ASSESSEMENT OF THE LEVEL OF KNOWLEDGE, SELF CARE PRACTICE AND GLYCEMIC CONTROL AMONG PATIENTS WITH TYPE 2 DIABETES ATTENDING THE DIABETES CLINIC AT KENYATTA NATIONAL HOSPITAL.

TO BE SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE IN INTERNAL MEDICINE OF THE UNIVERSITY OF NAIROBI.

DECLARATION

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

I will be thankful to the Almighty God always for through Him all things are possible.

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This book is dedicated to all the patients who have dared to hope in spite of adversity.

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LIST OF ABBREVIATIONS

ADA- American Diabetes Association

DASH – Diet Against Stopping Hypertension

DM- Diabetes Mellitus

DSME- Diabetes Self Management Education

EASD- European Association for the Study of Diabetes

HbA1C- Glycated hemoglobin

KNH- Kenyatta National Hospital

SKILLD – Spoken Knowledge in Low Literacy in Diabetes Scale.

SDSCA – Summary of Diabetes Self care Activities Scale.

UKPDS - United Kingdom Prospective Diabetes Study

WHO - World Health Organization

ABSTRACT.

Background. Self care among patients with diabetes plays an integral role in achieving desirable outcomes. We sought to identify knowledge deficits and inadequacies in self care practices among patients with type 2diabetes. This may facilitate interventions that are specific to the patients' needs.

Objectives. To determine the level of knowledge on diabetes, self care practices and glycemic control among patients with type 2 diabetes.

Methods. This was a descriptive cross sectional study conducted at the diabetes outpatient clinic at Kenyatta National Hospital. A structured questionnaire was used to evaluate knowledge on diabetes and self care practices and blood samples were drawn to measure hemoglobin A1C.

Results. 171 patients were recruited. There was a female preponderance at 64%. The mean age was 59 years with a median duration of illness of 9 years. The level of knowledge was good with a mean of 5.8 out of 10; 77.2% of the patients scored more than 5 out of 10 on the SKILLD questionnaire. More than 40% of patients had knowledge deficits in identifying hypoglycemia, frequency and duration of physical activity and targets for glycemic control for hemoglobin A1C and fasting glucose. The self care practice was suboptimal; physical activity and self monitoring of blood glucose were practiced approximately 2.8 and 1.3 days in a week respectively. Only 29.5% of patients achieved a glycated hemoglobin equal to or less than 7%.

Conclusion. Patients demonstrated good knowledge of diabetes though with poor self care practice particularly in areas where they had significant knowledge deficits. There is need to emphasize practical diabetic skills and self care activities in diabetes self management education to enhance knowledge, facilitate problem solving and improve self care among patients.

1.0 INTRODUCTION;

1.1 Background

Diabetes mellitus is one of the most common non-communicable diseases globally. The burden of diabetes worldwide was approximated to be 366 million in 2011. In Kenya, the prevalence amongst the adult population was estimated at 4.2% in 2009 with a range of between 3 and 7% and showing a urban-rural variation(1). The global prevalence is estimated to rise to 9.9 % with the total number of patients with diabetes expected to rise to approximately 552 million by 2030(2).

The number of people with type 2 diabetes is increasing in every country. It constitutes about 85 to 95% of all diabetes in high-income countries and may account for an even higher percentage in low- and middle-income countries. It is now a common and serious global health problem, which, for most countries, has evolved in association with rapid cultural and social changes, ageing populations, increasing urbanization, dietary changes, reduced physical activity and other unhealthy lifestyle and behavioral patterns(3).

Type 2 diabetes in Kenya has been associated with significant morbidity. The population affected is mainly between 40 to 59 years of age and in the peak of their productive years. These patients develop complications as early as 2 years into their diagnosis(4). The burden of cardiovascular risks is high in this population(5). Diabetic foot ulcers and diabetic foot with peripheral vascular disease also contributes significantly to lower limb amputations(6). Diabetes is certainly one of the most challenging health problems in the 21st century.

1.2 Strategies for improving diabetes care

Diabetes is associated with a myriad of complications that are a major cause of disability, reduced quality of life and death. Since type 2 diabetes can remain asymptomatic for many years prior to detection, identification and screening of high risk groups with incorporation of lifestyle(7) and medical interventions(8,9) have been identified as ways of decreasing the rate of onset of the disease. Treatment of diabetes mellitus is based on the evidence that lowering blood glucose to as close to normal range as possible is a primary strategy for reducing or preventing complications or early mortality(10). Persons with diabetes also require management of their comorbidities and follow up with involvement of a multidisciplinary team designed to offer comprehensive care(11).

Diabetes self management education and ongoing support has been recognized as an integral part of care. Persons with no diabetes education have significant knowledge deficits for managing their disease and are more likely to develop complications(12). Individuals with diabetes have been shown to make a dramatic impact on the progression and development of their disease by actively participating in their own care(10).

Diabetes education is now formally being carried out in Kenya under the National Diabetes Program which was launched in 2009. This 6 year program is in partnership with the World Diabetes Foundation and the Ministry of Public Health and Sanitation to mainstream comprehensive diabetes care into the national health care delivery system. So far, 30

comprehensive care clinics have been launched and over a thousand health care professionals trained.

Studies done locally among patients with type 2 diabetes in Kenya have shown that there is poor glycemic control in this population and that they have many associated co morbidities and complications(4,5,13). The level of knowledge on diabetes in the community has been found to be low with less than half the population demonstrating good practices as far diabetes care is concerned(14). There are however no studies that have evaluated the level of diabetes knowledge or self care practices among patients with type 2 diabetes. This would be useful in establishing the demand for diabetes education and guide recommendations for making Diabetes Self Management Education an effective intervention to improve health outcomes.

2.0; LITERATURE REVIEW

2.1 Introduction

Although the importance of glycemic control is well established in various studies, it is often not realized among patients. The inability of patients to manage their diabetes has been attributed to their lack of compliance to prescribed medication regimens(15). This is because health care provision has traditionally been based on models designed to treat acute illnesses which have the health care provider at the centre of care; being the authority in diagnosis, treatment and patient outcomes. These models were not effective in diabetes care due to the chronic nature of this illness and the complexity of management(16,17). The approach to care among patients with diabetes like other chronic illnesses has shifted to a patient centered model that places the patient and his or her family at the center of care in collaboration with the health care providers(11). The role of professionals is to help patients make informed decisions to achieve their goals and overcome barriers through education, appropriate care recommendations, expert advice and support.

Diabetes is a complex disease that requires adoption of various skills and behaviours in order to manage the disease effectively. Knowledge of diabetes through a diabetes self management education program is aimed at enabling patients to understand the etiology and symptomatology of the disease, facilitating problem solving. Other goals of diabetes education are to provide necessary skills training and motivate patients to adapt positive lifestyle changes that help them cope with the disease. Patients are in charge of their self-management behaviors and the choices that they make each day as they care for diabetes have a greater impact on their outcomes than those made by health professionals(18).

2.2 Evaluating the level of knowledge among patients with type 2 diabetes.

The level of knowledge among patients with type 2 diabetes has been studied extensively in various regions and clinical settings. Al –Adsani et al(19) evaluated the level of diabetes knowledge and its determinants in 5114 Kuwaiti patients with type 2 diabetes in a primary care setting and found a mean score of 58.9%. This population had a high illiteracy rate at 45%. Knowledge deficits were present in questions relating to diet and self care. Shah et al in Saurashtra, Gujarat in India found nearly 50% of patients knew the pathophysiology and complications of diabetes(20). Padma et al found a high level of knowledge among 117 patients receiving care from a tertiary care hospital in India(21).

In Africa the data on the level of knowledge of diabetes amongst these patients is limited. Odili et al(22) evaluated the level of knowledge among 100 patients with diabetes; 96% having type 2 diabetes in a Nigerian city using the 14 item Diabetes Knowledge Test and found it to be low with a mean of 39% ± 16.7%. Patients demonstrated significant knowledge deficits in diet and self monitoring of blood glucose. The duration of disease awareness was the only factor that was significantly associated with the level of knowledge. Baumann et al(23) in Kampala, Uganda assessed the self care beliefs and practices among 340 patients with type 2 diabetes and found that less than 40% knew the signs and symptoms of hypoglycemia. In a South African primary care setting, Moodley et al(24) using the Modified Diabetes Knowledge Test found the African population to have significantly lower levels of diabetes knowledge with an average of 52.2.% compared to their Indian counterparts with an average of 75.9%.

Some of the factors that have been found to predict the level of knowledge include; the level of education, age(19,25), disease duration(25) and the level of income(19,26).

The level of literacy of patients exerts significant influence on the quality of diabetes care. Patients with low literacy skills encounter challenges in following physician instructions, reading and following prescribed medications(27). These patients have poor knowledge on diabetes self management(19) putting them at risk for worse health outcomes(26). Increased knowledge of diabetes has been associated with lower HbA1C(26,28) although majority of studies show a weak or no association(29–31).

