KNOWLEDGE ON DIABETES MELLITUS AMONG DIABETIC PATIENTS ATTENDING KENYATTA NATIONAL HOSPITAL OUTPATIENT CLINIC.

BY

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Declaration

I declare that this dissertation is my original work and has never been presented for a degree award in any other university. No part of this research project may be reproduced without prior permission of the author and/or University of Nairobi.

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I thank the LORD for making me what I am and for giving me the greatest gift of all, life.

Dedication

This work is dedicated to my wife, Lydiah and my son, Alvin. You have all always been there for me and you have persevered during my long hours of absence during the course of my study. It is also dedicated to my parents, especially my mum, who imparted the value of education on me early in life. Finally to my brothers, sisters, nephews and nieces for their invaluable encouragement.

List of Abbreviations

ADA	: American Diabetes Association.
ADRs	: Adverse Drug Reactions.
B.C.	: Before the birth of Christ.
CME	: Continuous Medical Education.
CPHR	: Centre for Public Health Research.
DKA	: Diabetic Ketoacidosis.
DM	: Diabetes Mellitus.
DTP	: Drug Therapy Problems.
DR	: Doctor.
ESRD	: End- Stage Renal Disease.
HbA1C	: Glycosylated Haemoglobin.
Id/Pp No	: National Identity card number/Passport number.
IDDM	: Insulin Dependent Diabetes Mellitus.
KDA	: Kenya Diabetes Association.
KEMRI	: Kenya Medical Research Institute.
KNH	: Kenyatta National Hospital.
Kshs	: Kenya Shillings.
LDL	: Low Density Lipoproteins.
MI	: Myocardial Infarction.
n	: Sample size.
NIDDM	: Non-Insulin-Dependent Diabetes Mellitus.
NKHS	: Non Ketotic Hyperosmolar Syndrome.
OHAs	: Oral Hypoglycaemic Agents.
OPD	: Out-patient Department.
PC	: Pharmaceutical Care.
PCS	: Pharmaceutical Care Services.
PILs	: Patient Information Leaflets.
PROF	: Professor.
SMBG	: Self Monitoring of Blood Glucose.
SPSS	: Statistical Package for Social Sciences.
US	: United States (of America).

Definitions of Terms

1. **Diabetes Mellitus (DM)** is a group of metabolic disorders characterized by hyperglycaemia associated with abnormalities in carbohydrate, fat and protein metabolism.[1,2]This group of metabolic disorders is caused by an absolute or relative lack of insulin; a hormone produced by the pancreas.[3]
2. **Sufficient knowledge/adequate knowledge** includes knowledge on diabetes disease itself, importance of dietary control, DM complications, exercise programs, importance of patient's involvement with diabetes organizations and rational use of DM medication.[4] A patient who scored 50% and above in any of these parameters was termed to have sufficient knowledge in that particular parameter.
3. **Insufficient knowledge/inadequate knowledge** includes inadequate knowledge on diabetes disease itself, importance of dietary control, DM complications, exercise programs, importance of patient's involvement with diabetes organizations and rational use of DM medication. A patient who scored less than 50% in any of these parameters was termed to have insufficient knowledge in that particular parameter.

4. **Independent variables:** Patients' Gender, Education levels and Age Categories.
5. **Dependent variables:** Knowledge on DM Disease, the disease Complications, DM medication, importance of Dietary control, Exercise programmes and patients' involvement with DM Affiliate Organizations.
6. **Outcome** –End result of treatment (Death or Discharge after recovery).
7. **Prognosis-** Is the forecast or likely outcome of a disease and it is usually based on the existence of different signs, symptoms and circumstances.
8. **Rational Use of Medication**-Means using the right medication for the intended purpose, the right dose and dosage regimen, at the right time.

Abstract

Background: Diabetes mellitus (DM) is a disease that has significant morbidity and mortality worldwide resulting from complications arising from poor control.[1,3]
There is no local data to show the level of diabetic patients' knowledge on this disease at KNH, an important aspect in DM management.
In the present cross-sectional study, determination of the diabetic patient's knowledge of his/her disease was undertaken for the first time at KNH.

Study Objectives: To determine the proportion of KNH DM outpatients with adequate knowledge on the disease and to determine the level of provision of diabetic education to the DM outpatients.

Study design: This was a descriptive cross-sectional study from September 2007 to January 2008. 105 DM patients (above 18 years) who had given informed consent were interviewed to determine the level of their knowledge on DM and hence the proportion of respondents with adequate knowledge. Codes were manually assigned to all questions and the respective answers. Five randomly selected KNH DM OPD healthcare providers were also interviewed to determine the level of KNH preparedness in the provision of diabetic education to the DM outpatients.

A sequential sampling procedure was used to interview the diabetic patients. Every Wednesday during the course of the study one different DM healthcare provider was picked and interviewed.

Data Analysis: The data obtained were captured using Epi-data computer software which was then exported to SPSS version 15.0 for analysis. Statistical significance was determined using the Pearson Chi Square at $p<0.05$, at 95% confidence limit.

Results: 105 diabetic patients aged 18 years and above were interviewed; 53(50.5%) were males and 52 (49.5%) females.

The age categories 18-30, 31-40, 41-50, 51-60, 61-70 and above 70 years accounted for12 (11.4%), 24 (22.9%), 21 (20.0%), 21 (20.0%), 22 (21.0%) and 5(4.8%) DM patients respectively.

The highest education levels; College/University, Secondary, Primary and Non-formal accounted for 27(25.7%), 42(40.0%), 25(23.8%) and 11(10.5%) DM patients respectively.

52 (49.5%)patients had sufficient knowledge on the diabetes mellitus disease itself, 64(61%) on DM complications, 35 (33.3%) on DM medications, 84 (80%), on the importance of dietary control, 73 (70%) on the importance of doing exercises and 11 (10.5%) on the importance of DM Affiliate Associations.

Patients with highest academic level had the highest proportion of patients with adequate knowledge on the disease (p=0.0001), dietary control (p=0.01) and exercise (p=0.03). Patients' age influenced the proportion of patients with adequate knowledge on DM complications (p=0.03).

The study also showed that diabetic patients' education was conducted mainly verbally at OPD clinic once a week for two hours and only one healthcare provider conducted the training at each education session though the number of staff was ten.

Conclusion: Patients were mainly taught verbally. Two-thirds to three-quarter of the patients had sufficient knowledge on the DM disease, importance of dietary requirements and exercise programs.90% of patients had insufficient knowledge on diabetes organizations and two-thirds on rational use of DM medications.

Recommendation: Hospital's training and education on rational use of DM medications should be improved. The hospital should make the healthcare providers and the DM patients aware of the DM associations for patients' benefit. More research involving larger samples over longer periods should be carried out in order to reflect what happens over a longer period of time.

CHAPTER ONE

1.0 Introduction

Definition of Diabetes Mellitus

Diabetes mellitus (DM) is a group of metabolic disorders characterized by hyperglycaemia associated with abnormalities in carbohydrate, fat and protein metabolism.[1,2] This group of metabolic disorders is caused by an absolute or relative lack of insulin, a hormone produced by the beta cells of the Islets of Langerhans of the pancreas.[3] Diabetes Mellitus is a chronic, incurable condition that has considerable impact on the life of each individual; therefore, patient involvement is paramount for the successful management of the disease.[5]

In normal individuals, insulin is secreted after a meal to lower to normal the blood glucose levels.[6] Insulin promotes the absorption of glucose into the cells such as skeletal muscle and adipose tissue. This system is dysfunctional in diabetic patients.[3]

Glucose is a simple sugar found in food. It is an essential nutrient that provides energy for the proper functioning of the body cells. After meals, food is digested in the stomach and the intestines into glucose and other nutrients. The glucose in digested food is absorbed by the intestinal cells into the bloodstream, and is carried by blood to all the cells in the body[1, 3]. However, glucose cannot enter the cells alone. It needs assistance from insulin in order to penetrate the cell walls. Insulin therefore acts as a regulator of glucose metabolism in the body.[2]

When the blood sugar levels go below the lower normal level, glucagon, a hormone secreted by the α-cells of the Islets of Langerhans of the pancreas is produced. This stimulates glycogenolysis and gluconeogenesis with the overall effect of raising the blood glucose level.[3]

This system of auto regulation and homeostasis is the function of the pancreas and it works around the clock.

Dysfunction of this auto regulation system - either inability of the pancreas to secrete any or sufficient insulin, or pancreas overload from too much sugar ingested over a long period of time, or over compensatory mechanism, or a combination of these, results in the relative or absolute lack of insulin, and hence high blood sugar. This is the hallmark of diabetes mellitus (commonly called diabetes) [1,3]

In a patient with Diabetes Mellitus, blood glucose concentrations remain high after a meal because the uptake, utilization and storage of glucose by adipose tissue and muscle are diminished secondary to an absolute or relative lack of insulin. If these blood sugar concentrations remain high for a long time without optimal control, chronic complications of DM result.[3,7]

In view of the above, an understanding of the signs and symptoms associated with diabetes mellitus is based upon the knowledge of glucose metabolism and metabolic effects of insulin in diabetic and non-diabetic individuals during the postprandial and post-absorptic states.[6,8]

Types of Diabetes Mellitus

There are two main types of DM. These are Type I diabetes mellitus, also called insulin dependent diabetes mellitus (IDDM), or juvenile onset diabetes mellitus and Type II diabetes mellitus is also referred to as non-insulin dependent diabetes mellitus (NIDDM).[2,9]

Management of DM

The major goal in management of diabetes mellitus is controlling elevated blood sugars (glucose) without causing abnormally low levels of blood sugar.[3] Type I diabetes mellitus is treated with insulin, exercise, and a diabetic diet.[10] Type II diabetes mellitus is treated with concurrent employment of nutritional supplements, a low glycaemic index diet to control blood sugar level, and exercise.[11,12] If these measures fail to contain the elevated blood sugars, oral medications and insulin need to be considered.[13] Patients' counselling is mandatory in management of both types of DM.[14]

Problems associated with Management of DM.

Diabetes, if unmanaged properly can lead to various complications such as neuropathy, nephropathy, retinopathy, hyperlipidaemias, diabetic foot ulcers and infections.[2,15]

Other chronic complications of DM include microvascular and macrovascular disorders.[16]These complications adversely affect the quality of life of the patient. Quality of life is a multidimensional concept referring to a person's total well being, including his or her psychological, social, and physical health status. [17] Therefore, there is need for proper management of DM to optimally control the blood sugar levels.

The following are the Drug Therapy Problems (DTP) associated with the management of diabetes mellitus, which should always be resolved: -

- Unnecessary drug therapy;
- Need for additional drug therapy;
- Too low dose of drug;
- Adverse Drug Reactions (ADRs);
- Dose too high;
- Non-Adherence due to improper patient counselling/health education.[16]

The principal task of the health care team is to give each patient sufficient knowledge about the disease and its management, self- confidence and support. [5] Sufficient knowledge includes; knowledge on diabetes disease itself, and recognition of hypoglycaemia and hyperglycaemia signs and symptoms, importance of dietary control, strict glycemic control, exercise programs, importance of patient's involvement with diabetes organizations and rational use of DM medication. [4]

Patients with diabetes mellitus and their families provide 95% of the care themselves, [5,18] and as a consequence, educational efforts to improve self- management are central components of any effective treatment plan. Although the role of the pharmacist in monitoring diabetes mellitus is not well defined, it might include such things as ascertaining that physician visits are adhered to and testing to assess long-term glycemic control.

The pharmacist can also play an important role in diabetes care by screening patients at high risk for diabetes, assessing patient health status and adherence to standards of care, educating/counselling patients to empower them to care for themselves, referring patients to other health care professionals as appropriate, and monitoring outcomes.[4]

Self management including patient adherence to the prescribed medication and lifestyle modifications such as dietary control, strict glycaemic control, having exercise programs, patient's involvement with diabetes organizations are very essential in the management of DM. A pharmacist can play an important role in providing such information through counseling[3,16]on the nature of the disease, lifestyle modifications, medications, and acute and chronic complications.[1]

Counselling is a process that is interactive in nature. It should include a one-to–one interaction between a pharmacist and a patient and/or caregiver.[19] It should include an assessment of whether or not the information was received as intended and that the patient understands how to use the information to improve the probability of positive therapeutic outcomes. [20] The ultimate goal of counselling is to provide information directed at encouraging safe and appropriate use of medications, thereby enhancing therapeutic outcomes. [21] There is considerable evidence that Pharmacist provided counselling enhances the patient compliance and improves the quality of life outcomes in diabetes.[9]

Traditionally pharmacists were viewed as individuals who dispensed medicine to the public. This role slowly got transferred into one that involved more of development of drugs. The later stage of 1960s revealed the growth of a new discipline that changed the concept of pharmacy from a product oriented to a patient focused one, called clinical pharmacy. Pharmacists are now becoming indispensable in monitoring patient drug therapy through the study of clinical pharmacy. [3] The clinical pharmacy grew with the concept of pharmaceutical care, the responsible provision of drug therapy for the purpose of achieving definite outcomes such as optimal control of blood sugar in DM patients, which improve the patients' quality of life. It involves the pharmacist's decision to provide, initiate, maintain, or discontinue drug therapy, both of prescription and non- prescription drugs.

It is thus practiced in collaboration with patients, physicians, nurses, and other health care workers.[10,19] The ultimate goal of pharmaceutical care is to optimize a patient's quality of life.

These outcomes can be achieved by influencing the control of the disease, elimination or reduction of symptoms, arresting or slowing the disease progress, prevention and diagnosis of disease or desired alterations in the physiological process. [16]
Though counselling is considered as one of the important pillars of management of DM, it is seldom properly practised at KNH (author's observation in KNH diabetic OPD)

1.1 Justification of the Study

Diabetes Mellitus has been recognised for over 100 years [22] though KNH diabetics' admissions continue to increase (author's observation in wards). Reasons for this increase in admissions are not clear. One such reason could be lack of knowledge among the diabetics regarding their disease. This research, therefore, was aimed at finding the extent to which this lack of knowledge/counselling is, and which could partly explain increasing cases of DM admissions at KNH.

Patient counselling is an important means for achieving optimal pharmaceutical care. It is defined as providing medication related information orally or in written form to the patients or their representatives, on topics like direction of use, advice on side effects, precautions, storage, diet and lifestyle modifications.[23] Studies have shown that the complications of diabetes can be reduced by optimal control of blood glucose by patients' adherence to medications, lifestyle modifications and frequent monitoring of blood glucose.[24,25,26]

For instance: - Powell et al investigated (n=40 patients) the impact of a specially designed patient education program upon the diabetes-related knowledge and adherence to insulin use by IDDM patients. In their study, they designed and conducted a DM training program and evaluated the impact of the training on the adherence of IDDM patients to the administration of insulin. The training program was successful in producing improvements in both knowledge, adherence to insulin administration and blood sugar control. [27]

Odegard et al evaluated the effect of a pharmacist intervention i.e. face-to-face goal-directed medication and lifestyle counselling on improving diabetes control; secondary endpoints were medication appropriateness and self-reported adherence. Seventy-seven subjects, were randomized to receive a pharmacist intervention (n = 43) or usual care (i.e. patient receives the DM medication and no further counselling on improving diabetes control, n = 34) for 6 months, followed by a 6-month usual-care observation period for both groups.

The study concluded that pharmacist intervention significantly improved diabetes control. Patients who had Pharmacist intervention had lower HbA (1c) compared to the ones who did not. There were also fewer physician visits by this group of DM patients. [28]

From the above instances, it is clear that education of DM can bring about improvements in the control of their disease and hence the need for this study at KNH.

1.2 Problem Statement

Diabetes Mellitus (DM) is a group of metabolic disorders characterized by hyperglycaemia associated with abnormalities in carbohydrate, fat and protein metabolism.[1,2,3] If not controlled, diabetes mellitus has been implicated as the underlying cause of 12% of all new cases of legal blindness, over one third new cases of end- stage renal disease (ESRD), and nearly half of non traumatic lower – extremity amputations.[1] Evidence has also shown that people with diabetes are two to four times more likely to die from heart disease or suffer stroke. [29]

The worldwide prevalence of DM has risen dramatically over the past two decades and it is projected that the number of individuals with DM will continue to increase in the future. [30]

Prevalence of diabetes in adults worldwide was estimated to be 4.0% in 1995 and was expected to rise to 5.4% by the year 2025. The major part of this numerical rise would occur in developing countries. The countries with the largest percentage proportion of people with diabetes are, and by the year 2025 will be India, China, and the US. The largest percentage proportion of diabetics is in the age range of 45- 64 years in the developing countries and 45-65 years in developed countries. This pattern would be accentuated by the year 2025.[31]

Kenyatta National Hospital is a tertiary hospital in a developing country, Kenya. Because of the possibility of future numerical rise of DM in developing countries[31].there is need to optimize DM patients' blood sugar control to prevent complications. One such way is by equipping the patients with sufficient knowledge on the disease and its management. Since the level of patients' knowledge on DM in KNH is not known, it would be beneficial to carry out a study to find out the level of knowledge of these patients and determine the proportion of patients with adequate knowledge.

