ASSESSMENT OF ANTIDIABETIC MEDICINES USE AND GLYCEMIC CONTROL AMONG TYPE 2 DIABETES MELLITUS PATIENTS AT LACOR HOSPITAL, UGANDA

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This book is dedicated to my beloved father Mzee Augustine Jeremiah Anywar for the passion he had in educating his children and for all diabetes patients who yearn for hopes in their lives.

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ABBREVIATIONS AND ACRONYMS

ADA -	American Diabetes Association
ADRs -	Adverse Drug Reactions
AOR -	Adjusted Odd Ratio
BDA -	British Diabetes Association
BMI -	Body Mass Index =Kg/M^2
CI -	Confidence Interval
COR -	Crude Odd Ratio
CVD -	Cardiovascular Disease
DKA -	Diabetic Ketoacidosis
DL -	decilitre
DM -	Diabetes Mellitus
FBG -	Fasting Blood Glucose
HbA1c -	Glycosylated Haemoglobin
IDDM -	Insulin Dependent Diabetes Mellitus
IDF -	International Diabetes Federation
Mmol/l -	millimol per litre
NKHS-	Non-Ketotic Hyperosmolar Syndrome
OHA -	Oral Hypoglycaemic Agents
OPD -	Out Patient Department

SD -	Standard Deviation
SMBG -	Self-Monitoring of Blood Glucose
Uonbi -	University of Nairobi
WHO -	World Health Organization

OPERATIONAL DEFINITION OF TERMS

Adequate knowledge: this includes knowledge on diabetes, rational use of antidiabetic medications and its side effects, importance of dietary restrictions, exercise programs, routine self-monitoring, and awareness of DM complications.

Controlled blood sugar: Absence of clinical symptoms of hypoglycemia or hyperglycemia and random blood sugar (RBS) ranging 4 mmol/l to 10.9 mmol/l or fasting blood sugar (FBS) ranges 3.9 mmol/l to 5.5 mmol/l or Glycated hemoglobin (HbA1c) concentration of 5% to 7% within 2 to 3 months.

Dependent Variables: Knowledge on antidiabetic medication use, diabetes disease and its complications, dietary restrictions, exercises, glucose self-monitoring and glycemic control.

Diabetes mellitus: is a syndrome characterized by chronic hyperglycemia and disturbances of carbohydrate, fat, and protein metabolism associated with absolute or relative deficiencies in insulin secretion and /or insulin action.

Diabetic- related Complications: Complications which arise after chronic uncontrolled blood sugar levels in diabetes mellitus. They include: Neuropathies, Heart, micro & macro vascular complications, foot ulcers & amputations, compromised immunity and retinopathy.

Glycosylated haemoglobin test: is a test that measures the amount of haemoglobin bound to glucose. It is a measure of how much glucose has been in the blood during the past two to four months.

Hyperglycemia: is a condition in which an excessive amount of glucose circulates in the blood plasma. It occurs when the body does not have enough insulin or cannot use the insulin it has to turn glucose into energy.

Inadequate knowledge: lack or insufficient knowledge on diabetes, use of antidiabetic drugs and its side effects, importance of exercise programs, dietary control and DM complications

Independent variables: Patient's gender, age, level of education and occupation.

Rational use of medicines: this means using the prescribed medications for the intended purpose, in the right dose and dosage regimen, and at right time.

Type 2 diabetes mellitus: It is a metabolic disorder resulting from the body's inability to produce enough, or properly use of insulin, affects older age group, often obese individuals

Uncontrolled blood sugar: Presence of clinical symptoms of hypoglycemia or hyperglycemia and RBS below 4 mmol/l and above 10.9 mmol/l or FBS below 3.9 mmol/l above 5.5 mmol/l or HbA1c below 5% and 7%.

ABSTRACT

Background: Diabetes mellitus (DM) is one of the non-communicable diseases (NCDs) that is on the rise and causes serious health problems. Appropriately chosen antidiabetic drug therapy controls the associated complications of DM. Insufficient knowledge on the use antidiabetic drug therapy among other factors causes a decrease in drug efficacy and thus poor glycemic control. Measuring glycated hemoglobin (HbA1c) levels has been known to be a good indicator of the extent of glycemic control in such patients.

Objectives: The purpose of this study was to assess the patients' knowledge on the use of antidiabetic medicines and its impact on glycemic control using HbA1c measurement among type 2 DM patients at Lacor hospital in Uganda.

Method: A simple random sample of 126 type 2 DM patients were recruited at the diabetes clinic at Lacor hospital in Gulu, Uganda. The study was a cross-sectional descriptive study, carried between April and June 2017 and data was collected from patients who consented. The participants were interviewed using a structured questionnaire to evaluate knowledge on the use of antidiabetic medicines and a blood sample was drawn to measure the HbA1c level as a measure of glycemic control. Five healthcare providers sampled from the outpatient department were interviewed using a second structured questionnaire to determine the level of Lacor preparedness in the provision of diabetic education to the DM patients. Descriptive statistics have been used to summarize data. The data has been tabulated and presented graphically. Univariate and bivariate statistical analysis has further been carried on obtained data.

Results: Overall, 72.3% (n=64) of study targeted patients had good knowledge on antidiabetic medicine use (mean average 59.8%). The level of education was strongly significant a predictor of adequate knowledge on use of diabetic medicines (AOR =4.501, 95% CI; 1.94, 7.06, P = 0.001). However, high knowledge score on DM management was negatively associated with poor glycemic control (COR= 0.793, (95% CI; 0.64, 0.98). Generally, good glycemic control was reported in 48.4 % of participants. Female had 3 fold (AOR=0.373, 95% CI; 0.16, 0.93, p= 0.031) lower odds of having poor glycemic control. In addition, taking diclofenac tablets in combination with antidiabetic medicines (COR= 7.241, 95% CI; 0.86, 60.7) and identification of drug by color (AOR=5.043, 95% CI; 2.16, 10.80, P= 0.000) were positively associated with poor

glycemic control. Other factors found to affect glycemic control in the study population were adherence to regular exercise, reduction consumption of fatty meals, and self-monitoring of blood glucose which related to good glycemic control.

Conclusion and recommendation: Majority of type 2 diabetic patients had poor glycemic control. Patients with high level of education had adequate knowledge on the use of antidiabetic medicines. Strategies to improve on quality of education on diabetic management and promoting self-care activity could promote good glycemic control.

CHAPTER ONE: INTRODUCTION

1.1 Background

Currently more than 80% of people with diabetes live in low and middle Income countries. The global prevalence of diabetes is 8.3% in 2012, with an estimated 366 million people were living with diabetes in 2011 (1). The number is expected to grow to 552 million by 2030 and the largest age group currently affected by diabetes is between 40-59 years (1). However, the African region is expected to experience the highest increase in coming years with estimated increase in prevalence rates of 98% for sub-Saharan Africa, and 94% for North Africa and the Middle East (1,2).

Diabetes mellitus (DM) is a heterogeneous group of disorders characterized by varying degrees of insulin hypo-secretion and /or insulin insensitivity (3). Regardless of the cause, it is associated with hyperglycemia and deranged metabolism. The chronic hyperglycemia of diabetes is linked with the long term damage, dysfunction, and failure of various organs, especially the eyes, kidney, nerves, heart and blood vessels (4).

Several pathogenic processes are involved in the development of diabetes (5). These range from autoimmune destruction of the beta cells of the pancreas with consequent insulin deficiency to abnormalities that result in resistance to insulin action (6). The basis of abnormalities in carbohydrate, fat and protein metabolism in diabetes is the deficient action of insulin on target tissues. Deficient insulin results from inadequate insulin secretion and /or diminished tissue responses to insulin at one or more points in the complex pathways of hormone action (4).

Several forms of the disease exist and their prevalence throughout the world varies greatly. Type 1, also known as Insulin dependent diabetes mellitus (IDDM), is due to destruction of β-cells in the pancreatic islets of Langerhans with resulting loss of insulin production (7). In genetically susceptible individuals, a combination of environmental and genetic factors triggers an autoimmune attack on the β-cells. Indeed, circulating islet cell antibodies (ICAs) are present in more than 70% of IDDM at the time of diagnosis (3,5,7). Family studies have shown that the appearance of ICAs often precedes the onset of clinical diabetes by as much as 3 years. People

with type 1 DM present with a history of feeling tired and unwell together with weight loss, polyuria and polydipsia, and are prone to ketoacidosis (7,8).

Type 2 diabetes mellitus or Non-insulin dependent diabetes mellitus (NIDDM)on the other hand, is due to either diminished insulin secretion from an islet defect, increased peripheral resistance to the action of insulin resulting in decreased peripheral glucose uptake or increased hepatic glucose output (9).

It is estimated that as many as 98% of type 2 diabetic patients are "idiopathic", that is, no specific causative defect has been identified. It is still uncertain on what occurs first: decreasing insulin secretion or increasing insulin resistance; but the sequence of events may vary in different individuals. There is another form of type 2 diabetes that is insulin dependent, latent autoimmune diabetes of adulthood (LADA). This condition occurs in some adults especially those not overweight and over twenty five years of age (7).

When diabetes is not well managed, complications develop that threaten health and endanger life. Acute complications are a significant contributor to mortality, costs and poor quality of life (10, 11). Abnormally high blood glucose can have a life-threatening impact if it triggers conditions such as diabetic ketoacidosis (DKA) in type 1 DM, and hyperosmolar coma in type 2 DM (4,11). Abnormally low blood glucose can occur in all types of diabetes and may result in seizures or loss of consciousness. It may happen after skipping a meal or exercising more than usual, or if the dosage of anti-diabetic medication is too high (4). Anti-diabetic therapy therefore plays a pivotal role in the glycemic control in patients with diabetes (10). There are however, some drug therapy related problems associated with management of DM such as too low or high dose, adherence, lack of knowledge by patients and on disease states, that need to be addressed to avoid complications and adverse effects (12).

1.2 Statement of the Problem

Type 2 DM is a chronic disease that usually co-exists with other medical conditions (13). Over time, it may progress with micro- and macro- vascular complications (affecting eyes, kidneys, heart and lower extremities) in relation to glycemic control (14).

Following a 2014 WHO global survey, the prevalence of diabetes among Ugandans was 2.8%, with 2.7% male and female 3.0%, Uganda's population was 39 million. Total deaths attributable to high blood glucose in the 30- 69 age group were; 1450 males, 1120 females and in persons 70+ age, 1130 males and 1470 females were recorded.

Uganda diabetes association (UDA) estimates indicate that about 4% of Ugandans (or 1,120,000) people suffer from type 2 DM in 2010 (15). The Northern Province, that suffered long time insurgency by the rebels for over twenty three years, has inhabitants with lots of challenges such as poverty; physical disability due to limb amputations and non-communicable diseases (NCDs) like hypertension, diabetes, mental illness and nodding disease syndrome to mention a few. Those persons with diabetes do not get the optimal management including disease monitoring and treatment. There are many evidence-based studies that provide the benefits of pharmacist intervention by giving adequate knowledge on medication use, counseling patients about diabetes, its complications, lifestyle modifications and self-monitoring of the disease(16). Majority of type 2DM patients from such rural areas cannot afford a glucometer and constant supply of strips for self-monitoring (15,17). The pharmacist-to-population ratio in Uganda is as low as 1.6:100,000 in 2013/14

Most of the up country hospitals either public or private are operating with one or no pharmacist which makes many patients to probably get little or inadequate information concerning their therapies including those on anti-diabetics. There is an evidence-based national diabetic guidelines/protocol/standard but is partially implemented (4). No available standard criteria for referral of patients from primary care to higher level of care exists (18).

Management of diabetes mellitus presents considerable challenges to medical, pharmacy and nursing staff, a process requiring a great deal of effort on the part of the patient. The patient, more than any health care provider, is the key successful management.

Inappropriate use of antidiabetic agents leads to failure of therapy and subsequently poor control of blood glucose (20).

A situation where diabetes patients visit clinics regularly and their blood glucose levels still remain high despite being on treatment is a common problem that calls for attention. .

Sometimes, slight symptoms that these patients could easily take care of at home bring them back to the hospitals for medical checks (1). A good number of them, however, report to the hospital with severe complications, like gangrene that might be due to lack of appropriate self-care practices (2,9,22). All the effort to provide funding and set up of effective supply systems are futile if medicines are not used correctly at the service delivery point (18). However, there's need to make patients adequately aware of the importance of correct medications use, dietary and regular exercises are major contributory factors to effective management of type 2 diabetes mellitus.

1.3 Purpose of the study

The greatest weapon in the fight against diabetes mellitus is knowledge (1). Information can help people assess their risk of diabetes, motivate them to seek proper treatment and care, and inspire them to take charge of their disease for their lifetime (22). In view of the increasingly high incidence of complications in diabetic patients (23,24), it would be valid to assess the perception of the primary healthcare patient of his or her actual disease state and the problems that may arise. Proper management requires life style changes, adequate physical activities, counseling and diabetes knowledge of which is considered a key component of diabetes management. Differences in knowledge level have been described depending on level of education, gender and social classes. Assessment of the level of knowledge on antidiabetic medication use among persons with diabetes can assist in targeting public health efforts to reduce diabetes related complications (25).

To the best of my knowledge, evidence-based research on antidiabetic medication use and adherence for glycemic control among type 2 DM patients in Uganda is scanty. The present study will therefore be carried out to assess the rate of knowledge of antidiabetic medication use including adherence, level of glycemic control and different factors associated with both variables together with reasons for lack of knowledge among ambulatory type 2 diabetic patients in Lacor hospital. The findings will contribute to the existing body of knowledge in the area and improve correct medication use through identifying areas of intervention.

1.4 Justification of the study

This study will promote strategies to improve quality of education during initiation, knowledge on how to use medication and subsequent routine refilling of drugs, to control blood sugar near to normal.

The development of long term complications of diabetes, morbidity and mortality can be prevented if patient are educated on the importance of exercise, weight loss and choice of diet to reach optimum glycemic control (4,7,14,21).

The findings of this study will be useful in establishing the demands for diabetes education and encourage pharmacists' intervention to help improve quality of life in these patients.

1.5 Research questions

1. What is the proportion of patients at Lacor hospital with type 2 DM that are on antidiabetic medication?
2. What are the types of antidiabetic agents used?
3. How do knowledge and other contributory factors (age, weight, education status, and obesity) affect the optimal blood sugar control?
4. What is the relationship between antidiabetic medication use and overall control of blood glucose among type 2DM at Lacor hospital?

1.6 Hypotheses

The study will be based on the null hypotheses (Ho) that there is no significant relationship between patient knowledge and optimum management of diabetes mellitus against the alternative hypothesis (H_A) that there is significant relationship between patient knowledge and optimum management of diabetes mellitus.

1.7 Study objectives

1.7.1 General objective

To assess the use of antidiabetic medicines and control of blood sugar among patients with type 2 DM attending diabetic clinic at Lacor hospital in Gulu.

1.7.2 Specific Objectives

1. To determine the proportion of type 2 DM patients at Lacor hospital on antidiabetic medication
2. To identify the types of antidiabetic agents used by type 2 DM patients at Lacor hospital.
3. To assess patients' knowledge on the use of antidiabetic medications.
4. To determine glycemic control of patients on antidiabetic agents using HbA1c measurement.

CHAPTER TWO

LITERATURE REVIEW

2.1 Definition and etiology of type 2 diabetes mellitus

Type 2 diabetes mellitus consists of an array of dysfunctions characterized by hyperglycemia resulting from the combination of resistance to insulin action, inadequate insulin secretion, and excessive or inappropriate glucagon secretion (26). Insulin resistance which is attributed to elevated levels of free fatty acids and pro-inflammatory cytokines in plasma leads to decreased glucose transport into muscle cells, elevated hepatic glucose production and increased breakdown of fat (7,8,27).

The role of excess glucagon cannot be underestimated; as type 2 diabetes is an islet paracrinopathy in which the reciprocal relationship between the glucagon-secreting pancreatic alpha cell and the insulin-secreting beta cell is lost, leading to hyperglucagonemia and hence the consequent hyperglycemia (26).

For type 2 DM to occur, both insulin resistance and inadequate insulin secretion must co-exist (29). For example, all overweight individuals have insulin resistance (2,27,29), but diabetes develops only in those who cannot increase insulin secretion sufficiently to compensate for their insulin resistance. Their insulin concentrations may be high, yet inappropriately low for the level of glycaemia (30).

With prolonged diabetes, atrophy of the pancreas may occur. Studies using computed tomography(CT) scan findings, glucagon stimulation test results, and fecal elastase-1 measurements confirmed reduced pancreatic volume in individuals with a median 15-year history of diabetes mellitus (range, 5-26 years).This may also explain the associated exocrine deficiency seen in prolonged diabetes (31).

2.1.1 Beta cell dysfunction

Beta-cell dysfunction is a major factor across the spectrum of pre-diabetes to diabetes. A study of obese adolescents confirms what is increasingly being stressed in adults as well (32). Beta-cell dysfunction develops early in the pathologic process and does not necessarily follow the stage of insulin resistance. Singular focus on insulin resistance as the "be all and end all" is gradually shifting, and hopefully better treatment options that address the beta-cell pathology will emerge for early therapy (33).

2.1.2 Insulin resistance

In the progression from normal to abnormal glucose tolerance, postprandial blood glucose levels increase first (34). Eventually, fasting hyperglycemia develops as suppression of hepatic gluconeogenesis fails (35). During the induction of insulin resistance (such as occurs with a high-calorie diet, steroid administration, or physical inactivity), increased glucagon levels and increased glucose-dependent insulinotropic polypeptide (GIP) levels accompany glucose intolerance (36). However, the postprandial glucagon like peptide-1 (GLP-1) response is unaltered (37).

The etiology of type 2DM appears to involve complex interactions between environmental and genetic factors (2,12,38). The disease develops when a diabetogenic lifestyle (excessive caloric intake, inadequate caloric expenditure, obesity) is superimposed on a susceptible genotype. The body mass index (BMI) at which excess weight increases risk for diabetes varies with different racial groups (24). For example, compared with persons of European ancestry, persons of Asian ancestry are at increased risk for diabetes at lower levels of overweight (4,6,39).

2.1.3 Risk factors

The major risk factors for type 2 DM include: age greater than 30 years (though, as noted above, type 2 DM is increasingly occurring in young and adolescent individuals); weight greater than 30kg m^{-2} of desirable body weight (40); family history of type 2DM in a first-degree relative (for example, parent or sibling); Hispanic, Native American, African American, Asian American, or Pacific Islander descent; history of previous impaired glucose tolerance (IGT) or impaired fasting glucose (IFG). Hypertension (>140/90 mm Hg) or dyslipidemia (HDL cholesterol level <

40 mg/dL or triglyceride level >150 mg/dL), hypertension and pre-hypertension are also associated with a greater risk of developing diabetes in Whites than in African Americans; history of gestational diabetes mellitus or of delivering a baby with a birth weight of over 3.5kg and polycystic ovarian syndrome (which results in insulin resistance) (2,21).

Age is the other factor reported to influence glycemic control among type 2 DM patients (4,41). A study conducted in Karbala city in Iraq found diabetic ketoacidosis (DKA) occurs more frequently in the younger people, but mortality is higher in the elderly. Approximately 25% of the new patients with diabetes will present with DKA (42). Similar results were reported by studies conducted in Netherlands (43) and in Brazil, amongst women with diabetes where life expectancy was found to be 5.8 years shorter than in women without diabetes (44). A study conducted in Virginia revealed that better metabolic control was independently associated with increasing age as was also observed in USA CDC studies (45).

Further in literature, sex has been mentioned as one of the factors influencing glycemic control (46). In a cross sectional study carried out among type 2DM in India it was observed that male sex was found to be a risk factor for poor glycemic control (17). Low level of education was also another factor which negatively affects blood glucose control among diabetic patients. In a cross sectional study carried out to assess the determinants of loss of glycemic control among patients with diabetes in Basrah, Iraq (47),less educational level was found to be one of the contributing factors for worse glycemic control. The result was also supported by similar studies carried out in Jordan (48), Spain (49) and Netherlands (14).

2.2 Prevalence of type 2 diabetes mellitus

Type 2 diabetes mellitus is the most prevalent form of diabetes with increasing numbers in each country. Recent report by WHO estimated 1.6 million deaths worldwide, 43% of these are attributable to high blood glucose occur prematurely, before the age 70 years (4,50,51). Globally, high blood glucose causes about 7% of deaths among men aged 20–69 year (4,50). Accordingly, only 41(12.7%) patients attained adequate glycemic control with the mean glycemic level at 192.7 (standard deviation = 76.5) mg/dl, with a range of 52.0 - 444.0 mg/dl (17)

The global prevalence of diabetes has grown from 4.7% in 1980 to 8.5% in 2014, during which time prevalence has increased or at best remained unchanged in every country. Previously seen mainly in middle-aged and elderly people, type 2 DM occurs increasingly frequent in children and young people. Type 2 DM is often undiagnosed and studies to assess the number of newly occurring cases are complicated and consequently there are almost no data on true incidence (52). In high-income countries the prevalence of type 2DM is frequently highest among people who are poor. There are few data on the income gradient of diabetes in low and middle-income countries, but data that exists suggests that although the prevalence of diabetes is often highest among wealthy people, the trend is reversing in some middle-income countries (2,4,53)

The prevalence of type 2 DM is increasing accounting for as much as 90% of all cases of DM (10,14,51). The overall prevalence of type 2 DM in the United States is approximately 9.6% in persons age 20 years or older in the United States, increases with age, it is more common in women than in men, and varies widely among various racial and ethnic populations, being especially increased in some groups of Native Americans, Hispanic American, and Asian-American, African- American, and Pacific Island people (39). Type 2 DM also has a strong genetic predisposition and is more common in all ethnic groups other than those of European ancestry (10).

The WHO Africa region, which consists of all of sub-Sahara Africa currently, has the lowest prevalence of diabetes at 4.5% (4,11,52,54). Available evidence suggests that in sub-Sahara Africa, type 2 DM is primarily related to obesity resulting from dietary and lifestyle changes, suggesting it can be a preventable condition (8,13,14,55). A dietary change from high fiber diet with complex carbohydrates and fruits to a diet that includes edible oils, processed foods, refined sugars, and non-alcoholic ready to drink beverages (NRTD) has resulted in a pandemic of obesity in urban dwellers (54,56,57).

Studies have identified a higher prevalence of type 2 DM in the urban communities compared to rural dwellers in Tanzania, Mozambique, Cameroon, and Kenya (2,26,35,58). Understanding the prevalence rates of Type 2 DM in sub-Sahara Africa is important because of the significant financial burden associated with the diagnoses and treatment of diabetic complications, which

include retinopathy, neuropathy, nephropathy, coronary artery disease, and cerebrovascular disease (2,4,11).

