ADEQUACY OF GLYCAEMIC CONTROL AND KNOWLEDGE OF DIABETES AMONG AMBULATORY TYPE 2 DIABETIC PATIENTS AT MBAGATHI HOSPITAL, NAIROBI

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DECLARATION

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

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This book is dedicated to my mother, Benedetta Nabwire Okwera, for the remarkable tireless and relentless struggle in life despite the adversity.

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LIST OF ABBREVIATIONS

ADA	American Diabetes Association
BP	Blood pressure
DASH	Dietary Approaches to Stop Hypertension
DCCT	Diabetes Control and Complications Trial Research Group
DKT	Diabetes knowledge test
DOPC	Diabetic outpatient clinic
DPP-IV	Dipeptidyl peptidase IV
DSME	Diabetes Self-Management Education
EDTA	Ethylene diamine tetra acetic acid
EQA	External quality assurance
FBG	Fasting blood glucose
GIP	Glucose-dependent insulinotropic polypeptide
G.i.t.	Gastrointestinal tract
GLP-1	Glucagon-like peptide-1
HbA_1c	Glycated haemoglobin A_1c
HDL-c	HDL cholesterol
IDF	International Diabetes Federation
IQC	Internal quality control
IQR	Interquartile range
KNH	Kenyatta National Hospital
LDL-c	LDL cholesterol
MB., ChB.	Bachelor of Medicine and Bachelor of Surgery
MDRT	Michigan Diabetes Research and Training Centre
M. Med	Master of Medicine
NHANES	National Health and Nutrition Examination Survey
OHAs	Oral hypoglycaemic agents
PPAR-γ	Peroxisome proliferator-activated receptor-γ
SD	Standard Deviation
SMBG	Self-monitoring of blood glucose
SPSS	Statistical Package for the Social Sciences
T1DM	Type 1 diabetes mellitus
T2DM	Type 2 diabetes mellitus
TGs	Triglycerides
TODAY Study Group	Treatment Options for Type 2 Diabetes in Adolescents and Youth Study Group
UKPDS	UK Prospective Diabetes Study Group
U.O.N	University of Nairobi
US	United States

ABSTRACT

Background: Diabetes mellitus is associated with high morbidity, premature mortality and socioeconomic burden globally. Knowledge of diabetes plays an integral role in attaining desirable diabetes self-care and clinical outcomes of patients. However, frequently diabetes is inadequately controlled in clinical practice despite provided diabetes self-management education and advances in treatment. Optimal glycaemic control prevents or delays diabetic complications, morbidity and premature mortality.

Objectives: To determine the level of adequacy of glycaemic control and knowledge of diabetes among ambulatory T2DM patients at Mbagathi Hospital, Nairobi.

Design: Cross-sectional descriptive study.

Setting: Diabetes outpatient clinic, Mbagathi Hospital.

***Subjects*:** One hundred and sixty five patients with T2DM selected by random sampling, aged 40 years and above, each on one anti-diabetes regimen for a period of not less than 3 consecutive months.

Methods: The study was undertaken over a period of six months from June 2015 during routine diabetes clinics. Glycaemic control was assessed using HbA_1c assay, while knowledge of diabetes and adherence to medications were evaluated using the MDRTC diabetes knowledge test questionnaire and the 4-point modified Morisky Medication Adherence Scale respectively.

Results: Of the 165 patients with T2DM recruited, 66.1% females. Mean age (±SD) was 55.7 ± 9.5 years. Level of glycaemic control was 25.5%, knowledge of diabetes was 90.9% and adherence to medication was 37.6%. Mean DKT score (±SD) was 64.3 ± 15.3%, which was satisfactory. Non-adherence to medication was high, at 62.4%. Literacy rate was 93.3%. The study population was largely of low socio-economic status. Sub-optimal glycaemic control was possibly due to low socio-economic status, which impacted on adherence to diabetic diet and medications. Glycaemic control was significantly associated with single (marital) status (p = 0.005), formal employment (p = 0.05), and diabetes education acquired over one year prior to study entry (p = 0.014). Association of glycaemic control and formal employment was attributed to the ability of the employed patients to meet costs of medical care, including medication, while association of glycaemic control and diabetes education acquired over one year prior to study entry was ascribed to possible adequately internalized and utilized gained knowledge of diabetes. Patient knowledge of diabetes was significantly associated with female gender (p= 0.025), and unemployment (p = 0.045), likely due to the postulated better health-

seeking habits of females and the unemployed availing time to acquire knowledge of diabetes. Knowledge deficits were identified in aspects related to diet, treatment of hypoglycaemia and effect of physical activity on blood glucose. Non-adherence to medication was significantly associated with low family income (p = 0.043), provision of medications by spouses (p = 0.030), patient diabetes education gained 7-12 months prior to the study entry (p = 0.031) and multiple anti-diabetes drug regimen (p = 0.004). Association of non-adherence to medications with low family income was possibly because of inability to buy medications, while association of non-adherence to medications with multiple anti-diabetes drug regimens was also likely due to inability to afford high cost of multiple anti-diabetes drug regimens. Association of non-adherence to medications with patient diabetes education gained 7-12 months prior to the study entry was probably due to less conceptualized and internalized knowledge of diabetes. There was no association between glycaemic control, knowledge of diabetes and adherence to medications (p >0.05).

Conclusion: The proportions of patients with glycaemic control and adherence to medication in this study were low, while that of patients with knowledge of diabetes was high, evident of dissociation of glycaemic control and knowledge of diabetes. Barriers to glycaemic control and adherence to anti-diabetic medication and identified knowledge deficits should be promptly addressed, as re-enforcement of knowledge of diabetes is maintained.

1. LITERATURE REVIEW

1.1 Introduction

Among the environmental risk factors that predispose to type 2 diabetes mellitus (T2DM), over-nutrition and sedentary lifestyle are the major factors. These predispose to overweight and obesity, which in turn lead to T2DM. Diabetes mellitus poses substantial public health and socio-economic burden worldwide due to diabetes-associated morbidity and mortality. It constitutes a risk factor for microvascular disease (retinopathy, nephropathy and neuropathy) and macro-vascular disease (cardiovascular disease, stroke, and peripheral vascular disease that results in non-traumatic lower-limb amputation) leading to premature death worldwide.[1,2] The risk of these long-term diabetes complications is related to overall glycaemic burden over time.[2] Glycaemic control is influenced by several factors, including patient knowledge of diabetes and adherence to anti-diabetic medication.

Poor understanding of the long-term ramifications of inadequate glycaemic control has a significant impact on long-term diabetes complications. In order to provide the essential healthcare services for optimal management of diabetes mellitus in a managed primary care facility, clinicians should determine the prevailing levels of glycaemic control, patient knowledge of diabetes and adherence to anti-diabetic medication of the patients; adherence to anti-diabetic medications is closely linked to glycaemic control and patient knowledge of diabetes. Further, the factors affecting glycaemic control, patient knowledge of diabetes and adherence to anti-diabetic medication of the patients should also be determined. The aim of this study was to determine the levels of glycaemic control, patient knowledge of diabetes, adherence to anti-diabetic medication, as well as the factors associated with sub-optimal glycaemic control, poor patient knowledge of diabetes and non-adherence to anti-diabetic medications so as to facilitate adequate glycaemic control.

Patients with diabetes who have adequate knowledge of diabetes have demonstrated better glycaemic control, and research has revealed that enhanced glycaemic control lessens the rates of diabetes-related complications.[3] Knowledge of diabetes plays crucial informative role in diabetes management. Coupled with skills in diabetes self-care and behaviour change strategy, knowledge of diabetes is essential for glycaemic control, quality diabetes self-care, and subsequent reduction

in acute and long-term diabetes complications and socioeconomic burden. It is thus necessary that patients with diabetes are offered knowledge of diabetes, and adhere to healthcare advice to prevent or minimize diabetes complications. Further, it is imperative that the patient knowledge of diabetes, or where possible diabetes self-management education (DSME) program, should be evaluated in healthcare settings from time to time to identify knowledge gaps and determinants of diabetes knowledge that may need addressing in the DSME program to achieve adequate glycaemic control.

1.2 Epidemiology

The burden of diabetes mellitus was estimated at 415 million adults (aged 20-79 years) worldwide in 2015, with 14.2 million adults with diabetes residing in Africa.[4] In absence of strategic interventions, the global figure is projected to rise to 642 million people by 2040. Africa is expected to have 34.2 million people then. Kenya had 1.8 million people with diabetes in 2015, with an estimated prevalence of 3.3 %. From projections, the prevalence will increase to 4.5 % by 2025.[5] Globally, the exponential rise in prevalence is attributed to rapid population growth, urbanization and its associated lifestyle changes (unhealthy dietary habits and physical inactivity), increasing prevalence of obesity and population ageing.[4]A sum total of US$ 673.0 billion was expended on diabetes-related healthcare globally in 2015. By extrapolation it is anticipated that this expenditure will be in excess of US$ 802.0 billion in 2040.[4]

1.3 Glycaemic control targets in diabetes mellitus

Recent epidemiological data from various regions of the world show that most patients with diabetes are not controlled to the recommended target glycated hemoglobin (HbA_{1c}) levels. According to Gracia-Perez LE, et al. studies have shown that despite the benefits of therapy, the recommended glycaemic goals are achieved by less than 50% of the patients,[6] which may be attributed to diverse barriers to glycaemic control, including poor patient knowledge of diabetes and non-adherence to medications.

The primary glycaemic goal of diabetes management is to lower glycated haemoglobin (HbA_{1c}) to normal or near-normal range so as to minimize long-term diabetes-related micro- and macrovascular diseases.[7,8] Glycated haemoglobin (HbA_{1c}) level has a remarkable predictive

value for the long-term diabetes complications.[9] As a strategy for glycaemic control, the American Diabetes Association (ADA) recommends the glycaemic goal as a target $HbA_{1c} \leq 7\%$, while the IDF recommends $HbA_{1c} \leq 6.5\%$.[10] The intensive glycaemic control prevents acute illnesses, and delays onset or slows progression of chronic diabetes-related complications. Ideally HbA_{1c} should be monitored at least biannually in patients who meet treatment target goals and who have stable glycaemic control (treatment not altered),[11,12] and quarterly in patients who do not meet glycaemic goals (HbA_{1c} above the target) or whose therapy has changed.[11,13]

The significance of intensive glycaemic control for protection against microvascular disease in diabetes mellitus was demonstrated in two large randomized clinical trials on intensive glycaemic control by the Diabetes Control and Complications Trial (DCCT) Research Group and the UK Prospective Diabetes Study (UKPDS) Group for T1DM[7] and T2DM[8] respectively. Two other randomized clinical trials have demonstrated reduction of risk of macrovascular (cardio-vascular) disease in T1DM,[14] and T2DM[15] (if intensive strategy is initiated shortly post-diagnosis). Thus guidelines for good glycaemic control recommend HbA_{1c} goal of <7% for most adults with T2DM and a long life expectancy. More relaxed target HbA_{1c} levels may be preferable in older patients with long-standing T2DM and cardiovascular disease.[1] It is important that intensive diabetes treatment should be achieved without provoking severe or frequent hypoglycaemia, overweight and under-nutrition.

1.4 Knowledge of diabetes

Basic patient knowledge of diabetes is a key component of diabetes self-management education (DSME). Its overall objective is to promote clinical outcomes (such as optimal HbA_{1c} and quality of life with minimal diabetic complications) in the ongoing self-care of diabetes, enhance patient-provider communication and reduce healthcare cost. Patient knowledge of diabetes and practical skills on diabetes self-care focus on behaviour change targeting positive behaviours that can prevent or minimize diabetic complications. These intervention strategies are fundamental to reducing the barriers to diabetes self-care and glycaemic control, and consequently to improving the quality of life of the patients with diabetes. Therefore, diabetes knowledge and skills should be available and accessible to patients with diabetes, persons at risk of diabetes, their families and/or care-givers when diabetes is diagnosed (baseline information), and thereafter when and as necessary depending on need(s), with subsequent annual reinforcement.

Knowledge of diabetes and the attendant skills focus on life-style modification (healthy eating and physical activity), taking medications, blood glucose monitoring, surveillance and reduction of risks of complications (including hypo-/hyperglycemia prevention and management), diabetes self-care related problem identification and solving, and psychosocial adaption of living with diabetes (healthy coping). [16,17]

Knowledge of diabetes is best provided through a structured DSME program, an integral component of diabetes self-care for promotion of patient health outcomes. [18] According to the American Diabetes Association (ADA), DSME is the ongoing process of facilitating the knowledge, practical skills, and ability essential for pre-diabetes and diabetes self-care.[18,19] Its objectives are to support patient informed decision-making, self-care behaviours and problem-solving to improve and sustain clinical outcomes, health status and quality of life of the patient cost-effectively. Further, it supports active collaboration of the patient with the healthcare providers. It incorporates patient's specific needs, goals, life experiences, health and cultural beliefs of the individual and community, behavioural strategies and psychosocial issues. [19] DSME is modeled around a patient-centered and theoretically based empowerment approach (combining didactic, interactive and collaborative teaching) tailored to assist patients make informed self-care decisions.[18]

The knowledge of diabetes should be appropriately measured and monitored periodically as part of care, using the right techniques, to identify gaps in services and fill the void so as to improve the positive patient outcomes, including reinforcement of suitable behaviour. The periodic monitoring also aims to improve the effectiveness of the DSME program. Thus, evaluation of the outcomes of knowledge of diabetes, and consequently DSME program, should address clinical, behavioural and psychosocial outcomes.

1.5 Association of glycaemic control and patient knowledge of diabetes

Patient knowledge of diabetes has been associated with improved glycaemic control. However, despite patient knowledge of diabetes offered, virtually all local studies involving glycaemic control conducted at Kenyatta National Hospital (KNH), Nairobi, a national referral and teaching hospital (level VI hospital), have revealed sub-optimal glycaemic control, as measured by

HbA_1c.[20-24] Similar studies in other countries have also shown sub-optimal glycaemic control.[25-27] Factors that impact on glycaemic control are multifaceted, and include factors related to the patients, healthcare-providers and healthcare systems.[28] Studies have researched the interplay of these factors to determine those that can be influenced to improve glycaemic control and hence outcomes of diabetes care..