2.3; Measuring self care behaviours in patients with type 2 diabetes

Self care is defined as the daily regimen of tasks that the individual performs to manage diabetes (32). The American Association of Diabetic Educators has identified 7 components of self care activities that comprise useful skills and knowledge among diabetic patients (33).

These self care practices include; healthy eating or medical nutrition therapy, regular physical exercise, daily self monitoring of blood glucose, adherence to taking medication, problem solving, reducing risks of complications of diabetes by cessation of smoking, having regular eye, foot and dental examinations and healthy coping with the disease. Healthy eating or medical nutrition therapy, physical exercise, self blood glucose monitoring and medication taking are the self care behaviors that have been widely studied as they impact directly on glycemic control.

2.3.1; Medical Nutrition Therapy

Medical Nutrition Therapy is an integral component of diabetes prevention, management and self management education. The recommendations from ADA are that it should be individualized and be carried out by a dietician who is familiar with components of therapy in order to achieve treatment goals(11). Due to the known effects of obesity on insulin resistance, weight loss is an important therapeutic intervention for overweight and obese individuals with pre diabetes or diabetes(34). Short term studies have shown that moderate weight loss of 5% of body weight in patients with type 2 diabetes is associated with a decrease in insulin resistance, improved measures of lipaemia, glycemia and reduced blood pressure(35). Monitoring carbohydrates by counting, estimation and appropriate choices is a key strategy in glycemic control(11). In the UKPDS, subjects received 3 months of intensive nutrition therapy before randomization that resulted in a 1.9% reduction in A1C and a mean 5 % weight loss(10). Other

recommendations include limiting saturated fats to < 7% of total calories. Evidence from the DASH study which advocates for increased consumption of fruit and vegetables(8-10 servings per day), low fat dairy products(2-3 servings per day), reducing sodium intake and limiting alcohol consumption to less than one serving in females and two in males can also substantially lower blood pressure (36). Hypertension is a common co morbidity among patients with diabetes.

2.3.2; Physical Activity

Exercise plays an important part in diabetes management. Regular exercise has been shown to improve blood glucose control, reduce cardiovascular risk factors, contribute to weight loss and improve well being. ADA recommends at least 150 minutes per week of moderate intensity aerobic physical activity that achieves 50 -70% of maximal heart rate. Structured exercise interventions of at least 8 weeks duration have been shown to lower A1C by an average of 0.66% in people with type 2 diabetes even with no significant change in Body Mass Index(37). Higher levels of exercise intensity are associated with greater improvements in A1C and fitness(38). There is additive benefit of combined aerobic and resistance exercise in adults with type 2 diabetes(39). Resistance exercise has been shown to be beneficial even in the older population with type 2 diabetes(40) and is also recommended 3 times per week in the absence of contraindications.

2.3.3; Self Monitoring of Blood Glucose

Self monitoring of blood glucose has proved to be essential among patients with diabetes as it allows them to evaluate their individual response to therapy and assess whether their glycemic targets are being achieved. It is also useful in preventing hypoglycemia and adjusting medications, postprandial insulin doses, medical nutrition therapy and physical exercise. The optimal frequency and timing of Self Blood Glucose Monitoring in patients with type 2 diabetes on non insulin therapy has remained controversial(41). Most studies have included several other self care activities like diet, exercise and education making it difficult to assess the contribution of Self Monitoring of Blood Glucose alone to glycemic control(42–44).

2.3.4; Taking Medication

The approach to management of hyperglycemia in patients with diabetes has been elucidated in a consensus statement by the ADA and EASD that has a combination of lifestyle interventions and antidiabetic medication(45). Pharmacologic therapy for type 2 diabetes can facilitate excellent control with the potential of normalization of A1C by insulin and a reduction of A1C by 0.5 to 2 % for oral antidiabetic medication (45). Despite the benefit of pharmacotherapy, adherence to medication has been found to be poor, ranging from 36 to 85 % to oral medication(46–48). Medication taking behavior has been well studied in patients with diabetes with verification of adherence to medication having been assessed through medication electronic systems(49,50) and patient questionnaires(26,51). Factors that have been found to adversely affect adherence to medication are complexity of regimens(52), medication side effects, severity of depression(53) and the patients' lack of belief in the immediate and future benefits of the medication prescribed. Insulin use presents unique challenges including education on use, follow up and monitoring, fear of needles and regimen complexity(54).

All patients with diabetes should be advised not to smoke due to the heightened risk of cardiovascular events, premature death and increased rate of micro vascular complications. Routine thorough assessment of tobacco use is an important way of preventing smoking and encouraging cessation. Clinical trials have demonstrated reduction of tobacco use in patients from cost effective methods like brief counseling(55).

Patients with diabetes should receive general foot care education and annual comprehensive foot examination to identify risk factors predictive of foot ulcers and amputations(11). A multidisciplinary approach is needed for those with high risk feet especially if they already have a history of previous ulcer or amputation. Optimization of glycemic and blood pressure control is essential in reducing and slowing down progression of retinopathy and nephropathy in these patients(10). Patients with type 2 diabetes should be screened for these complications at diagnosis and undergo follow up depending on the progression of disease.

Although randomized control trials have shown that lifestyle interventions improve glycemic control, translating these interventions into clinical practice and the daily lives of patients still remains a challenge. Patients are unsupervised outside of clinical trials. Assessment of self care behaviors in patients is difficult because of the complexities involved in trying to quantify the day to day activities of patients in a measurable manner. The diverse socio cultural environments in which patients live in also affect the certain self care behaviors like diet(56,57) and physical activity(23). Treatment regimens are also individualized; there is no specific unchanging standard against which these behaviors can be compared.

Few studies have evaluated self care practice among patients with type 2 diabetes in Africa. This is in a background where formal diabetes education is lacking(58) and the level of literacy in the population with type 2 diabetes is low. Ayele et al(59) in Ethiopia evaluated the self care behaviour of 343 patients in Harari of which patients with type 2 diabetes were 66.2%. Self care behavior was assessed using the Self Care Inventory Revised (SCIR) scale and found to be poor. Only 39.2 % of patients followed the recommended self care practices. Diet and medication taking were the most practiced self care behaviours by 57.7% and 78.4 % of patients respectively. Only 25.7 % exercised for 30 minutes per day and 42.3 % did not have a blood glucose measurement within 3 days prior to participating in the study. Baumann et al(23) in Kampala, Uganda showed that patients did believe that diabetes is a serious chronic illness that required practice of certain behaviors in order to manage the disease. However, self care behavior which was assessed using a modified version of the Diabetes Self Management Assessment Tool (DSMART) was found to be poor. Dietary measures were the most practiced self care practice with up to 88% of patients able to limit fatty foods. 38% of patients had a regular program of exercise. Only 15% of patients were able to monitor their blood glucose at home citing financial constraints in obtaining a glucometer but could have access to glucose monitoring at a nearby health facility. The most frequently identified self care goals were to exercise more and to make better food choices both at 23%. This therefore emphasizes the need to evaluate each population in order to make recommendations that are sensitive and relevant.

2.4; Association of glycemic control with the level of knowledge on diabetes and self care practice in patients with type 2 diabetes.

One of the techniques available for health providers and patients to assess the effectiveness of diabetes management on glycemic control is HbA1C. It is thought to reflect the average glycemia(60) over months and has a strong predictive value for diabetes complications(10,61). Lowering A1C to7 or below has been shown to reduce microvascular complications(61) and if implemented soon after diagnosis of diabetes is associated with long term reduction of macrovascular disease(10).

The proportion of patients with poor glycemic control as measured by A1C in Kenyan studies has been found to be high, a situation which is similar to what has been found in other countries(62,63). Factors associated with poor glycemic control are multifaceted, and involve patients, health care providers and health care systems(64).

Various studies have explored the interplay of these factors in order to identify those that can be positively influenced to improve outcomes. Diabetes Self Management Education is one such strategy that has been associated with improved diabetes knowledge, self care practices(65) and better outcomes such as lower A1C(66,67), lower self reported weight(65), improved quality of life(68,69), healthy coping(70) and lower costs of care(71).

Although knowledge on diabetes is aimed at improving self care practice which in turn should improve glycemic control, this has not been demonstrated in all studies. Bains et al(26) studied the association of health literacy, diabetes knowledge, self care practice and glycemic control in a low income population with type 2 diabetes in South Carolina, U.S.A. In the adjusted models

for the various parameters only health literacy was associated with the level of knowledge among the patients. Diabetes knowledge and perceived health status were the only independent factors significantly associated with glycemic control in this study.

Padma et al in India(21) who was evaluating the role of knowledge and self care in disease management among 117 patients with type 2 diabetes in a tertiary care centre found a high level of knowledge on diabetes. These patients demonstrated good practice of diet, physical activity and medication taking and these self care practices were significantly associated with good glycemic control which was a fasting blood glucose level less than 110mg/dl.