A literature search of PubMed using the key words: Africa, Diabetes, Type 2 Diabetes, Prevalence, and Epidemiology between the years of 2006 and 2016, resulted in 455 citations.
A recent survey from rural Eastern Uganda showed a diabetes prevalence of 7.4% and pre-diabetes 8.6% (38). There have been four meta-analyses conducted with type 2 DM prevalence ranging between 1% in rural Uganda to 12% in urban Kenya (15,59).

A study conducted (n=100) in Pakistan in 2010 to determine the knowledge, attitudes and practices among patients with type 2 DM showed that literacy rate was very low among females compared to males. Patient's general knowledge about diabetes was very low and that about antidiabetic drugs was low (1,22,60). Only 58% of the patients knew that diet, OHA as well as insulin can help to control blood sugar while 42% had no idea of insulin benefits.

Another study done at Mekelle and Adyer referral hospitals in Ethiopia to assess knowledge and its associated factors among type 2 DM patients, showed that there was significant association between diabetes family history and diabetes knowledge level [P<0.025, AOR (95% CI)=1.860 (1.077-3.209)] (1)

2.2.1 Type 2 diabetes mellitus in Uganda

Uganda has a predominantly agrarian economy with increasing urbanization and a rapidly growing population (52). The most common NCDs in Uganda are diabetes, hypertension and other cardiovascular diseases, and some cancers(18). In the early 70's, diabetes cases were rare in Uganda. However, three decades later Mulago National Referral Hospital registered over 5,000 new patients in a five year period in the 1990s, (un-published Ministry of Health reports) (52).Uganda is experiencing a marked upsurge of diabetes. In a random sample from Kampala, the capital city, and its neighboring district Mukono; the prevalence was estimated to be up to 8.1%. Similar trends have been registered in up-country hospitals. In Mbale regional referral hospital (Eastern Uganda) diabetes cases increased from 80 patients per year in 1994 to over 600 per year in 2004(52). A 10 fold increase in type 2 diabetes is projected between 2005 and 2025.

The highest increase is recorded in the Central Region, probably due to higher socio-economic status, urbanization, and adoption of western life-styles (52).

Available information concerning type 2 DM is limited in the northern part of the country. A key knowledge gap exists including estimates for the burden and management of DM in the country. There is no published or unpublished information on the prevalence of type 2DM in the northern part of the country. Hence, this research will assess and provide information on prevalence type 2 DM and its management.

2.2.2 Screening of type 2 diabetes mellitus

Guidance by organizations such as, the American Diabetes Association (ADA) recommends screening for type 2 DM every three years in all adults beginning at the age 45 years. Testing should be considered at an earlier age and more frequently in individuals with known risk factors. The recommended screening test is the fasting plasma glucose (FPG). An oral glucose tolerance test (OGTT) can be performed alternatively or in addition to FPG when a high index suspicion of the disease is present.

The revised diagnostic criteria accord greater importance to the fasting plasma glucose (FPG) concentration as a criterion for diagnosis. The FPG value considered diagnostic of diabetes has been lowered to ≥126mg/dL (≥7.0 mmol/L) from the former value of 140mg/dL (7.8 mmol/L) and over. The category of impaired glucose tolerance (IGT) was retained at 2-hour post-load glucose levels from 140mg/dL (7.8 mmol/L) to less than 200mg/dL (11.1 mmol/L). An additional category, impaired fasting glycaemia (IFG), was introduced to categorize individuals who have FPG levels that are above normal but fall short of the new diagnostic FPG level for diabetes, i.e. FPG 110mg/dL (6.1 mmol/L) to 125mg/dL (≤7.0 mmol/L).

It is now apparent that only minority of individuals with IGT has IFG, and conversely, only a minority of those with IFG has IGT. The change in diagnostic criteria has resulted in some individuals being reclassified as having diabetes, i.e. individuals with FPG from 126mg to 139mg/dL and with post-load 2-hour glucose values of≤ 200 mg/dL, thereby resulting in an increase in prevalence (57).

2.3 Types of Antidiabetic agents

Currently, six classes of oral agents are approved for the treatment of type 2 DM: alpha-glucosidase inhibitors like acarbose, biguanides such as metformin, meglitinides like repaglinide, peroxisome proliferator-activated receptor γ-agonists (which are also commonly identified as thiazolidinedione [TZDs] or glitazones) such as pioglitazone, Dipeptidyl peptidase-IV inhibitors like sitaglitin, and sulfonylureas such as glimepiride.

Oral antidiabetic agents are often grouped according to their glucose-lowering mechanism of action. Biguanides and TZDs are often categorized as insulin sensitizers because of their ability to reduce insulin resistance. Sulfonylureas (SU) and meglitinides are often categorized as insulin secretagogues because they enhance endogenous insulin release. New options for implementation of insulin therapy are now available. For example, detemir is one of the long acting insulins has a unique pharmacokinetic with an onset consistent across doses but the peak is delayed slightly with higher dosing and has been given an additional option for choice of basal insulin for type 1 and 2 DM patients (8).

According to Intercontinental Marketing Service (IMS) data, the leading groups of drugs utilized worldwide are cardiovascular drugs which are usually co-prescribed along with anti diabetic drugs as result of co-existence of the two diseases (61)

Concurrent illness such as hypertension in diabetics makes it more difficult to avoid multiple drug use; so diabetics are more prone to polypharmacy and sometimes irrational prescriptions. Drug utilization study of antidiabetic agents is of paramount importance to promote rational drug use in diabetics and make available information for the health care team (61).

In diabetic patients, there exists other medical conditions especially cardiovascular diseases and to prevent or reduce proteinuria, blood pressure control, glycemic control and particularly, the blockade of renin-angiotensin system are essential to prevent or delay the vascular diabetes complications. Based on recommendations, drugs acting on renin-angiotensin- aldosterone axis should be the key therapy for these patients (62)

Sulfonylureas are the oldest and most widely used medication for the treatment of type 2 DM. Although SU therapy effectively lowers blood glucose concentrations (average decrease in FPG of 1-4 mmol/l, accompanied by a decrease in HbA1c of 1-2 %) by stimulating insulin release from β-cells, treatment with SUs is associated with a progressive decline in β-cells function and eventual inability to maintain glycemic control reflects an advanced stage of β-cells failure (63).

In a study done in Addis Ababa, Ethiopia the profile of prescribed antidiabetic medications among type 2 DM revealed that metformin 72.4% was the most commonly prescribed drug followed by Insulin 53.4% and glibenclamide 41.0% (17).

Some non-insulin antidiabetic drugs (NIADs) have contraindication or must be used with caution in patients with type 2 DM and especially with co-morbid conditions. Major risk conditions that required tailored management of hyperglycemia include heart failure, HIV-AIDS, chronic kidney disease, liver dysfunction or history of cancer (such as bladder cancer, cervical, Kaposi's sarcoma) (64).

2.4 Knowledge on the use of Antidiabetic medications

A study conducted in Saudi Arabia highlighted the importance of proper education and awareness program in changing the attitude of the public towards diabetes (65).
Similarly studies conducted in Los Angeles, Orange, San Bernadine, San Diego, Riverside countries and southern California among the Filipino-Americans have clearly shown that diabetes education and care management can significantly improve the patient outcomes, glycemic control and quality of life in diabetic patients (6).

Findings in India, Western Nepal and Cambodia revealed a patient knowledge of dispensed drugs at 64, 81, and 55%, respectively (66).Conversely, a study carried out in Portugal, J. Rubio *et al* showed that 85.5% (CI 95%: 79.3-85.3%) of patients do not know the medication they use (49).

Few studies have characterized and quantified socio- behavioral risk factors for type 2 DM in low income settings, and even fewer studies have explored the underlying drivers of the proximate risk factors in sub-Saharan Africa. Knowledge of such drivers would allow

interventions to target the root causes of the proximate risk factors (67). The World Health Organization (WHO) 2002 report reported an adherence to oral OHA of 75%among patients (n=91) receiving medication from community pharmacies in northern California. Dose omissions represented the most prevalent form of non-adherence; however, one third of the patients took more doses than prescribed. This over-medication was observed more frequently in those patients prescribed a once daily dose (68).

There is, however, limited data on the utility and cost implications of available screening tests that can aid in identification of the most-at-risk persons at primary care levels in sub-Saharan Africa (52). There is also limited data on suitable socio- behavioral correlates of abnormal glucose regulation that can be used to develop risk scores to help in identification most-at-risk persons. These risk scores could provide an alternative to screening which is likely not affordable in most primary care contexts in LICs. Risk stratification allows scarce resources to be targeted to most at-risk groups (67).

Few studies have assessed the context specific perceptions of type 2 DM related risk factors, community perceptions regarding preventive behaviors and forms of these behaviors that are relevant and acceptable to target communities in rural Africa (69).This information is necessary to guide development of contextually relevant lifestyle interventions.

In view of the above studies, it is clear that patient education on the use of their antidiabetic medications and counseling on diet and regular activities are important for optimal therapeutic outcome in the management of type 2 DM. It is, therefore, important to evaluate the level of education that is given to outpatient DM patients who attend at Lacor hospital.

2.5 Glycemic control using glycosylated hemoglobin

Glycemic control as measured by glycosylated hemoglobin (HbA1c) is one of the widely used clinical indicators of the quality of diabetic care. (70). The ADA has determined glycosylated hemoglobin(HbA1c) as the best measure of glycemic control, with a level less than 7% as a goal of optimal blood glucose to prevent the complications and to reduce overall disease management

cost (71).The glycosylated hemoglobin test reveals how close to normal glycemic control has been maintained during the past two to three months. This information helps a physician evaluate how well a person is responding to diabetes treatment and to determine how long sugar levels have been high in a person newly diagnosed with diabetes (20).

Controlled clinical trials provide ample evidence that glycemic control is paramount in reducing microvascular complications in both types 1 and 2 DM. Measurement of HbA1c is the gold standard for following long-term glycemic control for the previous 2 to 3 months. Haemoglobinopathies, anemias (iron deficiency, hemolytic) and red cell membrane defects can affect HbA1c measurements. Other strategies such as measurement of fructosamine, which measures glycated plasma proteins and correlates to glucose control over the last 2 to 3 weeks, can be necessary to assess diabetes control in these patients (72).

However, HbA1c levels may be misleading as a measure of glycemic control. This was evidenced by a clinical case report, where a patient with diabetes remained undiagnosed for several years and then, despite moderately elevated FPG levels, received suboptimal therapy for his diabetes, probably because his HbA1c levels were still in normal range(73). The patient had a rare hemoglobin variant (haemoglobinopathies), hemoglobin Leiden, which is associated with a mild hemolytic anemia and splenomegaly, resulting in a shortened red cell survival and normal HbA1c values.

The use of HbA1c can avoid the problem of day-to-day variability of glucose values, and importantly the need for a person to fast more than seven hours preceding a test (74). However, most common important factors worldwide affecting HbA1c levels include a variety of genetic, hematologic and illness-related factors. (See appendix V)
The utility and convenience of HbA1c compared with measures of plasma glucose for the diagnosis of DM need to be balanced against the fact it is unavailable in many countries. Factors influencing HbA1c assays are presented in Appendix VI and VII.

Type 2 DM is an insidiously progressive disease (7). Gradually decreasing insulin secretion leads to a slow increase in hyperglycemia and a rise of HbA1c values, often despite vigorous clinical attempts to maintain control. Blood sugar control during early years is often straightforward, but

it becomes increasingly difficult with the progression of other co-morbid illness, so that the appropriate need for tablets and insulin requires continuing consideration.

Whether a patient is obese or not may affect the way their condition is managed. Non-obese patients require different consideration compared to the obese. They are much more likely to require insulin early in the course of treatment, and indeed apparent presentation as Type 2 DM may be deceptive when they progress to Type 1 DM as cases of latent autoimmune diabetes of adulthood (LADA) (7). Sulphonylureas treatment is used initially while metformin treatment is inappropriate for these patients (4,35). Some patients cling desperately to minute diet with the large doses of sulphonylureas as weight and health decline: these patients regain their health rapidly when insulin treatment is started and indeed it should not be delayed.

Obese patients require a different approach of managing their glycemic control. The need for healthy eating and exercise in an attempt to reduce weight are important yet difficult to achieve. It has been demonstrated that one-third of patients who receive care in a pharmacist managed diabetes care clinic reach the goal of HbA1c and blood pressure values, less than 7% and 130/80 mm/Hg , respectively (75). It has been demonstrated that a clinical pharmacist can effectively care for patients with diabetes referred by their primary care provider because of poor glycemic control that is associated with an array of microvascular, macrovascular, and neuropathic complications (30).

An evaluation of the effect of a pharmacist intervention that was face-to-face goal- directed medication and lifestyle counseling on improving diabetes control; secondary endpoints were medication appropriateness and self-reported adherence has been done. Seventy- seven subjects, were randomized to receive a pharmacist intervention (n = 43) or usual care(DM medication only and no counseling/ education, n = 34) on improving diabetes control for 6 months, followed by a 6-month usual-care observation period for both groups (19,76). The study concluded that pharmacist intervention significantly improved diabetes control and this group were found to have lower HbAlc levels compared to the group which received usual care. The group which had pharmacist intervention had fewer physician visits.

Kiel and McCord evaluated the changes in clinical outcomes for patients enrolled in a pharmacist-coordinated diabetes management program (n=45, $p<0.05$). In this study, the pharmacist was leading the diabetics' healthcare team as well as providing counseling to the patients. Data collection included baseline and follow-up values for HbAlc and lipids as well as frequency of adherence to preventive care, including annual foot and eye examinations and daily aspirin therapy (20,58,76,). The study concluded that the pharmacist-coordinated diabetes management program was effective in improving clinical markers for enrolled patients. Significant improvements were observed in HbA1c and LDL (Low Density Lipoproteins) values as well as adherence to the preventive care.

In a study conducted in Kenyatta National Hospital (KNH), the population (n=171) glycemic control was relatively poor with 29.5% achieving HbA1c of 7% and below. Knowledge deficits were apparent in recognizing hypoglycemia as up to half of the patients were unable to give at least two signs and symptoms of hypoglycemia (77).

In Uganda, a study done in the central part showed that the strength of a correlation between FPG and HbA1C is higher among people with risk factors (R^2=0.69) among obese persons) (52). However, agreement between FPG and HbA1C in classifying abnormal glucose regulation does not improve among people with risk factors, except in obese people (Kappa=42.9)
In view of all the studies done, the northern part of Uganda still has no valid information in the control of blood sugar using HbA1c and its benefits.

There was however a study conducted in two general hospitals (Iganga and Bugiri) (n=521) that showed a 83.3% level of adherence to antidiabetic medication use and factors that were independently associated with adherence were; having been on antidiabetic drugs for at least three years (OR=1.89, 95% CI=1.11-3.22), availability of diabetic drugs (OR=2.59, 95% CI= 1.54- 3.70) and having ever had diabetic health education (OR= 4.24, 95% CI= 1.15- 15.60) (78). A similar study conducted in Mulago National Referral Hospital to assess the factors related to non-adherence of antidiabetic medications showed the prevalence of non-adherence was 28.9% (n = 116, 95%CI = 24.5 – 33.3%). Factors that were independently associated with non-adherence were: female gender (OR = 2.9, 95%CI = 1.4 – 6.3), not understanding the drug regimen well (OR = 4.0, 95%CI = 1.0 – 16.3), affording only some or none of prescribed drugs

(OR = 3.7, 95%CI = 1.8 – 7.6) and longer time since last visit to a health worker (OR = 7.3, 95%CI = 2.7 – 19.9) (79).

There is need to improve knowledge on medication use through strategies helping patients understand their drug regimens, always availing drugs in the hospital so that they do not have to buy them elsewhere and giving shorter time between visits to health worker. This can be conceptualized as illustrated in Figure 1

2.6 Conceptual Framework

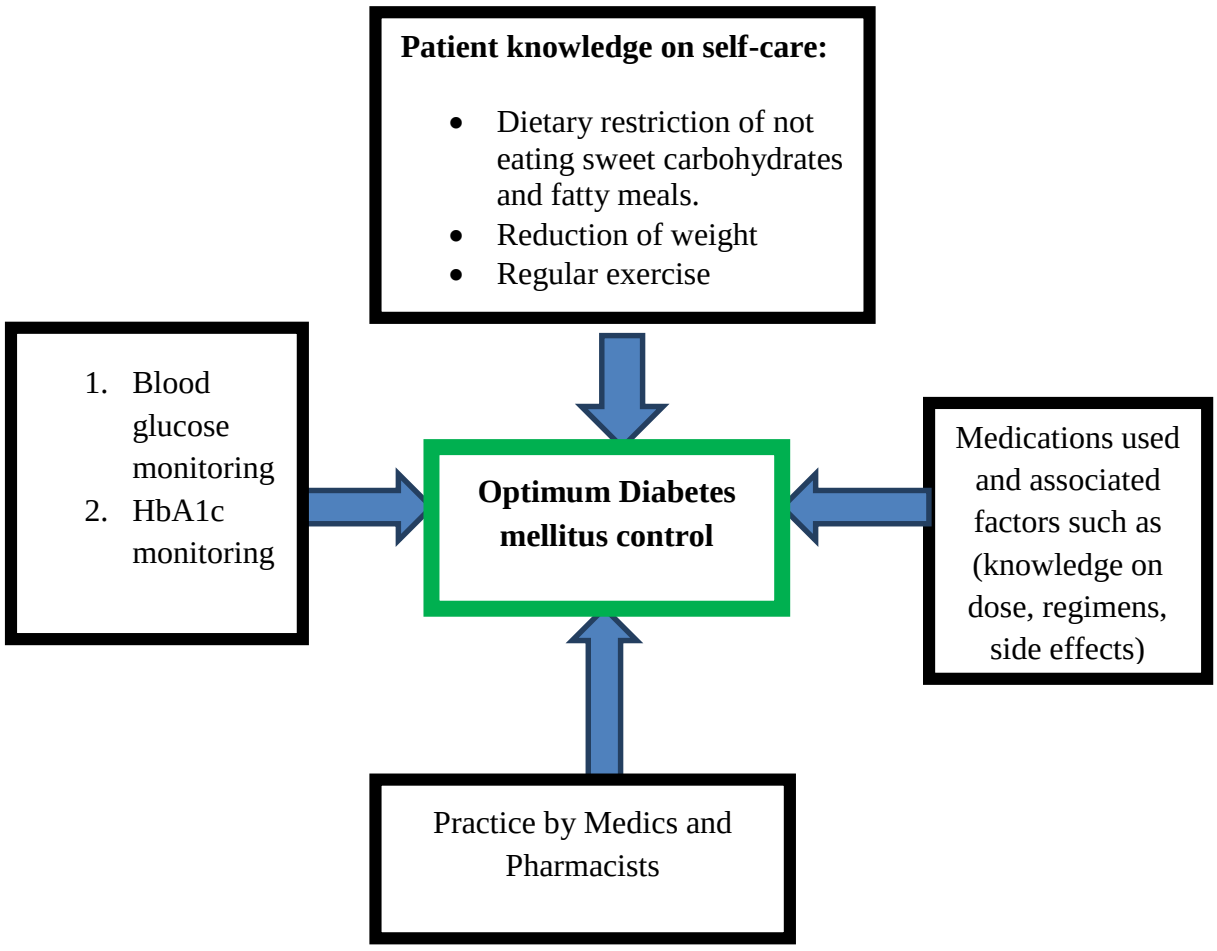

Figure 1: Conceptual framework

CHAPTER THREE: METHODOLOGY

This Chapter highlights methods that were employed in carrying out the study.

3.1 Research Design

This was a descriptive, cross-sectional study conducted at Lacor hospital in northern Uganda. Structured research tools were used to abstract patient information as well information from health care workers.

3.2 Location of the Study

The study was carried out in the medical outpatients' diabetes clinic of a tertiary-level healthcare facility in Uganda during a three-month period (April to June 2017). The study center was St. Mary's Hospital Lacor (commonly known as Lacor hospital) which is located six kilometers west of Gulu town along Juba road. It is a non- governmental institution, owned by the trustees of Archdiocese of Gulu. The hospital has 520 beds, providing clinical diagnostic, curative and preventive treatment. It's also a research site for training of nurses, laboratory technicians, intern pharmacists and medical doctors from within and outside the country. The hospital also serves as the Gulu University Teaching Hospital. This hospital, the major referral hospital in the northern part of province, serves the entire population of Uganda Northern Province and its neighboring Southern Sudan. The medical outpatients' clinic is manned by a physician, registrars (senior and junior) in internal medicine, and medical interns. The center runs a two days weekly diabetes clinic with an average attendance of between15 and 25 patients. Total number of diabetes patients that receives care at the clinic ranges from 550 to 670 per year.

3.3 Target Population

All type 2 DM patients who attended diabetic clinic at Lacor hospital during the data collection period and had fulfilled the inclusion criteria were targeted.

3.4 Inclusion and Exclusion criteria

3.4.1 Inclusion criteria

This included all adult patients with type 2 DM and on treatment with antidiabetic drugs for at least for 3 months before study and had been followed in the Lacor hospital DM clinic. In addition, adults aged ≥18 years and above (males and females) who understand English or Luo language (Luo being the language of the local people) and patients who gave informed consent were considered.

3.4.2 Exclusion Criteria

Patients with other types of diabetes mellitus, pregnant, had a documented history of haemoglobinopathies, hemolytic anemia, repeated venesection, for example in the treatment of haemochromatosis and those who had more than 3 months use of phenytoin, glucocorticoids and estrogen were excluded. These drugs and disorders mentioned were exclusion as they are documented to affect the assay and interpretation of HbA1c test (See Appendix III).

3.5 Sampling Techniques

3.5.1 Sample Size

Since there were no previous studies on the level of knowledge of antidiabetic medicine use among type 2 DM patients at the study site, the percentage proportion of patients with adequate knowledge was estimated to be 50% with an error margin of ± 5%. With a 95% confidence level, the minimum sample size was thus calculated using Fisher's formula (80).

$$n = \frac{Z^2 \times P (1- P)}{d^2}$$

Where

n= sample size

Z = 1.96 which is normal deviate corresponding to confidence interval of 95%

P = prevalence = 50%, which is 0.5 (the average estimated level of knowledge of antidiabetic medicine use since there were no such previous studies on glycemic control in the northern part);

d = 0.05 (5% error margin)

Substituting in the formula; $n = \frac{1.96^2 \times 0.5(1-0.5)}{0.05^2} = 384.16 \sim 384$

However, since study population was less than 10,000 the estimated the sample size used the following reduction formula (81).