It is hoped that the study will provide useful information that will form a basis for future studies and also improvements of DM patients' quality of life.

1.3 Study Objectives

1.3.1 Broad Objective

To determine the proportion of DM patients with adequate knowledge on their disease at KNH DM OPD and the level of KNH preparedness in the provision of diabetic education to these patients.

1.3.2 Specific Objectives

1. To establish the proportion of diabetic patients with adequate knowledge about their disease at KNH's OPD DM clinic.
2. To establish the proportion of diabetic patients without adequate knowledge about their disease at KNH's OPD DM clinic.
3. To determine the extent of KNH preparedness in the provision of diabetic education to the DM patients at DM OPD clinic.

1.4 Research Questions

1. What is the proportion of DM patients with adequate knowledge on the DM disease itself, disease complications, DM medications, importance of dietary control, doing exercises, and being affiliated to DM organizations, for example, Kenya Diabetic Association (KDA) for optimal management of DM disease?

2. Does KNH's DM OPD have a programme, space and personnel for providing diabetes mellitus education to DM outpatients and what is the frequency of this education?

3. Does gender, age and education level affect the proportion of patients with adequate knowledge in DM patients?

1.5 Research Hypotheses

The study was done one null hypothesis (H_0) that there is no significant relationship between the dependent and independent variables of the study against the alternative hypothesis (H_A) that there exists a significant relationship between the dependent and independent variables.

CHAPTER TWO

2.0 Literature Review

Reference to clinical states resembling Diabetes Mellitus can be found in medical literature dating many years before the birth of Christ and emanating from various centres of ancient civilization both in Europe and Asia.[22]

The detailed description of "PRAMEHA" or abnormal urination can be found in ancient Hindu literature dating as far back as the sixth century B.C. Some varieties of Prameha (over 30 were described) were characterized by polyuria, sweet urine, weakness, wasting and boils.[22]Similar descriptions are also found in Chinese and Japanese of roughly the same period in time.[22]

Definition of Diabetes Mellitus

Diabetes mellitus (DM) is a group of metabolic disorders characterized by hyperglycaemia associated with abnormalities in carbohydrate, fat and protein metabolism.[1,2] This group of metabolic disorders is caused by an absolute or relative lack of insulin, a hormone produced by the Beta cells of the Islets of Langerhans of the pancreas. In normal individuals, insulin is secreted after a meal to lower to normal the blood glucose levels. Insulin promotes the absorption of glucose into the cells such as skeletal muscle and adipose tissue. This system is dysfunctional in diabetic patients.[3]

Diabetes Mellitus is a chronic, incurable condition that has considerable impact on the life of each individual; therefore, patient involvement is paramount for the successful management of the disease.[19] Glucose is a simple sugar found in food. It is an essential nutrient that provides energy for the proper functioning of the body cells. After meals, food is digested in the stomach and the intestines into glucose and other nutrients. The glucose in digested food is absorbed by the intestinal cells into the bloodstream, and is carried by blood to all the cells in the body.[3] However, glucose cannot enter the cells alone. It needs assistance from insulin in order to penetrate the cell walls. Insulin therefore acts as a regulator of glucose metabolism in the body.[3,10]

This system of auto regulation and homeostasis is the function of the pancreas and it works around the clock. Dysfunction of this auto regulation system - either inability of the pancreas to secrete any or insufficient insulin, or pancreas overload from too much sugar ingested over a long period of time, or over compensatory mechanism, or a combination of these, results in the relative or absolute lack of insulin, and hence high blood sugar. This is the hallmark of diabetes mellitus (commonly called diabetes) [1,2]

When the blood sugar levels go below the lower normal level, glucagon, a hormone secreted by the α-cells of the Islets of Langerhans of the pancreas is produced. This stimulates glycogenolysis and gluconeogenesis with the overall effect of raising the blood glucose level. [3,14]

In a patient with diabetes, blood glucose concentrations remain high after a meal because the uptake, utilization and storage of glucose by adipose tissue and muscle are diminished secondary to an absolute or relative lack of insulin.[3,19]
If these blood sugar concentrations remain high for a long time without optimal control, chronic complications result.[2]

The chronic complications of DM may lead to microvascular, macrovascular, and neuropathic disorders. [16] Therefore, there is need for proper management of DM to optimally control the blood sugar levels and avoid or control these complications.

Self management including patient adherence to the prescribed medication and lifestyle modifications such as dietary control, strict glycemic control, having exercise programs, patient's involvement with diabetes organizations are very essential in the management of DM.[32,33] A pharmacist can play an important role in providing such information through counseling[3,16]on the nature of the disease, lifestyle modifications, medications, and acute and chronic complications.

There are two main types of DM. these include; Type I diabetes mellitus, also called insulin dependent diabetes mellitus (IDDM), or juvenile onset diabetes mellitus. This is an autoimmune disease in which the pancreas produces no insulin at all, and the patient relies on insulin medication for survival.[2,10]

Type I diabetes tends to occur in young, lean individuals, usually before 30 years of age. Approximately 10% of the patients with diabetes mellitus have IDDM.[23]

Type II diabetes mellitus is also referred to as non-insulin dependent diabetes mellitus (NIDDM). It is a metabolic disorder resulting from the body's inability to make enough, or properly use insulin. 90% of all Diabetes Mellitus are of Type II.[2] Type II diabetes mellitus occurs mostly in individuals over 40 years old. The incidence of type II diabetes increases with age. Unlike type I diabetes mellitus, 80% of type II diabetic patients are obese. Type II diabetes mellitus also has a strong genetic tendency.[34]

In a patient with diabetes mellitus, blood glucose concentrations remain high after a meal because the uptake, utilization and storage of glucose by adipose tissue and muscle are diminished secondary to an absolute or relative lack of insulin.[3]

The early symptoms of untreated diabetes mellitus are related to elevated blood sugar levels, and excretion of it in the urine. High amounts of glucose in the urine can cause increased urine output and lead to dehydration. Dehydration causes increased thirst and water consumption.[1] Some untreated diabetic patients also complain of fatigue, nausea, and vomiting. Patients with diabetes are prone to developing infections of the bladder, skin, and vaginal areas. Fluctuations in blood glucose levels can lead to blurred vision.[30]

Extremely elevated glucose levels can lead to lethargy and coma (diabetic coma).[2] If blood sugar concentrations remain high for a long time without optimal control, chronic complications result.[3]

The most unrecognized symptom of NIDDM is weight gain. High insulin levels prohibit the release of serotonin, a neurotransmitter in the brain that informs the body to slow down eating. Without serotonin, there is a tendency to overeat hence gaining weight.[8]

The fasting plasma glucose test is the standard and preferred way to diagnose diabetes mellitus. Normal fasting plasma glucose levels are less than 7.8mMol/L.[6,8]

If the overnight fasting blood glucose is greater than 9.0mMol/L on two different tests on different days, the diagnosis of diabetes mellitus is made.[3,8]

Random blood glucose alone is seldom used because it is not reliable. Monitoring of haemoglobin A1C level is a test to measure the overall effectiveness of blood glucose control over a period of time (more than two months). Elevated haemoglobin A1C levels indicate a poor overall control of blood sugar.[3,6]

The management of DM involves rational use of medication, strict dietary control and exercise programmes aimed at reducing the weight. Patient counselling/ education about the importance of combination of these is important.[11,12]

The Pharmacist should be able to explain the purpose and methods of mixing, storing, and injecting insulin properly. The necessity of regular scheduled exercises and a balanced nutritious diet in combination with prescribed medicine should be made clear to the patient. Only by educating patients about diabetes mellitus is it possible to bring the disease under control.[35]

Several studies have acknowledged the importance of pharmacist provided counselling in diabetic patients. The Fremantle Diabetes Study (n=64) examined the effect of a 12-month pharmaceutical care (PC) program on vascular risk in type II diabetes. Patients were randomized to PC and or usual care (i.e. patient provided with the DM medication only and there was no counselling or any other medical care). PC patients had face-to-face goal-directed medication and lifestyle counselling at baseline and at 6 and 12 months plus 6-weekly telephone assessments and provision of other educational material including patient information leaflets about the disease. The main outcome measure was change in HbA (1c). The study concluded that the 12-month PC program in type II diabetes reduced glycemia. There was optimal blood sugar control evidenced by low levels of HbA (1c) (below 6.0mMol/L) measured in these patients. Thus, Pharmacist involvement contributed to improvement in HbA (1c) independently of pharmacotherapeutic changes. Patients who were not provided with counselling (i.e. on usual care) had poor glycaemic control.[36]

Cioffi et al conducted a study (n=58) to determine the effect of a clinical pharmacist-directed diabetes management and counselling clinic on glycemic control and cardiovascular and renal parameters in patients with type II diabetes. The primary endpoint was the impact of 9-12 months of participation in the clinic on HbA1C. The study demonstrated that a clinical pharmacist can effectively care for patients with diabetes referred by their primary care provider because of poor glycemic control.[37]

Gerber et al conducted a study to assess the impact on healthcare utilization and costs of pharmacist consultations provided to patients with diabetes mellitus. These consultations involved direct patient education/counselling on the disease, nutrition, lifestyle modifications and exercise programs. The study (n=88, $p<0.05$) suggested that pharmacist consultations provided to patients with diabetes can decrease total healthcare costs in a health maintenance organization. The study showed that patients' counselling lead to optimal blood sugar control and hence less physician visits or hospitalization.[38]

Cranor et al assessed (n=30) the persistence of outcomes for up to 5 years following the initiation of community-based pharmaceutical care services (PCS) for patients with diabetes mellitus. A Quasi-experimental, cross-sectional cohort study was conducted in twelve community pharmacies in Asheville, New castle (N.C). In this study the mean total direct patients' medical costs on DM were measured against the provision of pharmaceutical care services provided by the pharmacist.PCS offered were DM patients' education on importance of dietary control, lifestyle modification and importance of optimal blood glucose control. The study concluded that patients with diabetes who received ongoing PCS maintained improvement in HbA1c over time, and employers experienced a decline in mean total direct medical costs.[39]

Powell et al investigated (n=40) the impact of a specially designed patient education program upon the diabetes-related knowledge and compliance of insulin dependent diabetic patients. The variables measured included methods of mixing, storing, and injecting insulin properly against the optimal control of blood sugar in IDDM. The necessity of regular scheduled exercises and a balanced nutritious diet in combination with prescribed medicine were made clear to the patient.

The program was successful in producing improvements in both knowledge and compliance but the need for individualization of patient education efforts was indicated. [39]

Odegard et al evaluated the effect of a pharmacist intervention i.e. face-to-face goal-directed medication and lifestyle counselling on improving diabetes control; secondary endpoints were medication appropriateness and self-reported adherence. Seventy-seven subjects, were randomized to receive a pharmacist intervention (n = 43) or usual care (i.e. DM medication only and no counselling/ education, n = 34) on improving diabetes control for 6 months, followed by a 6-month usual-care observation period for both groups. The study concluded that pharmacist intervention significantly improved diabetes control and this group were found to have lower HbA (1c) levels compared to the group which received usual care. The group which had pharmacist intervention had fewer physician visits. [40]

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 counselling to the patients. Data collection included baseline and follow-up values for HbA1c and lipids as well as frequency of adherence to preventive care, including annual foot and eye examinations and daily aspirin therapy. The study concluded that the pharmacist-coordinated diabetes management program was effective in improving clinical markers for enrolled patients. Significant improvements were observed in Hb A1C and LDL (Low Density Lipoproteins) values as well as adherence to the preventive care.[41]

In view of the above studies, it is clear that patient education/ counselling is important for optimal therapeutic outcome in the management of diabetes mellitus. It is, therefore, important to evaluate the level of education that is given to DM patients' who attend outpatient DM at KNH; hence the need for this study.

2.1 Patients' Counselling

Essential components of diabetic counselling

Diabetes mellitus is a chronic complication affecting the diabetic patient at various levels-Physically, psychologically, socially and economically. Counselling process should focus on the nature of the disease, lifestyle modifications, medications, and acute and chronic complications.[32]

I. Counselling regarding the disease: The diabetic patients should be explained that the disease is lifelong, progressive and needs necessary modifications in the lifestyle pattern such as dietary control, strict glycemic control and exercise programs.[19] They should also stress upon the importance of pharmacotherapy, especially the need for strict adherence with the prescribed medication. The patients should be also explained that the disease may affect the quality of life if not well controlled.[32]

II. Counselling regarding lifestyle modifications: While counselling regarding the life style modifications, the pharmacist should focus on the key areas including diet, exercise, smoking and alcohol intake.[10]

Diet: Dietary control is the mainstay of treatment in type II diabetes and an integral part in type I diabetes mellitus. Among the dietary counselling, importance should be given for the dietary content including carbohydrate, fat and fibre intake.[10,19,32]

Carbohydrates: The blood glucose level is closely affected by the carbohydrate intake. Daily intake should be kept fairly constant and the amount given should be appropriate to the level of physical activity. Most young people will require 180 g of carbohydrate by day, whereas 100 g may suffice for an elderly patient. If fibre rich food such as whole meal bread and jacket potatoes are eaten, then the carbohydrate content of the diet make up to 50% to 55% of the calories. People with diabetes should limit their sugar intake, but total exclusion of sugar from the diet is impractical and unnecessary.[10]

Fat: Since there is an increased risk of death from coronary artery disease in diabetics, it is wise to restrict saturated fats and to substitute them with unsaturated fats. Furthermore, obesity is a major problem in diabetes, and fats contain more than twice the energy content by unit weight than either carbohydrate or proteins. More severe restrictions may be indicated for individuals with hypercholesterolemia.[10,19]

Fibre: Dietary fibre has two useful properties. Firstly it is physically bulky and increases satiety. Secondly, fibre delays the digestion and absorption of complex carbohydrates, thereby minimizing hyperglycemia.[10] For an average person with NIDDM, 15gm of soluble fibre (from fruits, pulses and vegetables) is likely to produce a 10% improvement in fasting blood glucose, glycosylated Hb and low- density lipoprotein cholesterol.[4]

B. Exercise and physical activity: Exercise can help to promote weight loss and maintain ideal body weight when combined with restricted caloric intake. Exercise also prevents impotence. In type II diabetes, the desired level of exercise is 50% to 80% of maximal uptake of oxygen three to four times a week. In type I diabetes, care must be taken to have adequate metabolic control prior to exercise and to monitor blood glucose before and after exercise. Exercise is not recommended if the patient has poorly controlled labile blood glucose level or is at increased risk of diabetic complications. Strenuous exercise is not wise in patients prone to develop hypoglycaemia.[42]

A standard recommendation for diabetic patients, (as for nondiabetic individuals), is that exercise should include a proper warm-up and cool- down period. A warm up should consist of 5-10 min of aerobic activity (walking, cycling, etc.) at a low intensity level. The warm-up session is to prepare the skeletal muscles, heart, and lungs for progressive increase in exercise intensity. After a short warm- up, muscles should be gently stretched for another 5- 10 min. primarily, the muscles used during the active exercise session should be stretched, but warming up all muscle groups is optimal. The active warm up can either take place before or after stretching. Following the activity session, a cool-down should be structured similarly to the warm-up. The cool- down should last about 5- 10 min and gradually bring the heart rate down to its pre- exercise level.[10,43]

C. Alcohol intake: Even if the blood glucose of the patient is well controlled, modest amount of alcohol will significantly alter blood glucose levels. In general, the same guidelines of alcohol use applicable to the general public apply to patients with diabetes.[44]

D. Smoking: People with diabetes, especially those over age 40 years, who smoke and have high blood pressure and cholesterol, are at a higher risk for cardiovascular problems.

When the large blood vessels (arteries) are blocked, heart attack and stroke often result. This hardening or blockage may also occur in the small arteries that supply blood to the legs and feet. Smoking can also lead to serious complications like infections, ulcers, gangrene, and even amputations. Pharmacist should counsel patients regarding the bad effects of smoking and educate the patients regarding the various strategies to stop smoking. Emphasis should be laid on the pharmacological measures to stop smoking[10,44]

III. Counselling regarding medications: Though lifestyle modifications play an important role in diabetes management, it is well established by land mark studies that the chronic complications can be prevented by strict glycemic control.

Hence, the pharmacist has an immense role in counselling diabetic patients regarding the drugs. Counselling should be emphasized for oral anti diabetic agents as well as for insulin.

1. Oral hypoglycaemic agents (OHAs): [45] If the patient is diagnosed with Type II diabetes, he/ she is more likely to be prescribed OHAs. Some of the commonly prescribed oral hypoglycaemic agents and the important counselling points are discussed below.

Some general principles to be followed for patients on OHAs

The patient should be cautioned not to skip meals at any time and to follow regular eating patterns to prevent hypoglycaemia. OHAs are comparatively safe drugs.