Ayele et al in Ethiopia(59) using a structured questionnaire found 93 % of patients to have both general knowledge on diabetes and specific knowledge on self care. However, only 39 % followed the recommended self care practices. This was attributed to high self perception of barriers to self care among these patients and a low self perceived severity of disease that may have prompted infrequent cues to action.

Exploring the association of knowledge and self care practice with glycemic control may be useful in establishing if there exists any unidentified barriers that may contribute to poor outcomes.

3.0 STUDY RATIONALE, RESEARCH QUESTIONS AND OBJECTIVES.

3.1 Study justification.

Type 2 Diabetes mellitus is a major public health concern associated with significant morbidity, and mortality. Diabetes education, which enhances knowledge on diabetes and good self care practices, has been associated with better glycemic control and quality of life

.

Studies in Kenyatta National Hospital have shown that glycemic control is poor in this population. There is no data on the level of knowledge and practice of self care behaviors among patients with type 2 diabetes at Kenyatta National Hospital. More than 90% of diabetes care is done by patients and this contribution to outcomes in diabetes is rarely quantified. This study will assist in identifying any deficits in knowledge and inadequacies in self care practices among these patients. This will enable clinicians to plan interventions that are specific to the patients' needs.

3.2 Broad objective

The main objective of this study was to evaluate the level of knowledge on diabetes and the self care practice of patients with type 2 diabetes attending the diabetes clinic at Kenyatta National Hospital. We also sought to determine the level of glycemic control among these patients and to determine association between the levels of knowledge and self care practice with glycemic control as measured by glycated hemoglobin.

3.3 Primary objectives

- 1. To determine the level of knowledge on diabetes among patients with type 2 diabetes attending the diabetes clinic at Kenyatta National Hospital.
- 2. To determine the self care practice among patients with type 2 diabetes attending the diabetes clinic at Kenyatta National Hospital.
- 3. To determine the level of glycemic control among patients with type 2 diabetes attending the diabetes clinic at Kenyatta National Hospital.

3.4 Secondary objective

1. To determine association of knowledge on diabetes and self care practice with glycemic control as measured by HbA1C.

4.0; METHODOLGY

4.1 Study design

This was a descriptive cross sectional study.

4.2 Study population and case selection

The study population was ambulatory patients on management for type 2 diabetes attending the diabetes outpatient clinic. A case was defined as a patient on management for type 2 diabetes who has at least 2 outpatient visits to the clinic within the previous 12 months to establish that he/she is a regular clinic patient.

The diagnosis of patients with type 2 diabetes was clinical and confirmed in the patients' files. It was based on WHO criteria; that is either RBS > 11.1 with symptoms or a FBS > 7.0 mmoles/l.

4.3 Inclusion criteria

Patients who were 18 years and above on management for type 2 diabetes.

Patients who gave consent.

Patients who were able to understand English or Kiswahili.

4.4 Exclusion criteria

Patients with a documented history of psychiatric illness, dementia.

Patients who were pregnant.

Patients with a documented history of haemochromatosis, acute or chronic pancreatitis, cystic fibrosis, pancreatic cancer, pheochromocytomas, acromegally and cushings syndrome.

Patients who had more than 3 months use of phenytoin, glucocorticoids and estrogens.

4.5 Sample size determination

The sample size was estimated based on the mean knowledge score on diabetes among diabetic patients in a Nigerian tertiary health care facility.

Using the formula:

$$n = \frac{Z_{1-\alpha/2}^2 \sigma^2}{d^2}$$

n – Sample size

 $Z_{1-\alpha/2}$ - Two-sided significance level (1-alpha) (95% CI) =1.96

 σ – Estimated standard deviation of mean knowledge score on diabetes among diabetic patients = 16.7% (Odili et al, 2011. Reference 22)

d – Precision error = 2.5%

n = 171

4.6 Sampling, screening and recruitment

Simple random sampling was used in selecting the cases from the diabetes outpatient clinics using a table of random numbers. Files of patients attending the clinics were retrieved daily on weekdays and allocated numbers and a list of numbers drawn. Every third file selected beginning from a random number one to three. These patients on arrival at the clinic were screened for case definition using their appointment cards. Identified cases were further screened for other eligibility criteria. Those who were eligible were recruited into the study.

The study content was introduced to the patients as they moved from registration, triage, laboratory, meeting the clinician to exit with minimal interference with the clinic activities.

4.7 Instrument

An investigator administered questionnaire was used that had 5 main parts;

The first section had screening questions that were asked to eligible patients in order to identify those who would be excluded from the study. The second part had demographic information which included age, sex, marital status, level of income and level of education. The clinical parameters included; duration of disease, treatment modality, BMI and A1C. The patients' weight and height were taken and body mass index calculated. The patients also had a HbA1C recorded if it was done within three months from the time of the study. If no recent HbA1C was available then a blood sample was taken for HbA1C measurement after completing the questionnaire.

The third part had questions adapted from The Spoken Knowledge in Low Literacy in Diabetes Scale. It has 10 primary open ended questions and secondary questions or prompts.

The fourth section had 11 questions adapted from The Summary of Diabetes Self Care Activities Scale. It is a 7 day recall questionnaire that was used to document the number of days in a week patients were able to practice self care behaviors. The fifth part had the 4 point Morisky Adherence scale. These are 4 yes/no response questions that were used to assess medication adherence.

4.8 Data collection

After obtaining consent data was collected through an investigator administered questionnaire in a face to face interview and analysis of blood samples for A1C as the main instruments. The language of the questionnaire was English but with Swahili translation for each question. In order to maintain consistency in the questions asked all the questionnaires were administered by

the principal investigator in the same manner. During administration of The Spoken Knowledge in Low Literacy Scale, a patient was read the primary question and given 10 to 15 seconds to respond. If the patient was unable to respond to the primary question, then the secondary questions were asked and another 10 to 15 seconds are allotted for patient response. The investigator gave full marks only for complete answers. All questions were weighted equally (maximum score =100%).

In the Summary of Diabetes Self Care Activities Score the patient's responses were filled as the frequency of each of the activities asked in a week. The scores had a range of 0-7days. The scoring scales were done for individual items on the questionnaire and a mean of the two questions asked on general diet, specific diet, physical activity, foot care and self monitoring of blood glucose documented. A 4 point morisky scale was used to assess for medication adherence and every 'yes' response scored1 point while a 'no' response scored no point.

Approximately 2 mls of blood sample was then drawn from a peripheral vein under aseptic conditions. The samples were collected in EDTA bottles and then dispatched to the laboratory within 5 hours on the same day. All the samples were analysed in a central laboratory (Lancet laboratory) by use of COBAS INTEGRA 400/800 analyzers. The analysis was based on turbidimetric inhibition immunoassay (TIMA) for hemolysed whole blood. Three quality control checks were done for this assay during the study period. The laboratory also undergoes external and internal quality control checks regularly.

4.8; Study variables

Independent variables

This included the following sociodemographic and clinical variables;

Age: This was determined to nearest number of years as the period from the reported or documented date of birth.

Sex: This was determined by the observed phenotypical sex, which is, observed secondary sexual characteristics of male or female sex.

Level of education: This was determined as the patient's report of the highest grade reached; primary, secondary or tertiary education.

Level of income: This was estimated as the annual combined family income before taxes from all sources.

Duration of disease: This was determined as the period in the nearest number of years from the reported or documented date of disease onset. The date of disease onset is the date when the patient learnt about the diagnosis for the first time or documentation of the date when the diagnosis was made for the first time.

Treatment modality: This was defined as the current pharmacotherapeutic and non pharmacotherapeutic modalities being employed by the patient to achieve glycemic control. 4 categories of treatment modalities were used; Oral antidiabetic agents, Insulin, Insulin and oral anti-diabetic agents and Diet only.

Outcome/dependent variables

Level of knowledge; This comprised of the patient's score from the Spoken Knowledge of Low Literacy in Diabetes Scale.

Self care behavior; This comprised of a score of the self care practices that was compiled from the Summary of Diabetes self Care Activities Questionnaire. Medication adherence score was obtained from the 4 point Morisky Medication Adherence scale.

Quality of glycemic control: This was determined by levels of A1C.

5.0 ETHICAL CONSIDERATIONS

This study was done after the approval of the proposal by the Department of Clinical Medicine and Therapeutics (U.O.N) and authorization by the KNH/U.O.N Scientific Research and Ethical Review Committee. Written consent was obtained from all patients participating in the study. The objective of the study was explained to the participants. The risks, benefits and the confidentiality issues were conveyed before consent to participate in the study was obtained. Participation in the study was voluntary and participants were encouraged to complete the study, however, they were free to withdraw without compromising their care in any way. Results from the biochemical analysis of collected blood samples were communicated to all participants and filed in the patients' records for interpretation and incorporation into the patients care by the primary care provider. Appropriate advice was given on diabetes knowledge and self care practice. No patient identifiers were used in the data entry and all data was kept confidential.