Corrected sample size = n x N / n + N

= 384 x 160 / 384+ 160 = 113

Where, N= source population and n= estimated sample size for N≥10,000 population.

An average of 160 diabetes patients were reported to have attended to at both the medicine ward and outpatient diabetes clinic of Lacor hospital in the preceding three months (October-December, 2016. The final targeted corrected sample size taking into consideration a 10% contingency for incomplete medical records and non-response was 125 patients.

3.5.2 Sampling, screening and recruitment of patients

Simple random sampling method using a table of random numbers was used to recruit the cases from the diabetes outpatient clinics. Files of patients attending the clinics had been retrieved daily on a clinic day and allocated numbers and a list of numbers drawn. The patients on arrival at the clinic were screened for case definition using their appointment cards and identified cases further screened for the eligibility criteria. Those found eligible and willing to participate in study were taken through the consent process using the consent information and consent form (Appendix IA). The procedure was repeated on following clinic days until the desired sample size was attained.

3.6 Research Instruments

The structured questionnaires (Appendix IIA) comprising of seven parts were used as the study tool. The tool was used to collect socio-demographic data, disease related characteristics, non-pharmacological approaches to diabetic care, knowledge on the use of antidiabetic medication use and reasons for non- adherence to medications. An abstraction form (Appendix IIIA of questionnaire) was used to capture the participant information from their medical files including

fasting blood glucose (FBG), level of glycosylated hemoglobin, total cholesterol, triglycerides, HDL and LDL, co-morbidities, diabetic complications and information on prescribed medications.

To test the suitability of the data collection forms, they were pre-tested before use by randomly interviewing ten patients outside Lacor diabetes clinic but these respondents were excluded from the actual study. Appropriate amendments to the tool were made before use.

Appendix IB had a different set of questionnaires that were administered to consenting five out of ten diabetic health care providers at Lacor hospital. This was to determine the level of preparedness of the team on diabetic education on adequate antidiabetic medicine use and patients' counseling.

3.7 Data Collection methods

3.7.1. Consent process and questionnaire data collection

Prior to data collection, each patient was taken through the consent process by being informed about the objective of the study, procedures of selection and study, access to their medical files and assurance of confidentiality through non-use of names on study documents to minimize social desirability bias and enhance anonymity. The participants were informed about the need to draw of a small blood sample for further tests as part of the study. The participants were informed that they could withdraw from the study at any time without prejudice to their regular service at the hospital. Thereafter, patient willingness to take part in the study was affirmed by the signing of the consent form (Appendix IA).

Enrolled participants were then interviewed using the study tools followed by perusal of individual medical files before proceeding for the relevant laboratory tests.

The following data was captured: socio-demographic data, disease related characteristics, non-pharmacological approaches to diabetic care (diet, exercise, self-monitoring of blood glucose, alcohol and tobacco consumption), knowledge on the use of anti-diabetic medication use and reasons for non- adherence to medications. In addition, the participant information from medical files including fasting blood glucose (FBG), level of glycosylated hemoglobin, total cholesterol,

triglycerides, HDL and LDL, co-morbidities, diabetic complications and information on prescribed medications was noted.

Every questionnaire was serialized to prevent duplication during data collection and avoidance of confusion between patients during interview. The serial number was also used as a unique participant identification number on all study documents. The patient responses were directly captured and recorded in the questionnaire. The principal investigator reviewed and checked the collected data for completeness and relevant up feedback were forwarded daily to the data collectors throughout the study period. The coded data were then entered in the computer using Epi-info version 7.2 software to form a database.

3.7.2 Laboratory methods

The participant's files were perused by principal investigator to check any previous HbA1c measurements in the past one or two months. All patients were then tested for the HbA1c test on enrolment into study as per standard procedures (Appendix IV) for the estimation of HbA1c. The tests were performed by an experienced laboratory technologist.

3.7.2.1 Quality assurance for estimation of glycated hemoglobin

The patient's code was accurately labeled on the vacutainer tube as well as recorded in the laboratory request form and register book. Blood specimens were collected using a sampling sticks which provided in the laboratory kit. For finger prick blood sample, the finger was made warm, dry at surface and cleansed, before using a single lancet to prick the finger. Blood was allowed to flow about the size of sampling stick before drawing specimen. For venous samples; blood samples were collected into EDTA tubes. Prior to collecting a sample, thorough mixing was done by inverting the tube 8 to 10 times. Blood was collected using a sampling stick to avoid air bubbles. Venous samples were stored refrigerated at 2-8°C for up to ten days before use and could be used without equilibration to room temperature. For patient who had a venesection, blood sample was not removed near the site.

The analyzer, HumaMeter A1C system, used each sampling stick with new lot of cartridges that were stored at room temperature in a dark room. The HumaMeterA1c is certified by the National

Glycohaemoglobin Standardization Program (NGSP with the analyzer and cartridges having been calibrated using samples provided by the European Reference Laboratory (ERL) via the NGSP network.

Results thus obtained using the analyzer is traceable to the NGSP (National Glycohaemoglobin Standardization Program) network.

The interpretation of test results against the expected values was done with careful consideration to the specific patient's age, ethnicity, medical history, clinical examination, and other laboratory result. The obtained values were then compared to the National Guidance reference ranges as presented in Table 1.

Table 1: Interpretation of glycated hemoglobin test

ADA recommendation(74)	**Interpretation**
4 - 5.7% DCCT (20 - 39 mmol/mol IFCC)	Non- diabetic patient
5.7 - 6.0% DCCT (39 - 42mmol/mol IFCC)	Risk of developing diabetes
6.0 - 6.5% DCCT (42 - 48 mmol/mol IFCC)	High risk of developing diabetes
<7% DCCT (<53 mmol/mol IFCC)	Goal for effective management of diabetes to minimize long term complication

ADA- American Diabetes Association, DCCT =Diabetes Control and Complication Trial, IFCC = International Federation of Clinical Chemistry.

Performance characteristics for the equipment used was stated for linearity and category. The HumaMeter A1c reagent kit had linear working range of 4 - 15 % DCCT (20 –149 mmol/mol IFCC) (82) while the HbA1c readings were categorized as normal, borderline or high (poor control) if <5.7%, 5.7 - 6.9% and ≥7.0 %, respectively.

3.7.2.2 Determination of glycosylated hemoglobin levels

All consenting patients who had not previously measured their HbA1c levels, within the last two to three months, were prepared by the laboratory technologist for the 5ml blood sample draw. Aseptic procedures were observed with the needles for blood collection sterile from an individual sachet and one used for each patient and then discarded to the sharps container after a single use. This was to avoid any cross contamination and biohazards exposure. The collected blood sample were quickly put in the right vacutainer tube and coded as per the assigned patient code and transferred to the clinical chemistry laboratory. The HbA1c test was then determined using the instrumental analyzer, HumaMeter A1C system and the result recorded in the respective study questionnaire.

3.8 Study variables

3.8.1 Independent variables

Patients' demographic information (gender, age, level of education, monthly income, marital status, occupation), Patient characteristics (presence or absence of co-morbidities) were considered as independent variables.

3.8.2 Dependent variables

The dependent variables comprised: level of glycosylated hemoglobin, blood sugar level, and knowledge on the use of antidiabetic agents, DM complications, diet restrictions and exercise programs.

3.9 Validity

All results were double checked before recording in the questionnaire forms. This was to avoid biases such as information, observer and measurement bias.

3.10 Reliability

The laboratory technologists as study assistants ensured that the HbA1c analyzer was validated and set for measuring the blood sample in a correct and standard way. The Standard operating procedures were followed in every step in the analysis. Two technicians did the test on each sample independently under same conditions. Before recording the results of the test, it was counter checked by another senior laboratory technologist. Any misunderstanding in interpreting the result was checked with reference to the standard / gold standard. Results were carried out in replicate and the standard deviation (SD) determined as a measure of reliability and variability.

3.11 Data management

All the information recorded had three copies: one in a personal computer, in an external hard drive and a hard copy. Backing up of the personal computer and the external hard drive was done regularly. This electronic data were password protected and accessible was only allowed to the researcher. The data collection questionnaires were stored away in a lockable cabinet accessible only to the researcher and authorized data collectors.

3.12 Data Analysis

Epi-info version 7 computer software was used for data entry and to create the database. The data was double checked for authenticity and clarity, cleaned and then exported to the STATA version 13.0 software for analysis. Summary data analysis was conducted by computing the mean and standard deviation of the mean or the median and interquartile range (IQR) for continuous variables that were normally and not normally distributed, respectively. The Shapiro-Wilk test was used to determine if the continuous variable were normally distributed or not. Categorical variables were summarized as proportions and percentages. The results have been summarized in form of tables and presented graphically and in form of figures.

Inferential test

The Kruskal Wallis statistical test was used to determine if there was a significant difference in the median, or levels of continuous variable across categorical variables that had their two levels.

It was used where the continuous variable was not normally distributed. The Wilcoxon rank-sum test was used of inferential data analysis to compare the medians of continuous variables across variables that had only two categories or levels. It was used for variables that were not normally distributed. The chi square test was used to compare the distribution of categorical variables across groups.

Linear regression analysis with robust estimation was carried out to determine variables that determined the patient's knowledge of diabetic management. Patient's knowledge, as assessment of their responses to a number of questions, was scored and expressed as a percentage.

Using the patient's glycated hemoglobin levels, a binary variable was generated that dichotomized patients into those with poor and adequate glycemic control. With a cut-off for poor glycemic control at HbA1c level of greater than 7.0%, determinants for good glycemic control were determined using both linear and logistic regression.

For both linear and logistic regression, model building was done using a manual forward stepwise approach. For all analyses, the level of significance was set at 0.05 or less.

3.13 Ethical Considerations

Ethical approval for the study protocol was sought and granted by Kenyatta National Hospital - University of Nairobi, Ethics and Research Committee **(P48/01/2017, dated 20th April 2017)**. In addition, official letters of permission from the Executive director of Lacor hospital, as well as head of internal medicine department and diabetic clinic were obtained for the study to be conducted in the clinic. See appendix IX.

Before consenting the patients were appropriately informed about the study objectives, benefits and risks, procedures of selection and study. Assurance of confidentiality, anonymity and withdraw from the study at any time without any dire consequences were made. Only consenting patients were recruited into study as affirmed by free consenting and signed consent form.

Any obtained participant's information was kept confidential as well as password protected on the computer to maintain confidentially. Results from the biochemical analysis of collected blood samples borne at the investigators' cost were communicated to all participants and filed in

their records for interpretation and incorporation into the patients care by the primary health care provider. Appropriate advice / counseling to patients were given to participants by the investigator on the knowledge of antidiabetic medication use and its side effects, diabetes knowledge and self- care practice.

CHAPTER FOUR: RESULTS

This chapter presents the findings of the investigation involving a total of 126 study participants with type 2 DM attending the diabetic clinic at Lacor hospital in Gulu.

4.1 Screening and recruitment

This study was conducted in the months of April to June 2017 at St. Mary's hospital Lacor, outpatient diabetic clinic in the northern part of Uganda, Gulu district. A total of 303 files were screened, out of which 157 met the inclusion criteria. Patients were randomly selected but six declined to consent to participate in the study and 25 had missing information as indicated in flow chart in figure 2. Those recruited had similar characteristics of the study target in terms of age, duration of illness and treatment modality. The study population (n=126) were recruited and had the structured questionnaire administered and blood samples taken both for glycated hemoglobin and lipid profile tests.

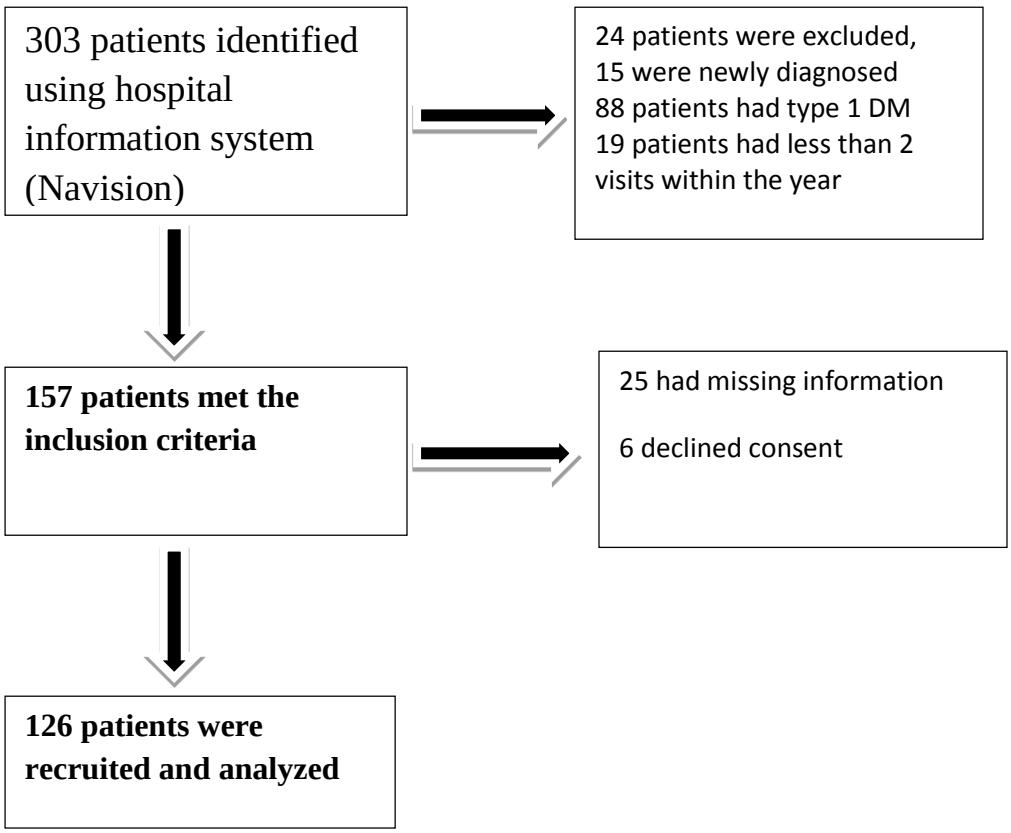

Figure 2: Flow chart on patient's screening and recruitment

4.2. Socio-demographic characteristics of the respondents

Majority of the respondents were in the 51 to 60 years age group with the highest score was (26.9%, n=34), and few were of the range 31-40 age in years had the lowest score (5.6%, n=7). The overall average mean age was 55.6 standard deviation, SD=14.1) with lowest and highest age of 19 and 83, respectively.

Most patients were female (65.1%, n=82) compared to males 34.9, n=44). A good number of the type 2 DM patients live within the urban area, 50.8 % (n=64) while 49.2 % were from the rural places. Although few were single and divorced 13.5 and 7.1 %, respectively), great proportions of the participants were married 54.8%, followed by 23.0 % widowed. The most prevalent occupation was farmer (37.3%), housewife (17.4%) and 15.9%. were retired. Most of the subjects were non-health professionals 93.8% (Table 1) while 65.1% had very low monthly income.

Table 2: Socio-demographic characteristics of the study participants

Variable	Frequency (%)
Gender	
Female	**82(65.1)**
Male	**44(34.9)**
Age (years)	
Less than 30	**9(7.1)**
31-40	**7(5.6)**
41-50	**27(21.4)**
51-60	**34(26.9)**
61-70	**30(23.8)**
≥ 71	**19(15.1)**
Residence	
Urban	**64(50.8)**
Rural	**62(49.2)**
Marital Status	
Single	**17(13.5)**
Married	**69(54.8)**
Divorced	**9(7.1)**
Widowed	**29(23.0)**
Cohabiting	**2(1.5)**
Occupation	
Farmer	**47(37.3)**
Housewife	**22(17.4)**
Retired	**20(15.9)**
Merchant/Trader	**17(13.5)**
Government employee	**12(9.5)**
Daily labourer	**8(6.4)**
Profession	
Non health professional	**118(93.8)**
Health profession	**5(3.9)**
Work in a health facility	**3(2.4)**
Level of Education	
Primary	**44(34.9)**
Secondary	**32(25.5)**
Can't read and write	**28(22.2)**
Higher education	**18(14.3)**
Vocational training	**4(3.2)**
Monthly income (UGX'000)	
Very low: ≤ 450	**83(65.9)**
Low: 451-1,200	**25(19.8)**
Average: 1,200-2,500	**9(7.1)**
Above average: 2,501-3,500	**2(1.6)**
High: ≥ 3,501	**7(5.6)**

4.3 Clinical characteristics of the study population

Majority of the participants (n=112) had been diagnosed with the diabetes for the last 7.1 (SD= 6.83) average mean years, ranging between 1- 5 (n= 59, 46.8%) and over five years (n=53, 42.1%) as seen in table 3.

Table 3: Clinical characteristics of type 2 DM study participants

Variable	Mean ± SD	Min- Max
Age (years)	55.6 ± 14.12	19 - 83
Duration of illness (years)	7.1 ± 6.83	1 – 31
BMI (Kg/m^2	26.6 ± 5.77	16.9 - 46.0
HbA1c (%)	7.2 ± 2.27	3.8 - 15.5
TC (mg/dL)	176.4 ± 37.77	98 – 293
TG (mg/dL)	156.8 ± 45.44	62 – 398
HDL (mg/dL)	44.5 ± 10.73	10 – 84
LDL (mg/dL)	57.6 ± 17.60	30 – 166

TC = total cholesterol, TG = total triglyceride, HDL = high density lipoproteins, LDL = low density lipoproteins

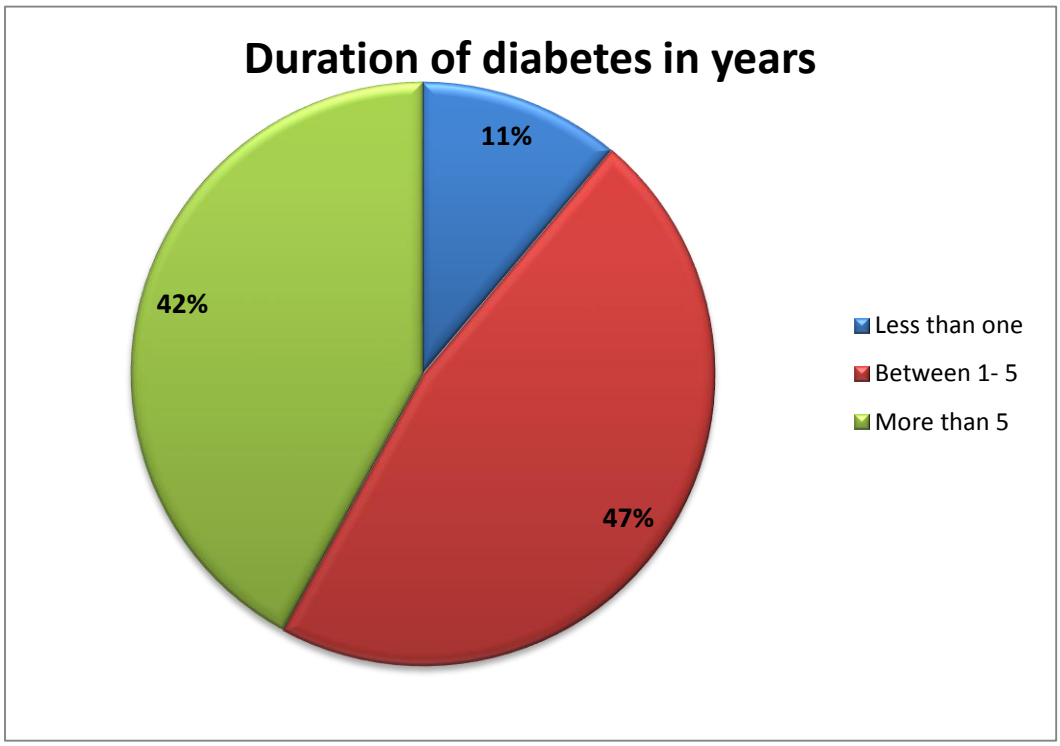

Figure 3: A pie chart showing duration of illness among the study participants

4.4 Assessment of knowledge on the use of antidiabetic medicine among type 2DM patients

Generation of knowledge scores gave, a 59.79 mean score, SD = 18.74, Interquartile range = [77.78-88] and median = 66.67. As observed in histogram plot (Figure 4) of knowledge percentage score versus frequency, it's negatively skewed, non-normal distribution, and majority of the scores were at the higher end of the possible scores.

As shown in Table 4, the level of knowledge on anti-diabetic medication use was assessed among the study participants (n=126) and half of the patients (n=68, 54.0%) did read and mention the name of the antidiabetic medicine prescribed to them. Majority of the participants (n=102) knew the dose to take, similarly, nearly all the participants (123, 97.6%) knew the time and frequencies at which to take their medications.

Unfortunately a great number of the patients (103, 81.8%) were not aware of any side effects associated with antidiabetic drugs they were taking with only 23 patients having knowledge on

some few. As regards diabetic complications, 65 patients knew them well with 61 having no knowledge of DM complications.

