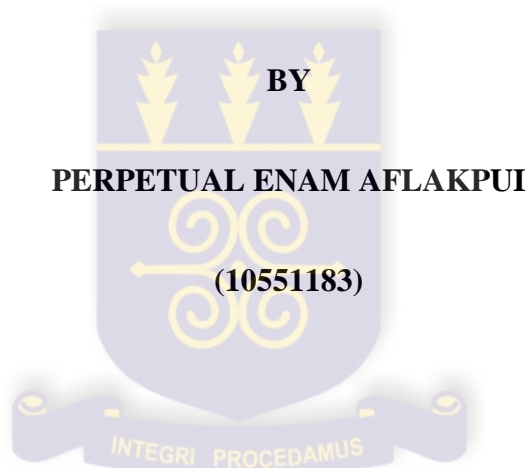


SCHOOL OF PUBLIC HEALTH

COLLEGE OF HEALTH SCIENCES

UNIVERSITY OF GHANA

**NON-ADHERENCE TO MEDICATION REGIMEN AMONG TYPE 2 DIABETES
MELLITUS PATIENTS AT TEMA GENERAL HOSPITAL**



**THIS DISSERTATION IS SUBMITTED TO THE UNIVERSITY OF GHANA,
LEGON IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE
AWARD OF MASTER OF PUBLIC HEALTH DEGREE.**

JULY, 2016

DECLARATION

I PERPETUAL ENAM AFLAKPUI confirm that this work submitted for review is my own work, under the supervision of DR. ADOLPHINA ADDO- LARTEY. I have made acknowledgement of other works cited in this dissertation. I declare that this dissertation has not been presented elsewhere, either in part or in whole for another degree.

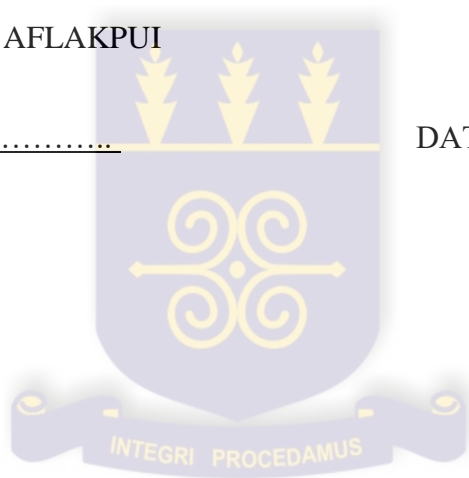
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ACADEMIC SUPERVISOR:

DR. ADOLPHINA ADDO-LARTEY

.....

DATE.....

SIGNATURE

DEDICATION

I dedicate this dissertation to my beloved family.



ACKNOWLEDGEMENT

I am grateful to the almighty God for His faithfulness and love.

I wish to express my gratitude to Dr. Addo-Lartey Addolphina my academic supervisor for her expert, sincere and valuable time, guidance and encouragement and the HOD of department of HPPM Dr. Reuben Esena for his timeless effort and continuous and unconditional support and assistance given me throughout the period. My sincere thanks go to all the lectures at the Epidemiology and Disease Control Department for their support. Without them this project would not have been a success.

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ABSTRACT

Background: Non-adherence to diabetic medication is one of the major public health challenges to diabetes management and poses a major risk factor for developing cardiovascular and other chronic diseases.

Objectives: This study sought to assess non-adherence to medication regimen among type 2 diabetes mellitus patients at the diabetic clinic at Tema General Hospital (TGH).

Method: A descriptive cross sectional study using quantitative method were employed. A structured questionnaire and Morisky Medication Adherence Scale (MMAS-8) were used to measure the levels of non-adherence to medications. Data were entered and analyzed using STATA version 13. The association between exposure variables and non-adherence were analyzed using cross-tabulation, and the significances were tested using Chi square. Crude and adjusted odds ratio (COR/ AOR) were used to determine the factors associated with medication non-adherence and a p-value less than 0.05 were considered statistically significant.

Results: Data were collected from 206 patients between the ages 24 to 90 years with a mean age of 59.1 years. The prevalence of non-adherence to medication was 47.6% among T2DM patients at the TGH. Non-adherence was found among males 52.8% between ages 60-69 years while females recorded 47.2%. Non-adherence to medication was mostly 71.4% (5/206) seen among the unmarried and 62.5% (25/206) was seen among unemployed.

Conclusion: Non-adherence to DM medication should be paid a particular attention and given intense education by the health providers to the patients and families. Patients' knowledge about diabetes is associated with higher adherence proportion and better glycemic control.

Key Words: Diabetes Mellitus, non-adherence to medication, T2DM, glycemic control.

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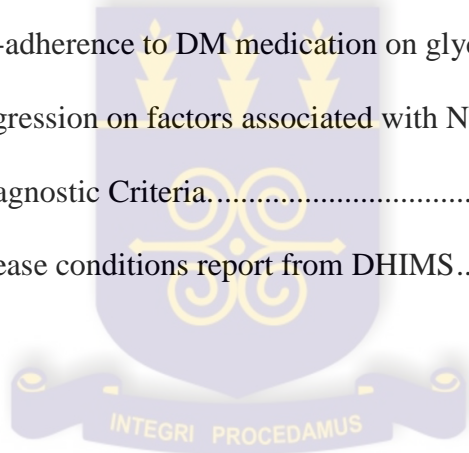
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LIST OF ABBREVIATIONS

AOR	-	Adjusted Odd Ratio
COR	-	Crude Odd Ratio
MMAS	-	Morisky Medication Adherence Scale
MPR	-	Medication possessing ratio
IDDM	-	Insulin Dependent Diabetes Mellitus
NIDDM	-	Non-insulin Dependent Diabetes Mellitus
OADs	-	Oral Anti-diabetic Drugs
OHA	-	Oral Hypoglycemia Agent
PGC	-	Poor Glycemic Control
T2DM	-	Type 2 Diabetes Mellitus
TGH	-	Tema General Hospital
WHO	-	World Health Organization
DHIMS	-	District Health Information Management System
DBP	-	Diastolic blood pressure
SBP	-	Systolic blood pressure

DEFINITIONS OF TERMS

MMA8: A scale used to measure adherence level among patients who are on medications.

Medication regimen: A systematic plan of medication intake.

Glycemic control: Are typical levels of blood glucose in a person with diabetes mellitus.

Fasting blood glucose: A test that most commonly used to diagnose diabetes or a test that measures blood glucose levels after a period of fasting for at least 8 to 12 hours.

Non-adherence to medication: Not taking medication intentionally or non-intentionally.

Oral hypoglycemic agents: Oral anti-diabetic drugs that lowers glucose level in the blood which is taken by mouth.

Non-adherence to medication level: The level at which a test can detect whether a medication is taken or not.

Pill Burden: The number of pills (tablets or capsules) that a patient takes on a regular basis, along with all associated efforts that increases with the number of pills ingested and also understanding the different medications in one's regimen.

CHAPTER ONE

INTRODUCTION

1.1 Background

Diabetes Mellitus is a chronic disease that occurs when insulin production is compromised or the insulin produced cannot effectively be used by the body. Insulin is a hormone that regulates glucose production in the body.

Diabetes medication non-adherence is the patient's passive failure to follow the prescribed treatment regimen (Latif and McNicoll, 2009). Diabetes medication adherence demands the patient's compliance with the provider's recommendation with respect to timing, dosage, and frequency of medication during the prescribed length of time. It is an integral component in the treatment regimen of diabetic patients. Diabetes non adherence has intense implications on the patient as well as on the doctor-patient relationships and interactions, plans of care and healthcare system.

Diabetes global morbidity and mortality have been estimated to be 387 million and 1.5 million respectively (WHO, 2012). Additionally, more than 80% of these deaths occur in the low income countries.

Two major forms of diabetes mellitus are Type 1 which is known as insulin-dependent diabetes mellitus (IDDM) and Type 2 which is known as non-insulin dependent diabetes mellitus (NIDDM). IDDM is caused by failure for the beta cells of the islets of Langerhans in the pancreas and NIDDM is caused by insulin resistance due to few insulin receptors (Parving et al., 1992).

IDDM can be caused by genetic predisposition, environmental factors such as nutrition, having contacts with viruses and allergens and autoimmunity leading to destruction of insulin-producing pancreatic beta cells (Naqvi et al., 2009). NIDDM can be caused by combination of resistance to insulin action, inadequate insulin secretion and excessive or inappropriate glucagon secretion requires insulin injection to prevent ketosis and other complications.

Medication non-adherence among diabetes mellitus patients is one of the major public health challenges and poses a major risk factor for developing cardiovascular, other complications and chronic diseases. This results in increased family and societal burdens (Awodele & Osulale, 2015). Thirty to fifty percent of the patients do not adhere to medication resulting in sub-optimal treatment (Adisa et al., 2014). Challenges in education and the knowledge regarding diabetes might affect the diabetic patient's adherence to their medication regimen (Al-Qazaz et al., 2011).

The rapid growth and westernization of lifestyle, rapidly decreasing physical activity, changes in dietary habits as well as the ageing of the African population contributes to the diabetic burden (Doherty et al., 2014). Compounding these is lack of national diabetes programmes in most countries, medications unavailability and unaffordability, lack of well-structured educational programmes and health professionals. According to WHO report (2015), Africa recorded 80% mortality from diabetes mellitus and this is projected to rise 7.1% by 2030.

In Ghana, Bruce et al, (2015) reported 6.8% of all admission are attributable to diabetes mellitus and 7.8% of all mortalities are attributable to diabetes mellitus in one of the

premiere teaching hospitals in Ghana. Similarly, diabetes is ranked among the top 10 hospital admissions and mortality at Korle Bu Teaching Hospital (Korle Bu Annual Report, 2013).

Based on the annual report on diabetes mellitus at the Tema General Hospital. Diabetes is also ranked among the top 10 hospital cases both OPD, admissions and mortality. Diabetes mellitus had increasing total morbidity proportions, out of 314,061 total morbidity cases in 2013, diabetes mellitus was 16,679 (9.1%) ranked the fourth and out of 318,100 total morbidity cases in 2014, diabetes mellitus was 24,645 (14.4%) ranked the third among the top 10 top cases Table 12.

Despite many efforts to help curb the diabetes mellitus related complications and non-adherence to medications, only little progress was made. The purpose of this study therefore is to assess the factors influencing non-adherence to medication regimen among people with type 2 diabetes mellitus patients at Tema General Hospital. The results of this study would be used to inform interventions aimed at improving medication adherence to diabetes medication among diabetes.

1.2 Problem Statement

Diabetes mellitus is a global health burden as a result of its increasing prevalence and associated complications, leading to premature mortalities. Evidence has shown that there are 4.6 million diabetes mortality cases accounting for 8.2% of global deaths and an estimation of 366 million adults living with diabetes mellitus (Leone, et al 2012). Furthermore, it has been noted that out of 387 million diabetes cases worldwide, Africa has 80% mortality WHO (2015) and it is expected to rise in 2030 by 7.1%. Leone et al.,

(2012) estimated that 82.5% of people will develop diabetes in middle or high income countries by 2030.

Non-adherence to prescribed diabetes medication is a major reason for poor glycaemic control in developing countries which results in high morbidity and mortality. It is therefore not surprising that 450,000 Ghanaians are diabetic (IDF, 2014). Diabetes is one of the top 10 causes of OPD hospital attendance at Tema General Hospital (Appendix iv) with an increasing morbidity and mortality proportion in females compared to males as a result of non-adherence to medication (WHO, 2014). According to Whiting, Hayes and Unwin (2003), effective adherence in specific medication results in better treatment outcome. However the Diabetic clinic reported an increasing hospital attendance from 2010 to 2015. There are no data on the factors contributing to the increase. This study assessed the non-adherence to medication among T2DM at TGH.

Management of diabetes include prolonged use of pharmacotherapy which combats diseases and their full remunerations are not frequently seen. WHO, (2003) reported that about 50% of patients do not take their prescribed medications. Non-adherence to diabetes medication can cause therapeutic failure leading to poor treatment outcomes and complications such as cardiovascular disease, neuropathy, retinopathy, kidney failure, sexual impotence and diabetic foot gangrene leading to amputation (Jackson et al., 2015; WHO, 2015), due to poor glycaemic control due to non-adherence to medication. IDF, (2015) quickens the development of long-standing complications which as a result leads to increased hospitalization and mortality (Munger, et al 2007). Medication adherence is therefore crucial as an integral component in diabetes management.

This study therefore seeks to assess non-adherence to medication regimen among type 2 diabetes mellitus patients at the Tema General Hospital in order that interventions may be designed to improve medication adherence among diabetes mellitus patients.

1.3 Research Questions

1. What is the prevalence of non-adherence to medication regimen among type 2 diabetes mellitus patients who attends Tema General Hospital?
2. What are the factors that influence non-adherence to medication among type 2 diabetes mellitus patients?
3. What are the effect of non-adherence to diabetes mellitus medication on glycemic control?

1.4 Objectives

1.4.1 General objectives

To assess non-adherence to medication regimen among type 2 diabetes mellitus patients at Tema General Hospital.

1.4.2 Specific objectives

1. To determine the prevalence of non-adherence to medication regimen among type 2 diabetes mellitus patients who attends Tema General Hospital.
2. To assess the factors that influences non- adherence to medication among type 2 diabetes mellitus patients.
3. To determine the effect of non- adherence to medication on glycemic control.