6.0 DATA MANAGEMENT AND STATISTICAL ANALYSIS

DATA PROCESSING

Data collected was preserved in a secure environment to avoid loss and breach of confidentiality. All collected data was cleaned, validated, coded, processed and stored at the end of each day by the principal investigator. Processing and storage was done both electronically by entering data into Microsoft Excel spreadsheet.

7.0 DATA ANALYSIS

The Statistical Packages for Social Scientists (SPSS) version 17.0 was used for analysis. Continuous variables such as age, duration of disease, self care practices and A1C levels were summarized into means, medians and standard deviation while categorical data such as sex, level of education, treatment modality and status of glycemic control was presented as proportions.

Age and A1C levels were entered as continuous data then categorized into age groups and status of glycemic control respectively. A1C was dichotomized into poor and good control. Levels 7% and below were categorized as good glycemic control whereas levels above 7% were categorized as poor glycemic control. The levels of knowledge were categorized into poor with scores below 50% and good as scores above 50%. The morisky adherence score was categorized; 0 points was interpreted as high adherence, 1-2 points as intermediate adherence and 3 -4 points as low adherence. Patients in the two categories of glycemic control were compared for any statistical difference in their levels of knowledge and self care practice using the student t test and multivariate analysis done to identify any independent factors associated with glycemic control. The level set for statistical significance was p≤0.05.

8.0 RESULTS.

This study was conducted in the months of January and February 2013 at the diabetes outpatient clinic in Kenyatta National Hospital. 599 files were screened, out of which 548 met the inclusion criteria.172 patients were randomly selected but one declined to consent to participate in the study. The 376 patients not recruited were similar to the study population in terms of age, sex, treatment modality and duration of illness.171 patients were recruited and had the questionnaire administered and blood samples taken for hemoglobin A1C. The response rate of the participants was 100%.

Figure 1; Flow chart on patients' screening and recruitment.

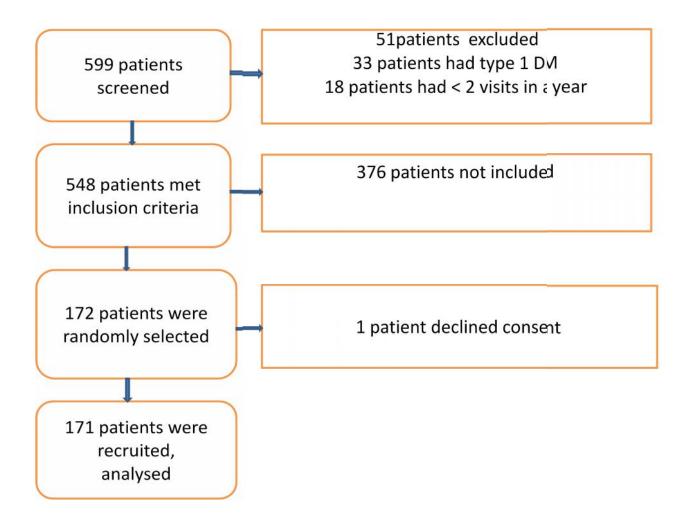


Table 1; Sociodemographic Characteristics of The Study Participants.

Variable	Frequency (%)
Gender	
Male	66 (38.6)
Female	105 (61.4)
Level of Formal Education	
None	12 (7.0)
Primary	75 (43.9)
High school	62 (36.3)
College	22 (12.9)
Marital status	
Unmarried	13 (7.6)
Married	121 (70.8)
Separated	6 (3.5)
Divorced	2 (1.2)
Widowed	29 (17.0)
Level of annual income(kshs)	
Less than 50,000	12 (7.0)
50,000 – 99,999	32 (18.7)
100,000 – 149,999	13 (7.6)
More than 150000	41 (24)
Dependent	73 (42.7)

Majority of the study participants were female at 61.4 %. The mean age of the participants was 59.8 with majority, 63.2% being between 50 to 70 years. Almost three quarters of the patients (70.8%) were married. The level of literacy in the study population was moderate with up to 43.9% of patients having attained a primary school education and 36.3 % having been educated to secondary level. The questionnaire had a Swahili translation and 73% of the participants preferred to have the questions asked in Swahili. Almost half of the patients at 42.7% did not engage in gainful economic activities and were dependent.

The median duration of illness among the patients included in the study was 9 years with majority of patients at 62.6 % having been known to have diabetes for less than 10 years. About 80 % of the patients were on oral antidiabetic agents with half this number on combination therapy with insulin. The average Body Mass Index of the study participants was in the overweight range at 27.7.

Glycemic control in these patients was poor. The average HbA1C was 8.4% with a minimum A1C of 5.4% and a maximum of 16.5%. Only 50 patients (29.2%) achieved target HbA1c of 7 % and below. Other clinical characteristics of the patients are depicted in the Tables 2 and 3.

Table 2; Clinical Characteristics of The Study Participants.

Variable	
Age(years)	
Mean (SD)	59.8(11.5)
Min – Max	30 - 87
Duration of illness(years)	
Mean(SD)	9.7(6.8)
Min – Max	1- 35
Median (IQR)	9.0(4.0-13.0)
BMI kg/m²	
Mean(SD)	27.7(4.8)
Min - Max	18.0 - 44.7
HbA1C(%)	
Mean (SD)	8.4(2.3)
Min – Max	5.4 – 16.5

Table 3; Clinical Characteristics of The Study Participants.

Variable	Frequency (%)
Duration of illness(years)	
1 - 10 years	107 (62.6)
11 - 20 years	52 (20.4)
21 years and above	12 (7.0)
Treatment modality	
Insulin only	35 (20.5)
Oral anti diabetic agents only	67 (39.2)
Oral antidiabetic agents and insulin	69 (40.4)
BMI(body mass index) Category	
Underweight(<18.5)	3 (1.8)
Normal(18.5 – 24.9)	48 (28.1)
Overweight(25 – 29.9)	80 (46.8)
Obesity(>30.0)	40 (23.4)
HbAIC Category	
7% and below	50 (29.2)
7.1 - 8.5%	50 (29.2)
8.5 - 10.0%	34 (19.9)
More than 10.0%	37 (21.6)

The level of knowledge on diabetes among the study population was high. The mean score on knowledge on diabetes was 5.8 with a range of 0 to 9 over 10. Above three quarter of the patients (77.2%) had a good score of more than 5 out of 10.

A large number of patients, 153(89.5 %) were able to give at least 2 signs and symptoms of hyperglycemia. The signs and symptoms that were most frequently mentioned were fatigue by 86% of patients, extreme thirst by 45%, frequent urination by 36% and drowsiness by 30%. A smaller proportion, 97 patients (56.7%) were able to describe signs and symptoms of hypoglycemia. A fifth of the patients reported not to know any sign or symptom of

hypoglycemia, 36% of the patients mentioned hunger and drowsiness and a quarter of the patients mentioned sweating. Majority of the patients, 154(90.1%) knew how to manage hypoglycemia.

One hundred and forty seven patients (86.0%) were able to give at least 2 chronic complications associated with uncontrolled diabetes. The frequently mentioned complications were blindness or impaired vision by 67% of patients, kidney disease by 46%, amputation by 38% and cardiovascular disease by 22%. Neuropathy and impotence were mentioned by less than 10% of the patients.

Most patients, 127 (74.3%) had the right knowledge on the frequency of self feet examination and 114(66.7%) knew why it was important to do so. Ninety patients (56.1%) were aware of the frequency and importance of eye examination in patients with diabetes. About a third of the patients, 64 (37.4%) knew the frequency and duration of physical activity in a week. Only 47(27.5%) knew the expected range of fasting glucose level and only 1 patient knew of the target hemoglobin A1C level among patients with diabetes.

Table 4; Knowledge As Assessed By The Spoken Knowledge In Low Literacy In Diabetes (SKILLD) Questionnaire.

Variable	Frequency (%)
Hyperglycemia signs and symptoms	
Correct response	153 (89.5)
Incorrect response	18 (10.5)
Hypoglycemia signs and symptoms	
Correct response	97 (56.7)
Incorrect response	74 (43.3)
Management of hypoglycemia	
Correct response	154 (90.1)
Incorrect response	17 (9.9)
Frequency of checking feet	
Correct response	127 (74.3)
Incorrect response	44 (25.7)
Why are feet exams important	
Correct response	114 (66.7)
Incorrect response	57 (33.3)
Frequency of eye exams and why	
Correct response	96 (56.1)
Incorrect response	75 (43.9)
Range of normal fasting blood sugar	
Correct response	47 (27.5)
Incorrect response	124 (72.5)
Normal HbA1c	
Correct response	1 (0.6)
Incorrect response	170 (99.4)
Frequency/duration of exercise	
Correct response	64 (37.4)
Incorrect response	107 (62.6)
Complications of diabetes	
Correct response	147 (86.0)
Incorrect response	24 (14.0)

The self care practice among the study population was less than optimal in the various domains that were assessed. Among the recommended self care behaviors, diet, medication taking and foot care were the most practiced while physical activity and self monitoring of blood glucose were the least practiced. The mean number of days in a week in which the patients maintained a general healthy diet and followed specific diet recommendations was 4.4 and 4.9 days respectively. Patients reported to have practiced foot care on an average of 4.4 days in a week.