Table 4: Assessment of knowledge on the use antidiabetic medicines among type 2 Diabetes mellitus at Lacor hospital

Variable	Frequency (%)
Know medication	
Read & pronounce name	68(54.0)
Can't read and pronounced name	58(46.0)
Know the dose to take	102(81.8)
Know the frequencies and time to take the medication	123(97.6)
Know the correct dose	102(80.9)
Know drug side effects	
No	103(81.3)
Yes	23(18.3)
Know the disease condition	
No	35(27.8)
Yes	91(72.2)
Know diabetes complication	
No	61(48.4)
Yes	65(51.6)
Next refill of medicine	
Aware	116(92.1)
Not aware	10(7.9)

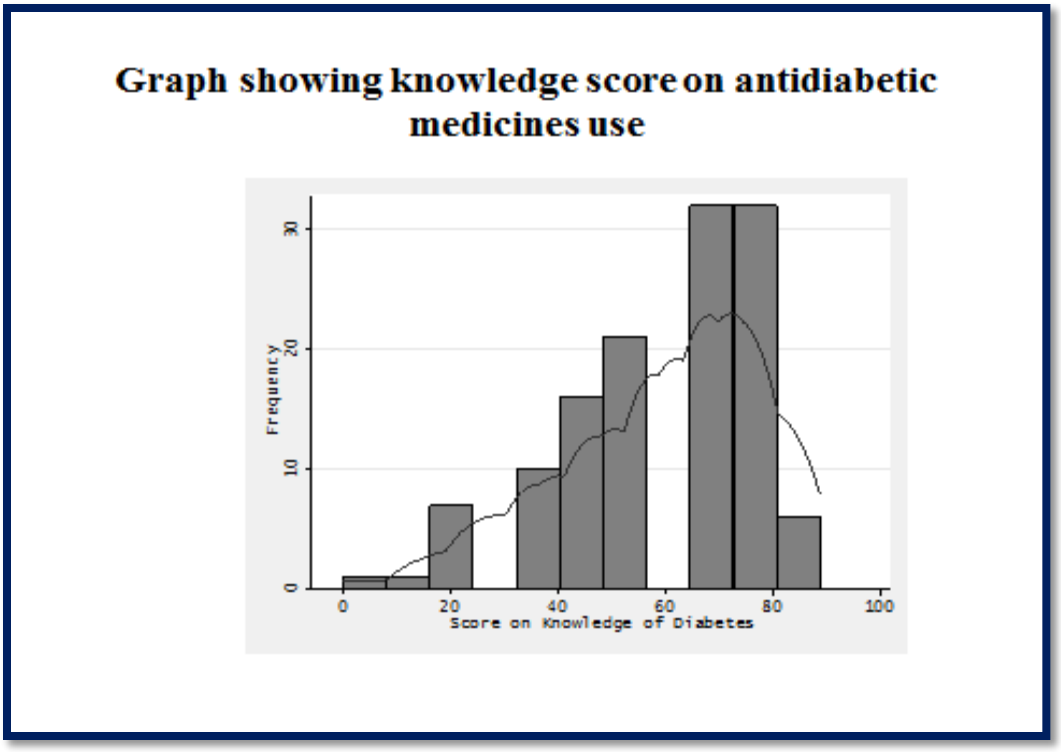

Figure 4: Histogram showing knowledge score on the use antidiabetic medicines

4.5 Assessment of knowledge on safe handling of antidiabetic medicines among type 2 DM patients.

Half of patients 63(50.0%) identified their medication by color; while about 55 (46.8%) identified medicines only when it was labeled. The medicine shape and size were used by 48 (38.1%) and 24(19.1%), respectively to identify their medications. A good practice noted by majority (104, 82.5%) of the respondents was that they would not recommend same prescription to either any intimate friend or relative to buy in case they had same type 2 DM. As reflected in Table 5, a good number of the patients (71, 56.4%) kept their oral medicines in a bag and insulin, a cold chain item either in the refrigerator (n=15, 11.9%) or under a cold pot of water (18, 14.3%)

Nearly all type 2 DM participants were aware of their next refill date (92.1%) and 64 participants (50.7%) knew their antidiabetic medication was for long term use. About two thirds of the participants had no idea of any possible side effects of medication(s) they were using. Only few

did mention impotence (12, 9.5%) and hypoglycemia (10, 7.9%). A small proportion 13, (10.3%) admitted that it would be inappropriate, to take double the dose upon forgetting to take antidiabetic medicine(s) for previous day.

Table 5: Assessment of knowledge on safe handling of antidiabetic medicines among type 2 DM patients attending diabetic clinic at Lacor hospital in Gulu

Variable	Frequency
Identification of medicine	
Shape	48(38.1)
Color	63(50.0)
Size	24(19.1)
Label	59(46.8)
Route of administration	
Oral	93(73.8)
Parenteral	18(14.3)
Both oral and parenteral	15(11.9)
Suggest same prescription to an intimate	
Yes	22(17.5)
No	104(82.5)
Storage of medicines	
Refrigerator	15(11.9)
Small bag	71(56.4)
Under a cold pot	18(14.3)
Cupboard	20(15.9)
Small tin	17(13.5)
Duration of therapy	
Had no idea	48(38.1)
Knew it was for long term	64(50.7)
Knew it was for short term	8(6.4)
Depends on doctors' decision	6(4.8)
Knowledge on possible side effects	
No idea	77(61.1)
Know some side effects	44(34.9)
Knows all important side effects	5(3.9)
Some mentioned some side effects	
Impotence	12(9.5)
Hypoglycemia	10(7.9)
drowsiness, sweating &general weakness	9(7.1)
Blurred vision	8 (6.4)
Action taken if you forgot to take dose	
Act in appropriately	13(10.3)
Seek advice	17(13.5)
Take correct dose next time	82(65.1)
First perform smbg then decide	4(3.2)
Take immediately	10(7.9)
Take antidiabetic drugs as advised by doctor	102(80.9)

Smbg = self-monitoring of blood glucose

4.6: Assessment of diabetes complications of type 2 DM patients attending diabetic clinic at Lacor hospital.

The study assessed the proportion of study participants with adequate knowledge on the type of disease, duration since first diagnosis, its complication and those that have one or more of the complications. The findings are shown in Table 6 and figure 3.

Majority of the study population (72.2 %) knew they had type 2 DM, while 22.8% did not know. Among the study participants, (n=126, 71.3%) had no history of family DM, while 28.5 % were linked with history of DM in the family.

Almost half of the patients in the study (51.6%) had some knowledge on DM complications in contrast with 48.4% who had no idea of any complication. Over three quarter of participants (89.7%) were found with one or more DM complications with the most common being neuropathy (58.7%), retinopathy (51.6%) and heart complication being 39.7 % (Figure 5).

Table 6: Presence of comorbidities and diabetes mellitus complications among type 2 DM patients attending diabetic clinic at Lacor hospital in Gulu (n=126).

Variable	Frequency	Percentage (%)
Aware of type of DM	91	72.2
Not aware of the type DM	35	27.8
Duration of illness (years)		
Less than one year	14	11.1
1-5	59	46.8
More than 5 year	53	42.1
History of family diabetes		
Yes	36	28.6
No	90	71.4
Can mention one or two DM complication		
Neuropathy	35	27.8
Diabetic foot ulcer	21	16.7
Kidney problems	25	13.5
Heart complications	23	15.9
Eye complications	43	34.1
Have at least one or more DM complication(s)	113	89.7
Neuropathy	74	58.7
Kidney complications	22	17.5
Eye problems	61	58.4

Diabetic foot ulcer	11	8.7
Presence of comorbidity		
Yes	93	73.8
No	33	26.2
Specific co-morbidities		
Hypertension	81	64.3
Peripheral vascular disease	11	8.7
Dyslipidemia	3	2.4
Ischemic heart disease	3	2.4
Osteoporosis	4	3.2
HIV-AIDS	2	1.6
Pancreatitis	2	1.6
Asthma	2	1.6
Obesity	6	4.8
Arthritis	3	2.4

About 73.8 percent (n= 93) had one or two co-morbidities with 26.2% having none. Out of those with co-morbidities, n=81, 64.3% had hypertension, followed by peripheral vascular disease (8.7%) and the rest were not very common amongst the study participants (Figure 4)

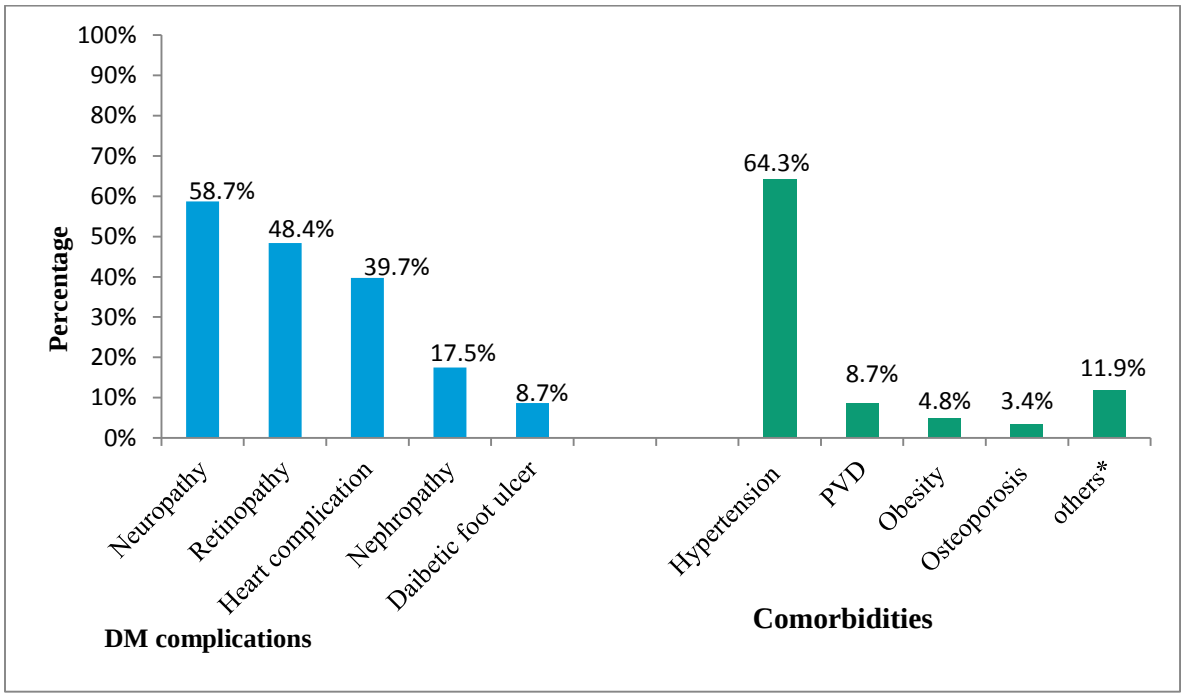

Figure 5: Presence of comorbidities and diabetic complications among type 2 patients attending diabetic clinic at Lacor hospital in Gulu.

4.7 Non Pharmacological Self-care activities among type 2 Diabetes Mellitus patients

The non-pharmacotherapy practices by type 2 DM patients to achieve quality care involved: diet, such as always not eating sweet carbohydrates, avoiding fatty meal, eating plenty of green vegetables; exercise; no alcohol intake and smoking. Of the study participants, (106, 84.1%) indicated that they had a diet plan set by their doctor with 73 (57.9%) adhering to dietary plan. In practice, only 56 (44.4%) regularly avoided sweet carbohydrates and fatty meals (Table 7).

Half of the patients acknowledged that they had exercise plan given by their prescribers. The most carried out exercise was digging (60, 47.6%), followed by walking (28, 22.2%) and riding a bicycle (14, 11.1%). Nearly all the study participants did at least thirty minutes of moderate intense exercise every day.

About 85% (n=107)of participants had ever taken alcohol, out of these 36.5% had ceased taking alcohol many years ago while few patients still take alcohol daily (22, 17.5%). Majority of the respondents (109, 86.5%) had never smoked tobacco but only 17 males were current smokers.

Self-monitoring of blood glucose was done only by few patients (28, 22.0%) who had a glucometer as shown in Table 7.

Table 7: Non-pharmacological diabetes self- care activities

Variable	Frequency	Percentage
Had diet plan	106	84.1
No diet plan	20	15.9
Adhered to diet plan	73	57.9
Not adhere to diet plan	53	42.0
Always cut off sweet CHO	55	43.7
Occasionally cut off sweet CHO	56	44.4
Regularly cut off fatty meal	56	44.4
Occasionally cut off fatty meal	59	46.8
Exercise		
Digging	60	47.6
Walking	28	22.2
Riding	14	11.1
Gym exercise	6	4.8
Had doctor's exercise plan	63	50.0
Had no exercise plan	63	50.0
Adhered to exercise plan	30	34.5
Occasionally to adhered to exercise plan	16	18.4
Exercise days per week		
≤ 3 days	61	54.9
≥ 4 days	50	45.0
None	15	11.9
Minutes per day		
≤ 30	50	44.6
≥40	62	55.4
Other form of exercise	63	50.0
Alcohol		
Had ever taken alcohol	107	84.9
Had never taken alcohol	19	15.1
Stopped alcohol	46	35.5
Daily alcohol intake	22	17.5
Smoking		
Yes	17**	13.5
No	109	86.5
Smoked 5 sticks per day	8	6.5
More than 5 sticks per day	8	6.5
Self-monitoring of blood glucose(Smbg)		
Had a glucometer	28	22.2
No	98	77.2
Performed Smbg per week		
Less than 3x per week	9	7.1
More than 3x per week	18	14.3

**= Males

4.8. Evaluation of reasons for non-adherence.

Assessment of patients' responses of reasons for non-adherence showed that 58 (46.0%) patients missed dose due to lack of finance **(**Table 8**).** Nearly a quarter of respondents (43, 34.1%) mentioned that this was due to forgetting, due to lack of family support (26, 20.6%), side effects (23, 18.3%), or complexity of regimen (17, 13.5%).Though few patients (n=8) were affected by lack of antidiabetic medicines at the facility, it was quite alarming.

Table 8: Reasons for non- adherence for type 2 DM participants at Lacor hospital

Variable	Frequency	Percentage
Reason for non- adherence		
Lack finance	58	46.0
Forgot	43	34.1
Poor family support	26	20.6
Fear of side effects	23	18.3
Complexity of dose regimen	17	13.5
Too busy	14	11.1
Been taking for many years	9	7.1
Stock out the facility	8	6.4
Pain at injection (insulin)	8	6.4

4.9. Profile of prescribed antidiabetic medications

There were two treatment modalities prescribed for type 2 DM patients in the study population. It was either combination of two drugs or a single medicine (biguanide + sulfonylurea, biguanide + insulin, sulfonylurea + insulin or single biguanide / insulin).

As reflected in Table 9, there were three types of antidiabetic agents being prescribed among the participants. Metformin (104, 82.5%) was the most commonly prescribed drug, followed by glibenclamide (44, 34.9%) and insulin (33, 26.2%). Amongst the 33 patients on insulin, 30(23.8%) were prescribed insulin mixtard, 2 were on soluble insulin and only one patient was prescribed humulin insulin. Nifedipine (30, 23.8%) was the most commonly prescribed antihypertensive, followed by amlodipine (18, 14.3%), lisinopril 12.7%, losartan + hydrochlorthiazide 5.6% and bisoprolol 3.9%. The diuretic of choice was furosemide (23, 18.3%)

Table 9: Profile of prescribed medications

Variable	Frequency	Percentage
Drug		
Metformin	104	82.5
Glibenclamide	44	34.9
Insulin	33	26.2
Type of Insulin		
Mixtard	30	23.8
Soluble	2	1.6
Humulin	1	0.79
Classes of antidiabetic medications		
Biguanide	104	82.5
Sulfonylurea	44	34.9
Insulin	33	26.2
Combination therapy		
Glibenclamide + Insulin	5	3.9
Metformin + Insulin	13	10.3
Metformin + Glibenclamide	38	30.2
Total number of prescribed medications		
1	5	3.9
2	15	11.9
3	31	24.6
4	39	30.9
5	21	16.7
> 5	14	11.1
Other prescribed medications		
Nifedipine	30	23.8
Furosemide	23	18.3
Bendrofluazide	21	16.7
Amlodipine	18	14.3
Lisinopril&Vitamin B complex	16	12.7
Amityptiline	13	10.3
Amoxicillin	9	7.1
Losartan + Hydrochlorothiazide	7	5.6
Bisoprolol& metronidazole	5	3.9
Statins	6	4.7
Others*	8	6.3

*spironolactone,calciumlacatate, cloxacillin, carvedilol,salbutamol,neurorubin, ciprofloxacin,oral morphine, propranolol, ibuprofen

4.10 Association of independent variables with knowledge on use of antidiabetic medicine

On considering the univariable linear regression analysis on the different independent variables and knowledge on the use of antidiabetic medicine(s), the findings showed (Table 10) that occupation, education, health professional and income were statistically significant (p-values less than 0.05)

It is noted that as age increases the knowledge score increases by 1.2 units and as income improves, the knowledge score also increases by 0.62 units. Health professional scored highest and the knowledge score was 5.46 units greater than that of non- health professionals.

Unexpectedly having family history of diabetes had a negative effect on knowledge of management of type 2 DM. Those with family history of DM had a score that was about -4.81% lower than those without family history. This observation was supported by the fact that the median score of patients who had family history of DM was 55.6 which was lower than that of patients without family history of DM who had a score 66.7%. However, this observation was not statistically significant.

Increased duration of treatment for the diabetic tended to increase the knowledge score. Increasing duration of illness by one year improves the knowledge score by five units (5.072) units. For every one year of living with the diabetes, there is an increase in knowledge on the use of antidiabetic medicine.

Table 10: Comparison of the performance of participants' knowledge of diabetes across socio-demographic and disease related characteristics

Demographic factors		Knowledge scores Median [IQR]	P-value > |z|
Sex	Female	61.1 [44.4, 77.8], n= 82	0.106
	Male	66.7 [55.0, 77.8], n= 44	
Marital status	Single	77.8 [55.6, 77.8], n= 17	0.325
	Married	66.7 [44.4, 66.7], n= 69	
	Divorced	55.6 [44.4, 77.8], n= 9	
	Widowed	66.7 [44.4, 66.7], n= 29	
	Co-habiting	61.1 [55.6, 77.8], n= 2	
Occupation	Retired	66.7 [61.1, 77.8], n= 20	
	Daily labourer	66.7 [55.6, 77.8], n= 8	0.004*
	Gov't employee	77.8 [66.7, 77.8], n= 12	
	Merchant/trader	55.6 [33.3,66.7], n= 17	
	Housewife	55.6 [33.3,66.7], n= 22	
	Farmer	66.7 [55.6, 77.8], n= 47	
	Can't read &write	55.6 [33.3,66.7], n= 28	
Education	Primary	55.6 [44.4, 66.7], n= 44	
	Secondary	72.2 [61.1, 77.8], n= 32	0.0001*
	Vocational training	66.7 [55.6, 66.7], n= 4	
	Higher education	77.8 [44.4, 77.8], n= 18	
Health Professional	Non-health prof.	66.7 [44.4, 77.8], n= 118	
	Health prof	77.8 [77.8, 77.8], n= 5	0.017*
	Work in health fac.	55.6 [44.4, 88.8], n= 3	
	Less than 30	66.7 [44.4, 77.8], n= 9	
	31-40	55.6 [33.3,66.7], n= 7	
Age category (years)	41-50	66.7 [44.4, 66.7], n= 27	0.648
	51-60	66.7 [44.4, 77.8], n= 34	
	61-70	66.7 [55.6, 77.8], n= 30	
	71 and above	66.7 [44.4, 77.8], n= 19	
Family history	No family DM	66.7 [44.4, 77.8], n= 91	0.255
	Has family DM	55.6 [44.4, 77.8], n= 35	
Income	Very low	55.6 [44.4, 77.7], n= 82	
	Low	66.7 [66.7, 77.8], n=26	
	Average	77.8 [66.7, 77.8], n=9	0.003*
	Above average	77.8 [77.8, 77.8], n=2	
	High	66.7 [44.4, 77.8], n=4	
Duration of DM	Less than one year	50.0 [22.2, 66.7], n= 14	0.060
	5 years	66.7 [44.4, 77.8], n= 59	
	Over 5 years	66.7 [55.6, 77.8], n= 53	
	No	66.7 [44.4, 77.8], n=42	
	Yes	66.7 [55.6, 77.8], n= 30	

Upon carrying out on bivariable analysis (multiple regressions) the considered variables had significant association with knowledge score. All the associations became insignificant on multivariable analysis when education level was used to adjust for confounding. The only variable that was almost significant after adjusting for confounder was duration on management for type 2 DM. Therefore, this was considered for the Parsimonious model, showing: education; AOR= 4.501; 95% CI (1.94, 7.06), p= 0.001 and years of diabetes duration; AOR = 5.072; 95% CI (-0.61, 10.75), p=0.08) as the most important predictors. Tables 11 provide the summary of the results after adjusting the variables.

Table 11: Variables that determined the knowledge score with regard to management of type 2 diabetes mellitus

	BIVARIABLE ANALYSES		**MULTIVARIABLE ANALYSES**	
Variable	**Crude beta coefficient(95% CI)**	**p-value**	**Adjusted Beta coefficient**	**p-value**
Sex	5.525 (-1.20, 12.25)	0.106	-	-
Marital status	-2.330 (-5.49, 0.84)	0.148	-	-
Occupation	-2.225 (-3.82, -0.63)	0.007*	-	-
Health professional	7.488 (-2.48, 17.45)	0.139	-	-
Education	4.68 (2.12, 7.26)	0.000*	4.501 (1.94, 7.06)	0.001*
Age category	1.423 (-1.27, 4.15)	0.297	-	-
Income	3.733 (0.48, 6.99)	0.025*	-	-
Exercise	0.373 (-2.66, 3.41)	0.808	-	-
Duration of diabetes in years	5.693 (0.12, 11.27)	0.045*	5.072 (-0.61, 10.75)	0.08
Adherence to exercise plan	1.857 (-3.26, 6.98)	0.473	-	-
Family history of diabetes	-4.172 (-12.45, 4.11)	0.320	-	-

** Statistically significant*

4.11. Evaluation of glycemic control levels

Using the fasting blood sugar values, that were obtained instantly, as the participant glycemic control can be categorized as reflected in Table 12. With only 49 (38.8%) participants attaining adequate glycemic control compared to 77 (61.1) that had poor control. The mean glycemic value was 9.03 (SD=3.93) mmol/L with a range values of 4.0-27.1mmol/L.

Table 12: Glycemic control as determined using fasting blood glucose values

FBG values	Frequency (%)	Mean	Min- Max	Standard Deviation(SD)
Normal 3.9-5.5 mmol/L	**18 (14.2)**	**9.03**	**4.0-27.1**	**3.92**
IGT values 5.6-7.0 mmol/L	**31 (24.6)**			
More than 7.0 mmol/L	**77 (61.1)**			

IGT= impaired glucose tolerance

4.12 Level of glycated hemoglobin

Using the HbA1c as the gold standard test, the patients were also categorized into two groups depending on their glycemic control: the cut off for poor glycemic control was a HbA1c value >7.0% and for normal <7.0 %. Overall poor glycemic control was obtained in 65 (51.6%) while 61 (48.4%) had good glycemic control (0= good and 1= poor glycemic control). Determinants of good glycemic control were identified using both linear and logistic regressions in Tables 13-20.

