KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY,

KUMASI, GHANA

The Management of Type 2 Diabetes Mellitus: Compliance, Barriers and Effect on Glycaemic Control of Adult Outpatients in Sunyani Municipality, Brong Ahafo Region - Ghana

By

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MASTER OF PHILOSOPHY IN HUMAN NUTRITION AND DIETETICS

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DECLARATION

I hereby declare that this submission is my own work towards the MPhil and that, to the best of my knowledge, it contains no material previously published by another person nor material which has been accepted for the award of any other degree of the University, except where due acknowledgement has been made in text.

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ABSTRACT

Type 2 diabetes mellitus (T2DM) is a metabolic disorder characterized by persistent high levels of blood glucose with serious micro- and macro-vascular complications. Effective management of T2DM including lifestyle changes can minimize the levels of diabetes related diseases and deaths. A person affected by T2DM should learn to accept the new lifestyle modifications because poor glycaemic control puts type 2 diabetics at higher risks of developing life threatening complications. This makes adherence to management therapies paramount in achieving good glycaemic control. The study aimed to assess compliance, barriers to diabetes self-care management practices and effect on glycaemic levels of adult type 2 diabetes outpatients receiving care at four selected hospitals in Sunyani, Ghana. A cross - sectional study design was used and 300 known type 2 diabetics aged 30 years and above attending diabetes clinic in four selected health facilities in Sunyani were recruited using simple random sampling technique. Structured questionnaires comprising both open and close ended questions were used to collect demographic data and data on compliance and barriers. Fasting blood glucose levels were measured with a glucose metre. The study results revealed that 11.7%, 24.3% and 20.7% of the study participants had fasting blood glucose levels ranging between 4.0 - 6.0mmol/L, 6.1 - 7.9mmol/L and 8.0 - 9.9mmol/L respectively while the majority (43.3%) of the participants had fasting blood glucose levels of 10mmo/L or above. Greater proportions (78%) of the participants have had diabetes self-care management education with only 22% reporting no education. The study showed self-reported compliance of 79%, 18.3% and 6% for medication, diet and exercise respectively. Factors such as forgetfulness, financial constraints, bitterness of drugs, pains from injections; restrictive diets, small portion sizes and lack of support; fatigue, pains in limbs and laziness were identified to be barriers to medication, diet and exercise regimen adherence respectively. Although compliance to

medication was found to be higher than diet and physical activity recommendations, there were no significant associations between medication ($p = 0.789$), dietary regimen ($p = 0.341$), physical activity ($p = 0.547$) and fasting blood glucose levels.

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DEDICATION

I dedicate this work to my dear wife, Mrs. Leticia Ansong, my three beautiful daughters namely: Nana Ama Abrafi Ansong, Ama Owusuaa Ansong and Yaa Dede Boadu Ansong for their sacrifices which have brought me this far.

TABLE OF CONTENT

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS AND ACRONYMS

ADA - American Diabetes Association

ADL - Activities of Daily Living

BMI - Body Mass Index

BP - Blood Pressure

CHRPE - Committee on Human Research, Publications and Ethics

DCCT- Diabetes Control and Complications Trial

DKA - Diabetic Ketoacidosis

DPP-4 - Dipeptidyl Peptidase-4-Inhibitors

DSME - Diabetes Self- Management Education

FBG - Fasting Blood Glucose

FPG - Fasting Plasma Glucose

GDM - Gestational Diabetes Mellitus

GLP-1 - Glucagon- Like Peptide- 1 Agonist

GSTG - Ghana Standard Treatment Guidelines

HbA1C - Glycated Haemoglobin

HHS - Hyperosmolar Hyperglycaemic State

IBM SPSS - International Business Machines Corporation Statistical Package for Social Science

IDD- Insulin Dependent Diabetes

IDF - International Diabetes Federation

IOM - Institute of Medicine

KNUST - Kwame Nkrumah University of Science and Technology

KATH - Komfo Anokye Teaching Hospital

MODY- Maturity Onset Diabetes of the Young

NGSP- National Glycohaemoglobin Standardization Program

NHIS - National Health Insurance Scheme

NICE - National Institute for Health and Care Excellence

NIDD - Non-Insulin Dependent Diabetes

OHA - Oral Hypoglycaemic Agents

OGLA's- Oral Glucose Lowering Agents

OGTT- Oral Glucose Tolerance Test

PA - Physical Activity

SMS - School of Medical Sciences

2HPG- 2-Hour Plasma Glucose

T1DM- Type 1 Diabetes Mellitus

T2DM - Type 2 Diabetes Mellitus

TZD's- Thiazolidinedione

WHO – World Health Organization

CHAPTER ONE

1.0 INTRODUCTION

1.1 BACKGROUND

Type 2 diabetes mellitus (formerly known as non-insulin dependent diabetes [NIDD] or adult onset diabetes) is characterized by chronic hyperglycaemia resulting from limited pancreatic insulin release, insulin resistance in the peripheral tissues or inability to inhibit glucagon function. This phenomenon disrupts macronutrients metabolism leading to increased hepatic output and elevated blood glucose levels (Spellman, 2010).

The symptoms that may classically be presented with hyperglycaemia are polyuria, polydipsia, polyphagia, weight loss and blurred vision. Symptoms of type 2 diabetes are most instances mild, or may not be present. The hyperglycaemia adequate to trigger any pathophysiological changes may consequently be existing for a while before diagnosis is established. As a result, patients with T2DM are often not aware of their status. Patients therefore do not seek medical attention early and may present features of diabetic complications when medical care is finally sought. The consequences of these diabetes complications in the long term may result in damage, dysfunction or organ failure as the disease progresses. The obvious medical manifestation presented due to these complications are blindness from retinopathy, kidney failure from nephropathy, foot ulcers, loss of limbs, charcot joints and with risk of sexual dysfunction from neuropathy. Type 2 diabetes patients are also highly susceptible to cardiovascular and other related events such as peripheral and cerebro-vascular attacks (WHO, 1999; ADA, 2014b).

Globally, type 2 diabetes mellitus is more prevalent and constitutes about 90 to 95% of persons living with diabetes (ADA, 2010). Although, the specific causes of this type of diabetes are unknown, the destruction of the beta-cells caused by autoimmunity does not

happen. The most commonly attributable risk factors associated with T2DM include obesity, genetic and environmental influences, ethnic background, sedentary lifestyle, age, female with history of gestational diabetes mellitus (GDM) and patients with high blood pressure or dyslipidaemia, and its occurrence differs from one ethnic/racial sub-group to the other (IDF, 2006; Tfayli and Arslanian, 2009).

The management of diabetes seems straight forward sometimes but the seriousness of the complication burdens and their outcomes may present a serious problem for diabetics, families, health care systems, and the government as a whole (IDF, 2006). According to Unger (2011), all type 2 diabetics are required to strictly follow their therapies to achieve adequate glycaemic targets. Despite the available therapies for type 2 diabetes management, compliance still continues to be poor (Shama and Barakat, 2010).

It is therefore essential to assess the compliance and factors influencing diabetes care management among adult type 2 diabetics to minimize or totally avoid complications.

1.2 PROBLEM STATEMENT

According to the World Health Organization (2016), diabetes remains one of the largest health emergencies in the world currently, and about 422 million adults are estimated to have diabetes mellitus. In the African Region alone, approximately 6% (25million) of this cohort resides in this continent. Globally, hyperglycaemia is ranked the third highest risk factor for premature death after cardiac problems and tobacco use, and the 8th leading cause of death among both genders. In 2012 alone, mortalities directly attributable to diabetes stood at 1.5million (IDF, 2015; WHO, 2016).

In Ghana, the impact of diabetes is rising steadily, and as of the year 2015, 266, 200 adults (20-79yrs) were reported to be living with diabetes and about 4,790 deaths were attributable to diabetes of which Sunyani is of no exception (WHO, 2016). The most alarming concern is the middle-aged adults who developed diabetes and die prematurely than peers in other parts of the developed world due to non-compliance and poor management (WHO, 2008; Oputa and Chinenye, 2012). This is of a significant problem for the health system of the Brong Ahafo Region particularly Sunyani, and a barrier to the sustainable economic development of the region and the country at large. It is therefore worth studying, to ascertain compliance and obstacles to type 2 diabetes management and its impact on glycaemic control.

1.3 MAIN OBJECTIVE

The main objective was to assess compliance and barriers to effective diabetes self-care management practices and effect on glycaemic control of adult type 2 diabetes out-patients in Sunyani Municipality, Brong Ahafo Region.

1.3.1 Specific Objectives

1. To assess compliance to diabetes self-care management practices.
2. To identify barriers to compliance of diabetes self-care practices.
3. To determine the effect of compliance on glycaemic levels of participants.

1.4 JUSTIFICATION

The steady rise in diabetes cases in Ghana imply expected proportional rise in complications due to poor management (WHO, 2014). Early detection of obstacles to T2DM management

compliance would help curb the burden on health care systems, loss of manpower and continuous support that would be needed to overcome complications associated with non-compliance to diabetes management protocols.

Studies have shown that compliance can improve glycaemic levels, reduce healthcare cost and the risk of diabetes-related complications caused by micro-vascular damage as well as other patients-related outcomes (Lawrence *et al*., 2006; Lee *et al*., 2006; NICE, 2009; ADA, 2013).

This study sought to ascertain compliance and barriers of complying with diabetes management practices and impact on glycaemia. The findings of the study will help tailor specific strategies in addressing this problem among people living with T2DM. More so, the findings of the study will help contribute in modifying existing management and educational materials to help patients achieve optimal glycaemic levels to delay or prevent long-term diabetes complications among patients in the various health facilities in Ghana.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 DEFINITION AND DESCRIPTION OF DIABETES MELLITUS

The World Health Organization (1999) defines diabetes mellitus as a ‘‘metabolic disorder of multiple aetiology characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both’’. Insulin is a hormone secreted by the pancreas and required to carry glucose from the bloodstream into the cells of the body where it is utilized as energy. The disruptions in secretion of insulin and/or action results in elevated levels of blood glucose (hyperglycaemia). The elevated levels of glucose over time progressively damages and alters the functions of different organs in the body resulting in the development of life-threatening complications.

Symptoms classically marked with hyperglycaemia may include polydipsia (excessive thirst), polyuria (frequent urination), blurring of vision, weight loss and sometimes polyphagia (excessive hunger). Other diabetes emergencies such as diabetic ketoacidosis (DKA) together with hyperosmolar hyperglycaemic state (HHS) may develop in most severe states and result in stupor, coma and death if medical attention is not sought early. In most cases, the above mentioned symptoms may not be present or severe enough and as a result, hyperglycaemia adequate to trigger any pathophysiological changes may be in existence before the disease is diagnosed.

The chronic hyperglycaemia in diabetes mellitus may progressively develop into some specific complications in the long-term such as retinopathy (with potential blindness), nephropathy (that leads to renal failure), and/or neuropathy (with risk of foot ulcers, amputation), charcot joints and autonomic dysfunctional features, for instance sexual

dysfunction. Diabetics are highly susceptible to cardiovascular events, high blood pressure (hypertension) as well as lipoprotein metabolism abnormalities (WHO, 1999).

A high proportion of diabetes cases come under two broad aetiopathogenetic categories. In the first category, there is a destruction of the beta-cell of the pancreas which is autoimmune mediated leading to complete insulin deficiency. This category corresponds to type 1 diabetes mellitus (TIDM). The other category which is more prevalent and known as type 2 diabetes mellitus (T2DM) is predominantly caused by either resistance in insulin with relative insulin deficiency or disruption in insulin release with or without insulin resistance (WHO, 1999; ADA, 2010).

2.2 TYPES OF DIABETES MELLITUS

Diabetes mellitus is designated aetiologically into defects, disorder or processes which usually lead to chronic hyperglycaemia (WHO, 1999). According to the American Diabetes Association [ADA] (2014a), diabetes mellitus is clinically classified into four (4) main types:

- Type 1 diabetes mellitus (T1DM)
- Type 2 diabetes mellitus (T2DM)
- Gestational diabetes mellitus (GDM)
- Other specific types of diabetes

2.2.1 Type 1 Diabetes Mellitus (TIDM)

Type 1 diabetes mellitus (formerly known as insulin dependent diabetes (IDD) or juvenile-onset diabetes) is caused by an autoimmune destruction of the beta-cells in the pancreas, resulting in absolute insulin deficiency. This type of diabetes mellitus accounts for about 5-10% of the population living with diabetes. The disease tends to affect all manner of people irrespective of age, but onset normally happens in children or young adults. This type of

diabetes is one of the commonest endocrine and metabolic diseases in childhood (ADA, 2010; IDF, 2015).