1.5 Conceptual framework

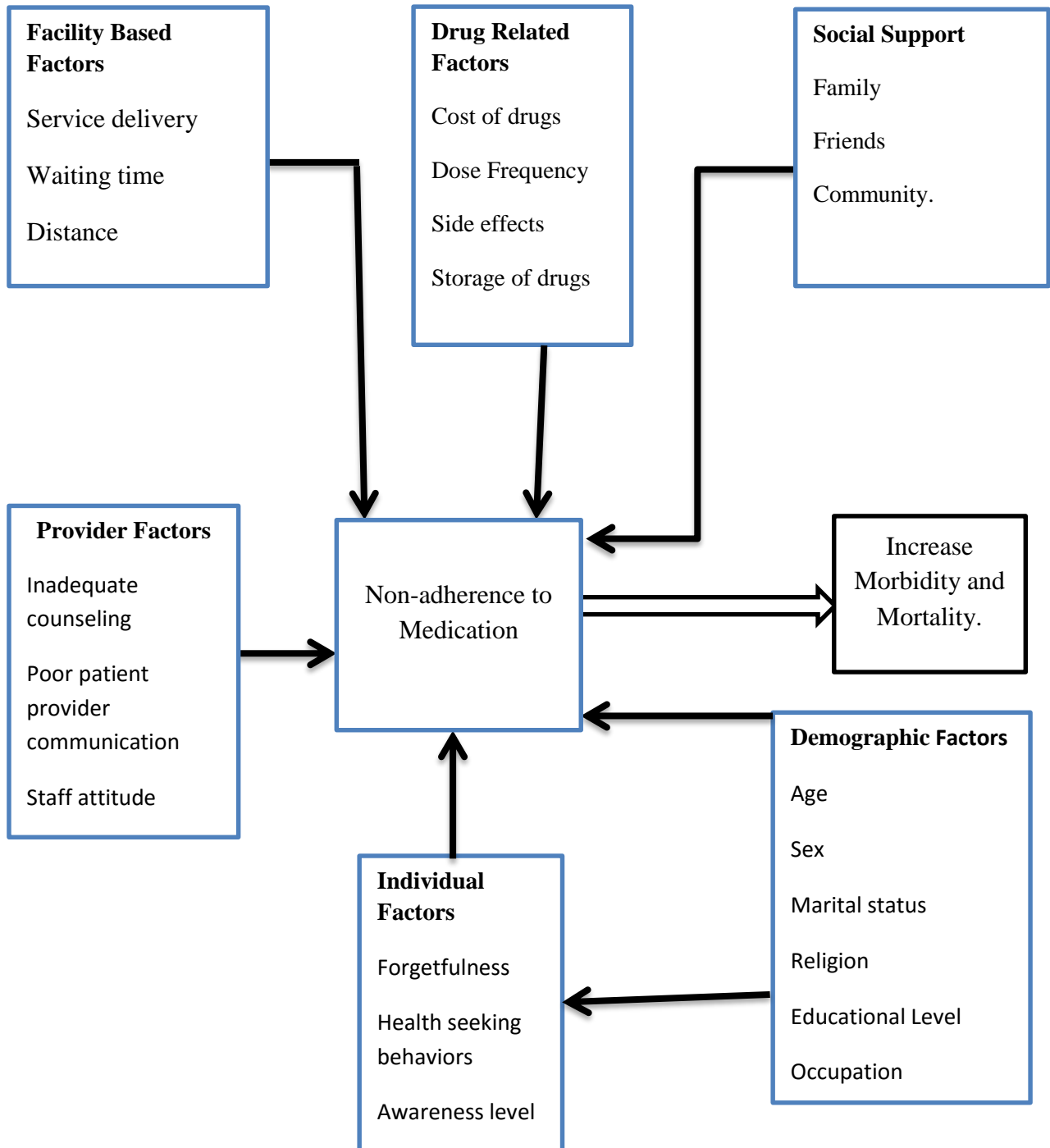


Figure 1: showing the conceptual framework on factors influencing non-adherence to medication regimen among people with T2DM.

1.6 Narrative

As shown in Figure 1, the factors that affect non-adherence to diabetes mellitus medication regimen are categorized into six main groups; demographic characteristics, facility based factors, provider's factors, drug related factors, social support and individual factors.

At the facility setting, negative attitude of the health providers (staff), inadequate or bad service delivery and long waiting time can affect non-adherence to medication, however, consistently development of confidential and trusting relationship with the patient may improve adherence remarkably (Kalyango et al., 2008b). Transportation cost is directly related to distance. The closer the facility is to the patient, the less the cost required to reach it. Patients who must travel long distances to the clinic or private pharmacies are often not able to raise the money required to meet the transportation cost (Adisa, et al., (2009).

Freeman et al., (2012) explored another important patient (individual) factor which has an impact on non-adherence: namely, a person's 'beliefs' and knowledge about the need for medication (awareness level) and concerns about negative side-effects. Based on these two concepts, the patient will make a determination on whether to take the medication or not. Demographic characteristics also affect non-adherence to medication. According to (Boyce, 2009) there was a higher proportion of non-adherence among married women as compared to single (unmarried) women. Low educational level can interfere with understanding of the disease and medication to some extent. In a study by Divya & Nadig (2015) showed that the risk of non-adherence is very high when patients cannot read and

understand basic written medical instructions, other patient related factors, non-adherence to dietary and physical activity are advice.

Non-availability of social support can as well influence non-adherence, when patient have friends and families who offer support in diverse ways and such help is absent, causes patients to non-adherence to medication regimen. Also drug related factors adversely interfere with non-adherence to medication regimen, since the cost of medication may affects patients ability adhere to medication regimen (Adisa et al., 2009). Fatigue related to having to routinely take medication may results in frustration and deliberate rejection of medication.

Provider related factors such as health worker absenteeism and poor communications between health worker and patient affect patients' understanding to medication regimen and adherence to medication resulting in increased morbidity and mortality.

1.7 Justification

The purpose of this study is to determine non-adherence to medication, explore factors that influence non-adherence and also determine the effect of non-adherence to medication on glycemic control.

Non- adherence to medication among T2DM has become rampant and it is associated with adverse health outcomes due to inadequate knowledge and awareness about the importance of medication adherence in the management of diabetes. However, according to Divya et al., (2015) patient education is a key role in the improvement of non-adherence proportion among diabetes patients. The findings from the study would help provide necessary information for policy makers on the burden and factors that influence

non-adherence to medication among T2DM patients. Furthermore, this could provide relevant information for interventions needed to improve medication adherence by improving the health care system and provide health education to patients, the hospital, their families, community and the entire country. This would also broaden the understanding of medication regimen and the benefit of adherence.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This review examined the prevalence of non-adherence, factors that contributed to non-adherence and the effects non-adherence had on glycemic control. This chapter also reviewed studies on non-adherence to medication regimen among type 2 diabetes mellitus patients. These are presented as follows:

2.2 Diabetes Mellitus as a Global Burden

Diabetes Mellitus is a metabolic disorder characterized by chronic hyperglycemia and disorders of carbohydrates fat and protein metabolism resulting from defects of pancreas producing insulin or the body inability to utilize insulin (Ozougwu, 2013).

According to May, (2013), studies projected that the incidence of diabetes tend to rise up 64% by 2025, meaning that surprisingly 53.1 million citizens will be affected by the disease. Zhang et al., (2010) also estimated the worldwide prevalence of diabetes among adults in 2010 was 285 million (6.4%) and this value is also predicted to rise to around 439 million (7.7%) by 2030. The effects of diabetes mellitus on mortality and morbidity has drawn the attention of the healthcare community to the need of effective management.

T2DM is the most prevalence type of diabetes. It appears later in life and it is due to the combination of insulin resistance and defective secretion of insulin by pancreatic beta cells. Diabetes mellitus is a global burden and it is a common endocrine disease found in the world. People with diabetes mellitus suffer premature mortalities (Butt,et al 2015).

An estimated 347 million of people living with diabetes globally (WHO, 2012). The prevalence of diabetes is increasing rapidly worldwide and it has been predicted that by 2030 the number of people living with diabetics would be doubled worldwide, from 177 million in the year 2000 to 370 million in the year 2030 WHO, (2003).

There are two main types of diabetes mellitus: Type 1 diabetes, which is also called insulin dependent diabetes mellitus (IDDM), is caused by autoimmune destruction of beta cells of the pancreas which produces no or inadequate insulin. While Type 2 diabetes is also called non-insulin dependent diabetes mellitus (NIDDM), is caused by decreased sensitivity of target tissues to insulin. In both types of diabetes mellitus, metabolism of food is altered.

Complications of IDDM can be diabetic ketoacidosis, retinopathy, infection, nephropathy, diabetic foot ulcer (Holt, 2004). Diabetic foot ulcer occurs when there is ulceration when there is a neuropathic damage or complete loss of feeling in the foot or leg (peripheral neuropathy) often leads to ulceration in the limb amputation. Skin disorders are also common in diabetes (Holt, 2004). There have been various approaches in the management of diabetes mellitus.

The management of diabetes mellitus includes pharmacotherapy and non-pharmacotherapy such as dietary changes and lifestyle modifications. Pharmacotherapy of T2DM is with either oral anti-diabetic drugs (OADs) or insulin (Ozougwu, 2013).

2.3 Pharmacological Management of Diabetes Mellitus

Insulin therapy

Normal glucose level suppresses ketogenesis by delaying diabetic complications. It stimulates the synthesis of glucokinase and moderates gluconeogenesis. Some common side effects of insulin therapy are weight gain, allergy, skin reaction, hypoglycemia, visual disturbance, insulin resistance due to antibody reaction. Socioeconomic factors can be contributing factors to availability or inaccessibility of insulin in health facilities (Hall et al., 2011).

Adherence proportions were assessed among three studies using insulin were comparable due to the different methods of analysis. A retrospective study showed a mean of only 24% of new adults with T2DM who are insulin users (Horne et al., 1999).

Adherence proportions were seen to be lower among insulin users and higher among oral hypoglycemic agents (OHA) users (Horne et al., 1999). A study by Ciechanowski et al., (2000) who followed a cohort of newly diagnosed diabetes patients who were started on insulin. However, 80% of the patients persisted with insulin therapy for only 24 months and 20% were found to be non-adherent to insulin medication than patients who were put on OHA by discontinuing their medication in the second year of follow up.

This systematic review by Herman WH, (2005) showed diabetes patients do not adhere to their prescribed medication. Surprisingly few studies confirmed that the proportions of adherence with OHA was 36 to 93% in both retrospective and prospective studies.

The persistence intake of OHAs from 6 to 24 months suggested that shortage of the diabetes medications was a major issue that could lead to complications. Persistence

intake of drug often less than a year even with good adherence to medication, patients still require insulin one way or the other most especially with T2DM.

Horne et al., (1999) evaluated good adherence level of T2DM patients who receives insulin therapy are 63%. A cohort study showed that only 80% follow prescribed insulin medications persistently for two years despite the need for long term glycemic control as well as increase hospitalization on developing complications of diabetes Swaby et al., (2001).

Oral Hypoglycemic Agents (OHA)

Oral hypoglycemic agent are drugs used in the management of diabetes mellitus by lowering high glucose levels in the blood and also in the treatment of diabetes when there is a resistance or defect in insulin secretion by the pancreatic beta cells.

Sulfonylurea (Glibenclamide) is used in T2DM because it has functional beta cells for endogenous insulin production. The side effect of sulfonylurea is hypoglycemia and weight gain due to hyperinsulinemia. Therefore weight gain could be a cause of medication failure (Melikian et al., 2002).

Increase hepatic insulin sensitivity thereby reducing intestinal absorption of glucose production by the liver reduces glucose production by the liver. These includes; Metformin is an agent that lowers blood glucose by decreasing hepatic glucose production and increases muscle glucose intake. It also decreases plasma triglyceride and low density lipoprotein (LDL).

Metformin can be used as a single or in combination with sulfonylureas in the management of T2DM. Its side effect is weakness, easy fatigability, shortness of breath,

nausea and kidney toxicity (Richard, 2005). Another type of OHA is the Herbal therapy such as green tea also known as Calmette-Guerin. It is a nonspecific immunostimulant which has been shown to reduce extended remission in newly diagnosed patients by unknown mechanism. Many pharmaceutical drugs are derived from plants that were first used in traditional system of medicine. According to WHO, (2003), 25% of medicines are derived from plants (Gordon, 1983). More knowledge has been channeled towards traditional medicine and this knowledge has shown useful tool in the search for new plants based medicines. Studies by Awanish et al., (2013) have shown that there are about 250,000 species of medicinal plants and less than a quarter have hypoglycemic activity.

2.4 Non-pharmacological Management of Diabetes Mellitus

Self-management behavior with emphasis on Self-monitoring of blood glucose (SMBG) was found to be extremely low as more patient were aware of SMBG for their regular diabetes checkup and also for prompt detection of instabilities in their glucose levels. A study done in US showed that diabetes patients never monitored their glucose level due to the cost of the blood glucose monitoring device. This happens especially in the developing countries both low and middle countries and this was as a results of low awareness level among the diabetes patients. SMBG could mean that there is dynamic commitment of patient to his or her diabetes management.

Management of type 2 diabetes in a study by Koro et al., (2004) indicated that adequate exercise and dietary control plays a substantial role in controlling glucose level but many of them do not understand the essence of these non-drug therapies in the management of type 2 diabetes. However, this implied that many patients would not adhere to dietary and

lifestyle modifications acclaimed by their health care providers. An arbitrary survey study had reported that adherence to diet and exercise regimen is often suboptimal in people with T2DM (Koro et al., 2004).

Diet therapy

Dietary approach is appropriate for diabetes mellitus patients. Meal and diet modification are required to meet patients' needs and lifestyles. A conventional approach would recommend a diet composed of 60 – 65% carbohydrate, 25- 35% fat, and 10- 20% protein with little or no drinking of alcohol (IDF 2006).

Vegetables are among the numerous plant adjuncts that serves as a hypoglycemic agents. Examples are green leafy vegetables, beans, and tubers. However, the experiment was carried on animals and human to identify the hypoglycemic agents in vegetables.

Acupuncture is effective in treating diabetes and preventing complications. It acts on the pancreas to enhance insulin synthesis, increase the number of receptors on target cells and increase the utilization of glucose resulting in lowering of blood glucose. It also has an anti-obesity effect which is a risk factor for T2DM. It has a major therapeutic effect which acts on multiple organ system in lowering the glucose level. However, hot- tub has been recommended for T2DM patients who are unable to exercise since it has effects on skeletal muscles and also help in weight reduction.(Schmitt et al., 2013)

2.3 Adherence to diabetes medication

Medication adherence is termed as taking medication as prescribed by a health worker without any form of noncompliance. In one retrospective study, Cramer (2004) reported that medication adherence proportion among T2DM patients aged 50 and above on OHA's was 79 to 85%. In the same study once daily medication regimen was found to

have a higher adherence proportion than twice daily medication regimen. Dzeii et al., (2015) reported that patient on monotherapy regimens have higher proportion of adherence than polytherapy regimen. In another study, (Caren et al., & Chang, (2013) indicated that patient who switch from multiple medication intake to single medication have higher adherence proportions. In comparing adherence proportions between patients on insulin treatment and OHA, Brown et al., (1999) in a retrospective study found that adherence proportions was lower for insulin users than for OHA users. A ten year follow up also found that newly diagnosed T2DM patients on insulin usage, discontinued the treatment in 2 years of follow up. The available evidence points to a better medication adherence proportion among patients on OHA or take prescribed oral medication than those on insulin.

2.4 Non-adherence to diabetes medication.

Medication non-adherence is a patient's failure to follow an ordered plan for therapy. It remains a significant concern and an increasing problem for healthcare professionals and patients. Failure to adhere to medication leads to complications of the diabetes mellitus disease, high cost of health care and increase proportions of mortality.

There are several types of non-adherence which can be categorized as primary, non-persistence, non-conforming. Primary means any prescriptions given to patients by the health care provider, the medications has neither been bought or started (Gellad et al., 2009).

A second type of non-adherence is non-persistence to medications simply means patients stops taking medications abruptly without any medical advice. This could be as a results

of medication side effect, awful taste or when patient feels the diabetes has been controlled. Non-persistence can be intentional non-adherence which happens when there is a miscommunication between patients, the health care provider and the management plan. It could be as a result of one's belief and attitude that affects patient's motivation to begin the medication regimen. Non-persistence can be unintentional non-adherence which happens when there are restrictions or there are barriers preventing patients from following medication therapy. For example distance, waiting time, cost of drug, dose frequency, side effects, staff attitude and forgetfulness.