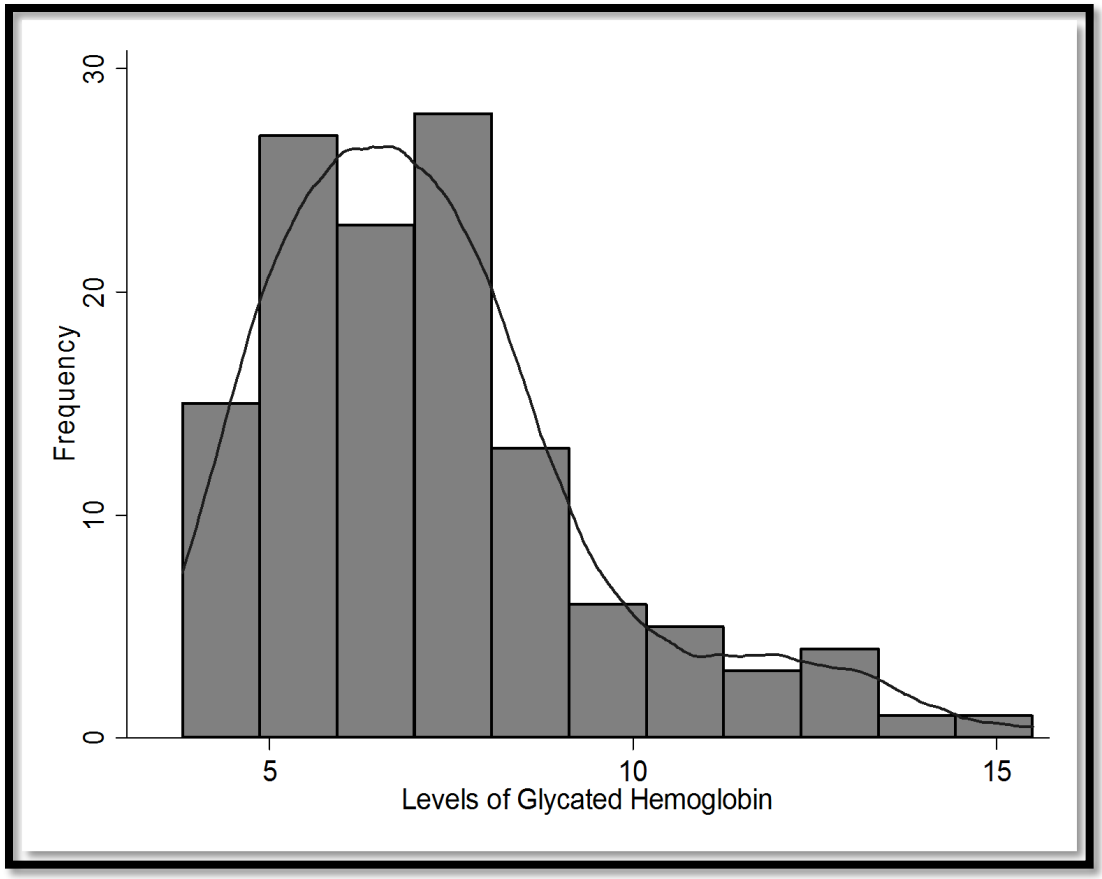

Figure 6: Level of glycated hemoglobin among the study participants

Table 13: Multivariable logistic regression of socio-demographic factors associated with glycemic control among type 2 diabetes patients attending diabetic clinic at Lacor hospital-Gulu

Variable	Glycemic Control		Crude Odds Ratio (95% CI)	p- value	Adjusted Odds ratio (95% CI)	p- value
	Good	Poor				
Sex						
Female	32(39.1)	50(60.9)	0.331	0.005*	0.378	0.031*
Male	29(65.9)	15(34.1)	(0.15, 0.71)		(0.15, 0.91)	
Age category						
18 to less than 30	7(77.8)	2(22.2)				
31- 40	5(71.4)	2(28.6)	1.337		1.308	0.057
41- 50	12(44.4)	15(56.6)	(1.03, 1.74)	0.032*	(0.99, 1.72)	
51- 60	17(50.0)	17(50.0)				
61- 70	14(46.7)	15(53.3)				
≥ 71	6(31.6)	13(68.4)				
Marital						
Single	9(52.9)	8(47.1)				
Married	36(52.2)	33(47.8)	1.276	0.165	-	-
Divorced	5(55.6)	4(44.4)	(0.90, 0.17)			
Widowed	10(34.5)	19(65.5)				
Cohabiting	1(50.0)	1(50.0)				
Occupation						
Retired	50(50.0)	10(50.0)				
Daily labourer	4(50.0)	4(50.0)	1.005			
Government employee	7(58.3)	5(41.7)	(0.83, 1.22)	0.957	-	-
Merchant	8(47.1)	9(52.9)				
Housewife	6(27.3)	16(72.7)				
Farmer	26(55.3)	21 (44.7)				
Non health Professional	56(47.5)	62(52.5)	0.845			
Health professional	4(80.0)	1(20.0)	(0.32, 2.26)	0.737	-	-
Work in health facility	1(33.3)	3(66.7)				
Education						
Can't read & write	8 (28.6)	20 (71.4)				
Primary	23 (52.3)	21 (47.7)	0.769	0.070	-	-
Secondary	18 (56.3)	14 (43.7)	(0.58, 1.02)			
Vocational training	1 (25.0)	3 (75.0)				
Higher education	6 (48.4)	65 (51.)				
Income						
Very low	35 (42.7)	47 (57.3)				
Low	14 (53.9)	12 (46.1)	0.767			
Average	7 (77.8)	2 (22.2)	(0.54, 1.08)	0.131	-	-
Above average	1 (50.0)	1 (50.0)				
High	4 (57.1)	3 (42.9)				

4.13. Progression of diabetes and presence of comorbidities on glycemic control

A statistically significant association was observed between duration of diabetes, family history and knowledge of diabetic complication with poor glycemic control. It was noted that those who knew the type of diabetes they had, had better glycemic control (COR = 0.447, 95% CI; 0.19, 1.01). Patients with hypertension tended to have poor glycemic level with only 41.9% achieving adequate glycemic control. Patients not on antihypertensive therapy had better glycemic control with 60 % having HbA1c < 7%. The difference in glycemic control between patients with hypertension and those without in the study group was statistically significant (p-value = 0.04). All four patients who had osteoporosis had poor glycemic control. The only disease related factors that were associated with glycemic control were the presence of hypertension and diabetic foot ulcer. It was noted that patients with hypertension had a 2 fold higher odds of having poor glycemic control. Patients with diabetic foot ulcer had good glycemic control with crude odd ratio equal to 0.183, (95% CI: 0.04, 0.89) as presented in Table 14.

Table 14: Presence disease complication, comorbidity associated with glycemic control in the study participants

Variable	Glycemic control		COR (95% CI)	P-value	AOR (95% CI)	P-value
	Good	Poor				
Progression of diabetes						
Know the disease type			0.447	0.052*		
No	12(34.3)	23(65.7)	(0.19, 1.01)			
Yes	49(53.9)	42(46.1)				
Know DM complication			1.206	0.601		
No	31(50.8)	30(49.2)	(0.59, 2.43)			
Yes	30(46.2)	35(53.8)				
Family history of diabetes						
No	42(44.2)	53(55.8)	0.500	0.102		
Yes	19(61.3)	12(38.7)	(0.22, 1.15)			
Duration of diabetes (year)						
Less than one year	7 (50.0)	7 (50.0)	5.693	0.045*	5.072	0.08
Between 1-5 years	27 (45.8)	32 (54.2)	(0.118, 11.267)		(-0.61,10.75)	
Above 5 years	27 (50.9)	26 (49.1)				
Have diabetic complication						
Diabetic foot ulcer						
No	52(45.2)	63(54.8)	0.183			
Yes	9(81.8)	2 (18.2)	(0.04, 0.89)	0.035*		
Retinopathy			1.570			
No	35(53.9)	30(46.2)	(0.78, 3.17)	0.209		
Yes	26(42.6)	65(51.6)				
Heart complication						
No	40(52.6)	36(47.4)	1.534	0.244		
Yes	21(41.0)	29(51.6)	(0.75, 3.15)			
Neuropathy						
No	28(53.9)	24(46.2)	1.449	0.307		
Yes	33(44.6)	41(55.4)	(0.71, 2.95)			
Presence of disease comorbidity						
Hypertension:			2.074			
No	27(60)	18(40)	(0.99, 4.35)	0.054*		
Yes	34(41.9)	47(58.0)				
Ischaemic heart disease			0.460	0.532		
No	59(47.9)	64(52.0)	(0.17, 5.22)			
Yes	2(66.7)	1(33.3)				
Dyslipidemia			1.905	0.603		
No	60(48.8)	63(51.2)	(0.18, 21.56)			
Yes	1(33.3)	2(66.7)				
Obesity			0.935	0.936		
No	58(48.3)	62(51.7	(0.18, 4.82)			
Yes	3 (50)	3(50.0)				
Osteoporosis:						
No	61(50.0)	61(50.0)				
Yes	0(0)	4(100)				

4.14 Influence of self- activities on glycemic control

The association between exercise, self-monitoring of blood glucose (smbg) and dietary restrictions were evaluated. None of the recommended dietary restrictions such as decrease intake of fatty food and sweet carbohydrates were associated with glycemic control.

4.14.1 Effect of diet on glycemic control

Most patients, 106 out of 126, had been given a diet plan. There were no differences in glycemic control amongst patient with diet plan and those without a diet plan as in both groups approximately 50.0% had poor glycemic control (p-v = 0.535) as shown in Table 15.

Those with a diet plan, 54% (n=68) and adhered to the plan. Eleven (8.7%) participants did not respond to the question on adherence to diet plan. Surprisingly, contrary to expectation, 63.2%(43/68) of the patients who claimed they adhere to diet plan had poor glycemic control as opposed to 36.2% who did not adhere to the diet plan. There was a statistically significance in glycemic control amongst patients who claimed they adhered to a diet plan and those who did not (p-value = 0.015).

There was difference in adequacy of glycemic control amongst patients who cut off fatty food, sweet carbohydrates and alcohol. However, it was notable that those who had strictly cut off fatty food had better glycemic control than those who occasionally cut off the fatty meal (55.9% versus 35.7%). Unexpectedly, 72.7% of patients who had not cut off fatty food had good glycemic control. Cutting off fatty food was a significant determinant of glycemic control (p-value = 0.023)

Quantity of alcohol consumed and the type of beverages had no bearing on adequacy of glycemic control. The effects of tobacco smoking were not significant.

4.14.2 Effect of exercise on glycemic control

Regular physical activity in 64.3% of participants was associated with glycemic control (Table 15). The common activity was bicycle riding with 9 out of 14 patients who rode showing good glycemic control. Patients who stated that they did exercise by walking had the worst

performance in terms of glycemic control. Of 28 whose only regular form of exercise was walking, only 39.3% had adequate blood glucose control.

Surprisingly those who stated they had no regular activity had better glycemic control than those who claimed they exercise by digging (54.2% versus 45.7%). Only 6 patients went to the gym and 66.7% (n=4) had good glycemic control as opposed to 47.1% of those who didn't go the gym. This difference however was not statistically significant and this could be attributed to the small number of patients who went to the gym.

About 70 % (n=88) of patients had been given exercise plan by the doctor. Out of the 88 patients who had the plan, 50.0% didn't adhere to the exercise plan at all. This indicated that in general adherence to exercise plan was poor. Those who adhere to exercise plan had the best glycemic control, only 31.3% who occasionally adhere to the plan had inadequate blood sugar control. Glycemic control was poorest in those who didn't adhere at all to exercise plan with 64.3% having poor control.

Table 15: Self- care activities associated with glycemic control

Variable	Glycemic control		COR (95% CI)	P- value	AOR (95% CI)	P-value
	Good	Poor				
Have a glucometer						
No	42(42.9)	56(57.1)	0.355	0.022*		
Yes	19(67.9)	9(32.1)	(0.15, 0.86)			
Smbg per week						
No smbg	45(43.7)	58(56.3)	0.793	0.065		
Strips expensive	3(60.0)	2(40.0)	(0.62, 1.01)			
Smbg ≥ 3 per week	11(81.7)	5(31.3				
Had diet plan	51(48.1)	55(51.9)	1.078	0.877		
No diet plan	10(50.0)	10(50.0)	(0.41, 2.80)			
Adhered to diet plan	30(63.8)	17(36.2)	0.460			
No adherence to diet plan	30(63.8)	17(36.2)	(0.25, 0.86)			
Cut off fatty food						
No	8(72.7)	3(27.3)	0.872	0.624		
Yes	20(35.7)	36(64.3)	(0.50, 1.50)			
Occasionally	61(48.4)	65(51.6)				
Cut off sweet CHO						
No	9(60.0)	6(40.0)	0.923	0.762		
Yes	22(40.0)	33(66.0)	(0.55, 1.55)			
Occasional	30(53.6)	26(46.4)				
Take alcohol			0.952	0.921		
No	9(47.4)	10(52.6)	(0.36, 2.53)			
Yes	52(48.6)	55(51.4)				
Tobacco			0.462	0.155		
No	50(45.9)	59(54.1)	(0.16, 1.34)			
Yes	11(64.7)	6(35.3)				
Exercise						
None	13(54.2)	11(45.8)	1.137	0.460		
Digging	28(46.7)	32(53.3)	(0.81, 1.60)			
Riding bicycle	9(64.3)	5(60.7)				
Walking	11(39.3)	17(60.7)				
Go gym	4(66.7)	2(33.3)				
No gym	56(47.1)	63(52.9)				
Adhere to exercise plan				0.025*		
No	15(35.7)	27(64.3)	0.513			
Yes	15(50.0)	15(50.0)	(0.29, 0.92)			
Occasionally	11(68.8)	5(31.3)				

4.14.3 Effect of medication adherence on glycemic control.

Surprisingly, those who stated they always take their medicines regularly, only eight patients (53.3% had good glycemic control as outlined in Table 16. Unexpected the association between good adherence and glycemic control was not significant. There was a very strong negative association between awareness of refill to obtain antidiabetic medicines with glycemic control.

Those who knew when to obtain a refill had a 10 fold lower odds of poor glycemic as compared to those who were unaware of when to obtain a refill. A higher knowledge score with test on diabetes management was negatively associated with poor glycemic control (COR = 0.793, 95% CI; 0.64, 0.98). Specific domains of knowledge that had positive impact on glycemic control, the ability to name medicine and route of administration.

Nonetheless, there was a weak negative association of good adherence and poor glycemic control. Similarly, there was no association between various reasons given for poor adherence and glycemic control. It's however notable that there's strong positive association between failure to obscure the antidiabetic medications at the facility because out of stock situation cause poor result in glycemic control. Patients who were unable to obtain medicines at the facility had seven fold times' odds of poor glycemic control to patients who had easy access to medications.

Notably, patients who stated they were too busy to adhere to medication time schedules had lower odds of poor glycemic control. However, this association was not statistically significant. Older patients had higher odds of poor glycemic control and this was significant.

Table 16: Adherence and non- adherence factors associated with glycemic control

Variable	Glycemic control		COR	P-value	AOR	P- value
	Good	Poor	(95% CI)		(95% CI)	
Adherence						
No	53(47.8)	58(52.2)	0.799	0.685		
Yes	8 (53.3)	7 (46.7)	(0.27, 2.36)			
Knowledge score			0.793	0.039*		
			(0.64, 0.98)			
Aware of drug refill			0.104	0.034*		
No	1(10.0)	9 (90.0)	(0.02, 0.85)			
Yes	60 (51.7)	56 (48.3)				
Can name medicine			0.302	0.001*		
No	19 (32.8)	39(67.8)	(0.14, 60.63)			
Yes	42 (61.8)	26(38.2)				
Reason for non- adherence						
Drug out of stock			7.241			
No	60(50.9)	58 (49.1)	(0.86, 0.70)	0.038*		
Yes	1 (12.5)	7 (46.5)				
Too busy			0.334			
No	51(45.5)	61(54.5)	(0.10, 1.13)	0.078		
Yes	10 (71.4)	4 (28.6)				

4.14.4 Medication factors associated with glycemic control

Regarding insulin storage, 15 patients stored their insulin in the refrigerator, out of which, 5 (33.0%) had inadequate glycemic control. 18 patients stored insulin under a cold water pot. There were no differences in prevalence of poor glycemic control amongst those who stored insulin refrigerator or under a cold water pot because in both the prevalence of poor glycemic control was 33.3%.

A total of 93 patients were not on insulin. Of these, 17 stored medicines in a small tin and 65% had poor glycemic control. The prevalence of poor glycemic control amongst those who stored medicine(s) in a tin was much higher than those that did not and this was significant (p=0.02) (76.5% versus 47.7%).

59 out of 93 patients stored medicines in a bag but no difference in glycemic control amongst those who stored in a bag and other places. (p = 0.226)

Patients who stated that they identify their antidiabetic medicine using color, shape of the drug were more likely to have poor glycemic control. For instance patients who stated they identified their medicine using color had five fold of poor glycemic control and were highly significant. The ability to read medication label were negatively associated with poor glycemic control.

4.15. Effects of other prescribed medication

There was no significant association between other prescribed antihypertensive, antidepressants, diuretics and analgesic medicines. However, there was a very strong positive association between use of diclofenac and poor glycemic control with a **(COR = 7.241, 95% CI; 0.86, 60.70).** This association was not however statistically significant.

Table 17: Medication factors associated with glycemic control amongst type 2 DM patients

Variable	Glycemic control		COR (95% CI)	P-value	AOR (95% CI)	P- value
	Good	Poor				
Storage of antidiabetic agents			0.425	0.140		
Refrigerator:			(0.14, 1.32)			
No	51(45.9)	60 (54.1)				
Yes	10(66.7)	5(33.3)				
Under cold pot						
No	49(45.4)	59(54.6)	0.415	0.101		
Yes	12(66.7)	6(33.3)	(0.15, 1.18)			
Cupboard			0.445	0.111		
No	48(45.3)	58(54.7)	(0.16, 1.21)			
Yes	13(65.0)	7(35.0)				
Bag			1.548			
No	30(54.6)	25(45.5)	(0.76, 3.14)	0.226		
Yes	31(43.4)	40(56.3)				
Small tin			3.563			
No	57(52.3)	52(47.7)	(1.09, 1.62)	0.035*		
Yes	4 (23.5)	13 (76.5)				
Traits used to identify drugs						
Shape:						
No	44 (56.40	34 (43.6)	2.359	0.023*		
Yes	17 (35.4)	31 (64.6)	(1.12, 4.95)			
Color:						
No	42 (66.7)	21 (33.3)	4.632	0.000*		
Yes	19 (30.2)	44 (69.8)	(2.19, 9.81)			
Size:						
No	48 (47.1)	54 (52.9)	0.752	0.531		
Yes	13 (54.2)	11 (45.8)	(0.31, 1.84)			
Label:						
No	27 (40.3)	40(59.7)	0.496	0.053*		
Yes	34 (57.6)	25 (42.4)	(0.24, 1.01)			
Prescribed antidiabetic agents	**Glycemic control**		**COR (95% CI)**	**P-value**	**AOR (95% CI)**	**P-value**
	Good	**Poor**				
Metformin :						
No	15(68.2)	7(31.8)	2.702	0.046*		
Yes	46(44.2)	58(55.8)	(1.02, 7.18)			
Glibenclamide:						
No	39(47.6)	43(52.4)	0.907	0.794		
Yes	22(50)	22(50)	(0.44, 1.89)			

Insulin:				
No	39(41.9)	54(58.1)	0.361	0.017*
Yes	22(66.7)	11(33.3)	(0.16,0.83)	
Types of insulin				
Mixtard	20(66.7)	10(33.3)	3.167	0.007*
soluble	2(100)	0	(1.37, 7.30)	
Humilin	0	1(100)		
Combination therapy				
Metformin + insulin	9 (60.0)	6 (40.0)	0.552	0.322
			(0.17, 1.79)	
Metformin + glibenclamide			1.061	0.878
			(0.49, 2.27)	
Insulin + Glibenclamide			0.222	0.185
			(0.02, 2.05)	
Other prescribed drugs				
Furosemide	8(34.8)	15 (65.2)	1.987	0.153
			(0.78, 5.09)	
Losartan + HCZ	4 (57.1)	3 (42.9)	0.689	0.636
			(0.15, 3.21)	
Nifedipine	15 (50.0)	15 (50.0)	0.929	0.842
			(0.41, 2.09)	
Diclofenac	1 (12.5)	7 (87.5)	7.241	0.068*
			(0.86, 60.70)	

HCZ= hydrochlorothiazide

4.16 Link between blood fasting glucose, lipid profile and glycemic control

Five patients had a very low BMI of less than18.5, all had good glycemic control. Other categories of BMI (normal, obese and very obese) had almost the same proportion of patients with poor glycemic control. BMI seems to have no statistically significant effect on glycemic control (P-value= 0.144)

LDL category: 7 patients who had high LDL level surprisingly all had adequate glycemic control. The proportions of patients with good glycemic control as well near normal LDL was less than patients with poor glycemic and normal LDL. And the difference was significant P-value = 0.005.

Patients whose fasting blood glucose were within the targeted therapeutic range tended to have better glycemic control and this statistically significant. There was no association between TC, TG levels and the degree of poor glycemic control. The only lipid profile that was associated

with glycemic control was HDL levels. Those with a favourable HDL profile had reduced odds of poor glycemic control and that was significant.

According to glycemic control there is difference in FBS, HDL, LDL and income. The ratio of LDL/HDL is 0 - 3.55. Total cholesterol /HDL ratio is 0- 4.5.

Table 18: Clinical characteristics of the study participants associated with glycemic control

Variable	Glycemic control		COR (95% CI)	P- value	AOR (95% CI)	P- value
	Good	Poor				
Duration of illness (years)					-	-
Less than a year	7 (50.0)	7 (50.0)	1.074	0.900		
5	27 (45.8)	32 (54.2)	(0.35, 3.26)			
Greater than 5	27 (50.9)	26 (49.1)				
BMI (Kg/m^2						
Underweight (≤ 18.5)	5(100)	0(0)	1.210	0.379	-	-
Normal (18.6-24.9)	24(46.2)	28(53.9)	(0.79, 1.85)			
Overweight (25.0-29.9)	20(45.5)	24(54.6)				
Obesity (≥30.0)	12(48.0)	13(52.0)				
FBG category Mmol/L			0.484	0.007*	0.528	0.023*
3.5-5.5	4 (22.2)	14 (77.8)	(0.29, 0.82)		(0.30, 0.91)	
5.6-7.0	13 (41.9)	18 (58.1)				
≥ 7.0	44 (57.1)	33 (42.9)				
TC (mg/dL)						
≤ 200	45 (44.6)	56 (55.4)	0.555	0.101	-	-
201- 239	12 (63.2)	7 (36.8)	(0.28, 1.12)			
≥ 240	4 (66.7)	2 (33.3)				
TG (mg/dL)						
≤ 150	26 (42.6)	35 (57.4)	0.779	0.333	-	-
151- 199	27 (55.1)	22 (44.9)	(047, 1.29)			
≥ 200	8 (50.0)	8 (50.0)				
HDL (mg/dL)						
≤ 40 (men)	7 (53.9)	6 (45.1)				
≤ 50 (women)	27 (39.1)	42 (60.9)	0.702	0.034*	0.702	0.044*
41- 50 (men)	10 (52.6)	9 (47.4)	(0.51, 0.97)		(0.51, 1.00)	
Between 50 -59 (women)	7 (58.3)	5 (41.7)				
≥ 60 (both)	10 (76.9)	5 (41.7)				
LDL (mg/dL)						
Optimal (≤ 70	54(45.8)	64(54.2)	0.952	0.018*	0.962	0.048*
Near optimal (100-129)	5(100.0)	0(00.0)	(0.92, 0.99)		(0.93, 1.00)	
High (130-159)	1(100.0)	0(00.0)				
Very high (≥ 160)	1(100.0)	0(00.0)				

Considering the multivariable analysis, results of the predictors associated with glycemic control were obtained as shown in Table 19. The predictors that were associated with either good or poor glycemic control were noted as ; identification of medicine using color, knowing the drug by name, having complication of diabetic foot ulcer, fasting blood glucose and sex. To evaluate how well these predictor variables explain variances in the glycemic control, we used the Parsimonious model. The structural equation modeling using AIC (Akaike Information Criterion) fit the statistic and was of advantage over regression models and R-square.