Table 5; Self Care Practices As Assessed by The Summary Of Diabetes Self Care Activities

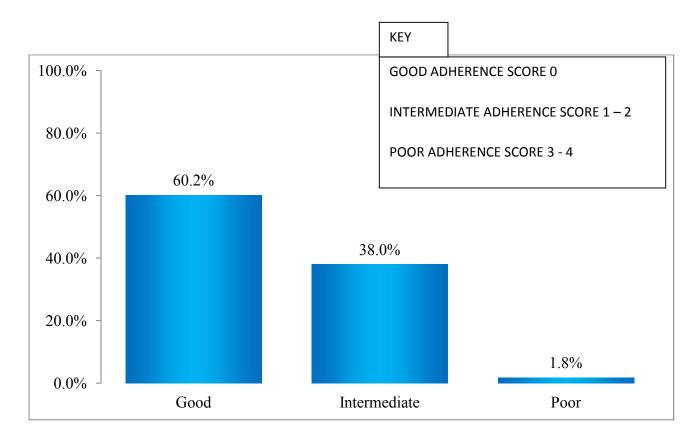
Questionnaire (SDSCA)

Variable	Mean (SD)
Number of days for general diet in a week	4.4 (1.2)
Number of days for specific diet in a week	4.9 (1.2)
Number of days for physical activity in a week	2.8(1.3)
Number of days for self monitoring of blood glucose in	1.3 (0.9)
a week	
Number of days for foot care in a week	4.4 (2.6)

The mean number of days in a week that patients reported to have engaged in moderate physical activity was 2.8 days. Eighty three percent of the patients did not engage in any physical activity outside of their daily routine. Patients reported to have monitored their blood glucose at an average of 1.3 days in a week. Only 21 patients (12.3%) had glucometers and could do self monitoring of blood glucose at home; majority had their blood glucose measurements done in a nearby facility. Eighty percent of the patients reported that their health care provider had recommended monitoring of blood sugar once in a month and less than 10% reported that they had been advised to check their blood sugar at least once a week.

Medication adherence was assessed using the modified morisky adherence scale with 103 patients (60.2 %)having good adherence,65(38 %)intermediate adherence and 3(1.8 %)having poor adherence as shown in the graph below.

Figure 2; Medication Adherence As Assessed By The Modified Morisky Medication Adherence Scale.



There was no difference in the self care behaviors based on gender and treatment modality.

The study participants were categorized into good glycemic control by HbA1C level of 7% and below and poor control being above 7%. Diabetes knowledge and self care practice was compared among patients with good and poor glycemic control using the student t test. The level of knowledge did not differ significantly in the two groups but in the self care practice diet, adherence to taking medication and physical activity showed a significant difference.

Table 6; Association of The Level of Knowledge and Self Care Practice With Glycemic Control.

Variable	HbA1c ≤7% (n=50)	HbA1c >7% (n=121)	P value
	Mean(SD)	Mean (SD)	
Mean knowledge score	5.4 (2.2)	6.0 (1.9)	0.069
Mean no of days for general diet in a week	5.0 (1.1)	4.2 (1.2)	< 0.001
Mean no of days for specific diet in a week	5.6 (1.0)	4.7 (1.2)	< 0.001
Mean no of days for physical activity in a week	3.5 (0.7)	2.5 (1.4)	< 0.001
Mean no of self monitoring of blood glucose in a week	1.2 (0.6)	1.4 (1.0)	0.445
Mean no of days for foot care in a week	4.4 (2.4)	4.4 (2.7)	0.874

Patients with good glycemic control had a higher mean number of days in a week in which they followed a recommended general diet of 5.1 days as compared to 4.2 in the group with poor glycemic control. Patients with good glycemic control had a higher mean number of days in a week in which they adhered to specific diet recommendations of 5.6 as compared to 4.7 in the group with poor glycemic control.

The mean number of days in which patients with good glycemic control engaged in moderate physical activity in a week was significantly higher than in the poor glycemic control group; 3.5 verses 2.5. The difference in general diet and exercise was independent of the duration of illness, body mass index, level of income and age as depicted in the table below.

Table 7; Association of Specific Self Care Behaviors With Glycemic Control After Multivariate Analysis.

Variable	Hb	A1c	P value		
	≤7%			Adjusted for	
	(n=50)	(n=121)		age, duration of illness,	
				BMI, income	
Mean no of days for general diet in a week(SD)	5.1 (1.1)	4.2 (1.2)	< 0.001	0.038	
Mean no of days for specific diet in a week(SD)	5.6 (0.9)	4.7 (1.2)	< 0.001	0.078	
Mean no of days for exercise in a week(SD)	3.5 (0.7)	2.5 (1.4)	< 0.001	0.001	

A higher proportion of patients with good glycemic control had good adherence to medication at 74% as assessed by the modified morisky scale compared to those with poor glycemic control at 54.5%. Patients with intermediate and poor adherence to medication had a twofold likelihood of poor glycemic control albeit a wide confidence interval. A larger sample size may give more clarity as to if this association between adherence to medication and glycemic control is present in this clinic study. The other self care practices assessed; self monitoring of blood glucose and foot care were not significantly different between the patients with good and poor glycemic control.

Table 8; Association of Medication Adherence With Glycemic Control.

Variable	HbA1c > 7%	HbA1c≤7%	OR (95% CI)	P value
Adherence to				
medication				
Good	68 (54.8%)	35 (74.5%)	1.0	
Intermediate/Poor	56 (45.2%)	12 (25.5%)	2.4 (1.1-5.1)	0.019

Each of the two categories of patients with good and poor glycemic control had a good mean score in the knowledge questionnaire of 5.4 in the group with good glycemic control and 6.0 in the group with poor glycemic control. The difference in the knowledge scores in the two categories was not statistically significant. Patients with good knowledge scores did not demonstrate better self care practices or glycemic control as compared to those with poor knowledge scores. In this study, age, gender, level of formal education, duration of illness and the mode of treatment were not significantly associated with the level of diabetes knowledge among patients.

9.0 DISCUSSION.

9.1 Introduction.

This study was an audit of the contribution of patients to their diabetes care by evaluating their diabetes knowledge and documenting their self care practices. Diabetes self management plays an integral role in the care of patients and is currently taught to patients through Diabetes Self Management Education. This program is available at the Kenyatta National Hospital and has been incorporated as part of routine patient care through face to face interviews and group sessions. Patients also get simple reading material that emphasizes key areas in self care. Other supportive care that is availed to patients includes nutrition counseling, foot and wound care. These services have been availed to patients attending the diabetes clinic at Kenyatta National Hospital for the past 11 years.

The socio demographic characteristics of the study population was similar to that of patients studied previously in the diabetes clinic at Kenyatta National Hospital (4,5,13). Majority of these patients were middle aged and female, which is reflection of the Diabetes Outpatient Clinic attendance. The reason as to the female preponderance is unclear, but has been postulated that females may have better health seeking behaviors.

9.2 The level of knowledge on diabetes as assessed by the SKILLD questionnaire.

The study participants demonstrated a high level of knowledge on diabetes with 77.2 % of the patients having a good knowledge score of more than 50 %. The mean knowledge score was $5.8(58\%\pm20\%)$ out of 10 with a range of 0-9. This may reflect on the quality of diabetes self care management education offered at this particular center. Odili et al assessed the level of knowledge amongst patients with diabetes using the Brief Diabetes Knowledge Test in a tertiary care setting in Nigeria and found it to be quite low at $39.5\%\pm16.7\%(22)$. In his study population only 56% of patients had undergone formal diabetes education unlike in our study where diabetes education is availed to all patients. The Diabetes Knowledge Test which was used has aspects of diabetes care that are impractical in our African setting for example calorie counting. It is worth noting that the tool used in our study had questions assessing practical diabetes knowledge and skills. Having a local language translation may have improved comprehension of the questions asked in this study population where majority had a primary level of education as three quarters of the patients preferred to answer in Swahili.

More than 85% of the study population was able to give two signs and symptoms of hyperglycemia and two long term complications of uncontrolled diabetes. Bauman and others in a similar study in Uganda also found that 87% of the patients reported that they were able to tell when their blood sugar is high (23). The long term complications of diabetes mentioned were blindness or impaired vision, kidney disease, amputation and cardiovascular disease. These complications are associated with significant morbidity and mortality and are likely to be remembered by patients. Erectile dysfunction was hardly mentioned probably because of the perceived social stigma of discussing sexual dysfunction in the African society.