Type 1 diabetes in most cases develop suddenly and is associated with symptoms such as polydipsia and dryness of mouth, polyuria, energy deficiency, extreme fatigue, polyphagia, drastic weight loss and blurring of vision. This form of diabetes is diagnosed by hyperglycaemia in the presence of the symptoms listed above. These symptoms may also be mistaken for other disease conditions in other parts of the world and it is important to measure blood glucose when one or more of the above symptoms are present.

Patients with this type of diabetes need insulin to survive on daily basis but, access to this medicine, supply and self-management education are limited in most countries. This can result in serious health complications and diabetes-related mortalities in children. With daily insulin administration, regular blood glucose monitoring and maintenance of an appropriate diet and lifestyle, persons with this condition can lead a healthy normal life (IDF, 2015).

The incidence of T1DM in children worldwide is on the rise and the actual causes are yet to be defined. This may probably be attributed to changes in the risk factors of the environment, and/or viral infections (ADA, 2014a; IDF, 2015).

2.2.2 Type 2 Diabetes Mellitus (T2DM)

Type 2 diabetes mellitus, previously called non-insulin dependent diabetes (NIDD) or adult onset diabetes is predominantly caused by insulin resistance with relative deficit in insulin or defect in insulin secretion with insulin insensitivity. This type is predominant and forms about 90-95% of people living with diabetes (WHO, 1999; ADA, 2010).

The symptoms of T2DM include polyuria, polydipsia, loss of weight and blurred vision. At the early stages of diagnosis and mostly throughout the lifetime, individuals with T2DM do not require insulin therapy to survive. The cause of type 2 diabetes may be varied however,

the specific aetiologies are clearly unknown and the destruction of the cells mediated by autoimmune response is non-existent (IDF, 2015).

Persons with type 2 diabetes are mostly overweight or obese and the excessive weight itself triggers some level of resistance to insulin. On the other hand, persons who are not overweight by traditional anthropometric standards may have a higher proportion of body fat widely spread in the abdominal area.

Diabetes emergency such as ketoacidosis rarely occurs in type 2 diabetes; when detected, it is often triggered by infections linked with illness stress. Type 2 diabetes most often goes undetected for a number of years because the hyperglycaemia develops over time and at the initial stages is mostly not serious for the individual to experience any of the known diabetes symptoms. These individuals however exhibit some evidences of macrovascular and microvascular complications when the condition is finally confirmed (IDF, 2015).

Although the exact aetiology of T2DM is not fully understood, there are still several important risk factors. The most important are obesity, sedentary lifestyle (physical inactivity) and poor dietary lifestyle. The probability of developing type 2 diabetes also increases with ageing, ethnicity, family record of diabetes, women with past medical history of gestational diabetes mellitus (GDM) and patients with hypertension or dyslipidaemia (IDF, 2015).

Unlike type 1 diabetes, most patients with T2DM do not need daily shots of insulin to live. The adoption of appropriate diet, regular exercise and the attainment and maintenance of normal body weight form the important pillars of type 2 diabetes management. There are other oral pharmacological agents which are available and accessible to all people living with T2DM in most areas of the world to aid in glucose control. Insulin treatment may however, be considered in type 2 diabetes if blood glucose levels persistently become uncontrollable. In all over the world, the numbers of T2DM cases are growing rapidly and

this has been attributed to ageing populations, economic transformation, growing urbanization, less healthy foods and increasing sedentary lifestyle (IDF, 2015).

2.2.3 Gestational Diabetes Mellitus (GDM)

Hyperglycaemia that is detected at the initial period of pregnancy may be classified as either gestational diabetes mellitus (GDM) or diabetes mellitus in pregnancy. Women with elevated plasma glucose levels slightly above the normal reference values are categorized as gestational diabetics, whereas those with blood glucose levels substantially elevated are categorized as having diabetes in pregnancy (IDF, 2015).

Gestational diabetes tends to manifest from the second trimester (24^{th} week) of pregnancy. The classical symptoms of hyperglycaemia presented during pregnancy are seldom and could be mistaken for the symptoms of normal pregnancy, but may include excessive thirst and frequent micturition. The detection of blood glucose slightly higher than optimal necessitates careful management and indication for conducting an 'oral glucose tolerance test' (OGTT). This should be conducted early in pregnancy for a high risk woman, and between the second and third trimester (between 6^{th} and 7^{th} month) of pregnancy in all women as well (WHO, 1999; IDF, 2015).

The risk of developing GDM increases with ageing, past history of glucose intolerance, records of macrosomia deliveries and ethnicity (belonging to high risk racial groups). Women with chronic elevated plasma glucose levels detected during pregnancy are at a higher risk of adverse pregnancy outcomes. These include very high blood pressure and foetal macrosomia, which can result in delivery through caesarian section. Early detection and good regulation of blood glucose during pregnancy can decrease these risks. Pregnant women with elevated blood glucose level can regulate their hyperglycaemia through a

healthy diet, moderate physical activity and blood glucose monitoring. Insulin and other oral agents in some situations may in addition be recommended (IDF, 2015).

Most of the gestational diabetes often resolves postpartum (after giving birth) but a few women with past history are more prone to developing GDM in subsequent conceptions and full T2DM in the course of life. Neonates born to these women with GDM also have an increased chance of developing T2DM in some stages of their lives (during teens or early adulthood) (WHO, 1999; IDF, 2015).

2.2.4 Other Specific Categories of Diabetes

There are other specific categories of diabetes which are less common. These include:

2.2.4.1 Genetic Defects in Beta-Cells

These categories of diabetes, also known as ‘‘maturity onset diabetes of the young (MODY)’’ are related to monogenetic abnormalities in cell function. Monogenetic diabetes, often are characterized by onset of slightly elevated blood glucose levels, the result of genetic mutation leading to disruption in insulin production with minimal or no defects in insulin function. This tends to occur at an early age (which is normally before the age 25years). The characterized autosomal dominant pattern and the defects occurring at the 6 loci on separate chromosomes are inherited.

2.2.4.2 Genetic Defects in Insulin Action

There are rare aetiologies of diabetes mellitus that emanate from genetically determined defects of insulin action. The metabolic defects linked to mutations of the insulin receptor may vary from hyperinsulinemia and mild hyperglycaemia to symptomatic diabetes. Some individuals with these abnormalities may have acanthosis nigricans. Women may develop masculine traits (virilization) as well as enlarged cystic ovaries (WHO, 1999).

This syndrome was previously termed as type A insulin resistance. Two uncommon pediatric syndromes, for example, Leprechaunism and the Rabson-Mendenhall have defects on the insulin receptor gene which alters the function of the insulin receptors resulting in extreme insulin insensitivity. Leprechaunism syndrome is usually deadly in infants and has typical facial traits whereas Rabson-Mendenhall syndrome is characterized by defects of the teeth, nails as well as pineal gland hyperplasia (WHO 1999; ADA, 2010).

2.2.4.3 Diseases of the Exocrine Pancreas

Diabetes mellitus in some cases may be caused by processes that will lead to the damage of the pancreas. This may include instances of trauma, pancreatitis, infection, pancreatectomy, cystic fibrosis, haemochromatosis and pancreatic carcinoma.

2.2.4.4 Endocrinopathies

Some hormones including growth hormone, cortisol, glucagon and epinephrine antagonize insulin function. Diseases associated with large secretions of these hormones may result in diabetes mellitus (e.g., acromegaly, Cushing's syndrome, glucagonoma, pheochromocytoma, hyperthyroidism, somatostatinoma, aldosteronoma). This type of hyperglycaemia is usually normalized when the hormonal levels are corrected (WHO, 1999).

2.2.4.5 Drug - Or - Chemical Induced Diabetes

Some drugs are known to affect the function of insulin. Although, these chemical agents may not necessarily cause diabetes themselves, they may on the other hand trigger diabetes in patients by altering insulin action. Examples of such drugs include vacor (a rat poison), glucocorticoids, dilantin, pentamidine, diazoxide, nicotinic acid, γ- interferon, thyroid hormone, β-adrenergic agonists and thiazides (WHO, 1999; ADA, 2010).

2.2.4.6 Infections

Certain infections caused by viruses have been linked to the destruction of the β-cells. A typical example is the congenital rubella which predisposes individuals to diabetes. In addition, conditions such as coxsackie B, cytomegalovirus, adenovirus, and mumps have also been implicated in inducing diabetes (WHO, 1999; ADA, 2010).

2.3 DIAGNOSIS OF DIABETES MELLITUS

The World Health Organization (2006) recommendations criteria for diabetes diagnosis are centered on blood glucose criteria (either the fasting plasma glucose (FPG) or the 2-hour plasma glucose value) following a 75-g oral glucose tolerance test (OGTT). The International Expert Committee (2009) however, has recently recommended HbA1C as a third option of diabetes diagnosis. Diabetes mellitus should be diagnosed if any of the following criteria are met:

- Fasting plasma glucose (FPG) ≥ 7.0 mmol/L (126 mg/ dl). Fasting is defined ‘as no caloric intake for at least 8 hours’.

- Two-hour plasma glucose (2-h PG) ≥ 11.1 mmol/L (200 mg/dl) following oral glucose load.

- Random plasma glucose ≥ 11.1 mmol/L (200 mg/dl) in the presence of diabetes symptoms.

- Glycated Haemoglobin (HbA1C) ≥ 6.5%. The test should be done in a laboratory where approved methods of National Glycohaemoglobin Standardization Program (NGSP) to the Diabetes Control and Complications Trial (DCCT) reference assay are used

According to WHO (2013), the diagnostic criteria for gestational diabetes (GDM) are based on the adverse outcomes of pregnancy. This type should be diagnosed if any of the following standards are met at any time in pregnancy:

- Fasting plasma glucose: 5.1- 6.9 mmol/L (92-125 mg/dl).
- Two-hour plasma glucose: 8.5-11.0 mmol/L (153 -199 mg/dl) following a 75g oral glucose load.

2.4 DIABETES COMPLICATIONS

Diabetes mellitus can result in a couple of disabling and life threatening complications when not properly managed. Progressively, it affects other organs of the body and can increase ones' risk of premature death. Over time, hyperglycaemia can result in severe outcomes which are detrimental to the eyes, cardiovascular, renal and nervous system. This increases individual's risk of foot ulcers, infections and subsequently amputation. Diabetes is one of the main causes of renal failure (IDF, 2015; WHO, 2016).

All over the world, especially in the developed countries, diabetes is a major contributor to cardiovascular diseases, vision loss, kidney failure and lower extremity amputations. In the developing nations, the rate of T2DM prevalence is growing rapidly and is becoming alarming. This implies that complications due to diabetes are also expected to increase. It is therefore important to put effective interventions in place to better manage the disease.

Diabetes in pregnancy can have a devastating impact on both mother and the unborn child's health if not well-controlled. This substantially raises the chances of foetal loss, congenital deformities, stillbirth, perinatal death, obstetric complications as well as maternal morbidity and mortality. Gestational diabetes has also been shown to expose women to a higher risk of some adverse outcomes such as preeclampsia and eclampsia, foetal macrosomia and shoulder dystocia during and after pregnancy (WHO, 2016).

Interestingly, it is however unclear as the percentage of obstetric complications and mortalities that are gestational diabetes related. Apart from the above described traditional adverse outcomes, diabetes has also been found to be linked to some forms of cancers and cognitive disabilities (WHO, 2016).

The adverse outcomes of diabetes can be delayed or prevented by keeping blood glucose, blood pressure and lipid profiles within the acceptable ranges as possible. Many associated complications of diabetes can be detected early by screening interventions that initiate treatments to prevent them becoming more severe (IDF, 2015).

2.5 MANAGEMENT OF TYPE 2 DIABETES MELLITUS

Type 2 diabetes mellitus constitutes over 90% of all diabetes cases in the sub- Saharan Africa. It is becoming more prevalent due to the emergence of obesity, physical inactivity and urbanization (Levitt, 2008). Type 2 diabetes is a life threatening condition which, if not properly managed can affect every system of the body as a result of long-term complications (ADA, 2014b). The effective management of T2DM is very necessary to avert the long – term complications associated with it.

The goals of diabetes mellitus management are therefore; to return to normal altered metabolic functions of individual with diabetes, keeping plasma glucose levels within range and to minimize risk factors of diabetes - related complications. It is also aimed to empower

individuals with self-care skills to manage their own diabetes and to restore persons with diabetes to a lifestyle which is independent (Abioye-Akanji, 2013).

To assist individuals with diabetes to achieve these management goals, a set of behaviours are recommended which includes: self-management education, monitoring of blood glucose level, physical activity, taking medication, monitoring food intake and knowing appropriate nutrition, and appointment keeping with the health care professional (Peyrot *et al*., 2005; Nyenwe *et al*., 2011 and Evert *et al*., 2014). The adherence or compliance to these sets of recommended behaviours are established to improve significantly glycaemic levels, reduce complications and improve quality of life (Shrivastava *et al.,* 2013).