When adjusting for confounding those who identified their antidiabetic medicines using color had poor glycemic control (AOR= 5.043, (95% CI; 2.16, 11.79), P = 0.000).

Those who were able to name their medicines had lower odds of poor glycemic control and this association remained significant even when adjusted for confounders, diabetic foot ulcer, sex as well as identification of drug using color (AOR = 0.394, 95% CI; 0.17, 0.92)

From the crude measure of association there was a negative association between having diabetic foot ulcer and poor glycemic control. This association remained significant even after adjusting by sex, fasting blood glucose and patient's knowledge of their drug. The association was strong (AOR = 0.162, (95% CI; 0.03, 0.91)

As expected there was a negative association between fasting blood glucose levels and poor glycemic control. Those whose FBG was within the targeted therapeutic range had half odds of poor glycemic as compared to those with very high fbg at the time of investigation (AOR = 0.501, 95% CI; 0.27, 0.92)

Consistent with the finding on bivariable analysis, female gender tend to have better glycemic control than male counterpart (AOR = 0.378, 95% CI; 0.16, 0.92)**.**

Table 19: Summary of multivariable analysis adjusting for confounders using Parsimonious model.

Variable	COR (95% CI)	P- value	AOR (95% CI)	P- value
Color	4.632 (2.19, 9.81	0.000	5.043 (2.16, 11.80)	0.000
Ability to name the drug	0.302 (0.14, 60.63)	0.001	0.394 (0.17, 0.92)	0.030
Diabetic foot ulcer	0.183 (0.04, 0.89)	0.035	0.162 (0.03, 0.91)	0.039
Fasting blood glucose	0.484 (0.29, 0.82)	0.007	0.501 (0.27, 0.94)	0.030
Sex	0.331 (0.15, 0.71)	0.005	0.378 (0.16, 0.92)	0.031

4.17 Preparedness of the health care providers on diabetic patient training at Lacor hospital

Physician in-charge of diabetic clinic, 1 clinical officer, 1 pharmacist, 2 registered nurses and one health educator were interviewed. The summary of the findings as follows;

Diabetic patient's education is carried out every week of the DM clinic (Wednesdays and Thursdays) and any other day on encounter of a new diabetes patient.

Education and counseling is done both as individual and as group at the OPD reception for all patients. The tools used are diabetic diet list, insulin syringe and hygiene chart that guide the education.

The medical officer on duty, clinical officer, pharmacist, trained nursing officers, counselor and health officers all play their role to give education at their point of service.

The medical officer/ physician in-charge of OPD normally coordinates that education or counseling should be adequately provided to DM patients.

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

Diabetes is a complex, chronic illness requiring continuous medical care with multifactorial risk reduction strategies beyond glycemic control. Patient self-care education and support are critical to preventing acute complications and reduction of long-term morbidity and mortality (83).

This study was conducted in a private teaching hospital located in the northern part of Uganda. It assessed the knowledge on antidiabetic medicine use and glycemic control among type 2 DM patients. It also evaluated the knowledge on self-care activities and its impact on the control of blood sugar near to euglycemia. Results suggest that diabetes type 2 is more prevalence among of the 51-60 years age group (26.9%). This is similar with results of a study conducted in Ethiopia where the majority of the study participant were in the 40 to 69 years age group of (1) and contrast to studies done in Awka, Nigeria which revealed prevalence of diabetes among age group 71- 80 years(12). On running the logistic regression factors associated with glycemic control include; sex, presence of comorbidity (hypertension and diabetic foot ulcer), use antidiabetic- metformin , insulin, route of administration, storage of medicine in a small tin, FBG, LDL, HDL, having glucometer for smbg, exercise and adherence to diet plan on glycemic control as is reported elsewhere (39)(70)(84).

Females predominated as participants at 65% of total and were significantly associated with glycemic control, in that, they were 0.3 (AOR =0.378, 95% CI: 0.2-1.0) times more likely to have adequate glycemic control compared to males. This study finding is contrary to a study done in Bharati hospital in India where males 57.14 % and 42.86% females (85). Reasons for the high turnover could be attributed by the fact that females get fast access to health care at any initial cause of an illness. The study population had a mean average age of 55.6 year (SD = 14.1) and majority were in the range 51-60 years age group. It is also comparable with a study conducted in India that revealed most of the type 2 DM patients' were in 41-60 years age group.

We generated the knowledge score from the structured questionnaire with the sum of variables eventually converted to percentage. Overall type 2 DM patients had scored 72.2%, considered a good knowledge on antidiabetic medicine use (mean average 59.8%). Majority of the study

population had suffered from one or two diabetes complications (89%) and equally had limited knowledge (82%) on side effects of the antidiabetic medicines they were using. This is similar to a study done in Muranga- Kenya, that indicated a majority of diabetes patients were using herbal remedies (45%) on trial basis not on grounds of prior knowledge or experience (69). There are several studies done on assessment of antidiabetic medication adherence but many lack information on knowledge of drug side effects. Males scored 66.7 % slightly higher than women 61.1% on general knowledge of antidiabetic medicine use and 31-40 age category had the lowest score (n=7, 5.56%)compared to other categories. Knowledge intervention should therefore target this specific patient gender. Type 2 DM patients who were divorced had the lowest score 55% on knowledge of antidiabetic medicine use compared to those patients who were living single 77.8%. About 54% of the study respondents were able to read and pronounced the antidiabetic drug by name, while 46.0 % did not know the drug by name and pronounced it. Similar study done in Lagos (Nigeria) revealed that, 52 of the respondents (34.2%) knew all the antidiabetic drugs they were taking by name, 64 of the respondents (42.1%) knew only a few drugs they are taking by name, 23 of the respondents (15.1%) knew most but not all the drugs by name, 10 of the respondents (6.6%) knew some of the drugs by name while 3 respondents (2.0%) did not know the name of the diabetic drugs they were taking(41).

On bivariate analysis using linear regression, education was the powerful predictor on knowledge of antidiabetic medicine use among type 2 DM study participants and it was statistically significant p value = 0.0001. This meant that the higher the level of education one had the better use of antidiabetic medicines. This is long held observation that education is the key in the management of diabetes for proper use of medicines, self-care and goal to achieve adequate glycemic control(86).

Slightly over 70% of the participants had no family history of diabetes while 28.5 % confirmed familial linkage. Nearly three quarter of the patients had one or more diabetic complications and comorbidities with 89.7% versus 73.8% respectively. Hypertension was the most common comorbidity among the study group (64.3%). Similar studies done in India showed a total 88 (83.81%) patients suffered from co-morbid conditions. Hypertension accounted for 27.27% of the total complications which is lower than the study reported in Nepal where hypertension accounted for 70.62% of the total complication. It is also consistent with study findings

conducted in Texas medical Centre that hypertension is more common complication affecting 20-60% of people with diabetes (85). The goal of managing diabetes care involves increasing awareness among victims of diabetes. Processes of care include; periodic testing of HbA1c, lipids, urinary albumin, examining the retina, proper cleaning of feet, encouraging individual to perform Smbg, do regular exercises, follow diet plan, cessation of alcohol intake and cigarrete smoking.

The overall results of glycemic control among the study participants showed that 65 patients (51.6%) had poor and only 48.4% achieved good glycemic control. This result is comparable with a cross-sectional survey studies done in south-west, Ethiopia reveal three quarter of type 2 diabetic patients (n=325) had poor glycemic control(83). Other similar early studies include; results from Bangladesh (n=515) demonstrated only 32.6% had optimal, 25.8% fair and 40.6% had poor glycemic control(87).

Hypertension was the most comorbidity affecting type 2 DM patients. In this study it was significant that those with hypertension were two (COR= 2.1 95% CI= 1.0-4.4) times more likely to attain adequate glycemic control compared to those with other comorbidities. This can be explained basing on the findings that patients with higher comorbidity tend to have better glycemic control at first presentation though this was not statistically proven(84).

Expectedly, those who stated they always take their medicines regularly; only eight patients (53.3%) had good glycemic control. The association between good adherence and glycemic control was not significant. This may be attributed to the fact that it's difficult to accurately measure adherence and non- adherence often respondents do not give true responses. Similar study done at Ayder hospital also revealed the same challenges(1).

Exercise, however was associated with good glycemic control. Patients who stated that they adhere to exercise plan had about half the odds of poor glycemic control compared to those who did not adhere to exercise. This was statistically significant (COR =0.513, 95% CI; 0.29, 0.92). this finding is consistent with the study done in South Texas were exercise and diet were strong predictors of reduced blood glucose (21).

It is also consistent with study findings conducted in Texas Medical Centre that hypertension was more common a complication affecting 20-60% of people with diabetes (84). Also similar with a study conducted in a tertiary hospital, Ahmedabad where hypertension accounts for (n= 70%) of the DM patients(61).

Hypertension was the most comorbidity affecting type 2 DM patients. In this study it was significant that those with hypertension were two (COR= 2.1 95% CI= 1.0-4.4) times more unlikely to attain adequate glycemic control compared to those with other comorbidities. This is in contrast with the findings that patients with higher comorbidity tend to have better glycemic control at first presentation though this was not statistically proven(88). Surprisingly, patients who had a complication of diabetic foot ulcer demonstrated good glycemic control and this remained statistically significant even when adjusted (AOR =0.162, (95% CI; 0.03, 0.91), p-value = 0.030 with other factors like sex, fasting blood glucose, ability to name antidiabetic agent and identifying the drug using color. Our observation is line with a similar study conducted among the predominant African American population with type 2 DM in Wash, where those with chronic complications and comorbidity had better glycemic control at first presentation. However, after correcting with age and other factors the contribution of comorbidity to glycemic control became insignificant(88).

The goal of managing diabetes care involves increasing awareness among victims of diabetes. Processes of care include; periodic testing of HbA1c, lipids, urinary albumin, examining the retina, proper cleaning of feet, encouraging individual to perform Smbg, do regular exercises, follow diet plan, cessation of alcohol intake and cigarrete smoking.

In our study, biguanide, sulphonylureas and insulin were commonly prescribed classes of antidiabetic agents. Metformin (n=104) being one of the insulin sensitizers because of their ability to reduce insulin resistance, glibenclamide (n=44) categorized as insulin secretagogues because they enhance endogenous insulin release, and insulin (n=33) were the common oral hypoglycemics prescribed at Lacor diabetic clinic. Similarly, study done in India also revealed metformin (n=100), followed by glimepiride (n= 78) and insulin (n=26) being prescribed(61).

As stated in literature review, the ADA has determined glycosylated hemoglobin(HbA1c) as the best measure of glycemic control, with a level less than 7% as a goal of optimal blood glucose to prevent the complications and to reduce overall disease management cost (71).

Expectedly, those who stated that they always take their medicines regularly only eight patients (53.3%) had good glycemic control. The association between good adherence and glycemic control was not significant. This may be attributed to the fact that it's difficult to accurately measure adherence and non- adherence often respondents do not give true responses. Similar study done Ayder hospital also revealed the same challenges(1). It was however notable that there was a strong positive association between failures to obtain antidiabetic medicine(s) at the facility due to out of stock situation with poor glycemic control. Patients who were unable to obtain medication had seven fold (COR = 7.241, (95% CI; 0.86, 0.70, P-value = 0.038) times odds of poor glycemic control to patients who had easy access to availability of medications. This observation emphasizes the need to ensure constant surplus of medicines as a means of improving diabetes management.

Exercise, however was associated with good glycemic control. Patients who stated that they adhered to exercise plan had about half the odds of poor glycemic control compared to those who did adhere to exercise. This was statistically significant (COR =0.513, 95% CI; 0.29, 0.92). Although those who stated they went to the gym had lower odds of poor glycemic control. This difference however was not statistically significant and this could be attributed to the small number of patients who went to the gym. This finding is consistent with the study done in South Texas were exercise and diet were strong predictors of reduced blood glucose (21). It is also well elaborated in the 2012 SEMDSA guideline for the management of type 2 DM when large cohort studies have demonstrated that, in people with type 2 DM, regular physical activity and moderate to high levels of cardiorespiratory fitness are associated with reductions in cardiovascular and overall mortality of 39-70% over a 15- to 20-year period. People with type 2 diabetes will derive the following benefits from regular physical activity: Increased cardiorespiratory fitness, improved glycemic control, decreased insulin resistance, improved blood lipid profile, improved blood pressure(89).

In our study findings, having a glucometer significantly decrease the odds of poor glycemic control by about a 1/3. This was supported by the observation that the frequency of smbg levels

(weekly intensity) has negatively associated with poor glycemic control although this was statistically significant (COR =0.793, 95% CI; 0.62, 1.01, p-value = 0.065)

We found a negative association between fasting blood glucose with poor glycemic control. This can be explained that blood glucose rises as insulin action declines, even when no food is taken, because of hepatic gluconeogenesis. This accounts especially for the rapid increase in blood glucose which occurs in the small hours of the morning before breakfast(7). It's probably a minor though or speculation be attributed to the fact that most of these patients do take breakfast as they come to the clinic day knowing that they wait for long in the queue. And as soon as they arrived sample for fbg is withdrawn and tested immediately. These rapid changes in blood glucose also explain why so many patients record different blood glucose readings each day, since even a half to one hour difference in timing can give a very different result. However, to eliminate errors reproducible blood glucose profiles are essential for making rational adjustments to treatment.

Another observation we found in the study was trait used by patients to identify their antidiabetic tablet. These include; shape, size, color, and label. Patients who identified their medicines using color had poor glycemic control. This was significant in both bivariable and multiple logistic regression analyses with P-value =0.000. Similarly, it was also noted that the prevalence of poor glycemic control amongst those who stored medicine(s) in a tin was three fold (AOR = 3.503, 95% CI; 1.09, 1.62, p-value = 0.035) much higher than those that did store in other places such as cupboard, and bag.

Consistent with our finding in this study was the female gender that was protective and had good glycemic control than males. Women seem to be the most vulnerable and thus present at medical services earlier in search of cure or prevention.

High density lipoprotein (HDL) was the only lipid profile that had a good association with adequate glycemic control and it was significant (AOR =0.702, 95% CI; 0.51, 1.00, P-value = 0.044)

5.2 Limitations

The study design (cross-sectional) allowed information to be collected within the frame time and did not allow follow up of participants.

Our study was limited in one private diabetic clinic and this make it impossible to generalize the findings since it might have left the highest number of type 2 DM patients in other clinics within the region to conclude of the target population.

In response to self-care activities questionnaire there may be information bias due to recall responses since this was not physically observed as they perform their activities.

In many of the previous studies done it has pointed out fasting blood glucose having a strong significant positive correlation with adequate HbA1c level. However, in our data analysis fasting blood glucose level within normal was not a good marker predict good glycaemia.

5.3 Conclusion

The average mean duration of diabetes since first diagnosis among the study respondents was 7.1 years, with majority (46.8%) between 1-5 and over 5 years (42.1%)

54.0% of the patients had adequate knowledge on use of their medication but little knowledge on the side effects.

In our assessment of glycemic control using HbA1c as a gold standard test, significant number (n=65) had poor glycemic control while sixty one of them attained good blood glucose level of less than 7%. It was demonstrated that patients who use~~s~~ color to identify their medicines, presence of comorbidity like hypertension, absence of antidiabetic medicine at the facility, old age and storing medicines in a small tin were contributing factor to poor glycemic control. On the other hand our data also showed that adequate glycemic control was enhanced by knowledge of the drug itself, dose, frequencies, and timely refill of the medicines promoted good glycemic outcome.

In addition, self-activities such as adhering and performing regular exercises, following diet plan of restricting intake of highly sweet carbohydrates, abstaining from fatty meals and avoiding heaving consumption of liquor were predictors of near normal euglycemia. Our strategies therefore are to strengthen the existing team at diabetic clinic and educate patients constantly.

5.4 Recommendations

5.4.1 For policy and practice

There is need for the stakeholders to guide in the implementation of lifestyle interventions to reduce the prevalence of non-communicable diseases.

It is advisable for any diabetic association team to periodically offer free screening of individuals in the communities both rural and urban as a way of awareness and saving victims at early stage of disease progression.

Promote training and education for patients and device means of low cost sharing that gadgets for self-monitoring available for diabetes patients as well as affordable medicines for all.

Implementation of evidence-based diabetic guidelines/protocol and formulate standard criteria for referral of patients from primary care to higher level of care.

5.4.2 For future research

This study was more of the knowledge of antidiabetic medicine use and realizing the knowledge gap that exist during the interview, there is need for further research to dwelt more on knowledge of side effects of these hypoglycemic and create awareness.

Majority of the study did not adhere to diet or exercise plans are natural way to attain adequate glycemic control. Thus is need for future studies to dwell more on barriers that might contribute to self-care activities.

The need for prospective studies with sizeable number of patients and multiple methods to identify other factors enhancing glycemic control and vice versa.

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APPENDICES

Appendix 1A: Participant information and informed consent

Tittle of the study: Assessment of the use of antidiabetic medicines and glycemic control among patients with type 2 diabetes mellitus at Lacor hospital, Gulu- Uganda

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Introduction

I am Oyella Josephine Mary, studying at the University of Nairobi, College of Health Sciences, School of Pharmacy for a master's degree. I am conducting a study on the use of antidiabetic medicines, knowledge on diabetes, self-care practice and glycemic control among adult patients with type 2 diabetes mellitus. Diabetes has become rampart and progressively causing a lot of suffering and premature death to the people in Uganda. I am going to give you information and invite you to be part of this research.

Purpose of the research

The objective of this study is to assess antidiabetic medicine use, and its effect in the control of blood sugar at Lacor hospital. I am going to ask you some few questions regarding the type of drugs, knowledge on how you are using your medicines, any other disease you have that require additional drug therapy, dosage of medicine you take, adverse drug reactions, drug interactions, laboratory monitoring of your condition and compliance to given instructions.

Participant selection

You are being invited to take part in this research because you are diabetic and because we feel that your input will be extremely valuable as the information you give will be used to assess drug related problems to identify gaps in the knowledge of how to use the drugs and treatment outcome.

Voluntary participation or withdrawal from study

The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. It is your choice whether to participate or not. If you choose not to participate, you are not going to lose any service that you normally get from the hospital. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. Even after joining the study, you still have the right to withdraw from the study at any time you want.

Risks and benefits

Participating in this study may be associated with no or minimum risk, there's pain on pricking to draw about one teaspoonful of blood sample but aseptic technique by experienced laboratory technicians will be used to ensure that no infection will take place. You will be interviewed guided by a questionnaire to abstract some information which may take at most fifteen minutes. We will also access your treatment file to get further information about your condition. You will not be provided any incentive to take part in the research. However, your participation is likely to help us in assessing drug related problems among diabetes patients, to improve dissemination of knowledge pertaining treatment care and good monitoring of blood sugar at Lacor hospital.

Assurance of confidentiality

The information that we collect from this research project will be handled with care and confidentiality and will only be used for the purpose of the study. Your name will not be used and any information about you will have a code. Only the researchers will know what your number is and we will keep that information secure and confidential. You are free to decide to participate in this study or withdraw even if you have started. The results of this study will be used to improve knowledge on how to use antidiabetic medicine for the good of treatment care outcomes.