Thirdly, non-conforming, as another type of non-adherence. It is when medications are not been taken the way it has been prescribed. This can be skipping doses, taking medications at an inappropriate times or in correct dosage that is taking over dosage or under dosage prescribed medications (Osterberg & Blaschke.,2005). The extent of non-adherence to medication is recorded as low as 10% and as high as 92% in a study reviewed by Ciechanowski et al., (2000). Studies Jackevicius et al., (2002) revealed that 50% adherence to medication was observed. These could either be intentional or unintentional non-adherence. Mostly adherence proportions are higher among patients with acute diseases as compared to those with chronic diseases. This is because chronic diseases are being managed for a long time or forever whiles the acute diseases are managed for a short duration. Morris et al., (2012) studies reveals that the outcome of non-adherence to medication is waste of medication, reduction of functional abilities, lower quality of life and increase use of medical resource such as nursing homes, hospital admission (Kalyango et al., 2008a).

Morris et al., (2012) economic studies reveals that non- adherence to medication results to serious health outcome and death.

Munger et al.,(2007) discovered patient's non-adherence to medication is often associated with poor glyceimic control, thereby affecting the development of further vascular disorders such as heart failure, coronary heart disease, renal insufficiency, and stroke.

Non-adherence to diabetes medication regimen is the most common reasons for developing adverse diabetes complications (Fedrick et al., 2012) and proportions of non-adherence are relatively high across disease states, treatment regimens, and age groups. Treatment discontinuation often starts in the first few months following treatment commencement. Luyster et al.(2000) stated that non-adherence to medication poses a significant burden to healthcare usage. Munger et al., (2007) added that from one third to two thirds of all medication related hospital admissions are attributed to non-adherence.

The occurrence of depression appears to be accompanying with the manifestation of diabetes. Thomas Willis (1684), a Physician first recognized glycosuria as a sign of diabetes and he stated that diabetes resulted from "*sadness or long sorrow*".

Studies by Morisky et al., (2008) showed that non-adherence can be deduced from observing medication organizations such as pill counts, and refill history thus using information on the refill date and quantity of medication dispensed printed on the label. The reasons why people do not adhere to medication regimens include forgetfulness, dose omission, cost of medication, and side effects of medication (Munger et al., 2007).

There is dearth of knowledge on the association between non-adherence to medication and outcome such as mortality. However, it would seem reasonable that non-adherence to

medication regimen among diabetes patients would worsen disease condition and leading to premature mortality.

2.5 Factors that influences non-adherence to Medication

There are factors that contribute to non-adherence, which negatively affects treatment outcomes. These factors are as follows:

2.5.1 Demographic characteristics and Non- adherence

Demographic characteristics such as age, sex, educational level, marital status, occupation have been documented in literature to be associated with non-adherence to medication among diabetes mellitus patients (Naranjo et al., 2011).

2.5.2 Age

Mandewo et al., (2014) reported that most elderly diabetic patients do not adhere to medication regimen as prescribed, possibly because they have difficulty injecting themselves with the insulin since they stay alone and as a result take under dose or overdose of the medication which results to non-adherence to medication. Old age has an association with non-adherence to medication since there is poor or reduction in reasoning or cognition (Borges et al.,2014).

Kalyango et al.,(2008a) conducted a study which showed patients between the ages 36 to 50 years have higher non- adherence proportion.

2.5.3 Sex

Adisa et al.,(2009) reported that male diabetic patients have higher tendencies of not adhering to medications as compared to the female diabetic patients. They are likely to

forget taking their medications than the female diabetic patient. This showed that there is an association between gender specific difference and non-adherence to medication.

Kalyango et al., (2008b) noted that women are three times increase in risk of becoming non-adherence to medication as compared to men.

2.5.4 Religion

Studies by Mandewo et al., (2014) showed that some patients do not take their medication because they believe that God can cure them from diabetes without taking their medication. Other patients claimed that there were no religious or cultural convictions on their adherence behavior. However, some believe that their culture prevented them from adhering to treatment recommendations particularly to drugs. They also admitted to have consulted apostolic faith healers to deliver them from diabetes. Again, some also admitted to have consulted traditional healers for treatment of the diabetes.

2.5.5 Educational level

Lack of education pose a challenge to understanding the nature of the disease and medications to be taken. Studies by Martin et al.,(2005) reported that non-adherence is very high when patients cannot read and understand basic written medical instructions.

Studies by Gimenes et al.,(2009) showed that medication adherence was improved among people with higher educational level.

2.5.6 Marital Status

Unmarried person were more likely to have poor glycemic control as a result of not adhering to medication than the married persons (Ali et al.,2012).

2.5.7 Occupation

Patients who adhere to their medication regimen are mostly the traders and also office workers while patients who do not adhere to medication are mostly the unemployed (Adisa et al., 2009).

2.6 Social factors

Studies by Mandewo et al., (2014) showed that patients mostly receive social support either from their children in terms of financial, material, moral and emotional support, their spouses and some from distant relatives.

However, those with social links are being supported by Governmental Organizations, whereas some are supported by their friends. In the absence of all these supports will lead to non-adherence to medication.

2.7 Facility Based factors and Non-adherence to medication

It involves lacks of accessibility, long waiting time, difficulty in getting drugs supplied, poorly developed health services, short consultations, unwelcoming attitudes from hospital staffs and also delay in the reimbursement of private health insurance as well as national health insurance scheme and lack of training of health care providers on managing chronic disease (WHO, 2013)

Unavailability of prescribed medication affects adherence. If the medication is available and not accessible by the patient on the national health scheme or private patients, adherence would be compromise. Availability of essential medicine is an issue in low or middle income countries (Saboor et al., 2013).

2.7.1 Distance

Diabetic patients might not adhere to treatment recommendations due to travel costs particularly those who travel long distances to the health care facilities. Mandewo et al., (2014) reported that lack of standardized syringes may lead to wrong dosage. Shortage of syringes at local clinics poses major problem since patients have to travel long distance to purchase medication from the hospital or from private pharmacies especially diabetes patients who live in rural areas.

2.7.2 Waiting time

In the Mandewo et al., (2014) study, assessing non-adherence to treatment among diabetic patients, they observed that there was no statistically significant association between waiting time and non-adherence to medication regimen. Although they noted that patients who bought their medication from private pharmacies than spending long waiting time at health facility were not encouraged to adhere to their medication regimen. There was no statistically significant association between the time last seen by a health worker and non-adherence to treatment recommendations.

2.7.3 Staff attitude

Poor health worker attitude towards diabetes patients such as unnecessary delay and disrespectful behaviors are factors that contributes to non-adherence to medication. Although health staff may show considerable care to diabetes patients, especially in ensuring that they are served early to prevent hypoglycemia, patients who are dissatisfied with the way they are treated by health staff may not adhere to their medication. Kalyango et al. (2008) found that speaking harshly to patients affects their medication adherence.

2.8 Individual Based Factors to Non-adherence to medication

Individual based factors such as forgetfulness, pill burden, financial constraints and travelling away from home are factors contributing to non-adherence to medication regimen.

Unwillingness of the side of the patient to accept the awful side effect of the medication could be lack of responsibility, lack of motivation, loss of hope in the diabetes therapy (Garber et al., 2013).

Patient's factors represents having knowledge about the disease, attitude, and perception. Mostly diabetics do not know when their blood glucose increases. However they either have little idea or no idea on the diabetes disease and finds it difficult to adhere to take their medications regularly and decides when to take their medications and also the need to take their medications. These however, leads to poor adherence or non-adherence to medication.

Some patient have little or no knowledge on the side effects of the anti-diabetic medication, they tend to pay little or no attention to their medications leading them to complications.

Non-adherence to medication could results when some patients belief herbal medications are more effective in controlling diabetes so little or no attention is paid to the orthodox medications and rather focus on taking herbal medication for the management of their diabetes until they start developing complications (King, 2008).

Non-adherence include the fear of having to be dependent on the medication for life, the medications are taken for some time by the patients, but discontinue medication intake realizing their glucose level is under control.

Low awareness of the diabetes disease leads patients not to adhere to medication. Some patients believed that the diabetes has been cured provided the blood glucose level has been controlled.

2.8.1 Forgetfulness

Wabe et al., (2011) indicated that some patients who take alcohol may forget to take their medication or may intentionally leave their medication due to the influence of alcohol.

Divya and Nadig, (2015) record states;

“That one of the three diabetic cases who died in January 2012, died because he used to forget to take his medication after drinking beer. The wife of the deceased who was his care giver also confirmed that the patient did not want to take his medication after consuming alcohol”.

Forgetfulness can also be permanent failure to remember to take medication. Depression has been associated with the progression of diabetes. As patients get depressed their ability to remember decreases and forgetfulness have shown to impair adherence to medication (Saboor et al., 2013).

Forgetfulness comes as a result of anxiety disorder reported by Hasan et al., (2015) that there is an association with non-adherence to medication.

2.8.2 Health seeking behaviors

In a review by Divya & Nadig (2015), they observed that taking herbal medications in addition to their prescribed orthodox medication contributes to non-adherence.

2.9 Provider's Factors

The physician-patient rapport plays a major role in keeping the patient informed about the medications he or she munches (Martin et al., (2005). Patients who do not have adequate information about their medication regimens are at a probable risk of non-adherence because they had not understood how to take their medication. Martin et al., (2005) study showed lack of knowledge about adverse drug reaction also affected non-adherence to medication. In the said study, patients' lack of knowledge about the importance of medication adherence was also observed to contribute to non-adherence.

2.9.1 Patient-provider communication

The Patient-provider relationship quality include the way health care provider communicate and build trust with their patients, relates to favorable adherence patterns among chronically ill patients.

Dimatteo et al., (2000) meta-analysis showed that communication is positively correlated with patient adherence and 19% higher risk of non-adherence was found among patient whose physician communicate poorly to them than among whose physician communicates well by (Martin et al., 2005).

Language barrier is also a contributory factor to medication non-adherence. Nurses or care givers are expected to interpret and explain what the doctor says to the patient. Communication between doctors and patients is vital for medication adherence, however,

when doctors fail to clearly explain what the patients should do or know, patients' adherence to medication might be compromised. Partnership between patient and physician is important when choosing management option to improve patients' medication satisfaction and reduces risk of non-adherence which promote good health outcome (Martin et al., 2005). In the Mandewo et al. (2014) study however, no significant association was established between patient-doctor communication and non-adherence to treatment recommendations.

Patients who did not understand their medication regimen had higher risk of non-adherence than those who really understand their medication regimen (Richard, 2005; Vermeire et al., 2009).

The use of more medication than clinically indicated. This can be due to prescribers doing symptomatic management or patient being managed by one or more prescribers. However to meet patients expectation more medications are prescribed and this leads to increase adverse reactions and low adherence (Austin, 2006; Harder et al., 2009).

2.10 Drug related factors

2.10.1 Cost of drugs

Diabetic drugs are expensive especially insulin and patients on insulin may not afford to maintain a regular supply thereby affecting their adherence to medication regimen. NHIS card bearers may however enjoy the luxury of treatment without having to pay for them (Kalyango et al., 2008). Nonetheless, lacking the capital to buy medications is one of the major patient-centric factor found in non-adherent patients. Wabe et al.,(2011) observed that 37% of patient's financial limitations contributed to non-adherence.

Mandewo et al., (2014) observed that most patients do not adhere to treatment recommendations due to inability to afford the cost of medical care services and also prescribed drugs.

Patient with multiple medical condition decide on which medication to stop taking when the medication prescribed are very expensive to buy (Chapman et al., 2005).

The cost of the diabetes management is mainly with the reactive stripes and it causes lots of financial burden to both the individual and the country. For instance, Ghana spent an average of 123 US dollars on every individual living with diabetes (Trivedi et al.,2016; Álvarez et al., 2013). The average cost per every patient in a year is 1844 US dollars of which proportion spent medication with this high cost of medication most patients are not able to afford therefore leading to non-adherence since patients are low income earners (Borges et al., 2014).

2.10.2 Storage of drugs

Most of the patients particularly those from rural areas reported to have storage problems for insulin which need to be stored in cool places with temperatures ranging from 2-8^{0c}. Although diabetic patients are taught how to preserve their insulin (for example, in a clay pot placed on top of wet sand, refrigerator). It might lose its potency because temperatures may exceed the recommended temperatures or may not reach the required degree of coolness for preserving (Mandewo et al., 2014).

2.10.3 Side effects

Side effects such as gastrointestinal disorders (nausea, vomiting, and diarrhea), following medication has been shown to be significantly associated with non-adherence (Fischer et

al., 2010). Patient who experience adverse reaction from medication are more likely to discontinue with the medication than those who do not.

Kalyango et al., (2008) however, did not find an association between side effects and non-adherence to medication.

Freemark and Bursey, (2001) observed transient abdominal discomfort or diarrhea occurred in 40% of treated participants with no episodes of vomiting or lactic acidosis. Metformin was tolerated by the majority of their study participants.

Richard, (2005) reported that, patient who do not adherence was caused by the side effect of the anti- diabetic medication.

2.10.4 Effects of Non-adherence to medication on Glycemic control

Diabetes mellitus management is routinely measured by Glycated hemoglobin in glycemic control. Findings from diabetes mellitus population have shown that good medication adherence has been associated with lower HbA1C levels (Egede, 2015). Although few studies have examined the relationship between medication non-adherence and glycemic control, there are insufficient studies that have examined this relationship using quarterly assessments of medication adherence and HbA1c over several years.

Glycemic control is referred to as typical levels of blood sugar (glucose) in a person with diabetes mellitus. Management of diabetes is routinely measured by Glycated hemoglobin in glycemic control. In one study among T2DM, glycemic control was found to decline over time in non-adherence to medication (Egede, 2015).

Medication non-adherence can worsen glycemic control. Poor glycemic control is defined as glycosylated hemoglobin (HbA1c) $\geq 7.5\%$ (Adams et al., 2008; Pladevall et

al., 2004). Imad et al., (2015), reported that 37% of men and 19% of women who had PGC were also medication non-adherent. Studies by Heisler et al., (2007) among both blacks and whites shows that black were found to have higher average Glycated hemoglobin A1c values than in whites. This is because blacks tend to adhere to medication than whites, which accounted for 20% differences observed in glycemic control. Butt et al., (2015) indicated that patient who adhere to medication had their HbA1c values reduced from 9.66% to 8.47% as well BMI reduced from 29.34kg/m² to 28.92kg/m² and MMAS 8 increases from 5.83 to 6.77.

CHAPTER THREE

METHODOLOGY

3.1 Introduction

This chapter presents the various techniques and tools that were used to collect data from the participants who decided to take part in the study. It discussed the type of study, research design, study area, population, sample size, variables that were measured and sampling technique that were used to analyze the data. Furthermore, it also presents the ethical considerations and issues of the study.

3.2 Research design

This research is a quantitative descriptive cross-sectional study. This is because the study estimated the prevalence of non-adherence to medication among T2DM patient at Tema General Hospital within a short period of time.