2.5.1 Education

Self-management education of diabetes is an essential component of type 2 diabetes care for all individuals or groups with diabetes and is needed to improve patient management outcomes (Norris *et al*., 2002; Umpierre *et al*., 2011; Funnell *et al.,* 2012; Marrero *et al.,* 2013). Diabetes self-management education (DSME) is defined as an uninterrupted process of facilitating knowledge, skill and ability necessary for diabetes self-care. This process uses scientific information to guide diabetics to integrate their needs, expectations and experiences in their care. The main goals of the education are to empower patients with decision making tools as well as problem solving skills to foster collaboration with the diabetes management team to attain positive clinical outcomes, improved health status and quality of life (Funnell *et al.,* 2012).

According to Haas *et al.* (2014), the national standards of self-management of diabetes and education for type 2 diabetes should involve the following areas of content depending on the assessment needs of the patients:

- explaining diabetes disease process and management options,
- integrating dietary management into lifestyle,
- integrating exercise into lifestyle,
- safe use of drug (s) and maximizing their therapeutic effectiveness,
- monitoring plasma glucose and other parameters and interpreting and applying the results to make self-management decisions,
- 'preventing, detecting, and treating acute complications',
- 'preventing detecting, and treating chronic complications',
- formulating tailored interventions to solve psychosocial problems and concerns, and
- developing tailored strategies to promote health and lifestyle change.

A study carried out by Heinrich *et al. (*2010) demonstrated that, DSME is linked with improved metabolic control, improved knowledge and understanding of diabetes and improvement in relevant clinical outcomes (such as reduced HbA1C). Haas *et al*. (2012) found an association between DSME and improved self-management behaviours. Karter *et al*. (2001) in a previous study also established that self-management behaviour such as self-monitoring among patients with diabetes significantly lower glycaemic levels. In addition, the study established a significant association between frequent monitoring of plasma glucose and better glycaemic levels irrespective of diabetes type or therapy (Karter *et al.,* 2001).

A meta-analysis conducted on the effect of DSME on glycaemic control of adult type 2 diabetes showed a reduction of less than 1% in the glycosylated haemoglobin levels (Norris *et al*., 2002). Another interventional study conducted by Sone *et al.* (2002) demonstrated a significant improvement in glycated HbA1C level (i.e. less than 1%). Although, the reduction in HbA1C in both studies were small, this is still clinically significant as studies have established that a decline in the HbA1C by 1% over a period of years is linked with 37% reduction in micro vascular complications (Stratton *et al.,* 2000).

Deakin *et al*. (2005) and Thoolen *et al*. (2007) in a meta-analysis, demonstrated the effectiveness of DSME in achieving sustained reduction in clinical outcomes (HbA1C, FBG and blood pressure[BP] levels), improved behaviour outcomes (such as diabetes knowledge and self-management skills) and body weight reduction as well as body mass index (BMI:-0.77kgm^{-2}). Steinbekk *et al.* (2012) in a systematic review also indicated that DSME results in improved behaviour outcomes such as self-efficacy or empowerment, enhanced life skills and satisfaction of therapy among T2DM patients.

Type 2 diabetes management requires a continuous medical attention together with multifactorial risk reduction interventions beyond glycaemic control. Patients' education on self-management and support are very important in curbing acute complications and minimizing long-term complication risks. Studies have so far shown the evidences that support a number of strategies to improve outcomes of diabetes (ADA, 2014a). All patients living with T2DM should therefore receive standardized education on diabetes with specific attention on nutrition therapy and the need of increasing physical activity (ADA, 2014a; Inzucchi *et al*., 2012).

2.5.2 Physical Activity or Exercise

The International Diabetes Federation [IDF] (2012) recommends exercise or physical activity as one of the essential components in T2DM prevention and management. Although, the word physical activity (PA) or exercise are used interchangeably at times, physical activity is defined as the movement of the body triggered by skeletal muscle contractions resulting in substantial rise in energy expenditure whereas exercise is defined as a component of physical activity performed with the aim of developing physical fitness (Colberg *et al*., 2010).

Physical activity done regularly has been established to enhance insulin action by improving blood glucose levels. It also reduces blood lipids, blood pressure and other heart-related deaths (Colberg *et al*., 2010). Regular physical activity contributes to weight loss and improves quality of life of type 2 diabetics (Castaneda, 2003; ADA, 2014a).

A study conducted by Castaneda (2003), revealed that 23% of chronic condition deaths related to cardiovascular diseases and diabetes are linked with physical inactivity. Another study conducted by Nyenwe *et al*. (2011), established that sedentary lifestyle contributes to one's risk of developing type 2 diabetes.

According to the Ghana Standard Treatment Guidelines [GSTG] (2010), simple physical activity such as walking done regularly for 60 minutes/day, has been shown to help control blood glucose levels. Other studies also recommend a duration of 90 to 150 minutes of moderate – to – intense physical activity for persons living with type 2 diabetes for at least 3 - 5 days per week (Colberg *et al*., 2010; Franz *et al*., 2010; Geidl and Pfeifer, 2010; IDF, 2012). The American Diabetes Association (2014a) recently published standards of care on diabetes and recommended at least 2½ hours of moderate-to-intense aerobic exercise for adults with T2DM for a minimum period of 3 days/week.

Geidl and Pfeifer (2010) demonstrated in a study that, engaging in physical activity (aerobic and resistance training) decreases glycated haemoglobin by 0.5% to 0.8%. Boule *et al*. (2001), in a review showed that performing moderate physical activity for 150 minutes for 3 days per week resulted in approximately 0.66% decrease in glycated haemoglobin. Another study conducted by Umpierre *et al*. (2011), also reported that exercising for more than 150 min per week is associated with 0.89% reduction in haemoglobin A1C or 0.36% HbA1C reduction when duration of exercise was ≤ 150 minutes per week.

According to Balducci *et al*. (2012), it is established that type 2 diabetes patients who performed both aerobic and resistance training recorded a reduction in glycated haemoglobin, lipids, blood pressure and body weight. This study was consistent with the earlier work done by same authors. The study reported that exercising for 150 minutes for duration of one week, resulted in reduction of glycated haemoglobin A1C and modifiable risk factors of cardiovascular diseases in type 2 diabetes patients (Balducci *et al*., 2008).

Although exercise is considered as one of the management pillars of type 2 diabetes, the age of the patient, physical fitness status, socio-economic status and lifestyle, the presence of complications as well as the glycaemic level of the patients should be considered before exercise session commences (GSTG 2010; ADA 2014a).

2.5.3 Nutrition Therapy

Nutrition therapy is critical component of healthy lifestyle and continues to be a cornerstone of type 2 diabetes prevention and care (IDF 2006). It is defined as ‘‘nutritional diagnostic, treatment and counseling services for the aim of disease management’’. Nutrition therapy assists in priority setting, establishing targets and formulating personalized plan of actions which acknowledge and nurture self- care responsibility (Morris and Wylie-Rosett, 2010).

Generally, it involves a couple of appointment sessions between nutrition expert and a client, in which the professional carries out a complete nutrition care process on the client (Lacey and Pritchett, 2003).

According to Evert *et al*. (2014) and Asif (2014), the main aims of nutrition therapy of diabetes are as follows; to

- achieve optimal plasma glucose levels,
- achieve optimal lipid and lipoprotein levels,
- prevent, delay and treat diabetes related complications through food intake and behaviour change,
- meet personal dietary requirements by prioritizing individual and cultural preferences, and
- sustain the pleasure of eating by limiting food options specifically based on scientific information.

Funnell *et al*. (2011) demonstrated that adherence to medical nutrition therapy results in a sustained reduction in haemoglobin A1C in persons with type 2 diabetes mellitus. Nutrition therapy has also been established to improve clinical outcomes as well as reducing the cost of managing the condition according to the Institute of Medicine [IOM] (2000). Despite the effect of this component on diabetes care, it has been the most difficult and problematic part of diabetes self-care. The efforts made by people living with type 2 diabetes to follow the general dietary principles most often has led to lifestyles which are not sustainable (Asif, 2014).

According to Wheeler *et al*. (2012), type 2 diabetes patients averagely receive 48% of their energy from carbohydrates, 36-40% energy from fats/oils and 16-18% from protein. Fadupin *et al*. (2000) and Nyenwe *et al.* (2011) also reported that meal plan for type 2

diabetics should constitute 50-60% daily calories from carbohydrates, 25-30% from fat/oils and 15-20% from protein. Studies have however, established that there is no one personalized dietary pattern for all diabetics and evidence has shown that combination of different eating patterns/macronutrient distribution have yielded some improvement in glycaemic control (Wheeler *et al.,* 2012; Evert *et al*., 2014). The standards of medical care in diabetes also demonstrated that there is no ideal amount of macronutrients consumption for persons with T2DM for optimizing glycaemic control (ADA, 2014a).

According to the various studies, people with type 2 diabetes should consume complex carbohydrates high in fibre (low-glycaemic-index source) such as vegetables, fruits, whole grains, legumes and dairy products other than known sources containing added fats, sugars or sodium (IDF, 2006; NICE, 2009; GSTG, 2010; Inzucchi *et al.,* 2012). This recommendation is consistent with the recently released standards of T2DM care (ADA, 2014a).

Even though the results on ideal combination of macronutrients proportions/distribution for optimal glycaemic control for type 2 diabetics is mixed, the eating patterns should be individualized based on food availability, preferences, metabolic goals and appropriate nutrition that are in accordance with the general dietary prescription for the population (Bantle *et al*., 2008; Inzucchi *et al*., 2012; IDF 2012; Evert *et al.*, 2014). In addition, the quality of macronutrient and the total energy intake should be of paramount interest irrespective of the individual preference of eating pattern (ADA 2014a).

Several studies have demonstrated the effectiveness of nutrition therapy in weight reduction irrespective of the eating pattern, provided there is adequate caloric restriction, appreciable intake of dietary fibre (vegetables and /or fruits) and reduced intake of fats especially the saturated fats (Foster *et al*., 2003; Nyenwe *et al.,* 2011). Weight reduction achieved through

dietary regimen only or lifestyle interventions has been confirmed to lower plasma glucose levels and other heart-related risk factors in type 2 diabetics (Inzucchi *et al.*, 2012; Look AHEAD Research Group, 2014).

2.5.3.1 General Dietary Principles for Type 2 Diabetes

The modification of diet should be based on the healthy eating principles, and this is essential for the current management of diabetes. The following dietary guidelines are recommended for individuals with diabetes (IDF, 2006; NICE, 2009; ADA, 2014a; Asif, 2014; Evert *et al.*, 2014):

- all diabetic patients should be given dietary counseling by nutrition experts with interest in diabetes in simple explained terms and written dietary instructions provided,
- appropriate diet together with an exercise regimen should be prescribed to achieve ideal weight loss,
- balanced diet should be served yet with moderate calorie restrictions,
- at least 3-main meals should be provided and excessive eating should be avoided,
- the dietary pattern should be personalized based on individual and cultural preferences,
- complex carbohydrates should be mostly consumed in the form of starches and meal plans higher in fibre content, vegetables and fruits be encouraged,
- all refined sugars in foods , drinks and products (soft drinks, sweets, toffees, etc.) and honey should be avoided, except during severe illness or episodes of hypoglycaemia. These foods contain simple sugars, which are easily absorbed causing rapid rise in blood sugar,

- sweeteners are not essential but may be used as suitable substitute of sugars for people living with diabetes without concern for their safety,
- animal fat (e.g., egg yolk, lard, butter) should be avoided or reduced to a minimum and be substituted with vegetable oils, especially polyunsaturated fatty acids,
- reduce salt intake whether the subject is known hypertensive or not,
- restrict protein consumption and sodium intake in patients with kidney problems,
- alcohol consumption should be moderated or avoided. Cigarette smoking should be avoided by diabetic patients,
- the foods and drinks freely allowed for consumption include: vegetables, water, tea, coffee and drinks with very little or no calories,
- patients on insulin treatment or certain OGLAs, e.g., sulfonylureas must be advised to eat regularly and often to prevent hypoglycaemia episodes, and
- the so-called diabetic diets and drinks are increasingly becoming available. These products are highly expensive and should be avoided because they are not essential.

2.5.4 Pharmacotherapy

Dietary modifications and physical activity alone are usually not sufficiently effective to meet individualized glycaemic target over time because of the chronic nature of the disease (Evert *et al.*, 2014). The failure to combine dietary behaviour and exercise interventions in the long-term to maintain glycaemic targets in patients with T2DM however shows that, majority of the patients will need supplementary pharmacological agents over the course of their disease condition. This could be in the form of ‘‘Oral Glucose Lowering Agents (OGLA’s)’’ or insulin injection therapy administered as a single therapy or in combination therapy (IDF, 2012).