Exploring association of glycaemic control and patient knowledge of diabetes is invaluable in identifying barriers that contribute to poor glycaemic control and clinical outcomes of diabetes self-care. Provision of knowledge of diabetes targets enhancing diabetes self-care that in turn improves glycaemic control. However, studies in different countries globally show varied results. Islam SMS, et al, in a study of diabetes knowledge and glycaemic control among patients with type 2 diabetes in Bangladesh noted knowledge of diabetes was not significantly associated with glycaemic control.[29] In Libya, Elkharam WM et. al. in a study of knowledge of and adherence to health advice among adults with diabetes showed poor glycaemic control (63.2 %) and poor knowledge of diabetes (48.6% of the patients correctly answered the DKT 23 questionnaire).[30] On the contrary, meta-analysis of randomized controlled trials of diabetes patient education to quantitatively assess and characterize the effect of patient education on glycated hemoglobin (HbA_1c) by Ellis SE et. al. in US (2004) showed modest improvements in glycaemic control in diabetic adults.[31] Bains SS et al (2011) in a US study that assessed associations of health literacy, knowledge of diabetes, self-care, and glycaemic control in a low income, predominantly minority population with type 2 diabetes noted that knowledge of diabetes and perceived health status were associated with glycaemic control.[32]

1.6 Taking medications

Approaches to glycaemic control in patients with type 2 diabetes mellitus have been elucidated in the Standards of Medical Care in Diabetes (2016) by the ADA[33] that advocate for lifestyle interventions and pharmacologic therapy. Despite well explained benefits of pharmacotherapy use, adherence to medication remains one of the major clinical setbacks in the management of patients treated with lifestyle modification and pharmacotherapy. Adherence to medication refers to the degree to which a patient conforms to treatment as prescribed by a health-care provider.[34] This is in terms of active, voluntary, and collaborative involvement in a mutually acceptable

course of behaviour, and is in contradistinction to compliance, which may only refer to passively following orders. Non-adherence to anti-diabetic therapies among patients with diabetes is one of the major factors predisposing to sub-optimal glycaemic control, accelerated development of diabetes complications, and increased morbidity and mortality. Adherence to diabetes management is variable. Data from different studies show that adherence to oral hypoglycemic agents (OHAs) range from 36% to 93%, and 62% and 64% for long-term and new-start insulin users respectively. [35-36] Several methods of measuring adherence to medication have been described, [34,36-38] but none has been documented as gold standard for precise measurement of adherence.[38] Adherence to medication may be assessed through patient questionnaires (e.g., Morisky Medication Adherence Scale, MMAS) and medication electronic devices/systems (e.g., Medication Event Monitoring System, MEMS). [34,36-38]

1.7 Current medical treatment options for type 2 diabetes

The management goals for T2DM include glycaemic control (figure 1), management of coincident abnormalities (insulin resistance, obesity, dyslipidaemia, hypertension and hypercoagulability) and screening and management of long-term diabetes complications.[1,2] The treatment options for diabetes comprise of pharmacologic and non-pharmacologic approaches.[2,39] Assiduous pharmacologic treatment is essential, but non-pharmacologic approaches are equally important.

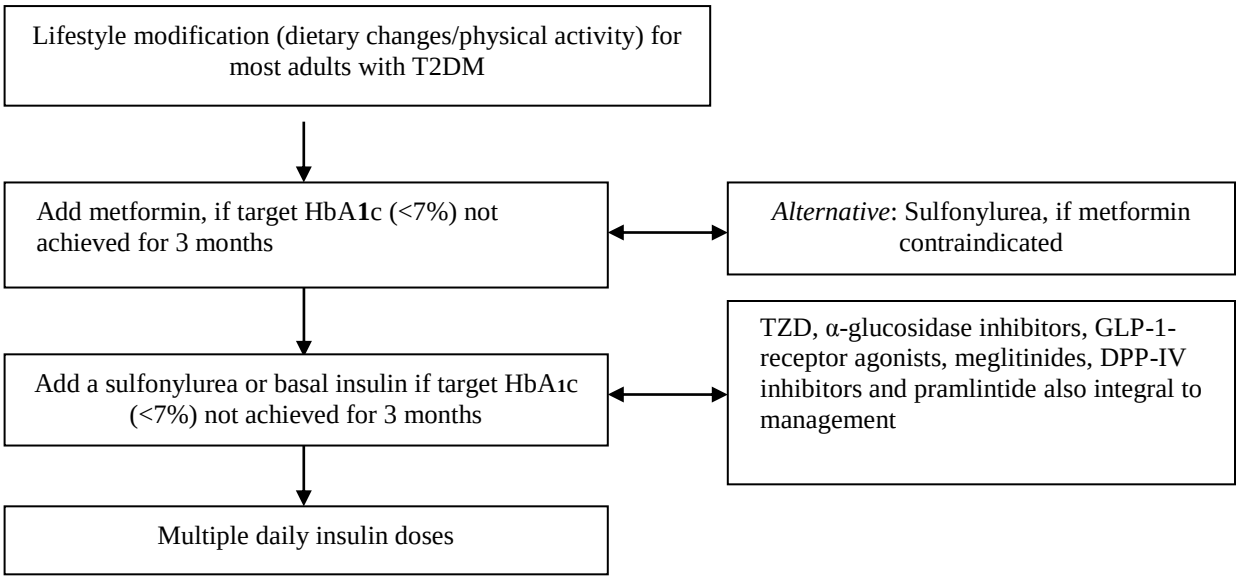

Figure 1: Treatment for type 2 diabetes mellitus (T2DM)

1.7.1 Non-pharmacologic (lifestyle) approaches

Lifestyle modification (dietary changes and enhanced physical activity) promotes weight loss and improves glycaemic control. Dietary strategies include fiber-rich/whole grains, reduced calories and dietary fat, while regular physical exercise consists of at least 150 minutes per week of moderate-intensity aerobic activity, spread over at least 3 days per week with no more than 2 consecutive days without exercise.[1,2]

1.7.2 Pharmacologic therapy

Due to limited long-term success of lifestyle modification and disease progression (characterized by worsening glycaemia), most patients with type 2 diabetes require hypoglycaemic agents. Pharmacologic options have lately expanded with therapeutic advances that have generated various new classes of hypoglycemic drugs. Classes of hypoglycaemic agents include biguanide, sulfonylurea, thiazolidinedione (TZD), alpha-glucosidase inhibitor, meglitinide, dipeptidyl peptidase IV (DPP-IV) inhibitor, insulin, glucagon-like peptide 1 (GLP-1)–receptor agonists and amylin analogue.[2,33] Agents in the latter three classes are injectable.

Lifestyle changes and metformin are the initial cost-effective therapies in most patients if target HbA_1c is not achieved with lifestyle approach alone. Other agents may be added to metformin as necessary to control glycaemia, depending on affordability, long-term safety profile, side-effects and effects on co-existing diabetic complications. Eventually intensive insulin therapy may be required.

All the pharmacologic agents are well tolerated and effective hypoglycaemic agents. Save for metformin (biguanide) and sulfonylureas, which are widely used worldwide, all the other agents are expensive. Metformin rarely causes hypoglycemia and may cause slight weight loss, gastrointestinal intolerance, lactic acidosis (rare) and vitamin B_{12} deficiency. Sulfonylureas (e.g., glipizide, gliclazide and glimepiride) are associated with weight gain and hypoglycemia.

Thiazolidinediones (pioglitazone and rosiglitazone) cause weight gain, increased risks of oedema and heart failure, and possibly bladder cancer (pioglitazone).[40] Hypoglycemia is rare. There is empirical evidence of beneficial effect of pioglitazone on coronary atherosclerosis and

cardiovascular disease.[41] Use of rosiglitazone has been restricted due to increased potential risk of myocardial infarction.[42] The other agent in this class, troglitazone was withdrawn from the market due to associated risk of hepatotoxicity and liver failure.[43]

Alpha-glucosidase inhibitors (acarbose, miglitol and voglibose) rarely cause hypoglycemia, and possibly reduce risk of cardiovascular disease events. Their use is limited by side-effects - flatulence and diarrhea. DPP-IV inhibitors, e.g., sitagliptin and vildagliptin have benefit of weight neutrality,[44] and hypoglycemia is rare (unless administered concomitantly with sulfonylureas or insulin). Meglitinides (repaglinide and nateglinide) have actions similar to sulfonylureas but the duration of action is short and are most effective in pre-prandial glycaemic control. Side-effects includes weight gain and hypoglycemia.

GLP-1–receptor agonists, e.g., exenatide and liraglutide, cause weight loss in most patients, and although rarely cause hypoglycemia, this may occur if used concurrently with insulin or sulfonylureas. Side-effects are nausea, vomiting and possibly high risks of pancreatitis. Pramlintide (amylin analogue) has clinical benefits of weight loss in most patients and control of postprandial glycaemia. It causes nausea and vomiting, and hypoglycemia with insulin use. Insulin is the most potent agent for controlling glycaemia, and many of its formulations are cheap and readily available. Common side-effects are hypoglycemia and weight gain.

Patients with diabetic also require management of their co-morbidities, and follow-up involving a multi-disciplinary team designed to provide comprehensive care. This includes counselling, which should be incorporated in routine diabetes care. Counselling should strongly advise against cigarette smoking[33] and emphasize the potential risk of alternative/herbal medicine.

2. STUDY JUSTIFICATION

Diabetes is one of the common non-communicable diseases posing substantial public health and socio-economic burden globally as a consequence of its related morbidity and mortality. Its prevalence is exponentially increasing. Knowledge of diabetes, skills for self-care and behaviour change provided by Diabetes self-management education (DSME) program target achieving adequate glycaemic control and quality diabetes self-care. Locally, provision of DSME is inclined towards empowerment of patients with diabetes knowledge. It is anticipated that the skills of self-care will be improved for better metabolic control and entire diabetic care.

Most local studies have documented sub-optimal glycaemic control among patients with T2DM. This is despite significant advances in diabetes treatment protocols and the provision of DSME. The underlying reasons for sub-optimal glycaemic control, including levels of and factors affecting knowledge of diabetes and adherence to medications, have not been documented. Local data on patient knowledge of diabetes (and effectiveness of DSME) is limited.

The aim of this study was to determine the adequacy of glycaemic control, levels of patient knowledge of diabetes and adherence to medication, as well as factors associated with glycaemic control, patient knowledge of diabetes and non-adherence to anti-diabetic medications among the ambulatory adult patients with T2DM in a managed care setting. Implementation of the recommended interventions may enhance the clinical outcome of the patients with T2DM.

3. RESEARCH QUESTIONS

1. What is the level of glycaemic control, knowledge of diabetes and adherence to medication among the patients with T2DM at diabetes outpatient clinic (DOPC) at Mbagathi Hospital, Nairobi?
2. What is the association between glycaemic control, knowledge of diabetes and adherence to medication among the study patients with T2DM?

4. OBJECTIVES

4.1 Broad objective

To determine adequacy of glycaemic control and level of knowledge of diabetes among ambulatory patients with T2DM attending DOPC at Mbagathi Hospital, Nairobi.

4.2 *Specific objectives*

4.2.1 Primary objectives

1. To determine adequacy of glycaemic control among the study patients.
2. To determine the level of knowledge of diabetes among the study patients.
3. To determine the level of adherence to anti-diabetes medication among the study patients.

4.2.2 *Secondary objectives*

1. To determine the association of glycaemic control with the patient knowledge of diabetes and adherence to medication among the study patients.
2. To determine the association of knowledge of diabetes and adherence to medication among the study patients.

5. STUDY METHODOLOGY

5.1 *Study design*: Descriptive, cross-sectional study.

5.2 *Study site*: Mbagathi Hospital, a level IV urban public healthcare facility in Nairobi with 227 bed capacity, which serves as a primary hospital and the Tuberculosis Referral Centre for residents of Nairobi city and its environs. There were no standard treatment protocols locally established for use in the setting, and management of diabetes mellitus was based on guidelines from the developed countries.

5.3 *Study population*: This was composed of ambulatory patients documented to have T2DM, on management and follow-up for diabetes mellitus at diabetic outpatient clinic (DOPC), Mbagathi Hospital.

5.4 Patient selection

5.4.1 ***Case definition:*** Patient with T2DM documented by criteria for diagnosis of DM,[39] an adult at age 40 yrs or above, on one continuous drug prescription for diabetes control (without switches and additions) for a period of not less than three consecutive months prior to study entry.

5.4.2 ***Inclusion criteria***

1. Fulfillment of the criteria for case definition.
2. Ability to understand and speak English and/or Kiswahili.
3. Duly signed written informed consent to participate in the study.

5.4.3 ***Exclusion criteria***

1. Diagnosis of T1DM
2. Pregnancy (pregnant mothers)
3. Too ill or cognitively impaired to participate

5.5 Sample size calculation

The sample size for the study was determined using the validated formula below (Daniel, 1999),[45] employed for estimating proportions of a disease in a single population of subjects in a study. Though this was not a prevalence study, the objective of this study was to determine the adequacy of glycaemic control and the level of knowledge of diabetes as proportions in a population of patients with diabetes. Thus, the formula for cross-sectional studies was used.

$$n = Z^2 P (1-P)/ d^2$$

Where:

n = desired sample size,

z = 1.96, statistic for 95% confidence interval,

p = estimated prevalence rate of adequate glycaemic control among T2DM patients of 29.5% based on a study in Kenyatta National Hospital, Nairobi, by Omari BG (2013).[21]

d = margin of error for the p, which was ± 7%,

$$n = 165$$

5.6 Patient sampling, screening and recruitment procedure of the study patients

The study was designed as a randomized study. It was conducted from June 2015 through November 2015 at the diabetes outpatient clinic (DOPC) in Mbagathi Hospital, Nairobi. The hospital ran one DOPC weekly on Monday morning. It usually served 25-35 patients on each clinic day. DSME is provided on individual and group basis mostly before the clinic commences.