3.3 Study area

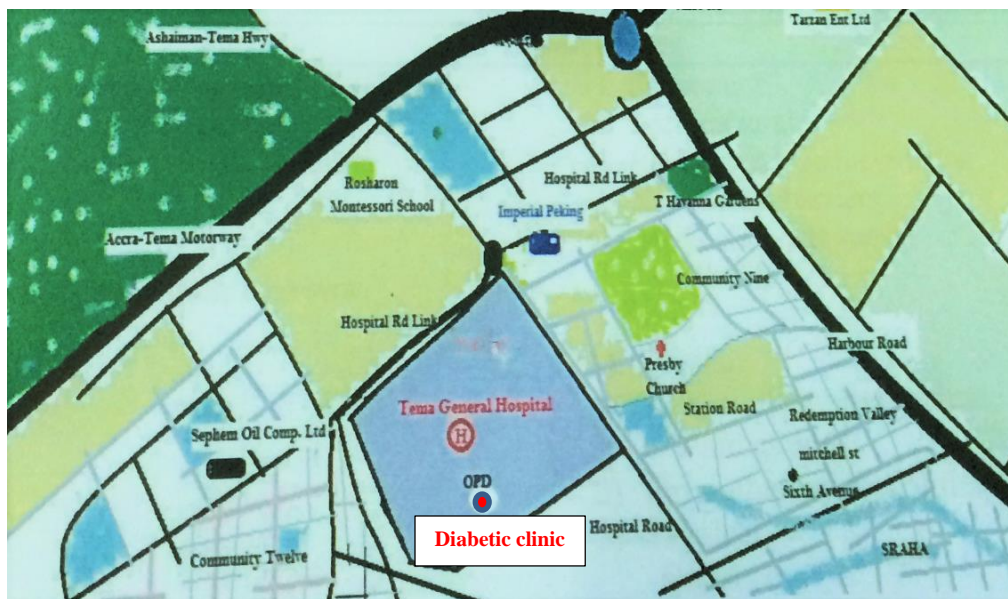


Figure 2: Map of Tema Metropolis showing Tema General Hospital

The study was carried out at the Tema General Hospital (TGH), located in the Tema Metropolis (fig 2). Tema metropolis is one of the 16 districts in Greater Accra Region and is a vibrant commercial and industrial city. The population of Tema metropolis was estimated at 403,934 projection from 2010 population census (GSS PHC., 2012), making it the second largest populated district in the Greater Accra Region. The estimated 2016 population of Tema Metropolis is 351,616 as projected from the 2010 Census, making it the second largest-population of the ten districts in the Greater Accra Region, after Accra Metropolis. TGH was constructed in 1954 by J.W Harrow and Sons Ltd was handed over to the government of Ghana in 1965.

Tema Metropolis is a coastal district situated about 30 kilometers East of Accra, the Capital City of Ghana. It unions boundaries in the northeast with the Dangme West District, south-west by Ledzokuku Krowor Municipal, north-west by Adentan Municipal and Ga East Municipal, north by the Akuapim South District and south by the Gulf of Guinea. The Ashaiman Municipal is an in-lock enclave within the Tema Metropolis. The Metropolis covers an area of about 87.8 km with Tema as its capital. The metropolis lies in the coastal savannah zone.

The Greenwich Meridian (i.e. Longitude 0°) passes through the Metropolis, which meets the equator or latitude 0° in the Ghanaian waters of the Gulf of Guinea. The Metropolis proximity to the sea with its low lying terrain which projects into the sea makes it a natural endowment for a harbor.

The topography of the Tema Metropolis is generally lowland and from its lowest parts, just 50 feet above sea level, mainly at the central parts along the banks of the streams and

rivers. The land gently rises easterly and westerly to form part of the coastal plains with considerable crinkle to about 100 feet in the sophisticated parts where Tema General Hospital is located fig 2. However, the only major constraint to this strength is the erratic rain fall pattern in the region.

The Tema General Hospital is the largest Public Health Institution in Tema Metropolis, which promotes, protect and ensure good health and well- being of clients and the community at large. The geographical location of the Hospital is surrounded by road networks, making the Hospital the major referral point for all other clinics/ hospitals, public and private in and around the Metropolis. The catchment area includes the whole of Tema metropolis, its satellite town and villages. The Tema General Hospital has ten (10) wards and 280 to 300 bed capacity of 80% Tema metropolitan, Dstrict Analytcal Report.,(2014)

There are several departments at TGH of which Diabetes unit is included in the medical department. Other departments includes Surgical, Dental, Physiotherapy, and Eye.(Tema metropolitan, 2013). The hospital delivers medical services to both in- patients and out-patients. Diabetes mellitus appears to be among the top (10) commonest conditions at the medical department at the TGH. For the past 3 years there has been amassed in hospital attendance of diabetes mellitus patients at the diabetic clinic at the Tema General Hospital (GHS-Report, 2013).

The study area was selected due to the high patient's attendance at the diabetes clinic and its wide catchment area. It renders services to all the communities within the Tema

metropolis Nungua, Teshie, Spintex, Sakumono, Tema New town, Manhean, Ashaiman and Afienya, among others.

The diabetic clinic at TGH is the only government hospital in the area which serves over thousand patients in year. However, it has other private hospital who attends to diabetes patients but Tema General Hospital diabetic clinic is the main referral center as shown in figure 2. The client population has also grown steadily over the years. The diabetic clinic has six (6) staffs comprises of four (4) nurses, a doctor and one record officer.

The diabetic clinic has been able capture information on total hospital admissions, diabetics with comorbidities such as hypertension, number of amputations, new diabetes patients, and people living with diabetes less than 40 years and mortalities but unfortunately, information has not been captured on non-adherence to medication among diabetes patients. However, there is the need to identify the prevalence of non-adherence to medication among with T2DM patients at TGH.

3.4 Study population

The targeted population for this study were the diabetic patients' aged 18 years and above who attended the Out Patients Department (OPD) at TGH Diabetic clinic.

3.4.1 Inclusion criteria

- Patients 18 years and above diagnosed with T2DM
- Male and Female with T2DM
- Patients who had clinical records in the hospital.
- Patients who were on medication (oral medication and Insulin) to achieve glycemic control.

- Patients who attended the diabetic clinic for at least 6 months.
- Patients who consented to be part of the study.

3.4.2 Exclusion criteria

- Diabetes patients less than 18 years.
- Pregnant and lactating women.
- Patients who were on admission.
- Patients who had less than 6 month hospital attendance.
- Patients who were newly diagnosed.
- Patients with type 1 diabetes.

3.4.3 Study Variables

The dependent variable of the study is the number of times patients do not adhere to their medication, missing of prescribed dosages, not adhering to prescribed time and the factors are the independent variables which were measured in the study. The factors were classified into demographic, providers, facility based, drug related, individual, social factors.

3.4.3.1 Dependent Variable

Non-adherence to Medication

3.4.3.2 Independent Variables

Demographic Factors: Age, Sex, Educational level, Religion, Marital status

Providers Factors: Staff Attitude, Patient- provider communication

Facility Based Factors: Waiting time, Distance,

Drug Related Factors: Cost of medication, Side effects

Individual Factors: Forgetfulness, Awareness level, health seeking behaviors

Social Factors: Friends, Family, Support groups,

The demographic factors were assessed under the age, sex, religion, marital status, educational level and occupation. Provider's factors were assessed under the staff attitude, provider patient's communications. Drug related factors were assessed under cost of medication, Side effect of medication, non-availability of the medication, dose frequency and shortage of medication. Facility based factors were assessed under the waiting time, distance (hospital proximity to patients residence). Individual factors were assessed under forgetfulness, level of awareness, health seeking behaviors (healthy diet, Physical activities, monitoring of glucose level). Social factors were assessed under family, friends and community.

3.5 Sampling procedure

A purposive sampling was adopted to select the study participants based on their knowledge about the study and willingness to participate in the research. This is due to the criteria set for this type of study. It was difficult to determine the sample frame for diabetic patients who attends the diabetic clinic before the start of the study. Hence using a random sampling procedure in selecting patients was impossible. Patients were interviewed and also answering of the questionnaire as they queue and wait for the clinic to commence or as they wait to see the doctor. Administering of the questionnaire continued until the total number of patients at the diabetic clinic were exhausted.

Participants who cannot read and write were interviewed in order to help them fill the questionnaire. Each day, an average of 30 respondents were obtained.

Purposive sampling is when a researcher decide on definite people within the population to use for a particular study and the notion is to focus on people with certain characteristics who will be better to help with the pertinent research.

Participants were given a questionnaire and a consent form to read and signed prior to answering the questions. Questionnaire and consent forms were read out and explained to participants who could not read and write. Each questionnaire took 5-10 minutes on the average to be completed. A period of 2 weeks was used to collect data by administering questionnaire to the T2DM patients at the diabetic clinic. Administering of the questionnaire was done among patients who were qualified for the study, during the diabetic clinic days from Wednesdays, Thursdays and Fridays only with the hours of 6am to 11am on Wednesdays and Fridays whiles on Thursdays were the main clinic days, however patients comes to the hospital and are attended to as early as 5am till the time the diabetic patients are exhausted from the hospital.

3.5.1 Sample Size

Adopting sample size indicated by Cochran, (1963) for cross-sectional study using 50% precision of non-adherence to medication from previous studies (Bruce et al., 2015) in Ghana on non-adherence to medication.

$$n = [Z^2 p (1-p)]/d^2 \dots\dots\dots (1)$$

Where:

N: Estimated minimum sample size

Z: Standard deviation of 1.96 at 95% confidence interval.

P: the proportion of unknown prevalence of non-adherence to medication among diabetes mellitus patients at Tema General Hospital, estimated to be $p= 50%$ (Bruce et al.,2014; Divya & Nadig, 2015)

D: margin of error is 8%. The precision of 8% was used instead of 5% because of the limited duration of the study and 8% gave a sufficient sample size needed for the study.

$$d= 0.08$$

Inputting the above into equation (1), the minimum sample size required for this study is given by $n= [(1.96)^2 \times 0.50 (1- 0.50)] / (0.08)^2$

$$n= [3.842 \times 0.50(0.50)]/0.0064 = 150.078$$

Therefore, $n= 150$

A 30% non- response proportion was assumed and estimated to be $N = 150 \times 0.3 = 45$.

This was therefore added to the sample size initially calculated;

The minimum sample size = $150 + 45 = 195$. Hence 195 patients were required for the study.

3.6 Data collection tools

The study was employed using structured questionnaire (Appendix iii), The Morisky 8-Item Medication Adherence Scale, (2008) (Appendix iii, section c) and data extraction form (Appendix iii) to obtain needed information from the respondents. The questionnaire captured the information on factors to evaluate non-adherence to

medication (Appendix iii.), patients' age, sex, weight, height, body mass index (BMI), date of first diagnosis, previous and current diabetic medication and laboratory results used to measure the levels of medication non-adherence. Three recent Fasting Blood Glucose (FBG) recordings were taken from the patient's folders. Recordings were taken in the months of April, May, June (last 3 months) preceding the surveys and an average was chosen with referenced to diabetes diagnostic criteria (table 11, Appendix iv).

The structured questionnaire called forth information on the number of times of missing hospital visits, missing of prescribed medications, not adhering to prescribed dosage and not taking medications at all. Morisky 8 item medication adherence tool was used accordingly as: zero (0) as high adherence, one (1) and two (2) as medium adherence and more than two (> 2) and above as low adherence or non-adherence. Data was entered and analyzed using STATA version 13.

3.6.1 Administration of questionnaire

Each selected participant were given a questionnaire to complete ensuring anonymity and confidentiality in the process. Participants were allowed to complete the questions individually and at the time they were waiting to see the doctor. Questions that participants do not understand were explained to them. Participants who were unable to fill the questionnaire by themselves were interviewed by the research assistants and principal researcher to help complete questionnaire.

3.6.2 Non-Adherence Assessment

The level of non-adherence was assessed using the eight item morisky medication adherence scale-8 (MMAS- 8). The questions are as follows:

1. “Do you sometimes forget to take your medication?
2. Thinking over the past 2 weeks, were there any days when you did not take your medication?
3. Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?
4. When you travel or leave home, do you sometimes forget to bring along your medicines?
5. Did you take all your medicines yesterday?
6. When you feel like your symptoms are under control, do you sometimes stop taking your medicines?
7. Taking medicine every day is a real inconvenience for some people, do you ever feel hustled about sticking to your treatment plan?
8. How often do you have difficulty remembering to take all your medicines?
1. Never/ rarely 2. Once in a while 3. Sometimes 4. Usually 5. All the time”

This is a self-reporting assessment scale. The scale is articulated to escape a yes saying bias. The question 5 is reversed to avoid the predisposition to respond the same way as the question one to seven. The response choice are yes or no for question 1 through question 7 and question 8 five has a point Likert response scale. A “No” response scores 0 and a “yes” response scores 1 except for question in which each “yes” response scores 0 and “No” response scores 1.

Clinical evaluation:

Patients' weight and height were measured and used to compute the body mass index (BMI) as a ratio of weight in kilogram/height in meters squared. Patients' blood pressure was recorded during the assessment and hypertension defined conferring to systolic blood pressure ($Sbp \geq 140\text{mmhg}$) and diastolic blood pressure ($dbp \geq 90\text{mmhg}$).

Glycemic control

Patients' glycemic control was assessed using fasting blood glucose (FBG). The level of FBG between 4.0mmol/l to 6.0mmol/l, were defined as agreeable glycemic control. Patients with poor glycemic control were those who had fasting blood glucose $>6.0\text{mmol/l}$ (IDF, 2016).

3.6.3 Data processing and analysis

The data collected were screened or validated and coded before entry. Data were entered using Microsoft excel 2013. The data was cross checked by data with hard copies to ensure there were no errors. Data cleaning was done in order to remove all duplicate records and also to identify abnormal data records that must be removed manually and also identify missing values in the data by removing invalid and left only valid data to be used for the analysis and also to avoid any repetition and wrong spelling to ensure no errors made. The data set was then imported to STATA software version 13.0 for analysis.

3.6.4 Statistical Analysis

The data were analyzed using STATA Version 13.0. Descriptive statistics were used to analyses demographic characteristics of respondent and other factors. The association

between variables and non-adherence was analyzed by cross-tabulation, and the significances were tested using Chi square. Crude and adjusted odds ratios (COR/ AOR) and 95% confidence interval (CI) were performed to determine the factors associated with medication non- adherence and a p-value less than 0.05 was considered statistically significant.. Associations between dependent variable (non-adherence to medications) and independent variables (demographic characteristics and factors leading to medication non-adherence) were analyzed using logistic regression model. The results were analyzed and presented in a form of frequencies, tables, charts, means, standard deviation, proportions, graphs and percentages.

3.6.5 Data storage/ data protection

Questionnaires were kept in a locked file and stored in a locked cabinet. A soft copy of the data collected was coded and locked on a computer and only accessible to the principal investigator.

3.6.6 Quality Control

Pretesting/Pilot study: The questionnaire was designed to reflect objectives of the study. Pretesting of Data collections tools was done at both Tema General Hospital and a Private Hospital called New Crystal hospital at Ashaiman, with 10 participant each from both hospital to validate survey tool or to ensure its feasibility and accuracy. The purpose was to establish if the tool was clearly worded and devoid of major biases and can seek the type of information intended. Pretesting was carried out with the aim of eliminating irrelevant questions so as to make it reliable before the actual study took place at the diabetic clinic TGH.

Training of Research Assistants: The research assistants were given an orientation and training earlier in time before the start of the data collection. All completed data were validated daily before data entry. The entire uncompleted questionnaires were completed and entered. After data entry process, dataset was cleaned before running the analysis.