The main consideration for therapy initiation or change is the level of glycaemia. For instance, oral agents with higher or more rapid glucose lowering effect are recommended for glycaemia levels more than 8.5% whereas oral agents with lower glycaemic potential and /or slower onset of action may be selected for glycaemic levels closer to targets [less than 7.5%] (Mazzola 2012). Other factors that may also influence choice of an agent include medical needs of the patient, treatment goals, efficacy, cost, tolerability, potential side effect, comorbidities, hypoglycaemia risk, ease of administration and convenience, patient preferences and mutual agreement between the doctor and the patient (IDF, 2006; ADA , 2014a).

Pharmacological agents used as monotherapy have been found to reduce HbA1C level by 0.5 to 2.0% with the exception of insulin which can reduce glycated haemoglobin by more than 3.0% (Nathan *et al*., 2009). Nyenwe *et al*. (2011) have also demonstrated that oral agents used separately may not likely achieve glycaemic goals but when taken in combination seem to have a synergistic effect and can therefore decrease glycated haemoglobin A1C up to 3.5%.

The antihyperglycaemic agents usually used to augment dietary and physical activity regimens in diabetes treatment include metformin, sulfonylureas, insulin, glinides (e.g. repaglinides, nateglinides), α-glucosidase inhibitors (e.g. acarbose), thiazolidinedione [TZDs] or glitazones (e.g. pioglitazone, rosiglitazone) and other known agents (Mazzola, 2012; Inzucchi *et al*., 2012).

Evidence has shown that metformin and sulfonylureas are most commonly and widely available agents usually prescribed in the African region (IDF, 2006). These drugs are captured on the essential medicines list of WHO for diabetes and both should be available and accessible to all type 2 diabetics all over world, according to need (IDF, 2015).

2.5.4.1 Metformin

Metformin (biguanide) is mostly preferred starter drug for type 2 diabetes treatment when lifestyle modification is unsuccessful in achieving or maintaining glycaemic targets (ADA 2014a). Metformin works in lowering glucose level by reducing hepatic glucose output and increasing insulin sensitivity. Metformin as monotherapy will reduce haemoglobin A1C level [~ 1.5 % points] and it is well tolerated generally (Inzucchi *et al*., 2012). Studies have established that biguanide has a long proven record for efficacy and safety and may also lower episodes of cardiovascular events (Holman *et al.*, 2008). It is considered generally as less expensive, weight-neutral and does not raise hypoglycaemia risk. The side effects associated with metformin use may include metallic taste, nausea, anorexia, abdominal pain and diarrhoea. The side effects are minimized when a smaller dose of 500mg is initiated and gradually increased to the maximum effective recommended dose of 2500mg (Rodbard *et al*., 2009).

It has been observed that the gastrointestinal disturbances associated with metformin usually diminished with the continuous use of the agent. It is administered 2 to 3 times per day due to its relatively short-acting period and tolerated best if taken with foods (Rodbard *et al*., 2009).

Metformin is excreted by the kidneys primarily and any dysfunction in the kidneys may lead to excessive plasma concentrations and predisposition to lactic acidosis (Rodbard *et al*., 2009). Type 2 diabetics with kidney problems should avoid metformin use because of lactic acidosis which is a very uncommon but serious complication (Inzucchi *et al*., 2012).

Metformin can be administered effectively as a single-dose treatment. The addition of other OGLAs such as sulfonylureas, thiazolidinedione, α-glucosidase, dipeptidyl-peptidase-4 inhibitors, a glucagon-like peptide-1agonists and pramlintide however, become necessary if it fails. It can also be used in combination with insulin (Rodbard *et al*., 2009; ADA 2014a).

2.5.4.2 Sulfonylureas

Sulfonylureas are the oldest insulin secretagogues which work by stimulating insulin release. It is administered as an additional therapy when glycaemic levels persistently remains high with metformin use (NICE, 2009). It is similar in efficacy to metformin by reducing HbA1C levels up to 1.5% by enhancing insulin secretion.

The side effects associated with sulfonylureas include hypoglycaemia, with severe occurrence of coma or seizures more frequently in the aged. Hypoglycaemia episodes are usually caused by the long-acting OGLAs (glibenclamide, sustained release glipizide, glyburide, and chlorpropamide) than the agents such as glipizide and glimepiride which are second generation agents. Weight gain of approximately 2kg has also been related to the use of some sulfonylureas but the current brands like glimepiride have been shown to be weight

neutral (Mazzola, 2012). Studies suggest that outcomes such as weight gain, retention of fluids and congestive heart failure have been related to sulfonylureas administration together with other agents especially insulin or TZDs (Inzucchi *et al*., 2012).

According to Rodbard *et al*. (2009), the benefits of insulin secretagogues (sulfonylureas) are achieved with sub-maximal doses. If blood glucose levels still remain uncontrollable, introduction of another drug from different brand is more effective than continuous increase of secretagogues to the highest dose.

2.5.4.3 Insulin Therapy

Type 2 diabetes in early stages may require lifestyle modification and oral antihyperglycaemic agents to control and manage the condition (Garber *et al*., 2013). Insulin therapy is however initiated if the lifestyle modification and oral hypoglycaemic agents do not achieve optimal glycaemic control or target.

According to Li *et al*. (2012), type 2 diabetes patients may require insulin therapy to address the ‘‘underlying pathogenic abnormalities’’ in the course of the disease to improve glycaemic control. The available evidence has shown that insulin remains the most effective antiglycaemic agent which ultimately can control and maintain blood glucose level to or close to the therapeutic goal (Lovre and Fonseca, 2014).

Generally, basal insulin is added to patients who do not achieve glycaemic control with oral agents alone (ADA, 2013). Inzucchi *et al*. (2012), showed that, basal insulin (e.g. once daily) is effective in fasting plasma glucose control among people living with diabetes. The post-prandial plasma glucose excursions in patients with higher levels of glycaemial may require prandial treatments rather than basal insulin (Inzucchi *et al.*, 2012).

Lovre and Fonseca (2014) revealed that when basal insulin is used as the second-line of treatment for type 2 diabetics, glycated HbA1C less than 7% is safely achieved and maintained than when initiation of therapy is delayed. Holman *et al.* (2009) also established that, an ‘‘addition of basal insulin or prandial insulin-based regimen’’ to diabetics oral treatment results in better glycaemic control. A research conducted by Sanden *et al*. (2010) demonstrated a reduction in mean haemoglobin A1C (median reduction = 1.5%) in majority (53%) of the participants after switching to insulin treatment. Sakharova *et al*. (2012) in another study established a significant improvement in the post-prandial glucose levels in type 2 diabetics initiated on premixed insulin regimen twice daily.

According to Caballero (2009), tight glycaemic control and earlier insulin therapy initiation results in improved outcomes (i.e. reducing both macro and micro-vascular complications) in obese type 2 diabetics. More so, insulin may provide additional protection against atherosclerosis development due to its seemly anti-inflammatory effects (Caballero, 2009).

The side effects of insulin therapy that may affect adherence to prescribed treatment include hypoglycaemia, pains associated with injections and blood test, and weight gain (Nakar *et al*., 2006). A study conducted by Russell-Jones and Khan (2007) revealed that, the excessive weight gain attributed to insulin use can adversely influence the cardiovascular risk profiles as well as increase diabetes-related morbidity and mortality. This may eventually be a psychological obstacle to the commencement or ‘‘intensification of insulin’’.

The latest insulin formulations however, can significantly improve glycaemic control without affecting the weight of people living with type 2 diabetes (Caballero, 2009).

2.6 BARRIERS TO DIABETES MANAGEMENT

Diabetes self-care behaviours are very important to the disease progression, but patients unfortunately, do not comply with recommendations despite their importance. Research has established that effective diabetes care demands patient's adherence to recommended therapies (Engler *et al*., 2013) and adherence or compliance have also been shown to improve glycaemic levels, reduce healthcare cost and the risk of diabetes-related complications caused by microvascular damage (Lawrence *et al*., 2006; Lee *et al*., 2006; NICE, 2009; ADA, 2013).

According to a study conducted by Sekhar *et al*. (2013), 59% and 63% of the study subjects were non-adherent to diet and exercise respectively. This reflected in almost half of the patients having HbA1C above 7%. Lerman *et al*. (2004), also established that, only around a quarter (i.e. 26%) of people living with type 2 diabetes in Mexico adhered to meal planning, medication and physical activity therapy recommendations. In one study, only 16.4% of study participants followed the dietary prescription (Tan *et al*., 2011).

Al-Sinani *et al*. (2010), reported low dietary compliance among 75% of the study subjects. This was due to lack of awareness as well as lack of knowledge on the possible outcomes of the condition on quality of life. In another study, Vijan *et al.* (2005), revealed that, cost, small portion sizes, rigid schedules of diet, and support were the reported barriers to dietary recommendations. Nwankwo *et al*. (2010), established that, majority (93%) of the study subjects lacked the knowledge of basic diabetes care and only reported to a doctor when exhibiting serious complications. Other studies have also demonstrated lack of education, inadequate knowledge, lack of skills and misconception as barriers to diabetes care compliance (Brown *et al*., 2007; Mansour, 2008; Mann *et al*., 2009; Karter *et al*., 2010; Shakibazadeh *et al.*, 2011; Islam *et al*., 2012; Lee *et al*., 2013). Elliott *et al*. (2013) in a study established that, formal education is associated with diabetes self-management and

education significantly. Zhou *et al*. (2013) also demonstrated that, poor glycaemic control among type 2 diabetes patients may be predicted by low education as a result of poor diabetes self-care. Hernandez-Tejada *et al*. (2012), however showed that, empowerment is associated with better self-care improvement in diabetes behaviour (nutrition, physical activity, medication, plasma glucose testing, foot care and diabetes knowledge) adherence.

Another study by Reichsman *et al*. (2009), revealed that, most of the diabetics reported difficulty in adherence to recommended therapies. Mohebi *et al*. (2013), also identified patients' difficulty to adhere to dietary recommendation, and Schillinger *et al*. (2002), established relationship between health literacy and outcomes of diabetes. The finding showed that type 2 diabetics with inadequate health literacy were at risk of uncontrolled glycaemic episodes [A1C > 9.5%] than diabetics with adequate health literacy. In addition, Kokanovic and Manderson (2007), and Kollannoor-Samuel *et al*. (2012), reported difficulty by type 2 diabetics to understand and retain practical information received from the healthcare professionals with poor communication style while Rustveld *et al*. (2009), showed an application difficulty of the information by type 2 diabetes patients to manage their condition.

Lack of support (Rosal *et al*., 2008; Choi, 2009, and Rosland *et al*., 2010) and motivation (Islam *et al*., 2012; Elliott *et al*., 2013) were identified as barriers to diabetes care adherence. Kiawi *et al*. (2006), reported lack of accurate knowledge of the diabetes disease process and care, lack of knowledge on healthy diet composition, lack of facilities to do physical activity, lack of time to exercise, cultural attachment to traditional management of diabetes, and socio-cultural factors as barriers to poor diabetes care outcomes.

Al-Kaabi *et al*. (2009) established that, only 3% of T2DM patients met the recommended guidelines for physical activity. Factors such as pain, time, tiredness, lack of family support,

disease condition, lack of time and weather conditions were reported barriers to diabetic's compliance to physical activity. Rosal *et al.* (2008), reported fatigue and laziness whilst Orzech *et al*. (2013), identified barriers such as pains, preference for doing other things and aversion to exercise.

A study conducted by Yusuf *et al*. (2008), established that 59% of a study cohort was non-adherent to medication regimen (OHA) due to lack of finance, side effect of the medication and self-medication with alternative medicine (local herbs) as a result of patients' perceived inefficacy of the prescribed OHA. Brown *et al.* (2007) and Lee *et al*. (2013), also reported patients' preference for alternative natural complementary medicine to evidence-based professional advice as a result of mistrust in the care system. Phobia toward insulin treatment and perceived oral agents as mild form of treatment was established to be barriers to adherence (Brown *et al*., 2007). Lee *et al.* (2013), also reported that, adverse outcomes such as weight gain and hypoglycaemia have been cited as reasons for insulin treatment non-compliance.

In one study, reasons usually given by patients for insulin non-adherence included ''too busy, skipped meals, travelling, stress, public embarrassment and restrictive'' (Peyrot *et al*., 2012). Other studies conducted by Kent *et al*. (2010), Weinger and Beverly, (2010) and Mohebi *et al*. (2013) also revealed factors such as embarrassment, pains and stigma as barriers to insulin therapy non-adherence.

Adisa *et al*. (2009) reported omission of dose, being fed up with the daily oral intake and inconveniences with outside home medication intake as intentional non-adherence barriers whereas forgetfulness and high cost of medications were mentioned as non-intentional non-adherence. Other studies have also established polypharmacy as a barrier to compliance. In situations when diabetics need to take many different drugs for their condition and concurrent conditions, compliance is most often poor (Cramer *et al*., 1989; Paes *et al*., 1997;

Reasner and Goke 2002 and Emslie-Smith *et al*., 2003). One study however, revealed a high adherence rate to medication taking irrespective of the quantity prescribed (Grant *et al*., 2003).