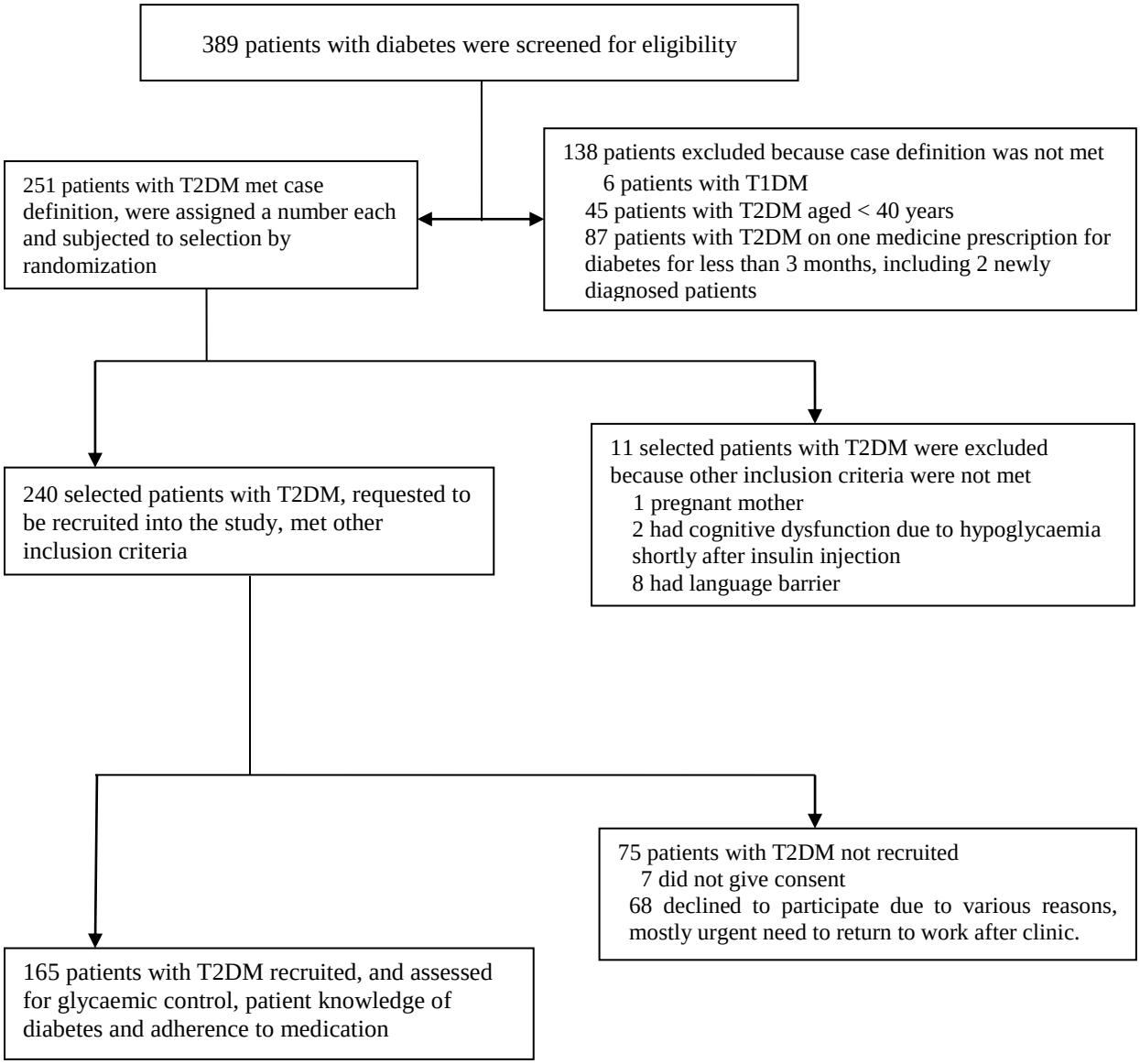

Figure 2: Flow chart on participant recruitment for the study

Flow-chart in figure 2 describes the screening, sampling and recruitment of the analyzed study population. Prior to the start of each DOPC, patients were briefed regarding the study. Files retrieved from records office for use during medical review of the patients were perused to identify patients who met criteria for case definition, and each patient eligible for recruitment by way of case definition was asked to provide variance in the information, if any existed. The eligible patients were allocated a number each, and a list of the numbers allocated drawn out for purpose of random sampling process.

Using the numbers allocated to the patients and a list of the random numbers generated electronically by the computer Microsoft Office Excel, a target of nine patients were selected for recruitment by simple random sampling during each clinic. The selected patients were requested to be recruited into the study and then screened further for the other inclusion criteria. Those who fulfilled all the inclusion criteria were recruited into the study upon signing informed consent after consent explanation to each individually.

A total of 389 patients with diabetes were screened for eligibility for recruitment into the study. Two hundred and forty patients out of the 251 patients with T2DM, who met case definition criteria and were subjected to selection by randomization, fulfilled all inclusion criteria. One hundred and sixty five of these patients were recruited into the study, while 75 patients were excluded for various reasons. The recruited patients were assessed for adequacy of glycaemic control, patient knowledge of diabetes and adherence to medication. Most patients participated in the study after review by the attending clinicians, while a few before review.

5.7 Clinical method

A 2.0 ml blood sample was drawn from each patient for HbA_{1c} assay under universal aseptic precautions, dispensed into individual patient's pre-labeled sterile EDTA (Ethylene diamine tetra acetic acid) vacutainer bottle and dispatched to the laboratory at a temperature of about 25 ºC. The time interval between collection of blood samples and laboratory sample testing was less than 4 hours; blood samples remain stable for three days at a temperature range of 15-25 ºC (Data on file at Roche Diagnostics).

HbA_1c determination was based on the turbidimetric inhibition immunoassay method run on Roche Cobas Integra 400/800 analyzer. The glycohemoglobin (HbA_1c) in the sample reacts with anti-HbA_1c antibodies in the reagent to form soluble antigen-antibody complexes. The polyhaptens contained in a second reagent react with excess anti-HbA1c antibodies to form insoluble antibody-polyhapten complex that is determined immunoturbidimetrically. The final result is expressed as a percent (%) HbA_1c and is calculated from the HbA_1c/Hb ratio as follows (according to the DCCT/NGSP): HbA_1c (%) = (HbA_1c/Hb) x 91.5 + 2.15

5.8 Study instrument

Instruments used for data collection were the glycosylated haemoglobin A_1c (HbA_1c) assay, [46,47] the Michigan Diabetes Research and Training Centre (MDRTC) diabetes knowledge test,[48] and the 4-point modified Morisky Medication Adherence Scale (MMAS-4).[49] Confirmation of diagnosis of diabetes mellitus was done through individual patient's file records.

Glycated haemoglobin (HbA_1c) assay is a valuable technique for assessment of effectiveness of diabetes management on glycaemic control. It provides information about the degree of long-term glucose control, which reflects the average blood glucose concentration over the preceding eight to twelve weeks,[10,46,47] unlike fasting and random blood glucose concentrations that commonly fluctuate and indicate the levels of short-term glycaemic control.

The MDRTC diabetes knowledge test is a 23-item questionnaire developed by the Michigan Diabetes Research Training Center, USA. It is a two-part, 23-item questionnaire that measures general knowledge of diabetes. The first 14 questions (appendix 2) are relevant to patients with diabetes who are not on insulin therapy (most patients with T2DM), while the entire 23-item questionnaire is applicable to insulin-treated patients.

The rationale for using the MDRTC diabetes knowledge test include its reliability and validity as a research instrument,[50] and its use in studies in Nigeria and Malaysia in Africa. It can be self- or investigator administered in a short while (about 15 minutes[48]) as patients wait to be attended to by the clinicians. It interrogates and elicits information about various key themes of diabetes self-care, namely diabetes diet, blood glucose monitoring and interpretation of HbA_1c test,

treatment profiles (including management of symptomatic hypoglycaemia), effect of physical activity and infection on blood glucose levels, foot care, and signs and symptoms of diabetic neuropathy.

The 4-point modified Morisky Medication Adherence Scale (appendix 4), a structured four-item self-reported adherence measure, is composed of four Yes/No response questions that are used to assess medication adherence. MMAS-4 is categorized into high adherence (score = 0), medium adherence (score = 1 - 2) and low adherence (score = 3 - 4). The tool has been shown to provide good specificity for adherence to medication. Items in the scale address barriers to medication-taking and allow the healthcare provider to reinforce positive adherence behaviors.

The MDRTC instrument, MMAS-4, the patient consent explanation form and the consent form for participation in the study were all translated into Kiswahili versions. Forward translation of the original documents was done by translation from English to Kiswahili language to generate a version that was as close as possible to the original documents. Translation was carried out by a qualified linguist, proficient in English and Kiswahili languages. Reverse translation from Kiswahili to English language was undertaken by an independent translator. Comparison of the two versions for content and meaning was done and agreed upon by the research team. The documents were pre-tested on five patients at Mbagathi Hospital DOPC who met the set inclusion criteria, prior to use in order to test the questions and to estimate how long it took to complete the questionnaire. The five patients were not included in the final sample of the study.

5.9 Laboratory method

The laboratory method used for data collection was $HbA_{1}c$ assay. This assay for glycaemic control was performed using Roche Cobas Integra 400/800 analyzer by trained technologists at the Metropolis Star Lab - Kenya, under the supervision of a clinical pathologist. Metropolis Star Lab (K) is an accredited ISO 15189 certified laboratory. It provides quality services. The laboratory is located within the vicinity of Mbagathi Hospital.

The laboratory was supportive and convenient, with rapid test turn-around time without compromising on quality. Testing was done in accordance with defined standard operating procedures (SOPs). Internal quality controls (IQC) were run on each day of patient testing using commercial controls to confirm calibrations of the analyzer. These control checks were found to be within accepted limits; this ensured that performance was acceptable. The laboratory undertakes external quality assurance (EQA) checks regularly provided by HuQAS.

5.10 Data collection

Data on knowledge of diabetes and medication adherence was collected by the research team (consisting of the principal investigator and two trained research assistants) in a face to face interview through a structured socio-demographic questionnaire (appendix 1) and clinical questionnaires, the 14-item questionnaire excerpted from MDRTC diabetes knowledge test (appendix 2) and the 4-point modified Morisky medication adherence scale (appendix 4). Questionnaires were investigator administered so as to ensure that, through standardized explanations, the patients understood the questions before answering them. Scoring for patient knowledge of diabetes was done by summing the number of questions answered correctly. All questions were weighted equally. The total scores were converted into percentages. Blood HbA_1c was assessed in the laboratory for glycaemic control. The test results were delivered to the principal investigator, and entered in the proforma in preparation for data analysis.

5.11 Study variables

5.11.1 Independent variables*:*

These included the following sociodemographic and clinical variables:

(a) *Categorical variables*:

(i) Gender – categorized as male or female sex

(ii) Marital status – categorized as single, married, widowed or separated/divorced,

(iii) Level of formal education – patient's reported highest grade reached in education: primary, secondary, tertiary education or no formal education

(iv) Employment status – categorized as unemployment, formal or informal employment.

(v) Income – Estimated combined pre-tax annual family income from all sources, verbally reported by the patients (no corroborating evidence was provided); categorized as income

≤ Ksh. 50,000.00, Ksh. 50,001.00 - 100,000.00, Ksh. 100,001.00 - 150,000.00 and > Ksh. 150,000.00. (Kshs. 107.80 was equivalent to one US dollar).

(b) *Continuous variables*:

(i) Age – period from the reported or documented date of birth, estimated to nearest number of years.

(ii) Duration of diabetes – period from the reported or documented date of diagnosis of diabetes, estimated to nearest number of years.

(iii) HbA_1c level – This was determined by HbA_1c assay.

(iv) Types of treatment – defined as the current pharmacotherapeutic modalities, categorized into oral anti-hypoglycaemic agent (OHAs), insulin alone and insulin plus OHAs.

5.11.2 Dependent/Outcome variables

(i) Glycaemic control: This was determined using HbA_1c levels as a continuous variable, and categorical variable (where glycaemic state was categorized as good control if HbA_1c was 7% or less, and poor control if HbA_1c more than 7%).

(ii) Patient knowledge of diabetes: Patient's score was evaluated using the MDRTC diabetes knowledge test. Knowledge of diabetes was categorized as good if DKT score was 50% or more, and poor if DKT score was less than 50%.

(iii) Adherence to medication: patient's score evaluated using the modified Morisky Medication Adherence Scale (MMAS-4). Adherence to medication was considered high if MMAS score = 0, and low if MMAS score = 1 - 4.

6. DATA MANAGEMENT AND STATISTICAL ANALYSIS

6.1 Data handling

All the raw study data collected was captured, transcribed and stored electronically in Microsoft Excel spreadsheets. This was entered into SPSS version 21.0 database, cleaned to avoid errors and verified for accuracy. Answered questionnaires and laboratory reports were filed in a suitable inaccessible box-file kept under safe custody of the principal investigator to avoid loss and breach of confidentiality.

6.2 Data analysis

Statistical analysis was carried out using the Statistical Package for the Social Sciences (SPSS) version 21.0 under the guidance of a statistician. Continuous data e.g., age, HbA_1c, duration of disease was summarized in means, medians and standard deviation (SD). Categorical data e.g., sex, marital status was in summarized in frequency distributions and percentages. Comparative statistics was calculated using Student's *t*-test for continuous variables and *chi*-square test for categorical variables. Correlation of glycaemic control and patient knowledge of diabetes was tested using the Pearson's correlation. Findings were considered statistically significant if *p* value was <0.05. Data was presented in tables, pie-charts and bar charts.

Glycaemic control was evaluated as mean HbA_1c and categorized into good (HbA_1c level $\leq$ 7%) and poor (HbA_1c level > 7%). This was presented as a percentage with 95% Confidence Interval. Knowledge of diabetes was calculated as mean DKT score and categorized into good score (DKT score $\geq$ 50%), implying good patient knowledge of diabetes, and low scores (DKT < 50%) for the reverse. Adherence to medication was assessed by a self-reported 4-point modified Morisky Medication Adherence Scale (MMAS-4). MMAS score = 0 was considered high adherence to medication, while MMAS score = 1 - 4 (constituting medium adherence, score = 1 - 2, and low adherence, score = 3 - 4) was considered poor adherence or non-adherence to medication.

Data was analyzed to determine:

1. proportion of study population according to socio-demographic and diabetes-related characteristics.
2. proportion of study population with optimal glycaemic control, using HbA_1c levels.