However some patients may develop loss of appetite, nausea and vomiting, abdominal pain, cramps, malaise, diarrhoea or weight loss.[3,12,46] The counselling points for individual OHAs are listed in the table 2.1.

Table 2.1: Counselling points for oral hypoglycaemic agents

Drugs	Administration time	Dosing schedule	Possible side effects	Comments
Glibenclamide	Taken with meals Or 15 to 30 minutes before food.	Usually taken in one to two doses	Hypoglycaemia, obesity.	Interacts with oral anticoagulants
Glimepiride	Taken with meal	Usually taken in a single dose.	Hypoglycaemia	Interacts with oral anticoagulants
Gliclazide	Taken with meal	Usually taken in one to two doses	Hypoglycaemia	Interacts with oral anticoagulants
Glipizide	Taken with meal	Usually taken in one to two doses	Hypoglycaemia	Interacts with oral anticoagulants
Metformin	Taken during or immediately after a meal to minimize gastrointestinal side effects.	Usually taken in one to three doses	Gastrointestinal disturbances	Should be stopped before surgery and radiological investigations involving contrast media
Acarbose	Swallowed whole with liquid before meal or chewed with the first few mouthfuls of food.	Usually taken in one to three doses	Gastrointestinal disturbances	Sucrose should not be administered if the patient experiences hypoglycaemia
Repaglinide	Taken with meal	Usually taken in one to three doses	Hypoglycaemia	-
Pioglitazone	Taken with meal	Usually taken in single dose	Hypoglycaemia	-

Insulin: All patients with type I diabetes require insulin. Some patients with type II diabetes who initially respond to dietary modification and/ or oral anti diabetic medications eventually require insulin therapy.

There are a wide variety of insulin preparations available now. These may differ in source, onset of action, time to peak effect, and duration of action.[10,11] Some of the counselling points for patients on insulin are listed in Table 2:2.

Table 2.2: Counselling Points for Insulin Use

Steps	Counselling points
Drawing of insulin from the vial	Draw air into the syringe in an amount corresponding to the prescribed amount of insulin. Inject air into the vial. Invert the vial and draw up insulin little more than the prescribed amount. Hold the vial vertically at eye level. Inject the excess amount of insulin, together with any air bubbles, back into the vial. Pull out the needle.
Site of injection	The best sites for insulin injection are the front and outer sides of the thigh, and the abdomen.
Injection techniques	Clean the injection site with spirit. Pinch the skin at injection site in a broad fold and insert the needle at an angle of 45°C into the subcutaneous tissue. Inject the insulin slowly. Then press your finger against the injection site while pulling out the needle.
Rotating the injection sites	Rotate the injection site in the chosen area so as not to injure the tissue beneath the skin.
Disposal of the needles	Disposable syringes must be discarded, so that they do not harm to others. Glass and metal syringes must be thoroughly cleaned before every use.
Time of administration	The patient should be advised to administer the insulin as per the doctor's advice. In general insulin preparations should be administered 30 minutes before meals.
Storage of insulin	Insulin should be stored at temperature of 2 to 8°C. Incase the patient doesn't have the refrigerator he/she can be advised to put the vial in a glass of water. The patient can also be advised to have thermostat bags that can retain the stability of the preparation.
Adverse drug reactions	The patient should be advised to monitor allergic reactions (especially with bovine or porcine insulin) and also for hypoglycaemia.
Specialized devices in administering insulin	Insulin pen has several advantages (easy to carry, less pain and accurate dose administration). Suitable candidates for insulin pen should be isolated and advised by the pharmacist.

IV. Counselling regarding acute complications: Though rare and not directly linked with the quality of life, the acute complications of diabetes mellitus can be morbid if not treated properly.[3,7,19] The pharmacist should focus on strategies to prevent the occurrence of the acute complications and if they have occurred the methods to overcome and to manage the same. Some of the acute complications of diabetes are discussed below.

1. Hypoglycaemia: It is a condition caused by abnormally low level of blood glucose. Hypoglycaemia is caused by taking too much of certain diabetic medicines, missing a meal or delaying a meal, exercising more than usual, or drinking alcohol. The symptoms can be classified as initial, intermediate and advanced symptoms.[6,11]

Initial symptoms may start with sweating, tremulousness, nausea and vomiting, dizziness, mood change, hunger, weakness and progress to the intermediate symptoms of confusion, poor coordination, headache and double vision. The advanced symptoms are unconsciousness and seizures.[19]

The management of hypoglycaemia includes taking half a cup of any fruit juice, 2 or 3 glucose tablets, 2 tablespoons raisins, 1 or 2 teaspoons of sugar or honey, half cup of regular soft drink or liquid concentrated glucose. For advanced hypoglycaemia, medical intervention is needed with glucagon 1 mg subcutaneously or intramuscularly.[45]

Hypoglycaemia can largely be prevented by taking antidiabetic medications properly, eating regular meals, and regular checking of blood glucose.[46] Table 2.3 lists the summary of counselling points for preventing hypoglycaemia.

Table 2.3: Counselling regarding hypoglycaemia

Causes	Missing meal, antidiabetic medications
Symptoms	Sweating, weakness, confusion
Management	Fruit juice, chocolates
Prevention	Regular eating plans, regular blood glucose checkups

2. Diabetic ketoacidosis (DKA): DKA is a serious complication characterized by hyperglycaemia, elevated serum ketones, and an anion gap metabolic acidosis. It mainly affects the individuals with type I DM but may also affect type II diabetes patients in response to acute stress.[1,3]

In general, insulin omission or non-compliance is identified as an important contributing factor for development of DKA.[47]

3. Non Ketotic Hyperosmolar Syndrome (NKHS): It is a constellation of severe hyperglycaemia, dehydration, and hyperosmolarity in the absence of severe ketosis. It commonly occurs in elderly patients with type II DM. Among the various risk factors for NKHS are advanced age, female gender, acute infection and non-compliance.

Hence counselling regarding the importance of compliance can be helpful in reducing the occurrence of NKHS.[10,47]

V. Counselling regarding chronic complications: Chronic complications of diabetes mellitus can adversely affect the quality of life. It is well established that the chronic complications of diabetes can be prevented by strict compliance and suitable lifestyle modifications, such as dietary control and exercise programmes.[10,19,32] Some of the chronic complications and the role of pharmacist in counselling the patients regarding these complications are mentioned below.

Diabetic neuropathy: It is characterized by nerve damage caused by chronic high blood glucose levels. Neuropathy can lead to loss of pain or touch sensations on the feet. It can also cause pain in legs, arms or hands. Nerve damage can progress slowly and most of the time the patients may not even be aware that they have nerve problems. Hence regular check ups to rule out diabetic neuropathy is essential. For prevention of diabetic neuropathy the blood glucose and blood pressure should be kept as close to normal as possible. The other precautions include stopping/limiting alcohol intake, regular checking of feet every day and quitting the smoking.[48]

Diabetic retinopathy: Retinopathy is a disorder of the eye that occurs in majority of the adults with diabetes. The patient suffering from retinopathy may complain of blurring of vision, seeing black spots, flashing lights etc. Once detected proper treatment of diabetes can reduce the progression of retinopathy[3]

Diabetic nephropathy: Nephropathy (disorder of the kidney) is one of the potential life threatening complications of diabetes. Poor control of diabetes is associated with enlargement of the kidneys and impairment in their function. The development and progression of nephropathy in diabetics can be delayed by tight glycemic control[7,48]

Infections: Many infections, particularly cellulitis, are seen commonly in diabetic patients. This is an indication of poor diabetes control. Infections at mild stages, if not treated, can lead to life threatening sepsis in these patients.[14,48]

VI. Counselling in special populations: [45] Since the progression and the management pattern of diabetes vary significantly among different populations, the pharmacist should also tailor his counselling pattern by the population. Some of the special populations with diabetes are mentioned below with the outline of the counselling in these patients.

Elderly: Elderly diabetic patients usually have various other comorbid conditions like hypertension, hyperlipidemia and ischemic heart disease. They may also have some degree of psychiatric imbalance. The counselling in these patients should also address the emotional impairment due to diabetes.[19,45]

Children: Children, especially the type I diabetes patients, require several special precautions. In addition to other essential counselling points, the pharmacist should also focus on the administration time of insulin during school days, storage of insulin in the school and risk of hypoglycaemia while playing.[10]

Pregnancy: Since elevated blood glucose is associated with congenital abnormalities, the pregnant patients should be asked to have strict control over the blood glucose[45]

Multiple disorders: Patients with multiple diseases need special counselling for those diseases other than diabetes. Patients with underlying cardiac problems should be cautioned that they may not experience pain during myocardial infarction and hence should be advised to have regular cardiac checkup.[1,3]

Frequent travelling: Diabetes patients who travel frequently should be advised regarding the use of insulin pen. They should be also counselled regarding the importance of food plan during their journey and the possibility of hypoglycaemia. They should be warned not to neglect even a simple infection as it may turnout to be fatal.[45]

VII. Counselling regarding self Monitoring of Glucose: With the availability of blood glucose monitoring devices for the monitoring of blood glucose, patients can monitor glucose levels more frequently and have a control over blood glucose.[52] A Pharmacist can play a vital role in educating the patients regarding the use of blood glucose monitors. Pharmacists can help right from choosing a proper glucose monitor, training them in proper use of glucose meters. Pharmacist can explain the significance of various blood glucose levels and maintaining proper blood glucose levels. As the patients gain confidence in measuring the blood sugar, managing diet and medications better outcomes can be expected[47]

VIII. Miscellaneous: Besides the above-mentioned topics, the pharmacist should also provide additional counselling for the patients who need it. Some of the additional points to be counselled are mentioned below.

1. Foot care: Meticulous foot care[49] and the choice of suitable footwear can prevent serious damage, which is likely to occur in diabetics[45] and cause serious problems.

2. Eye care: Individuals with diabetes mellitus could have underlying eye problems that might not be noticed by the patient early. It is important to recognize eye problems early while they can be treated to prevent blindness.[19,45]

3. Oral hygiene: People with diabetes are prone to many changes in the mouth such as dry mouth, burning sensations, painful sores, and loss of taste and coating on the tongue. The most common oral complication of diabetes is gum (periodontal) disease. If un-treated, gum disease can be very serious and lead to tooth loss.[19,32]

Early signs of gum disease include long term bad breath or bad taste, swollen, red, tender, shrinking or bleeding gums, pus between teeth; changes in bite, teeth position or denture fit or tooth loss.[45]

Tips for oral hygiene: Brush teeth after every meal and before bedtime use a soft bristled brush, brush all surfaces of all teeth, lightly brush the tongue, and massage gums lightly with finger or brush. The patient should be advised to visit the dentist every three months for cleaning, polishing and inspection. [16]

2.2 Strategies to Improve Counselling in Diabetes Patients

1. Patient information leaflets (PILs): Patient information leaflets can help the patients in getting the information regarding diabetes. The PILs should focus on the lifestyle modifications and the medications. [32,45]

2. Compliance aids: The compliance aids like medication envelopes and medication calendars can help in making the patient understand the different dosing schedule of the medication, especially the OHAs.[19,48]

3. Use of audiovisual aids: A study by Wedman and Kahan found that a group of patients with diabetes counselled by a dietician who used graphic teaching aids, complied with health care advice better than did a control group advised by the same counsellor without the use of graphic teaching aids.[39] Similarly the counselling pharmacist can also use audiovisual aids in order to improve the outcome of counselling. [50]

4. Establishing patient counselling centre: Establishing a separate counselling area near the dispensing area of the pharmacy can be beneficial for effective counselling. It also improves the quality and the outcomes of the counselling process.[32,50]

CHAPTER THREE

3.0 Study Design

This was a tertiary hospital based cross-sectional descriptive study.

Study Area

The study was carried out at Kenyatta National Hospital (KNH). KNH is the biggest hospital in East Africa.

Study Population

The study was carried out among the outpatient adult diabetics (aged 18 years and above) who attended KNH DM OPD and diabetics' healthcare providers at the clinic. Both males and females were included.

Sample Size (n)

There were no previous studies on the level of knowledge among diabetic patients attending KNH OPD clinics. Therefore, it was estimated that the percentage proportion of patients with adequate knowledge in each study variable was 50% with an error margin of ± 10%. So at 95% confidence level, the minimum sample size was calculated as:-

$$n \geq Z^2pq/d^2$$

Where; n=Sample Size;

Z=1.96 i.e. the value of Z corresponding to 95% confidence level;

P, prevalence=50%=0.5(the average estimated level of knowledge since there were no such previous studies);

q=1-p=1-0.5=0.5;

d=0.1(10% error margin)

By substituting z, p, q and d;

$$n \geq (1.96^2 \times 0.5 \times 0.5/0.1^2)$$

$$n \geq (3.8416 \times 0.25/0.01)$$

$$\mathbf{n \geq 96}$$

The author took a sample size n=105 DM respondents which is 96 plus a 10% to allow for data losses.

Sampling Method

A sequential sampling procedure was done. DM patients were interviewed as they came for clinic. Both DM males and females (aged 18 years and above) were recruited.

In this setting the sample size was 105 DM patients and 5 DM healthcare providers.

Inclusion Criteria

The patient had to:-

- Be a proven diabetic;
- Be from Nairobi and environs so that a repeat interview could be carried out easily, should it become necessary;
- Give a free un-coerced. informed consent;
- Aged 18 years and above, both males and females.

Exclusion Criteria

Patients with the following were excluded from the study:-

- All psychiatrically ill patients or unable to communicate verbally;
- Patients aged under 18 years;
- Patients who did not give free uncoerced and informed consent;
- Patients who withdrew consent;
- Non-diabetic patients;
- Patients who lived far away from Nairobi and its environs.

Study Variables.

Independent variables: Patients' Sex, Education level, and Age.

Dependent variables: Patients' knowledge on DM disease, DM Complications, Importance of dietary control, Importance of doing exercises, rational use of DM medication and knowledge of DM Affiliate Organizations.

3.1 Study Methods

This study was carried out between September 2007 and January 2008 (4 months). Two sets of questionnaires, one for the DM patient and the other for the KNH DM OPD healthcare provider (Annex III and IV, respectively) were designed for data collection.

105 DM patients (both males and females aged 18 years and above), who had given informed consent, were interviewed sequentially as they came for their clinic appointments.

5 DM OPD healthcare providers were interviewed.

For the DM patients:

Data were collected from the KNH DM OPD as the patients came during clinic visits.

The consent information was read and the contents therein explained to each and every recruited patient. Thereafter, the patients consented by signing the consent form.

After signing the consent form, the questionnaire (Annex III) was administered to the DM patient who had satisfied the inclusion criteria. In each and every questionnaire, a different study serial number was assigned to prevent duplication of data collection. The study serial number was a unique identifier to avoid confusion in data collection between patients. Each of the questions in the questionnaire was read and interpreted, in a comprehensible manner, to each and every recruited patient. The answers that the patients gave were written in the questionnaire in the way they were provided by the patients. Information gathered included patients' age, sex, highest academic level and patients' knowledge on the disease, nutrition, exercise, DM medication use, DM complications and DM affiliate organizations/associations.

For the ease of creation of database in the computer, the answers collected from the DM respondents were manually marked using codes for each question. Codes were assigned against each question. Code 0 was used to denote an incorrectly answered question(s) while code 1 denoted a correctly answered question(s).

These codes were captured into the computer using the Epi-data computer software to form the data base. Then the data were cleaned and exported to SPSS computer software for analysis.

For the purpose of analysis, each of these parameters was rated at a 100 percent. Therefore, for every parameter, the patients' level of knowledge was expressed as a percentage by taking the number of questions correctly answered by the patient divided by total number of questions in each parameter; and the answer multiplied by 100.

A patient who scored 50% and above in each of the above parameters was termed to have sufficient knowledge in that particular parameter. A patient who scored less than 50% was termed to have insufficient knowledge in the respective parameter.

Thus for each and every parameter, our study could establish the number of DM patients with adequate knowledge.These parameters were evaluated against the patients' age, sex and the highest academic attainment.

The data obtained were presented using tables, bar graphs, figures, pie charts and summary statistics.

For the healthcare providers:

A different set of questionnaires (Annex IV) was administered to 5 (five) out of ten (10) diabetics' healthcare providers at KNH DM OPD to establish the level of preparedness of diabetic patients' counselling. The personnel interviewed were three nurses, one registered clinical officer and one nutritionist.

One different personnel was interviewed every Wednesday during the study. Therefore, it took five weeks to interview the healthcare providers.

Each healthcare provider was requested to kindly:

- Tell whether they conducted diabetic patients' education in KNH and whether there was a room or space preserved for counselling.
- If yes, how frequently they conducted diabetic patients' education in the hospital and about how many patients are trained in one session;
- If no, what could have been the problems;
- If the education/counselling is done to describe how it was conducted in the hospital, whether to individual patient at a time or groups and how;
- Tell , who provided the education/counselling;
- Who co-ordinated the education/counselling.