According to Abioye-Akanji (2013), barriers including financial difficulties, poor nutritional habit, cultural attachments to traditional management of diabetes, medication regimen non-adherence, negative rapport with doctors and inadequate cultural care knowledge by their practitioners, were reported by the study participants.

Reichsman *et al*. (2009) and Shakibazadeh *et al*. (2011) have shown that, inadequate insurance coverage is a major barrier to compliance among type 2 diabetics. In addition, the cost of medication, investigation and medical care make diabetes self-care compliance difficult (Mackey *et al*., 2012; Shrivastava *et al.,* 2013; Bhojani *et al*., 2013).

A study reported that, the care system poses a major challenge to quality diabetes self-care (Peyrot *et al*., 2005). The negative attitudes of some health professionals toward patients, inadequate communication with patients, and fragmented health care provision have been identified as barriers to adherence (Lee *et al*., 2012; Bhojani *et al*., 2013). In one study, Raaijmakers *et al*. (2013), revealed lack of awareness of lifestyle programmes by people living with diabetes due to inadequate communication by the care system. Rosal *et al*. (2008) and Parker *et al*. (2012) also reported lack of time, space, logistics and staff to educate patients on lifestyle modification programmes. This has resulted in inconsistent delivery of diabetes self-care interventions.

2.7 GLYCAEMIC CONTROL OF ADULT TYPE 2 DIABETES PATIENTS

2.7.1 The Glycaemic Control Targets of Diabetes Mellitus Patients

The available evidence has demonstrated that, strict plasma glucose control can lower the risk of diabetes-related retinopathy and nephropathy caused by micro vascular damage (ADA, 2013). According to Blaum *et al*. (2010), some individuals with diabetes may not adhere to this strict blood glucose regulations due to other comorbidities and adverse outcomes related to diabetes (See Table 2.1). The blood glucose target for such individuals (older adults $\geq$ 65years) may however, be relaxed on the account of advanced complications, life-limiting comorbidities and functional or cognitive disabilities.

Generally, glycaemic target of 7.5% to 8.0% for HbA1C is recommended for older adults. The glycaemic target between 7.0% and 7.5% is suggested for relatively fit older adults with good functional status with little comorbidities whereas HbA1C levels of 8.0% is recommended for frail older adults (i.e. persons with limited expectancy or extensive comorbid conditions), and other individuals in whom the risk of strict glycaemic control far outweighs the benefits (ADA, 2013). Studies established an association between strict glycaemic control and hypoglycaemia as well as mortality among young type 2 diabetes adults [< 65years] (Gerstein *et al*., 2008).

The International Diabetes Federation [IDF] (2012) also recommended HbA1C targets to the levels of 8.5% for frail older adults and between 7.0 to 7.5% for relatively healthy older adults. In addition, there should be individualization of plasma glucose control targets among type 2 diabetics based on the functional status, comorbidities (especially the presence of established cardiovascular disease), history and the risk of hypoglycaemia and established micro vascular complications (IDF, 2012).

The recent American Diabetes Association (ADA) (2015), recommends fasting blood glucose targets of 80 to 130mg/dL (4.4 – 7. 2 mmol/L) for people living with diabetes instead of the previous 70 to 130mg/dL (3.9- 7.2mmol/L) glucose target.

Table 2.1 Patients Characteristics and Blood Glucose Targets

Patients characteristics /health status	**Rationale**	**Reasonable A1C goal (A lower goal may be set for an individual if achievable without recurrent or severe hypoglycaemia or undue treatment burden)**	**Fasting or pre-prandial glucose (mg/dL)**	**Bedtime glucose (mg/dL)**
Healthy(Few coexisting chronic illnesses, intact cognitive and functional status)	Longer remaining life expectancy	<7.5%	90 – 130	90 – 150
Complex/intermediate(multiple coexisting chronic illnesses or 2+ instrumental ADL impairments or mild to moderate cognitive impairment)	Intermediate remaining life expectancy, high treatment burden, hypoglycemia vulnerability, fall risk	<8.0%	90 – 150	100 – 180
Very complex/poor health (Long-term care or end stage chronic illnesses or moderate to severe cognitive impairment or 2+ ADL dependencies)	Limited remaining life expectancy makes benefit uncertain	< 8.5%	100 – 180	110 – 200

Source: Blaum *et al*., (2010).

2.7.2 The Effect of Compliance on Glycaemic Control

Many studies have measured compliance using glycaemic control (Cohen *et al.*, 2010; Raum *et al*., 2012). Glycated haemoglobin A1C is one of the measurements which are primarily

used to identify the mean plasma glucose concentration over the preceding three months in a single test. This test requires no special preparations (fasting) and can be done in a day at any time (Seides, 2014; WHO, 2006). This feature ‘‘has made it the gold standard for assessing glycaemic control’’ in diabetics (WHO, 2006).

Although HbA1C tests are considered desirable, it is often not performed in some of the primary and secondary health facilities in the Africa Sub-Region. The performance of HbA1C has been found to be problematic and global consistency remains a challenge (WHO, 2006). In addition, the test is affected by so many factors such as anaemia, haemoglobinopathies, pregnancy and uraemia (WHO, 2006).

According to Herman and Fajans (2010), HbA1C is found to be associated with inherent systematic errors when solely used as a diagnostic measurement for diabetes. More so, studies conducted by Selvin (2016) have also established consistent racial/ethnic disparities in HbA1c measurement. For example, the whites have been identified to have lower HbA1C levels than the African Americans. Glycated haemoglobin A1C could ‘‘be a biased measure of average glycaemia’’ and currently, not considered appropriate diagnostic measurement for average glycaemia (WHO, 2006; Selvin, 2016).

Studies have suggested other equally similar measurements such as FPG and 2-hour postprandial glucose to be used in assessing glycaemic control (IDF, 2006) and these measurements have been found to be reliable as well as useful for diabetes diagnosis and management (Myazaki *et al*., 2004; Xin *et al*., 2012).

Blood glucose control by means of strict monitoring improves both clinical and patient-related outcomes; however this can be achieved through compliance with the recommended regimen (Chiu *et al*., 2009; NICE, 2009).

At one stage in diabetes care, one cannot do without medication component of treatment which plays a critical role in the maintenance and achievement of glycaemic control. Peyrot *et al*. (2005), in a cross sectional study involving 5,104 participants revealed a compliance of 64%, 35% and 37% with medication, dietary and exercise regimen respectively, whilst Mohan *et al.* (2011), reported patient compliance of 66.2%, 54.5%, 37.2% with medication, diet and exercise recommendations respectively.

Ganiyu *et al*. (2013), in a cross-sectional study indicated that, the rates of non-compliance to dietary and physical activity recommendations were 37% and 52% respectively. One study demonstrated that, the rate of non-adherence to recommendations were 62% for diet, 85% for exercise, 30% for medication taking (both oral and insulin) and 3% for appointment keeping (Hernandez-Ronquillo *et al*., 2003). Broadbent *et al*. (2011), also established a compliance level of 86% for medication (insulin), 22% for dietary prescription and 17% for physical activity recommendations. Faria *et al*. (2013), in a similar study showed 84.4%, 58.6% and 3.1% for medication adherence, physical activity and dietary regimen adherence respectively.

Adherence to pharmacotherapy by diabetics has been shown to be associated with improved glycaemic control and reduction in costs of health care (Lawrence *et al*., 2006; Lee *et al*., 2006). Morris *et al*. (1997) demonstrated poor glucose control and ketoacidosis among poor adherent patients on insulin therapy. Another study by Broadbent *et al*. (2011) revealed that, medication taking is ranked the most essential component of therapy than the other regimens (both diet and exercise) by patients with diabetes. Study has therefore established that, drug compliance is linked to reduced perceived consequences of diabetes, higher personal control; reduced distress and minimal symptoms (Broadbent *et al.*, 2011).

Hunt *et al*. (2009) demonstrated that, poor glycaemic control results from decreasing medication adherence and this has often been attributed to the cost of medication. Yuan *et al.* (2014) also established that, patients with higher glycaemic levels [HbA1C > 8.0%] comply partially with prescribed medication regimen compared to patients with lower glycaemic levels (HbA1C<7.0%). The study found no association between patient's medication regimen adherence and glycated haemoglobin levels especially among men but significant association among women was found (Yuan *et al*., 2014). In another study, DiBonaventura *et al.* (2014) reported a significant association of noncompliance with higher glycaemic levels [i.e.0.21% increase in HbA1C levels] among type 2 diabetics on insulin. The study further demonstrated that, noncompliance among patients resulted in 4.6% increase in physician visits, 20.4% increase in emergency room visits and 20.9% increase in hospital admissions.

Dietary regimen compliance is associated with lower HbA1C, and improvement in other clinical outcomes (Dworatzek *et al*., 2013; Davison *et al*., 2014). Khattab *et al*. (2010) established that, patients who were non-adherent to their dietary plan experienced poor glycaemic control. Al-Hayek *et al*. (2012) also indicated that, type 2 diabetics who did not follow their prescribed dietary plan experienced higher blood sugar levels. Al-Hayek *et al*. (2013) and Shamsi *et al*. (2013) also established a significant relation between following meal plan and glycaemic control. One study however demonstrated that, adherence to dietary recommendations is not significantly associated with glycaemic control (Faria *et al*., 2013).

Takahashi *et al*. (2014), reported that poor glycaemic control was associated with unhealthy lifestyle behaviours whilst another study also established a significant reduction in blood glucose levels among adult type 2 diabetics who adhered to lifestyle recommendations (Lim *et al*., 2013).

Other studies have also showed better glycaemic levels among type 2 diabetics who adhered to recommended self-care management practices (Laxy *et al*., 2014; McClintock *et al*., 2014; Rho *et al*., 2014).

CHAPTER THREE

3.0 METHODOLOGY

3.1 STUDY TYPE/DESIGN

This was a clinic based cross-sectional study conducted at the outpatient clinics of four selected health facilities (Brong Ahafo Regional Hospital, Sunyani Municipal Hospital, Seventh Day Adventist (SDA) Hospital and Kenam Clinic) in Sunyani Municipality from May 1 to July 30, 2014.

3.2 ETHICAL APPROVAL

Approval was sought from the management of the four selected health facilities and verbal consent was also obtained from the individual respondents. The School of Medical Sciences (SMS), Kwame Nkrumah University of Science and Technology (KNUST) / Komfo Anokye Teaching Hospital (KATH) committee on human research, publications and ethics gave ethical approval for the study protocol (Clearance reference :CHRPE/AP/210/14). See appendix C.

3.3 SAMPLE SIZE ESTIMATION

The appropriate study sample size was estimated at 185 using the formula: $n = Z^2.pq/d^2$ (Snedecor and Cochran, 1989), where z = confidence level at 95% (standard value 1.96), p = estimated prevalence of type 2 diabetes at 14%, and d = margin of error at 5%. This number was increased to 300 to increase the power of the study. Three hundred (300) eligible ambulatory participants who were known type 2 diabetics were recruited randomly to complete the structured questionnaire from four selected health facilities.

3.3.1 Inclusion Criteria

All adult type 2 diabetes ambulatory patients, 30 years and above, diagnosed with diabetes for a year and above, and visiting the diabetes clinic as an outpatients for their scheduled follow-up appointments.

3.3.2 Exclusion Criteria

All T2DM patients < 30 years diagnosed less than a year, all pregnant women with diabetes and non-ambulatory T2DM patients.

3.4 MEASUREMENT OF FASTING BLOOD GLUCOSE

Procedure

A small drop of capillary blood sample was collected using lancet, test strips and glucose metre.

The thumb was cleaned with alcohol swipe and allowed to dry before pricking.

A small drop of capillary blood was obtained by gently applying pressure intermittently and the blood was allowed to completely fill the test strip.

The metre then displayed the blood glucose reading on its digital screen and the result recorded on the participant's form. The used lancets, strips and alcohol swipes were appropriately disposed of.

3.5 DATA COLLECTION AND TECHNIQUE

3.5.1 Medical Records Review

Medical record folders of participants were reviewed and those who met the inclusion criteria were selected. General education was given to explain the rationale of the study to the study population as well as the inclusion criteria. Eligible participants waiting to receive

care were randomly selected and approached to seek their consent. Those interested were chosen to complete the questionnaire.

In order not to delay eligible participants unnecessarily, the completion of the questionnaire was done before or after the participants had gone through the service depending on the flow of the clinic. Data collected were kept under lock and key to protect the subjects of the studies and to ensure confidentiality of data collected.