Who to contact

In case you have any questions related to this study and regarding your right as a research volunteer, you can contact the following:

1. Oyella Josephine Mary, Master of Pharmacy in Clinical Pharmacy student, University of Nairobi, CHS, SOP, Department of Pharmaceutics & Pharmacy Practice.
   Email: joyelah.329@gmail.com, Tel: +254-790499398, +256-772699398. OR
2. Dr. Sylvia Opanga
   Email: sylvia.adisa@gmail.com mobile telephone number: +254721296448
3. In case you have questions about your rights as a participant contact the secretary Kenyatta National Hospital- University of Nairobi who have approved this study on email: uonknh_erc@uonbi.ac.ke, P.O Box 20723-00202 Nairobi, Tel. 2726300 Ext. 44102.
4. Institutional director of Lacor hospital; Mr. Martin Ogwang.
   Email: ogwang.martin@lacorhospital.org **, mobile telephone number +256 772593901**

Consent form

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with the study investigator. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential. By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes ☐ **NO** ☐

I agree to have my blood sample taken for the determination of blood sugar level for the study: Yes ☐ No ☐
I agree to provide contact information for follow-up: Yes ☐ NO ☐

Participant printed name: _____

Participant signature / Thumb stamp _____ **Date** _____

Researcher's statement
I……. the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and have willingly and freely given his/her consent.
Researcher's Name: _____ **Date**: _____
Signature
_____
Role in the study: _____ *[i.e. study staff who explained informed consent form.]*
For more information contact _____ at _____ from

_____ to _____
Witness Printed Name (*If witness is necessary, A witness is a person mutually acceptable to both the researcher and participant*)

Name _____ **Contact information** _____

Signature _____ **Date**; _____

Appendix II A: Structured questionnaire

Part I: Eligibility (Screening questionnaire)(78)

1. Do you suffer from any of the following disease in addition to diabetes? (Sickle cell disease/ thalassemia/hemochromatosis/pancreatic cancer/pancreatitis/cystic fibrosis /Pheochromocytoma/acromegaly/Cushing's syndrome)

a. Yes (1)
b. No (2)

2. Have you been using the following drugs consistently in the last 3 months? Phenytoin/Steroids/Estrogen (such as oral contraceptives)

a. Yes (1)
b. No (2)

3. (For females only)Are you pregnant?

a. Yes (1)
b. No (2)

4. Has the consent been explained and obtained?

a. Yes (1)
b. No (2)

(Stop the interview if the answer to questions 1, 2 or 3 is Yes or to 4 is No)

Part II: Socio-demographic characteristics

1. **Patient Bio-data**

1.1 study code _____ Residence: 1.2 Urban ☐ 1.3 Rural ☐ 1.4 Weight _____ (Kg) 1.5 Height (cm) _____ 1.6 BMI _____ 1.7Allergies _____ 2. **Sex:** 2.1. Male ☐ 2.2. Female ☐ Date of Birth __/___/____ Date of Interview ___/___/_____
3. **Age _____ Years**

3.1. Less than 30 ☐ 3.2. 30 – 40 ☐ 3.3. 41- 50 ☐ 3.4. 51— 60 ☐

3.5. Greater or equal to 61 ☐

4. **Marital Status**

4.1. Single ☐ 4.2. Married ☐ 4.3.Divorced ☐ 4.4. Widowed ☐

4.5 Co-habiting ☐

5. **Occupation**

5.1. Farmer ☐ 5.2. Gov't Employee ☐ 5.3. Merchant/Trade ☐

5.4. Daily Laborer ☐ 5.5. House wife ☐ 5.6. Retired ☐

6. **Profession**

6.1. Health professional ☐ 6.2. Non-health professional ☐ work in a health facility ☐

7. **Educational Status**

7.1. Cannot read and write ☐ 7.2. Primary ☐ 7.3. Secondary ☐

7.4. Higher Education ☐

8. **Monthly Family Income (in UGX) _'000/=**

8.1. Very Low (<450) ☐ 8.2. Low (451-1,200) ☐ 8.3. Average (1,201-2,500) ☐

8.4. Above Average (2,501-3,500) ☐ 8.5. High (>3,501) ☐

Part III: Disease related Characteristics

9.0 Do you know the disease condition that you have? 9.0.1 Yes 9.0.2 No

9.1 Duration of diabetes_____ Years

9.1.1 Less than 1 ☐ 9.1.2. 1-5 ☐ 9.1.3. More than5 ☐

9.2. Do you have any member(s) of your family history who has/had diabetes? 9.2.1 Yes ☐ 9.2.1 No ☐

10. Do you know the diabetes complications?

10.1. Yes ☐ 10.2. No ☐

11. If yes to question. no 10, which of the following diabetes complication you know (can tick more than once)

11.1. Neuropathy ☐ 11.2. Kidney complications ☐

11.3 Diabetic foot ulcer ☐ 11.4. Heart complications ☐

11.5. Eye complication ☐ 11.6 Others ☐ Specify _____

12. Do you have any diabetic complications? Yes ☐ No ☐

13. If yes to Q 12, which diabetic complications are present (can tick more than once)

13.1. Neuropathy ☐ 13.2. Kidney complications ☐

13.3. Heart complications ☐ 13.4. Eye complications ☐

13.5. Diabetic Foot Ulcer ☐ 13.6. Others, if any_____

Part IV: Non-pharmacological approaches of diabetes care

14. **Diet**

14.1. Do you have dietary plan you set with your doctor? Yes ☐ No ☐

14.2. If yes to Q 14.1, do you always adhere to your plan? Yes ☐ No ☐ Sometimes ☐

14.3. What type of dietary plan you have?

14.3.1. Always cut off sweet carbohydrate meals Yes ☐ No ☐ sometimes ☐

14.3.2. Always cut of fatty meals (butter, cheese, fried foods, fatty cuts of red meat, egg yolks, poultry skin…) Yes ☐ No ☐ occasionally ☐

14.3.3. Other plan, if any _____

15. **Exercise**

15.1. Which of the following activities do you do? Riding bicycle ☐ Digging ☐

Walking more than 2 km ☐ Never ☐

15.2. Do you go the gym? Yes ☐ No ☐

15.3 If "No" do you do exercise that are not part of routine work? Yes ☐ No ☐

15.4 Do you have exercise plan you set with your doctor? Yes ☐ No ☐

15.5 If "Yes" to question no. 15.4, do you adhere to your plan? Yes ☐ No ☐

15.6. How many days per week you do moderate intensity exercise? _____ day(s)

15.7. How many minutes per week you do moderate intensity exercise? _____ minutes

15.8. Other forms of exercise, if any_____

NB. Moderate exercise means any form of exercise performed minimum of 30 minutes and above.

16. **Alcohol**

16.1. Do you ever drink alcohol? 16.1.1 Yes ☐ 16.1.2 No ☐

16.2 When did you last take alcohol? Yesterday ☐ A week ago ☐ A month ago ☐ Many year ago ☐

16.3 How often do you take alcohol? Daily ☐ Once a week ☐ Once a month ☐ Once a year ☐

16.4 Which of these brands do you take? Uganda waragi ☐ Beer ☐ Wine ☐ None ☐ Local brew ☐ others ☐

16.5 In one sitting about how much alcohol do you consume?

Bottle -- (300ml, 500ml)

Glasses—(100ml, 200ml)

17. **Cigarette smoking**

17.1. Do you ever smoke cigarettes? Yes ☐ No ☐ Formerly ☐

17.2. If yes to q. no 17.1, how much cigarettes you smoke per day? _____Packs

17.3.1. < half ☐ 17.3.2. Half ☐ 16.7.3. >half ☐

18. **Self-monitoring of blood glucose (SMBG)**

18.1. Do you have a glucometer? Yes ☐ No ☐

18.2. If yes to q. no 18.1, how frequently do you perform SMBG per week? _____times

18.2.1. 1 ☐ 18.2.2. 2 ☐ 18.2.3 3 ☐ 18.2.4 more than 4 ☐

19. Part V. Pharmacological approaches

Medication knowledge assessment

19. Can you name your medication? Yes ☐ No ☐

20. Do you know the dose to take? Yes ☐ No ☐

21. Does not know how many/or frequency of administration? Yes ☐ No ☐

22. Do you know when or what time to take your medication?

22.1 Yes ☐ 22.2 No ☐

23. How do you identify your medicine?

23.1 Shape ☐ 23.2. Color ☐ 23.3 Depend on others to identify ☐ 23.4 Label ☐

24. What is the route of administration? 24.1 Injection ☐ 24.2 Oral ☐ Both ☐

25. Are you suggesting the same prescription to your intimates with the same conditions?

25.1 Yes ☐ 25.2 No ☐

26. Where do you keep the medication? (To ascertain special storage conditions)

26.1 Fridge ☐ 26.2 Cupboard ☐ 26.3 bag ☐ 26.4 under a cold water pot ☐

26.5 In small tin ☐

27. When is the next refill due? (And plan or method for obtaining refills.)

25.1 Aware ☐ 25.2 Not aware ☐

28. How long do you have to take this medication for?

28.1 For a short term therapy ☐

28.2 Unsure, ☐

28.3 Knows if it is long or short term therapy ☐

29. Do you know about any possible side effects of this medication?

29.1 No idea of the side effects ☐

29.2 Knows some of the side effects ☐

29.3 Knows all of the important side effects ☐

30. Give at least one side effect _____

31. What would you do if you forgot to take a dose of this medication?

31.1 Would act inappropriately *(e.g. take double the quantity next time)* ☐

31.2 Would seek advice from pharmacist, nurse, care taker, or GP ☐

31.3 Would take appropriate action *(e.g. take correct dose next time)* ☐

32 Do you take your antidiabetic drugs as advised by your doctor? Yes ☐ No ☐

Sometimes ☐ Never ☐

Part VI: Reason for non- adherence

33. What reasons may prevent you from taking medicines regularly?

Please tick the options below (√)

Items	Yes	No	Items	Yes	No
Lack of finance			Side effects		
Feeling drug is not effective			Feeling dose is high		
Interferes with my meal plan			Complexity of drug regimen		
Had been taking since many years			Multiple medications		
I forget			Poor family support		
Feeling well without the medicine			Pain at injection (If Insulin)		

Appendix III A: Data Abstraction Format

Section a): Chart review

34. Fasting blood glucose value (mg/dl)

34.1. Recent _____ 34.2. On immediate previous appointment _____

35. Recent HA1c value, if any_____ current _____

36. Recent fasting lipid profile, if any

36.1. Total cholesterol _____ 36.2. HDL_____

36.3. LDL _____ 36.4. TG _____

Section b) Co-morbidities and DM Complication

37. Presence of co morbidities

37.1. Present ☐ 37.2. Absent ☐

38. If the response for the above question is *present*, which of the following co-morbidity is present? (Can tick more than once)

38.1. Hypertension ☐ 38.2. Ischemic Heart Disease ☐

38.3. Dyslipidemia ☐ 38.4. Peripheral Vascular disease ☐

38.5. Obesity ☐ 38.6. Others, Specify_____

Section c) Medications prescribed

39. Total number of prescribed drugs _____ (In number)

40. List of prescribed Antidiabetic medications (can tick more than once)

40.1. Metformin ☐ 40.2. Glibenclamide ☐

40.3. Insulin ☐ 40.4. Others, Specify_____

41. Type of insulin prescribed, if any

41.1. Regular insulin ☐ 41.2. Humulin ☐

41.3. Soluble insulin ☐ 41.4 Insulin mixtard ☐

42. List of prescribed medications

42.1. Furosemide ☐ 42.2. Spironolactone ☐

42.3. Atorvastatin ☐ 42.4. Nifedipine ☐

42.5. Propranolol ☐ 42.6. Hydrochlorothiazide + Losartan ☐

42.7. Enalapril ☐ 42.8. Acetyl salicylic acid ☐

42.9. Others Specify_____

Appendix 1B: Participant information and informed consent for the healthcare provider

Tittle of the study: Assessment of the use of antidiabetic medicines and glycemic control among patients with type 2 diabetes mellitus at Lacor hospital, Gulu- Uganda

Principal Investigator and institutional affiliation

Oyella Josephine Mary

Department of Pharmaceutics and Pharmacy Practice

School of Pharmacy

University of Nairobi

P.O Box: 19676-00202, Nairobi.

Co-Investigators and institutional affiliation

1. DR. SYLVIA OPANGA (PhD)

Department of Pharmaceutics and Pharmacy Practice, School of Pharmacy, University of Nairobi

2. DR. BEATRICE AMUGUNE (PhD)

Department of Pharmaceutical Chemistry, School of Pharmacy, University of Nairobi

Introduction

I am Oyella Josephine Mary, studying at the University of Nairobi, College of Health Sciences, School of Pharmacy for a master's degree. I am doing my research on the use of antidiabetic medicines and its effect on the control of blood sugar among adult patients with type 2 diabetes mellitus. Diabetes has become rampart and progressively causing a lot of suffering and premature death to the people in Uganda. I am going to give you information and invite you to be part of this research.

Purpose of the research

The objective of this study is to assess antidiabetic medicine use, and its effect in the control of blood sugar at Lacor hospital. I am going to ask you a few questions regarding the education and counseling of diabetes patients on the use of their medications and how it is done.

Participant selection

You are being invited to take part in this research because you are diabetic healthcare provider and because we feel that your input will be extremely valuable as the information you give will

be used to assess drug related problems to identify gaps in the knowledge of how to use the drugs and treatment outcome.

Voluntary participation or withdrawal from study

The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. It is your choice whether to participate or not. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect your employment status in this health facility. Even after joining the study, you still have the right to withdraw from the study at any time you want.

Risks and benefits

Participating in this study may be associated with no or minimum risk. You will be interviewed guided by a questionnaire to abstract some information which may take at most five minutes. . You will not be provided any incentive to take part in the research. However, your participation is likely to help us in assessing drug related problems among diabetes patients, to improve dissemination of knowledge pertaining treatment care and good monitoring of blood sugar at Lacor hospital.

Assurance of confidentiality

The information that we collect from this research project will be handled with care and confidentiality and will only be used for the purpose of the study. Your name will not be used and any information about you will have a code. Only the researchers will know what your number is and we will lock that information up with a lock and key. I will be very grateful if you are willing to participate in this study and hence we together can do something positive towards improving knowledge on how to use antidiabetic medicine for the good of treatment care outcomes.

Who to contact

In case you have any questions related to this study and regarding your right as a research volunteer, you can contact the following:

1. The principal investigator using the following address: Oyella Josephine Mary, Master of Pharmacy in Clinical Pharmacy student, University of Nairobi, CHS, SOP, Department of Pharmaceutics & Pharmacy Practice.
   Email**: joyelah.329@gmail.com,** Tel: +254-790-499398, +256-772-699398. OR
2. Study supervisor: Dr. Sylvia Opanga
   Email:**sylvia.adisa@gmail.com** mobile telephone number: +254-721-296448, OR
3. Secretary Kenyatta National Hospital- University of Nairobi who have approved this study on email: **uonknh_erc@uonbi.ac.ke**, P.O Box 20723-00202 Nairobi, Tel. 2726300 Ext. 44102.
4. Institutional director, Lacor hospital, Gulu- Uganda; Mr. Martin Ogwang.
   Email**:** ogwang.martin@lacorhospital.org mobile telephone number +256 772-593901

Consent form for healthcare providers

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with the study investigator. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential. By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes ☐ **NO** ☐

Participant printed name:
_____

Participant signature / Thumb stamp _____ **Date** _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and have willingly and freely given his/her consent.

Researcher's Name: _____ **Date**: _____

Signature _____

Appendix II B: Questionnaire for the diabetes healthcare providers in the diabetes outpatient clinic(77)

1. Do you conduct diabetic patients' education in this hospital?

1. Yes

2. No _____

If yes, how frequently do you conduct diabetic patients' education in the hospital and about how many patients do you train in one session?

If no, what could be the problems?

_____

_____

_____

_____

2. If the education/counseling is done, kindly describe how it is conducted here in LH. Is it to individual patient at a time or groups and how?

_____

_____

_____

3. Who gives the education/counseling?

_____

_____

4. Who co-ordinates the education/counseling?

_____

_____

_____

Thank you for your participation and support in this study.

Appendix IV: Estimation of HbA1c (83)

Apparatus: HumaMeter A1c reagent kit. REF: 16085/50

Intended use: For the vitro quantitative determination of glycated hemoglobin (HbA1c) in whole blood obtained from finger prick or venous blood samples collected into EDTA tubes.

Human red blood cells (erythrocytes) are freely permeable to glucose present in the surrounding liquid (plasma) of the blood. During the lifetime of the erythrocytes (normally up to 120 days) exposure to blood glucose results in binding of glucose to the hemoglobin A molecule present in erythrocytes. This is referred to as glycated hemoglobin.

Chronic elevated blood glucose will result in tissue and organ damage. Good control of blood glucose, evident as lower HbA1c values, has been proven to result in delayed onset and slower progression of the complications.

Method: The HumaMeter A1c reagent kit combines the chemical binding of boronate to glycated hemoglobin with the fluorescent quenching effect that this binding exerts on a fluorescent marker bound to the boronate molecule. The total hemoglobin concentration is determined from the initial decrease in the fluorescent signal. The fluorescent boronate conjugate binds to the glycated hemoglobin, which is measured by monitoring a decrease in the fluorescent of the active ingredient. The ratio of glycated hemoglobin to total hemoglobin is determined and the result is presented in up to two user selectable units: % DCCT (Diabetes Control and Complications Trial), mmol/mol IFCC (International Federation of Clinical Chemistry), % JDS (Japan Diabetes Society), mg/dl eAG or mmol/l eAG (estimation Average Glucose). Linear relationships have been established between these reportable units; mmol/mol IFCC = (% DCCT – 2.15) x 10.929,

% JDS = (0.09274 x mmol/mol IFCC) + 1.724

eAG mmol/l = (1.59 x % DCCT) – 2.59

eAG mg/dl = (28.7 x % DCCT) – 46.7

NGSP = (0.09148 x IFCC) + 2.152

eAG values are based on a correlation study linking % DCCT to the patient's average blood glucose concentration, resulting in published formula to derive the eAG (83).

Appendix V: Some of the factors that influence HbA1c and its measurement*.

Adapted from Gallagher et al (24)(74).

1. Erythropoiesis Increased HbA1c: iron, vitamin B12 deficiency, decreased erythropoiesis. Decreased HbA1c: administration of erythropoietin, iron, vitamin B12, reticulocytosis, chronic liver disease.
2. Altered Hemoglobin Genetic or chemical alterations in hemoglobin: haemoglobinopathies, HbF, methaemoglobin, may increase or decrease HbA1c.
3. Glycation Increased HbA1c: alcoholism, chronic renal failure, decreased intraerythrocyte pH. Decreased HbA1c: aspirin, vitamin C and E, certain haemoglobinopathies, increased intra-erythrocyte pH. Variable HbA1c: genetic determinants.
4. Erythrocyte destruction Increased HbA1c: increased erythrocyte life span: Splenectomy**.** Decreased A1c: decreased erythrocyte life span: haemoglobinopathies, Splenomegaly, rheumatoid arthritis or drugs such as anti-retroviral, ribavirin and dapsone.
5. Assays Increased HbA1c: hyperbilirubinaemia, carbamylated hemoglobin, alcoholism, large doses of aspirin, chronic opiate use. Variable HbA1c: haemoglobinopathies. Decreased HbA1c: hypertriglyceridemia. * Some of the above interfering factors are "invisible" in certain of the available assays

Appendix VI: Advantages and disadvantages of various HbA1c assay methods

Assay	Principle	Advantages	Disadvantages
Ion Exchange Chromatography	HbA1c has lower isoelectric point and migrates faster than other Hb components	Can inspect chromograms for Hb variants. Measurements with great precision	Variable interference from hemoglobinopathies, HbF and carbamylated Hb but the current ion exchange assays correct for HbF and carbamylatedHbdoes not interfere.
Boronate Affinity	Glucose binds to m-minophenylboronic acid	Minimal interference from haemoglobinopathies, HbF and carbamylated Hb.	Measures not only glycation of N-terminal valine on βeta-chain, but also β-chains glycated at other sites and glycated αalpha-chains.
Immunoassays	Antibody binds to glucose and between 4-10 N-terminal amino acids on βeta- chain.	Not affected by HbE, HbD or carbamylated Hb Relatively easy to implement under many different formats.	May be affected by haemoglobinopathies with altered amino acids on binding sites. Some interference with HbF.

Appendix VIII: Translated tools for the research in the Luo- language (Leb acoli)

(Participant information, informed consent form and structured questionnaire)

Ngec pi ngat oyee pire kene.

Titol me kwan: Yenyo kit me ngeyo kit ma lotwo cukari gitiyo kwede ki yat cukarigi kacel ki lok me pimo remo me neno ka cukari tye maber ikin lotwo cukari ma tye iot yat Lacor iGulu-Uganda

Layeny te lok man ki gang kwan

Oyella Josephine Mary

Departmenti me Rubu Yat ki Tic me Puamaci

Cukul me Yubu yat

University me Nairobi

P.O Box: 19676-00202, Nairobi.

Lodito ma ki konyo aye:

1. DR. SYLVIA OPANGA (PhD)

Department of Pharmaceutics and Pharmacy Practice, School of Pharmacy, University of Nairobi

2. DR. BEATRICE AMUGUNE (PhD)

Department of Pharmaceutical Chemistry, School of Pharmacy, University of Nairobi

Acaki

An nyinga Oyella Josephine Mary, akwano iuniversity me Nairobi- Kenya, icukul me Yubu Yat me nongo digiri me aryo. Abitimo ricac ma mega ikom lok dok ikit me tic yat cukari kacel ki pimo remo me nenoni cukari odok maber tutwale pi jo ma two cukari omakogi iwi dito.

Two cukari kombedi odoko dwong dok tye ka weko dano too atura ma pe guyube tutwale ilobowa me Uganda. Abimini lok mogo manok ci alwongi me dyere me timo ricac man.

Tyen lok me timo ricac

Gin ma pire tek aye me yenyo ki ngeyo kit jo ma gitye ki two cukari tiyo kede ki yat me dwoko lebol me cukari iremo piny, iot yat Lacor. Atye ki lapeny mogo me niang kit ma lotwo tiyu kwede ki yat, ka gingeyo adwogi me yat, ka ngeyo doc me yat, ka gingeyo labila yat ma megi onyo gilubu gin ma gititti gi ma dok ikom tic ki yat maber.

Yero lotim ricac

Alwongi me timo ricac man pien pire tek ni in latwo me cukari iminiwa tam mabeco ma weko watwero tic kede me yubu peko mogo ma yat kelo ki bene konyo me niang kit me tic ki yat cukari wek kwogi oyube maber.

Dyere piri keni nyo kwero timo ricac man.

Ma pire tek aye, yee piri keni labongo dic mo, me miyo ni tami mabeco ma ibimiyo konyo me timo nyo kwero ricac. Bed agonya me penyo lapeny mo keken ikom lok ma dok ikwan me ricac man.

Ngo ma time ka itimo ricac eni, onyo ma bedo rac , nyo ber , meno ducu tye itwero ma megi me timo ricac nyo pe timo ne. Ka itimo nyo petimo ducu weng pe gengo nongo kony mo keken ki iot yat me Lacor. Ka iniang maber ci iyee me timo ricac, ci alegi ni iket cingi karatasi man, coyo nyingi bene ki nino dwe. Niang maber ni cik tye pi dano ducu ma gitimo ricac ma dok ikom yat ni:

i)Tami me yee timo ricac obedo piri keni labongo dic mo ii) ka imito weko ricac icawa mo keken tye itwero ni labongo miyo kit lagam mo. iii) kwero timo ricac pe gengo nongo kony mo keken ma itwero nongo ne ki iot yat Lacor nyo ka mukene. Kabene idonyo iricac itwero weko ne caa mo keken ka imito.

Race ki ber ne

Timo ricac man tye ki rac mo manok ni gibituci cingi me kwanyo remo mo matidi pore ki cipun me cai matidi me apima ento ladiro bineno ni jami weng tye maleng mupore labongo kelo peko me two mukene.

Gibipenyi ki lapeny mukene me ngeyo jami mogo manok ma tero dakika apar wiye abic keken. Wa bingiyo karatasi macon weng me yati mene ma itye iye ki two mukene ka tye bene . Gin mo ma waromo mini pe ento dyere ni me timo ricac eni konyo me ngeyo peko mogo yat twero kelo ni ikom lotwo cukari. Ci ngec man, konyo me poko ngec ducu bot lwak mukene ki bene ber me gengo two cukari iot yat Lacor.

Gen ikom mung

Lok ducu ma wanongo ki iricac man wa bigwoko imung ma ngat mo pe twero ngeyo ne dok watiyo kwede ilok me ricac keken. Nyigi pe gibicoyo ikaratac man ento wabitiyo ki alama mapatpat pi jo ducu ma gitye katimo ricac. Mung ma lube ki kwan eni weng gikano kama oyo

dot iye ci ka kwan otum bene pe binonge kamo keken. Cwinya obibedo yom ka itye agonya me timo ricac man wek wakony lwak me niang ikit me tic ki yati mapol me gwoko kwo maber.