3. proportion of study population with good knowledge of diabetes (DKT score ≥ 50%).
4. knowledge deficits (incorrect answers above 50% in DKT)
5. proportion of study population with good adherence to medication.
6. association of the level of glycaemic control with patient knowledge of diabetes and adherence to medication.
7. association of knowledge of diabetes and adherence to medication.

7. QUALITY ASSURANCE

Blood samples for HbA_1c assay were collected under sterile techniques. Assay was performed at Metropolis Star-lab (K) using Cobas analyzer. Metropolis Star-lab (K) is accredited ISO 15189 certified laboratory. The commercial controls were used for IQC to confirm calibrations; EQA was provided by HuQAS. Laboratory Standard Operating Procedures (SOPs) were followed during HbA_1c testing to ensure quality and reliability of HbA_1c results.

8. ETHICAL CONSIDERATIONS

This study was conducted after the pre-requisite ethical approval of the proposal was granted by DCMT (UON), KNH/UON Research and Ethics Committee, and authorization to collect data given by Mbagathi Hospital Administration. The purpose and benefits of the study were explained to each patient, and individual written informed consent (appendix 8) obtained prior to recruitment and data collection. Patients' socio-demographic and diabetes-related data were obtained anonymously using assigned study code numbers, which were linked to individual patients' medical file numbers and telephone numbers to facilitate filing of HbA_1c results at the hospital and relaying of HbA_1c results to patients respectively. Similarly, MDRTC diabetes knowledge test questionnaires and laboratory request forms bore study code numbers only.

Blood samples were collected strictly for HbA_1c assay; unused blood was discarded immediately. Copies of HbA_1c results were submitted to the hospital records office for retention and reference purposes. The results were appropriately filed in respective patients' files. Abnormal HbA_1c results (HbA_1c >7%) were promptly relayed by phone to the affected patients and the primary doctors for suitable management and follow up of the patients. Normal HbA_1c results ($HbA_1c \leq 7\%$) were relayed to patients through mobile telephone short message service

(sms). Receipt of results was confirmed through telephone calls made to patients. Brief interpretation of the results was given via the same, and patients asked to seek further advice from the primary doctors. Patients who did not consent for participation in the study were not discriminated against in terms of services offered, neither were the patients who opted out of the study later on as data collection continued. Patient data was treated with utmost confidentiality during and after the study.

9. RESULTS

One hundred and sixty five patients with T2DM fulfilled the inclusion criteria and were recruited into the study, and assessed for adequacy of glycaemic control, patient knowledge of diabetes and adherence to medication.

9.1 Socio-demographic and diabetes-related characteristics of the study patients

Table 1 describes analyzed socio-demographic characteristics of the study patients. The mean age of the study patients was 55.7 years, median age 54 years and range 40 - 89 years. There was a female predominance (66.1%); male:female ratio was 1:2. Over three quarters of the patients (77.0%) were married. The vast majority of the patients (93.3%) had formal education, female patients (61.8%) more than male patients (31.5%). Almost two thirds (61%) of the patients were in gainful employment, with only 17.6% in formal employment. Of the patients who were single 76.2% were and employed, while among the married 58.3% were employed. Fifty percent of the patients who were widowed or separated and 80% of patients who were divorced were employed. About two thirds (68.5%) of the patients had family annual income not exceeding Kshs. 50,000.00 (Kshs. 107.80 was equivalent to one US dollar). Only 6.7% of the patients had an estimated family annual income in excess of Kshs. 150,000.00. Close to 78% of the patients paid for their medications, while the others were bought medications as indicated in table 1.

Table 1. Distribution of socio-demographic characteristics of the patients with T2DM in the study

Characteristic	Frequency, *n* (%)
Mean (±SD) age in years (range in years)	55.7 ± 9.5 (40 - 89)
Gender	
Male	56 (33.9)
Female	109 (66.1)
Marital status	
Single	21 (12.7)
Married	127 (77.0)
Divorced/separated	5 (3.0)
Widowed	12 (7.3)
Level of formal education	
No formal education	11 (6.7)
Primary school education	97 (58.8)
Secondary school education	44 (26.7)
Tertiary (College/University) education	13 (7.9)
Employment	
Unemployed (patients: single 5, married 53, divorced/separated 1, widowed 6)	65 (39.4)
Formal employment (single 4, married 19, divorced/separated 0, widowed 6)	29 (17.6)
Informal employment (single 12, married 55, divorced/separated 5, widowed 0)	71 (43.0)
Family annual income, Ksh. *(pre-tax annual family income from all sources)*	
≤ 50,000.00	113 (68.5)
50,001.00 - 100,000.00	31 (18.8)
100,001.00 - 150,000.00	10 (6.1)
> 150,000.00	11 (6.7)
Who buys medication	
Self	128 (77.6)
Spouse	14 (8.5)
Child	19 (11.5)
Employer/Health Insurance Company	4 (2.4)

Table 2 shows the distribution of the diabetes-related characteristics of the study patients. The median duration of diabetes was 3.0 years (interquartile range, IQR, 1.0 - 7.0; range 3 months - 26 years). Family history of diabetes was noted among 46.7% of the patients. Most (92.1%) of

patients obtained diabetes self-management education, the bulk of whom (70.9%), 2 - 6 recent sessions over a period not exceeding six months prior to their study entry. Less than one fifth (15.2%) of patients had periodic diabetes education for over one year to re-enforce DSME, while about a tenth of the patients (7.9%) had not accessed diabetes education since diagnosis of diabetes mellitus. About a third (34.5%) of the patients performed self monitoring blood glucose (SMBG) at home. The largest proportion of the patients (84.9%) was using oral hypoglycaemic agents (metformin and/or glibenclamide) for glycaemic control.

Table 2. Distribution of the diabetes-related characteristics of the patients with T2DM in the study

Characteristic	Frequency, *n* (%)
Median duration of diabetes in years (interquartile range, IQR) Range of duration of diabetes in years	3.0 (1.0 - 7.0) 3 months - 26 years
Family history of diabetes	
Yes	77 (46.7)
No	88 (53.3)
Diabetes education/update sessions	
None since diagnosis	13 (7.9)
≤ 6 months prior to recruitment into the study	117 (70.9)
7-12 months prior to recruitment into the study	10 (6.1)
> 1 year prior to recruitment into the study	25 (15.2)
Self monitoring blood glucose (SMBG), glucometer utilization	
Yes	57 (34.5)
No	108 (65.5)
Anti-diabetic medications used	
Oral hypoglycaemic agent(s): Metformin ± Glibenclamide or Gliclazide	140 (84.9)
Insulin only	6 (3.6)
Insulin and oral hypoglycaemic agent: Insulin + Metformin	19 (11.5)
Median number of anti-diabetic drugs (interquartile range , IQR)	2 (1 - 2)

9.2 Glycaemic control of the study patients

Figure 3 illustrates glycaemic control among the patients with T2DM in this study population. The adequacy and level of glycaemic control among these patients was low. Only 25.5% of the study population was found to be in good glycaemic control ($HbA_1c \leq 7\%$), with M:F 1:2 (table 4). Among the patients who were poorly controlled ($HbA_1c > 7\%$), female patients constituted the majority (65.9%), M:F 1:1.9. Notably, 35.4% of the patients (corresponding to nearly a half of the poorly controlled patients) had HbA_1c level of more than 10%. The mean (± SD) HbA_1c level was 9.5 ± 3.1% (range 5.0 - 18.1%). The mean age (± SD) of the study patients with good glycaemic control was 53.9 ± 8.6 years, and that for patients with poor glycaemic control was 56.4 ± 9.7 years. The median duration of diabetes for patients with good glycaemic control was 2.5 years (interquartile range, IQR 1.0 - 4.0) and that for patients with poor glycaemic control was 4 years (interquartile range, IQR 1.0 - 8.0). Only 10.3% of the patients performed SMBG at home with good glycaemic control (table 5).

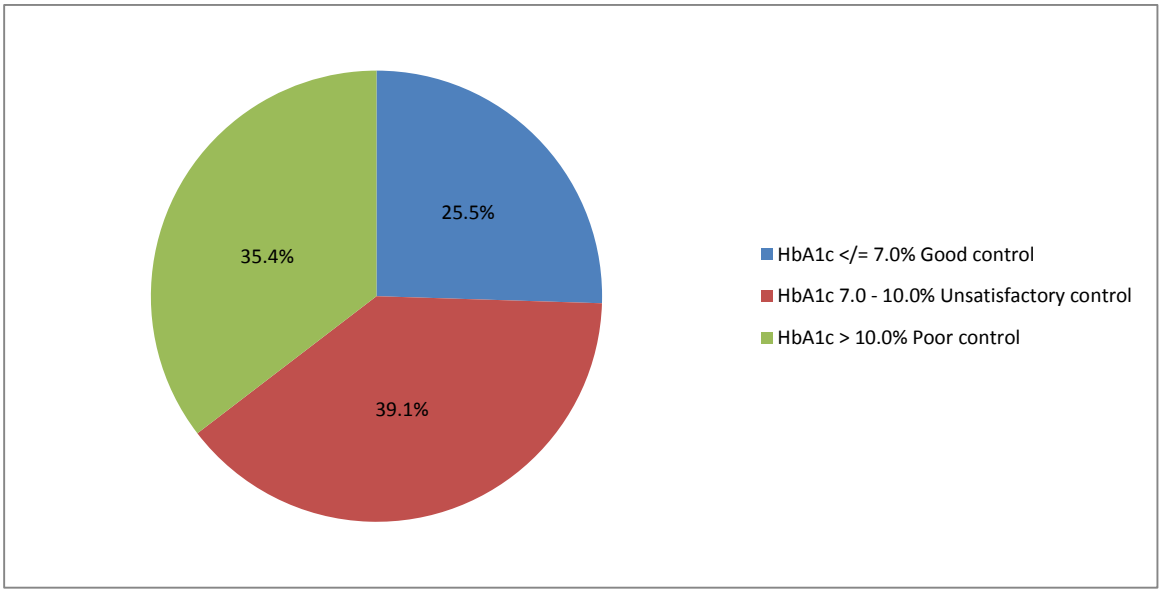

Figure 3. Glycaemic control among the study patients

Table 3 presents anti-diabetes medications used by individual patients and the attendant glycaemic control. About 85% of the patients were on OHAs (metformin ± glibenclamide or gliclazide), while 15% were on insulin injection ± metformin (3.0% of the patients on insulin only). Approximately 28% of the patients on OHAs attained glycaemic control, compared to 12% of the patients on insulin injection ± metformin. Of the 19.4% of the patients on one anti-diabetes medication only 6.7% had good glycaemic control. Slightly over four fifths of the patients (80.6%) were on two anti-diabetes medications, and only 18.8% had good glycaemic control. One eighth of the patients on insulin with/without metformin had good glycaemic control.

Table 3. Anti-diabetes medications used by patients versus glycaemic control of the patients

Medications	Controlled glycaemia ($HbA_{1c} \leq 7.0\%$) Frequency, *n* (%)	Uncontrolled glycaemia ($HbA_{1c} > 7.0\%$) Frequency, *n* (%)
Metformin only	10 (6.0)	15 (9.1)
Glibenclamide only	0 (0)	2 (1.2)
Metformin/Glibenclamide combination	29 (17.6)	83 (50.3)
Metformin/Gliclazide combination	0 (0)	1 (0.6)
Mixtard insulin only	1 (0.6)	4 (2.4)
Mixtard insulin/Metformin combination	2 (1.2)	18 (10.9)

Table 4 presents a summary of comparison of socio-demographic characteristics among the patients with controlled and uncontrolled T2DM in this study. Bivariate analysis showed statistically significant differences in glycaemic control between the patients who were single and the married, $p = 0.005$ (OR 3.9, 95% CI, 1.5 to 10.1). There was also statistically significant difference in glycaemic control between the patients in formal employment and the unemployed, $p = 0.05$ (OR 2.6, 95% CI, 1.0 - 6.6). Single (marital) status and formal employment were associated with good glycaemic control.

Table 4. Comparison of socio-demographic characteristics among the patients with controlled and uncontrolled T2DM in the study

Characteristic	Controlled glycaemia (HbA1c ≤ 7.0%) *n* (%)	Uncontrolled glycaemia (HbA1c > 7.0%) *n* (%)	OR (95% CI)	*p*-value
Gender				
Male	14 (25.0)	42 (75.0)	1.0	
Female	28 (25.7)	81(74.3)	1.0 (0.5 - 2.2)	0.923
Marital status				
Single	11 (52.4)	10 (47.6)	3.9 (1.5 - 10.1)	0.005
Married	28 (22.0)	99 (78.0)	1.0	
Separated/divorced	0 (0.0)	5 (100.0)	-	0.999
Widowed	3 (25.0)	9 (75.0)	1.2 (0.3 - 4.6)	0.814
Level of formal education				
No education	2 (18.2)	9 (81.8)	1.0	
Primary education	21 (21.6)	76 (78.4)	1.2 (0.2 - 6.2)	0.790
Secondary education	14 (31.8)	30 (68.2)	2.1 (0.4 - 11.0)	0.381
Tertiary education	5 (38.5)	8 (61.5)	2.8 (0.4 - 18.7)	0.285
Employment				
Unemployed	14 (21.5)	51 (78.5)	1.0	
Formal employment	12 (41.4)	17 (58.6)	2.6 (1.0 - 6.6)	0.050
Informal employment	16 (22.5)	55 (77.5)	1.1 (0.5 - 2.4)	0.889
Family annual income (KES)				
≤ 50,000.00	27 (23.9)	86 (76.1)	1.0	
50,001.00 - 100,000.00	10 (32.3)	21 (67.7)	1.5 (0.6 - 3.6)	0.347
100,001.00 - 150,000.00	1 (10.0)	9 (90.0)	0.4 (0.0 - 2.9)	0.335
> 150,000.00	4 (36.4)	7 (63.6)	1.8 (0.5 - 6.7)	0.367
Who buys medication				
Self	40 (31.3)	88 (68.7)	1.0	
Spouse	0 (0.0)	14 (100.0)	-	0.998
Child	2 (10.5)	17 (89.5)	0.3 (0.1 - 1.2)	0.080
Employer/Insurance Co.	0 (0.0%)	4 (100.0)	-	0.999

Table 5 shows a summary of comparison of diabetes-related characteristics among the patients with controlled and uncontrolled T2DM in the study. There was statistically significant difference in glycaemic control between patient diabetes education acquired over one year and diabetes education acquired over 6 months prior to the study, p = 0.014 (OR 0.3, 95% CI 0.1 - 0.8). Patient diabetes education acquired over one year was associated with good glycaemic control compared to education acquired over 6 months.