3.5.2 Questionnaires

Copies of pre- tested questionnaire consisting of both closed and open ended questions were administered directly to 300 eligible participants on one-to-one basis. Information on socio - demographic variables, barriers that affect compliance to recommended treatments and self-care management practices were collected. A total of three hundred (300) T2DM patients from the four centres of study consented and completed the questionnaire.

3.6 STATISTICAL ANALYSIS

Statistical analyses were conducted using the International Business Machines Corporations - Statistical Package for Social Sciences (IBM SPSS) software version 20.0.

Descriptive and Fisher's exact tests were used to analyze the data. A p-value less than 0.05 was considered statistically significant.

CHAPTER FOUR

4.0 RESULTS

4.1 GENERAL DEMOGRAPHIC INFORMATION OF STUDY POPULATION

A total of 300 participants within an age range of 30 to 83 years were recruited for the study. There were 179 (59.7%) females and 121(40.3%) males.

A majority of the study respondents were Akans (90%) with participants belonging to other ethnic groups forming the other 10%. Most (69%) of the study participants were married. A greater proportion (77%) of the study participants were employed while 23% were unemployed at the period of the study. Most of the respondents had some level of formal education with middle school being the highest (32%) and tertiary lowest (10.3%). About 20% had no formal education. Slightly more than half (57.7%) of the participants in the study had been living with diabetes for one to four years. These results are presented in Table 4.1.

Table 4.1 General Demographic Information of Study Participants

DEMOGRAPHICS DESCRIPTIVE INFORMATION	
AGE (Years)	**N (%)**
30-40	58(19.3)
41-50	83(27.7)
51-60	80(26.7)
≥61	79(26.3)
GENDER	
Male	121(40.3)
Female	179(59.7)
ETHNICITY	
Akan	270(90.0)
Ga	5(1.7)
Frafra	3(1.0)
Ewe	2(0.7)
Others	20(6.7)
RELIGION	
Christian	281(93.7)
Muslim	18(6.0)
Others	1(0.3)
MARITAL STATUS	
Single	17(5.7)
Married	207(69.0)
Divorced	36(12.0)
Widow	40(13.3)
EDUCATION	
No formal education	59(19.7)
Primary	72(24.0)
Middle School	96(32.0)
Secondary	42(14.0)
Tertiary	31(10.3)
OCCUPATION	
Traders	101(33.7)
Public Servants	53 (17.7)
Farmers	35(11.7)
Artisans	21 (7.0)
Unemployed	43(14.3)
Others	47(15.7)
NHIS	
Insured	293 (97.7)
Non-insured	7 (2.3)
PERIOD/DURATION OF DIABETES (Years)	
1-4	173(57.7)
5-10	95(31.7)
11-15	26(8.7)
≥16	6(2.0)

4.2 DIABETES SELF-CARE MANAGEMENT PRACTICES AND REPORTED BARRIERS BY STUDY PARTICIPANTS

Most of the participants (78%) have some education on diabetes self-care management practices and the various management practices are indicated in Table 4.2.

With regards to compliance to the components of diabetes self-care management practices 55 (18.3%), 237 (79%) and 18 (6%) of the study participants reported complying strictly with dietary prescriptions, medication and physical activity respectively.

Several reasons were given by participants for not complying with diabetes self-care management. These are presented in Table 4.3. While 17% of those on physical activity attributed the non-compliance to tiredness or fatigue, 15% of those on diet found it restrictive. About 8% of those on medication attributed the non-compliance to forgetfulness. These figures represent the highest in each group as other reasons were given.

Table 4.2 Reported Diabetes Self-Care Management Education and Components Practiced by Study Participants

PARAMETER	N	%
Diabetes self-care management educations		
Yes	234	78.0
No	66	22.0
Total	300	100.0
Components of diabetes self-care management Practiced		
Diet, exercise and medication	104	34.7
Diet and exercise	49	16.3
Diet and medication	31	10.3
Diet only	43	14.3
Medication only	63	21.0
Others	10	3.3
Total	300	100.0

The parameters on the table are presented in frequencies(N) with their corresponding percentages(%)

Table 4.3 Compliance to Recommended Self-Care Management Components by Study Participants

COMPLIANCE	N	%
Diet		
Never	154	51.3
Sometimes	91	30.3
Always	55	18.3
Total	**300**	**100.0**
Medication		
Never	14	4.7
Sometimes	46	15.3
Always	237	79.0
Total	**297***	**99.0***
Physical Activity		
Never	67	22.3
Sometimes	137	45.7
Always	18	6.0
Total	**222***	**74.0***

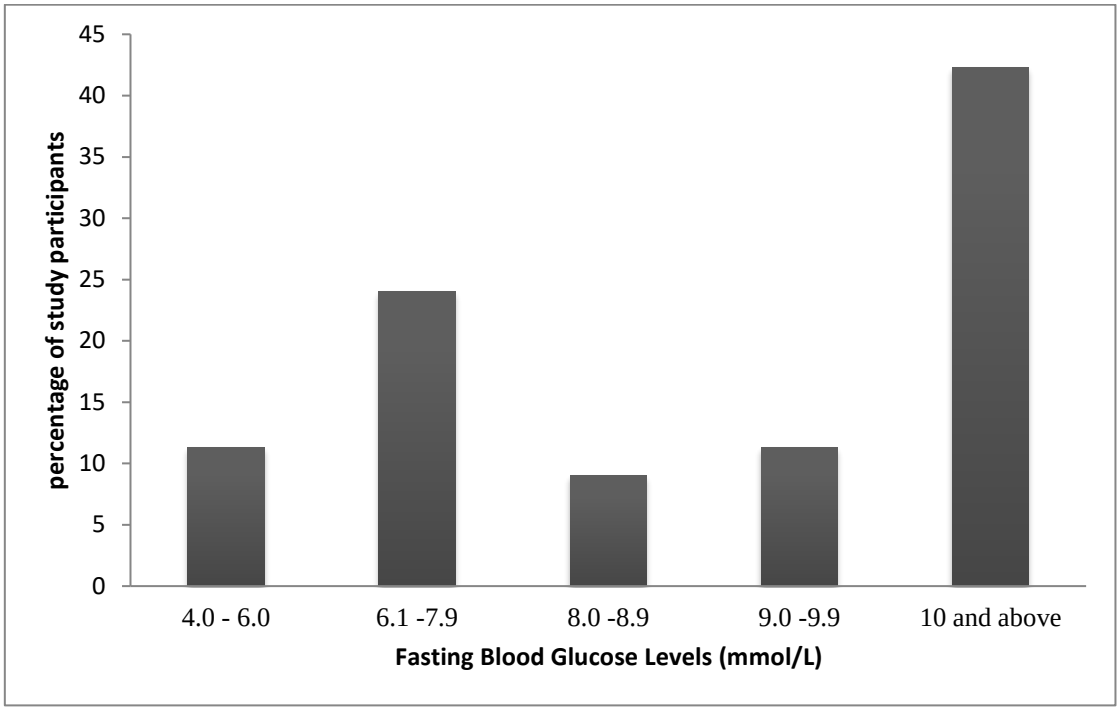
***Missing data because participants did not respond to them.**

Table 4.4 Reported Barriers to Diabetes Self-Care Management Practice

BARRIERS	N	%
Diet		
Restrictive diet	45	15.0
Loss of appetite	32	10.7
Finance	31	10.3
Satisfaction	24	8.0
Work	21	7.0
Difficulty in following meal schedule	19	6.3
support	12	4.0
Travelling	8	2.7
No barriers	81	27.0
Others	27	9.0
Total	**300**	**100**
Medication		
Forgetfulness	23	7.7
Bitterness of the drug	16	5.3
Pains of injection	15	5.0
Finance	11	3.7
Time	8	2.7
Work	6	2.0
Travelling	3	1.0
Polypharmacy	1	0.3
No barriers	174	58.0
Other	43	14.3
Total	**300**	**100**
Physical Activity		
Tiredness/fatigue	51	17.0
Laziness	40	13.3
Work	30	10.0
Pains in the limb	25	8.3
Ill health	21	7.0
No knowledge	14	4.7
No support	6	2.0
No barriers	92	30.7
Others	21	7.0
Total	**300**	**100**

4.3GLYCAEMIC LEVELS OF THE STUDY POPULATION

Approximately 35 % of the study participants had fasting blood glucose levels less than 8mmol/L. The majority (42.3%) of the participants had FBG levels of 10mmol/L and above. This is shown in the Figure 4.1.



Fasting blood glucose level 4.4-7.2mmo/L is considered as a reasonable FBG goal (ADA, 2015 and Blaum et al., 2010).

Fig 4.1 Fasting Blood Glucose Levels Among the Study Participants.

4.3.1 Effect of Diabetes Self-Care Management Practices on Glycaemic Levels

About 40% of study participants who had received some form of education on diabetes care practices tended to have fasting blood glucose levels below 8mmol/L. The majority (57.4%) who had not received any form of DSME recorded fasting blood glucose levels 10mmol/L or greater. There was a significant association between diabetes self-care management education and glycaemic control levels ($p = 0.004$).

On the dietary regimen compliance, out of the 55 study participants who reported of adhering strictly to their meal plan, about 38.2% had FBG levels less than 8mmol/L while 36.4% of the participants recorded glycaemic control levels of 10mmol/L or greater. The association was however, not statistically significant ($p = 0.341$).

Regarding physical activity compliance, approximately 44% of the study participants had fasting blood glucose levels below 8mmol/L, and about more than half (56%) of the participants had blood glucose levels 10mmol/L and above. There was no significant association between following a 30minutes physical activity plan and fasting blood glucose levels of study participants ($p = 0.547$) according to the Fisher's exact test.

With respect to medication prescription adherence, out of the 237 participants who reported adhering to their prescription always, about one-third (36%) had glycaemic levels less than 8mmol/L. A greater proportion of the study population (44%) however, had glycaemic control levels around 10mmol/L and above. There was no significant association between medication prescription adherence and glycaemic control levels ($p = 0.789$). These results are indicated in the Table 4.4.

Table 4.4 Comparison of Diabetes Self-Care Management Practices and Glycaemic Control Levels of Study Participants.

Variables	Fasting Blood Glucose in mmol/L						P-value***
	4.0 - 6.0	6.1 - 7.9**	8.0 - 8.9	9.0 - 9.9	≥10	Sum	
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Education on DSME							0.004
Yes	34(14.5)	60(25.6)	19(8.1)	29(12.4)	92(39.3)	234(100)	
No	1(1.5)	13(19.7)	8(12.1)	6(9.1)	38(57.6)	66(100)	
Total	**35(11.7)**	**73(24.3)**	**27(9.0)**	**35(11.7)**	**130(43.3)**	**300(100)**	
Diet compliance							0.341
Never	18(11.7)	32(20.8)	18(11.7)	18(11.7)	68(44.2)	154(100)	
sometimes	9(9.9)	28(30.8)	4(4.4)	8(8.8)	42(46.2)	91(100)	
Always	8(14.5)	13(23.6)	5(9.1)	9(16.4)	20(36.4)	55(100)	
Total	**35(11.7)**	**73(24.3)**	**27(9.0)**	**35(11.7)**	**130(43.3)**	**300(100)**	
Physical activity compliance							0.547
Never	5(7.5)	16(23.9)	5(7.5)	11(16.4)	30(44.8)	67(100)	
Sometimes	21(15.3)	32(23.4)	11(8.0)	19(13.9)	54(39.4)	137(100)	
Always	2(11.1)	6(33.3)	2(11.1)	0	8.0(44.4)	**18**(100)	
Total	**28(12.6)**	**54(24.3)**	**18(8.1)**	**30(13.5)**	**92(41.4)**	**222(100)***	
Medication compliance							0 .789
Never	1(7.1)	3(21.4)	0	4(28.6)	6(42.9)	14(100)	
Sometimes	5(10.9)	13(28.3)	4(8.7)	5(10.9)	19(41.3)	46(100)	
Always	29(12.2)	56(23.6)	23(9.7)	25(10.5)	104(43.9)	237(100)	
Total	**35(11.8)**	**72(24.2)**	**27(9.1)**	**34(11.4)**	**129(43.4)**	**297(100)***	

DSME: Diabetes Self-Care Management Education.

n : Frequency of participants and parenthesis ( ): indicate the percentages of the frequencies.

*Missing data due to non-response.