The answers collected were recorded in the questionnaire in the way they were provided. These formed the basis of analysis of the hospital preparedness in counselling OPD DM patients.

The results obtained were summarised.

CHAPTER FOUR

This chapter presents analysis of the field data and presentation of the findings (results).

4.0 Data Management

A total of 105 DM patients and 5 KNH DM OPD healthcare providers were interviewed and these formed the basis of data analysis.

Structured questionnaires containing open and closed questions with patient's age, sex and the highest academic level were used to gather data.

To ensure quality (reliability and credibility) of the data, each questionnaire was provided with a unique study serial number to prevent duplication of data collection.

Epi-data computer software was used to capture the field data to form the data base. The data were double checked for authenticity and clarity. The cleaned data were then exported to Statistical Package for Social Sciences (SPSS) version 15.0 for analysis.

The variables were analyzed descriptively using SPSS which was followed by computation of inferential statistics, namely Pearson Chi-Square test.

Pearson Chi-Square test was used to test the level of significance among the variables of the study at a p value of <0.05. This was achieved through analysis of the independent variable with the corresponding dependent variable, using SPSS.

This test was performed on the null hypothesis that there is no significant relationship between the dependent and independent variables against the alternative hypothesis that there exists a significant relationship between the dependent and independent variables.

For instance: Null hypothesis-there is no significant relationship between highest academic attainment of the DM respondents and the proportion of patients with adequate knowledge of DM complications.

Alternative hypothesis- there is a significant relationship between the highest academic level of the DM respondents and the proportion of patients with adequate knowledge of DM complications.

4.1 Testing for the Level of significance of Various Variables

Pearson Chi-Square Test

The chi-square statistic (χ^2) was computed using the formula below.

$$\chi^2 = \sum_{i=1}^{k} \frac{(O_i - E_i)^2}{E_i}$$

Where; X^2 is the chi-square value; O_i is the observed value; E_i is the expected value. The chi-square statistic and p-value of the test (indicated in brackets) are shown in the table 4.1 below:-

Table 4.1: Pearson Chi-Square Statistical Test Table

Dependent variables	Chi-Square Statistics for Testing H_0					
	Disease	Complication	Medication	Diet	Exercise	Affiliate organizations
Gender	$\chi^2_{(1,0.05)} = 21.46$* (p=0.01)	$\chi^2_{(1,0.05)} = 4.60$* (p=0.05)	$\chi^2_{(1,0.05)} = 3.097$ (p=0.08)	$\chi^2_{(1,0.05)} = 16.10$* (p=0.02)	$\chi^2_{(1,0.05)} =$ 8.333* (p=0.04)	$\chi^2_{(1,0.05)} = 0.979$ (p=0.32)
Age category	$\chi^2_{(5,0.05)} = 2.847$ (p=0.72)	$\chi^2_{(5,0.05)} = 60.75$* (p=0.03)	$\chi^2_{(5,0.05)} = 3.671$ (p=0.60)	$\chi^2_{(5,0.05)} = 7.958$ (p=0.16)	$\chi^2_{(5,0.05)} =$ 28.81* (p=0.07)	$\chi^2_{(5,0.05)} = 45.0$ 3* (p=0.05)
Highest Education levels	$\chi^2_{(3,0.05)} = 19.024$* (p=0.0001)	$\chi^2_{(3,0.05)} = 0.9991$ (p=0.19)	$\chi^2_{(3,0.05)} = 0.29$ 2 (p=0.96)	$\chi^2_{(3,0.05)} = 62.65$ * (p=0.01)	$\chi^2_{(3,0.05)} = 34.53$ * (p=0.03)	$\chi^2_{(3,0.05)} = 4.38$ 6 (p=0.22)

- **Independent variables = Gender, Highest Education attainment, and Age Categories.**
- **Dependent variables= Knowledge on DM Disease, Complication, Diet, Exercise, and DM Affiliate Organizations.**
- **H_0: There is no statistical significant difference between the dependent and independent variables.**
- **H_A : There is a statistical significant difference between the dependent and independent variables.**
- *** Denotes significant at 5% level, i.e. (P-value < 0.05)**
- **The values in the brackets indicate the status of the P-Values for the test.**

The findings showed that in terms of gender (both males and females), there is a statistical significant difference between the proportion of patients with adequate knowledge on disease (X^2 =2.14; P = 0.01), diet (X^2 =1.61; P = 0.02) and knowledge on doing exercises (X^2=0.83; P = 0.04).

The findings further showed that there is no statistical significant difference between the gender (in both males and females) and the proportion of patients with adequate knowledge on medication (X^2= 3.976; p=0.08) and knowledge on affiliate organizations (X^2 =3.979; P =0.32).

The findings showed that there existed no statistical significant difference between age and the proportion of patients with adequate knowledge on the DM disease (X^2 =11.970; P=0.72), DM medications (X^2 =11.671; P=0.60) and diet (X^2 =11.958; P=0.16).

However, a statistical significant difference was found to exist between patients' age and the proportion of patient with adequate knowledge on complications (X^2 =6.075; P =0.03).

The study further showed that there existed no statistical significant difference between the patients' highest academic level and the proportion of patients with adequate knowledge on DM complications (X^2 =9.991; P=0.19), DM medications (X^2 =8.292; P=0.96) and DM affiliate organizations (X^2 =8.386; P = 0.22).

There was a statistical significant difference between the patients' highest academic attainment and the proportion of patients with adequate knowledge on the disease (X^2=7.02; P=0.0001), knowledge on diet (X^2 =6.265; P =0.01) and knowledge on doing exercises (X^2=3.453; P = 0.03).

This means that there is a disparity on the proportions of patients with adequate knowledge on the diabetes mellitus disease, knowledge on diet and knowledge on exercises among the various levels of education. However, there existed no significant level of disparities on the proportion of the patients with adequate knowledge on DM medication and DM affiliate organizations among the various patients' highest academic attainments.

4.2 Results

4.2.1 Gender and Age Category of the Respondents

The findings indicate that out of 105 DM respondents, 53(50.5%) were males while 52(49.5%) were females.

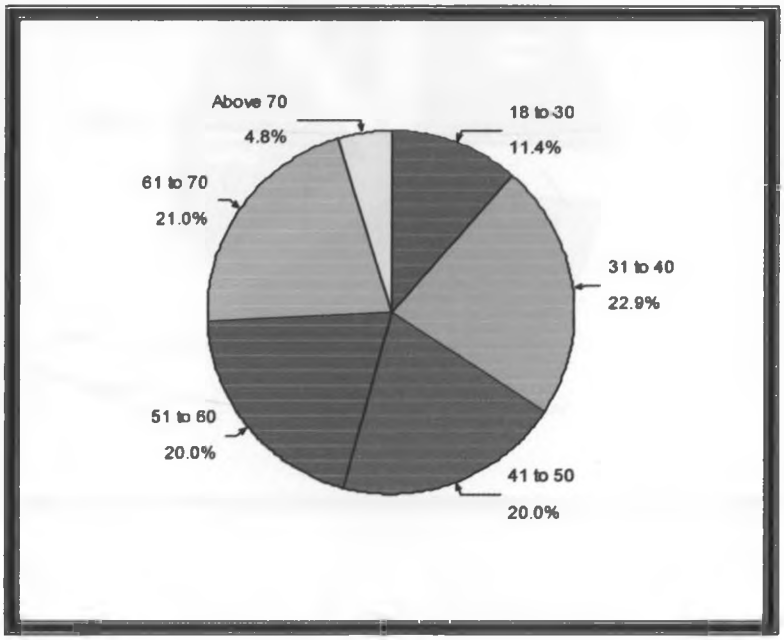
Of the 105 patients interviewed, 88(83.8%), were aged between 31 to 70 years.

Age categories; 31-40 years accounted for 24 (22.9%), 41-50 years, 21(20.0%), 51-60 years, 21(20.0%), and 61-70 years, 22(21.0%) respectively of the105 DM respondents. Only 12 (11.4%) and 5 (4.8%) of the 105 DM respondents were within the age category of 18-30 and above 70 years respectively.

This shows that the respondents were evenly distributed in the main age categories that were the main focus of this study.

Figure 4.1 below shows the distribution of the DM respondents by age categories.

Figure 4.1: Age Category of the Respondents in years



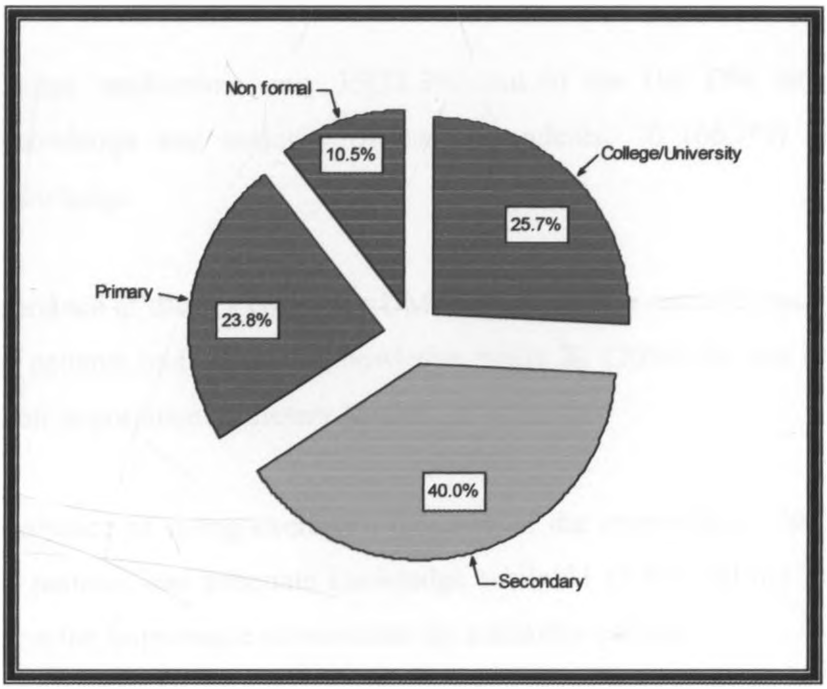
4.2.2. Highest Level of Education of the Respondents

Figure 4.2 shows the distribution of the 105 DM respondents based on their highest level of education.

Out of the 105 DM patients, majority of the respondents, 42 (40%) were in the category of the ones who had secondary education as their highest level of education while 27 (25.7%) had attained college/ university education as the highest academic level. Primary and non-formal highest academic levels accounted for 25 (23.8%) and 11 (10.5%) out of the 105 DM respondents respectively.

This shows how all academic levels were represented in the study.

Figure 4.2: Highest Level of Education



4.2.3 Overall Proportions of Patients With/without adequate Knowledge against the parameters measured in the study

The study sought to determine the proportion of DM patients with adequate knowledge on; the disease, its complications, rational use of Diabetes Mellitus medication, importance of dietary control, importance of doing exercises and awareness on the existence of DM affiliate organizations/associations.

The study showed that out of the 105 DM patients, 52 (49.5%) of the respondents had adequate knowledge on the disease while 53 (50.5%) of the respondents did not have adequate knowledge on the diabetes mellitus disease.

64(61%) of the 105 DM respondents had sufficient knowledge on the disease complications, while 41(39%) of the 105 DM respondents did not have adequate knowledge on the disease complications.

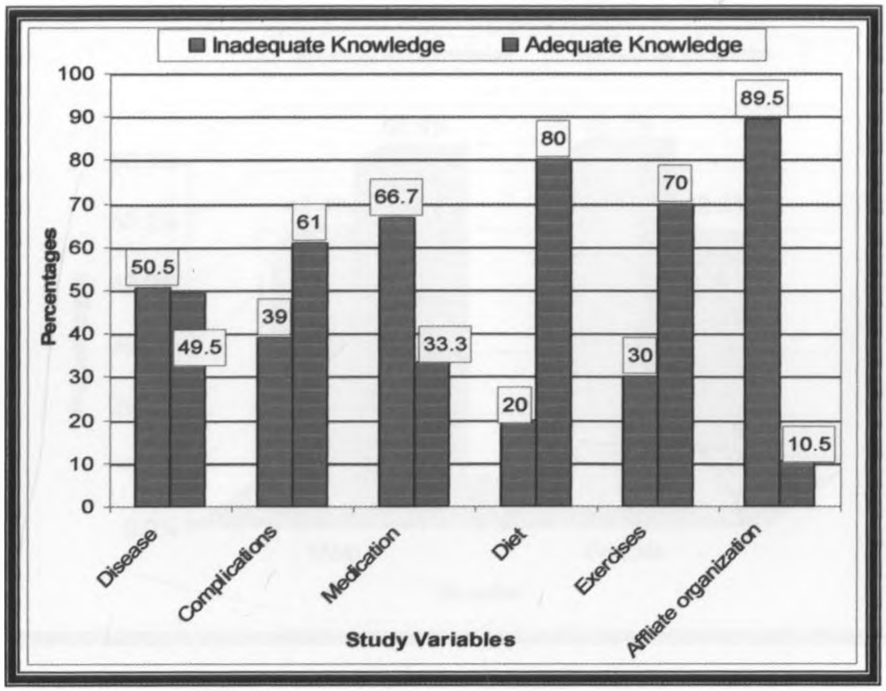
On DM disease medication, only 35(33.3%) out of the 105 DM interviewed had adequate knowledge and majority of the respondents, 70 (66.7%) did not have adequate knowledge.

On the importance of dietary control in DM, majority of the respondents, 84 (80%) out of 105 DM patients had adequate knowledge while 21 (20%) did not have adequate knowledge on importance of dietary control.

On the importance of doing exercises, majority of the respondents, 74 (70%) out of the105 DM patients had adequate knowledge while 31 (30%) did not have adequate knowledge on the importance of exercises for a diabetic patient.

On the knowledge on the DM Affiliate Organizations/Associations, only 11 (10.5%) of the 105 DM patients had adequate knowledge on the existence and importance of the DM Affiliate Organizations/Associations. 94 (89.5%) of the 105 DM respondents did not have adequate knowledge on existence and importance of the DM Affiliate Organizations/Associations. This information is shown in figure 4.3 below.

Figure 4.3: Overall Proportions of Patients with/without adequate Knowledge



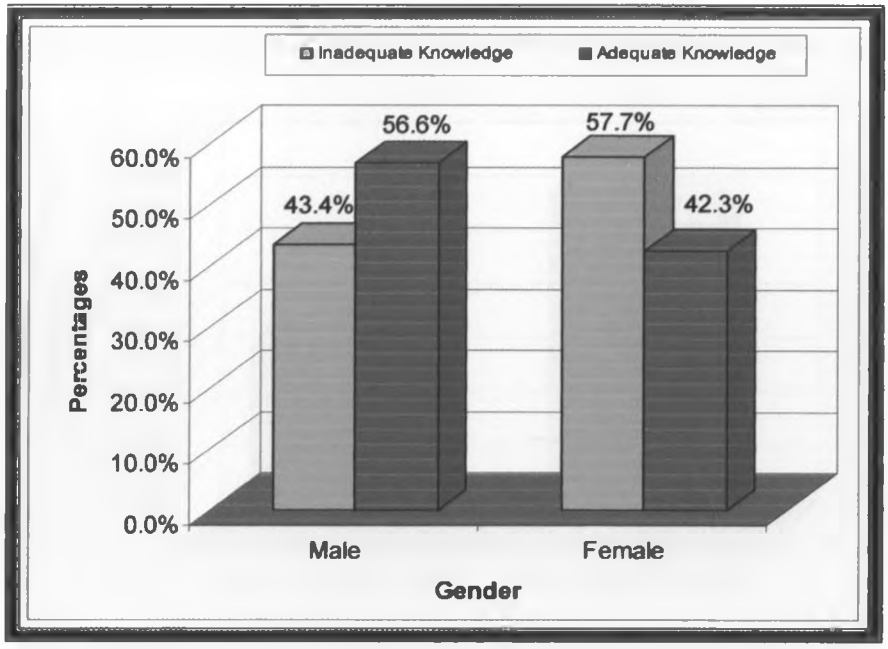
4.2.4Adequate/Inadequate Knowledge by Gender

4.2.4.1 Patients' Knowledge on Disease by Gender

The findings revealed that majority of male respondents, 30 (56.6%) of the 53 male DM respondents had adequate knowledge on the disease while the 23 (43.4%) of the 53 male DM respondents did not have adequate knowledge on the DM disease.

From the female respondents, 22 (42.3%) of the 52 female DM respondents had sufficient knowledge on the disease while majority, 30 (57.7%) of the 52 female DM respondents did not have adequate knowledge on the disease. This is shown in figure 4.4 below.