Table 5. Comparison of diabetes-related characteristics among the patients with controlled and uncontrolled T2DM in the study

Characteristic	Controlled glycaemia (HbA1c ≤ 7.0%) *n* (%)	Uncontrolled glycaemia (HbA1c > 7.0%) *n* (%)	OR (95% CI)	*p*-values
Family history of diabetes				
Yes	21 (27.3)	56 (72.7)	1.0	-
No	21 (23.9)	67 (76.1)	0.8 (0.4 - 1.7)	0.616
Diabetes education/update sessions				
None since diagnosis	2 (15.4)	11(84.6)	0.2 (0.0 - 1.1)	0.061
≤ 6 months prior to the study	27 (23.1)	90 (76.9)	0.3 (0.1 - 0.8)	0.014
7-12 months prior to the study	1 (10.0)	9 (90.0)	0.1 (0.0 - 1.1)	0.060
> 1 year prior to the study	12 (48.0)	13 (52.0)	1.0	-
SMBG, glucometer utilization				
Yes	17 (29.8)	40 (70.2)	1.4 (0.7 - 2.9)	0.349
No	25 (23.1)	83 (76.9)	1.0	-
Anti-diabetic medications used				
Oral hypoglycaemic agent(s)[a]	39 (27.9)	101 (72.1)	1.9 (0.2 - 17.1)	0.554
Insulin monotherapy	1 (16.7)	5 (83.3)	1.0	-
Insulin and metformin combination	2 (10.5)	17 (89.5)	0.6 (0.0 - 7.9)	0.689

[a]Metformin ± glibenclamide or gliclazide9.3 Knowledge of diabetes among the study patients

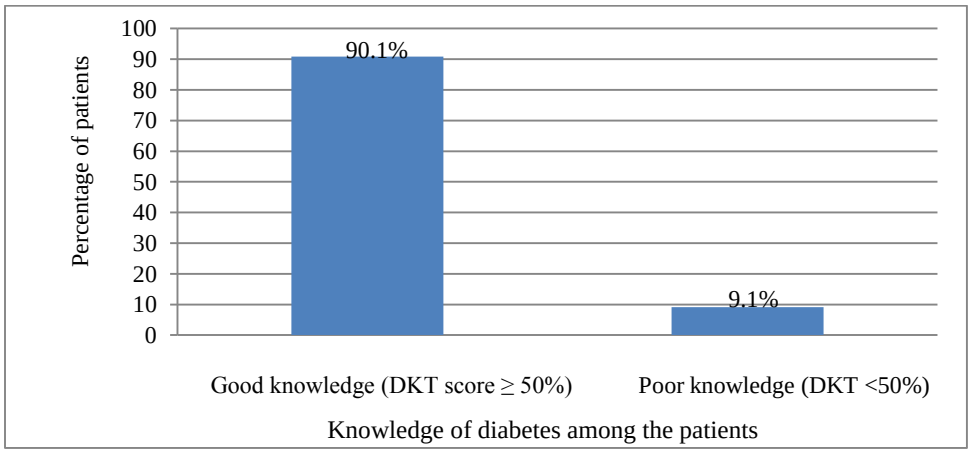

Figure 4. Knowledge of diabetes among the study patients

Figure 4 summarizes the level of knowledge of diabetes among the patients with T2DM in this study. The overall patient knowledge of diabetes, based on the 14-item general knowledge MDRTC diabetes knowledge test, was high. Majority (90.9%) of patients passed the diabetes

Table 6. Comparison of socio-demographic characteristics among patients with good and poor knowledge of diabetes in the study

Characteristic	Knowledge of diabetes, *n* (%)		OR (95% CI)	*p*-value
	Good (DKT ≥ 50%)	Poor (DKT < 50%)		
Gender				
Male	47 (83.9)	9 (16.1)	1.0	
Female	103 (94.5)	6 (5.5)	3.3 (1.1 - 9.8)	0.025
Marital status				
Single	20 (95.2)	1 (4.8)	2.3 (0.3 - 18.4)	0.439
Married	114 (89.8)	13 (10.2)	1.0	
Separated/divorced	4 (80.0)	1 (20.0)	0.4 (0.0 - 4.4)	0.497
Widowed	12 (100.0)	0 (0.0)	-	0.999
Level of formal education				
No education	9 (81.8)	2 (18.2)	1.0	
Primary education	91 (93.8)	6 (6.2)	3.4 (0.6 - 19.2)	0.171
Secondary education	39 (88.6)	5 (11.4)	1.7 (0.3 - 10.4)	0.548
Tertiary education	11 (84.6)	2 (15.4)	1.2 (0.1 - 10.5)	0.855
Employment				
Unemployed	61 (93.8)	4 (6.2)	1.0	
Formal employment	23 (79.3)	6 (20.7)	0.3 (0.1-1.0)	0.045
Informal employment	66 (93.0)	5 (7.0)	0.9 (0.2-3.4)	0.835
Family annual income (KES)				
≤ 50,000.00	104 (92.0)	9 (8.0)	1.0	
50,001.00 -100,000.00	29 (93.5)	2 (6.5)	1.3 (0.3 - 6.1)	0.779
100,001.00 -150,000.00	9 (90.0)	1 (10.0)	0.8 (0.1 - 6.9)	0.882
> 150,000.00	8 (72.7)	3 (27.3)	0.2 (0.1 - 1.0)	0.054
Who buys medication				
Self	118 (92.2)	10 (7.8)	1.0	
Spouse	13 (92.9)	1 (7.1)	1.1 (0.1-9.3)	0.929
Child	16 (84.2)	3 (15.8)	0.5 (0.1-1.8)	0.263
Employer/Insurance Co.	3 (75.0)	1 (25.0)	0.2 (0.0-2.7)	0.254

knowledge test (DKT score ≥ 50%), and were thus considered to have good knowledge of diabetes. Less than one tenth (9.1%) of the patients failed the diabetes knowledge test (DKT score < 50%), and were deemed to have poor knowledge of diabetes. Mean DKT score (± SD) was 64.3 ± 15.3% (range, 14 - 93%). Female patients (62.4%) comprised the majority of the patients with good knowledge of diabetes.

Table 6 demonstrates comparison of socio-demographic characteristics of the patients with good knowledge of diabetes versus the patients with poor knowledge of diabetes. Multivariate analysis revealed female gender was significantly associated with good knowledge of diabetes, $p = 0.025$ (OR 3.3, 95% CI 1.1 - 9.8). There was also statistically significant difference in the knowledge of diabetes between the patients who were unemployed and those in formal employment, $p = 0.045$ (OR 0.3, 95% CI 0.1-1.0). Female gender and unemployment were significantly associated with increased odds of good knowledge of diabetes. There was a trend towards poor knowledge of diabetes among patients with family annual income in excess of Kshs 150,000.00, but this was not statistically significant, $p= 0.054$.

Table 7. Comparison of diabetes-related characteristics among patients with good and poor knowledge of diabetes in the study

Characteristic	Knowledge of diabetes, *n* (%)		OR (95% CI)	*p*-value
	Good (DKT ≥ 50%)	Poor (DKT < 50%)		
Family history of diabetes				
Yes	69 (89.6)	8 (10.4)	1.0	
No	81 (92.0)	7 (8.0)	1.3 (0.5-3.9)	0.587
Diabetes education/update sessions				
None since diagnosis	9 (69.2)	4 (30.8)	0.2 (0.0-1.3)	0.086
≤ 6 months prior to recruitment	109 (93.2)	8 (6.8)	1.2 (0.2-5.9)	0.837
7-12 months prior to recruitment	9 (90.0)	1 (10.0)	0.8 (0.1-9.7)	0.849
> 1 year prior to recruitment	23 (92.0)	2 (8.0)	1.0	
SMBG, glucometer utilization				
Yes	52 (91.2)	5 (8.8)	1.0	
No	98 (90.7)	10 (9.3)	0.9 (0.3-2.9)	0.918
Type of treatment				
Oral hypoglycaemic agent(s) [a]	124 (91.2)	12 (8.8)	1.0	
Insulin monotherapy	4 (100.0)	0 (0.0)	-	0.998
Insulin and metformin	20 (95.2)	1 (4.8)	0.6 (0.1-5.1)	0.603

[a]Metformin ± glibenclamide or gliclazide

Comparison of diabetes-related characteristics of patients with good knowledge of diabetes and those of patients with poor knowledge of diabetes is presented in table 7. Patient knowledge of diabetes was not significantly associated with diabetes-related characteristics, $p > 0.05$. Although there was a trend towards poor knowledge of diabetes among patients not exposed to diabetes education since diagnosis, this was not statistically significant, $p = 0.086$.

9.4 Association of knowledge of diabetes and glycaemic control among the study patients

Table 8 shows comparison of knowledge of diabetes among the study patients with T2DM who had controlled and uncontrolled glycaemia. Multivariate analysis showed knowledge of diabetes was not significantly associated with glycaemic control, $p = 0.910$ (OR 0.9, 95% CI 0.3 - 3.1). Pearson's correlation revealed no significant association between glycaemic control (HbA_{1c}) and knowledge of diabetes (DKT score), $r = -0.042$, $p > 0.05$.

Table 8. Comparison of patient knowledge of diabetes among the patients with controlled and uncontrolled T2DM

Characteristic	Controlled glycaemia ($HbA_{1c} \leq 7.0\%$) *n* (%)	Uncontrolled glycaemia ($HbA_{1c} > 7.0\%$) *n* (%)	OR (95% CI)	*p*-values
Level of diabetes knowledge				
Good knowledge	38 (25.3)	112 (74.7)	0.9 (0.3-3.1)	0.910
Poor knowledge	4 (26.7)	11 (73.3)	1.0	

9.5 Independent associations of glycaemic control with the socio-demographic and diabetes-related characteristics of the study patients

Multiple logistic-regression analysis was performed to identify the independent associations between good glycaemic control and the socio-demographic and diabetes-related characteristics of the study patients. Table 9 illustrates the independent associations of glycaemic control and the characteristics of the patients. Single (marital) status and formal employment were independent determinants of good glycaemic control, $p = 0.013$ (OR 3.6, 95% CI 1.3 - 9.9) and $p = 0.042$ (OR 3.0, 95% CI 1.0 - 8.5) respectively. The only identified predictor of poor glycaemic control was diabetes education/update sessions obtained over a period of not more than six months, $p = 0.022$ (OR 0.3, 95% CI 0.1 - 0.9). There were no independent determinants

of knowledge of diabetes among the socio-demographic and diabetes-related characteristics of the study patients.

Table 9. Independent associations of glycaemic control with socio-demographic and diabetes-related characteristics in the study

Characteristic	Controlled glycaemia (HbA1c ≤ 7.0%) *n* (%)	Uncontrolled glycaemia (HbA1c > 7.0%) *n* (%)	OR (95% CI)	*p*-value
Marital status				
Single	11 (52.4)	10 (47.6)	3.6 (1.3 - 9.9)	0.013
Married	28 (22.0)	99 (78.0)	1.0	
Separated/divorced	0 (0.0)	5 (100)	-	0.999
Widowed	3 (25.0)	9 (75)	1.4 (0.3 - 6.0)	0.615
Employment				
Unemployed	14 (21.5)	51 (78.5)	1.0	
Formal employment	12 (41.4)	17 (58.6)	3.0 (1.0 - 8.5)	0.042
Informal employment	16 (22.5)	55 (77.5)	1.3 (0.5 - 3.1)	0.601
Diabetes education/update sessions				
None since diagnosis	2 (15.4)	11(84.6)	0.3 (0.0 - 1.5)	0.129
≤ 6 mo prior to the study	27 (23.1)	90 (76.9)	0.3 (0.1 - 0.9)	0.022
7-12 mo prior to the study	1 (10.0)	9 (90.0)	0.2 (0.0 - 1.7)	0.138
> 1 year prior to the study	12 (48.0)	13 (52.0)	1.0	-

9.6 Response to specific questions in diabetes knowledge test (DKT)

Table 10 shows a summary of response to specific questions in diabetes knowledge test. None of the patients responded correctly to all the fourteen DKT questions. The three questions most correctly answered were about "the best method for testing blood glucose", "risk mitigated by eating foods low in fat" and "disease usually not associated with diabetes" (appendix 2). Each of these questions was answered correctly by 89.1% of the patients. The four questions most incorrectly answered were about the definition of a "free food", "effect of unsweetened fruit juice on blood glucose", "food that should *not* be used to treat low blood glucose" and “effect of exercise on blood glucose”. These questions were answered correctly by 30.9% to 46.1% of the patients. Other questions answered relatively poorly were on the definition of "diabetes diet", and "the average duration glycosylated haemoglobin (HbA_1c) test measures blood glucose".

The knowledge deficits, based on questions *incorrectly* answered by more than 50% of the patients, were identified in aspects related to diet, treatment of hypoglycaemia and effect of physical activity on blood glucose.

Table 10. Proportion of patients who answered correctly each DKT question

Questions	No. of patients with correct answers (%)
1. The diabetes diet is:	96 (58.2)
2. Which of the following is highest in carbohydrate?	141 (85.5)
3. Which of the following is highest in fat?	118 (71.5)
4. Which of the following is a "free food"?	56 (33.9)
5. Glycosylated hemoglobin (hemoglobin A_{1c}) is a test that is a measure of your average blood glucose level for the past:	92 (55.8)
6. Which is the best method for testing blood glucose?	147 (89.1)
7. What effect does unsweetened fruit juice have on blood glucose?	51 (30.9)
8. Which should not be used to treat low blood glucose?	54 (32.7)
9. For a person in good control, what effect does exercise have on blood glucose?	76 (46.1)
10. Infection is likely to cause:	134 (81.2)
11. The best way to take care of your feet is to:	122 (73.9)
12. Eating foods lower in fat decreases your risk for:	147 (89.1)
13. Numbness and tingling may be symptoms of:	133 (80.6)
14. Which of the following (diseases) is usually not associated with diabetes?	147 9.1)

9.7 Adherence to medications among the study patients

Adherence to medication among the study patients with T2DM is described in figure 5. The level of good adherence to medications (MMAS = 0 point) was low at 37.6%, female (23.7%) more than male patients (13.9%). Non-adherence to medications (MMAS = 1 - 4 points) was high (62.4%), with females 42.4% and males 20%. The mean age of patients with good adherence to medication was 56.1 years, while that for patients with non-adherence to medication was 55.5 years. Median duration of diabetes mellitus for patients with good adherence to medication was 4.5 years and that for patients with non-adherence to medication was 5.1 years.