** FBG levels 4.4-7.2mmo/L is considered as reasonable glycaemic control target (Blaum *et al.*, 2010; ADA, 2015).

***P-value refers to Fisher's exact test and values < 0.05 were considered statistically significant.

CHAPTER FIVE

5.0 DISCUSSION

5.1 COMPLIANCE TO DIABETES SELF-CARE MANAGEMENT PRACTICES.

Compliance to recommended regimen is very critical in the management of T2DM. The result of the study showed a self-reported compliance of 79% for medication, 18.3% for diet and 6% for exercise. The reported compliance of self-care management practices by the study participants was highest for medication recommendation (79%) than the other pillars (i.e. diet and exercise) of diabetes care. This is in conformity with earlier studies conducted by Hernandez-Ronquillo *et al*. (2003) and Broadbent *et al.* (2011), where 70% and 86% of the study subjects respectively adhered to medication prescriptions. Mohan *et al*. (2011), in another study demonstrated a compliance of 66.2% of study participants to medication regimen. On the other hand, this is inconsistent with the study conducted by Yusuf *et al*. (2008), where about 60% of the subjects reported non-adherence to medication due to financial difficulties and side effect of the medication. The study revealed that, over 97% of the study participants were on the National Health Insurance Scheme (Table 4.1) and medications for diabetes care were covered under this scheme. The diabetes medication security enjoyed by the study participants might have contributed to the highest reported medication compliance to other recommendation regimens. People living with type 2 diabetes over time have also built some trust in medication use and ranked medication taking above other equally essential components of diabetes self-care (Broadbent *et al*., 2011). Patients see medication adherence as a key to lowering their glycaemia as well as reducing their health care cost (Lawrence *et al*., 2006 and Lee *et al*., 2006).

In relation to medication compliance barriers, the findings of the study identified forgetfulness, bitterness of the drug (side effect), pains of injecting insulin, financial difficulties, travelling, time and polypharmacy as barriers to medication regimen adherence. This is in conformity with a similar study by Yusuf *et al.* (2008) and Peyrot *et al*. (2005), where lack of finance, side effect of the medication, time (too busy) and travelling were reasons given for medication non-adherence. This finding is also consistent with the studies conducted by Adisa *et al*. (2009), where forgetfulness and financial difficulties were cited as factors for medication non-compliance. Another study by Mohebi *et al*. (2013), was in agreement with the study where pains of injecting insulin were reported as a factor for insulin treatment non-adherence. Few participants reported polypharmacy as a barrier to medication adherence. This finding is in conformity with the studies carried out by Cramer *et al*. (1989), Paes *et al*. (1997), Reasner and Goke (2002), and Emslie-Smith *et al*. (2003), where adherence rate decreased with multiple daily dosing and combination treatment. In contrast, the study conducted by Grant *et al*. (2003) was inconsistent with the findings in that, adherence level increased regardless of the quantity of drugs prescribed. For this reason, caregivers should not be discouraged from prescribing multiple drugs to type 2 diabetics with other comorbidities, but rather explain the benefits of multiple agent therapy adherences for the attainment of adequate glycaemic control.

Regarding dietary regimen compliance, the study showed a reported dietary adherence of 18.3% by the participants. This is similar to the studies conducted by Broadbent *et al*. (2011), Tan *et al*. (2011) and Faria *et al*. (2013), where 22%, 16.6% and 3.1% of study subjects respectively adhered to dietary recommendations. Al-Sinani *et al*. (2010) also confirmed a dietary non adherence of 75% among the study participants. The adherence to dietary regimen recommendations is established to be central to T2DM care and necessary for the achievement of good glycaemic control (Singh *et al*., 2012). The patients' literacy skill,

ability to recall and process instructions is key to dietary regimen compliance. This is termed as health literacy (Schillinger *et al.*, 2002), and the available demographic information of the study depicts about a quarter (24.3%) of participants having appreciable level of education (secondary and tertiary level) [Table 4.1]. This may be a contributing factor to the low dietary regimen compliance. In addition, inadequate money to buy healthy foods (Rosal *et al*., 2008; Marcy *et al*., 2011; Abioye-Akanji, 2013) as well as lack of support to engage in healthy lifestyle (Shakibazadeh *et al*., 2011) may also have contributed to the low dietary regimen compliance. Most of the health facilities lack the health professionals knowledgeable in medical nutrition therapy of type 2 diabetes, and dietary instructions given to patients were inadequately communicated sometimes by the care system (Lee *et al*., 2012; Parker *et al*., 2012; Bhojani *et al*., 2013; Raaijmakers *et al*., 2013).

In relation to barriers to following recommended dietary prescriptions, the main barriers that decreased compliance to dietary recommendations as reported by the study participants include restrictive diet, lack of finance, lack of satisfaction due to small portion sizes, difficulty in following meal plan and lack of support. This finding is in agreement with the previous study conducted by Vijan *et al*. (2005), where barriers such as cost, small portion sizes and support were identified to be influencing dietary compliance among type 2 diabetics. Unlike diabetes medications (oral agents + insulin) which were covered by the national health insurance scheme, feeding is the responsibility of the patients and the cost of purchasing healthy food is a major concern raised by the diabetics. This barrier is in agreement with the studies conducted by Rosal *et al*. (2008) and Abioye-Akanji (2013), where the cost of buying healthy foods is a major challenge to dietary adherence. This implies that health professionals rendering nutrition therapy should be aware of this challenge and give appropriate dietary prescriptions based on preference and economic

strength of individual patients using culturally acceptable and available foods for dietary management.

The study also identified lack of satisfaction due to small portion sizes as barrier to dietary prescription. This is also consistent with the study conducted by Vijan *et al*. (2005), where subjects of the study often reported small portion sizes of meals and frequent hunger when following the dietary recommendations. Another major barrier identified by the study was difficulty in following the dietary plan. This barrier was reported by few of the study participants and this is in conformity with the works done by Al-Sinani *et al*., (2010), Singh *et al*. (2012) and Mohebi *et al*. (2013), where participants found it challenging to modify their old eating habits. Dietary prescription for type 2 diabetics should be individualized and flexible to meet the nutrition and calorie requirements of patients to ensure adherence rather than restrictions that are not based on any scientific evidence.

The study participants also reported lack of support as barrier to their dietary regimen recommendations and this was also mentioned in the study conducted by Vijan *et al*. (2005). Support for diabetics, both social and family has been cited as a major barrier to dietary regimen adherence. Chary *et al*. (2012) confirmed this in a study that, limited social support for dietary and lifestyle modifications result in diabetes management difficulties. Other studies have also established that, diabetics with strong family and social support easily comply with dietary prescriptions and this is associated with lower glycaemic control (Vijan *et al*., 2005; Choi, 2009; Singh *et al*., 2012). In one study, participants reported cheating on their diabetic diets when friends and family members consume foods (e.g. sugary, fatty and salty foods) they are advised to stay away from (Orzech *et al*., 2013).This implies that support for T2DM patients is essential in the disease management. Families, friends as well

as health professionals, should offer a hand of support to diabetics in following their dietary prescription to ensure quality of life.

On physical activity compliance, the majority of the study population although, had responded positively to have received education on exercising for at 30minutes daily, only 6% reported compliance. This is in conformity with the study conducted by Al-Kaabi *et al*. (2009), where only 3% of the subjects adhered to the recommended physical activity prescriptions due to barriers such as cost of exercising, lack of family support, fear of injury, tiredness and lack of time. Hernandez- Ronquillo *et al*. (2003) and Broadbent *et al.* (2011), in a similar study reported compliance of 15% and 17% respectively to physical activity. In contrast, Faria *et al*. (2013) reported a higher compliance of about 60% to physical activity regimen due to its importance in type 2 diabetes care. The reported compliance of the study was very low, especially for regular physical activity, implying that the attainment of therapeutic goal with this component by the majority of the study participants would be very difficult if not impossible. In this case, type 2 diabetics should be assisted to overcome barriers they encounter in adhering to their regular physical activity regimen.

In relation to barriers of physical activity, the participants reported tiredness/fatigue, laziness, pains in the limbs, ill-health, lack of knowledge on exercise and lack of support were identified. This is in agreement with the study conducted by Al-Kaabi *et al*. (2009), where diabetics in United Arab Emirate found cost of exercise, lack of family support, disease conditions, lack of time, tiredness, lack of local facilities and weather conditions as barriers to their physical activity adherence. The works of Qiu *et al.* (2012) and Orzech *et al*. (2013) are also in conformity with the findings of the study.

The cost of exercise and facilities for exercise was not of a major concern to the study participants. Lack of knowledge however, on appropriate exercise regimen was strongly

established in some type 2 diabetics and this has been reported as one of the barriers to exercise adherence. This barrier may be attributed to inadequate communication by the care system on lifestyle awareness among type 2 diabetics (Raaijmakers *et al*., 2013). In one study, lack of time, space, logistics and staff to educate diabetes patients by health professionals have led to lack of knowledge on exercise (Rosal *et al*., 2008). This implies that most type 2 diabetics self-efficacy on diabetes care management is low and therefore should be empowered to adopt appropriate physical activity regimen lifestyle.

Another barrier reported by the participants was ill-health. The progressive nature of the disease in a long term may lead to the manifestation of other macro- and micro-vascular complications. This newly acquired health status often acts as barrier in the performance of prescribed exercise. In one study, comorbid conditions such as asthma, bone aches, leg swelling, back pains are perceived to be affecting exercise adherence (Rosal *et al*., 2008). This is also consistent with Qiu *et al*. (2012), where poor health was a barrier to exercise.

The other barriers reported by study participants include fatigue/tiredness, laziness and lack of time to exercise. These barriers impeded majority of the study participants to engage in productive exercises which have been established to improve glycaemic levels and quality of life (Colberg *et al*., 2010; ADA 2014a). These factors for exercise non-adherence may be due to individual's unawareness of the disease outcome on their quality of life (Kiawi *et al.,* 2006; Nwankwo *et al*., 2010) as well as lack of motivation to exercise (Islam *et al*., 2012 and Elliott *et al*., 2013). This implies that adherence to exercise may be poor, and type 2 diabetics should be motivated and supported by both health professionals and families to engage in exercises they enjoy best in order to maximize the benefits of exercise.

Regarding the effect of self-care management practices on fasting blood glucose levels, the result of the study indicated that, there was no significant association between following

dietary regimen (p = 0.341), medication treatment (p = 0.789), physical activity regimen (p = 0.547) and fasting blood glucose levels. This is consistent with the study carried out by Faria *et al*. (2013) and Lim *et al*. (2013) which showed that, compliance to dietary, medication and physical activity recommendations had no significant association with fasting blood glucose levels. Lifestyle behaviours established during childhood within families and communities largely make compliance to dietary regimen difficult (Lerman, 2005). Moreover, cohabitating with a disease condition over time tends to present adherence challenges, and the adoption of lifestyle modification (dietary prescription) for the attainment of glycaemic goals become ineffective. This suggests that, support systems (families, friends, communities and healthcare facilities) should encourage and motivate patients to continue the agreed recommendations to the latter.

In contrast to these findings, similar studies by Khattab *et al*. (2010), Al-Hayek *et al*. (2012) and Davison *et al*. (2014) using glycated haemoglobin as a measure of glycaemic control suggested that there is relationship between compliance and HbA1C levels. Studies however suggest that, either fasting blood glucose or HbA1C considerations are ‘‘equally reliable’’ measurements for the purposes of glycaemic control (Xin *et al*., 2012). Although the measurement of HbA1C is considered as the ‘gold standard’ of assessing glycaemic control, it has been established that, it is influenced by factors such as anaemia, haemoglobinopathies, uraemia and other inherent systematic errors which remains a challenge, globally (WHO, 2006). For example, a recent study conducted by Selvin (2016) revealed that, African Americans have higher HbA1C levels than their white counterparts. This suggests that using HbA1C as a measure of glycaemic control could be affected by racial/ethnic disparities and therefore measuring FBS is just as reliable and useful for glycaemic control as the other measurements.

On medication adherence and glycaemic control, this is similar to the results of Faria *et al*. (2013), which demonstrated that medication taking adherence was not associated with glycaemic control. This is also in conformity with the study conducted by Yuan *et al*. (2014), where no relationship was established between following medication recommendations and glycaemic control especially among men. In contrast, studies conducted by Lawrence *et al*. (2006), Hunt *et al*. (2009), Al-Hayek *et al*. (2012) and DiBonaventura *et al*. (2014) disagree with the findings. The studies found an association between medication adherence and improved glycaemic control. The adherence to medication therapy is very essential for improving the disease outcomes in the long term. Lack of compliance is most often a major challenge, and in this situation, appropriate adherence lifestyles to medication should be strengthened to improve glycaemic control.

Regarding physical activity compliance and glycaemic control, the study indicates no significant association between following exercise plan of at least 30minutes and glycaemic control levels of participants ($p = 0.547$). This finding is inconsistent with the study conducted by Al-Hayek *et al*. (2012) and Faria *et al.* (2013), which demonstrated that, adherence to physical activity is associated significantly with glycaemic control. Healthy lifestyles which include exercises are the most essential non-pharmacological ways by which type 2 diabetics may improve their blood glucose levels significantly. Physical activity regimen adherence has been demonstrated to lower glycaemic levels by increasing insulin sensitivity as well as reducing weight (Colberg *et al*., 2010). The blood glucose levels can fall during exercise because of increased utilization of glucose as a fuel during the physical activity and uptake of sugar into the active muscles (Al-Hayek *et al*., 2012).