Figure 4.4: Proportions of patients with/without adequate Knowledge of the Disease by Gender



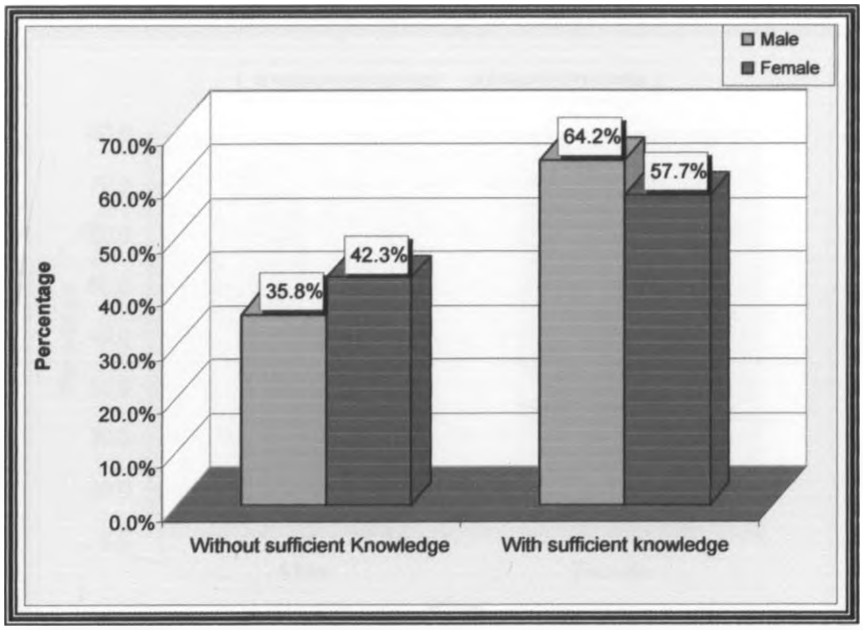
4.2.4.2 Patients' Knowledge on Disease Complications by Gender

The findings showed that, 34 males (64.2%) out of the 53 male respondents have adequate knowledge on diabetes mellitus complications while 19 (35.8%) of the total 53 male respondents did not have adequate knowledge on DM disease complications.

30 females (57.7% of the 52 female respondents had adequate knowledge on disease complications while 22 (42.3% of the 52 female respondents did not have adequate knowledge on DM disease complications.

The above is shown in Figure 4.5.

Figure 4.5: Proportions of patients with adequate/inadequate Knowledge on Complications by gender



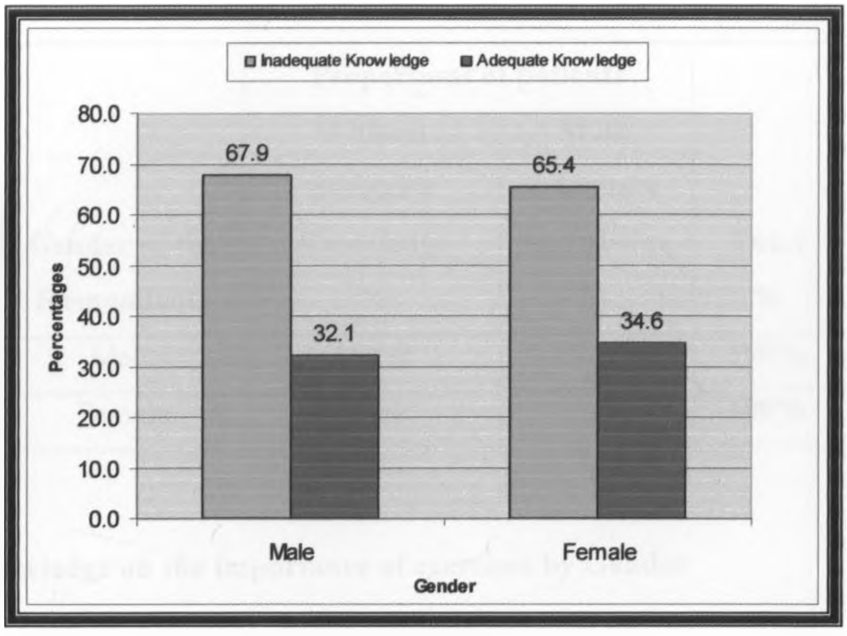
4.2.4.3 Proportions of patients with adequate/inadequate Knowledge on Medication by Gender

The findings revealed that only 17 male patients (32.1%) of the 53 male DM respondents and 18 (34.6%) of the 52 female DM respondents) had adequate knowledge on the medication of diabetes mellitus.

Majority of male, 36(67.9%) out of 53 males and 34(65.4%) out of 52 females did not have adequate knowledge on the medication of diabetes mellitus.

This means that both sexes do not have adequate knowledge on diabetes mellitus medication. Figure 4.6 shows this.

Figure 4.6:Proportions of patients with Adequate/Inadequate Knowledge on Medication by gender



4.2.4.4 Knowledge on the Dietary Control by Gender

The findings revealed that majority of males, 45(84.9%) out of 53 male respondents and females, 39(75.0%) out of 52 female respondents had adequate knowledge on the dietary control.

Only 8(5.1%) out of 53 male respondents and 13(25%) out of 52 female respondents) did not have adequate knowledge on the importance dietary control in diabetes mellitus as shown in table 4.2.

This means that both sexes have adequate knowledge on the importance of dietary control in diabetes mellitus.

Table 4.2: Cross Tabulation of Gender versus proportion of patients with adequate/ inadequate Knowledge on Dietary Control

Gender of the Respondents	Proportions of patients		Total %
	Without adequate Knowledge %	With adequate knowledge %	
Male	15.1%	84.9%	**100%**
Female	25%	75.0%	**100%**

4.2.4.5 Knowledge on the importance of exercises by Gender

The findings show that out of 53 male patients 39(73.6%) had sufficient knowledge on importance of doing exercises while 14 (26.4%) did not have sufficient knowledge on the importance of doing exercises for diabetic patients.

Out of 52 female respondents 34(65.4%) had adequate knowledge on the importance of doing exercises while 18 (34.6%) did not have adequate knowledge on the importance of exercises.

This shows that most of the diabetic patients in both male and female categories have adequate knowledge on the importance of exercises for diabetic patients with male category being dominant at 73.6%.

Table 4.3 shows a cross tabulation of gender against the proportion of patients with/without adequate knowledge on the importance of exercises to a diabetic patient.

Table 4.3: Gender versus knowledge on Exercise

Gender of the respondents	Proportions of patients		Total %
	Without adequate Knowledge on exercises %	With adequate knowledge on exercises %	
Male	26.4%	73.6%	**100%**
Female	34.6%	65.4%	**100%**

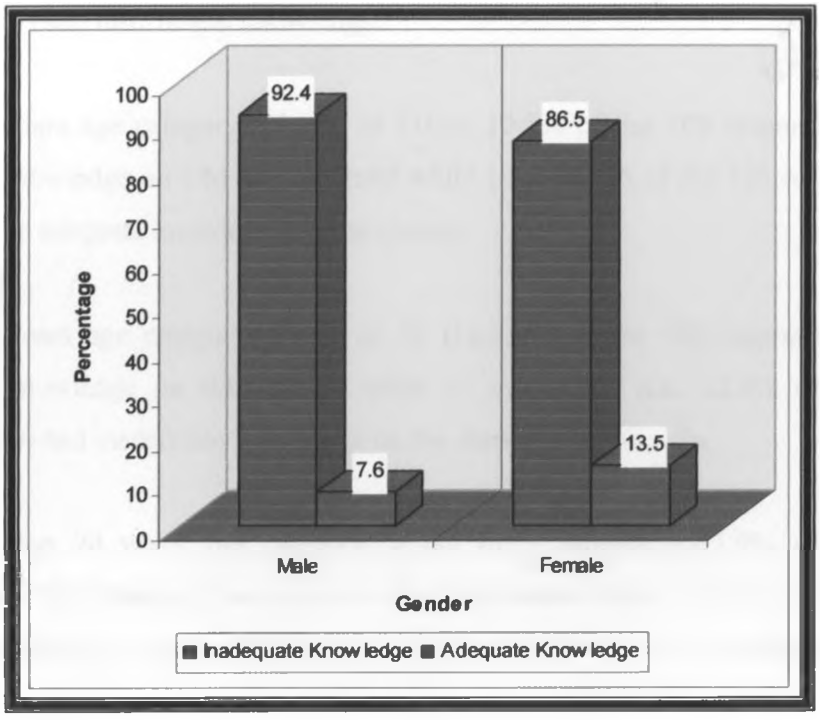
4.2.4.6 Knowledge on DM affiliate organizations/ Associations by Gender

The findings revealed that out of 53 male respondents, only 4 (7.6%) had sufficient knowledge on the existence of DM affiliate organizations/ Associations and 49 (92.4%) had inadequate knowledge on the DM affiliate organizations/ Associations.

Out of 52 female patients, only 7(13.5%) had sufficient knowledge on the DM affiliate organizations/ Associations and 45 (86.5%) did not have adequate knowledge on the affiliate organizations/ Associations of DM.

This implies that most patients attending the diabetic outpatient's clinics do not have adequate knowledge on the existence and importance of DM affiliate organizations/ Associations hence the need for awareness creation. This is shown in figure 4.7.

Figure 4.7: Proportions of patients with adequate/inadequate knowledge on the DM Affiliate Organizations/ Associations by gender.



4.2.5 Knowledge by Age Categories

4.2.5.1 Knowledge on the DM Disease

The study sought to establish the proportion of the respondents with/without adequate knowledge on the DM disease by age categories.

The study established that in the age category of 18-30 years, 5 out of 12 patients (i.e. 4.8% of the 105 respondents) had sufficient knowledge on the DM disease while 7 out of 12 patients (i.e. 6.6% of the 105 respondents did not have adequate knowledge).

In 31-40 years age category, majority of the respondents in this age category, 15 out of 24 patients (i.e.14.3% of the 105 respondents) had adequate knowledge on the disease while 9 (i.e.8.6% of the 105 respondents) did not have adequate knowledge on the same.

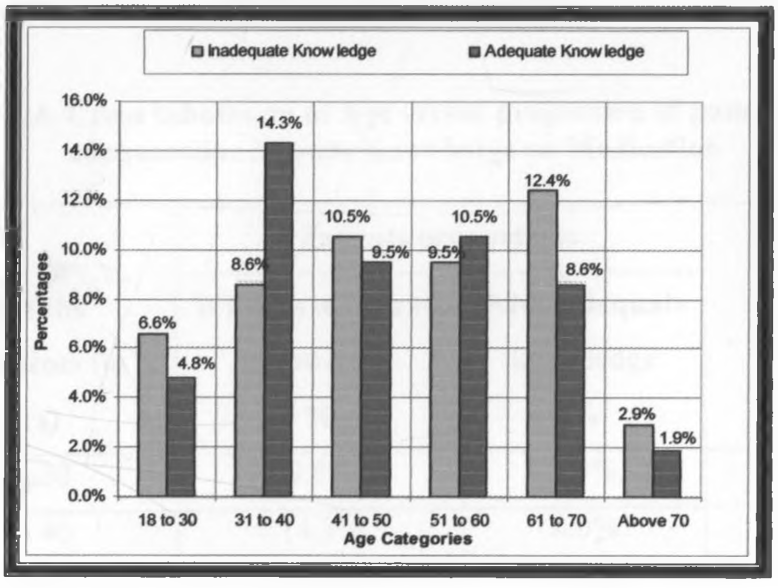
In 41-50 years age category, 10 out of 21(i.e. 9.5% of the 105 respondents) had adequate knowledge on the disease while 11 out of 21 (i.e.10.5% of the 105 respondents) had insufficient knowledge.

In 51-60 years age category, 11 out of 21(i.e. 10.5% of the 105 respondents) had adequate knowledge on DM disease itself while 10 (i.e.9.5% of the 105 respondents) did not have adequate knowledge on the disease.

In 61-70 years age category, 9 out of 22 (i.e.8.6% of the 105 respondents) had adequate knowledge on the disease while 13 out of 22 (i.e. 12.4% of the 105 respondents) had inadequate knowledge on the disease.

In more than 70 years age category, 2 out of 5 patients (i.e.1.9% of the 105 respondents) had adequate knowledge on the DM disease while 3 out of 5 (i.e. 2.9% of the 105 respondents) had inadequate knowledge on the disease. This is shown in figure 4.8.

Figure 4.8: Proportions of patients with adequate/ inadequate Knowledge on the Disease by Age categories



4.2.5.2 Knowledge on the Diabetes Mellitus Medications by Age

Table 4.4 shows a cross tabulation of age in years against proportion of Patients with adequate/inadequate Knowledge on the Diabetes Mellitus Medications.

Out of 105 DM respondents, those without adequate knowledge on medication in the age categories; 18 to 30, 31 to 40, 41 to 50 and 51 to 60, 61 to 70 and above 70 years accounted for 10 (9.5%), 15(14.3%), 15(14.3%),15(14.3%), 12(11.4%) and 3(2.9%) respectively.

Out of 105 DM respondents, those with adequate knowledge of the disease medication in the age categories; 18 to 30, 31 to 40, 41 to 50, 51 to 60, 61 to 70 and above 70 years accounted for 2(1.9%), 9(8.6%), 6(5.7%), 6(5.7%), 10(9.5%) and 2(1.9%) respectively.

The findings revealed that majority of the respondents in all the age categories did not have adequate knowledge on diabetes mellitus medication. This is shown in table 4.4 below.

Table 4.4: Cross tabulation of Age versus proportion of patients with adequate/inadequate Knowledge on Medication

Age of the Respondents (in years)	Patients proportions		Total %
	Without Adequate Knowledge %	With Adequate knowledge %	
18 to 30	9.5%	1.9%	**11.4%**
31 to 40	14.3%	8.6%	**22.9%**
41 to 50	14.3%	5.7%	**20.0%**
51 to 60	14.3%	5.7%	**20.0%**
61 to 70	11.4%	9.5%	**21.0%**
Above 70	2.9%	1.9%	**4.8%**
Total	**66.7%**	**33.3%**	**100.0%**

4.1.5.3 Knowledge on the DM Complications

The study sought to establish the patients' level of knowledge on the disease complications in each of the age categories and hence determine the proportion of patients with adequate knowledge.

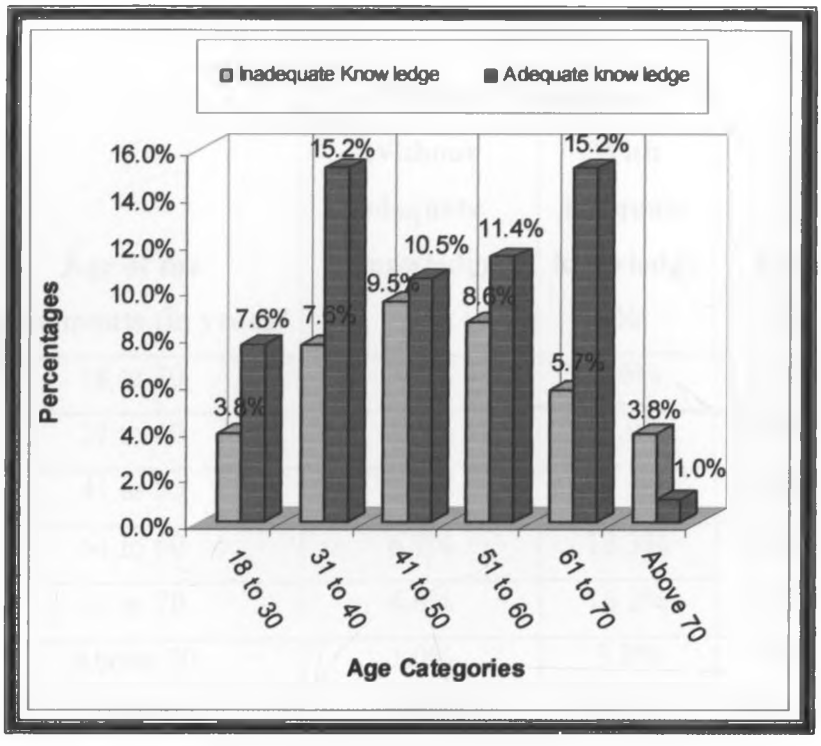
The findings in figure 4.9 reveal that majority of the respondents in almost all age categories had adequate knowledge on the complications of diabetes mellitus.

Out of 105 DM respondents, those with adequate knowledge on DM complications in age categories; 18 to 30, 31 to 40, 41 to 50, 51 to 60, 61 to 70 and above 70years accounted for 8 (7.6%), 16(15.2%), 11(10.5%), 12(11.4%), 16(15.2%) and 1(1.0%) respectively.

Out of 105 DM respondents, those without sufficient knowledge on the disease complications in the age categories 18 to 30, 31 to 40, 41 to 50, 51 to 60, 61 to 70 and above 70 years accounted for 4 (3.8%), 8(7.6%), 10(9.5%), 9(8.6%), 6(5.7%) and 4(3.8%) respectively.

This shows that most patients in the major age categories have adequate knowledge on the complications of diabetes mellitus disease.

Figure 4.9: Proportions of patients with/ without adequate Knowledge on the Complications by age



4.2.5.4 Knowledge on the Dietary Control by Age Category.

The study sought to establish the proportion of patients with adequate/inadequate Knowledge on the Dietary Control in the various age categories.