Knowledge deficits were apparent in recognizing hypoglycemia as up to half of the patients were unable to give at least two signs and symptoms of hypoglycemia. However, 90 % of patients were knowledgeable on the management of hypoglycemia. A significant proportion of patients also gave similar and non specific signs and symptoms for both hyperglycemia and hypoglycemia; fatigue and drowsiness. This presents a significant challenge as about 60% of the patients were on an insulin based treatment regimen which predisposes patients to hypoglycemia and death if not correctly identified and managed. Baumann et al in Uganda also had similar findings in that majority of patients were unable to distinguish between these two acute complications of diabetes(23). Some of the reasons for this lack of distinction of these two complications of diabetes may be lack of emphasis on the symptomatology of hypoglycemia and hyperglycemia in diabetes self management education. Patients may also not understand the consequences of lack of recognition and management of these acute complications of diabetes.

There were significant knowledge deficits among the study subjects on targets for glycemic control. Ninety nine percent of these patients did not know the target hemoglobin A1C. Rothman et al in a similar study among patients with low literacy and income in North Carolina also found that only 8 % of patients were aware of targets for hemogobinA1C(28). This test is not routinely done among patients in our clinic as part of standard of care mainly due to financial constraints. About three quarters of the study population did not know the targets for fasting blood glucose. This may be partly due to the infrequent self blood glucose monitoring among patients.

Knowledge on risk reducing behaviors like foot care is one of the strategies that have been used to reduce onset of diabetic foot ulcers. Studies done previously among patients with diabetes at Kenyatta National hospital had shown a prevalence of diabetes foot ulcers of 4.6% and found neuropathy to be the common risk factor in the patients with diabetes ulcers at 78%(72). Although majority of patients in this study mentioned foot amputation as a long term complication of diabetes very few mentioned neuropathy. Thirty three percent of the study participants were unaware that neuropathy was a causative mechanism in foot ulceration. This underscores the importance of diabetes education in not only imparting knowledge on self care skills but also improving patients' understanding of their illness. This may assist in performance of self care behaviors.

9.3 Self Care Practices as Assessed by The SDSCA Questionnaire And The Modified Morisky Medication Adherence Scale.

Although the study participants had substantial knowledge on diabetes, there were significant gaps in their self care practices especially in the areas where they had knowledge deficits. Of the self care practices that influence glycemic control, diet and medication taking were highly observed. Ayele and others in Hanari, Eastern Ethiopia evaluating self care practices among patients with diabetes also had similar results(59). This may be due to perceived consequences of not taking medication and an appropriate diet among the patients being higher than in the other self care behaviors. Patients may also not understand how physical activity or self monitoring of blood glucose mitigate glycemic control.

The mean number of days per week for physical activity among the patients studied was 2.8 days which was lower than the recommended moderate activity of at least three times per week (11). More than half of the study population did not seem to know about the duration and frequency of physical activity. Patients reported typical activities of daily living as regular exercise and a very small proportion did additional activities purely for exercise. This may also be a reflection of the cultural norm where extra recreation in the form of jogging or running has not been embraced by our society. There is also a shortage of amenities to facilitate physical activity within most urban areas in Kenya.

Self monitoring of blood glucose was the least undertaken self care behavior with a mean of 1.3 days in a week. This is likely an over estimate of the frequency of self monitoring of blood glucose as majority of patients reported having their serum glucose measured at least once or twice a month on dates close to their clinic appointments. This may be partly due to clinical

inertia as patients reported that this is what was recommended by their health care providers. Financial limitations in affording to pay for frequent blood glucose readings and lack of accessibility to glucometers may also be potential reasons for infrequent self monitoring of blood glucose as only a minority owned glucometers and were able to do self monitoring of blood glucose at home.

9.4 Glycemic Control And Its Association With Diabetes Knowledge And self Care Practice.

The glycemic control in this population was relatively poor with 29.2 % achieving HbA1c of 7% and below. These figures have remained relatively unchanged in this clinic of study as studies done in patients with type 2 diabetes in Kenyatta National Hospital 10 years ago still depicted similar results(5,72). This is despite significant improvement in the provision of care to these patients. This highlights the challenges that exist in management of chronic illnesses like diabetes where achieving glycemic control requires a multifaceted approach that involves input from patients, health care providers and social support to achieve these targets.

Patients with good glycemic control were found to have better self care practice in the aspects of diet and physical activity. These findings emphasize the role of lifestyle interventions in improving glycemic control which has been demonstrated in various other studies (10,21,37). In this study patients with good diabetes knowledge did not have better self care practice than their counterparts with poor knowledge. Several other studies have shown no association between diabetes knowledge and self care and also knowledge with glycemic control(29–31). Indeed having diabetes knowledge alone is insufficient to produce behavioral changes required for effective self management and eventual glycemic control.

9.5 Limitations.

- 1. The patients selected into the study were on regular follow up and therefore likely to be highly motivated in acquiring knowledge on diabetes and practice of self care behaviors. These results may therefore not be a true reflection of the entire clinic attendance.
- 2. There also may have been recall bias during administration of the diabetes knowledge and the one week recall questionnaire on self care.
- 3. The self care behaviors of the study participants were based on self reports and performance of these behaviors was not observed and could not be confirmed.

9.6 Conclusion.

- 1. Achieving health outcomes in patients with diabetes still remains a challenge in this clinic study with only a third of patients achieving target glycemic control.
- 2. The patients demonstrated adequate knowledge on diabetes but with knowledge deficits in identifying hypoglycemia, frequency and duration of physical activity and targets for glycemic control in fasting blood glucose and hemoglobin A1C levels.
- 3. The self care practice of these patients was suboptimal particularly in areas where knowledge deficits were present. Physical activity and self monitoring of blood glucose were poorly practiced among the patients.

9.7 Recommendations

- 1. There is a need to revisit the Diabetes Self Management Education program in order to make it less didactic and more applicable by patients; especially in aspects of identification and management of acute complications of diabetes.
- 2. The importance of self monitoring of blood glucose and physical activity need emphasis in diabetes education.
- 3. There is also a need to develop policies that encourage health promotion from a public health aspect especially in providing an enabling environment for physical activity within urban and rural areas and also public awareness of the risks of sedentary lifestyle.
- 4. This study has also demonstrated that knowledge on diabetes alone does necessarily affect self care practice and glycemic control. Further studies are needed to identify what barriers to self care behavior exist in these patients in attempts to bridge the knowledge practice gap currently present.

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11.0 APPENDIX

Appendix 1; Study Explanation (English)

My name is Dr Omari Beatrice. I am a postgraduate student in the Department of Clinical Medicine and Therapeutics, University of Nairobi. I am conducting a study on knowledge on diabetes, self care practice and glycemic control among patients with type 2 diabetes at KNH.

What is the study about?

The study is aimed at identifying knowledge gaps in self care among patients with type 2 diabetes. The results will help the health care providers to tailor diabetes self management education according to the patients' needs.

What does the study involve?

It involves answering questions from a questionnaire and a blood test for hemoglobin A1C.

You are free to accept or decline to participate in the study. If you accept, a set of questions will be put forward to you followed by drawing of small amount of blood (i.e. 2 mls) from your forearm under hygienic precautions. There is a minimal risk of bleeding associated with this procedure especially in persons with a known blood clotting problem. This blood will be used to measure the level of hemoglobin A1C in your blood which is a measure of the state of your blood sugar over the past 3 months.

Will I benefit from the study?

Yes. The results of the blood test will be recorded in your file and appropriate advice will be offered in consultation with your primary care provider. Answers provided in the questionnaire will not be

disclosed to anybody, will remain confidential and will be used solely for the purpose of the study. Your personal details such as names and contact details will be separated from the questionnaire.

Are there any dangers involved?

There are no dangers involved.

Can I withdraw from the study?

You are free to withdraw from the study and this shall not compromise your care in any way.

Thank you for your co – operation.

In case you have questions related to this study, you can contact the following:

- 1. Dr. Omari Beatrice, Tel. 0731421 822, Department of Clinical Medicine and Therapeutics, University of Nairobi
- 2. Prof. C.F. Otieno, Department of Clinical Medicine and Therapeutics, University of Nairobi.
- 3. Chairman, Ethics and Research Committee, Kenyatta National Hospital.

KIAMBATISHO 1:MAELEZO

Jina langu ni Dkt. Omari Beatrice. Mimi ni mwanafunzi wa masomo ya kiwango cha juu katika kitengo cha 'clinical medicine and therapeutics', katika chuo kikuu cha Nairobi. Ninaendeleza utafiti wa kuchunguza kiwango cha ujuzi kuhusu jinsi ya kujichunga unapougua ugonjwa wa kisukari na jinsi kiwango cha sukari kilivyo mwilini.