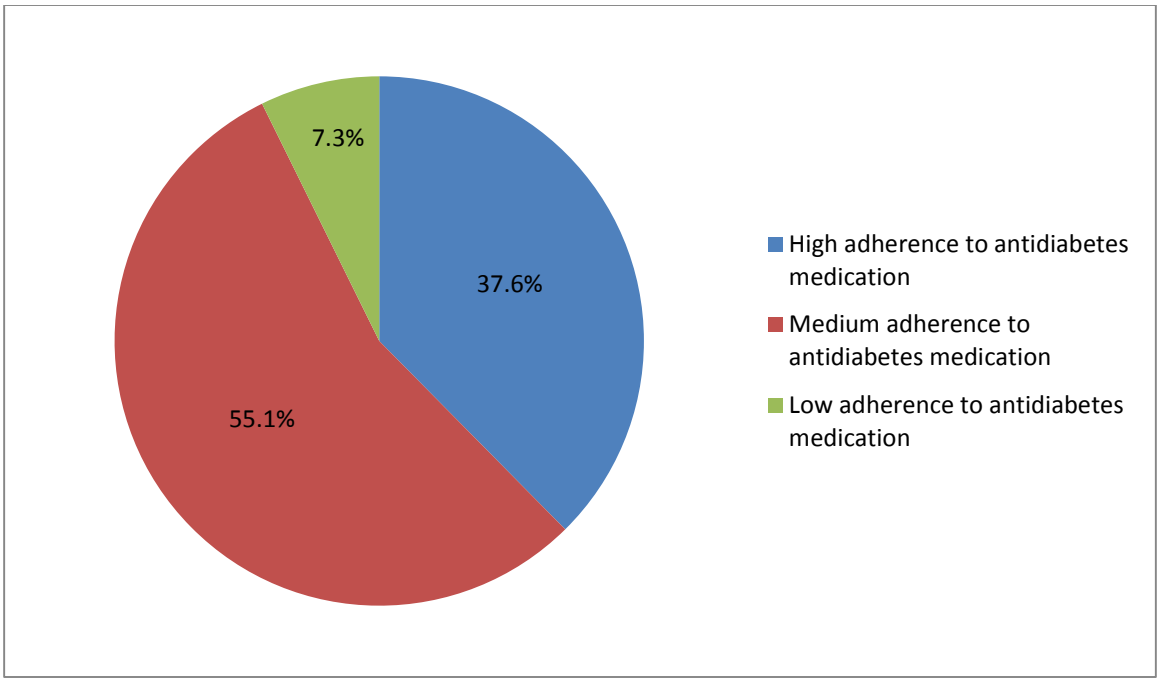

Figure 5. Adherence to medications of study patients as assessed by modified Morisky medication adherence scale

Table 11 summarizes the association of non-adherence to medications and socio-demographic characteristics of the study patients. There were statistical significant differences in non-adherence to medications between the patients with estimated family annual income of less Ksh. 50,000.00 and patients with income of Ksh. 50,001.00 - 100,000.00, p = 0.043 (OR 2.3, 95% CI, 0.0 - 5.2). The proportion of patients found non-adherent to medications was comparatively higher in the former income bracket. Statistically significant differences in non-adherence to medications were also observed among patients whose medications were procured by their spouses versus those who bought themselves medications, p = 0.030 (OR 0.1, 95% CI, 0.0 - 0.8). Family annual income of less Ksh. 50,000.00 and provision of medications by spouses of patients were associated with increased odds of non-adherence to medications.

Table 11. Association of adherence to medications and socio-demographic characteristics of the study patients

Characteristic	Adherence *n* (%)	Non-adherence *n* (%)	OR (95% CI)	*p*-value
Gender				
Male	23 (41.1)	33 (58.9)	1.0	
Female	39 (35.8)	70 (64.2)	0.8 (0.4 - 1.6)	0.507
Marital status				
Married	46 (36.2)	81 (63.8)	1.0	
Single	11 (52.4)	10 (47.6)	2.2 (0.8 - 5.6)	0.115
Separated/divorced	1 (20.0)	4 (80.0)	0.4 (0.1 - 4.1)	0.469
Widowed	4 (33.3)	8 (66.7)	0.7 (0.2 - 2.2)	0.583
Level of formal education				
No education	5 (45.4)	6 (54.6)	1.0	
Primary education	32 (33.0)	65 (67.0)	0.6 (0.2 - 2.1)	0.413
Secondary education	19 (43.2)	25 (56.8)	0.9 (0.2 - 3.4)	0.892
Tertiary education	6 (46.1)	7 (53.9)	1.0 (0.2 - 5.2)	0.973
Employment				
Unemployed	22 (33.8)	43 (66.2)	1.0	
Formal employment	13 (44.2)	16 (55.2)	1.6 (0.7 - 4.0)	0.294
Informal employment	27 (38.0)	44 (68.0)	1.2 (0.6 - 2.5)	0.577
Family annual income (KES)				
≤ 50,000.00	39 (34.5)	74 (65.5)	1.0	
50,001.00 - 100,000.00	17 (54.8)	14 (45.2)	2.3 (1.0 - 5.2)	0.043
100,001.00 - 150,000.00	1 (10.0)	9 (90.0)	0.2 (0.0 - 1.7)	0.147
> 150,000.00	5 (45.4)	6 (54.6)	1.6 (0.5 - 5.5)	0.472
Who buys medication				
Self	55 (43.0)	73 (57.0)	1.0	
Spouse	1 (7.1)	13 (92.9)	0.1 (0.0 - 0.8)	0.030
Child	6 (31.6)	13 (68.4)	0.6 (0.2 - 1.7)	0.350
Employer/Insurance Co.	0 (0.0)	4 (100.0)	-	-

Table 12 shows a summary of the association of non-adherence to medications and diabetes-related characteristics of the study patients. There were statistically significant differences in non-adherence to medications between patient diabetes education obtained for 7-12 months compared to diabetes education gained for a period of over one year, p = 0.031 (OR 0.1, 95% CI 0.1 - 0.8). Patient diabetes education obtained over 7-12 months was associated with non-adherence to medications compared to exposure to diabetes education over more than one year.

There were statistically significant differences in non-adherence to medications between patients taking one OHA and those taking two OHAs, p = 0.004 (OR 0.3, 95% CI 0.1 - 0.7). There were also significant differences in non-adherence to medications between patients taking one OHA and those on the combination of insulin and OHA, p = 0.001 (OR 0.1, 95% CI 0.0 - 0.3). Treatment with two OHAs and combined insulin with one OHA was associated with non-adherence to medications compared to treatment with a single OHA.

Table 12. Association of adherence to medications and diabetes-related characteristics of study patients

Characteristic	Adherence *n* (%)	Non-adherence *n* (%)	OR (95% CI)	*p*-values
Family history of diabetes				
Yes	32 (41.6)	45 (58.4)	1.0	
No	30 (34.1)	58 (65.9)	0.7 (0.4 - 1.4)	0.324
Diabetes education/update sessions				
None since diagnosis	4 (30.8)	9 (69.2)	0.4 (0.1 - 1.4)	0.146
≤ 6 months prior to the study	43 (36.7)	74 (63.3)	0.5 (0.2 - 1.1)	0.079
7-12 months prior to the study	1 (10.0)	9 (90.0)	0.1 (0.0 - 0.8)	0.031
> 1 year prior to the study	14 (56.0)	11 (44.0)	1.0	
SMBG, glucometer utilization				
Yes	25 (43.9)	32 (56.1)	1.0	
No	37 (34.3)	71 (65.7)	0.7 (0.4 - 1.3)	0.227
Type of treatment				
OHA (1) – metformin only	17 (68.0)	8 (32.0)	1.0	
OHAs (2)[a]	41 (35.7)	74 (64.3)	0.3 (0.1 - 0.7)	0.004
Insulin monotherapy	2 (33.3)	4 (66.7)	0.2 (0.0 - 1.6)	0.134
Insulin/metformin combination	2 (10.5)	17 (89.5)	0.1 (0.0 - 0.3)	0.001

[a]Metformin ± glibenclamide or gliclazide

9.8 Association of adherence to medications with glycaemic control and knowledge of diabetes in study

The association of adherence to medications with glycaemic control and knowledge of diabetes of the study patients is presented in table 13. Multivariate analysis showed no significant association between non-adherence to medications and poor glycaemic control, $p = 0.061$ (OR 0.2, 95% CI, 0.1 - 0.3). Similarly, adherence to medications was not significantly associated with knowledge of diabetes, $p = 0.905$ (OR 1.1, 95% CI, 0.3 - 3.4).

Table 13. Association of adherence to medications with glycaemic control and knowledge of diabetes in study

Characteristic	Adherence *n* (%)	Non-adherence *n* (%)	OR (95% CI)	*p*-values
Glycaemic control				
Controlled glycaemia (HbA1c < 7.0%)	38 (23.0)	4 (2.4)	1.0	
Uncontrolled glycaemia (HbA1c > 7.0%)	24 (14.5)	99 (60)	0.2 (0.1 - 0.3)	0.061
Patient knowledge of diabetes				
Good knowledge (DKT ≥ 50%)	59 (35.8)	91(55.2)	1.1 (0.3- 3.4)	0.905
Poor knowledge (DKT < 50%)	3 (1.8)	12 (7.3)	1.0	

10. DISCUSSION

This study was set out to determine adequacy of glycaemic control, levels of patient knowledge of diabetes and adherence to medication, as well as factors associated with glycaemic control, patient knowledge of diabetes and non-adherence to anti-diabetic medications among the ambulatory adult patients with type 2 diabetes mellitus (T2DM) in a managed care setting. The study was conducted among 165 patients with T2DM, who were mostly of low income status. There was a female predominance (66.1%), which probably reflected preferential attendance of the diabetic clinic rather than the national proportions. It was not clear why there was a female predominance, but it has been postulated to be a reflection of better health-seeking habits of females.[51,52]

The findings in this study were remarkably consistent with the findings in previous local studies and broadly agreed with published data elsewhere. There was evident low adequacy and level of glycaemic control (25.5%), with coincident high level of patient knowledge of diabetes (90.9%) and low level of adherence to medications (37.6%). The mean HbA_1c level was 9.5%, a figure higher than the recommended desired target of optimal glycaemic control by ADA, $HbA_1c < 7\%$. Thirty five percent of the patients (corresponding to nearly a half of the poorly controlled patients) had HbA_1c level of more than 10%, which reflected possible non-adherence to medications and/or inertia in management of diabetes by the prescribers. From the large number of patients with poor glycaemic control (74.5%), it was possible that, at the time of this study, a considerable proportion of these patients already required insulin therapy or oral anti-diabetic agents (either singly or in combination) were sub-optimal in doses.

Several studies from developing and developed countries have reported sub-optimal glycaemic control among most patients with T2DM.[20-27] Previous local studies at Kenyatta National Hospital (KNH)[20-23] have revealed low levels of glycaemic control, similar to the finding in this study. The levels vary, and range from 13.9 - 39.5%.[20,21] The large difference may be explained by HbA_1c cut-off levels used for assessment of glycaemic control by the investigators in the studies. Masoud SR, in a study on quality of glycaemic control among insulin-treated ambulatory diabetic patients (2011), using a cut-off level for HbA_1c of less than 7.0% found glycaemic control of 13.9%,[20] while Otieno CF et. al., in a similar study on T1DM and T2DM (1998), using

HbA_1c cut-off level of ≤ 8.0% (being the level achieved in the conventionally treated diabetic patients) found glycaemic control of 39.5%.[21] In studies involving T2DM patients, using HbA_1c cut-off level of ≤ 7.0%, Vaghela VP (2001) and Omari BG (2013) documented comparable levels of glycaemic control of 29.9% and 29.5% respectively.[22,23] Mwavua SM et. al., in 2016 noted a much lower level of glycaemic control of 17% in a multicentre comparative study of the quality of care and glycaemic control among ambulatory T2DM patients at KNH and Thika District Hospital (a peripheral urban level IV hospital),[24] suggesting that poor glycaemic control may be widespread.

The observational, cross-sectional multicentre study among T2DM patients in seven European countries (Finland, France, Germany, Norway, Poland, Spain and UK) between 2006 - 2007, by Alvarez GF et al., reported adequate glycaemic control among 25.5% of the patients after a mean of 2.6 years following initiation of combination OHA therapy,[26] which was similar to the finding in our study. In contrast to our findings, Pascal IGU et. al., in a study on blood glucose control and adherence to medications among adult T2DM Nigerians attending a primary care clinic in Eastern Nigeria, found high rates of both glucose control and adherence to medication, 61.7% and 72.5% respectively.[53] In that study blood glucose control was significantly associated with adherence to medication. CF Otieno et. al. in the study at KNH attributed poor glycaemic control to erratic supply of medications to the hospital, high cost of anti-diabetic medications (particularly insulin) and inaccessibility to medications in a low-income group that largely relied on the hospital to cater for nearly all of its requirements for diabetes care,[21] In our study, sub-optimal glycaemic control may have been in part due to low-income status of the patients that impacted on access to adequate healthcare services and thus adherence to medications. It is also possible that erratic supplies of medications to hospital, high cost of anti-diabetic medications and inaccessibility to medications, observed by CF Otieno et. al. in their study at KNH, may have similarly significantly influenced glycaemic control in this low-income study population dependent on the hospital in under-resourced environment for almost its entire needs for diabetes self-care.