As shown in table 4.5, out of 105 DM respondents, the age categories; 31 to 40 , 41 to 50, and 61 to 70 years had the highest distributions of the respondents with adequate knowledge on dietary control as accounted for by 23(21.9%), 17(16.2%) and 18(17.1%) respectively.

The findings show that majority of the respondents in all the age categories have adequate knowledge on the importance of diet to control diabetes mellitus.

Table 4.5: Cross tabulation of Age against proportion of patients with adequate/inadequate knowledge on Diet

Age of the participants (in years)	Patients' Proportion		Total %
	Without adequate Knowledge %	With adequate knowledge %	
18 to 30	3.8%	7.6%	**11.4%**
31 to 40	1.0%	21.9%	**22.9%**
41 to 50	2.9%	17.1%	**20.0%**
51 to 60	6.7%	13.3%	**20.0%**
61 to 70	4.8%	16.2%	**21.0%**
Above 70	1.0%	3.8%	**4.8%**
Total	**20.0%**	**80.0%**	**100.0%**

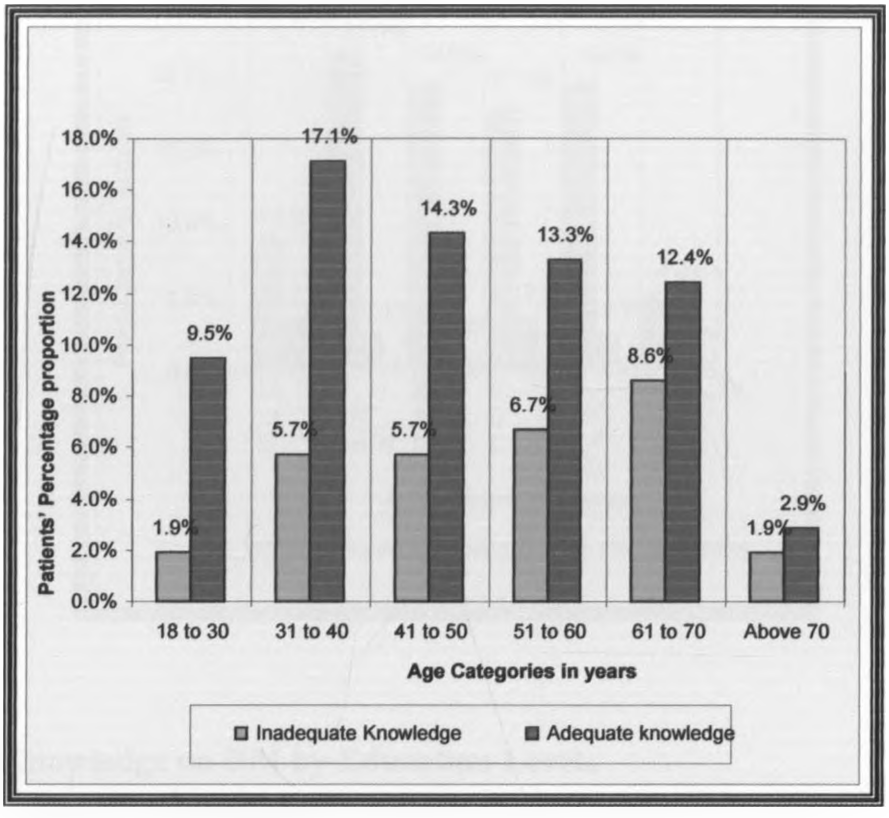
4.2.5.5 Knowledge on the importance of exercises by age categories

The study sought to establish the whether the patients had adequate knowledge on the importance of exercises in the various age categories and consequently determine the proportions of patients with/without adequate knowledge.

The results by the age categories revealed that 10 (9.5%), 18(17.1%), 15(14.3%), 14(13.3%), 13(12.4%), and 3(2.6%) out of the 105 DM respondents in age categories 18 to 30, 31 to 40, 41 to 50, 51 to 60, 61 to 70 and above 70years respectively had adequate knowledge on the importance of exercises as way of managing the disease while 2(1.9%), 6(5.7%), 6(5.7%), 7(6.7%), 9(8.6%) and 2(1.9%) of the respective age categories did not have adequate knowledge on the importance of exercises in the control of diabetes as shown in figure 4.10.

This shows that majority of the respondents in all age categories had adequate knowledge on the importance of exercises for a diabetic patient.

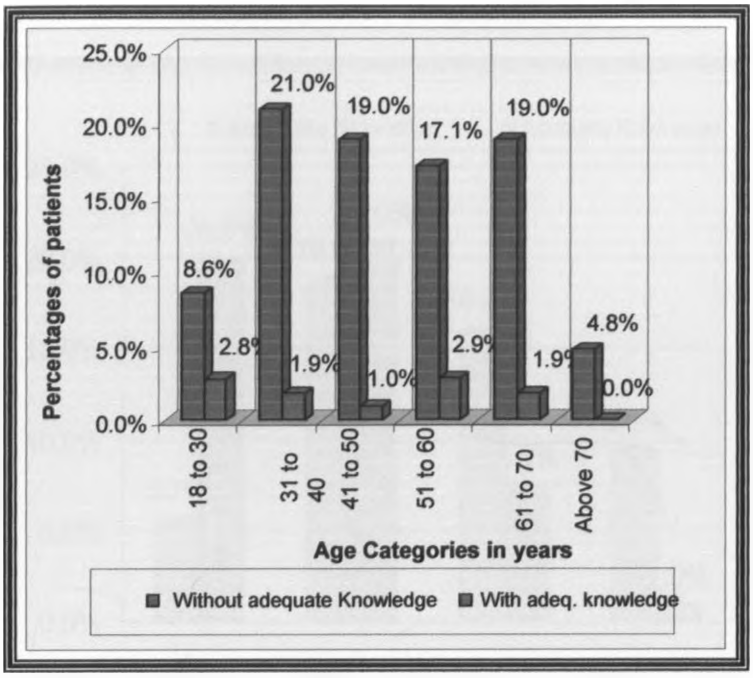
Figure 4.10: Proportions of patients with/without adequate Knowledge on the importance of exercises by age



4.2.5.6 Knowledge on DM affiliate organizations/ Associations by age.

The results in figure 4.11 show that majority of the respondents in all age categories did not have adequate knowledge on the existence and importance of DM affiliate organizations/ Associations as accounted for by 9(8.6%), 22(21%), 20(19%), 18(17.1%), 20(19%) and 5(4.8%) in 18 to 30, 31 to 40, 41 to 50, 51 to 60, 61 to 70 and above 70 years age categories respectively.

Figure 4.11: Proportion of patients with adequate/inadequate Knowledge on DM Affiliate Organizations by age



4.2.6 Knowledge on DM by Education Levels

4.2.6.1 Patients' Knowledge on the Disease by Education Level

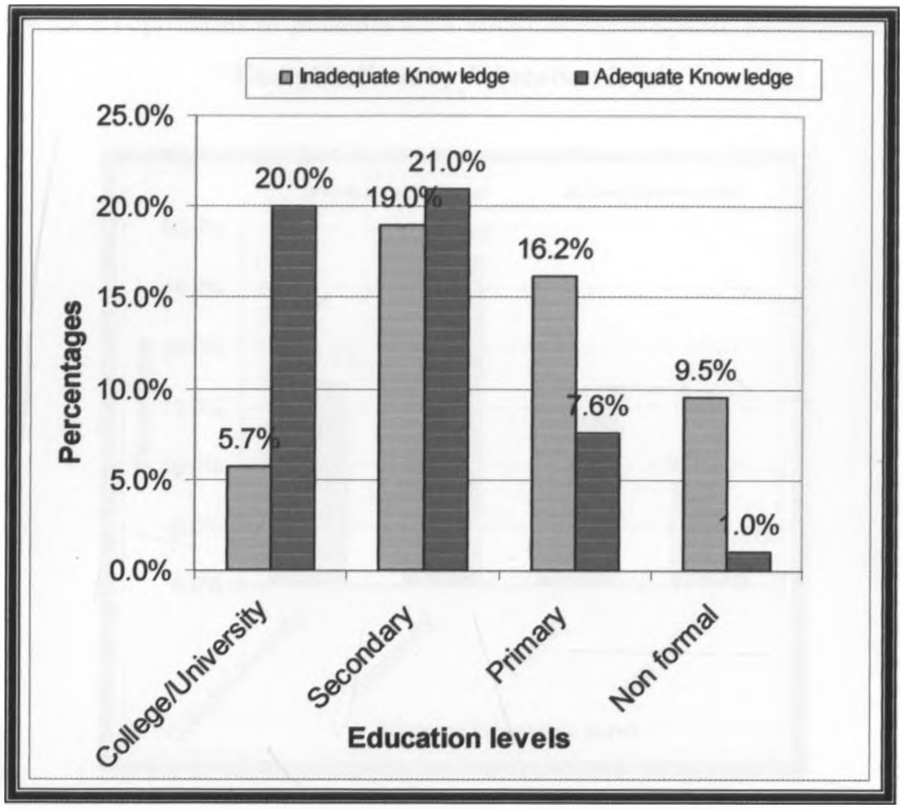
This study also sought to establish the proportion of DM respondents with adequate knowledge of diabetes mellitus based on their levels of education.

The findings revealed that majority of the respondents with university/college and secondary education had adequate knowledge on the disease as accounted for by 21(20%) and 22(21%) out of the 105 DM respondents respectively.

The study further revealed that majority of those with primary and non-formal education levels did not have adequate knowledge on the disease as accounted for by 17 (16.2%) and 10 (9.5%) respectively. This is shown in figure 4.12.

This implies that the higher the education levels of the patients the higher the proportion of patients with adequate knowledge on diabetes mellitus and vice versa.

Figure 4.12: Proportions of DM respondents with adequate/inadequate Knowledge on Disease by Education Level



4.2.6.2 Knowledge on Disease Complications by Education levels

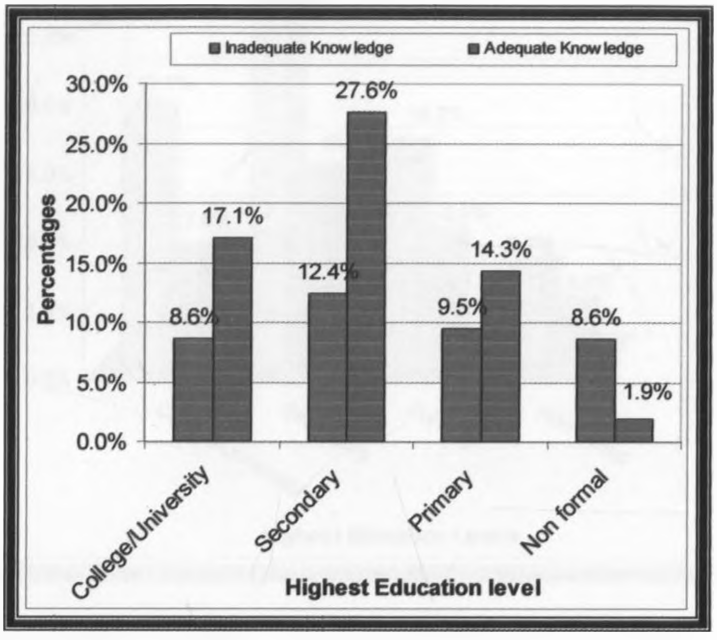
The findings revealed that majority of the respondents with university/college, secondary and primary education had adequate knowledge on the DM disease complications as accounted for by 18(17.1%), 29(27.6%) and 15(14.3%) out of the 105 DM respondents respectively.

The study further revealed that majority of the respondents with non-formal education level did not have adequate knowledge on the DM disease complications as accounted for by 9 (81.8%) out of the 11 DM respondents.

Out of 11 DM respondents with non-formal level of education, only 2(18.2%) had sufficient knowledge on DM complications. This is shown in figure 4.13.

This implies that the higher the education levels of the patients the higher the level of knowledge on diabetes mellitus complications and vice versa.

Figure 4.13: Proportions of patients with adequate/inadequate Knowledge on DM Complications by Education levels

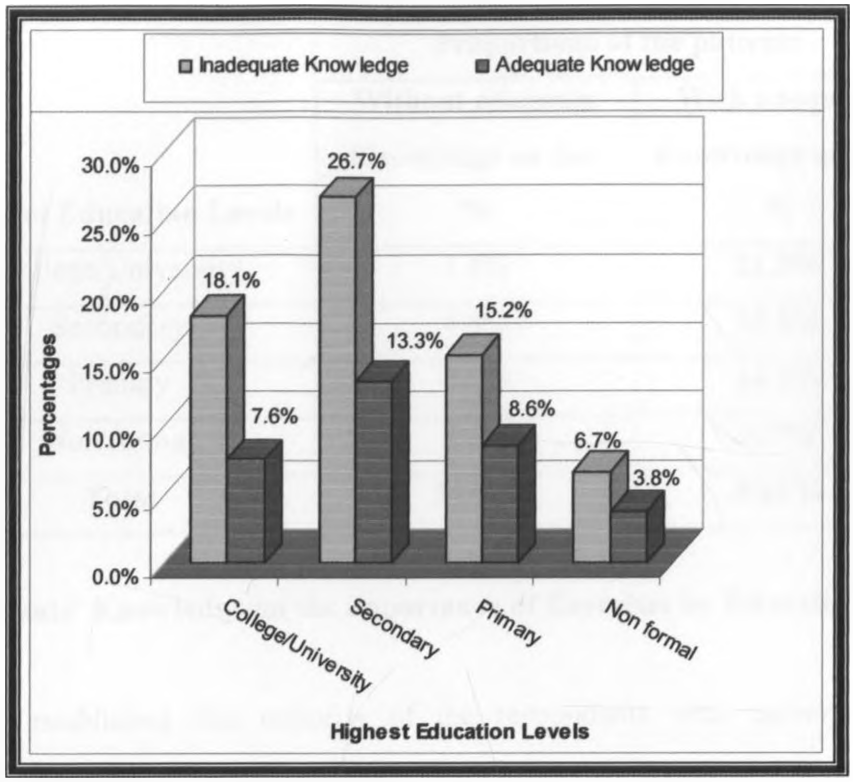


4.2.6.3 Patients' Knowledge on DM Medications by Level of Education

The findings revealed that majority of the respondents in all education categories; that is, university/college, secondary, primary and non-formal education level did not have adequate knowledge on the medications of diabetes mellitus as accounted for by 19(18.1%), 28(26.7%), 16(15.2%) and 7(6.7%) out of the 105 DM respondents respectively. This is shown in figure 4.14.

This implies that there is deficiency of knowledge on diabetes mellitus medications among most diabetic patients irrespective of their educational levels.

Figure 4.14: Proportions of DM patients with Adequate/inadequate Knowledge on Medication by Level of Education



4.2.6.4 Patients' Knowledge on the Dietary Control by Education Levels

The findings revealed that majority of the respondents in all education categories, that is; university/college, secondary, primary and non-formal education levels had adequate knowledge on dietary control in management of diabetes mellitus as accounted for by 23(21.9%), 37(35.2%), 17(16.2%), and 7(6.7%) respectively, out of the 105 DM respondents. This is shown in table 4.6.

This implies that there is a significant level of knowledge on dietary control among most diabetic patients in all educational levels.

Table 4.6: Knowledge on the Dietary Control by Education Levels

Highest Education Levels	Proportions of the patients	
	Without adequate Knowledge on diet %	With adequate Knowledge on diet %
College/University	3.8%	**21.9%**
Secondary	4.8%	**35.2%**
Primary	7.6%	**16.2%**
Non formal	3.8%	**6.7%**
Total	**20.0%**	**80.0%**

4.2.6.5 Patients' Knowledge on the importance of Exercises by Education Levels

The study established that majority of the respondents with university/college, secondary and primary education had adequate knowledge on the importance of exercises as accounted for by 19(18.1%), 31(29.5%) and 18(17.6%) out of the 105 DM respondents respectively.

The study further revealed that majority of the respondents with non-formal education level did not have adequate knowledge on the importance of exercises in DM control as accounted for by 6 (54.5%) out of 11 DM respondents with non-formal education level. This is shown in table 4.7.

This implies that most of the diabetic patients with formal education level have adequate knowledge on the importance of doing exercises.