3.6.7 Ethical consideration/ issues

Ghana Health Service ethical approval was sought (Approval ID Number: GHS-ERC: 07/12/15): Proposal was sent to the Ghana Health Service Review Committee for approval ensuring the project is feasible to be done (Appendix v).

Study Area Approval was sought: An introductory letter from School of Public Health was obtained to the Tema Metropolitan Health Directorate to seek permission to carry out the study in the area specifically at Tema Regional Hospital (Approval vi).

And introductory letter from the School of Public Health was obtained from the department of Epidemiology and disease control to seek permission from the TGH medical superintendent and head of the Diabetic Clinic, Tema General Hospital to carry out the study.

Informed Consent: Before the administration of the questionnaire and the interview, the purpose was explained to all respondents.

There was a structured consent form that was administered to patients who agreed to take part in the study. Participants were informed that participation is voluntary and that, one has the option to opt out.

Privacy and Confidentiality: Participants were assured that privacy and confidentiality were observed during data collection.

Detailed information was given or read out to the participants on how the study would be carried out, why the study is being conducted and the benefit the participants would get from the improvement of health care services as a result of the information the study intends to produce.

Description of Consent Process: Participation in the study was voluntary. The interview commenced after the participants had read and understood the consent form and what the research is all about. Further explanation was given where necessary before the participant would sign or thumbprint the information sheet and the consent form. The procedure and all detailed information was read out to participants who could not read to their understanding.

Voluntary withdrawal: There would be no penalty in opting out of the study. Participants have the right to withdraw at any time from the study if he or she wishes to.

Compensation: No financial benefits or any other material would be given to participants before or after the interview or administration of questionnaire.

Declaration of Conflict of Interest: The principal investigator has no conflict of interest in this study.

CHAPTER FOUR

RESULTS

A total of 206 T2DM were obtained from the TGH diabetic clinic. These are presented as follows:

4.1 Background characteristics of study participants

As shown in Table 1.3: below, the highest number of diabetes T2DM patients who visited the Tema General Hospital diabetic clinic. 82.5% (170/206) were females and 17.5% (36/206) were males. The age range were ages < 40 years 5.34% (11/206), 40 – 49 years 14.6% (30/206), 60 - 69 years 34.9% (72/206), and 28.7% (55/206) between the ages 50-59 years and 70 and above were 18.5% (38/206). The ages were between 24 to 90 years with a mean age of 59.06 years and standard deviation of (SD ± 11.45). Most diabetes mellitus patient 91.3% (188/206) were Christians and 7.3% (15/206) were Muslim. However, majority of the diabetes mellitus patient 56.8% (117/206) were married and the widow or widower were 28.2% (58/206) while those who were divorced were 11.7% (24/206) and 3.4% (7/206) were single. For educational level, 19.4% (40/206) of the participants reported SHS and primary as their highest form of education. However, 21.4% (44/206) reported to have no formal education. Most of the T2DM patients were observed to have had 42.7% (88/206, 28/206) for both JHS/ Middle and Primary education.

Table 1: Socio- demographic characteristics of diabetes mellitus patients at Tema General Hospital

Variable name	Frequency (%) N = 206
Age	
< 40	11 (5.34)
40 - 49	30 (14.6)
50 – 59	55 (28.7)
60 - 69	72 (34.9)
70+	38 (18.5)
Sex	
Male	36 (17.5)
Female	170 (82.5)
Religion	
Christian	188 (91.3)
Muslim	15 (7.3)
Traditionalist	3 (1.5)
Marital status	
Single	7 (3.4)
Married	117 (56.8)
Divorced	24 (11.7)
Widow/er	58 (28.2)
Educational status	
Tertiary	6 (2.9)
SHS	40 (19.4)
JHS/ Middle school	88 (42.7)
Primary	28 (42.7)
No education	44 (21.4)
Occupational status	
Unemployed	40 (10.0)
Trader	109 (12.0)
Artisan	25 (12.0)
Office worker	11 (5.4)
Retired	20 (9.8)
Total	206 (100.0)

4.2 Demographic factors associated with non-adherence to medication

Non-adherence among 60 – 69 years age group had higher non-adherence to medication, however non-adherence level in the years less than 40 were the least not adhering to medication, even though there was no statistical significant difference observed (p value 0.918). Males reported higher proportions of non-adherence 52.8% (19/206) compared to females 46.5% (79/206). There was no statistically significant difference observed (p value 0.491). Participants who are single reported higher non-adherence of 71.4% (5/206) and those who were married and are divorced had a lower proportions of non-adherence. Participants who lost either their wives or husband had 53.5% (31/206) non-adherence and those who were married had 45.3% (53/206) non-adherence and there was no statistically significant difference observed with a p value 0.318. Muslims have higher tendency of 66.7% (10/206) non-adherence to medication and the traditionalist have decrease tendency of non-adherence while the Christians were found to have 46.3% (87/206) of being non-adherence. For participants who had up to primary level education reported 67.9% (19/206) non-adherence and those who had no formal education had 52.3% (23/206) not adhering to medication. However, this difference were statistically significant with (p value 0.017), this implies that there is an association between educational level and non-adherence to medication. Participants who were unemployed had 62.5% (25/206) greater non-adherence. And non-adherence level among the strata of occupation who were traders and artisans were almost the same 44.9% (49/206), 44.0% (11/206), respectively and office workers and retired participants were both 45.0% (54/206, 44/206).

Participants having co-morbidities such as hypertension had 53.0% (44/206) of not adhering to medication compared to those with normotension 43.9% (54/206) and this difference was observed not statistically significant (p value 0.199). About 55.2% (16/206) participants reported non-adherence to medication having normal fasting blood glucose (FBG) less than 6mmol/l had higher non-adherence compared to those with FBG greater than 6mmol/l, however no statistically significant difference was seen (p value 0.377). Obese and overweight participants had 47.6% (46/206), 47.2% (34/206) respectively with higher non-adherence compared to participant who had normal body mass index who reported no statistically significant difference (p value 0.836).

4.3 Prevalence of non-adherence to medication among T2DM respondents

Total number sampled = 206

Number of T2DM respondents engaged in non-adherence = 98

Therefore;

Prevalence of non-adherence to medication = $\frac{\text{number engaged in non-adherence}}{\text{total number sampled}}$

$$\text{Prevalence} = \frac{98}{206} \times 100\% = 47.6\%$$

Table 2: Background characteristics associated with non-adherence to medication regimen among diabetes mellitus patients at Tema General Hospital

Characteristic	Adherence, N (%)		Total	p-value
	Medium-high	Low (non-adherence)		
Age				0.918
<40	7 (63.6)	4 (36.4)	11	
40 – 49	17 (56.7)	13 (43.3)	30	
50 – 59	28 (50.9)	27 (49.1)	55	
60 – 69	36 (50.0)	36 (50.0)	72	
70+	20 (52.6)	18 (47.4)	38	
Sex				0.491
Male	17 (47.2)	19 (52.8)	36	
Female	91 (52.7)	79 (46.5)	170	
Marital status				0.318
Single	2 (28.6)	5 (71.4)	7	
Married	64 (54.7)	53 (45.3)	117	
Divorced	15 (62.5)	9 (37.5)	24	
Widow(er)	27 (46.6)	31 (53.5)	58	
Religion				0.278
Christian	101 (53.7)	87 (46.3)	188	
Muslim	5 (33.3)	10 (66.7)	15	
Traditionalist	2 (66.7)	1 (33.3)	3	
Educational level				0.017
Tertiary	4 (66.70)	2 (33.3)	6	
SHS	29 (72.5)	11 (27.5)	40	
JHS/Middle	45 (51.1)	43 (48.9)	88	
Primary	9 (32.1)	19 (67.9)	28	
No education	21 (47.7)	23 (52.3)	44	
Occupation				0.331
Unemployed	15 (37.5)	25 (62.5)	40	
Trader	60 (55.1)	49 (44.9)	109	
Artisan	14 (56.0)	11 (44.0)	25	
Office worker	7 (63.6)	4 (45.0)	11	
Retired	11 (55.0)	9 (45.0)	20	
Hypertension status				0.199
Normotensive	69 (56.1)	54 (43.9)	123	
Hypertensive	39 (46.9)	44(53.0)	83	
FBG status (mmol/L)				0.377
Normal (< 6.0)	13 (44.8)	16 (55.2)	29	
High(> 6.0)	95 (53.7)	82 (46.3)	177	
BMI (kg/m²)				0.836
Normal	23 (56.1)	18 (43.9)	41	
Overweight	38 (52.8)	34 (47.2)	72	
Obese	47 (52.43)	46 (47.6)	93	
Total	108 (52.4)	98 (47.6)	206	

4.4 Association between Individual factors and non-adherence to medication

The individual factors associated with non-adherence to medication comprised of forgetfulness, health seeking behaviors which involves monitoring of glucose level, frequency on glucose monitoring, knowledge level, duration of diabetes and medication intake. Participants who never knew of having of diabetes had 58.2% (64/206) a higher non-adherence, compare to those who knew of their status of having T2DM had 35.4% (34/206). There was statistically significant association between family history and non-adherence having (p value <0.001).

Participants who have never heard of Glycated hemoglobin had 47.3% (97/206) of not adhering to medication as compared to those who have ever heard of Glycated hemoglobin. However, there was no statistically significant association between ever heard of Glycated hemoglobin and non-adherence to medication (p value 0.293).

It was observed that participants having family history of diabetes who reported non-adherence to DM medication 57.9% (33/206) had their parents having diabetes. Those who reported having 55.6% (5/206) of not adhering to DM medication had their grandparent having diabetes as compared to participants whose children have diabetes had 50% (5/206) of not adhering to DM medication. However, there was no statistically significant difference observed between family members living with diabetes and non-adherence to DM medication (p value 0.755).

Participants who have an idea or agree of fasting to reduce glucose level had 77.5% (31/206) highest non-adherence to DM medication and 72% (18/206) among those who strongly agree were observed to have higher non-adherence compared to those disagree.

There was a statistically significant association between knowledge on fasting blood glucose and non-adherence to medication (p value <0.001).

Participants who control their glucose level by checking their diet or having healthy diet were observed to have 45% (50/206) of not adhering and those who control their glucose level by only taking their medication had 43.5% (74/206) non-adherence as compared to those who do not exercise. There was a statistically significant between controlling of glucose level and non-adherence to medication with a p value 0.004.

There was no statistically significant difference between frequency of glucose level monitor and non-adherence because participants were observed to have higher non-adherence among those who do not adhere to their medication were on daily and monthly monitoring of glucose level had 50% (2/206) and 50% (34/206) compared to those who monitor glucose level weekly had 35.3% (12/206).

Participants who were observed to do self-monitoring of glucose level are 59.2% (29/206) non-adherence as compared to 43.9% (69/206) of the participants who do not adhere to DM medication were reported to do laboratory monitoring of blood glucose level. However, there was no significant difference between monitoring of glucose level and non-adherence to medication with a p value 0.062.

Participants living with diabetes between ages 5- 9 were observed to have 34.7% (34/206) non-adherence and age's 10-14 duration had 21.4% (21/206) of not adhering to DM medication. There was no statistically significant difference between duration of diabetes and non-adherence to medication (p value 0.073).

Current diabetes medication intake between the ages 5- 9 years duration were observed to have the highest 31.6% (31/206) non-adherence to DM medication. Those who started taking their medication less than five years had 25.5% (25/206) of non-adherence to DM medication compared to ages between 15 - 19 years were the least 10.2% (10/206) non-adherence to DM medication. There was no statistically significant difference observed between current medication intake and non-adherence to medication (p value 0.128).

Table 3: Individual factors associated with non-adherence to medication regimen among T2DM patients at Tema General Hospital

Characteristic	Adherence, N (%)		Total	p-value
	Medium-high	Low (non-adherence)		
Ever heard of Glycated hemoglobin				0.293
Yes	0 (0.0)	1 (100)	1	
No	108 (52.7)	97 (47.3)	205	
Family history of diabetes				<0.001
Yes	46 (41.8)	34 (35.4)	110	
No	62 (64.6)	64 (58.2)	96	
Family members with diabetes				0.755
Grandparent	4 (44.4)	5 (55.6)	9	
Parent	24 (42.1)	33 (57.9)	57	
Children	5 (50.0)	5 (50.0)	10	
Siblings	21 (45.7)	25 (54.6)	19	
Other	9 (47.4)	10 (52.4)	141	
Fasting reduces glucose level				<0.001
Strongly agree	7 (28.0)	18 (72.0)	25	
Agree	9 (22.5)	31 (77.5)	40	
Disagree	72 (69.9)	31 (30.1)	103	
Strongly disagree	8 (61.5)	5 (38.5)	13	
Don't know	12 (48.0)	13 (52.0)	25	
Controlling of glucose level				<0.05
Exercise	60 (61.2)	38 (38.8)	98	
Diet	61 (54.9)	50 (45.1)	111	
Medication	96 (56.5)	74 (43.53)	170	
Frequency of glucose check				0.292
Daily	2 (50.0)	2 (50.0)	4	
Weekly	22 (64.7)	12 (35.3)	34	
Monthly	84 (50.0)	84 (50.0)	168	
Monitoring of glucose level				0.062
Self- monitored	20 (40.8)	29 (59.2)	49	
Laboratory	88 (56.1)	69 (43.9)	157	
Duration of diabetes (years)				0.073
< 5	35 (32.4)	17 (17.6)	52	
5 - 9	36 (33.3)	34 (34.7)	70	
10 - 14	20 (18.5)	21 (21.4)	41	
15 - 19	9 (8.3)	10 (10.2)	19	
20+	8 (7.4)	16 (16.3)	24	
Total	108 (52.4)	98 (47.6)	206	

Characteristic	Adherence, N (%)		Total	p-value
	Medium-high	Low (non-adherence)		
Duration of current diabetes medication (years)				0.128
< 5	36 (33.3)	25 (25.5)	61	
5 - 9	36 (33.3)	31 (31.6)	67	
10 - 14	21 (19.4)	16 (16.3)	37	
15 - 19	9 (8.3)	10 (10.2)	19	
20+	6 (5.6)	16 (16.3)	22	
Total	108(52.4)	98(47.6)	206	

4.5 Knowledge on diabetes and non-adherence

Participants’ knowledge and its influence on non-adherence to medication is summarized in figure 3. About 83.3% non-adherence to DM medication reported that hypertension causes diabetes and 66.7% non-adherence reported that diabetes is either caused by disease or having a family history of diabetes and also 29.0% had the least non-adherence to DM medication who reported that diabetes was caused by late eating or eating unhealthy diet.