Factors associated with good glycaemic control in this study were patient diabetes education acquired over one year prior to study entry, formal employment and single (marital) status. Independent determinants of good glycaemic control were single (marital) status and formal employment, while the predictor of poor glycaemic control was diabetes education received within 6 months prior to the study entry. Association of glycaemic control and diabetes education acquired over one year prior to study entry was attributed to possible internalized and well utilized gained knowledge of diabetes, while association of glycaemic control and formal employment was likely due to the ability of the employed patients to meet the cost of medical care, including medications. Association of glycaemic control and single (marital) status was probably due to good knowledge of diabetes and some financial ability from employment; 95.2% of the patients had good knowledge of diabetes (table 6), and 76.2% of them were in gainful employment and thus able to cater for their medical care.

This study observed a high level of patient knowledge of diabetes. The level of 90.9% observed was to some degree comparable with the level of knowledge of diabetes of 77.2 % reported by Omari BG in a related study at KNH (2013), using SKILLD questionnaire.[23] Odili VU. et al. in Nigeria, in contrast, using DKT found a low level of knowledge of diabetes (39.5 %), which was considered to be due to the form of diabetes education or prevailing cultural beliefs about diabetes.[54] Elkharam WM et. al., in a study of knowledge of diabetes and adherence to health advice among adults with diabetes in Libya, found low level of glycaemic control (14%) and, unlike in our study, poor knowledge of diabetes (48.6%). The findings were attributed to poor health education programs, and long duration of the illness that resulted in despair.[30] In our study the level of knowledge of diabetes may have reflected quality of DSME offered at the healthcare facility and the relative high literacy level of the patients. Factors associated with patient knowledge of diabetes in this study were female gender and unemployment. The association between knowledge of diabetes with female gender was likely due to the postulated better health-seeking habits of females[51,52] and hence possible acquisition of high knowledge of diabetes for diabetes self-care. The association of knowledge of diabetes and unemployment was attributed to the unemployed having ample time to interact and consequently acquire substantial knowledge of diabetes; mostly patients who declined to participate in the study were the employed, who reportedly due to exigency of work needed to urgently return to their workplaces (figure 2).

Knowledge deficits were identified in areas related to diet, treatment of hypoglycaemia and physical activity. These findings suggested possible association of sub-optimal glycaemic control with poor dietary practices and inadequate physical activity (not helpful for glycaemic control) in this study population. It is likely that poor dietary practices and inadequate physical activity may have contributed to sub-optimal glycaemic control in this study. These findings were similar to the observations in the studies in Jordan and Saudi Arabia, which noted significant association of poor glycaemic control with poor adherence to appropriate dietary advice and physical activity.[55-57] Omari BG, in a study in KNH, found poor glycaemic control and poor physical activity (in 83% of the study subjects); in the study appropriate dietary practices were well observed.[23] Maina WK, et. al. in a study on knowledge, attitude and practices related to diabetes among community members in four regions in Kenya reported poor knowledge of diabetes (70%) with knowledge gaps in dietary practices (25%) and adherence to physical exercises (28%).[58] Identified knowledge gaps in that study were similar to the gaps noted in our study, which suggested possible high prevalence of these gaps in the general population. Al-Adsani A.M., et al. in study on the level and determinants of diabetes knowledge in Kuwaiti adults with T2DM, conducted in a T2DM population with limited family income, observed knowledge deficits in diet.[59] Unlike in our study, the population in that study had high prevalence of illiteracy. Speight J., et al, in UK in a study on identifying knowledge deficits in diabetes care noted deficits in areas related to diet and prevention of hypoglycaemia like in our study.[60]

The adherence to medications in this study was low (37.6%). The level of non-adherence to anti-diabetes medications of 62.4% was higher than that reported in a local study in 2013 at KNH by Omari BG (39.8%)[23] and in a study in the Eastern Nigeria by Pascal IGU, et al. in 2012 (27.5%).[53] It was lower than the level of 74% reported in the study by Sankar UV, et al., in the rural Kerala, India.[61] The latter study attributed its high rate of non-adherence to limited diabetes education, low per capita monthly expenditure, lack of family support, use of OHAs and irregular blood glucose monitoring. In our study, the factors associated with non-adherence to medications were low family income, patient diabetes education gained 7-12 months prior to the study entry, use of multiple anti-diabetes drug regimens and if the spouse of the patient provided medications. Association of non-adherence to medication with low family income was possibly because of inability to access medications due to financial limitations. Pascal IGU, et al., in the

study in the Eastern Nigeria, and Shaimol T, et al., in a study in Kerala, India, documented low-income as a factor significantly associated with non-adherence to medications.[53,62] Association of non-adherence to medications and patient diabetes education gained 7-12 months prior to the study entry was probably a result of the effect of inadequate conceptualized and internalized knowledge of diabetes. Association of non-adherence to medication and multiple anti-diabetes drug regimens was possibly due to the inability of the patients to meet the high cost of multiple anti-diabetes drug regimens.

In this study knowledge of diabetes was not significantly associated with glycaemic control, neither was non-adherence to medications associated with glycaemic control. Further, there was no significant association between non-adherence to medications and knowledge of diabetes. The dissociation between patient knowledge of diabetes and glycaemic control has been noted in various studies. Omari BG, in a study at KNH reported similar findings.[23] Islam SS et. al. in their study in 2015 in a tertiary hospital in Dhaka, Bangladesh, similarly reported no association; the study attributed that finding to lack of access to healthcare for the general population.[29] Positive association has been observed in a study by Bains SS et. al. in a primary care clinic among 125 patients with T2DM with low income in South Carolina community (US)[32] and Al-Qazaz HK et. al in a study in Hospital Pulau Penang, Malaysia.[63] In our study the dissociation of knowledge of diabetes and glycaemic control was not unusual because patient knowledge of diabetes is only a component of diabetes care, and knowledge does not invariably translate to good diabetes practice to facilitate adequate glycaemic control. Knowledge of diabetes is vital but may not be sufficient if other factors for glycaemic control and diabetes self-care (e.g., attitude, habit and behavioural change, income and inertia in patient management) are not suitably addressed and met to abate non-adherence to medication. In this study knowledge of diabetes may not have affected behaviour in the study population most likely due to patients' low socio-economic status, significantly affecting adherence to diabetic diet and medications.

11. CONCLUSION

There was evident dissociation between the levels of knowledge of diabetes and both glycaemic control and adherence to anti-diabetic medication. The patients demonstrated sub-optimal glycaemic control and adherence to medications despite good knowledge of diabetes, implying that diabetes knowledge did not translate to optimal adherence to medication and glycaemic control, and that the demands of glycaemic control stretch beyond patient knowledge of diabetes. Interventions need to focus on strategies in Diabetes Self-Management Education (DSME) program to assist T2DM patients with limited income and poor glycaemic control to manage their disease effectively. Further, strategies aimed at augmenting provision of diabetes education should be enhanced to improve patient adherence to medications. Knowledge deficits identified in this study, and other factors associated with poor glycaemic control and adherence to medications, should be promptly addressed by the relevant authorities to facilitate adequate glycaemic control.

12. RECOMMENDATIONS

Arising from these study results it is recommended that:

1. studies to address barriers that influence glycaemic control and adherence to medication, and improvement of knowledge of diabetes are highly required.
2. provision of skills in DSME program should be scaled up; mostly diabetes education is didactic.
3. areas of knowledge gaps, particularly lifestyle modification (dietary changes and enhanced physical activity) need to be addressed in DSME as this might influence glycaemic control and development of diabetes-related complications.

13. STUDY LIMITATIONS

1. Parts of the data were based on patient self-reports and therefore validity of such data could not be verified.
2. Generalizability of the study is limited given that the study was hospital based, and the majority of the study patients were in low income bracket.
3. The study was not powered enough to determine the association between glycaemic control, knowledge of diabetes and adherence to medication among T2DM patients.

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APPENDICES

Study on adequacy of glycaemic control and knowledge of diabetes among ambulatory patients with type 2 diabetes at Mbagathi District Hospital, Nairobi

Appendix 1: Proforma for socio-demographic and diabetes-related data

Date: _____

Study number: _____ Medical file no. _____

SOCIO-DEMOGRAPHIC AND DIABETES-RELATED DATA

1. Sex: *(Tick appropriately)* Male/Female
2. Date of birth _____ years
3. Age: _____ years
4. Marital status *(Tick appropriately)*

   Single _____ Married _____

   Divorced/separated _____ Widowed _____
5. Date of diagnosis of diabetes (month/year): _____
6. Duration of diabetes (*months/yrs*) _____
7. Family history of diabetes *(Tick appropriately)*: Yes _____ No _____
8. Level of formal education *(Tick appropriately)*

   No formal education_____ Primary level _____

   Secondary level _____ Tertiary level _____
   (Diploma/Degree)

   Other *(Specify)* _____
9. Employment *(Tick appropriately)*

   Unemployed _____

   Employed: Formal _____

   Informal _____
   Business, farming, etc *(Specify)*

10. Date previous diabetes education received *(Tick appropriately)*:

    None _____ At diagnosis *only* _____ ≤ 6months ago _____

    7-12 months ago _____ ≥ 1 year ago _____

11. Family annual income

    ≤ Ksh 50,000.00 _____ Ksh 50,001.00 - 100,000.00_____

    Ksh 100,001.00 - 150,000.00_____ > Ksh 150,000.00 _____

12. Do you measure of your blood glucose at home? Yes _____ No _____

13. Prescribed diabetes drug(s): _____

    _____

14. Who buys medications for you? *(Tick appropriately)*: Self _____ Parent(s) _____

    Child _____ Employer _____ Health insurance _____ Others *(Specify)* _____

15. Use of alternative/herbal medicine *(Tick appropriately)*: Yes/No

LABORATORY TEST RESULTS

1. Serum HbA_{1c} _____ %

Appendix 2

Study on adequacy of glycaemic control and knowledge of diabetes among ambulatory patients with type 2 diabetes at Mbagathi District Hospital, Nairobi

STUDY QUESTIONNAIRE (English)

Michigan Diabetes Research Training Center (MDRTC) diabetes knowledge test

Please answer the following questions about your knowledge and skills on diabetes.

1. The diabetes diet is:
   a. the way most American people *(or general population)* eat
   b. a healthy diet for most people*****
   c. too high in carbohydrate for most people
   d. too high in protein for most people
2. Which of the following is highest in carbohydrate?
   a, Baked chicken *(chicken)*
   b. Swiss cheese *(cheese)*
   c. Baked potato *(potato)******
   d. Peanut butter *(ground-nut)*
3. Which of the following is highest in fat?
   a. Low fat milk*****
   b. Orange juice
   c. Corn *(maize)*
   d. Honey
4. Which of the following is a "free food" *(additional low calorie food to the main meals)*?
   a Any unsweetened food *(no added sugar)*
   b. Any dietetic food *(food for a specific dietary need or restriction)*
   c. Any food that says "sugar free" on the label
   d. Any food that has less than 20 calories per serving *(as recommended for snacks in diabetes)******
5. Glycosylated hemoglobin (hemoglobin A_{1C}) is a test that is a measure of your average blood glucose level for the past:
   a. day
   b. week
   c. 6-10 weeks*****
   d. 6 months
6. Which is the best method for testing blood glucose?
   a. Urine testing
   b. Blood testing*****
   c. Both are equally good
7. What effect does unsweetened fruit juice have on blood glucose?
   a. Lowers it
   b. Raises it*****
   c. Has no effect

Michigan Diabetes Research Training Center (MDRTC) diabetes knowledge test

8. Which should not be used to treat low blood glucose?
   a. 3 hard candies *(sweets)*
   b. ½ cup orange juice
   c. 1 cup diet soft drink*****
   d. 1 cup skim milk

9. For a person in good control, what effect does exercise have on blood glucose?
   a. Lowers it*****
   b. Raises it
   c. Has no effect

10. Infection is likely to cause:
   a. an increase in blood glucose*****
   b. a decrease in blood glucose
   c. no change in blood glucose

11. The best way to take care of your feet is to:
   a. look at and wash them each day*****
   b. massage them with alcohol each day
   c. soak them for one hour each day
   d. buy shoes a size larger than usual

12. Eating foods lower in fat decreases your risk for:
   a. nerve disease
   b. kidney disease
   c. heart disease*****
   d. eye disease

13. Numbness and tingling may be symptoms of:
   a. kidney disease
   b. nerve disease*****
   c. eye disease
   d. liver disease

14. Which of the following is usually not associated with diabetes?
   a. vision problems
   b. kidney problems
   c. nerve problems
   d. lung problems*****

*******Correct answers*
Items in brackets are terms by which the foods are known locally.

Appendix 3

Study on adequacy of glycaemic control and knowledge of diabetes among ambulatory patients with type 2 diabetes at Mbagathi District Hospital, Nairobi

STUDY QUESTIONNAIRE (Kiswahili)

Michigan Diabetes Research Training Center (MDRTC) diabetes knowledge test

Tafadhali jibu maswali yafuatayo kuhusu elimu na ujuzi wako kuhusu ugonjwa wa kusukari

1. Mlo wa watu walio na ugonjwa wakisukari ni isharaya:
   a. Namna watu kutoka Marekani wanavyokula
   b. Mlo wenye afya bora kwa waliowengi
   c. Vyakula vilivyo na madini ya kabohaidreti ya kiwango cha juu kwa waliowengi
   d. Vyakula vilivyo na madini ya protini ya kiwango cha juu kwa waliowengi
2. Ni chakula kipi kilicho na viwango vikubwa vya madini ya kabohaidreti kati ya vyakula vifuatavyo?
   a. Kuku wakuoka
   b. Chizi au jibini ya Uswisi
   c. Viazi vyavkuoka
   d. Siagi ya njugu
3. Ni chakula kipi kilichona viwango vikubwa vya mafuta kati ya vyakula vifuatavyo?
   a. Maziwa yenye viwango duni vya mafuta
   b. Maji ya machungwa
   c. Mahindi
   d. Uki
4. Ni chakula kipi kilicho “huru” kati ya vyakula vifuatavyo?
   a. Aina yoyote ya chakula kisicho ongezwa sukari
   b. Aina yoyote ya chakula kinachotumiwa na wagonjwa
   c. Aina yoyote ya chakula chenye vibandiko vilivyo andikwa maneno “hakina sukari”
   d. Aina yoyote ya chakula kilicho na kiwango cha kalori ishirini kwa kila mlo
5. Aina ya kupima kiwango cha sukari katika damu inayo tajwa kama Hemoglobini A_1c inatumiwa kupima sukari hiyo:
   a. Kila siku
   b. Kila wiki
   c. Kuanzia wiki sita hadi kumi
   d. Kila miezi sita
6. Ni njia ipi kati ya hizi zifuatazo ambayo ni bora zaidi unapopima viwango vya sukari katika damu (mwilini)?
   a. Kupima mkojo
   b. Kupima damu
   c. Zote mbili – kupima mkojo na hata damu