Je, utafiti huu una lengo gani?

Lengo la utafiti huu ni kubainisha ukosefu wa ujuzi wa jinsi ya kujichunga unapougua ugonjwa wa kisukari. Matokeo ya utafiti huu utawawezesha wahudumu wa afya kuelewa jinsi ya kumsaidia mgonjwa ili aweze kujichunga vyema zaidi.

Je, utafiti huu unahusisha nini?

Utafiti huu unahusisha kujibu maswali kadhaa pamoja na upimaji wa damu kuthibitisha kiwango cha sukari kutumia kipimo cha hemoglobin A1C.

Uko na uhuru wa kukubali au kukataa kushiriki katika utafiti huu. Ukikubali kushiriki utaulizwa maswali kadhaa na kiwango kidogo cha damu, takriban mililita 2, kutolewa kutoka mkononi mwako kwa njia ya usafi unaostahili. Hakuna kipimo chengine chochote kitakachofanywa kwa damu hiyo.

Je, nitafaidika na utafiti huu?

Ndio. Utapata nasaha inayostahili kulingana na matokeo ya kipimo hicho na baada ya ushariano na mhudumu wako wa kila siku. Majibu utakayotoa kwa maswali utakayoulizwa yatabaki kuwa siri, hayatatobolewa kwa mtu yeyote na yatatumika kwa lengo la utafiti huu peke yake. Majibu yenye sifa ya ubinafsi kama majina na anwani yataekwa kando na majibu mengineo.

Je,kuna hatari inayohusika katika utafiti huu?

La. Hakuna hatari inayohusika.

Je, nitaruhusiwa kutoka katika utafiti huu?

Una uhuru wa kutoka kwenye utafiti huu na hakutaathiri kwa njia yeyote huduma unayopata kila siku. Asante kwa ushirikiano wako.

Kwa maelezo zaidi unaweza kuwasiliana na mmoja wa wanaofuata;

- 1. Dkt. Omari Beatrice, Tel. 0731 421 822, Department of Clinical Medicine and Therapeutics, University of Nairobi.
- 2. Prof. C.F. Otieno, Department of Clinical Medicine and Therapeutics, University of Nairobi.
- 3. Mwenyekiti, Ethics and Research Committee, Kenyatta National Hospital.

Appendix 2: Consent Form	
Study number	
Name	
Telephone number —	
I, above named, consent to participate in the study on known	owledge on diabetes, practise of self care
behaviours and glycemic control among patients with ty	ype 2 diabetes. I do this with the full
understanding of the purposes of the study and the proce	edures involved which include answering
questions and a blood test for AIC. The information pro	ovided shall be confidential. I have been
explained to the implications of this study. I also understand	nd that I can withdraw from the study any
time without my care being compromised. Having agree	eed on the above I voluntarily agree to
participate in this study.	
Cianatana/Thambanint of maticut	
Signature/ Thumbprint of patient Date	<u> </u>
Signature of witness Dat	e

Kiambatanisho 2; Fomu ya Ridhaa

Nambari ya utafiti	
Jina	
Nambari ya simu	
Mimi,niliyetajwa hapo juu naridhia (nakubali) kushir	iki katika utafiti wa ujuzi wa ugonjwa wa
kisukari, jinsi ya kujichunga na kiwango cha sukari ka	tika wanaougua ugonjwa wa kisukari katika
hospitali kuu ya Kenyatta'.	
Nakubali kushiriki nikifahamu malengo na taratibu za u	tafiti huu ikiwemo kujibu maswali na kipimo
cha damu cha A1C. Nimeelezwa lengo la utafiti huu na	hautanidhuru. Taarifa itakayotolewa itakuwa
siri. Ninafahamu ya kwamba naweza kujiondoa kut	oka utafiti huu wakati wowote bila kuathiri
huduma ninazopata. Baada ya kuelezwa haya yote,nin	akubali kwa hiari yangu kushiriki katika huu
utafiti.	
Sahihi au kidole cha mshiriki Tan	rehe
Sahihi ya shahidi Tareh	e

Aŗ	opendix 3; The Questionnaire
1.	Hospital Number (Nambari ya hospitali)
2.	Interview language (Lugha ya mahojiano)
3.	Telephone number where possible (Nambari ya simu ikiwezekana)
SE	ECTION 1; ELIGIBILITY (SCREENING QUESTIONS)
4.	Do you suffer from any of the following diseases in addition to diabetes? (Je, unaugua
	ugonjwa mwengine mbali na ugonjwa wa kisukari kati ya magonjwa yafuatayo? Sickle cell
	disease/ thelassemia/ hemochromatosis/ pancreatitis/ cystic fibrosis/ pancreatic cancer/
	pheochromocytoma/ acromegaly/ Cushing's syndrome.
	a. Yes (1)
	b. No (2)
5.	Have you been using the following drugs consistently in the last 3 months? (Je, umekuwa
	ukitumia dawa zifuatazo mfululizo kwa miezi mitatu iliyopita?) Phenytoin/ Steroids/
	Estrogens (such as oral contraceptives)
	a. Yes (1)
	b. No (2)
6.	(Ladies only) Are you pregnant? (Je, uko na mimba?)
	a. Yes (1)
	b. No (2)
7.	Has the consent been read and obtained?
	a. Yes (1)

b. No

(2)

(Stop the interview if the answer to question 4, 5 or 6 is YES or to 7 is NO).

SECTION 2; DEMOGRAPHIC CHARACTERISTICS

1. What is your gender? N	Male		Female		
2. What is your date of birth					
(siku ya kuzaliwa)	Day Mont	n rear			
3. What is the highest level of	of educatio	n you rece	ived?(kiwang	go cha juu zaidi	cha masomo
ulichofika ni kipi?)					
None at all(hakuna)					
Primary School(shule ya	a msingi)				
High School(shule ya up	ili)				
College(chuo kikuu)					
4. What is your marital statu	ıs?				
Single		Se _l	parated		
Married		Di	vorced		

Living as Married Widowed
5. What is your total combined family income for the past 12 months, before taxes, from all
sources, wages, public assistance/benefits, help from relatives, alimony, and so on?
If you don't know your exact income, please estimate.
(je,kiasi cha pesa ambazo mnapata nyumbani kama familia kwa jumla kabla ya kutozwa ushuru
ni ngapi? Jumuisha fedha kutoka mshahara,usaidizi wa jamaa na menginezo. Kama haujui kwa
hakika waweza kusema makadirio)
(Check one box)
a. Less than(chini ya) ksh5,000
b. Ksh5,000 - Ksh19,999.
c. Ksh20,000 - Ksh49,999
d. Ksh50,000 - Ksh99,999.
e. Ksh100,000 - Ksh149,999.
f. More than(zaidi ya) Ksh150,000
g. Don't know (sifahamu)
h.Chose not to answer (sitajibu
DISEASE AND TREATMENT CHARACTERISTICS
1. How many years has it been since you were diagnosed to have diabetes? (Umekuwa na
ugonjwa wa kisukari kwa miaka ngapi?)
2. Are you currently receiving any of the following treatments or advice for diabetes prescribed
by a health care worker? (Je, kwa wakati huu unapata matibabu au nasaha yeyote kati ya
yanayofuata kutoka kwa muuguzi kwa ajili ya ugonjwa wa kisukari?)

Tick in appropriate box(tia alama kwenye nafasi inayofaa)	
a.Insulin injections only (Sindano za insulin pekee)	
b. Oral anti-diabetic drugs only (Tembe za kisukari)	
c. Oral anti diabetic drugs and insulin injections (Tembe za kisukari pamoja na sindano	
za insulin)	
d.Diet only (lishe bora pekee)	
Height in meters;	
Weight in kilogrammes;———	
BMI;	
HBAIC;	
SECTION 3; The Spoken Knowledge in Low Literacy patients with Diabetes (Sk	(ILLD)
Scale;	
1. What are the signs and symptoms of High Sugar?	
How do you feel when your blood sugar is high or when you were diagnosed? Unah	hisi vipi
wakati kiwango cha sukari mwilini kiko juu,ulikuwa unahisi vipi ulipopatikana kuwa na u	ıgonjwa
wa sukari?	
Needs at least 2.	

Extreme thirst, frequent urination, drinking or eating, blurred vision and or drowsiness, fatigue.

2. What are the signs and symptoms of low sugar?

How do you feel when your blood sugar is too low? *Unahisi vipi wakati kiwango cha sukari mwilini kiko chini sana*?

Needs at least 2.

Hunger, nervousness, jitteriness, mood swings, irritability, confusion, sweaty, fast heart rate.

3. How do you treat low blood sugar? What should you do if your sugar is too low? How can you bring your sugar up if it's too low? *Ni nini unapaswa kufanya nini wakati kiwango cha sukari mwilini kiko chini ili kipande?*

Accept very general answer; juice, milk, hard candy, 15 g of carbohydrates.