Kontak

Ka itye ki lapeny mo dok ikom ricac eni nyo ikom twero ma megi calo ngat odyere me miyo tam, ci bed agonya me penyo jo ma areyo nyingi piny cake ki ngat ma oero lok me ricac man. Tye nying ki namba cim ducu ma itwero cwalo lapenyi iye.

1. Oyella Josephine Mary, Master of Pharmacy in Clinical Pharmacy student, University of Nairobi, CHS, SOP, Department of Pharmaceutics & Pharmacy Practice.
   Email: joyelah.329@gmail.com, Tel: +254-790499398, +256-772699398. OR
2. Dr. Sylvia Opanga
   Email: sylvia.adisa@gmail.com Mobile telephone number: **+254721296448**
3. In case you have questions about your rights as a participant conatact the secretary 3. 3. Kenyatta National Hospital- University of Nairobi who have approved this study on email: uonknh_erc@uonbi.ac.ke, P.O Box 20723-00202 Nairobi, Tel. 2726300 Ext. 44102.
4. Institutional director of Lacor hospital; Mr. Martin Ogwang.
   Email: ogwang.martin@lacorhospital.org **mobile telephone number +256 772593901**

Pwom me dyere labongo dic. (Consent form)

Lok pa latim ricac (Participant's statement)

An akwano gin ma gicoyo ipwom me dyere labongo dic. Abedo ki kare bene me rwate ki ladit ma obetimo ricac man ci waloko jami mapol bene ma ogamo lapenya ducu kakare. Otita bene ber ki rac mugo malube ki timo ricac, ci aniang maber ma atwero timo nyo kwero timo ne bene. An dong aye pira kena ni abitimo ricac dok aniang ni lok ducu gibigwoko imung tutwale nyinga.
Aye me timo ricac. Eyo ☐

Aye me kwanyo remo me pimo cukari: Eyo ☐ akwero ☐

Ayee miyo kontak mega me lubu lok ducu: Eyo ☐ akwero ☐

Participant printed name: _____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement (*Lok pa layeny kwan man*)
An, aketo cinga icoc kun angeyo ni atito lok ducu ma lube ki kwan man, ber ne wek latim ricac bene oyee kun niang jami ducu ci weko en mine pire kene ki cwinye ducu.

Researcher's Name: **_____ Date**: **_____**
Signature

_____
Witness Printed Name (*If witness is necessary, A witness is a person mutually acceptable to both the researcher and participant*)

Name _____ Contact information _____

Signature /Thumb stamp: _____ Date; **_____**

Structured questionnaire *(lapeny)*

Part I: Eligibility (Screening questionnaires) *(Kit me yero dano)*

5. Do you suffer from any of the following disease in addition to diabetes? (Sickle cell disease/ thalassemia/hemochromatosis/pancreatic cancer/pancreatitis/cystic fibrosis /phaeochromocytoma/acromegaly/cushing's syndrome) (*Itwoyo two mogo calo ma twoyo remo, kanca, two ma weko remo cwer caa ducu)*

c. Yes (1)

d. No (2)

6. Have you been using the following drugs consistently in the last 3 months? Phenytoin/Steroids/Estrogen (such as oral contraceptives) (*Dwe adek mukato cok coki imwunyu yat calo pill me gengo nyodo, yat cweyo dano nyo yat me two olili?)*

c. Yes (1)

d. No (2)

7. (For females only)Are you pregnant? *(lapeny pi mon keken, igamo iyi?)*

c. Yes (1)

d. No (2)

8. Has the consent been explained and obtained? (*gitito iri jami ducu ma lube ki mine piri keni labong dic?)*

c. Yes (1)

d. No (2)

(Stop the interview if the answer to questions 1, 2 or 3 is Yes or to 4 is No)

Part II: Socio-demographic Characteristics

2. Patient Bio-data *(Ngec ikomi)*

1.1 study code _____ Residence: 1.2 Urban ☐ 1.3 Rural ☐

1.4 Weight _____ (Kg) 1.5 Height (cm) _____ 1.6 BMI _____ 1.7Allergies _____

2. **Sex:** 2.1. Male ☐ 2.2. Female ☐

Date of Birth __/___/____ Date of Interview ___/___/_____

3. **Age _____ Years*(Mwaka ni adii?)***

3.1. Less than 30 ☐ 3.2. 30 – 40 ☐ 3.3. 41- 50 ☐ 3.4. 51— 60 ☐

3.5. Greater or equal to 61 ☐

4. **Marital Status *(inyome?)***

4.1. Single ☐ 4.2. Married ☐ 4.3.Divorced ☐ 4.4. Widowed ☐

4.5 Co-habiting ☐

5. **Occupation*(tic)***

5.1. Farmer ☐ 5.2. Gov't Employee ☐ 5.3. Merchant/Trader ☐

5.4. Daily Laborer ☐ 5.5. Housewife ☐ 5.6. Retired ☐

5.7. Others ☐ Specify _____

6. **Profession *(ibedo latic iot yat?)***

6.1. Health professional ☐ 6.2. Non-health professional ☐

7. **Educational Status*(Kwan ma ikwano)***

7.1. Cannot read and write ☐ 7.2. Primary ☐ 7.3. Secondary ☐

7.4. Higher Education ☐

8. **Monthly Family Income (in UGX) _'000/=*(cente pi dwe acel)***

8.1. Very Low (<450) ☐ 8.2. Low (451-1,200) ☐ 8.3. Average (1,201-2,500) ☐

8.4. Above Average (2,501-3,500) ☐ 8.5. High (>3,501) ☐

Part III: Disease related Characteristics

9.0 Are you aware of your disease type? 9.0.1 Yes 9.0.2 No

(ingeyo two ma itwoyo?)

9.1 Duration of diabetes_____ Years*(two cukari ocake orii pi kare mene?)*

9.1.1 Less than 1 ☐ 9.1.2. 1-5 ☐ 9.1.3. More than5 ☐

9.2 **Do you have any member(s) of your family history who has/had diabetes?**

9.2.1 Yes ☐ 9.2.1 No ☐

(Ngat mo igangwu ma twoyo onyo otwoyo cukari?)

10 **Do you know the diabetes complications** (*ingeyo rac pa two cukari?)*

10.1. Yes ☐ 10.2. No ☐

11. If yes to question. no 10, which of the following diabetes complication you know (can tick more than once)

11.1. Neuropathy ☐ 11.2. Kidney complications ☐

11.3 Diabetic foot ulcer ☐ 11.4. Heart complications ☐

11.5. Eye complication ☐ 11.6 Others ☐ Specify _____

12. Do you have any diabetic complications ☐ Yes ☐ No ☐

(Itye ki two mo marac ma cukari aye okelo ikomi?)

13. If yes to Q 12, which diabetic complications are present (can tick more than once)

13.1. Neuropathy ☐ 13.2. Kidney complications ☐

13.3. Heart complications ☐ 13.4. Eye complications ☐

13.5. Diabetic Foot Ulcer ☐ 13.6. Others, if any_____

Part IV: Non-pharmacological approaches of diabetes care*(Lapeny ikom kwo ni ma lube ki two sukari)*

14. **Diet *(cam)***

14.1. Do you have dietary plan you set with your doctor? Yes ☐ No ☐

(Ilubu cam ma daktari owaci icam?)

14.2. If yes to Q 14.1, do you always adhere to your plan? Yes ☐ No ☐ Sometimes ☐

14.3. What type of dietary plan you have?*(lici me loko cam tye?)*

14.3.1. Always cut off sweet carbohydrate meals Yes ☐ No ☐ sometimes ☐ *(icamo layata malim nyo jami malim?)*

14.3.2. Always cut of fatty meals (butter, cheese, fried foods, fatty cuts of red meat, egg yolks,poultry skin…) Yes ☐ No ☐ occasionally ☐

(icamo dek moo moo, tongweno, ringo nyo del kom gweno)

14.3.3. Other plan, if any _____

15. **Exercise *(timo tic mo)***

15.1. Which of the following activities do you do? Nyono gari ☐ pur ipoto ☐ Wot maromo kilomita aryo ☐ nyo kulu pe timo tic mo ☐

15.2. Do you go the gym? Yes ☐ No ☐

Icito I gimanasi mo?

(itimo tic mo calo ngwec, pyeekit ma daktari owaco?)

15.2. If yes to q. no 15.1, do you adhere to your plan? Yes ☐ No ☐ ☐

Ka pe ci ilubu kit me timo tic mo?

15.3 If "No" do you do exercise that are not part of routine work? Yes ☐ No ☐

15.4 Do you have exercise plan you set with your doctor? Yes ☐ No ☐

Itye plan mo ma datary oyubu me timo tic mo?

15.5 If "Yes" to question no. 15.4, do you adhere to your plan? Yes ☐ No ☐

Ci ilubu kare ducu?

15.6. How many days per week you do moderate intensity exercise? _____ day(s)

Pi nino acel timo dakika adii?

15.7. How many minutes per week you do moderate intensity exercise? _____ minutes

Pi cabit nongo itimo tic mo maromo dakika adii?

16. **Alcohol *(Kongo)***

16.1. Do you ever drink alcohol regularly? 16.1.1 Yes ☐ 16.1.2 No ☐

(Imato kongo kare ducu?)

16.2 When did you last take alcohol? Yesterday ☐ A week ago ☐ A month ago ☐
Many year ago ☐

Kongo me agiki ibilo awene?

16.3 How often do you take alcohol? Daily ☐ Once a week ☐ Once a month ☐
Once a year ☐

Imato tyen adii kare ducu?

16.4 Which of these brands do you take? Uganda waragi ☐ Beer ☐ Wine ☐
None ☐ Local brew ☐ others ☐

Kongo mene ma imaro mato ne ikin magi?

16.5 In one sitting about how much alcohol do you consume? Imato dwong from kwene?
Bottle -- (300ml, 500ml) Cupa adii?
Glasses—(100ml, 200ml) gilasi adii?

17. **Cigarette smoking**

17.1. Do you ever smoke cigarettes? *(Imato taa?)*Yes ☐ No ☐ Formerly ☐

17.2. If yes to q. no 17.1, how much cigarettes you smoke per day? _____Packs *(paket adii inino acel?*

17.3.1. < half ☐ 17.3.2. half ☐ 16.7.3. >half ☐

18. **Self-monitoring of blood glucose (SMBG)**

18.1. Do you have a glucometer? Yes ☐ No ☐

Itye ki macini me pimo cukaki?

18.2. If yes to q. no 18.1, how frequently do you perform SMBG per week? _____times

18.2.1. 1 ☐ 18.2.2. 2 ☐ 18.2.3 3 ☐ 18.2.4 more than 4 ☐

Ipimo tyen adii icabit acel?

19. Part V. Pharmacological approaches *(Lok me yat cukari)*

Medication knowledge assessment

19. Can you name your medication? *(Ingeyo lwongo nying cukari ni ni?)* Yes ☐ No ☐

20. Do you know the dose to take? Yes ☐ No ☐ *(ingeyo dosi ma myero imuny?)*

21. Does not know how many/or frequency of administration? Yes ☐ No ☐

22. Do you know when or what time to take your medication? *Inegyo cawa me munyo yat?*

22.1 Yes ☐ 22.2 No ☐

23. How do you identify your medicine? *Ingeyo kit me poko yat kace orube ki mukene?*

23.1 Shape ☐ 23.2. Color ☐ 23.3 Depend on others to identify ☐ 23.4 Label ☐

24. What is the route of administration? 24.1 Injection ☐ 24.2 Oral ☐ Both ☐

Ingeyo kit me munyu yat?)

25. Are you suggesting the same prescription to your intimates with the same conditions? *(Iromo waco ki laremi mo me wilo lakit yati ka en tye two calo megi ni?)*

25.1 Yes ☐ 25.2 No ☐

26. Where do you keep the medication? (To ascertain special storage conditions*) igwoko yati kwene ki gang?*

26.1 Fridge ☐ **26.2 Cupboard** ☐ **26.3 bag** ☐ **26.4 under a cold water pot** ☐

26.5 In small tin ☐

27. When is the next refill due? (And plan or method for obtaining refills.) *ingeyo awene ma myero idwog ka gamo yat?*

25.1 Aware ☐ 25.2 Not aware ☐

28. How long do you have to take this medication for*? Yati ni itamo ni imunyo pi kare rom mene?*

28.1 For a short term therapy ☐

28.2 Unsure, ☐

28.3 Knows if it is long or short term therapy ☐

29. Do you know about any possible side effects of this medication*? Ingeyo rac pa yati?*

29.1 No idea of the side effects ☐

29.2 Knows some of the side effects ☐

29.3 Knows all of the important side effects ☐

30. Give at least one side effect _____

31. What would you do if you forgot to take a dose of this medication? *Ka wiyi owil ka munyo yat ci itmo ango*

31.1 Would act inappropriately *(e.g. take double the quantity next time)* ☐

31.2 Would seek advice from pharmacist, nurse, care taker, or GP ☐

31.3 Would take appropriate action *(e.g. take correct dose next time)* ☐

32 Do you take your antidiabetic drugs as advised by your doctor? Yes ☐ No ☐

Sometimes ☐ Never ☐ (*imunyo yat kit ma datari owaco?)*

Part VI: Reason for non- adherence *(Gin ma weko cawa mukene pe imunyo yat kare ducu)*

33. What reasons may prevent you from taking medicines regularly? *(Kwet gin)*

Please tick the options below (√)

Items	Yes	No	Items	Yes	No
Lack of finance *(cente pe)*			Side effects		
Feeling drug is not effective			Feeling dose is high		
Interferes with my meal plan			Complexity of drug regimen		
Had been taking since many years			Multiple medications		
I forget			Poor family support		
Feeling well without the medicine			Pain at injection (If Insulin)		

Appendix III A: Data Abstraction Format
Section a): Chart review

34. Fasting blood glucose value (mg/dl)

34.1. Recent _____ 34.2. On immediate previous appointment _____

35. Recent HA1c value, if any_____ current _____

36. Recent fasting lipid profile, if any

36.1. Total cholesterol _____ 36.2. HDL_____

36.3. LDL _____ 36.4. TG _____

Section b) Co-morbidities and DM Complication

37. Presence of co morbidities *(two mapat ki cukari tye?)*

37.1. Present ☐ 37.2. Absent ☐

38. If the response for the above question is *present*, which of the following co-morbidity is present? (Can tick more than once) (*Kwet ki ducu)*

38.1. Hypertension ☐ 38.2. Ischemic Heart Disease ☐

38.3. Dyslipidemia ☐ 38.4. Peripheral Vascular disease ☐

38.5. Obesity ☐ 38.6. Others, Specify_____

Section c) Medications prescribed

39. Total number of prescribed drugs _____ (In number*) wel yat ma gicoyo adi?*

40. List of prescribed Antidiabetic medications (can tick more than once)

40.1. Metformin ☐ 40.2. Glibenclamide ☐

40.3. Insulin ☐ 40.4. Others, Specify_____

41. Type of insulin prescribed, if any (*ka inculin ci mene ma ituce kwede?*

41.1. Regular insulin ☐ 41.2. Humulin ☐

41.3. Soluble insulin ☐ 41.4 Insulin mixtard ☐

42. List of prescribed medications (*yat mukene ma gicoyo kwet gi)*

42.1. Frusemide ☐ 42.2. Spironolactone ☐

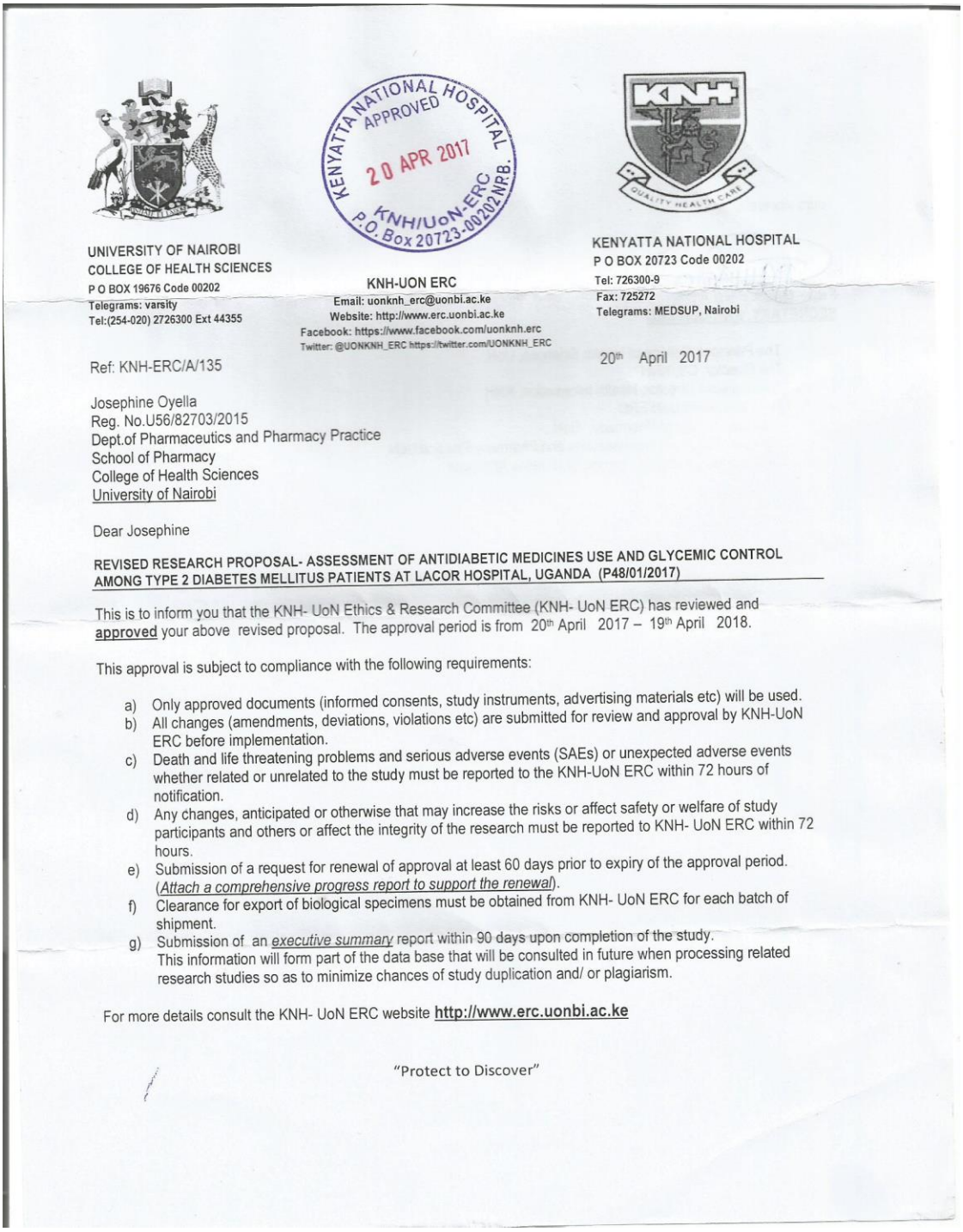
42.3. Atorvastatin ☐ 42.4. Nifedipine ☐

42.5. Propranolol ☐ 42.6. Hydrochlorothiazide + Losartan ☐

42.7. Enalapril ☐ 42.8. Acetyl salicylic acid ☐

42.9. Others Specify_____

Appendix IX: Approval Documents



KENYATTA NATIONAL HOSPITAL APPROVED 20 APR 2017 KNH/UoN-ERC P.O. Box 20723-00202 NAIROBI

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Ref: KNH-ERC/A/135

20th April 2017

Josephine Oyella
Reg. No.U56/82703/2015
Dept.of Pharmaceutics and Pharmacy Practice
School of Pharmacy
College of Health Sciences
University of Nairobi

Dear Josephine

REVISED RESEARCH PROPOSAL- ASSESSMENT OF ANTIDIABETIC MEDICINES USE AND GLYCEMIC CONTROL AMONG TYPE 2 DIABETES MELLITUS PATIENTS AT LACOR HOSPITAL, UGANDA (P48/01/2017)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above revised proposal. The approval period is from 20th April 2017 – 19th April 2018.

This approval is subject to compliance with the following requirements:

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

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

"Protect to Discover"

Yours sincerely,

PROF M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Assistant Director, Health Information, KNH
The Chair, KNH-UoN ERC
The Dean,School of Pharmacy, UoN
The Chair, Dept. of Pharmaceutics and Pharmacy Practice,UoN
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18th May 2017

Rev. Sr. Josephine Mary Oyella
University of
Nairobi- College of
Health Science

LHIREC: 002/02/17, **STUDY TITLE:** ASSESSMENT OF ANTIDIABETIC MEDICINES USE AND GLYCEMIC CONTROL AMONG TYPE 2 DIABETES MELLITUS PATIENTS AT LACOR HOSPITAL, UGANDA

Type: [√] **Initial Review**
[ ] Protocol Amendment
[ ] Letter of Amendment (LOA)
[ ] Continuing Review
[ ] Material Transfer Agreement
[ ] Other, Specify: _____

I am pleased to inform you that at the LHIREC has approve the above referenced application. Approval of the research is for the period of **31st March 2017** to **30th March 2018**

As Principal Investigator of the research, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the research.
2. Changes, amendments, and addenda to the protocol or the consent form must be submitted to LHIREC for re-review and approval **prior** to the activation of the changes. The REC application number assigned to the research should be cited in any correspondence.
3. Reports of unanticipated problems involving risks to participants or other must be submitted to the LHIREC. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for LHIREC review.
4. Only approved consent forms are to be used in the enrollment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. The LHIREC may conduct audits of all study records, and consent documentation may be part of such audits.
5. Regulations require review of an approved study not less than once per 12-month period. **Therefore, a continuing review application must be submitted to the LHIREC eight**

Logistic Office Kampala: Tel. +256 - 414 - 223014, Fax: +256 - 414 - 223013

weeks prior to the above expiration date of 30th March 2018 in order to continue the study beyond the approved period. Failure to submit a continuing review application in a timely fashion may result in suspension or termination of the study, at which point new participants may not be enrolled and currently enrolled participants must be taken off the study.

6. You are **required** to register the research protocol with the Uganda National Council for Science and Technology (UNCST) for final clearance to undertake the study in Uganda.

The following is the list of all documents approved in this application by LHIREC.

No	Document Title	Language	Version	Version date
1.	Proposal	English	2.0	20th April 2017
2.	Informed Consent forms	English	2.0	20th April 2017
3.	Questionnaires	English	2.0	20th April 2017

Thanks

OGWAL DAVID MARTIN Date 18/05/17

Names:

~~For~~ LHIREC Chairman

Appendix X: Map of Uganda showing Gulu district, where Lacor hospital is located.

Airview of Lacor Hospital- Gulu (Uganda)