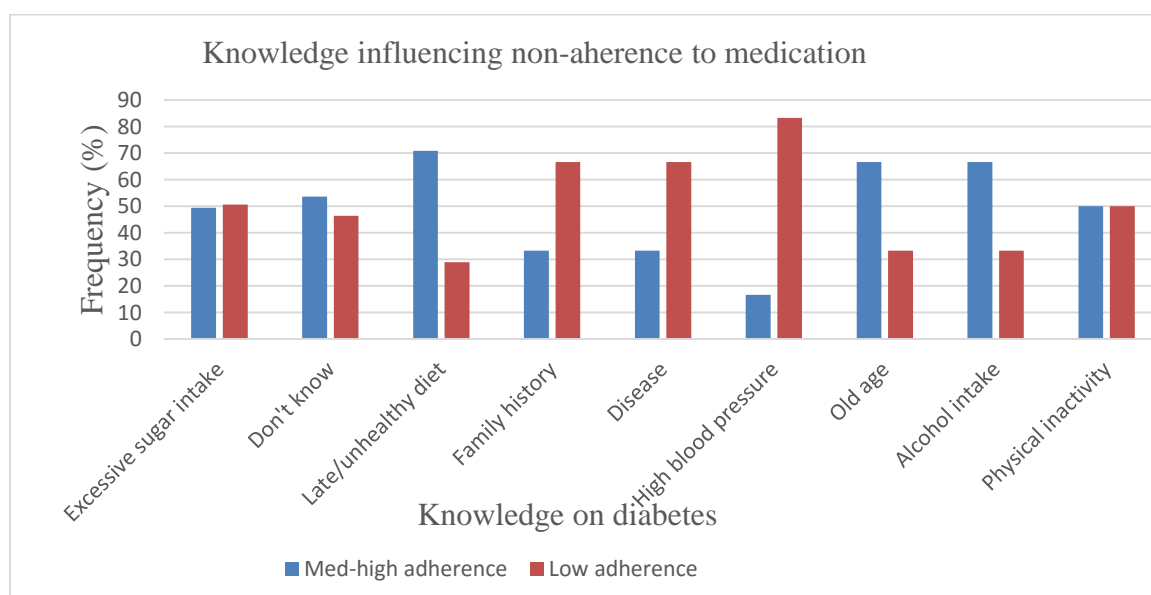


Figure 3: Distribution on participants’ knowledge level on diabetes and non-adherence.

4.6 Association between Providers factors and non-adherence to medication

Participants who admits that health providers do not explains their conditions to them (inadequate counseling) had 58.9% (77/206) non-adherence to DM medication as compared to participants who admitted that health provider explains their disease conditions to them. There was statistically significant association between inadequate counselling on patients disease condition and non-adherence to medication with a p value <0.001. Poor patient provider communication had 71.4% (5/206) non-adherence to medication as compared to patients who had 46.7% (93/206) good patients' provider communication. There was no statistically significant difference between adequate communication and the non-adherence (p value 0.198).

Among participants 75% (6/206) were not adherent who founds it difficult discussing complications with health provider as compared to 46.5% (92/206) of those who easily discuss complications with the health provider. No statistically significant difference was observed between discussing complications with health provider and non-adherence to medication (p value 0.113).

Participants who do not agree that health providers examines them had 75% (6/206) non-adherence to DM compared to 46.5% (92/206) those who were being examined by the health provider. However, no statistically significant difference was observed between staffs attitude (being examined by health provider) and non-adherence to medication (p value 0.113). There was a statistically significant association between staffs attitudes and non-adherence to medication. 100% (1/206) of participant do not adhere to DM medication when the health provider treated them very bad compared to those who were

treated excellent. However, there was a statistically significant association between staff attitude and non-adherence to medication (p value 0.002).

Table 4: Providers factors associated with non-adherence to medication regimen among T2DM patients at Tema General Hospital

Characteristics	Adherence, N (%)		Total	P-value
	Medium-high	Low (non-adherence)		
Adequate counselling disease condition				<0.001
Yes	54 (41.2)	21 (28.0)	75	
No	54 (72.0)	77 (58.9)	131	
Poor patient and Health provider communications				0.198
Yes	2 (28.6)	5 (71.4)	7	
No	106 (53.3)	93 (46.7)	199	
Discussion of complications with health provider				0.113
Yes	106 (53.5)	92 (46.5)	198	
No	2 (25.0)	6 (75.0)	8	
Being examined by health provider				0.113
Yes	106 (53.5)	92 (46.5)	198	
No	2 (25.0)	6 (75.0)	8	
Able to visit health provider regularly for consultation				<0.001
Yes	88 (60.7)	57 (39.3)	145	
No	20 (32.8)	41 (67.2)	61	
Staff attitude				<0.05
Excellent	23 (38.9)	36 (61.0)	59	
Very good	66 (64.7)	36 (35.3)	102	
Good	19 (43.2)	25 (56.8)	44	
Very bad	0 (0.0)	1 (100.0)	1	
Total	108 (52.4)	98 (47.6)	206	

4.7 Association between Facilities based factors and non-adherence to medication

Participants who visits the health facility quarterly reported 75% (3/206) non-adherence to DM medication compared to those who visits the health facility monthly 46.6% (90/206). There was no significant difference observed (p value 0.471).

66.7% (4/206) non-adherence to medication were observed among participants visiting the health facility on weekly bases and 57.1% (4/206) non-adherence were observed among participants who visits the health facility quarterly as compared to participants with 46.6% (90/206) non-adherence who visits the health facility of monthly bases. However, there was no significant difference observed with a p value 0.471. And also participants who admit of missing their visit to health facility for medication had 71.6 % (68/206) non-adherence compared to 27% (30/206) participants who do not miss their visit to the health facility. There was a statistically significant association between missing visit to health facility and non-adherence to medication (p value <0.001).

For participants who miss visit to the health facility for 6- 10 times were observed to have 100% (4/206) non-adherence compared 74.6% (41/206) to those who miss from 1- 2 times visits to the health facility. However no statistically significant difference was observed with a p value 0.131. Participants who had no reason for missing visits to health facility were observed to have high non-adherence than those who forgot their visits to the health facility. There was no significant difference between reasons for missing health facility and non-adherence to medication (p value 0.320).

Participants who reported spending more than 4 hours in the health facility had 48.6% (35/206) of not adhering to DM medication compared to those who spent 0-1 hour in the health facility. However, there was no statistically significant association between average time spent at the hospital (waiting time) and non-adherence to medication. Participants who live very far from the health facility were observed to be 54.1% (59/206) non-adherence to medication compared to those who live close to the health

facility 47.8% (11/206). No statistically significant difference was observed between distance and non-adherence to medication with a p value 0.096.

Table 5: Facility based factors associated with non-adherence to medication regimen among T2DM patients at Tema General Hospital

Characteristics	Adherence, N (%)		Total	p-value
	Medium-high	Low (non-adherence)		
Health facility visit for medication				0.471
Weekly	4 (44.4)	5 (55.6)	9	
Monthly	103 (53.4)	90 (46.6)	193	
Quarterly	1 (25.0)	3 (75.0)	4	
Last visit to health facility				0.548
Within 4 weeks	103 (53.4)	90 (46.6)	193	
Within last week	2 (33.3)	4 (66.7)	6	
Within the last 2 weeks	3 (42.9)	4 (57.1)	7	
Missed visit to health facility for medication				<0.001
Yes	27 (28.42)	68 (71.6)	95	
No	81 (72.9)	30 (27.0)	111	
Missed visits in a year				0.131
1 -2 visits	14 (25.5)	41 (74.6)	55	
3 – 5 visits	16 (44.4)	20 (55.6)	36	
6 – 10 visits	0 (0.0)	4 (100.0)	4	
10+ visits	1 (20)	4 (80.0)	5	
Reason for missed visits				0.320
Forgot	3 (14.3)	18 (85.7)	21	
No reason	1 (9.1)	10(90.9)	11	
Busy with something else	9 (32.1)	19 (67.9)	28	
Tired of frequent visits	2 (22.2)	7 (77.8)	9	
Average time spent				0.972
0 – 1 hour	22 (52.4)	20 (47.6)	42	
2 – 3 hour	49 (53.3)	43 (46.7)	92	
4 hour and above	37 (51.4)	35 (48.6)	72	
Time spent on last visit				0.539
0 – 1 hour	18 (58.1)	13 (41.9)	31	
2 – 3 hour	47 (48.5)	50 (51.6)	97	
4 hour and above	43(55.1)	35 (44.9)	78	
Distance from home to health facility				0.096
Close	12 (52.2)	11 (47.8)	23	
Far	46 (62.2)	28 (37.8)	74	
Very far	50 (45.9)	59 (54.1)	109	
Fasting blood Glucose				0.377
Normal	13 (12.0)	16 (16.3)	29	
High	95 (88.0)	82 (83.7)	177	
Total	108 (52.4)	98 (47.6)	206	

4.8 Association between Drug Related Factors and non-adherence to medication

It was observed that participants who took herbal medication had 87.5% (7/206) of non-adherence, and 70.2% (33/206) of those who take insulin + OHA were non-adherence compared to 41.7% (55/206) non-adherence who took only OHA. There was a statistically significant association between current medication and non-adherence to medication (p value 0.007).

Participants who were observed not to buy prescribed medication were 66.7% (34/206) non-adherence to DM medication compared to those who buy prescribed medication. However, there was statistically significant association between buying prescribed medication and non-adherence to medication (p value 0.002).

48.4% (77/206) Participants were observed not to adhere to medication when taking 2x daily medication, compared to 1x daily prescribed dosage. No statistically significant difference was observed (p value 0.899). However, 88.2% (15/206) non-adherence to DM medication were found among participants who do not follow prescribed medications compared to those who follow prescribed medication. There was statistically significant association between following prescribed medication (dose frequency) and non-adherence to medication (p value <0.001).

There was no statistically significant difference between total diabetes pills swallowed and non-adherence to medication (p value 0.698), among participant who were observed to take more than five pills were seen to be 44.4% (17/206) not adhering to DM medication compared to those who take less five pills in a day. The Total number of pills taken among participants affects continued usage were observed. 81.3% (52/206) do not

adhere since it affect their continued usage compared to 32.4% (46/206) seemed not to be affected in any way. Statistically significant association was observed between pill burden and non-adherence to medication (p value <0.001).

In order not to forget medication intake, about 66.7% (40/206) non-adherence to DM medication were seen among those who write down, 57.1% (28/206) of non-adherence were seen among those do pill count, compared to participant who do visual reminder. However, no statistically significant difference was observed with p value 0.294.

Side effect developed during medication intake were observed to have 66.7% (58/206) not to be adherent compared to those who developed no side effect developed during medication intake. There was statistically significant association between side effect developed during medication intake and non-adherence to medication (p value <0.001). However to discontinue medication among participants who developed side effect during medication intake were 83.7% (41/206) and those who do not developed side effect. A statistically significant association was observed. Common side effect among participants who develop constipation were observed to have the highest 75% (6/206) of not adhering to medication. 67.4% (29/206) not adhering to medication were found among those who developed dizziness and 64.7% (22/206) among those who developed weakness. No statistically significant difference was observed with a p value 0.647. Participants who were asked to report if they developed side effect had 57.1% (12/206) non-adherence compared to those who were not asked to report on developing side effect.

Table 6: Drug-related factors associated with non-adherence to medication regimen among T2DM patients at Tema General Hospital

Characteristics	Adherence, N (%)		Total	P-value
	Medium-high	Low (non-adherence)		
Current medication intake				<0.05
Metformin	77 (58.33)	55 (41.7)	132	
Glibenclamide	28 (46.7)	32 (53.3)	60	
Insulin	13 (54.2)	11 (45.8)	24	
Insulin +OHA	14 (29.8)	33 (70.2)	47	
Herbal medication	1 (12.5)	7 (87.5)	8	
Able to buy prescribed Medication				<0.05
Yes	91 (58.7)	64 (41.6)	155	
No	17 (33.3)	34 (66.7)	51	
Reason for not buying prescribed medication				1.000
Too expensive	18 (31.6)	39 (68.4)	57	
Difficult to find	0 (0.0)	1 (100.0)	1	
Not available	1 (31.2)	2 (66.7)	3	
Prescribed dosage				0.899
3x daily	9 (56.3)	7 (43.8)	16	
2x daily	82 (51.6)	77 (48.4)	159	
1x daily	17 (54.8)	14 (45.2)	31	
Followed prescribed dosage				<0.001
Yes	106 (56.1)	83 (42.9)	189	
No	2 (11.8)	15 (88.2)	17	
Total diabetes pills swallowed				0.698
< 5	87 (51.8)	81 (48.2)	168	
5+	21 (55.3)	17 (44.4)	38	
Total pills swallowed for all disease conditions				0.089
< 5	50 (46.7)	57 (53.3)	107	
5+	58 (58.6)	41 (41.4)	99	
Number of pills affect continued usage				<0.001
Yes	12(18.8)	52 (81.3)	64	
No	96(67.6)	46 (32.4)	142	
Total	108 (52.4)	98 (47.6)	206	

Table 7: Drug related factors associated with non-adherence to medication regimen among T2DM patients at Tema General Hospital

Characteristics	Adherence, N (%)		Total	p-value
	Medium-high	Low (non-adherence)		
In order not to forget medication intake				0.294
Pill count	21 (42.9)	28 (57.1)	49	
Write down	2 (33.3)	4 (66.7)	6	
Alarm alert	5 (62.5)	3 (37.5)	8	
Visual reminder	80 (55.9)	63 (44.1)	143	
Side effect of prescribed medication				<0.001
Yes	29 (33.3)	58 (66.7)	87	
No	79 (66.4)	40 (33.6)	119	
Side effect affects continued usage				<0.001
Yes	8 (16.7)	41 (83.7)	49	
No	100 (63.7)	57 (36.3)	157	
Side effects of medication				0.647
Dizziness	14 (32.6)	29 (67.4)	43	
Abdominal discomfort	8 (40.0)	12 (60.0)	20	
Frequency urinating	3 (50.0)	3 (50.0)	6	
Constipation	2 (25.0)	6 (75.0)	8	
Weakness	12 (35.3)	22 (64.7)	34	
Ever been ask to report on developing side effect				0.354
Yes	99 (53.5)	86 (46.5)	185	
No	9 (42.9)	12 (57.1)	21	
Probable reasons for missing medication				0.079
Forgetfulness	9 (20.5)	35 (79.6)	44	
Distance	7 (35.0)	13 (65.0)	20	
Waiting time	4 (100.0)	0 (0.0)	4	
Side effect	2 (20.0)	8 (80.0)	10	
Cost of medication	6 (42.9)	8 (57.1)	14	
Dose frequency	3 (27.3)	8 (72.7)	11	
Shortage of medication	1 (11.1)	8 (88.9)	9	
Total	108 (52.4)	98 (47.6)	206	

4.8 Association between Social support and non- adherence to medication

Participants who were being supported by family members were observed to be 49.7% (87/206) of non-adherence to DM medication and those that were supported by the community were observed to be 41.2% (14/206) non-adherence compared to those that were supported by friends had 31% (18/206) of non-adherence. There was statistically significant association between social support and non-adherence to medication (p value 0.034).