4. How often should a person with diabetes check his or her feet? *Mtu anayeugua ugonjwa wa sukari anapaswa kuichunguza miguu yake mara ngapi? Mara moja kwa siku, mara moja kwa wiki au mara moja kwa mwezi?*

Once a day, once a week or once a month?

Accept daily.

5. Why are feet exams important in someone with diabetes? Why is it important to look at your feet? What are you looking for? *Ni kwa nini kuichunguza miguu ni muhimu kwa anayeugua ugonjwa wa sukari? Mtu huwa anatafuta nini?*

Accept very general answer; prevention of morbidity due to neuropathic/immunological consequences of diabetes.

6. How often should you see your eye doctor and why is this important? *Ni mara ngapi unafaa kumwona daktari wa macho, umuhimu wa kufanya hivyo ni nini?*

How often? Why?

Accept; seen at least yearly AND screen/manage retinopathy, glaucoma, blindness.

7. What is a normal fasting blood glucose or blood sugar? When you wake up in the morning and check your sugar before you eat or take medicine, what should it be? What 2 numbers?

Unapoamka asubuhi na kupima sukari kabla ya kula au kumeza dawa, huwa kiwango cha sukari chafaa kuwa vipi?

Accepted range; 70 to 120 mg/dl or 3.8 to 6.6 mmoles/l.

8. What is a normal HbA1C(haemoglobin A1C) or average blood sugar test?

When they draw blood from your arm and get an average blood sugar reading, what should it be? Unapotolewa damu mkononi na kupimwa ili kupata kiwango cha sukari kwa muda wa takriban miezi mitatu ,chafaa kuwa kiwango kipi?

Accept either normal<6 % or target < 7%.

9. How many times per week should someone with diabetes exercise and for how long? How many times a week? How long or how much per day?

Mtu anayeugua ugonjwa wa sukari anapaswa kufanya mazoezi mara ngapi kwa wiki? kwa muda upi kwa siku?

Accept within 3 -5 times a week for a total of 30 - 45 minutes each. Must include frequency.

10. What are some of the long term complications of uncontrolled diabetes? Do you know anyone that has diabetes and had bad things happen to them/ what are some of those bad things? Ni shida zipi za kiafya zinazompata mtu anayeugua ugonjwa wa sukari kwa muda mrefu? Needs at least 2.

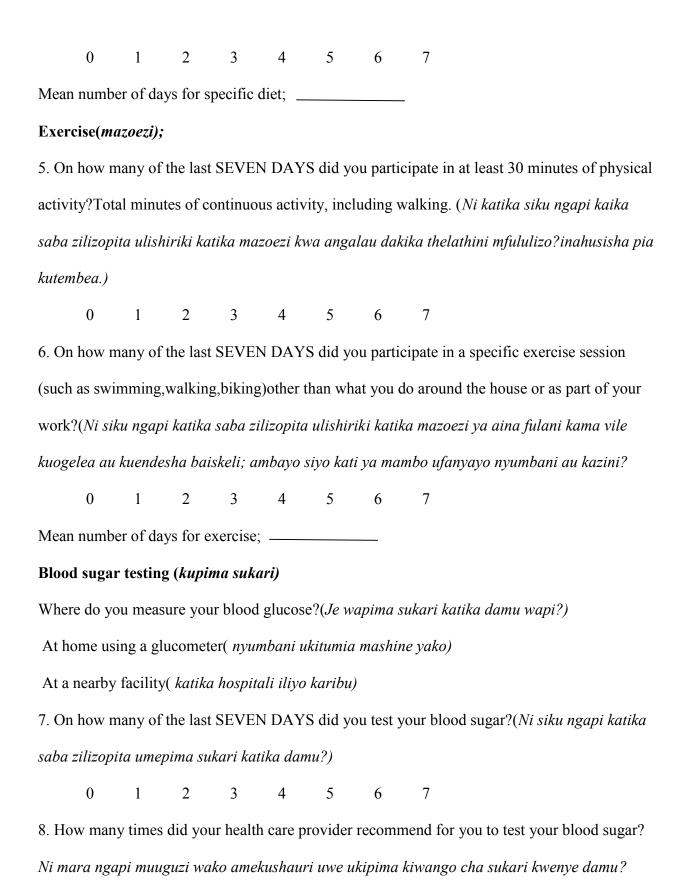
Blindness/impaired vision, kidney disease/dialysis, amputation, neuropathy, impotence, gastroparesis, cardiovascular disease.

SECTION 4; SELF CARE BEHAVIOURS.

The questions below ask you about your diabetes self care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick. (Maswali yanayofuata yanahusu jinsi unavyojitunza kulingana na ugonjwa wa kisukari katika siku saba zilizopita. Kama ulikuwa imeugua katika siku hizi saba zimepita,fikiria siku kabla ya kuugua.

siku sabo	a ziliz	opita. I	Kama ul	likuwa i	meugu	a katika	siku h	izi saba zimepita,fikiria siku kabla y
kuugua .								
Diet (lish	he)							
1. How n	nany	of the la	ast SEV	EN DA	YS hav	e you fo	ollowed	a healthful eating plan? (Ni siku
ngapi ka	tika s	aba zili	zopita u	mekula	lishe b	ora?)		
0		1	2	3	4	5	6	7
2. On ave	erage,	, over tł	ne past r	nonth,h	ow mai	ny DAY	S PER	WEEK have you followed your
eating pla	an?(k	atika m	wezi uli	opita ni	katika	siku ngo	api kwa	wiki uliweza kufuata mpango wako
wa kula?	")							
0		1	2	3	4	5	6	7
Mean nu	mber	of days	for gen	eral die	t; ——			
3. On ho	w ma	ny days	of the l	last SEV	EN DA	AYS dic	l you ea	at five or more servings of fruits and
vegetable	es? (/	Ni siku	ngapi k	atika so	aba zili	zopita u	mekula	zaidi ya vipimo vitano vya mboga na
matunda	?)							
0		1	2	3	4	5	6	7
4. On ho	w ma	ny of th	e last S	EVEN I	DAYS	did you	eat high	n fat foods such as red meat or full
dairy pro	ducts	?(Ni sil	ku ngapi	i katika .	saba zi	lizopita	umekul	a chakula chenye mafuta nyingi kama
vile nyan	na nye	ekundu	au mazi	iwa amb	ayo ha	yajatole	ewa maj	futa?)

62



Foot	care(<i>kud</i>	cnunga	miguu)								
9. On	how ma	ny of th	ne last S	SEVEN	DAYS	did you	check	your f	eet? (Ni si	iku ngapi	i katika s	aba
zilizopita umeitazama kwa makini miguu yako?)												
	0	1	2	3	4	5	6	7				
10. O	n how m	nany of	the last	SEVEN	N DAYS	S did yo	u inspe	ct the	inside of y	your sho	es? (Ni sī	iku
ngapi katika saba zilizopita umechunguza kilichoko ndani ya viatu vyako?)												
	0	1	2	3	4	5	6	7				
Mean	number	of days	s for foo	ot care;-								
Smoking(uvutaji tumbako)												
11. Have you smoked a cigarette – even - one puff for the last SEVEN DAYS?(Je, umevuta												
sigara katika siku saba zilizopita?)												
0. No (hapana)												
1. Yes. If Yes, how many cigarettes do you smoke on an average day? (Kama ndio,ni sigara												
ngapi unavuta katika siku moja?)												
Number of cigarettes ;(Nambari ya sigara												
SEC	ΓΙΟΝ 5;	4 poin	t Moris	sky adh	erence	scale;						
1. Do	you ev	er forg	et to ta	ke you	r medic	eine (ins	sulin,or	al ant	idiabetic (drugs)?	(Je, una	sahau
kujidunga insulin au kutumia tembe za sukari wakati mwengine?)												
Yes (1	Vdio)					No	(La).					
2. Do	you eve	er have	proble	ms rem	emberir	ng to tal	ke youi	r medi	ication (in	sulin,ora	al anti di	abetic
drugs)? (Je, unapata shida kukumbuka kujidunga insulin au kumeza tembe za sukari wakati												
mwen	gine?)											

Yes (Ndio)	No (La)
3. When you feel better do you sometime	es stop injecting yourself with insulin or using oral
antidiabetic drugs? (Je, ukisikia umepata n	afuu unaacha kujidunga insulin au kumeza tembe za
sukari wakati mwengine?)	
Yes (Ndio)	No (La)
4. Sometimes if you feel worse when you in	nject yourself with insulin or take the oral antidiabetic
drugs, do you stop injecting or using ora	l medication? (Je, wakati mwengine ukisikia vibaya
unpojidunga insulin au kumeza tembe za su	kari, unaacha kujidunga au kutumia tembe?)
Yes (Ndio)	No (La)
77 A 173	LE OF COMPENES
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