zisizonivutia.	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
3. Familia na marafiki hawaniungi mkono.	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa	Mara nne hadi sita kwa	Mara moja au zaidi kwa

T		•				
				wiki.	wiki	siku
4. Nikiwa siko nyumbani (aidha likizo, ziara za kibiashara, hotelini au shereheni).	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
5. Mpangilio wa kazi yangu za kila siku. (Kutembea, kwenda kulala, kula ni tofauti kila siku).	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
6. Navunjwa moyo kwa kukosa matokeo bora ninayotarajia (kukosa kupoteza uzito, kiwango cha juu cha sukari kwenye damu).	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
7. Kuwa na shughuli nyingi za familia, kikazi na majukumu mengineo.	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
8. Dawa zingine ni ghali/bei yake iko juu	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku

F. Kudhibiti Kiwango cha Glukosi Kwenye Damu

Maswali machache yafuatayo yanahusu kupima kiwango cha glukosi katika damu.

3.	Umeshauriwa upime kiwango cha gl	ukosi kwenye damu mara ngapi?
	Sijaambiwa nipime kwango cha g	lukosi kwenye damu
	Mara kwa mara inavyohitajika	Mara kadhaa kwa mwezi

	Mara moja au mbili kwa wiki	Mara tatu hadi sita kwa wiki
	Mara moja kwa siku	Mara mbili kwa siku
	Mara tatu hadi nne kwa siku	Mara tano au zaidi kwa siku
4.	Kwa hakika, unapima kiwango chako cha gli	ukosi katiaka damu mara ngapi?
	Sijaambiwa nipime kiwango cha gluko inavyohitajika	
	Mara moja au mbili kwa wiki	Mara Kadhaa kwa mwezi
	Mara tatu hadi sita kwa wiki	Mara moja kwa siku
	Mara mbili kwa siku	Mara tatu au nne kwa siku
	Mara tano au zaidi kwa siku	

G. Vizuizi unapodhibiti kwango cha Glukosi Katika Damu

Kwa miezi mitatu iliyopita, in mara ngapi shida zifuatazo zimeadhiri upimaji wa kusango cha glukosi kwenye mwili?

1. Mawazo mengi, wasiwasi, hasira, kukinai.	Hakuna	Mara moja au chini ya mara moja kwa mwezi	Mara mbili hadi tatu kwa mwezi	Mara moja hadi mbili kwa wiki	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
2. Naogopa kujiumiza kwa kujidunga sindano.	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
3. Familia na marafiki hawaniungi mkono.	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
4. Nikiwa siko nyumbani (likizo, ziara	Hakuna	Mara moja kwa mwezi	Mara mbili	Mara moja au	Mara nne	Mara moja

za kikazi, hotelini au na jamaa).		au chini ya mara moja kwa wiki.	hadi tatu kwa mwezi.	mbili kwa wiki.	hadi sita kwa wiki	au zaidi kwa siku
5. Ratiba ya shughuli za kila siku (kutembea, kwenda kulala, kula, kazi na kadhalika).	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
6. Huwa navunjwa moyo na kukosa matokeo bora (sipunguzi uzani, kiwango cha juu cha sukari kwenye damu).	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
7. Kuwa na shughuli nyingi za kifamilia, kikazi na majukumu mengine).	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
8. Vifaa vya kujipima ni ghali (kama glukomita)	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku

H. Mazoezi Ya Mwili

Maswali matano yafuatayo yanahusu kiasi cha mazoezi ya viungo.

1.	Daktari wako amekushauri kufanya mazoezi zaidi?					
	Ndio	La	Sijui			
2. katika	. Shughuli zako za kila siku zinahusisha mazoezi? Ni kiasi gani cha mazoezi unapatika kwenda kazini, kwenda shambani na kazi nyingine za kila siku?					
	Hakuna m	azoezi kabis	sa Hakuna mazoezi			

Mazoezi Machache	Mazoezi kiasi
Kuna mazoezi	Mazoezi mengi
3. Umetenga kiasi gani cha wakati cha k mara ngapi kama kutembea, kukimbia, kuend mazoezi ama kushiriki michezo?	tufanya mazoezi? Unafanya mazoezi ya viungo lesha baiskeli, kwenda katika vyumba vya
Sifanyi mazoezi kamwe	Mara kadhaa kwa mwezi
Mara moja au mbili kwa wiki	Mara tatu hadi nne kwa wiki
Mara tano hadi sita kwa wiki	Mara moja kwa siku
Zaidi ya mara moja kwa wiki	

I. Exercise Barriers

Maoni Mengine:

Kwa kipindi cha miezi mitatu iliyopita, ni mara ngapi umepata shida ya kufanya mazoezi kwa sababu ya mambo haya?

1. Kuwa na mawazo mengi, wasiwasi, hasira au kukinai.	Hakuna	Mara moja au chini ya mara moja kwa mwezi	Mara mbili hadi tatu kwa mwezi	Mara moja hadi mbili kwa wiki	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
2. Mazoezi ya kunyosha viungo yanasabibisha uchungu na kutotulia.	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
3. Familia na marafiki hawaniungu mkono.	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
4. Iwapo hauko nyumbani (mfano likizo, ziara ya kibiashara, kwa	Hakuna	Mara moja kwa mwezi au	Mara mbili hadi tatu	Mara moja au	Mara nne hadi	Mara moja au

jamaa).		chini ya mara moja kwa wiki.	kwa mwezi.	mbili kwa wiki.	sita kwa wiki	zaidi kwa siku
5. Unavunjwa moyo na kukosa matokeo bora (mfano kukosa kupoteza uzito kiwango cha juu cha sukari kwenye damu).	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku
6. Umeshikika sana na familia kazi au majukumu mengine.	Hakuna	Mara moja kwa mwezi au chini ya mara moja kwa wiki.	Mara mbili hadi tatu kwa mwezi.	Mara moja au mbili kwa wiki.	Mara nne hadi sita kwa wiki	Mara moja au zaidi kwa siku

APPENDIX 4: KNH-UON ERC APPROVAL LETTER



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Ref: KNH-ERC/A/1



KNH-UON ERC

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Fax: 725272 Telegrams: MEDSUP, Nairobi

6th January 2016

Kaitany Benjamin Kiplagat Reg. U51/75336/2014 Dept.of Pharmacology and Pharmacognosy School of Pharmacy College of Health Sciences University of Nairobi

Dear Benjamin

Revised research proposal: Management of Type 2 Diabetic patients at Vihiga County Referral Hospital: Compliance with Guidelines and the role of patients (P641/10/2015)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and <u>approved</u> your above proposal. The approval periods are 6th January 2016 -5th January 2017.

This approval is subject to compliance with the following requirements:

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

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

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