Table 8: Factors associated with non-adherence to medication regimen among T2DM patients at Tema General Hospital

	Adherence, N (%)		Total	p-value
	Medium-high	Low (non-adherence)		
Social Support				<0.05
Family	88 (50.3)	87 (49.7)	175	
Friend	40 (68.9)	18 (31.0)	58	
Community	20 (58.8)	14 (41.2)	34	
Total	108 (52.4)	98 (47.6)	206	

4.9 Effect of non- adherence on glyceimic control among T2DM patients at TGH

Participants who reported having high glucose level were observed to be 83.7% (82/206) non-adherence to medication as compared to 16.3% (16/206) of those who presents with normal glucose level were 26.3% (16/206) non-adherence. However, there was no statistically significant difference between fasting blood glucose and non-adherence to medication on glyceimic control (p value 0.377). The mean fasting blood glucose is (8.55± 2.67)

Table 9: Effect of non-adherence to DM medication on glycemic control among people with T2DM at Tema General Hospital

	Adherence, N (%)		Total	p-value
	Medium-high	Low (non-adherence)		
Fasting blood Glucose				0.377
Normal	13 (12.0)	16 (16.3)	29	
High	95 (88.0)	82 (83.7)	177	
Total	108 (52.4)	98 (47.6)	206	

4.10 Results on logistic regression analysis

In determining the relationship between participants' background characteristics and the factors contributing to non-adherence to medication, both simple and multiple logistics regression analyses were done.

As shown in Table 10, There was no significant difference between the participants with non-adherence to medication who were on current medication such as metformin, insulin + OHA, herbal medication, family history, rating of health provider, able to buy prescribed medication, following prescribed medications, side effect of medications and visiting health provider regularly for consultations.

However, there was statistically significant association between non-adherence and fasting to reduce glucose level, Missed visit to health facility for medication, health provider explaining disease condition and number of pill taken (pill burden).

The proportion of participants who disagree that fasting reduces glucose level, had 85% reduction in the odds of non-adherence (OR= 0.15; 95% CI= 0.07 - 0.29, p value= 0.025), and after adjusting for the other variables, there was 61% reduction in the odds of being

non-adherence to medication compared to those who agree. (OR = 0.39; 95% CI = 0.08 - 1.85, p value = 0.025).

The proportion of participants who do not know what fasting reduces glucose level is, had 73% reduction in the odds of non-adherence to medication compared to those who agree.

Participants who reported missed visit to the health facility for medication were more likely to be non-adherence (OR = 6.79; 95% CI = 3.68 - 12.54, p value = <0.001). Adjusting for other significant variables, participants who reported “missed visit to health facility for medication” had a 6.71 increase in the odds of non-adherence (OR = 6.71; 95% CI = 2.35 - 19.16, p value = <0.001).

Participants who reported that Health provider explains their disease conditions to them had 3.67 increase odds of being non-adherence (OR = 3.67; 95% CI = 1.99 - 6.76, p value = <0.001), after adjusting for the other variables participants who reported that health provider explain their disease conditions to them had 1.14 increase odds of being non-adherence (OR = 1.14; 95% CI = 0.15 - 8.75, p value = <0.001). There was a statistically significant association between health providers explaining disease condition to participants and non-adherence to medication.

Participants who reported that the number of pills (pill burden) affect their continued usage had 10.82 increase in the odds of becoming non-adherence and after adjusting for the other variables there was 8.25 increase in the odds of becoming non-adherence to medication (OR = 8.25; 95% CI = 2.91-23.08, p value = < 0.001). There was a statistically significant association between number of pills used and non-adherence to medication.

Table 10: Association between selected independent variables and Non-adherence using logistics regression among diabetes mellitus patients at Tema General Hospital.

	Outcome: Non-adherence to medication			
	Unadjusted		Adjusted	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Current medication				
Metformin	0.51 (0.29, .092)	0.024	1.24 (0.42, 3.68)	0.687
Insulin +OHA	3.41 (1.69, 6.87)	0.001	3.15 (0.79, 12.53)	0.103
Herbal medication	8.23 (1.00, 68.15)	0.051	5.99 (0.21, 171.65)	0.295
Family history of diabetes	2.54 (1.44, 4.46)	0.001	1.59 (0.66, 3.86)	0.440
Fasting reduces glucose level				0.025
Agree	Ref			
Disagree	0.15 (0.07, 0.29)	<0.001	0.39 (0.08, 1.85)	
Don't know	0.35 (0.13, 0.93)	0.035	0.36 (0.06, 2.34)	
Educational level				0.152
None	Ref	0.023		
Primary	1.93 (0.72, 5.18)	0.194	4.17 (0.90, 19.21)	
JHS/Middle	0.87 (0.42, 1.80)	0.712	1.39 (0.48, 4.07)	
SHS	0.35 (0.14, 0.86)	0.023	0.51 (0.14, 1.90)	
Tertiary	0.46 (0.08, 2.75)	0.393	1.01 (0.09, 11.14)	
Missed visit to health facility for medication	6.79 (3.68, 12.54)	<0.001	6.71 (2.35, 19.16)	<0.001
Health provider explains disease condition to patient	3.67 (1.99, 6.76)	<0.001	1.14 (0.15, 8.75)	0.040
Rating of health provider (staff attitude)				0.239
Excellent	Ref			
Very good	0.35 (0.18, 0.68)	0.002	0.56 (0.19, 1.64)	
Good	0.84 (0.38, 1.86)	0.668	1.46 (0.42, 5.12)	
Able to buy prescribed medication	0.35 (0.18, 0.68)	0.002	0.78 (0.26, 2.36)	0.669
Followed prescribed dosage	0.10 (0.02, 0.47)	0.003	0.42 (0.05, 3.31)	0.414
Number of pills affect continued usage	10.82 (5.16, 22.68)	<0.001	8.25 (2.95, 23.08)	<0.001
Side effect of prescribed medication	3.95 (2.19, 7.09)	<0.001	2.91 (1.16, 7.29)	0.022
Side effect affects continued usage	8.99 (3.94, 20.51)	<0.001	0.42 (0.12, 1.48)	0.176
Able to visit health provider regularly for consultation	0.65 (0.22, 1.62)	0.357	0.79 (0.30, 2.74)	0.752

CHAPTER FIVE

DISCUSSION

This chapter discusses the findings of the study in relation to the objectives of the study and are presented as follows:

5.1 Prevalence of non-adherence to medication among T2DM patients

The findings from the study showed that about 47.6% (98) out of the total number of 206 were non-adherent to medication regimen. The value slightly differed from the findings of Turki & Sulaiman, (2010) who reported that 51.5% (195/380) were non-adherent to medication in a study conducted to determine the effect of poor adherence on elevated blood pressure among patients with hypertension in the General Hospital of Penang, Malaysia. However this is expected, in that a higher sample size was determined in their study and hence there were more variability in the value obtained. Also the difference in the values obtained could be as a result of the location of the study sites and hospital attendance rates among T2DM patients at Penang General Hospital as compared to T2DM patients at Tema General Hospital.

5.2 Factors influencing non-adherence to medication among T2DM

5.2.1 Demographic characteristics influencing non-adherence to medication

Respondents' educational status was significantly associated with medication non-adherence. The study found out that 67.9% of the respondents engaged in non-adherence to medication had at least primary education. This is comparatively higher than the 50% value reported by Martin et al., (2005) in a study conducted to identify the challenges associated with non-adherence. A feasible explanation is that the study was made up of

participants predominantly in the upper and middle socioeconomic status and are more likely to have at least primary education. However, patients with JHS/ middle educational level had the least adherence proportion and this can be attributed to the fact that they can at least read and write. Among patients not adhering to medication, Participants who had no education and this can be as a result of inadequate knowledge on diabetes. This is consistent with a study by Martin *et al.*, (2005) who found out that the risk of non-adherence was very high when patient could not read and understand basic written or verbal medical instructions. The odds of non-adherence to medication is 93% more likely in patients without education compared to patients with primary education.

Also, for a country like Ghana, the possibility of obtaining employment that will ensure substantial income with such a low qualification, implies that lower income would be given and probably would be insufficient in purchasing medication.

5.2.2 Social support factors influencing non-adherence to medication

Among respondents who were supported by their families did not adhere to medication. This is in contrast with the findings by Awodele & Osulale, (2015) who reported that social support system among families takes full responsibility for their routine medications which encourages adherence. A possible explanation is that, respondents may not want to be a burden on these family support systems, as such they probably will not request for financial assistance in acquiring medications. Also studies by Mandewo *et al.*, (2014) reported that, support is mostly given by either relatives or children and the absence of this support leads to non-adherence. However, social supports was determined to be statistically significant as relating to non-adherence. Also findings from a study by Martin *et al.*, (2005) to determine the challenge of patients adherence was consistent with

the study findings which showed that patients social support available affect their compliance most especially when they are depressed or have anxiety disorder or other diseases.

5.2.3 Facility-based factors influencing non-adherence to medication

Most of the participants in the study indicated that the attitude of the staff did not serve as a reason not to adhere to DM medication. Staffs most especially the doctors were generally considered to be excellent, good in their profession and friendly towards the patients by encouraging them to adhere. However, those who indicated that the attitude of the staff had no effect on adherence to medication, still were not adherent to medication. Nonetheless, a significant association was found between staff attitude and patients' non-adherence to medication. However, participants who reported very good staff attitude had 65% reduction in the odds of not adhering to medication compared to those who reported excellent staff attitude.

Participants responded yes to having “missed visits to the health facility” for medication. This is consistent with research findings obtained by Mandewo et al., (2014) who reported that patients in hospitals are being cared for in a friendly way. And also it is more likely that health workers constantly remind patients to take their medication when they pay regular visits to the health facility. Comparing participants' who missed visits to health facility to those who do not missed visits, those who missed visits had 6.79 times the odds of not adhering to medication.. Again this could be as a result of travel cost. However, this is a key factor that prevents patients from visiting the health facility.

5.2.3 Individual factors influencing non-adherence to medication

Among medication non-adherent patients, who had no knowledge of diabetes occurrence in their families did not adhere to medication. This is consistent with the findings of Garber et al., (2013) who reported that patients who had no knowledge on diabetes find it very difficult to adhere to medication. There was a statistically significant association observed. Participants who disagree to fasting in order to reduce glucose levels were in the majority for medication non-adherence with 85% reduction in the odds of not adhering to medication compared to those who agree. This is consistent with a study done by King, (2008) in a study to determine the role of inflammatory cytokines in diabetes and its complications. Again, controlling glucose level can either be through exercise, healthy diet intake and medication intake and participants who admit to controlling glucose level by healthy diet were in the majority for non-adherence. Also participants controlling glucose level through physical activity were in the lower proportion to medication non-adherence. This is a similar findings by Awodele & Osuolale, (2015) reported that Exercise, diet, and medication had effect on non-adherence to medication. This can be explained in that, patients who tend to exercise and takes in healthy diet, had a strong assertion that such involvements reduced blood glucose level.

5.2.4 Provider's factor influencing non-adherence to medication

Participants who had no adequate counselling on their disease condition were found to be non-adherent to diabetes medication. This is similar to Miller & Dimatteo, (2013) who found that higher risk of medication non-adherence was found among patients whose doctors do not give them adequate counselling on their disease condition. Comparing those receive adequate counselling to those who do not receive adequate counselling.

Those who do not receive adequate counselling had 3.67 times the odds of not adhering to medication. Again studies by (Mandewo et al., 2014) showed that there was no statistically significant association between patient and health provider communication. This study also suggested that there was no association between health provider patient communication and non-adherence. The results of the study also revealed that non-adherence was determined among the majority of participants who confirmed to not visiting health provider regularly for consultation. There is a 35% reduced in the odds of not adhering to medication among those who were unable to visit health provider regularly compared to those who visits health provider regularly. However, this study identified a statistically significant association between adequate counselling and non-adherence to medication.

This could be explained in that, patients do not have in-depth understanding of the disease condition and however do not see the importance of adhering to medication.

5.2.5 Drug-related factors influencing non-adherence medication

Participants who were found to be on current medication such as metformin, glibenclamide, insulin, and herbal medication did not adhere to medication. This is consistent with Mandewo et al., (2014) reported that metformin and glibenclamide were associated with non-adherence because of adverse reactions of both drugs had respectively 0.51 times, 3.41 times and 8.23 times the odds of not adhering to medication.

Participants who were unable to buy prescribed medication also were found to be non-adherent to medication with 65% reduction in the odds of not adhering to medication. This is consistent with Wabe et al., (2011) who reported that patients financial limitations

contributes to non-adherence and Mandewo et al., (2014) observed that non-adherence to medication among most patients were due to inability to afford the cost of the medication. This can be explained that since most participants were unemployed and also anti-diabetic drugs were supposed to be subsidized by the national health insurance scheme (NHIS), patients could not afford medication not covered by NHIS. This is however consistent with the findings of Chapman et al., (2005) in a study to determine the predictors of adherence with antihypertensive and lipid-lowering therapy.

Difficulty in adhering to their medication was statistically significant with non-adherence to medication. Comparing those who taking large number of pills to those who take less number of pills, those who take large number of pills had 10.82 times the odds of not adhering to medication and to those who do not with a p value <0.001 . Khattab et al., (2010) reported that large number of pills to be swallowed had an association with non-adherence. This can be explained that there is difficulty in taking large quantity of medication. Patients who are both diabetic and hypertensive were more likely to not adhere to medication due to pill burden. Also some may be reluctant to take a lot of medication.

Mandewo et al., (2014) reported that there was no significant association between number of drugs and non-adherence to medication. This in contrast with other studies which indicated that frequency of medication tend to influence non-adherence.

Of the total number not adhering to medication, almost half of the participants did so because of side effects associated with taking the medication. Comparing those who develop side effect to those do not develop side effect, those who develop side effect had

8.99 times the odds of not adhering to medication. However, side effect had a significant association with non-adherence to medication. This study is consistent with Fischer et al., (2010) and Sud et al.,(2005), who reported that patients who experienced adverse reaction from medication intake were more likely to discontinue medication intake. A Study by Kalyango et al., (2008a) reported contrary that there is no association between the side effect and non-adherence.

Of the total number not adhering to medication, almost half of the participants were unable to follow prescribed medication were found to be non-adherent to medication with 90% reduction in the odds of not adhering to medication compared to those who follow prescribed dosage. This is consistent with the findings in the study by de Vries et al., (2014) to determine medication beliefs, treatment complexity and non-adherence to different drug classes in patients with T2DM, who reported that dosing frequency affects adherence to medication. There is a statistically significant association following prescribed dosage.

5.3 Effects of non-adherence to medication on glyceimic control

Fasting blood glucose (FBG) levels had no association with non-adherence to medication. However, a higher percentage of participants had high levels of fasting blood glucose, thus indicating a higher prevalence of non-adherence among the T2DM patients sampled. This can be explained that FBG alone cannot determine non-adherence level. This can be as a result of very high pricing for HbA1c test and most patients being unable to afford HbA1c. Also oral glucose tolerance test (OGTT) could have been the best but was also time consuming and probably most patients may not have agreed to do this test and also

very expensive since one reactive stripe is very expensive and with this OGTT, three (3) reactive stripes are used.

After adjusting for the effect of all significant respondents' factors relating to non-adherence (inadequate knowledge on fasting blood glucose, missed visit to health facility, inadequate education or counselling, pill burden, and side effects of medication) were found to be associated with non-adherence. As such, these characteristics complement one another in affecting non-adherence to medication among T2DM patients.