Although engaging in exercise is considered as one of the critical pillars of diabetes self-care, the achievement of this target is most often confronted with challenges as the disease

progresses. This implies that physical activity regimen should be personalized to meet individual's disease status to achieve the desired outcomes.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

The study findings established that higher proportions (78%) of the participants have received one or more forms of diabetes self-care management education. The study found a higher compliance to medication prescription among majority (79%) of participants and relatively low (18.3%) to lower (6%) compliance to diet and physical activity respectively. Factors such as forgetfulness, bitterness of drug, pains from insulin injection, and financial constraints are identified as key barriers to medication compliance. Restrictive diet, financial constraints, small portion sizes and lack of support among other factors are major barriers to dietary compliance whereas fatigue, laziness, pain in limbs, ill-health and lack of knowledge are found to be key barriers to physical activity. The study however found no significant association between compliance to diet, physical activity, medication prescriptions and fasting blood glucose levels.

6.2 RECOMMENDATIONS

The following recommendations are proposed based on the knowledge acquired through this study:

1. Further studies should also be carried out in the teaching hospitals with well-established diabetes clinics to assess and ascertain the impact of the recommended diabetes self – care management practices on the glucose levels of the patients.

2. Since compliance to dietary and physical activity was relatively low, there is the need to re-strategize and re-intensify diabetes self-care management education with emphasis on the non-pharmacological components to help improve

compliance as well as the attainment of glycaemic goals among type 2 diabetes patients.

3. For effective self-care management and adherence to diabetes self-care management educations, it is recommended that nutrition professionals knowledgeable in medical nutrition therapy should be engaged at the various diabetes clinics to help diabetics manage their condition.

4. It is also recommended that people living with diabetes should be assisted and supported by both the health facility and immediate family relations to overcome diabetes management related barriers to ensure quality of life.

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APPENDIX A

QUESTIONNAIRE ON EFFECTIVE MANAGEMENT OF TYPE 2 DIABETES: COMPLIANCE, BARRIERS AND EFFECT ON GLYCAEMIC CONTROL OF ADULT TYPE 2 DIABETICS ON OUTPATIENT DEPARTMENTS IN SUNYANI MUNICIPALITY, GHANA.

ID_____ Mobile_____

DEMOGRAPHIC INFORMATION

1. Age [ ] Gender: 1 [ ] F 2[ ]M
2. Ethnicity: 1[ ] Akan 2[ ] Ga 3[ ] Ewe 4[ ] Dagomba 5[ ] Gonja 6 [ ] Frafra others specify_____
3. What is your language of preference? _____
4. Marital Status: 1[ ]Single 2[ ] Married 3 [ ] Divorced 4[ ] Widowed
5. Religion:1[ ]Christian 2[ ]Muslim 3[ ]Traditional. Others specify_____
6. Are you currently employed?1 [ ] YES 2[ ] NO
7. What is your occupation?1[ ] Public servant 2 [ ] Trader 3 [ ] Farmer 4[ ] Artisan 5 [ ] Unemployed. Others specify_____
8. What is the last grade of school you have completed? 1[ ] Not been to school 2[ ] Primary3 [ ] middle school 4 [ ] secondary 5[ ] Postsecondary 6 [ ] Tertiary 7[ ] informal education.
9. Are you on insurance?1 [ ]YES 2 [ ]NO

Diabetes History and Knowledge

10. How long have you been living with Diabetes? _____

11. Have you ever received diabetes care education at this facility?1 [ ] Yes 2[ ] No

12. Which components of diabetes care education have you received? _____

Diet/Nutrition

13. Have you received education from your health care provider about importance of diet to the management of your condition? 1[ ] yes 2[ ] no 3[ ] not sure

14. Do you have a meal plan for diabetes? 1 [ ]Yes 2[ ] No

15. How often do you follow a meal plan or diet 1 [ ] never 2[ ] sometimes 3[ ] always

16. What are the challenges/barriers that make the following of the dietary regimen very difficult?_____

Physical Activity

---

17. Have you been educated to exercise for at least 30min per day (approximately 150minutes per week)? 1[ ] Yes 2[ ] No

18. How often do you exercise for at least 30minutes 5times per week? 1[ ] never 2[ ] sometimes 3[ ] always

19. What are the challenges/barriers that make physical activity very difficult to do?

_____

Using Medication

20. Have you received education from your health care provider on your medications?

1[ ]Yes 2 [ ]No

21. Are you currently taking diabetes medicine(s)? 1[ ]Yes 2 [ ] No

22. How often do you follow your medication schedules? 1[ ] never 2 [ ] sometimes

3[ ] always

23. Are you currently taking other medicine(s) aside your diabetes one(s)?

1[ ] Yes 2[ ] No. For what condition (s)? _____

24. What are your challenges in complying with your routine medication taking?

_____

Biochemical Data

FOLLOW-UP VISITS PER PARTICIPANT WITHIN THE FACILITY	**FASTING BLOOD GLUCOSE IN mmol/L**
1. (current)	
2. Previous visit	
3. Previous visit	
AVERAGE	

APPENDIX B

Participant Information Leaflet and Consent Form

This leaflet must be given to all prospective participants to enable them know enough about the research before deciding to or not to participate

Title of Research: The effective management of type 2 diabetes: compliance, barriers and effect on glycemic control of adult diabetics on outpatients department in the Sunyani Municipality of the Brong Ahafo region, Ghana.

Name(s) and affiliation(s) of researcher(s): Mrs. F. O. Mensah, Dr. P.K Brown ;College of Science, Dept. of Biochemistry and Biotechnology and Kwadwo Ansong, student of the Dept of Biochemistry and Biotechnology.

Background (Please explain simply and briefly what the study is about):

According to Amoah and colleagues, people living with type 2 diabetes in both rural and urban areas of West Africa were generally few except Ghana, where a high prevalence rate of 6.3% was reported a decade ago(Amoah *et al*., 2002).

The current trend in rural diabetes prevalence across the globe is increasing with faster growth in rural areas in low and middle income countries than high income countries (Zabetian *et al*., 2014). However, facilities and systems of diabetes care management were very unsatisfactory (Amoah *et al*., 1998).

It is estimated that 50% of people living with diabetes are not achieving satisfactory level of glycemic control which results in accelerated development of complications and increased deaths despite the effective management strategies put in place (Sham and Barakat, 2010).

The study will ascertain compliance and barriers to effective diabetes management practices and its impact on the glycemic control of patients.

Purpose(s) of research:

To ascertain the effectiveness of the management of T2DM in Sunyani Municipality, Brong Ahafo Region.

Procedure of the research, what shall be required of each participant and approximate total number of participants that would be involved in the research:

Semi - structured questionnaire would be administered to participants to respond appropriately. Less than 1ml of blood would also be taken from each participant and participants are required to participate in the study once.

Risk(s):

Since blood collection is involved, some discomfort may occur when participant is pricked with the needle. Taking blood sample might cause temporary local discomfort, soreness, redness, swelling or rarely, infection. These reactions usually last only a short time (1-3 days). The risk of infection will be minimized by the use of sterile, single-use needles. Experienced, skilled staff will obtain your blood sample.

Benefit(s):

- The findings of this research will equip doctors, nurses, dieticians, diabetes educators and other health professionals involved in diabetes management to deliver quality diabetes care.

- The result of the study will be made know to participants to help manage their conditions effectively.
- The findings of the study will be used to educate patients during their periodic visits to the facilities and during their monthly diabetes association meetings.

Confidentiality:

Any piece of information gathered will be mainly for the purposes of the research and shall not be used for other purposes. All participants' information shall be kept safe and no name will be documented. However, as part of our responsibility to properly conduct this study, we may allow officials from the ethics committees to have access to the records. No name or identifier will be used in any publication or reports from this study.

Voluntariness:

Participating in this research should be out of your own volition. You are not under obligation to participate in this study. The study is solely voluntary.

Alternatives to participation: Participants have a choice to take part in this study, failure to do so will not affect you in any way in this hospital.

Withdrawal from the research: You may choose to withdraw from the research at any point without having to explain yourself. You may also choose not to answer any question you find uncomfortable or private

Consequence of Withdrawal:

There will be no consequence, loss of benefit or care to you if you choose to withdraw from the study.

Costs/Compensation: Results of individual would be made known to him/her if interested.

Contacts: Please contact Kwadwo Ansong on 020 8238572 / 0242972966 on any question concerning this study.

Further, if you have any concern about the conduct of this study, your welfare or your rights as a research participant, you may contact:

The Office of the Chairman

Committee on Human Research and Publication Ethics

Kumasi

Tel: 0322063248 or 0205453785

CONSENT FORM

Statement of person obtaining informed consent:

I have fully explained this research to _____ and have given sufficient information about the study, including that on procedures, risks and benefits, to enable the prospective participant make an informed decision to or not to participate.

DATE: _____ NAME: _____

Statement of person giving consent:

I have read the information on this study/research or have had it translated into a language I understand. I have also talked it over with the interviewer to my satisfaction.

I understand that my participation is voluntary (not compulsory).

I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it.

I understand that I may freely stop being part of this study at any time without having to explain myself.

I have received a copy of this information leaflet and consent form to keep for myself.

NAME:_____

DATE: _____ SIGNATURE/THUMB PRINT: _____

Statement of person witnessing consent (Process for Non-Literate Participants):

I _____ (Name of Witness) certify that information given to

_____ (Name of Participant), in the local language, is a true reflection of what l have read from the study Participant Information Leaflet, attached.

WITNESS' SIGNATURE (maintain if participant is non-literate): _____

MOTHER'S SIGNATURE (maintain if participant is under 18 years): _____

MOTHER'S NAME: _____

FATHER'S SIGNATURE (maintain if participant is under 18 years): _____

FATHER'S NAME: _____

APPENDIX C

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF MEDICAL SCIENCES / KOMFO ANOKYE TEACHING HOSPITAL
COMMITTEE ON HUMAN RESEARCH, PUBLICATION AND ETHICS

Our Ref: CHRPE/AP/210/14

20th June, 2014.

Mr. Kwadwo Ansong
Post Office Box 1884
SUNYANI.

Dear Sir,

LETTER OF APPROVAL

Protocol Title *"The Effective Management of Type 2 Diabetes: Compliance, Barriers and Effect on Glycemic Control of Adult Type 2 Diabetic Out-Patients in the Sunyani Municipality, Brong Ahafo Region of Ghana".*

Proposed Site: *Brong Ahafo Regional Hospital and Municipal Hospital, Greenhill Clinic, Kenam Clinic, Sunyani Municipality.*

Sponsor: *Principal Investigator.*

Your submission to the Committee on Human Research, Publications and Ethics on the above named protocol refers.

The Committee reviewed the following documents:

- A notification letter of 20th March, 2014 from the Department of Biochemistry and Biotechnology seeking permission from the Municipal Hospital, Sunyani (study site) and which was approved.
- A notification letter of 20th March, 2014 from the Department of Biochemistry and Biotechnology seeking permission from the Achereko Memorial Hospital (study site) and which was approved.
- A notification letter of 20th March, 2014 from the Department of Biochemistry and Biotechnology seeking permission from the Brong Ahafo Regional Hospital (study site) and which was approved.
- A notification letter of 20th March, 2014 from the Department of Biochemistry and Biotechnology seeking permission from the Greenhill Hospital (study site) and which was approved.
- A completed CHRPE Application Form.
- Participant Information Leaflet and Consent Form.
- Research Proposal.
- Questionnaire.

The Committee has considered the ethical merit of your submission and approved the protocol. The approval is for a fixed period of one year, renewable annually thereafter. The Committee may however, suspend or withdraw ethical approval at anytime if your study is found to contravene the approved protocol.

Data gathered for the study should be used for the approved purposes only. Permission should be sought from the Committee if any amendment to the protocol or use, other than submitted, is made of your research data.

The Committee should be notified of the actual start date of the project and would expect a report on your study, annually or at the close of the project, whichever one comes first. It should also be informed of any publication arising from the study.

Room 7 Block J, School of Medical Sciences, KNUST, University Post Office, Kumasi, Ghana
Phone: +233 3220 63248 Mobile: +233 20 5453785 Email: chrpe.knust.kath@gmail.com / chrpe@knust.edu.gh

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF MEDICAL SCIENCES / KOMFO ANOKYE TEACHING HOSPITAL
COMMITTEE ON HUMAN RESEARCH, PUBLICATION AND ETHICS

Thank you Sir, for your application.

Yours faithfully,

Rev. Prof. John Appiah-Poku.
Honorary Secretary
For: CHAIRMAN

Room 7 Block J, School of Medical Sciences, KNUST, University Post Office, Kumasi, Ghana
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