Table 4.7: Knowledge on the importance of Exercises by education levels

Highest Academic Level	Proportion of DM patients %	
	Without adequate Knowledge on exercises	With adequate knowledge on exercises
College or University	7.6%	18.1%
Secondary	10.5%	29.5%
Primary	6.2%	17.6%
Non formal	5.7%	4.8%
Total	**30.0%**	**70.0%**

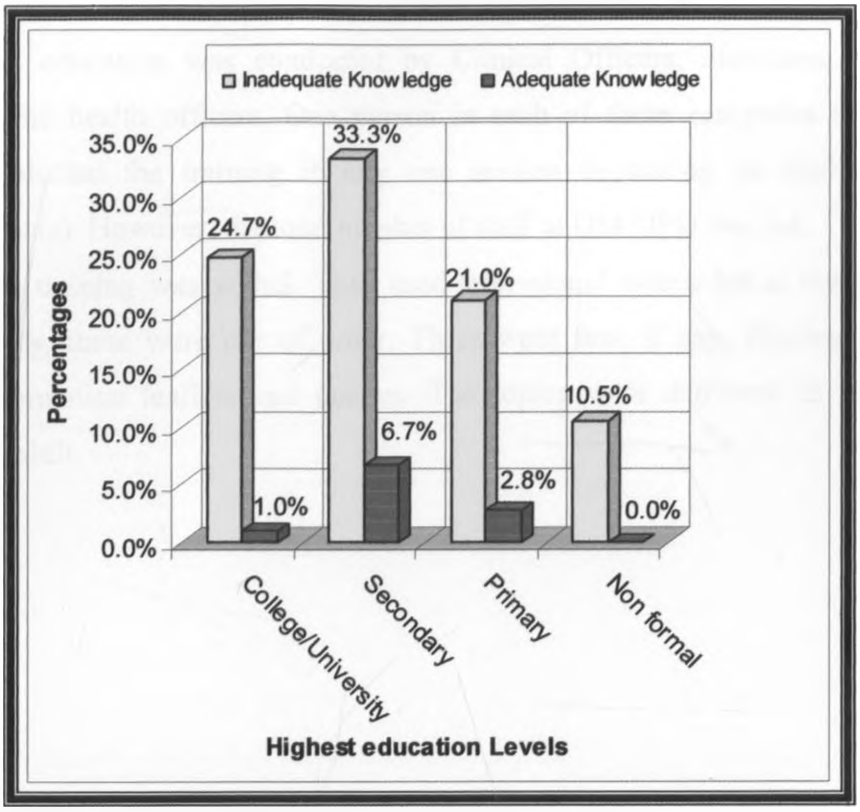
4.2.6.6 Patients' Knowledge on DM Affiliate Organizations by Education Levels.

The study sought to establish the proportion of patients with adequate knowledge on DM Affiliate organizations/ Associations based on their education levels.

The findings revealed that majority of the respondents in all education categories, that is; university/college, secondary, primary and non-formal education level did not have adequate knowledge on the existence and importance of DM Affiliate Organizations/ Associations as accounted for by 26(24.7%), 35(33.3%), 22(21.0%) and 11(10.5%) out of the 105 DM respondents respectively. This is shown in figure 4.14.

This implies that there is inadequacy of knowledge on DM Affiliate Organizations'/ Associations' existence and importance among most diabetic patients in all educational levels.

Figure 4.15: Proportion of the patients with adequate Knowledge on DM Affiliate Organizations by Education Levels



4.3 Existence and Preparedness of Diabetic Patient Training at KNH

Five (5) healthcare providers; three (3) nurses, one registered clinical officer and one nutritionist in the KNH OPD diabetic clinic were interviewed. The following is a summary of the findings:-

- Diabetic patients' education was conducted at KNH diabetic OPD clinic once weekly, that is, every Wednesday morning (8.00a.m-10.00a.m).
- There was a room reserved for training the DM patients. Patients gathered here every Wednesday morning.
- About 40-60 DM patients were trained in one session;
- The nursing officer I in-charge co-ordinated the education/ counselling by writing down the topics to be taught to the DM patients. The topics were written down depending on the relevant trainers in the clinic. For instance, a topic on dietary control to be delivered by a dietician and disease

complications by a nurse or clinical officer. The topics were then taken to the personnel conducting the training that particular day.

- The education was conducted by Clinical Officers, dieticians, nurses and public health officers. One person in each of these categories of personnel conducted the training in any one session depending on his/her assigned topic(s). However, the total number of staff in DM OPD was ten.
- The training was verbal. They used televisions/ videos but at the time of the study, these were out of order. There were few, if any, flipcharts, patients' information leaflets and posters. The topics were delivered in English and Swahili.

CHAPTER FIVE

Discussions

There are limited studies available on the level of patients' knowledge about DM. Therefore, the subsequent discussions have limited comparisons with other similar studies done elsewhere.

105 DM patients were interviewed. Out of these, 53(50.5%) were males and 52(49.5%) females. This compares well with literature which shows that there is no sex predilection in Diabetes Mellitus. [51] This suggests that distribution of the disease between the sexes was almost equal.

Of the 105 patients interviewed, majority 88(83.8%) were aged between 31 to 70 years. Although our study did not find out the different types of diabetes mellitus, probably majority of these patients had type 2. This is because type 2 DM is more common (than type 1) from the ages 30-40 years and accounts for 80-85% of the affected population.[3, 51]

Generally, our findings revealed that majority of the patients interviewed had adequate knowledge on importance of dietary control (80.0%) and doing exercises (70.0%). Usually patients undergo education (on dietary control and doing exercises) and training program which is conducted by physician, nurses and dietician immediately following the diagnosis of diabetes mellitus.[52]This study did not establish where the patients were first diagnosed with DM and what happens immediately after diagnosis. Our study was also localized and did not look at what happens in other hospitals where the patients may have been attending. Probably majority of the respondents had undergone through education following the diagnosis of diabetes mellitus, thus explaining the large proportion of the patients with adequate knowledge. Also the availability of trainers, nurses and dieticians, could have contributed.

Dietary control in diabetes mellitus is important. Patients are supposed to eat low glycaemic index foods that do not turn into sugar quickly. They are advised to eat less (fewer calories) in order to maintain ideal body weight and refrain from taking excessive proteins. Excessive proteins in the body can be converted into sugars and

fats, consequently causing complications. Patients are advised to split menu into about six small meals per day, rather than the traditional three square meals to prevent dangerous post prandial hyperglycaemia. [1,2,3]

No diabetes program is complete without a well- balanced exercise program. Exercise reduces body weight (especially since 80% of diabetes are obese) and also reduces insulin resistance.[2]

Overall, 64(61.0%) of the respondents had sufficient knowledge on the disease complications. Our study mainly focused on the patients' knowledge on the target body organs which can be damaged if blood sugar is not optimally controlled. The target organs that the study looked into were the eyes, kidneys, sex organs, brain and the heart. The three triopathies of DM are neuropathy (nerve damage), retinopathy (eye damage) and nephropathy (kidney damage).[3, 51] Patients were aware of the target organs likely to be damage especially the eyes and kidneys. Probably the availability of trainers (nurses and clinical officers) in the hospital contributed to the awareness of these complications.

Diabetic complications can lead to coma, stroke, heart attack, impotence, loss of vision, renal failure and eventually to death. Short term complications are normally due to imbalance of sugar level in the body as a result of hyperglycaemia due to lack of insulin or hypoglycaemia due to too much insulin or other glucose-lowering medications. Long-term complications are related to small blood vessel diseases.[3, 51]

More than 50.0% of the respondents had adequate knowledge on complications according to age categories except those above 70 years where the proportion was 21.0%. Further statistical analysis showed that there was a significant correlation between the proportion of patients with adequate knowledge on complications and age ($p=0.03$). Those above 70 years probably did not understand very well verbal education which was done in the hospital. Perhaps this group may do well with both non-verbal and verbal methods of teaching. A study done by Wedman and Kahan[39] found that a group of elderly patients (regardless of education levels) with diabetes mellitus counselled by using graphic teaching aids, understood well and complied with health care advice better than did a control group advised by the same counsellor

without the use of graphic teaching aids. From the findings of our study, teaching aids were rarely used in the hospital.

In terms of gender there were more males, 34 (64.2%) than females, 30 (57.7%) with adequate knowledge on complications of DM (p=0.05).However, the difference in proportions between the sexes is not statistically significant to conclude that a particular gender is better placed than the other probably because of equal education opportunities offered in the hospital.

A small proportion of respondents (33.3%) had adequate knowledge on rational use of antidiabetic drugs. In order to evaluate the patients' level of knowledge on the rational use of DM medication, this research looked at the classes of antidiabetic medications used, namely, oral hypoglycaemic agents and insulin, and their dosing schedules in relation to meals. The research also focused on insulin storage and the techniques of its administration. Most patients interviewed knew the times of the day when the drug should be administered but were wrong on dosing schedule in relation to meals. Most insulin users did not know appropriate injecting techniques and storage requirements of the drug. Thus majority of the patients, 70(66.7%) had inadequate knowledge on rational use of DM medications regardless of their sex, age and the education level. There was no relationship of statistical significance between these variables. The likely explanation to this observation was that the patients were not adequately instructed by the healthcare providers on proper usage and storage of the antidiabetic drugs. Proper dosing schedule of antidiabetic medication is important to prevent cases of hypoglycaemia if the drug is administered several hours pre prandial. Hyperglycaemic episodes may also be seen where patients take drugs several hours post prandial. Severe hypoglycaemia or hyperglycaemia is fatal. Insulin needs proper storage (at a temperature of 2-8^{0}C) to prevent denaturation which can render it ineffective.

Patients' education on rational use of oral antidiabetic medicines is important for maintenance of adequate glycaemic control in type 2 diabetes. [51] Furthermore, studies have shown that for optimal management of diabetes mellitus, rational use of medications, dietary control and physical activity are important to the patient.[53]

Only 10.5% of the patients were aware of the existence of organizations dealing with awareness and management of diabetes mellitus. This proportion is small despite the existence of several organizations like KDA, ADA and Diabetes Education & Training Centre in Westlands, Nairobi, Kenya. Reason for lack of awareness about their existence is probably because they do not advertise themselves adequately. A study done in Cameroon on DM patients (n=65) revealed the importance of DM affiliate organizations in creating public awareness, education and counselling patients about warning signs, complications and referral indicators. [54]According to the study, 78.5% of patients had optimal blood sugar control. This study took into account a multiplicity of factors to arrive at a good glycaemic control and the results suggested the relevance of involvement of affiliate organizations.

Most of the patients who had attained university and secondary education had adequate knowledge about DM compared to those with primary and non-formal education. The difference between patients' education levels and the proportions of DM respondents with adequate knowledge on disease was statistically significant ($p=0.0001$). In addition education levels had significant influence on proportions of patient with adequate knowledge on diet ($p=0.01$) and exercise ($p=0.03$).A possible reason for these findings could be that the highly educated patients are better placed in understanding the importance of dietary control and doing exercises in the management of DM. Also probably the highly educated patients went ahead to read more about diabetes mellitus in references like textbooks, magazines or internet because they are assumed to have a better understanding.

On the level of KNH's preparedness in educating diabetic patients, this research showed the exercise was conducted in the hospital's OPD clinic once a week for two hours. The space for training was available and the personnel involved were nurses, clinical officers and dieticians. A group of about 40-60 patients were trained in a single session and only one staff (out of ten) conducted the training. This was according to the arrangements made at the clinic.

A topic of discussion would be identified by the healthcare provider and delivered verbally. There were few flip charts and no posters or brochures. From the above discussions, patients with non-formal level of education could be disadvantaged with verbal education. There was no prior scheduling of topics before the training, which would have allowed the trainers to adequately prepare themselves and hence provide a systematic flow of information making it easier for patients to follow.

Study Limitations

1. A number of patients were reluctant to participate for unexplained reasons.
2. An assumption of 50% which was taken as adequate knowledge may not have been quite correct. Although this assumption was made because there were no such previous studies done over the same subject.
3. The study design was a constraint by itself because this was a cross-sectional study (September 2007 to January 2008) and what was found out may not be occurring throughout the year.
4. How frequent the interviewed patients came for training was not known and this could have affected the results.

CHAPTER SIX

6.0 Conclusions

The number of males and females were almost equal and about 80% of patients were aged between 31 and 70 years. Two-thirds to three-quarters of the DM patients had adequate knowledge on disease complications, dietary requirements and exercises. Two -thirds of the patients did not have adequate knowledge on rational use of medications and about 90% had insufficient knowledge on the existence of DM affiliate organizations.

Patients' training was conducted in the hospital's OPD clinic once a week for two hours. However, patients were mainly taught verbally because there were no posters, patients' information leaflets, audiovisual aids and brochures, an impression that the hospital was not adequately prepared.

6.1 Recommendations

1. There is need for the healthcare providers in the KNH to continuously educate the DM patients on rational use of drugs. This is important for the improvement of diabetes management.
2. DM organizations need to advertise themselves so that patients can join them and benefit in further education and support on the disease management.
3. There is need for the hospital to provide adequate teaching aids (flipcharts, posters and brochures) in DM clinic and then evaluate their impact. The hospital also needs to ensure availability of functional audiovisual teaching aids like videos and televisions. This would enhance a better understanding of education particularly among the elderly.
4. At least two trainers need to conduct the DM training (in a scheduled and systematic way) at any training session for this large group of 40-60 patients. This would ease the workload and create more individualized patient attention. Systematic flow of information would make it easier for patients to follow thus improving the training.

5. More research needs to be carried out involving a longer period of time and larger samples. Large samples over longer periods will show what happens over a long period of time.

REFERENCES

(1) Michael, R. *Diabetes Mellitus: In Adult Emergency Medicine.* **2003,** 2, 462-466.

(2) Albert, K.G.M.M.; Defronzo, R.A; Keen, H.; Zimmet, P. *International Textbook of Diabetes Mellitus.* John Wiley & Sons Ltd Chichester. **1992**: 343-350.

(3) MaryAnne Koda-Kimble; Brian, S.K.; Lloyd. *Applied Therapeutics for Clinical Pharmacists.* **1989**, 4, 49-59.

(4) Setter, S.M.; White, J.R.; Campbell, R.K. Diabetes. In: Herfindal, E.T. and Gourley, D.R., editors. *Text book of therapeutics drug and disease management.*Lippincots Williams & Wilkins, Baltimore.**1995,** 7, 377- 406.

(5) Glasgow, R.E.; Anderson, R.M. In diabetes care, 7. Moving from compliance to adherence is not enough: something entirely different is needed. Diabetes care.**1999**, 23, 2090-2097.

(6) Mayer, B.; Davidson, M. *Diabetes Mellitus: Diagnosis and Treatment.* New York Churchill Livingstone.**1991,** 3, 126-134.

(7) Abdullah, M.S. *Diabetic Nephropathy.***1996,** 29-32.

(8) Davidson, M.B. *Diabetes Mellitus: Diagnosis And Treatment.* **1988,** 2, 51-60.

(9) A Handbook of Non Prescription Drugs by American Pharmaceutical Association (APHA).**2000,**8, 294-295.

(10) Notes for diabetics. Diets and Instructions given to patients attending the diabetic clinic. University College Hospital.**1999,** 8, 25-31.

(11) Bacchus, H. *Rational management of Diabetes Mellitus*. Baltimore: University Park. **1997,** 132-141.

(12) Tatersall, R.B.; Gale, E.A.M. *Diabetes: Clinical Management.* Edinburgh Churchill. **2000,** 372-380.

(13) King, H.; Aubert, R.E.; Herman, W.H.*Global burden of diabetes, 1995-2025: Prevalence, numerical estimates and projections*. Diabetes care.**1998**, 21,1414-1431.

(14) Colwell, A.R. *Understanding You and Diabetes*. **2001**, 142-153.

(15) Steil, C.F.; Dipiro, J.T.; Talbert, R.L.; Yee, G.C. Diabetes mellitus Pharmacotherapy: A pathophysiological approach. Appleton &Lange, Connecticut. **1999,** 4, 12-12.

(16) Ndemo, A.F. Lecture notes *on "Drugs Do Not Think!"*. **January 19, 2006.**

(17) Coons, S.J. *Health outcomes and quality of life Principles.* In Dipiro, J.T.; Talbert, R.L.; Yee, G.C. , editors. *Pharmacotherapy: A pathophysiological approach.* Appleton & Lange, Connecticut. **1999,** 4, 12-20.

(18) Etzwiler, D.D. *Chronic care: a need in search of a system.* Diabetes Educ. **1997,** 23, 569- 573.

(19) Diabetes Mellitus. Basic Education for health Workers/Society for endocrinology, metabolism and diabetes of Southern Africa (SEMDSA), Durban. **1993,** 30-38.

(20) Popovich, N.G. Ambulatory patient care in Gennaro, A.R., editor. Remington: The science and practice of pharmacy. Mack publishing company, Pennsylvania. **1995,** 19, 2,1695- 1719.

(21) USP medication counselling behaviour guideline.USP DI update volumes I and II. Rockville, the United States Pharmacopoeia Convention Inc.**1997**, 664-675, 1739-1748.

(22) Kioy, P.G.*Electrophysiological Study of Diabetic Autonomic and Sensorimotor Polyneuropathy.* M.Med Thesis**. 1984**,1-2.

(23) Heidi, M.;Harby, A.; Berger, B.A.*Pharmacists predisposition to communicate-* Desire to counsel and job satisfaction.Am. J. Pharm. Educ. 1992,56, 252-253.

(24) UK Prospective Diabetes Study (UKPDS) Group.Intensive blood- glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type II diabetes (UKPDS33).Lancet, **1998**, 352, 837- 853.