Michigan Diabetes Research Training Center (MDRTC) diabetes knowledge test

7. Maji ya matunda isiyo ongezwa sukari ina athiri vipi viwango vya sukari mwilini?
   a. Inapungu za sukari hiyo
   b. Inaonge za sukari hiyo
   c. Haina athari yoyote
8. Ni ipi kati ya njia zifuatazo ambayo si mwafaka unapotibu viwango duni vya sukari mwilini?
   a. Peremende tatu ngumu
   b. Nusu kikombe cha maji ya machungwa
   c. Kikombe kimoja cha kinywaji kisicho na sukari
   d. Kikombe kimoja cha maziwa yaliochujwa mafuta
9. Je mazoezi yana athari gani kwa mtu aliyedhibiti kiwango chake cha sukari mwilini?
   a. Yanapunguza sukari hiyo
   b. Yanaongeza sukari hiyo
   c. Haina athari yoyote
10. Maambukizi ya ugonjwa yanaweza kusababisha:
   a. Kuinuka kwa kiwango cha sukari mwilini
   b. Kupunguka kwa kiwango cha sukari mwilini
   c. Hayana athari ya aina yoyote
11. Njia bora ya kutunza miguu yako ni:
   a. Kuitizama na kuiosha kila siku
   b. Kuipapasa na mvinyo wa pombe kila siku
   c. Kuitia katika maji kwa saa moja kila siku
   d. Kununua viatu saizi inayozidi ya kawaida
12. Kula vyakula vyenye viwango duni vya mafuta kunapunguza uwezekano wa:
   a. Ugonjwa wa mishipa
   b. Ugonjwa wa figo
   c. Ugonjwa wa moyo
   d. Ugonjwa wa macho
13. Kufa ganzi na kuwashwa ni moja wapo ya ishara ya:
   a. Ugonjwa wa figo
   b. Ugonjwa wa mishipa
   c. Ugonjwa wa macho
   d. Ugonjwa wa ini
14. Ni dalili ipi kati ya zifuatazo ambayo haiashirii ugonjwa wa kisukari?
   a. Shida za macho
   b. Shida za figo
   c. Shida za mishipa
   d. Shida za pafu

Appendix 4

4-point Modified Morisky medication adherence scale

1. Do you ever forget to take your anti-diabetes medicine? (Yes/No)
2. Do you ever have problems remembering to take your anti-diabetes medication? (Yes/No)
3. When you feel better, do you sometimes stop taking your anti-diabetes medicine? (Yes/No)
4. Sometimes if you feel worse when you take your anti-diabetes medicine, do you stop taking it? (Yes/No)

Scoring: “Yes” = 0, and “No” = 1, Range: 0-4.
High adherence: 0 (patients answering "yes" to 0 items), Medium adherence: 1-2, Low adherence: 3-4

Appendix 5

4-point Modified Morisky adherence scale (Kiswahili version)

1. Je, unasahau kujidunga insulin au kutumia tembe za sukari wakati mwengine? (Ndio/ La)
2. Je, unapata shida kukumbuka kujidunga insulin au kumeza tembe za sukari wakati mwengine? (Ndio/La)
3. Je, ukisikia umepata nafuu unaacha kujidunga insulin au kumeza tembe za–sukari wakati mwengine? (Ndio/La)
4. Je, wakati mwengine ukisikia vibaya unpojidunga insulin au kumeza tembe za sukari, unaacha kujidunga au kutumia tembe? (Ndio/La)

Appendix 6

Study on adequacy of glycaemic control and knowledge of diabetes among ambulatory patients with type 2 diabetes at Mbagathi District Hospital, Nairobi

PATIENT CONSENT EXPLANATION FORM (English)

I, Dr. Andrew AK Okwera, am a postgraduate student at the Department of Clinical Medicine and Therapeutics, University of Nairobi. I am the principal investigator in a research study that we are conducting at Mbagathi District Hospital, Nairobi. The objective of the study is to assess adequacy of glycaemic (blood sugar) control and knowledge of diabetes among ambulatory type 2 diabetic patients.

The issues to be evaluated in the study are adequacy of blood sugar control, and the factors that affect the control of blood sugar and the knowledge of diabetes among patients with diabetes. We do not know what these factors are among patients with diabetes in Kenya. We would like to know these factors because many diabetic patients have poor control of blood sugar, which leads to complications of diabetes. Hence, this study will generate information that will help improve blood sugar control and diabetes self-care, and minimize diabetic complications among patients with diabetes.

Assessment of blood sugar control and diabetes knowledge in this study entails that you take a diabetes knowledge test, give information about yourself and your illness (guided by structured questions under the assistance of the research team) and undergo a *free* blood sugar test known as HbA_1c test, in addition to your usual routine laboratory tests. HbA_{1c} test helps to determine the level of your blood sugar control over the period of the last 6-10 consecutive weeks.

The immediate benefits of this study to you include obtaining information on your blood sugar control and knowledge of diabetes. This will help you seek appropriate advice, and additional treatment for good blood sugar control from your attending doctor, particularly if you have poor blood sugar control.

There will be no risks involved during your participation in this study. However, needle prick may cause you some discomfort while blood is drawn. This is no different from the discomfort felt when blood is drawn for any other tests. To ensure confidentiality your questionnaires and laboratory request form will not bear your name, and your medical records and data obtained for the study will be accessible to authorized persons only. You and your doctor will be allowed access to this information promptly for advice and further treatment, particularly if you have poor blood sugar control.

We will highly appreciate your participation in this study, which should be voluntary. Your will be required to give written informed consent prior to recruitment into the study. The principal investigator and/or the trained research assistants will consent you for participation. You can decline to participate in the study or elect to opt out of the study at any point without losing any benefits or interference with quality of your care in the hospital.

If you accept to participate in this study, please sign the consent.

Contacts

For further information, you may contact any of the following:

Dr. AK Okwera - Principal investigator
Tel.: 0727952267

Prof. CF Otieno - Supervisor
Tel.: 0722752558

The Kenyatta National Hospital/University of Nairobi Ethics and Research Committee
(KNH/UON-ERC)
Tel.: (020) 2726300 ext. 44355

Appendix 7

Utafiti kuhusu njia faafu za kudhibiti sukari mwilini na kuthamini viwango vya elimu vya wangojwa wa kisukari aina ya pili ambao wasiolazwa katika hospitali ya wilaya ya Mbagathi, Nairobi.

FOMU YA KUFAFANUA IDHINI YA MGONJWA (Kiswahili)

Mimi, Daktari Andrew AK Okwera, ni mwanafunzi wa shahada ya upili katika idara ya matibabu na therapatikia ya chuo kikuu cha Niarobi. Mimi ni mtafiti mkuu katika utafiti unaoendeshwa katika Hospital ya wilaya ya Mbagathi, jijini Naitobi. Lengo ku la utafiti huu in kubaini namna za kudhibiti ugonjwa wa kisukari na viwango vya elimu ya wale wanaokumbwa na ugonjwa wa kisukari wasiolazwa.

Maswala yatakayo shughulikwa kwenye utafiti huu ni jinsi za kukabidhi ugonjwa wa kisukari na viwango mbali mbali vya elimu kati ya wagonjwa wa kisukari. Hatuelewi kwa uhakika maswala yote yanayoambatana na ugonjwa huu baina ya wangonjwa wenyewe nchini Kenya. Tungependa kujuwa maswala haya kwa sababu wagonjwa wengi wa kisikari hawana njia madhubuti za kudhibiti ugonjwa wenyewe, na hii husababisha madhara mengi ya ugonjwa wa kisukari. Kwa hivyo utafiti huu utaibwa habari muhimu za kuboresha jinsi ya kudhibiti ugonjwa, kujifunza kwa njia mwafaka na kupunguza madhara ya ugonjwa wa kisukari kwa wagonjwa wa kisukari.

Uchunguzi wa kudhibiti ugonjwa wa kisukari na viwango vya elimu ya ugonjwa wa kisukari kwenye utafiti huu wahitaji ~~(utahiniwe)~~ ufanye mtihani wa elimu ya ugonjwa wa kisukari, kujieleza kuhusu ugonjwa wako (kupitia mwaswali maalum yaliyotungwa ambayo yataongozwa na wadadizi wa utafiti huu) na kupimwa sukari mwilini kwa uchunguzi ambao unajulikana kama HbA_{1c} test bila malipo yoyote, pamoja na uchunjizi wa kawaida. Uchunjizi wa HbA_{1c} test unasaidia kubainiwa kiwango cha kudhibiti sukari mwilini kwa majuma sita hadi kumi yaliyopita.

~~F~~aida muhimu kwako zitakazopatikana kutokana na utifiti huu ni kuweza kujua udhibiti wa kiwango cha sukari mwilini na kiwango chako cha elimu kuhusu ungonjwa wa kisukari. Hii itakuwesha kupata mashauri mwafaka na matibabu bora ya kudhibiti hali yako ya sukari mwilini kutoka kwa dakatari wako, haswa ukiwa na kiwango cha sukari mwilini ambacho ni hafifu.

Hakuna madhara yatakayokupata ukihusika kwenye utafiti huu. Lakini kudungwa sindano kunaweza kukakuletea uchungu kidogo wakati wa kutolewa damu. Hii ni sawa na uchungu ule unaosikika wakati unapotolewa damu kwa kipimo kingine chochote.

Kuhakikisha siri zinalindwa, makaratasi ya mtihani na fomu za mahabara hazitakuwa ma jina lako, rekodi za matibabu na habari zote zitakazopatikana kutokana na utafiti huu zitatunzwa kikamilifu na kutolewa tu kwa wahusika wanofa pekee**.** Wewe na daktari wako mutaruhusiwa kapata habari za matokeo hayo haraka na kutumia kwa mashauri mwafaka na matibabu bora ya kudhibiti hali yako ya sukari mwilini, haswa ukiwa na kiwango cha sukari mwilini ambacho ni hafifu.

Tungependa kukushirikisha kwa ushirikiano wako katika utafiti huu kwa hiari yako. Utatakikana kutoa idhini kimaandishi kabla ya kusajiliwa kwenye utafiti. Mtafiti mkuu na/au wasaidizi wake watakuidhinisha kushiriki kwenye utafiti. Uko huru kukata kusajiliwa katika ufafiti huu au hata kujiondoa kwenye utafiti wakati wowote pasipo kuhujumu faida zinazoambatana na matibabu yako hosipitalini.

Ukikubali kushiriki kwenye utafiti huu, tafadhali weka sahihi kwenye fomu ya idhini**.**

Mawasiliano

Kwa maelezo zaidi, unaweza kuwasiliana na wafuatao:

Dkt. AK Okwera – Mtafiti mkuu
Nambari ya simu: 0727952267

Prof. CF Otieno – Msimamizi
Nambari ya simu: 0722752558

Kamati ya Maadili ya Hospitali ya Kenyatta na Chuo Kikuu cha Nairobi
Nambari ya simu: (020) 2726300, ext. 44355

Appendix 8

Study on adequacy of glycaemic control and knowledge of diabetes among ambulatory patients with type 2 diabetes at Mbagathi District Hospital, Nairobi

CONSENT FORM (English)

Consent to participation obtained from patients with diabetes, age 40 years and above. *(Please read the consent explanation provided)*

I, the undersigned, have read and fully understood all the aspects of this study that are relevant to my decision to participate in the study. All my questions have been satisfactorily answered by the research team. I understand the usefulness of the study and conditions of my participation. I hereby voluntarily consent to participation in the study.

Signed ……...……
(Participant)

……
Witness (Principal investigator or research assistant)

Date: ……

Appendix 9

Utafiti kuhusu njia faafu za kudhibiti sukari mwilini na kuthamini viwango vya elimu vya wangojwa wa kisukari aina ya pili ambao wasiolazwa katika hospitali ya wilaya ya Mbagathi, Nairobi.

FOMU YA RUHUSA (Kiswahili)

Ruhusa ya kushiriki inayopewa na wagonjwa wa kisukari walio wa umri wa miaka 40 na zaidi. *(Tafadhali soma maagizo yaliyotolewa)*

Mimi, niliyeweka sahihi kibali hiki, nimesoma na kuelewa maagizo yote yanayoambatana na kushiriki kwangu katika utafiti huu. Maswali yote niliyokuwa nayo kuhusu utafiti huu yanajibiwa kikamilifu na watafiti. Naelewa faida, umuhimu na masharati ya kushiriki utafiiti huu. Nashiriki utafiti huu kwa hiari yangu.

Sahihi ……...……

(Mshiriki)

……

Shahidi (Mtafiti mkuu au msaidizi)

Tarehe: ……

Appendix 10

Study on adequacy of glycaemic control and knowledge of diabetes among ambulatory patients with type 2 diabetes at Mbagathi District Hospital, Nairobi

Diagnostic tests for diabetes (Criteria for the diagnosis of diabetes mellitus)[39]

1. Glycosylated haemoglobin (HbA_{1C}) ≥ 6.5%. The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay.*****

   or

2. Fasting plasma glucose (FPG) ≥ 7.0 mmol/L (126 mg/dL). Fasting is defined as no caloric intake for at least 8 hours.*****

   or

3. 2-hour plasma glucose (2-h PG) ≥ 11.1 mmol/L (200 mg/dL) during an OGTT. The test should be performed as described by the World Health Organization (WHO), using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.*****

   or

4. Random plasma glucose ≥ 11.1 mmol/L (200 mg/dL), in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis.

*****In the absence of unequivocal hyperglycemia, result should be confirmed by repeat testing.