5.4 Study Limitation

- Language barrier contributed somehow to these limitations, not all participants could speak the language of the principal researcher and the research assistance.
- Another limitation that should be considered when interpreting these results related to the different screening methods and diagnostic criteria in diagnosing non-adherence among diabetes and the fact that Glycated hemoglobin (HbA1c) could not be retrieve from the patient's folder since patients could not afford HbA1c test.
- Ability to recall; may not be entirely accurate. However, this limitation can be overcome in future studies on the year's participants been living and taking medication.
- The nature of the sampling might have introduce bias which limits the findings to the population of the T2DM patients attending the diabetic clinic at TGH only.

CHAPTER SIX

CONCLUSION

This study sought to assess the factors associated with non-adherence to medication regimen among T2DM patients at Tema General Hospital.

The study showed 47.6% non-adherence to medication among T2DM patients at TGH. Significant factors such as inadequate knowledge on fasting blood glucose, side effect of medication, inadequate education or counselling on diabetes, missed visits to health facility and pill burden contributed to non-adherence to medication.

Adherence to medication is sub-optimal among T2DM patients at TGH diabetic clinic which can be improved through education, counselling and reinforcement of good self-care to prevent poor glycemic control leading adverse complications and increase mortality.

RECOMMENDATIONS

Policy

Considering the non-adherence level obtained from the study, there is the need for the health providers to give intense education on diabetes through pictures and verbal communications through media such as radios and televisions so that patients will be well informed about the side effect of their medication.

Education should be extended to families so that support is more meaningful and good adherence level maybe achieved.

Ministry of health should liaise with Pharmaceutical companies, in order to overcome the pill burden challenge, it recommended that the routine drugs prescribed for patient should be combined into a monotherapy for patients to adhere.

Also ministry of health should amend NHIS policy to cover all anti-diabetics medications, glucometer and reactive stripes to make it more accessible to patients, so that self-monitoring of blood glucose will reduce the incidence of diabetes related complications.

There should be community based doctors and Physician Assistants assigned to the communities to frequently monitor and managed patients at home but not necessarily patients travelling from far distance to the hospitals.

Research

Future studies should be conducted by school of Public health department and other research institution should conduct studies to confirm the risk factors and effect of non-adherence on glycemc control since non-communicable diseases has a rampant increasing prevalence.

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APPENDICES

Appendix i: Participant Information Leaflet

Title of Research: Non-adherence to medication regimen among Diabetes mellitus patient at Tema General Hospital.

This study is conducted by Miss. Perpetual Enam Aflakpui, a student at the University of Ghana, School of Public Health, as part of the requirement in pursuing an MPH programme.

This study seeks to determine non-adherence to medication among diabetes mellitus patient. A structured closed-ended and open- ended questionnaire covering all aspects of the objectives of the study will be used for data collection. The study will involve answering questions about you. Laboratory investigations such as fasting blood glucose, current medications intake will either be answered or extracted from your folders.

The interview will take some of your time and might take about 10- 15 minutes to complete the questionnaire which might be inconvenience to you.

Participants will gain a better insight on the benefits of adhering to medication, measures to take and ways of improving on adherence to medications to prevent complications. It will also inform policy makers on better and more effective ways of developing safety interventions and preventive educational campaigns on non-adherence to medication in Ghana.

All information collected in this study will be given code numbers. No name will be recorded. Data collected cannot be linked in any way to any participant. No name or identifier will be used in any publication or reports from this study. Diabetes mellitus patients shall participate in the study out of their own free will and not obligatorily. If a

patient chooses not to participate, this will not affect the quality of service(s) offered the patient in this hospital in any way.

A participant may also choose to stop the interview at any time. There will be no consequence, loss of benefit or care if a participant chooses to withdraw from the study.

If you have any question concerning the conduct of this study, please do not hesitate to contact Miss. Perpetual Enam Aflakpui on 0247197682, paflakpui@gmail.com or Dr. Addo-Lartey Addolphina, Email; aaddo.lartey@gmail.com, University of Ghana, School of Public Health and Mrs. Hannah Frimpong (Administrator), Ghana Health Service Ethical Review Committee Secretariat, Accra. Tel: 0507041223/0243235225.

Appendix ii: 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 the information leaflet and consent form to keep for myself.

NAME: _____

DATE: _____ SIGNATURE/THUMB PRINT: _____

Statement of person witnessing consent (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 I have read from the study Participant Information Leaflet, attached.

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

Appendix iii: Questionnaire

Data abstraction form

1. ID
2. Weight
3. Height.....
4. Date of first diagnosis.....
5. Fasting Blood Glucose (FBG).....
6. Blood Pressure (BP).....

Section A: Demographic Characteristics (Questionnaire adopted Divya and Nadig (2015))

1. Age.....
2. Sex: 1. Male [] 2. Female []
3. Religion: 1. Christian [] 2. Muslim [] 3. Traditionalist []
4. Marital Status: 1. Single [] 2. Married [] 3. Divorced [] 4. Widow/er []
5. Educational Level: 1. Tertiary [] 2. SHS/O and A levels [] 3. JHS/Middle school [] 4. Primary [] 5. None []
6. Occupation.....

Section B: Medical History/ Knowledge on Diabetes

1. How long have you had diabetes?
2. What is the current treatment for your diabetes?
 1. [] Metformin
 2. [] Glibenclamide
 3. [] Metformin + Glibenclamide
 4. [] Insulin
 5. [] Insulin + OHA
 6. [] Herbal medication
 7. Other (specify).....

3. How long (in years) have you been on current treatment?
4. What do you think causes diabetes?
5. What do you think fasting blood glucose means?
6. Have you ever heard of Glycated Hemoglobin or HbA1c? 1. Yes [] 2. No []
7. Do you have or have you ever had a diabetic patient in your family?
 1. Yes [] 2. No []
8. If yes, which of your family members has diabetes?
 1. Grandparent [] 2. Parent [] 3. Children [] 4. Siblings [] 5. Uncle/ Auntie []
 6. Nephew [] 7. Cousin []
9. Fasting reduces the sugar level in my blood. Indicate your level of agreement or disagreement. 1. Strongly agree [] 2. Agree [] 3. Disagree [] 4. Strongly disagree [] 5. Don't know []
10. How do you control your glucose level by
 1. Exercise [] 2. Diet []
 3. Medication [] 4. Other (specify).....
11. How often do you visit the health center for medication?
 1. Weekly []
 2. Monthly [] 3. Quarterly []
12. When last did you visit the health facility?
 1. [] within 4 weeks
 2. [] within the last week
 3. [] within the last 2 weeks.
13. Have you ever missed any of your visits to the hospital for review and medication?
 1. Yes [] 2. No []
14. If yes, how many visits do you miss in a month?
 1. 1 – 2 visits [] 2. 3-5 visits [] 3. 6 – 10 visits [] 4. Above 10 visits []
15. Why did you miss your visits?
 - 1 [] Forgot
 2. [] Decided not to go for no reason
 3. [] Was busy doing something else
 4. [] Was tired of frequent visits
 5. Other.....
16. Averagely, how much time do you spend in the health facility when you visit?
 1. [] 0- 1 hour
 2. [] 2-3 hour
 3. [] 4 hour and above.
17. How much time did you spend at the hospital on your last visit?
 1. [] 0- 1 hour
 2. [] 2-3 hour
 3. [] 4 hour and above.
18. Does your health provider explain your disease condition to you?
 1. [] Yes
 2. [] No
19. Does your health provider check up on you through Phones calls or by Sms?
 1. [] Yes
 2. [] No

20. Are you able to freely discuss with your health provider about your complications?
1. Yes 2. No No
21. Are you thoroughly examined by your health Provider? 1. Yes 2. No
22. How will you proportion treatment by your health provider?
1. Excellent 2. Very Good 3. Good 4. Very bad
23. How close is your home from the health facility? 1. close 2. far 3. Very far
24. Are you able to buy all your prescribed medications? 1. Yes 2. No
25. If no, why? 1. Too expensive 2. Difficult to find 3. Not available
26. Who supports you in financing the medication? 1. Self 2. Friends 3. Relatives
4. Organization
27. How many times are you supposed to take your prescribed medication in day?
1. 3x daily 2. 2x daily 3. 1x daily
28. Do u follow the above prescription? 1. Yes 2. No
29. How many pills do you have to swallow every day in total for your diabetes?
30. Do you think the number of pills to be swallowed in Q.15 affect your continued usage? 1. Yes 2. No
31. How many pills do you have to swallow in a day for all disease conditions?
32. Do you think the number of pills swallowed in Q.17 affect your continued usage?
1. Yes 2. No
33. Do you have any side effect when you take your diabetes medication?
1. Yes 2. No
34. Do these reactions affect you continued usage? 1. Yes 2. No
35. Which of the following social groups have been supportive since you were diagnosed of Diabetes Mellitus? 1. family 2. Friends 3. community
36. Check the following blocks that indicate how these support groups have been of support?
- A. Family: 1. Financially 2. Emotionally 3. Psychological
- B. Friends: 1. Financially 2. Emotionally 3. Psychological
- C. Community: 1. Financially 2. Emotionally 3. Psychological

Section C: Morisky medication adherence questionnaire

37. Do you sometimes forget to take your medication? 1. Yes [] 2. No []
38. Thinking over the past 2 weeks, were there any days when you did not take your medication? 1. Yes [] 2. No []
39. Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it? 1. Yes [] 2. No []
40. When you travel or leave home, do you sometimes forget to bring along your medicines? 1. Yes [] 2. No []
41. Did you take all your medicines yesterday? 1. Yes [] 2. No []
42. When you feel like your symptoms are under control, do you sometimes stop taking your medicines? 1. Yes [] 2. No []
43. Taking medicine every day is a real inconvenience for some people, do you ever feel hustled about sticking to your treatment plan? 1. Yes [] 2. No []
44. How often do you have difficulty remembering to take all your medicines? 1. Never/rarely [] 2. Once in a while [] 3. Sometimes [] 4. Usually [] 5. All the time []
45. What do you do in order not to forget to take your diabetes medicine?
1. Pill count [] 2. Write down [] 3. Alarm alert [] 4. Visual reminder []

Section D: Factors associated with non-adherence to medication

46. What are the probable reason for missing the medication? 1. Forgetfulness []
2. Distance [] 3. Waiting time [] 4. Side effect [] 5. Cost of medication []
6. Dose frequency [] 7. Shortage of medication []
47. Are you able to visit the physician regularly for consultation? 1. Yes [] 2. No []

48. What are the probable reasons for not visiting the Physician for regular consultation?

1. Forgetfulness [] 2. Distance [] 3. Waiting time [] 4. Side effect []

5. Cost of medication [] 6. Side effect [] 7. Shortage of medication

49 How often do you get your blood glucose checked? 1. Daily [] 2. Weekly []

3. Monthly [] 4. None []

50. How is your blood glucose monitored? 1. Self- monitored [] 2. Laboratory []

THANK YOU FOR PARTICIPATING IN THIS RESEARCH WORK.

Appendix iv: Diabetes Diagnostic Criteria (WHO/IDF, 2006)

Condition	2 hour glucose	Fasting glucose	HbA1c
	Mmol/l(mg/dl)	Mmol/l(mg/dl)	%
Normal	<7.8(<140)	<6.0(<110)	<6.0
Impaired fasting glycaemia	<7.8(<140)	≥6.1(≥140)&<7.0(126)	6.0 – 6.4
Impaired glucose tolerance	≥7.8(≥140)	<7.0(<126)	6.0 – 6.4
Diabetes mellitus	≥11.1(≥200)	≥6.0(≥126)	≥ 6.5

Table 11: Available at http://www.WHO.int/diabetes/publications/report-hbale_2011.pdf.

2013			2014			2015		
Conditions	Cases		Conditions	Cases		Conditions	Cases	
Malaria	55977	30.6%	Hypertension	44988	25.6%	Malaria	24389	19.3%
Hypertension	33496	18.3%	Malaria	42787	24.3%	Upper Respiratory Tract Infections	23020	18.3%
URTI	22329	12.2%	Diabetes Mellitus	24645	14.0%	Hypertension	21007	16.7%
Diabetes Mellitus	16679	9.1%	URTI	20010	11.4%	Gynaecological conditions	13875	11.0%
Rheum & Other Joint Pains	13852	7.6%	Acute Eye Infection	8452	4.8%	Rheumatism & Other Joint Pains	9627	7.6%
Skin Diseases	9662	5.3%	Preg. Related	8082	4.6%	Acute Eye Infection	9553	7.6%
Gynaecological cond.	8076	4.4%	Gynaecological conditions	7808	4.4%	Skin Diseases	7200	5.7%
Dental Caries	7770	4.2%	Rheum. & Other Joint Pains	6891	3.9%	Anaemia	6310	5.0%
Acute Eye Infection	7682	4.2%	Skin Diseases	6504	3.7%	Pregnancy Related Complications	5924	4.7%
Preg. Related	7467	4.1%	Diarrhoea Diseases	5898	3.3%	Diarrhoea Diseases	5209	4.1%
Total Top 10	182990	100%	Total Top 10	176065	100%	Total Top 10	126114	100%
Total Morbidity	314061		Total Morbidity	318100		Total Morbidity	163763	163763

Table 12: Conditions, 2015, Tema Metro DHIMS

Appendix v: Ethical Clearance form

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the number and date of this Letter should be quoted.



Research & Development Division
Ghana Health Service
P. O. Box MB 190
Accra
Tel: +233-302-681109
Fax + 233-302-685424
Email: Hannah.Frimpong@ghsmail.org

My Ref. GHS RDD ERC/Admin/APP/
Your Ref. No.

Perpetual Enam Aflakpui
University of Ghana
School of Public Health
Legon, Accra

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol.

GHS-ERC Number	GHS-ERC 07/12/15
Project Title	“Non-Adherence to Medication Regimen among Diabetes Mellitus Patients at Tema General Hospital”
Approval Date	12 th April, 2016
Expiry Date	11 th April, 2017
GHS-ERC Decision	Approved

This approval requires the following from the Principal Investigator

- Submission of yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months,
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.
- Submission of a final report **after completion** of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.

Please note that any modification of the study without ERC approval of the amendment is invalid.

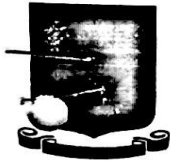
The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol

SIGNED.....
DR. CYNTHIA BANNERMAN
(GHS-ERC CHAIRPERSON)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra

Appendix vi: Approved introductory letter



UNIVERSITY OF GHANA
DEPARTMENT OF EPIDEMIOLOGY AND DISEASE CONTROL
SCHOOL OF PUBLIC HEALTH

Ref. No.:



30th May, 2016

The Medical Superintendent
Tema General Hospital
Tema

Dear Sir/Madam,

LETTER OF INTRODUCTION – PERPETUAL ENAM AFLAKPUI

We wish to introduce to you, *Perpetual Enam Aflakpui*, a Master of Public Health student in the Department of Epidemiology and Disease Control of the School of Public Health, College of Health Sciences, University of Ghana, Legon.

Ms. Aflakpui is conducting a research on the topic "*Non-adherence to Medication Regimen among Diabetes Mellitus Patients-at Tema General Hospital*".

It will be appreciated if you could provide her with the necessary support to undertake her research work in your institution.

We thank you for your cooperation.

Yours faithfully,

Dr. Patricia Akweongo
Head

cc: School Administrator - SPH, UG

COLLEGE OF HEALTH SCIENCES