(25) Testa, M.A.; Simonson, D.C. Health economic benefits and quality of life during improved glycemic control in patients with type II diabetes mellitus. JAMA, **1998**, 280, 1490- 1496.

(26) Sczupak, C.A.; Conrad, W.A. Relationship between patient-oriented Pharmaceutical Services and Therapeutic outcomes of ambulatory patients with diabetes mellitus. Am. J. Hosp. Pharm.**2003,** 34,1238-1242.

(27) Cranor, C.W.; Bunting, B.A.; Christensen, D.B.The Asheville Project: Long-term clinical and economic outcomes of a community pharmacy diabetes care program. J. Am. Pharm. Assoc. (Wash). **2003**, 43 (2),173-184.

(28) Powell, M.F.; Burkhart, V.D.; Lamy, P.P. *Diabetic patient compliance as a function of patient counselling*. Drug. Intell. Clin. Pharm. **1979**, 13 (9), 506-511.

(29) American Diabetes Association. Diabetes facts and figures. Available at: [diabetes.org/diabetes-statistics ...] . **(Accessed on 17th April 2007).**

(30) Powers, A.C. Diabetes mellitus. In: Braunwald, Fauci, Kasby et al 'editors'. Harrison's Principles of Internal Medicine. United States of America: McGraw-Hill. **2001**, 15,2109- 2137.

(31) Kahn, S.E.; Porte, D. Jr. The Pathophysiology of type II (non- insulin dependent) diabetes mellitus: Implications for treatment. In Porte, D. Jr.; Sherwin, R.S., eds.Ellenberg. Stamford, CT, Appleton & Lange. **1997**, 5, 487- 512.

(32) Kenya Diabetic Association. Diabetes and You-Nairobi: Diabetics Association of Kenya.**1993**, 1-12.

(33) Swai, A.B.; Mclarty, D.G. *The Management of Diabetes Mellitus.* Daresalaam: WHO Collaborating Centre for Diabetes Mellitus.**1990**, 122-132.

(34) Allen, F.M. *Blueberry Leaf Extract: Physiologic and Clinical Properties in glycaemic and insulin responses.*Eur. J. Clin. Nutr. **1994,** 48,10,749-752.

(35) A Handbook of Non Prescription Drugs by American Pharmaceutical Association (APHA).**2000**,8, 295-295.

(36) Clifford, R.M.; Davis, W.A.; Batty, K.T.; Davis, T.M. Effect of a pharmaceutical care program on vascular risk factors in type II diabetes: The Fremantle Diabetes Study. Diabetes Care. **2005**, 28, 4, 771-776.

(37) Gerber, R.A.; Liu, G.; McCombs, J.S. Impact of pharmacist consultations provided to patients with diabetes on healthcare costs in a health maintenance organization. Am. J. Manag. Care.**1998**,4, 7, 991-1000.

(38) Beardsley, R.S. Review of literature: oral patient counselling by pharmacists. Proceedings of the National Symposium on oral counselling by pharmacists about prescription medicines. Lansdowne, Virginia. **1997 Sep 19-21**.

(39) Wedman, B.; Kahan, R.S.Diabetes graphic aids used in counselling improve patient compliance.J. Am. Diet. Assoc.**1987**,87, 12,1672-1674.

(40) Odegard, P.S.; Goo, A.; Hummel, J.; Williams, K.L.; Gray, S.L. Intervention. Caring for poorly controlled diabetes mellitus: a randomized study by pharmacists. Ann. Pharmacother. **2005**, 39,3,433-440.

(41) Oki, J.C.; Isley, W.L. Diabetes mellitus. In: Dipiro, J.T.; Talbert, R.L.; Yee, G.C. editors. Pharmacotherapy: a pathophysiological approach. Appleton & Lange, Connecticut. **2002**,5,1335-1358.

(42) American Diabetes Association: Diabetes mellitus and exercise. Diabetes Care (Indian edition).**1998**, 1, 65-69.

(43) A Handbook of Non Prescription Drugs by American Pharmaceutical Association (APHA).**2000**, 8, 285-285.

(44) Campbell, S. Diabetes: recognizing symptoms, preventing complications. Am Pharm. **1992**, NS32, 414-418.

(45) Musey, V.C.; Lee, J.K.; Crawford, R. Diabetes in urban African- Americans. Cessation of insulin therapy is the major precipitation cause of diabetic ketoacidosis. Diabetes Care. **1995**, 18, 483-489.

(46) Bennet, P.N.; Brown, M.J. Clinical Pharmacology. **2003,** 9, 688-693.

(47) Diabetic control and complications (DCCT) trial research group. Effect of intensive therapy on the development and progression of diabetic nephropathy in the Diabetic Control and Complications Trial I. Kidney Int. **1995**, 47, 1703-1720.

(48) Dooley, M.; Lyall, H.; Galbriath. SHPA standards of practice for clinical pharmacy.In:SHPA practice standards and definitions. **1996**,2-11.

(49) Faris, I.M. *The management of Diabetic Foot.* Edinburgh, Churchill Livingstone. **1996,** 98-105.

(50) Kiel, P.J.; McCord, A.D. Pharmacist impact on Clinical Outcomes in a Diabetes Disease Management Program via Collaborative Practice. Ann Pharmacother. **2005**, 39, 1828-1832.

(51) Walker, R.; Whittlesea, C. *Clinical Pharmacy and Therapeutics*. **2007,** 4,629-650.

(52) Stanley, G.K. *The Therapeutic Management of Disease States*. THE ENDOCRINE SYSTEM. **1984.** 4, 28-29.

(53) Woodley, M.; Whelan, A. The Washington manual of Medical Therapeutics.**1992,** 27, 378-379.

(54) Awah, P.; Kengne, A.P.; Sobingwi, E.; Fezue, L.; Unwin, N.; Mbanya, J-C.Journal of Diabetes International Africa Edition. **May 2007**, 15, 1.7-11.

ANNEXES

Annex I: Acceptance Letter of Study from the KNH-ERC

KENYATTA NATIONAL HOSPITAL
Hospital Rd. along, Ngong Rd.
P.O. Box 20723, Nairobi.
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP", Nairobi.
Email: KNHplan@Ken.Healthnet.org

Ref: KNH-ERC/ 01/ 4742

19th September 2007

Dr. David G. Nyamu
Dept. of Pharmaceutics & Pharmacy Practice
School of Pharmacy
University of Nairobi

Dear Dr. Nyamu

RESEARCH PROPOSAL: "KNOWLEDGE ON DIABETES AMONG DIABETIC PATIENTS ATTENDING KENYATTA N. HOSPITAL OUT-PATIENT CLINIC" (P189/8/2007)

This is to inform you that the Kenyatta National Hospital Ethics and Research Committee has reviewed and **approved** your revised research proposal for the period 19th September 2007 – 18th September 2008.

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given. Clearance for export of biological specimen must also be obtained from KNH-ERC for each batch.

On behalf of the Committee, I wish you fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of database that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely

DR. L. MUCHIRI
AG. SECRETARY, KNH-ERC

c.c. Prof. K.M.Bhatt, Chairperson, KNH-ERC
The Deputy Director CS, KNH
The Dean, School of Pharmacy, UON
The Chairman, Dept, of Pharmaceutics & Pharmacy Practice, UON
Supervisors: Dr. Rashid Juma, UON
Prof. Gichuru Muriuki, Dept. of Pharmacology & Pharmacognosy,UON

Annex II: Consent and Consent Information

Dear Respondent,

My name is Dr. David Nyamu, a Pharmacist by profession. I am currently pursuing Masters of Pharmacy Degree in Clinical pharmacy [M.Pharm (ClinPharm)] programme at the School of Pharmacy, university of Nairobi, Kenya.

The Masters programme involves course work, practical work and clinical research in one's area of interest.

Research

My area of interest is diabetes mellitus and I am carrying out a study among diabetics like you attending outpatient clinics at Kenyatta National Hospital (KNH) to determine how much you know about the disease and this will eventually improve the level of the management of your disease to you and other similar people in future.

This is important because it is only from your understanding of this disease which will determine the proper management both by you and your doctor.

My objectives are:-

1. How many of you know about the disease?
2. How many of you do not know about the disease?
3. To find out if Kenyatta National Hospital is capable of conducting education on the disease.
4. The results obtained will help us improve the services or put the services in place for the betterment of all.

In this study, I intend:-

1. To determine the level of your knowledge on your disease at and;
2. To determine the level of KNH preparedness in the provision of diabetic education to you who attend outpatient DM clinic with a view to making recommendations for improving the management of the disease.

Methodology

I have a set of questions to ask you. These will be asked to patients above 18 years which I believe you belong.

Sampling Method

I intend to see and interview about 96 of you. Each of you will be given an equal chance of being chosen.

The Interview

A simple questionnaire will be administered to you as earlier mentioned. All questions will be read and interpreted to you in the simplest and comprehensible manner that you can understand and answer. You will be expected to answer the questions freely to the best of your knowledge. The answers you give will not, in any way, jeopardize your treatment and they will be kept under strict confidence.

Your responses/ what is gathered will be written down for further analysis, discussions, conclusions and recommendations, where possible.

Confidentiality

All the information you give will be treated in strict confident without sharing with the third party unless your consent is sought first. As you well know these are the ethics normally held my any healthcare provider.

The filled questionnaires will be locked securely where only I, the researcher, will have an access.

Benefits

There will be no immediate direct benefits to you. However, after completion of the study you will be the beneficiary as far as diabetic care delivery in the hospital is concerned. The community at large will also benefit from the study.

The results from the study will be used to make recommendations aimed at improving diabetes service delivery at KNH.

The recommendations will be used by KNH and her staff to improve diabetic patients care. It is hoped that this study will provide useful information that will form a basis for future studies and also improvements of your quality of life.

Risks

The study will be purely by interviewing you. It will not involve taking any of your specimens; blood, and urine for testing. This is a minimal or no risk study.

Participation

Your participation in the research is purely voluntary and one CAN withdraw anytime at his or her own will and that the patient will continue to have medical care even if he/she withdraws from the study. You are encouraged to ask any question regarding the study. You are also encouraged to ask any question for clarity, in case the questions are unclear to you or unsatisfactory.

DECLARATION BY THE RESEARCHER

I, **DR. DAVID GITONGA NYAMU, NATIONAL ID NO., 11608865 OF P.O. BOX 1003-00200 CITY SQUARE NAIROBI, TELEPHONE NUMBER 0722 40 36 71,** have clearly explained the purpose and the benefits of the interview to the participant.

I have also explained that this is purely voluntary and the research will not jeopardize the patient treatment in any way.

CONTACT NAME: DR. DAVID GITONGA NYAMU.

NATIONAL ID NO.:11608865

ADDRESS: DEPARTMENT OF PHARMACEUTICS & PHARMACY PRACTICE
SCHOOL OF PHARMACY, UNIVERSITY OF NAIROBI
P.O. BOX 19676, NAIROBI.

TELEPHONE NUMBER: 0722- 40 36 71 or 0721-51 44 96

SIGNATURE---------- DATE----------

DECLARATION

I, ----------Id/Pp No., ----------

do hereby voluntarily agree to take part in this research study of **DIABETIC PATIENT KNOWLEDGE ON THE DISEASE AS SEEN AT KNH.**

The nature and the purpose of the study have been explained to me. Additionally I am clearly aware of the procedures required. I also clearly understand the benefits involved and that my participation is purely voluntary.

I also understand that there are no risks involved because the study is purely interview.

I also understand that **my failure to participate will not jeopardize my treatment.**

DR. DAVID GITONGA NYAMU has EXPLAINED all the above information to me.

I have been adequately briefed on objectives and methodology of the research and I hereby agree to participate in the interview.

Name.....

Profession.....

Signature..... Date----------

Witnessed By: ---------- Date----------

Annex III: Questionnaire for the Patient

A) THE PARTICIPANT

1. a) PARTICIPANT DEMOGRAPHIC DATA

Participant initials…….. Serial study number----------

Age:

Sex:

Occupation:

Residence:

Address----------Telephone (if any) ----------

Next of kin (optional) ----------

INSTRUCTIONS: Kindly mark the number corresponding to your answer inside the box provided.

b.) Highest academic level:

1. College /University
2. Secondary
3. Primary
4. Non –formal

B.) THE DISEASE

2. Had you ever heard of diabetes before you were diagnosed with it?

1. Yes
2. No

3. Do you understand what diabetes is?

1. Yes
2. No

If yes, briefly describe what you think it is?

_____

_____

_____

What do you think causes diabetes?

_____

_____

_____

4. Kindly what were the chief complaints during your doctor's first visit? (List)

_____

_____

_____

_____

5. For how long did you experience these complaints before seeking for medical advice?

1. >12months
2. 4-12months
3. 1 – 3 months
4. <1 month

6. How frequently do you go for clinic appointments?

1. All the time
2. More than half the time
3. Less than half the time

If less than half the time, what could be the reason(s)?

1. Lack of money
2. Am usually not sick
3. Commitments
4. Others, specify----------

7. Do you discuss your disease condition with your doctor?

1. Yes
2. No

If yes, kindly state the issues he/she discusses with you.

_____

_____

_____

If no, kindly state why you don't discuss with him/her.

_____

_____

8. Do you routinely undergo urine tests and / or blood sugar level tests?

1. Yes
2. No

If yes, do you understand what the results mean?

1. Yes
2. No

If you understand, kindly explain what they mean.

_____

_____

_____

If no, kindly explain what you don't understand about their purpose.

_____

_____

_____

B.COMPLICATIONS

9. Do you undergo eye (ophthalmologic) check ups [fundoscopy] annually or occasionally?

1. Yes
2. No

If no, kindly give reasons why you don't?

_____

_____

_____

_____

10. Do you know of any complications that may arise if you don't control your condition?

1. Yes
2. No

If yes, please list

a) _____

b) _____

c) _____

d) _____

e) _____

11. Do you know of any organ(s) in your body that can be damaged if you do not properly adhere to your treatment guidelines/control your conditions?

1. Yes
2. No

If yes, which ones? _____

_____

_____

12. Do you carry sweets or glucose with you always?

1. Yes
2. No

If yes, kindly give reasons _____

_____

_____

_____

If no, kindly give reasons.

_____

_____

_____

C.)THE MEDICATION.

13. What drugs do you use?

1. Oral Hypoglycaemic Agents
2. Insulin
3. Herbal
4. None
5. Don't know

14. Who administers these drugs?

1. Self
2. Healthcare Provider (doctor, nurse etc)
3. Relative / friend

If self, briefly explain timings and dosage.

_____

_____

_____

_____

15. Is the treatment you are getting now making you feel better?

1. Yes
2. No

If yes, please state how _____

_____

_____

_____

If no, please explain how you feel.

_____

_____

_____

16. Are there any occasions you miss medication?

1. Yes
2. No

If yes, what could be the reasons? _____

_____

_____

17. How do you get your drugs?

1. Purchase from a pharmacy
2. Given freely at the hospital
3. Donated by somebody/charitable organization
4. Others (please specify) _____

18. What could be your average monthly cost of managing your conditions?

Kshs. _____

How do you finance this expenditure?

1. Personal income
2. Supplementation by relatives
3. Others (please specify) _____

_____

_____

19. If using insulin for your condition, were you explained the techniques of injecting it?

1. Yes
2. No

If yes, briefly explain this technique

_____

_____

_____

_____

Who explained the technique to you?

1. A doctor
2. A pharmacist
3. A nurse
4. A relative/friend.

20. If using insulin, briefly describe how you store.

_____

_____

D.)THE DIET

21. What foods do you regularly take? (List)

_____

_____

_____

_____

22. Which foods do you avoid? (List)

_____

_____

_____

_____

Why do you think it is important to avoid these foods?

_____

_____

_____

_____

23. How do you take care of your dietary needs when away from home e.g. at work or in a function?

_____

_____

_____

_____

E.)THE EXERCISE.

24. Do you do regular exercises?

1. Yes ☐

2. No

If yes, which one(s)?

_____

_____

If you do exercises, briefly explain why

_____

_____

F.)AFFILIATE ORGANIZATIONS/ASSOCIATIONS [AWARENESS]

25. Ever heard of Kenyan Diabetic Association (KDA), American Diabetes association (ADA)?

1. Yes
2. No

26. If yes to question 25 above, are you a registered member?

1. Yes
2. No

If yes, kindly give reasons for your answer.

_____

_____

_____

_____

27. Do you usually carry a 'Diabetic Alert' card?

1. Yes
2. No

If yes, please state why _____

_____

If no, please state why _____

_____

Thank you for your participation and support in this study.

Annex IV: Questionnaire for the Diabetics' Healthcare Provider in the KNH DM OPD Clinic

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/counselling is done, kindly describe how it is conducted here in KNH. Is it to individual patient at a time or groups and how?

_____

_____

_____

_____

3. Who gives the education/counselling?

_____

4. Who co-ordinates the education/counselling?

_____

_____

_____

Thank you for your participation and support in this study.